Regulating the Innovators:

Approval Costs and Innovation in Medical Technologies

Parker Rogers*

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Abstract

How does regulation affect innovation and market concentration? I examine this question by exploiting FDA deregulation events that affected certain medical device types but not others. To answer, I gather new, comprehensive data on medical device innovations, prices, and regulatory changes from eight different sources. My analysis of these data yields three core results. First, deregulation significantly increases the flow and quality of innovation in affected medical device types relative to control groups. These increases are particularly large among small and inexperienced firms. Second, deregulation increases firm entry and lowers the prices of medical procedures that use affected medical device types. Third, the rates of serious injuries and deaths attributable to defective devices do not increase measurably after deregulation. In fact, deregulating certain device types lowers these adverse event rates significantly, consistent with firms increasing their emphasis on product safety as deregulation exposes them to greater liability risk.

*University of California at San Diego, Economics Department, Econ 124, 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, Alexander Gelber, John Van Reenen, Itzik Fadlon, Karthik Muralidharan, Gordon Dahl, Mark Jacobsen, Jeffrey McCullough, Maggie Shi, Paul Kindsgrab, Ryan Hill, Alex Everhart, and Nathaniel Bechhofer for excellent feedback. I also thank participants at ASHEcon 2021, Young Economist Symposium 2021, SOCAE 2021, and UCSD Applied Micro. Thanks also to Parag Agnihotri and Kimberly Ruprecht for their generous help.

While most innovators create new products with the intention to make them safe and reliable, there is some chance that these products will harm consumers. One way to mitigate this uncertainty is to regulate new products through mandatory pre-market testing. Critics of this approach claim that regulations reduce innovation and shield established firms from competition due to higher entry costs and approval delays (Peltzman, 1973).[1] Proponents counter that regulations bolster innovation by allowing new firms to credibly signal the quality of their products without a longstanding reputation (Carpenter, 2017). Clear evidence testing these claims has been modest.

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

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

[1]Increased market concentration may independently affect the financial incentives to innovate. The literature on this question, however, is conflicted (e.g., Schumpeter (1934) versus Arrow (1962)).

My empirical analysis relies on a combination of eight data sources that provide an expansive view of the costs and benefits of medical device regulations.[2] First, a collection of all FDA policymaking across the last 40 years allows a comprehensive analysis of device regulations. Second, I draw from various measures of innovation, innovation quality, and firm participation to provide a fuller view of new technologies and market dynamics. Third, I detail trends in the safety of new devices using data from FDA adverse event reports and text analysis of patent documents. Linking these data with information on firm asset holdings uncovers how regulation affects small and large firms differently. Lastly, insurance claims data allow for a suggestive look into how regulation affects healthcare prices.

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

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

Second, deregulation led to significant changes in market structure. Class III to II events

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

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

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

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

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

I build a model that captures the incentives that drive firm investments in new products, which generates predictions that are consistent with my empirical results. The model incorporates the central concerns of medical device innovators. First, stricter regulation imposes longer FDA approval delays, but firms shorten delays as they gain more experience navigating FDA approval requirements (i.e., "learning by doing"). Firms also face financing costs if approval costs exceed their assets. Lastly, when regulations are lifted (Class I), firms are exposed to legal damages related to product design flaws. Small firms, however, are exposed to fewer damages, as they can use bankruptcy to avoid liabilities that exceed their assets. This characterization of the firm's decision shapes the benefits of deregulation and generates the following insights. Deregulation can improve product safety and can disproportionately increase the returns to R&D among firms with less regulatory experience.

My findings connect to several literatures. First, I add to a growing literature on the effects of public policy on medical innovation.[3] Despite the size and growth of the industry, the literature on medical devices is small and only partly confronts how regulation affects medical device innovation.[4] I address this gap by providing the first evidence of the effect of deregulation on medical innovation. These effects are measured across many device types and assessed at various degrees of regulatory scrutiny, adding to existing studies that exclusively examine cardiovascular device innovation under Class III regulations. My results also provide suggestive evidence on the safety benefits of FDA regulation, a topic that is under-explored (Grennan and Town, 2020).

I also add to a longstanding literature on the tradeoffs between regulation and litigation

[3]See Grennan and Town (2020); Clemens and Rogers (2020); Stern (2017); Budish et al. (2015); Acemoglu and Linn (2004); Finkelstein (2004); Peltzman (1973).

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

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

Lastly, my findings relate to the literature on endogenous growth (Romer, 1990; Aghion and Howitt, 1992). Researchers have shown that regulation can increase or decrease innovation—a key determinant of economic growth—depending on the implicit incentives that regulations create for scientists and innovative firms (Acharya et al., 2014, 2013; Aghion et al., 2019). Others broadly show 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). My findings build on this literature and suggest that regulatory knowledge does not smoothly flow across firms. Instead, regulatory proficiency stays with the firms that acquire it (akin to Azoulay et al. (2011)). Conceptually, my paper relates to models of productivity growth through learning by doing (Arrow, 1971; Auerswald et al., 2000) and models of productivity losses through capital frictions (Buera and Shin, 2013; Midrigan and Xu, 2014; Moll, 2014).

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

1 Background

At the turn of the 19th century, "corruption in the food and drug trade was unlike anything seen at any time in history" (Hilts, 2003, p.21). In response, the U.S. Progressive Era ushered in the 1906 Pure Food and Drugs Act, establishing consumer protection laws that led to the creation of the FDA. In this section, I describe the structure and legal consequences of FDA medical device regulations. Medical devices include products like pacemakers, X-ray machines, and tongue depressors.

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 that is regulated differently than "extended-wear soft contact lenses." The policy variation that I study occurs at the level of these generic device types, and I refer to them as "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 enough 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) and can impose substantial costs. The 510(k) process costs an average of $24 million (Makower et al., 2010), including approval timelines of up to a year. Class III, high-risk device manufacturers must perform clinical trials through the "premarket approval" (PMA) process to ensure their new device is safe and effective before commercialization. The PMA process is much longer than the 510(k) process and costs, on average, $75 million

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

(Makower et al., 2010). The average costs of these different levels of regulation are shown in figure 1. Appendix D.2 provides more details.

1.2 Deregulation of Medical Device Types

The FDA can lower the class of a medical device type as it learns about safety from marketed devices. Without any safety information, the FDA subjects new, markedly novel devices to stringent Class III regulations to ensure safety in the presence of unknown risks.[6] Surveillance data from marketed devices reveal these risks and inform the FDA's choice to move a device type into a lower class, or "down-classify" (see figure 1).[7] These events are described by onlookers as "unpredictable," suggesting the difficulty of anticipating such policy changes (Powell, 2018). My empirical analysis supports this assessment as I do not find evidence of divergent pre-existing trends when comparing down-classified device types to control groups.

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

All the Class II to I down-classifications I analyze are congressionally mandated. For example, the FDA Modernization Act (FDAMA; FDA (1995)) required the FDA to establish a list of Class II devices for deregulation. It did so by scoring all Class II devices according to annual adverse event counts using its "Device Priority Model" (DPM) (FDA, 1995). All device types with scores below an FDA-specified threshold were chosen for deregulation.

[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, thus were either automatically or intentionally classified into Class III.

[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).

Additionally, firms could not have expected a given device type's down-classification as the publication of the DPM occurred after the policy was announced.[8] Event studies strengthen this evaluation as deregulated devices do not exhibit divergent pre-existing trends.

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

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 federal device approvals bar legal claims against approved devices. This precedent offers manufacturers of Class III devices strong liability protection. Manufacturers of Class II devices are protected to a lesser extent due to legal ambiguity regarding whether Class II approvals are based on safety and efficacy. When device types are fully deregulated (Class I), manufacturers no longer receive FDA approval, completely exposing them to litigation.

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 a contact lens disinfectant manufactured by Alcon Laboratories did not prevent a severe eye infection due to a product flaw. The disinfectant, however, was approved by the FDA as a Class II regulated device. The district court handling the case deemed that the approval adequately tested the product's safety, preventing legal liability.

[8] See appendix D.1 for more details.

2 Conceptual Framework

In this section, I model regulated 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. Then, firms bring their products to market by attaining regulatory approval, forming distribution networks, etc. The commercialization delay of an R&D project is the amount of time between development and commercialization.

My intentionally simple model focuses on how regulation distorts the composition of firms and firm safety efforts. First, regulation can distort incentives to exert safety efforts in ways that *decrease* product safety. In some contexts, regulated firms are shielded from the legal consequences of product defects, leading to fewer safety efforts if regulation is ineffective. Second, regulation distorts the composition of innovating firms as smaller firms and firms with less regulatory experience incur higher commercialization costs. I focus my model on the medical device industry, though the implications may apply to other regulated products.

2.1 Model Preliminaries

In the model, 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. This process 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 number of years it takes to commercialize the product is t_{comm}. In the context of the medical device industry, FDA approval plays a key role in delaying commercialization (Makower et al., 2010; Pietzsch et al., 2012). Thus, for concreteness, think of t_{comm} as the approval delay. I assume t_{comm} and several other parameters below are deterministic for simplicity.

Delay Costs and the Learning Curve.—If a firm chooses to commercialize its product, it

awaits approval delays. However, approval delays are shorter for experienced firms (Olson, 1997; Carpenter, 2004b; Makower et al., 2010).[9] I model this relationship using a learning curve (Arrow, 1971; Auerswald et al., 2000). As firms experience more approval delays, their prior experience T increases, which shortens the present delay. Formally, the present delay t_{comm} is equal to the delay generated by the learning curve $\beta\, T^{-\gamma}$, where β is the delay time with no prior experience (i.e., $T = 1$) and $\gamma > 0$. Delay costs are given by χt_{comm}, where χ is the yearly cost of approval delays.

Expected Damages and Safety Effort Costs.—If a firm chooses to commercialize its product, it exerts costly effort to improve product safety at t_{invent}.[10] It does so to prevent expected legal damages that in incurs after t_{comm} or to satisfy regulatory requirements. Safety effort, given by x, costs ψ per unit. Firms must exert at least $\underline{x}$ effort for regulated products. Once a product is successfully commercialized, the product generates stochastic adverse events that yield legal damages; for medical devices, damages can amount to as much as 3.8% of annual revenues (Fuhr et al., 2018). The damages per year that the firm incurs is a random variable $\theta_x \phi(x)$ with expected value of $\theta_x D(x)$ and upper bound $\theta_x \bar{\phi}$. The expected damages function $D(\ )$ is a decreasing convex function of safety effort x, consistent with diminishing marginal returns to safety effort.[11] The parameter $\theta_x \in [0, 1]$ represents the fraction of damages not barred by federal preemption. For example, Class III approvals bar all tort liability (i.e., $\theta_x = 0$) but deregulated devices are not protected (i.e., $\theta_x = 1$).

Financing Costs.—A firm choosing to commercialize its product allocates capital at time

[9] Two factors may explain this pattern, both of which are driven by the complexity of the regulatory process. First, inexperienced firms express 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). Whether learning is on the part of the regulator or the firm, the learning curve accounts for these frictions.

[10] For simplicity, I assume firms exert safety effort instantaneously. Alternatively, safety efforts could prolong commercialization delays. Extending the model to include safety effort delays, however, would not change the central results of my theoretical model.

[11] Damages are greater than zero for all effort levels.

t_{invent} to cover the costs of development and commercialization.[12] Some firms, however, must raise external capital to cover these costs. Fundraising can be difficult: 56% of small medical device firms claim funding as a central challenge (Emergo, 2019).[13] Following Stein (2003), I capture these financing frictions by assuming deadweight costs given by $C(e)$, where $C(\ )$ is an increasing convex function of external funds e.[14] External funds e equal the difference between the non-financing costs and internal capital K. I omit other costs of commercialization for simplicity.

Obsolescence Risk and Discounting.—A successfully commercialized product faces a risk of being superseded by new products. New products become obsolete with a probability of $1 - \eta$ each year following t_{invent}. Although this 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). The R&D project has a neoclassical risk-adjusted discount rate of r. For expositional ease, I combine these two factors into an obsolescence-risk-adjusted discount factor of $\delta = \eta/(1 + r)$.[15]

Profits.—If the product is successfully commercialized and non-obsolete, it generates profits π per year to the innovating firm. Regulation can affect profits π by altering the market structure and bargaining dynamics. I do not model these relationships as they are beyond the scope of this study (I will address these features in a future study). Instead, for simplicity, I allow profits to vary exogenously with regulation.[16] I assume only expert regulators can perceive safety effort (i.e., asymmetric information); thus, safety effort does

[12]For simplicity, I assume firms finance their project instantaneously. Alternatively, fundraising could prolong commercialization delays. Extending the model to these delays, however, would only accentuate the central results of my theoretical model.

[13]These firms traverse a "funding chasm," a period of capital scarcity carved from long approval delays and uncertainty (Gaglani, 2014; Propel, 2017).

[14]A firm does not incur financing frictions if external capital is nonpositive (i.e., $C(e \leq 0) = 0$).

[15]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.

[16]This approach allows me to focus on modeling costs—the central aim of this study.

not affect profits once a product is approved.

2.2 Effective Life and Optimal Safety Effort

I focus on two regulatory environments: regulated "R" and deregulated "N." In the regulated environment R, federal preemption bars legal damages (i.e., $\theta_{x,R} = 0$), and approval delays are positive (i.e., $t_{comm,R} > 0$). In the deregulated environment N, the firm is exposed to all legal damages (i.e., $\theta_{x,N} = 0$) and there are no approval delays (i.e., $t_{comm,N} = 0$).[17]

Firms enjoy longer or shorter effective lives of their products depending on the regulatory environment. Under regulation, I define an invention's *Regulated Effective Life (REL)* as the expected number of 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}, and is shortened by obsolescence risk and discounting, given by $REL = \sum_{t_{comm}}^{\infty} \delta^t = \delta^{t_{comm}}/(1-\delta)$. 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 $REL < EL$ by definition. The regulated product's shortened effective life leads firms to more heavily discount future profit flows.

Firms also must exert costly safety effort at time t_{invent}. Under deregulation N, the firm exerts effort to maximize the returns to commercialization by equating the marginal cost of effort to the present value of its marginal benefits (i.e., marginal abatement of expected damages). Thus, the effort level is given by $\psi + C_x(x^*) = - EL \cdot D'(x^*)$. Notice that if firms cannot cover safety effort costs with internal capital, they incur additional financing costs of safety effort. Under regulation R, firms must exert the mandated level of safety effort $\underline{x}$. The counterfactual level of effort in a world without federal preemption (i.e, x_R^*)

[17] One could also analyze the moderate regulation environment (Class II). In this environment, firms would partially face legal damages and face nonzero but relatively short approval delays. However, the theoretical implications of deregulation within this environment are not substantively different than those derived in the environments I consider.

would be chosen using a similar condition, given that x_R^* is above mandated levels. The effort level would be given by $\psi + C_x(x_R^*) = - REL \cdot D'(x_R^*)$, which accounts for fewer years of marginal benefit.

2.3 Incentives to Invest

In the regulated environment R, the firm will commercialize its invention if and only if the expected profits are greater than the costs,

$$\text{Regulated Firm Invests} \iff REL \cdot \pi_R \geq \chi t_{comm} + \psi \underline{x} + C(e_R). \tag{1}$$

In words, the firm expects to receive a profit π_R from commercializing a device for REL years. If the costs of delay, safety effort, and financing $\chi t_{comm} + \psi \underline{x} + C(e_R)$ are less than $REL \cdot \pi_R$, then the firm will choose to develop and commercialize its invention.[18] The amount of external capital e_R needed to fund the project is given by the difference between the non-financing commercialization costs and the firm's own capital K (i.e., $e_R = \chi t_{comm} + \psi \underline{x} - K$ if $e_R \geq 0$, and 0 otherwise).

In the deregulated environment N, the firm will choose to commercialize if and only if the net expected profits (less expected damages) are greater than the costs,

$$\text{Deregulated Firm Invests} \iff EL \cdot [\pi_N - D(x^*)] \geq \psi x^* + C(e_N). \tag{2}$$

The firm expects to receive a net profit (accounting for damages) of $\pi_N - D(x^*)$ from commercializing a device for EL years. If the costs of optimal safety effort and financing $\psi x^* + C(e_N)$ are less than $EL \cdot [\pi_N - D(x^*)]$, then the firm will choose to develop and commercialize its invention.[19] The amount of external capital e_N needed to fund the project is given by the

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

[19] Note that financing frictions do not affect the payment of damages since damages can be paid out with

difference between safety effort costs and the firm's internal capital K (i.e., $e_N = \psi x^* - K$ if $e_N \geq 0$, and 0 otherwise).

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

2.4 Distortions from Regulation

I focus on model implications related to compositional distortions in firm participation and distortions in safety efforts that arise from regulation. Although theoretically ambiguous[20], I assume that deregulation increases the level of R&D. This assumption is supported by my empirical results and allows me to more clearly motivate the less intuitive and under-identified compositional changes that I find in my analysis.

The first distortion I detail arises from regulatory complexity (i.e., the delays from complex regulatory protocols). Complexity distorts the composition of firms that commercialize as inexperienced firms reap lower returns to commercialization. Deregulation removes these distortions and increases the returns to commercialization, especially for inexperienced firms. To formalize this claim, I present the following proposition:[21]

PROPOSITION 1. *(Deregulation disproportionately benefits inexperienced firms) For two regulated firms, A and B, with different regulatory experience $T_A < T_B$, but otherwise identical, increases in the returns to commercialization from deregulation will be higher for firm A.*

A hypothetical example helps illustrate the potentially dramatic implications of proposi-

profits (i.e., in expectation, damages will always be less than profits if a firm chooses to commercialize).

[20]Deregulation could decrease the returns to commercialization through decreased profits (e.g., increased competition) and increased legal damages (i.e., no preemption).

[21]Proofs are presented in appendix B.

tion 1. Firm A has no prior experience and must await a two-year delay, consistent with the learning curve estimated in subsequent sections. Firm B has commercialized one project, which was delayed for two years. By contrast, firm B awaits a one-year delay, incurring 50% fewer delay costs than firm A. Further, firm B's project yields a longer effective life and lower financing costs. Although deregulation removes delay-related costs for both firms, the increase in returns to commercialization is at least twice as large for firm A. Assuming an identical distribution of invention draws for both firms, deregulation leads firm A to commercialize a wider margin of previously abandoned projects.

Next, I explore how deregulation influences distortions that arise from federal preemption. On the one hand, preemption removes the incentive to exert costly safety efforts beyond mandated levels by shielding firms from damages. On the other, this shield can increase the returns to commercialization. These countervailing forces are changed by deregulation; Depending on certain factors, deregulation may improve safety by removing the safety distortions that preemption presents. I state this formally as follows:

PROPOSITION 2. *(Deregulation can lead firms to increase safety efforts) A regulated firm exerts safety effort $\underline{x}$. The firm's counterfactual optimal level of safety effort without preemption is x_R^*. Deregulation will lead to more safety effort if (i) the marginal costs of ex-ante mandated effort are less than the ex-post marginal benefit of that effort (i.e., $\psi + C_x(\underline{x}) < -EL \cdot D'(\underline{x})$) or (ii) $\underline{x} < x_R^*$.*

Figure E.1 helps clarify the necessary conditions for proposition 2. In the figure, the first condition holds as the ex-ante mandated safety effort is sufficiently low, leading the deregulated firm to exert more effort. This result implies that if regulation is ineffective at inducing high levels of safety effort, it could make products less safe. I show in section 5 that Class II regulations lead to such an outcome.

Lastly, I discuss distortions that arise from financing frictions and regulation. Small firms incur deadweight costs when raising capital to commercialize their products. Deregulation decreases commercialization costs, and may do so disproportionately for small firms. I state

this claim formally as follows:

PROPOSITION 3. *(Deregulation can disproportionately benefit smaller firms) Firm A has less internal capital than (i) firm B (i.e., $K_A < K_B$) and (ii) its non-financing commercialization costs (i.e., $K_A < \chi t_{comm} + \psi \underline{x}$). Firm A and B are otherwise identical. If firm A's safety effort costs under deregulation ψx^* are lower than its ex-ante non-financing commercialization costs, increases in returns to commercialization from deregulation will be highest for firm A.*

The ambiguity in proposition 3 is driven by the potential for financing costs to increase after deregulation. For example, if deregulation induces more safety efforts, the associated costs could outweigh approval delay costs and increase financing costs for smaller firms. In this case, deregulation would lead to lower increases in returns for small firms. For the proposition to hold, safety effort costs under deregulation must be less than ex-ante commercialization costs.

The results of my empirical analysis support the ideas that I detail in these propositions.[22] Namely, deregulation leads to outsized increases is innovation among inexperienced firms, Class II to I deregulation leads to increased efforts to improve safety, and small firms exhibit the greatest increases in innovation after deregulation.

I provide two extensions to the model in appendices A.1 and A.2. These extensions (i) allow firms the option of bankruptcy and (ii) detail the social planner's problem of optimal regulation. Bankruptcy allows smaller firms to discharge legal liabilities that exceed their assets. Hence, these firms face lower expected damages as they do not internalize the upper tail of the distribution of legal damages. This result implies that if deregulation increases safety efforts, increases will be concentrated among large firms.

I also conceptualize the problem of deciding when to deregulate a medical device type within this framework. The social planner weighs the innovative benefits of deregulation

[22]There are other implications of the model that are standard results in the literature. For evidence on capital frictions see Buera and Shin (2013); Midrigan and Xu (2014); Moll (2014). For evidence on complexity frictions see Olson (1997); Carpenter (2004b). For evidence on the interplay between preemption and regulation, with regards to safety efforts, see Philipson et al. (2010).

against uncertain costs of danger; as it waits, it learns about a device type's inherent risk but forgoes benefits (i.e., optimal stopping problem). This characterization is consistent with the FDA's current approach to regulating medical devices: Radical new devices are heavily regulated to accommodate learning. Then, the FDA chooses when (if ever) to deregulate, given a history of information on device risk. This characterization leads to several intuitive insights. The agency should deregulate sooner if (i) innovation increases after deregulation, (ii) deregulation is likely to make devices safer, and (iii) a device type's inherent risk is reasonably known. My empirical results identify the parameters that drive these decisions, namely, the effect of down-classification on innovation and device safety.

3 Data

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

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

firm has experienced up to the given point in time.

FDA Deregulation Events. To provide a comprehensive analysis of FDA deregulation events, I collect all down-classifications from 1980 to 2015. For Class III to II events, I also indicate whether the event was motivated by the FDA's "own initiative" or by industry petition. This distinction is empirically important. Figure E.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. Table E.1 shows the number of events collected by event type. The Class III to II events I consider are those enacted by the FDA's own initiative and for which down-classified device types experienced at least one PMA document submission beforehand.[23] For Class II to I events, I consider affected device types that experienced at least one 510(k) document submission beforehand.

FDA Adverse Event Reports (MAUDE). The FDA's Manufacturer and User Facility Device Experience (MAUDE) database contains adverse event reports related to medical devices. Using this data, I create measures of device safety 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 E.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. I follow a three-step procedure to form a patent-based measure of innovation within each device type. First, I gather a list of keywords from each FDA device type description. Second, I programmatically collect all

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

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

Patent and Patent Applicant Characteristics. I enrich the patent data with measures of innovation quality and applicant characteristics. A patent's quality is measured using the number of citations it received from other patents and its market value.[24] 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.[25] 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 pro-

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

[25]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).

vide information on how health care prices respond to deregulation. The direct prices paid for medical devices are difficult to obtain as they result from proprietary hospital–supplier negotiations. Moreover, survey data (like ECRI) do not cover the years that down-classification events occurred (pre-2011). Thus, I instead focus on the downstream prices of procedures that use medical devices contained in more readily available insurance claims data, centering my analysis on the price that the consumer ultimately pays (via increased premiums or out-of-pocket costs).[26] Procedures are defined by the Current Procedural Terminology (CPT).

Using claims data, however, presents another challenge. The leading private health insurance claims databases (e.g., MarketScan and Optum) only provide estimates of procedure prices. Exact paid amounts are only available at the encounter level, which would include expenses from other procedures unrelated to a given medical device. Thus, I acquire claims data from UC San Diego Health that breakdown prices at the procedure level. I then identify claims with procedures that use medical device types that were down-classified since 2006.[27] I also gather a set of procedures that use matched control device types and a set of 100 randomly selected procedures to form control groups. 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.[28]

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

[27]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.

[28]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.

4 Empirical Strategy

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

The first regression specification uses a staggered difference-in-differences design. I use a "stacked" regression, similar to Cengiz et al. (2019), which confronts issues that might arise from using staggered treatment designs in the presence of heterogeneous treatment effects within-unit over time (Goodman-Bacon, 2018; de Chaisemartin and d'Haultfoeuille, 2019).[29] 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 ocurred in device type c. The outcomes of interest are denoted by $Y_{t,c,r}$. Event-by-time fixed effects ($\gamma_{t,r}$) and event-by-device type fixed effects ($\gamma_{c,r}$) are included. The coefficient of interest, β_1, estimates the differential change in the outcome variable for treated device types relative to control device types after down-classification. I estimate equation 3 separately for Class III to II events and Class II to I events.

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

[29] 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 E.2, E.3, and E.4).

intervals.

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

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

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

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

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

I provide four control groups, each addressing aspects of these concerns, and find that

my results are robust across these groups. The first control group is broadly comprised of all Class III and II devices (for III to II events) and all Class II and I devices (for II to I events) that have not been down-classified. This group provides baseline DID estimates. Second, I construct a group of "later treated" control device types that were down-classified after treated device types and after the latest sample year.[30] This "later treated" group allows me to compare only device types which the FDA deemed appropriate for the same kind of down-classification.

Third, if later-treated device types are different from those treated earlier, the later-treated group may produce biased estimates. To this end, I compute a data-driven "matched" control group using nearest neighbor matching on baseline adverse events and innovation rates. Although I do not find evidence for spillovers in my context, I ensure that matched control device types do not treat the same medical ailments as treated device types.[31] Lastly, I provide a set of "intuitive" controls. This set of controls includes medical device types that target similar diseases.[32] I also ensure that device risk is intuitively and empirically comparable. For example, I avoid inappropriate comparisons between external-use devices and implantable or life-sustaining devices (e.g., contact lenses versus pacemakers), as these devices would have drastically different safety profiles. Instead, I compare like with like (e.g., daily- vs. extended-wear soft contact lenses). Profiles of the treatment and intuitive control groups are given in table E.6 for Class III to II down-classifications, and in tables E.7 and E.8 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

[30]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.

[31]See table E.5 for spillover estimates.

[32]Figure E.4 illustrates the medical device hierarchy that I used to determine which devices treat similar diseases.

from analyses that consider only treated and control device types with positive counts of a given outcome, in the appendix tables E.9, E.10, and E.11. My findings are robust to these restrictions.

As with every non-experimental research design, selection into treatment is a primary concern. Since the FDA selects medical device types to down-classify based on baseline adverse event rates, down-classification is endogenous to changes in adverse event rates.[33] 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 composition. Subsection 5.3 details how the effects of deregulation on innovation and market composition differ by firm characteristics. Subsection 5.4 presents the effects on adverse event rates.

5.1 Changes in Innovation

Table 2 reports estimates of equation 3 for my innovation outcomes.[34] Panel A provides estimates for Class III to II events, and panel B provides estimates for Class II to I events. Column (1) provides 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.

[33] See appendix D.1 for more details.

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

Table 2, panel A indicates that Class III to II events led to statistically significant increases in patenting rates, unique device approvals, citations-per-patent, and average patent values across control group comparisons (columns 2–5). The results reveal that these events generated 189%–470% more patents and new device approvals per year in affected device types. Patents filed after these events received 180% more citations and exhibited similar increases in market values. Patents filed after Class II to I events (complete deregulation) received 330%–1,070% more citations and yielded 10%–50% higher market values (Panel B of table 2), suggesting a divergence between private and scientific 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 event-study equation 4. The top subpanels of figures 3 and 4 plot the β_t coefficients for Class III to II and II to I events, respectively, when using the "matched" control groups.[35] 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 to investments in new technologies that would not otherwise have occurred, rather than a forward shift in the timing of those investments.

Third, the event-study estimates for Class III to II events suggest that the increase in new technologies (i.e., patents) was slow while the increase in access to existing technologies (i.e., unique devices approved) was fast. Several factors motivate this distinction; (i) existing

[35]Figures E.5 and E.6 show event study estimates for the innovation quality variables.

medical devices awaiting FDA approval in the old regulatory framework are fast-tracked in the new framework; (ii) firms exclusively marketing devices in Europe—where regulations are more lenient—could exploit looser U.S. regulations by quickly pivoting to U.S. markets (Grennan and Town, 2020); (iii) firms may promptly repurpose existing technologies for new indications in response to the policy change; (iv) deregulation slightly lowers denial rates, leading to small, but sharp, increases in the number of new devices approved, regardless of changes in innovative activity.[36]

By contrast, the patenting results show a gradual increase after deregulation, consistent with the time-intensive R&D process. U.S. patenting rates, unlike device approvals, are not affected by sudden influxes of 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 in which it desires protection within one year to receive protection in those countries (Popp, 2005). Applying for patents in multiple countries is inexpensive as firms can concurrently file patents in up to 153 countries through the Patent Cooperation Treaty (WIPO, 2020).

5.2 Changes in Market Composition (Firm Entrants and Prices)

To investigate the effect of deregulation on market composition, 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.[37] 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 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%, when measured by FDA

[36]The FDA approves 80% of Class III devices and 90% of Class II devices (GAO, 2009).

[37]Table E.10 presents results from including only device types with some positive outcome counts.

data, and by 150%–420% when measured by patent data.[38] The discrepancy between the magnitudes of these two estimates suggests a strong response from foreign firms bringing existing technologies to U.S. markets. 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 procedure prices for two out of three control groups (columns 2 and 3). The estimates translate to a 33–40% drop in prices, consistent with the increase in firm entry. There are several reasons why these price results should be interpreted with some caution. First, data limitations restrict 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. The results indicate that these events increased new firms patenting by 50%–145%, though the estimate under my preferred specification is only marginally significant. By contrast, incumbent firms are relatively unaffected by these events: Incumbent firm entry is statistically and economically insignificant under my preferred specification. The distinction between these two results suggests that, although Class II regulations lower the profitability of investments for new firms, they may be less burdensome for more experienced firms.

To better interpret my market composition findings, I present event-study estimates of equation 4. The bottom subfigures of figures 3 and 4 plot the β_t coefficients for Class III

[38]Supply-side factors may not be the sole driver of these dramatic changes in market composition. As shown in figure E.7, 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.

to II and Class II to I events, respectively.[39] The figures provide suggestive evidence that the identifying assumptions (i)–(iii) (listed above) are satisfied and that, when present, the estimated effects are persistent. For similar reasons given above, figures E.9 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 E.8 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 health care 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 and find results that align with the propositions in section 2. The findings in this subsection 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 approval outcome across proficiency quartiles. I center this analysis on FDA data, allowing a cleaner linkage between firms, 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 approvals 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 approvals compared to a 50% increase from firms in the top quartile. These results indicate a quickly diminishing response while moving up the proficiency distribution. This pattern is consistent with the estimated learning curves

[39]Figure E.8 plots these coefficients for the Class III to II price outcome and figure E.9 plots these coefficients for the Class III to II market structure outcomes measured using patent data.

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 1).

Designing regulation that is simpler and standardized could help less regulation-proficient firms. For example, setting straightforward approval expectations and providing user-friendly workflows could quicken the approval process for these firms.[40] To simulate the impact of these 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 E.10 and appendix C for more details). Table E.13 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.[41] 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 having 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.

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

[41] I focus on patents due to the availability of existing data linking patent applicants to capital holdings, and patents allow comparisons across down-classification types.

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 capital costs are key factors that influence R&D decisions.[42]

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.[43] 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 hospitalizations and a 49–69% reduction in deaths per year per treated device type. These reductions in adverse events are consistent with an increase in the rate at which inventors emphasize safety; panel B reveals that these events are associated with a statistically significant 100% *increase* in the share of patents emphasizing an advancement in product safety.

How could Class II safety regulations *worsen* device safety? As detailed in proposition 2, the answer stems from the tension between regulation and litigation. After deregulation, firms marketing Class I devices are no longer shielded from legal liability. Thus, to avoid legal damages, it may be cost-effective to exert more effort to improve product safety, especially

[42]Firm size, the most obvious potential confounder, is uncorrelated with firm FDA experience (see table E.14). This lack of correlation may result from publicly traded companies having high baseline assets relative to the average MedTech firm.

[43]Table E.11 presents the results from including only device types with some positive outcome counts.

if mandated efforts are not high ex ante. However, as discussed in section 2, deregulation does not pose the same legal risks to small and large firms: Small firms can avoid worst-case damages through bankruptcy. I use this variation to strengthen the assertion that liability risk is the key mechanism through which deregulation improves safety. 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 shows a significant drop in the likelihood that at least one serious adverse event occurs per year per treated device type. The reduction in likelihood across asset terciles mirrors the safety efforts, with the sharpest declines occurring in devices manufactured by the largest firms.

Figures E.11, E.12, and E.13 illustrate the dynamics of my device safety findings. These figures plot the β_t coefficients estimated from event-study equation 4. Figure E.11 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 E.12 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 figure E.13).

A few caveats accompany my device safety analysis. First, the FDA explicitly down-classifies device types for which prospective regulation adequately mitigates harm. Thus, the insignificant adverse event results associated with Class III to II events are not surprising and should not be interpreted as causal. For Class II to I events, however, I can use the FDA decision rule described in appendix D.1 to assess whether the FDA's decisions are optimal on the margin (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 decision rule. Figure E.14 shows that

marginal device types are associated with *fewer* deaths when compared to control groups, relative to less dangerous treated device types, suggesting the down-classification rule was too conservative. This pattern may generalize to most Class II device types, of which roughly 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 increases 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 E.7 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. 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). I also validate the adverse event results by analyzing the intensity with which inventors emphasize safety improvements in their patent documents and find that the results from both data sources are consistent.

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

This section presents the costs and benefits of deregulation, 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.

Figure 8 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.

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 composition, and adverse events. My theoretical model clarifies how "learning by doing" and capital costs make regulation especially burdensome for small and inexperienced firms investing in new technologies. The model implies that deregulation increases the profitability of innovation most for these types of firms. The model also shows how deregulation introduces legal liability when regulation precludes litigation, which can induce firms to improve product safety; it also illuminates how small firms face less liability risk and thus weaker incentives to improve safety. I then investigate these insights, and my broader questions, empirically in the context of the medical device industry, where inexperienced firms face longer approval delays than proficient firms and where regulation precludes litigation. I use a dataset that combines eight data sources on innovation, market dynamics, firm characteristics, and product safety. My empirical analysis of these data generates results that are consistent with the insights from my theoretical model. I find that deregulation disproportionately benefited small and inexperienced firms and broadly accelerated technological progress and firm entry. Firm entry increased competition, which subsequently reduced related health care prices. I show that some adverse events increase after moving from high to moderate regulation (Class III to II)—although insignificantly. By contrast, I show that complete deregulation (Class II to I) is associated with a significant decrease in adverse events, especially among devices originating from large firms that face stronger increases in liability risk.

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 likely generalize to other Class II devices.[44] These results align with sentiments from the National Institute of Medicine and physicians 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. In practice, 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 (Wilson, 1984; Carpenter, 2004a,b). In contrast, the technological benefits that come from deregulation are more abstract. 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 quantitative results, of course, are context-specific. FDA medical device regulations, however, are likely representative of regulations in other settings. FDA device regulations, for example, are similar to those in the European Union, and requirements for Class III devices resemble those for pharmaceuticals in the U.S. and abroad (Van Norman, 2016). This similarity suggests that medical technology regulations across the globe slow innovation and increase market concentration; whether MedTech regulations in other contexts are cost-effective, however, remains an open question. FDA Class II regulations may be representative of regulations that use imperfect proxies or heuristics to evaluate product quality (e.g., "substantial equivalence"). These heuristics may be especially prevalent when product quality is difficult to verify or when regulators are under-resourced. In these contexts, litigation may be more socially beneficial than regulation.

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

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

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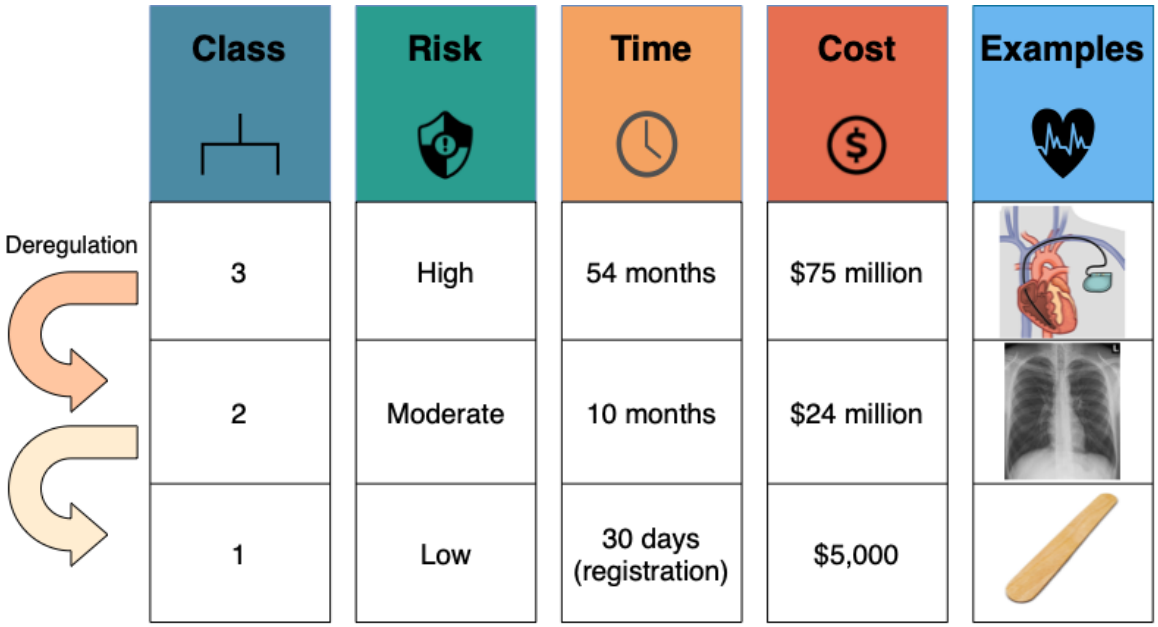
Figures and Tables

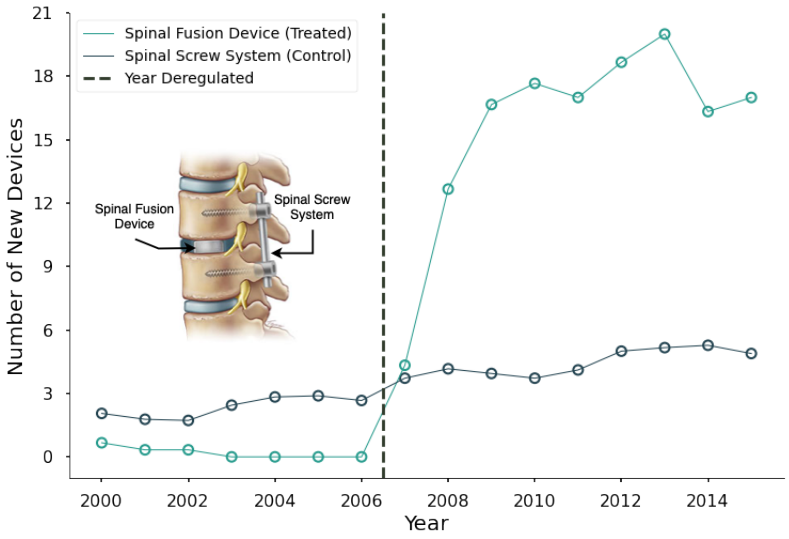
Figure 1: Background on Medical Device Regulations



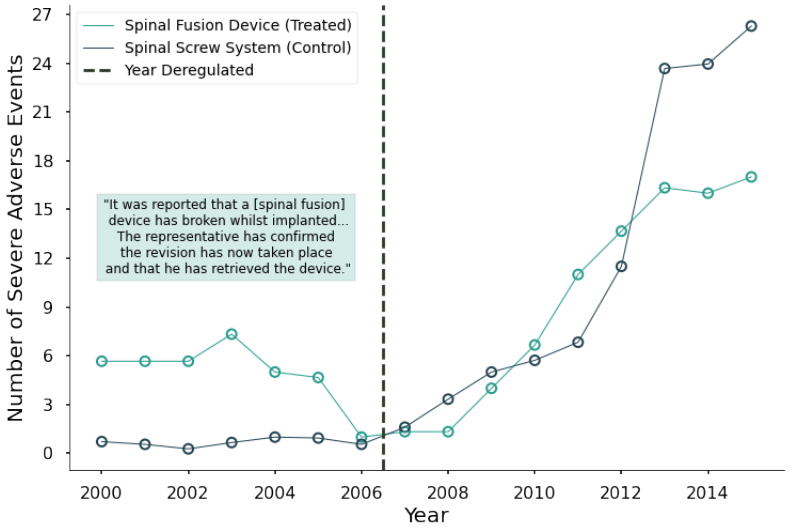
Note: This figure presents background on FDA Medical device regulations and the deregulation policy changes I leverage in my analysis. Device types are placed into one of three classes, each corresponding to a level of perceived risk. Higher perceived risk requires a longer approval process and additional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

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

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

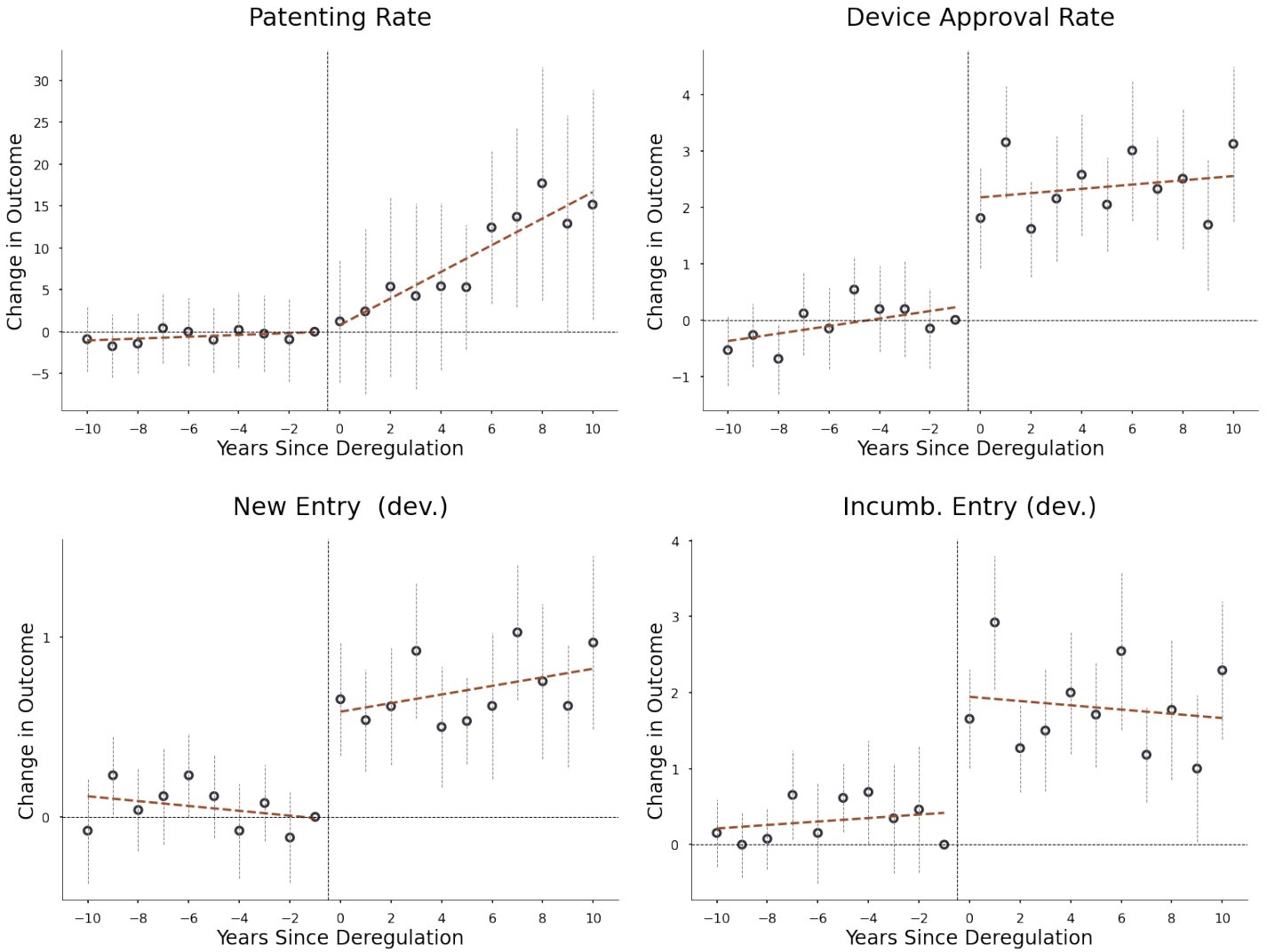


(b) Panel B: Annual Count of Serious Adverse Events



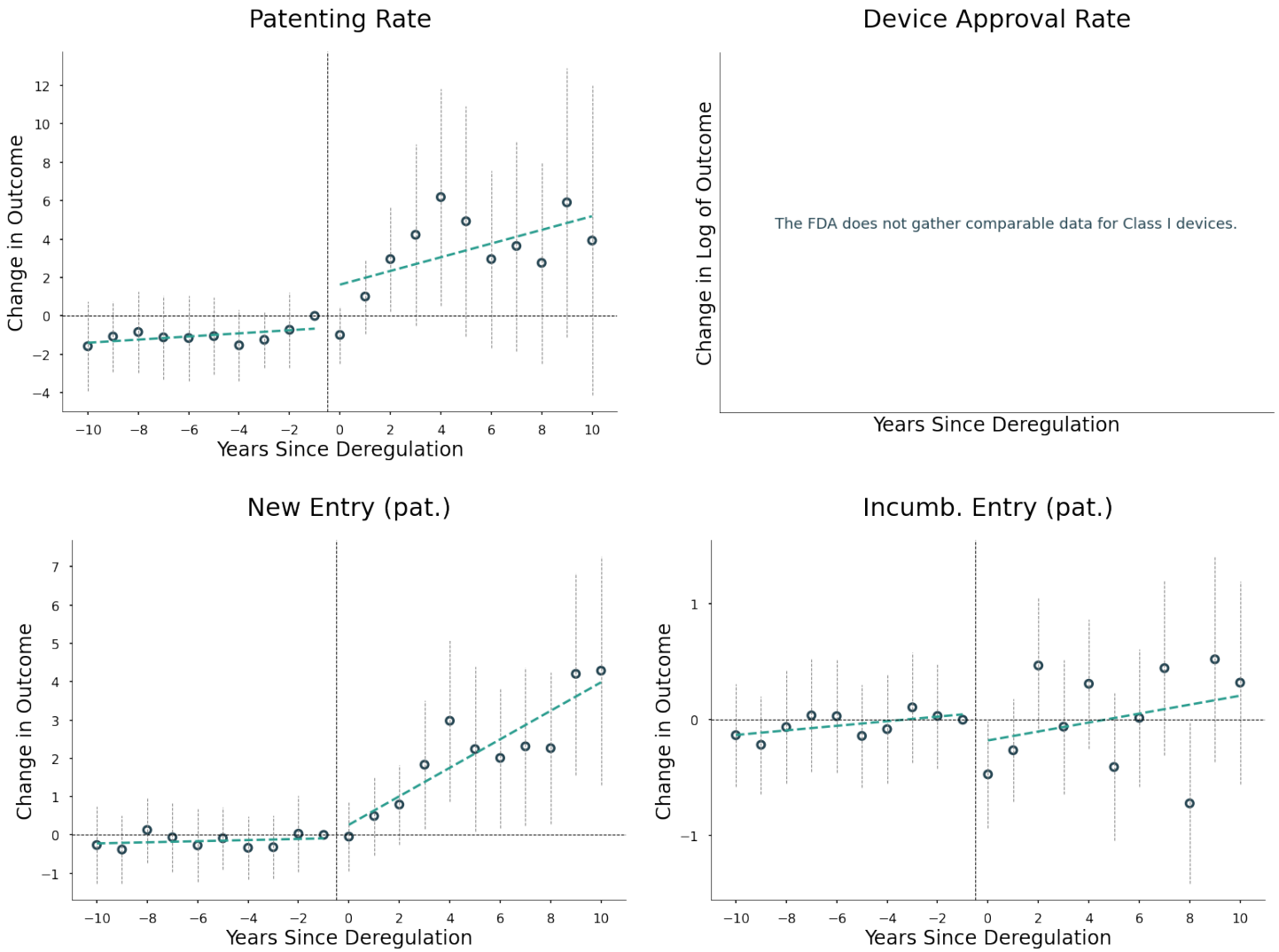
Note: This figure presents an example of a Class III to II down-classification event. In 2007, the FDA down-classified "intervertebral body fusion devices" to Class II. As a control case, "thoracolumbosacral pedicle screw systems" remained in Class II. Panel A measures the number of unique contact lens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

Figure 3: 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 the innovation outcomes. Only Class III to II down-classification events are considered. Controls are device types matched on baseline averages of the outcome. The coefficient β_{-1} is omitted and serves as the reference period. Data are analyzed at an annual frequency. The top-left subfigure illustrates the evolution of 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 approval 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 calulcated following Conley and Taber (2011).

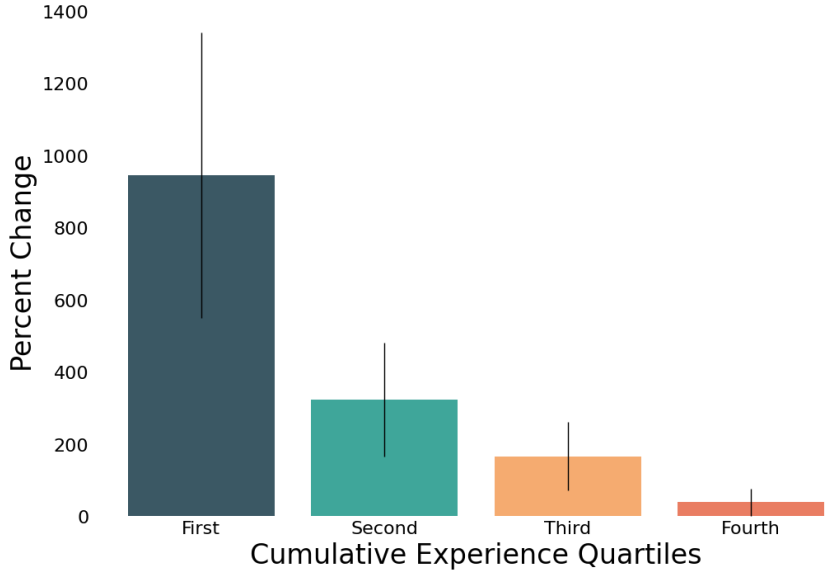
Figure 4: Effects of Class II to I Events (Moderate to Low Regulation)



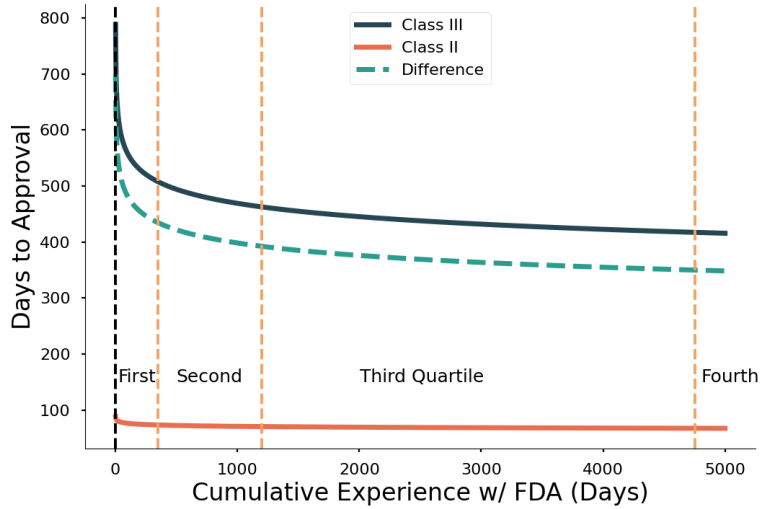
Note: This figure presents the estimates of the β_t coefficients from event-study equation 4 for my innovation measures. Only Class II to I down-classification events are considered. Controls are device types matched on baseline averages of the outcome. The coefficient β_{-1} is omitted and serves as the reference period. Data are analyzed at an annual frequency. The top-left subfigure illustrates the evolution of the patenting rate of treated device types relative to matched control groups. The top-right subfigure is blank as there is no comparable data for Class I approved devices. The bottom-left subfigure 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



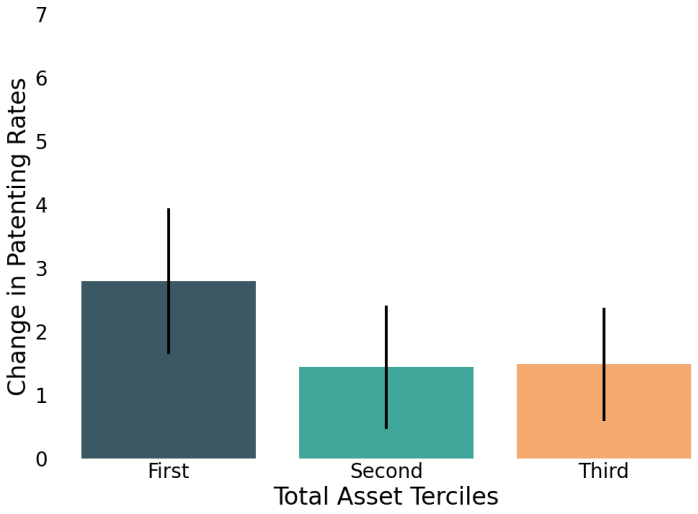
Panel B: Estimated Learning Curves



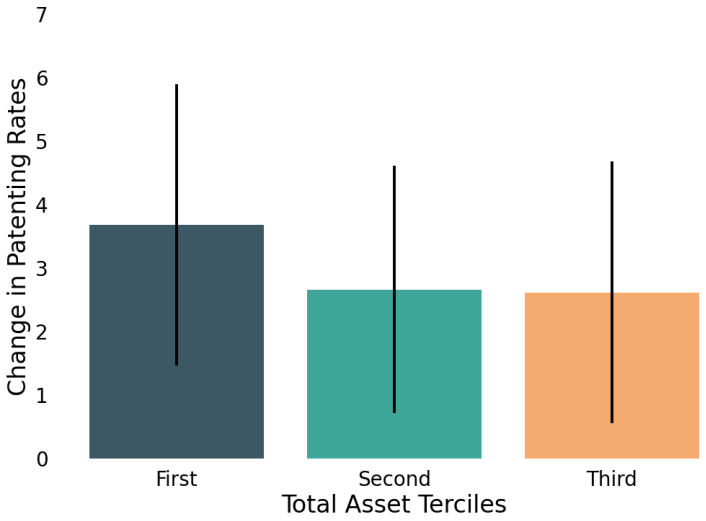
Note: This figure presents the experience-specific changes in the rates of newly marketed devices stemming from class III to II down-classification events and the learning curves estimated in equation C.1. Panel A provides the DID estimates of the rate of newly marketed devices in treated device types, 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 firms' total time spent satisfying FDA regulations up to the time of submitting an approval for the current device. Panel B presents the estimated learning curves for satisfying Class III and Class II regulations. The difference between Class III and Class II approval delays at a given level of FDA experience is also provided. The x-axis indicates the number of days spent on previous approvals. The y-axis describes the number of days taken for a current Class III or Class II device to be approved. I provide divisions of cumulative experience quartiles seen in the data. I exclude observations with no prior experience to avoid undefined outcomes and biases from the extensive margin in the estimation. 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



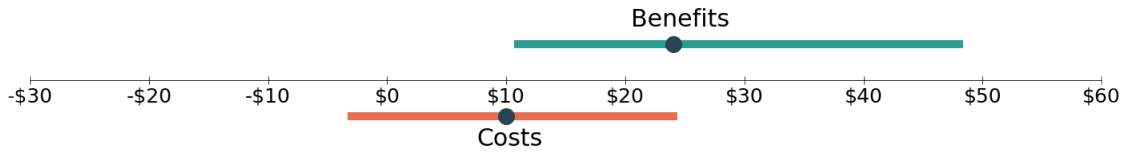
Note: This figure presents the DID estimates from equation 3 for the patenting rate across down-classification type and firm asset terciles. For the empirical estimates, I exclude patent data for private firms since I only observe firm asset data for publicly traded firms. Panel A presents the change 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 33-66th percentile, and the third represents the 66-100th percentile. Panel B presents the change in patenting rates in my Class II to I treated medical device types, relative to matched control groups, across asset terciles. 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)

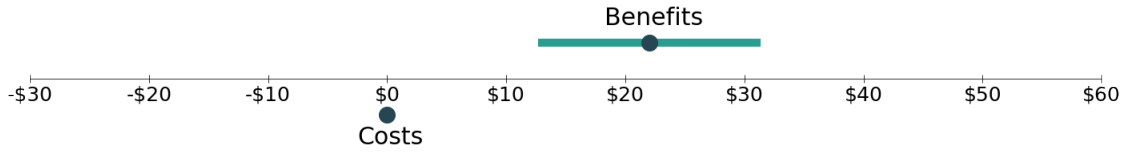
Note: This figure presents separate DID estimates of equation 3 for the change in the likelihood of device types exhibiting at least one annual occurrence of the given outcome variable by firm asset terciles. I set all outcomes greater than zero to one (LPM) as safety mentions and serious events are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

Figure 8: Annual Costs and Benefits of Down-Classifications (Dollars in Millions)

Panel A: Class III to II Down-Classifications



Panel B: Class II to I Down-Classifications



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

Table 1: Summary Statistics

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

Note: For information on the collection of all FDA policymaking across the last 40 years, see table E.1. See Kogan et al. (2017) for more information on the patent market valuation data, which was merged into my patent dataset. The CRSP/Compustat database was used to derive the total assets of the firms applying for patent protection and is a proxy for firm size. Market values and applicant assets are only available for patents filed by publicly traded firms, representing roughly 25% of the total sample of patents. Missing observations account for the discrepancies between (i) the number of total FDA device types (5,542) and the number of device types represented in device submissions, adverse event reports, and patents (many device types have no associated patents), (ii) the total number of patents and the number of patents with market valuations and applicant assets, and (iii) the total number of claims and claims containing amounts paid. *"Regulatory proficiency" indicates the total number of days a firm has experienced approval delays across all its submitted devices.

Table 2: Effect of Down-Classifications on Innovation

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

Note: The table presents estimates of equation 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 approvals are derived from FDA data and are not available for Class I devices. For column (4), Class III to II, control device types are treated after 2015; thus, all observations after 2015 are dropped. Confidence intervals are calculated using Conley–Taber test statistics. +, *, **, and *** correspond with statistical significance at the 0.10, 0.05, 0.01, and 0.001 levels respectively.

Table 3: Effect of Down-Classifications on Market Composition

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

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

Note: The table presents estimates of equation 3, which is a difference-in-differences (DID) style OLS regression model. Column (1) presents the 5-year baseline average of treated device types for the outcomes listed on the left-hand side. Adverse event outcomes are derived from the FDA MAUDE database. Columns (2)–(5) present DID estimates for the listed outcomes using different control groups. Namely, a matched control group, intuitively similar device types (treat similar diseases), "later treated" device types (treated after sample window), and the full sample, respectively. For column (4), Class III to II, control device types are treated after 2015; thus, all observations after 2015 are dropped. Confidence intervals are calculated using Conley–Taber test statistics. +, *, **, 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 Model Extensions

A.1 Bankruptcy Protection

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. I define the unspent capital available to cover damages as u. Unspent capital includes the capital not spent on commercialization costs $(K - c)$ and profits from the current period, given by $u = \pi + K - c$. This term incorporates the simplifying assumption that net profits from the last period are distributed as devidends.[45]

Let ν represent the total realized damages from product defects, with probability distribution function $f(\nu; x^*)$. In the presence of bankruptcy, the expected damages is given by

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

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 are fixed at u. Thus, instead of paying these

[45] 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 bankruptcy. However, the theoretical insights remain the same as initially smaller firms will face fewer expected damages for some time.

outsized damages, the firm declares bankruptcy and contributes the value of its total assets to partially cover its damages. Hence, expected damages $D^T(x^*)$ are determined by the probability-weighted sum of damages from 0 to u, plus the probability-weighted sum of u for all damages higher than u. Assume that the marginal benefit of safety effort for small firms is less than large firms as at levels of safety effort, as there are fewer damages to abate (e.g., $-D'_T(x) < -D'(X)$ for all x)

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 4. *(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., $K_A < \bar{\phi}$). Firm A and B are otherwise identical. If deregulation leads to an increase in safety effort (see proposition 2 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 iff $x^*_B > x^*_A$ (which can stack with proposition 3 part ii, if capital is also below safety effort costs).*

A.2 The Social Planner's Regulation Problem

In this appendix section, I conceptualize the regulating agency's decision to down-classify a medical device type. I characterize this decision as an optimal stopping problem, where there is value to waiting and learning a device type's inherent level of risk before down-classification.[46] This characterization aligns well with the FDA's current approach to regulating medical devices: FDA currently regulates radical new devices heavily in Class III to learn about the device type's inherent risk. Then, the FDA chooses when (if ever) to deregulate when the history of information on device risk suggests that stringent regulation

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

is not necessary.

This model borrows from the seminal job search model of Jovanovic (1979) and the drug-approval model presented in Carpenter et al. (2010).[47] The agency considers medical device type (product code) j with health benefit γ_j and underlying danger μ_j. The health benefit γ_j represents improvements in life expectancy and quality of life, and danger represents the expected number of adverse events (e.g., deaths) over a given interval of time.[48] Medical device type j faces regulation R_c in Class c, where $c \in \{I, II, III\}$. Flows of innovation $I_j(R_c)$ in device type j are dependent on regulation and affect the health benefits and danger. The device type j is used at the rate N_j. Together, society reaps a benefit flow $B(I_j(R_c), N_j, \gamma_j)$ when medical device type j is regulated in Class c. The agency establishes regulation R_c for Class c devices to mitigate harm. The share of unmitigated harm in device type j is denoted by $M_j(R_c, I(R_c)) \in [0, 1]$, with unmitigated harm decreasing in R_c. The agency values life lost from adverse events relative to lives saved from innovation flows at the rate ν.

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

With the device type subscript supressed, I charactize the agency's learning process.

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

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

With time t in the current regulatory framework and cumulative adverse events $X(t) = x$, the above assumptions imply that the information on harm μ can be characterized by a normal posterior distribution (Chernoff, 1968), with

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

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

I assume irrereversibility, or that once an agency down-classifies a medical device type from a class with high regulatory scrutiny ("H") to one with low regulatory scrutiny ("L," with $R_H > R_L$), they cannot subsequently up-classify. This assumption is consistent with what I see in the data. The FDA has down-classified hundreds of medical device types, but rarely up-classifies device types. This is also consistent with a desire for "reputation protection," as noted in Carpenter (2004b), in which the FDA cannot recover its repuational losses by up-classifying a device type—the public already internalized the bad decision the agency made. Together, the agency thus faces an optimal stopping problem of the learning process $\hat{\mu}_t$, characterized by a law of motion $d\hat{\mu}(t) = \frac{S(t)}{\sigma} dz(t)$, with $\hat{\mu}(0) = m$, and the objective

$$\begin{aligned} \max_{T(\omega)} E \Bigg\{ &\int_{T(\omega)}^{\infty} e^{-\delta t}[B(I(R_L), \cdot) - \nu M(R_L, I(R_L))\mu^*(t, \omega)]dt + \\ &\int_{0}^{T(\omega)} e^{-\delta t}[B(I(R_H), \cdot) - \nu M(R_H, I(R_H))\mu^*(t, \omega)]dt \Bigg\}, \end{aligned} \tag{A.3}$$

where δ is a discount factor and $\mu*$ is the agency's estimate of danger at the time of down-classification. The parameter ω denotes an elementary event in the probability space Ω, and t is the variable of integration. This objective illustrates that the agency should choose an optimal stopping time $T(\omega)$ only when the difference between the benefits of lifesaving inno-

vation and the costs of device harm is expected to be at least as large as the same difference before down-classification. The optimal policy occurs at the boundary (see appendix B.5 for derivation)

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

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

$$\hat{\mu} < \frac{B(I(R_L), \cdot) - B(I(R_H), \cdot) - \frac{S(t)^2}{2\sigma^2} V_{\hat{\mu}\hat{\mu}}(\theta(t), t)}{\nu[M(R_L, I(R_L)) - M(R_H, I(R_H))]}. \tag{A.5}$$

The quantity $\frac{S(t)^2}{2\sigma^2} V_{\hat{\mu}\hat{\mu}}(\theta(t), t)$ represents the value of waiting and learning more about the harm of the device type.[49] Thus, down-classifications should occur if the estimate of harm is less than the difference between the benefits from increased lifesaving innovation, less the option value of waiting, divided by the relative value of net unmitigated harm after down-classification.

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

[49] Note that as t approaches infinity, I can extract the deterministic boundary, with no underlying uncertainty about harm, given by $\theta = \frac{B(I(R_L),\cdot) - B(I(R_H),\cdot)}{\nu[M(R_L, I(R_L)) - M(R_H, I(R_H))]}$, where the agency should down-classify if $\mu < \frac{B(I(R_L),\cdot) - B(I(R_H),\cdot)}{\nu[M(R_L, I(R_L)) - M(R_H, I(R_H))]}$. Naturally, if μ is certain, there is no value in waiting for additional information. In this setting, the agency would down-classify if danger is less than the net benefits of innovation divided by the relative value of net unmitigated harm after down-classification. However, in a finite-time context, there will be an option value of waiting expressed by $\frac{S(t)^2}{2\sigma^2} V_{\hat{\mu}\hat{\mu}}(\theta(t), t)$.

time to down-classification increases.

This model helps characterize a regulatory response that maximizes social welfare when there is an uncertain risk of product harm within the FDA's current regulatory framework. In practice, the FDA regulates medical devices with the intent to mitigate harm and, to a lesser extent, ensure efficacy, and does not consider the potential for innovation.[50] Since device harm is the central focus in down-classification decisions, average adverse event rates of down-classified device types closely resemble those of device types within their prospective class (see figure E.3).

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

B Proofs

B.1 Proof of Proposition 1

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

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

firm A.

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

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

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

$$DiD = (Returns_{A,N} - Returns_{A,R}) - (Returns_{B,N} - Returns_{B,R}). \tag{B.1}$$

We WTS that this difference is positive, or that the increase in returns is higher for firm A. Rewriting equation B.1, gives

$$DiD = (Returns_{A,N} - Returns_{B,N}) - (Returns_{A,R} - Returns_{B,R}). \tag{B.2}$$

From part equation B.1 we get

$$DiD = -(Returns_{A,R} - Returns_{B,R}) > 0. \tag{B.3}$$

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

B.2 Proof of Proposition 2

I want to show that $\underline{x} < x^*$. To prove (i), assume $x_R^* > \underline{x}$. Note that x_R^* is chosen such that

$$\psi + C_x(\chi t_{comm} + \psi x_R^* - K) \; = - \; REL \cdot \; D'(x_R^*). \tag{B.4}$$

and x^* is chosen such that

$$\psi + C_x(\psi x^* - K) \; = - \; EL \cdot \; D'(x^*). \tag{B.5}$$

I want to show that $x^* > x_R^*$. Assume, by way of contradiction, that $x^* \leq x_R^*$. This means that $C_x(\chi t_{comm} + \psi x_R^* - K) \geq C_x(\chi t_{comm} + \psi x^* - K)$, since $C_x(\ )$ is increasing in x. This also implies that $C_x(\chi t_{comm} + \psi x^* - K) \geq C_x(\psi x^* - K)$, since $\chi t_{comm} > 0$. Thus, $C_x(\chi t_{comm} + \psi x_R^* - K) \geq C_x(\psi x^* - K)$. Further, we know that $REL < EL$, and that $D'(x_R^*) > D'(x^*)$. Together, these inequalities and optimality conditions imply that

$$\psi + C_x(\psi x^* - K) \ \leq - \ REL \cdot \ D'(x_R^*). \tag{B.6}$$

Further, these inequalities imply that

$$\psi + C_x(\psi x^* - K) \ < - \ EL \cdot \ D'(x^*). \tag{B.7}$$

A contradiction. Thus, $x^* > x_R^*$, which implies $x^* > \underline{x}$.

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

$$\psi + C_x(\psi x^* - K) \ = - \ EL \cdot \ D'(x^*). \tag{B.8}$$

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

$$\psi + C_x(\underline{x} - K) \ > - \ EL \cdot \ D'(\underline{x}). \tag{B.9}$$

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

B.3 Proof of Proposition 3

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 deregulated environment N, the returns to commercialization are given by:

$$Returns = EL \cdot [\pi_N - D(x^*)] - \psi x^* - C(\psi = x^* - K). \tag{B.10}$$

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. Assume, by way of contradiction, that exists a maximum 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 deregulated environment for both firms. If so, then commercialization is the same across both firms ("non-marginal").

Thus, we have

$$Returns_{A,N} - Returns_{B,N} < 0 \text{ and } Returns_{A,R} - Returns_{B,R} < 0. \tag{B.11}$$

I want to also show that the sign of the following difference-in-differences is ambiguous: $(Returns_{A,N} - Returns_{A,R}) - (Returns_{B,N} - Returns_{B,R})$. We have that $(Returns_{A,N} - Returns_{A,R}) - (Returns_{B,N} - Returns_{B,R}) = (Returns_{A,N} - Returns_{B,N}) - (Returns_{A,R} - Returns_{B,R})$. From part iii, we know this difference could be positive or negative. The first and second difference 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 safety effort costs (i.e., $K_A \geq \psi x_A^*$), despite being lower than non-financing costs before deregulation, then $(Returns_{A,N} - Returns_{B,N}) = 0$ 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. The larger change in returns for firm A would translate into a larger increase in net profits if both firm A and B experience increases in net profits from deregulation.

B.4 Proof of Proposition 4

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 deregulted firm B is chosen such that

$$\psi + C_x(\psi x_B^* - K_B) \ = - \ EL \cdot \ D'(x_B^*). \tag{B.12}$$

and for firm A:

$$\psi + C_x(\psi x_A^* - K_A) \ = - \ EL \cdot \ D_T'(x_A^*). \tag{B.13}$$

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

$$\psi + C_x(\psi x_A^* - K_A) \ < - \ EL \cdot \ D'(x_B^*). \tag{B.14}$$

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 strenthens the inequality if $K_A < \psi x_A^*$, or capital is less than safety effort costs). A contradiction. Thus $x_A^* < x_B^*$.

B.5 Proof of Optimal Stopping Problem Boundary Condition

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

$$\begin{aligned} \max_{T(\omega)} E \Bigg\{ \int_{T(\omega)}^{\infty} e^{-\delta t} [B(I(R_L), \cdot) - \nu M(R_L, I(R_L)) \mu^*(t, \omega)] dt + \\ \int_0^{T(\omega)} e^{-\delta t} [B(I(R_H), \cdot) - \nu M(R_H, I(R_H)) \mu^*(t, \omega)] dt \Bigg\}, \end{aligned} \tag{B.15}$$

where μ^* is the bayesian estimate of harm at the optimal stopping time, $M(R_c, I(R_c))$ is the mitigating factor, representing the amount a given regulation mitigates harm. By Jovanovic (1979), equation A.3 is equivalent to maximizing

$$\begin{aligned} \max_{T(\omega)} E e^{-\delta T(\omega)} \Bigg\{ \frac{B(I(R_L), \cdot) - \nu M(R_L, I(R_L)) \mu^*(T(\omega), \omega)}{\delta} \\ - \frac{B(I(R_H), \cdot) - \nu M(R_H, I(R_H)) \mu^*(T(\omega), \omega)}{\delta} \Bigg\} \end{aligned} \tag{B.16}$$

Using the Bellman equation and applying Ito's lemma to equation B.16, I have

$$\delta V(\hat{\mu}, t) = V_t(\hat{\mu}, t) + \frac{S(t)^2}{2\sigma^2} V_{\hat{\mu}\hat{\mu}}(\hat{\mu}, t). \tag{B.17}$$

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

Value matching:

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

Smooth pasting:

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

Plugging in the value matching and smooth pasting conditions above into equation B.17 gives

$$B(I(R_L), \cdot) - \nu M(R_L, I(R_L))\theta(t) - B(I(R_H), \cdot) + \nu M(R_H, I(R_H))\theta(t) - \frac{S(t)^2}{2\sigma^2} V_{\hat{\mu}\hat{\mu}}(\theta(t), t) = 0. \tag{B.18}$$

Solving for $\theta(t)$ in equation B.18 gives,

$$\theta(t) = \frac{B(I(R_L), \cdot) - B(I(R_H), \cdot) - \frac{S(t)^2}{2\sigma^2} V_{\hat{\mu}\hat{\mu}}(\theta(t), t)}{\nu[M(R_L, I(R_L)) - M(R_H, I(R_H))]}. \tag{B.19}$$

C Simulation Exercise

C.1 Estimation Framework for the Learning Curve Parameters

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

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

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

More novel devices within a given medical device type may face longer approval delays if the FDA is more careful with these devices to ensure that new scientific characteristics do not lead to unexpected harm. However, the structure of Class III regulations helps distinguish between more or less novel innovation. As mentioned in section 1, firms that have already submitted an original PMA in a Class III medical device type may use PMA supplements for follow-on innovation within that device type. PMA supplements experience shorter approval delays and face fewer data requirements. On the other hand, the FDA requires original PMAs when firms have not yet submitted a PMA in a given Class III medical device type or when an incumbent firm invents a new device that is sufficiently novel. Thus, I include only approval delays that firms encountered when submitting original PMA documents in my analysis to condition on device novelty. This ensures that novelty is not driving approval delays.[51] 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,

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

[51] 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.

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. Figure E.15 shows that the fit of the log-linear regression line that estimates equation C.1 is quite close after accounting for firm and device-type fixed effects.

C.2 Simulations

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

$$REL \ \cdot \ \pi_R - \chi t_{comm} - \psi \underline{x} - C(e_R). \tag{C.2}$$

I use patent valuations to capture the profits of commercialization, which can be thought of as a one-time payout. Thus, I assume that returns take the form of

$$\underbrace{\alpha_{f,j}(R_c, \cdot)}_{\text{Payout}} - \underbrace{\chi_j t_{comm}}_{\text{Delay Cost}} - \underbrace{(\psi x^* + REL \ \cdot \ D(x^*))}_{\text{Damages \& Effort Costs}} - \underbrace{C(e)}_{\text{Financing Cost}} \quad . \tag{C.3}$$

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

were included, they would push the simulation results further toward my empirical results.

The learning curve parameters γ and $\beta(R_c)$ are estimated in section 5, with these values for Class III and Class II devices given in table E.12. I perform two simulation exercises to further illustrate the heterogeneous effects of down-classification and to emphasize potential areas for improvement. First, I separately simulate the effects of down-classifications across firm size and firm experience. The results of these simulations are provided in section 5, and I show that they are similar to the results generated in my empirical estimation. I then simulate the effects of a flattening of the learning curve on the rate of unique device inventions to highlight what might happen if FDA policies were easier to navigate.

To execute these simulations, I first generate distributions of device payouts, firm sizes, and firm FDA cumulative experience. I proxy for device payouts using the stock market valuations of medical devices assessed upon their patent grant announcements. Using patent valuation as a proxy requires the assumption that the market can adequately identify the expected payoff that a given patented innovation will yield to a firm. The device payout distribution is generated by fitting a gamma distribution to the medical device patent values for Class III and Class II devices separately. I then fit a lognormal distribution to my firm size data to generate a distribution of asset values across firms. Lastly, I draw a distribution of firms' experience after fitting a gamma distribution to my firm FDA experience data.

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

$$\varepsilon_{p,R_c} = \frac{dln(p)}{dln(R_c)} \approx \frac{ln(p(R_c)) - ln(p(R_c'))}{ln(R_c) - ln(R_c')}. \tag{C.4}$$

Since the policy variation I analyze discretely changes regulatory stringency (instead of differential changes), I use the arc elasticity formula. Using patent valuations to measure the

payoff of a device invention, $\alpha_{f,j} = q_{f,j}[p(v_{f,j}, R_c) - AC_{f,j}]$, I derive the following relationship between the elasticity of payoffs (ε_{α,R_c}) and prices with some subscripts supressed,

$$\frac{ln(\alpha(R_c)) - ln(\alpha(R_{c'}))}{ln(R_c) - ln(R'_c)} = \frac{ln(q[p(R_c,\cdot) - AC]) - ln(q[p(R_{c'},\cdot) - AC])}{ln(R_c) - ln(R'_c)} = \frac{ln(\frac{p(R_c,\cdot)-AC}{p(R_{c'},\cdot)-AC})}{ln(\frac{R_c}{R_{c'}})}. \tag{C.5}$$

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

$$\frac{ln(\frac{p(R_c,\cdot)-AC}{p(R_{c'},\cdot)-AC})}{ln(\frac{R_c}{R_{c'}})} \approx \frac{ln(\frac{p(R_c,\cdot)}{p(R_{c'},\cdot)})}{ln(\frac{R_c}{R_{c'}})} = \frac{ln(p(R_c)) - ln(p(R'_c))}{ln(R_c) - ln(R'_c)}, \tag{C.6}$$

which is the same expression in equation C.4. Indeed, medical device markets are known to exhibit long-run profits that are greater than zero, suggesting that price is larger than average costs (Burns, 2012). Thus, using elasticity estimates from section 5, I calculate the resulting change in payouts after down-classification. This exercise requires the assumption of a one-to-one mapping between procedure price elasticities and the elasticities of negotiated prices between hospitals and device manufacturers, since my elasticity estimates relate to changes in procedure prices. More carefully, given a payout value $\alpha(R_c)$ and levels of regulatory stringency R_c and $R_{c'}$ in Classes c and c', I measure the change in the payout value from down-classification by plugging in the elasticity, ε_{α,R_c}, prior payout $\alpha(R_c)$, prior regulatory scrutiny R_c, and prospective regulatory scrutiny $R_{c'}$, and solving for the unknown value $\alpha(R_{c'})$ in the equation

$$\varepsilon_{\alpha,R_c} = \frac{ln(\alpha(R_c)) - ln(\alpha(R_{c'}))}{ln(R_c) - ln(R'_c)}. \tag{C.7}$$

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

I calibrate χ to match the cost of approval delays found in Makower et al. (2010) at the

daily level for both Class III and II devices.

After calibration, I first simulate the decisions to invent a new medical device for each firm in the distribution before and after a Class III to II and Class II to I down-classification event occurs. I then take the difference between the total number of firms innovating before and after the event and divide this difference by the baseline number of firms innovating to generate a percentage change in unique devices. Figure 6 shows the simulated percent change in the number of devices invented across firm asset terciles for both down-classification event types. Figure 5 shows the percent change in the number of unique devices simulated across firm experience quartiles for Class III to II down-classifications. I do not include simulations for Class II to I down-classifications as the FDA data does not provide reliable information on new device innovation for Class I devices). Thus I cannot measure which firms, with their cumulative FDA experience, are deciding to innovate.

I also model how flattening the learning curve affects the rate of new device inventions across the experience distribution. To this end, I anchor the days-to-approval value for the firm with the highest experience and iteratively reduce the learning parameter (γ) while solving for a $\beta(R_c)$ value that allows the new curve to pass through the anchored value. I then calculate the firms' decisions to innovate given the approval times corresponding to the new learning curve and take the difference between the decision after the learning curve is flattened and the decision at the baseline values of γ and β. I then sum these differences across each firm and calculate the percentage change in new device inventions relative to the baseline values. Figure E.10 shows the iterative flattening of the learning curve, and table E.13 provides the calculations of the percentage change in new device inventions.

D Additional Details

D.1 FDA Decision Rule for Reclassification

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

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

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

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

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

$$\text{Y} = \begin{cases} 0 \text{ if in "high" range,} \\ 50 \text{ if in "medium" range,} \\ 100 \text{ if in "low" range.} \end{cases} \tag{D.3}$$

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

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

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.

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

Manufacturers of Class I devices (those perceived as low-risk) must simply abide by a standard set of safe marketing practices called "general controls."[52] A newly marketed medical device can be categorized as Class I if it is reasonably similar (i.e., same intended use and broad characteristics) to another device categorized as Class I. However, if a new medical device has distinct characteristics or intended use, the new device is given a new class III product code.[53]

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

[53]The FDA can then evaluate the safety and efficacy of new product codes and reclassify them, or a device manufacturer can submit a "De Novo" petition for the formal classification of a new device type. A new device can be classified as Class I or II if "the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or...[The device requires a 510(k) (even if its generic

Manufacturers of Class II devices are required to follow specific guidelines, called special controls, designed to mitigate device-specific risk and submit a 510(k) document, or "premarket notification."[54] Through the 510(k) process, a manufacturer must demonstrate that their device is "substantially equivalent" to a previously marketed device for which a "premarket approval" (PMA) is not required. A device is substantially equivalent if it has the same intended use and technological characteristics as the predicate device. As seen in table E.15, the 510(k) path is shorter and less costly than the more intensive PMA process described below. However, the 510(k) process can be expensive, with an average cost of $24 million (Makower et al., 2010). If the FDA finds that a device is not sufficiently similar to a predicate device, the manufacturer must file a PMA, which carries the most stringent requirements.

Manufacturers of Class III devices must perform clinical trials through the PMA process to ensure their new device is safe and effective before commercialization.[55] Class III device types are perceived as high-risk since not enough information exists to establish special controls that ensure safety and effectiveness (i.e., new device types) or if special controls do not adequately mitigate device risk.[56] The PMA process takes much longer than the 510(k) process (see table E.15), and costs, on average, $75 million (Makower et al., 2010). After a manufacturer has submitted a PMA document for their device, any small changes to their device that affect the device's safety or effectiveness require a PMA supplement submission. PMA supplements often do not require premarket clinical data and experience shorter review timelines (Johnson, 2012).[57]

type is Class I) if] the device is intended for a use different from the intended use of a legally marketed device in that generic type of device...[or if] the modified device operates using a different fundamental scientific technology" (FDA, 2020a).

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

[55]Pre-amendment class III devices (those existing before 1976) only have to submit a 510(k) if the FDA has not issued a final order requiring PMA submission (Center for Devices and Radiological Health, 2018). A small percentage of 510(k)s also require a small amount of clinical data to support marketing clearance by the FDA.

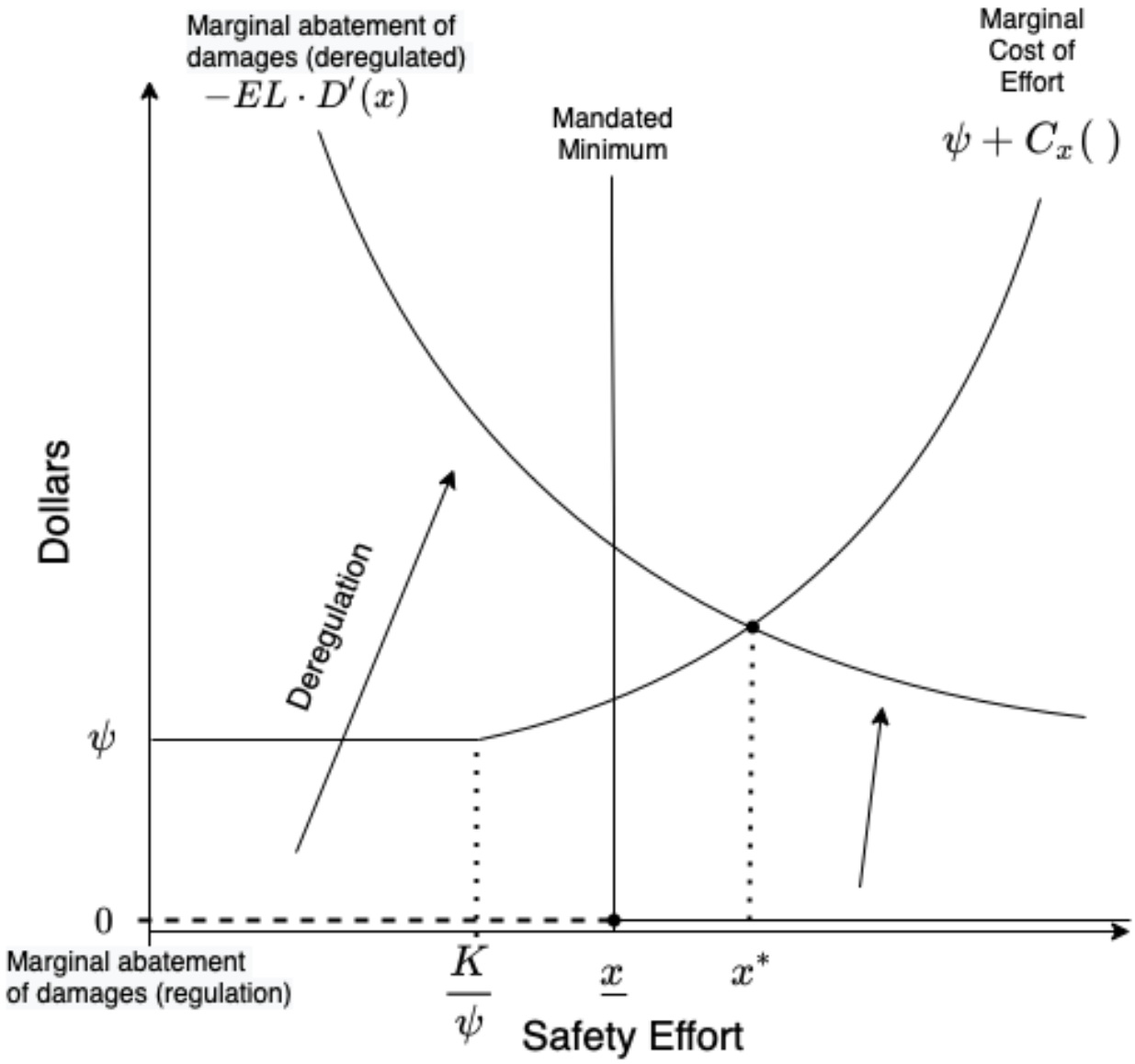
[56]Roughly 2% of product codes currently fall under this classification, although these product codes represent an outsized portion of U.S. medical device spending (Meier, 2009).

[57]However, the requirements associated with PMA supplements are dependent on the degree to which the new device has changed (see table E.15), with small changes (like labeling changes) requiring no fee and

design changes requiring preclinical testing. As seen in table E.16, most submitted class III documentation is PMA supplements.

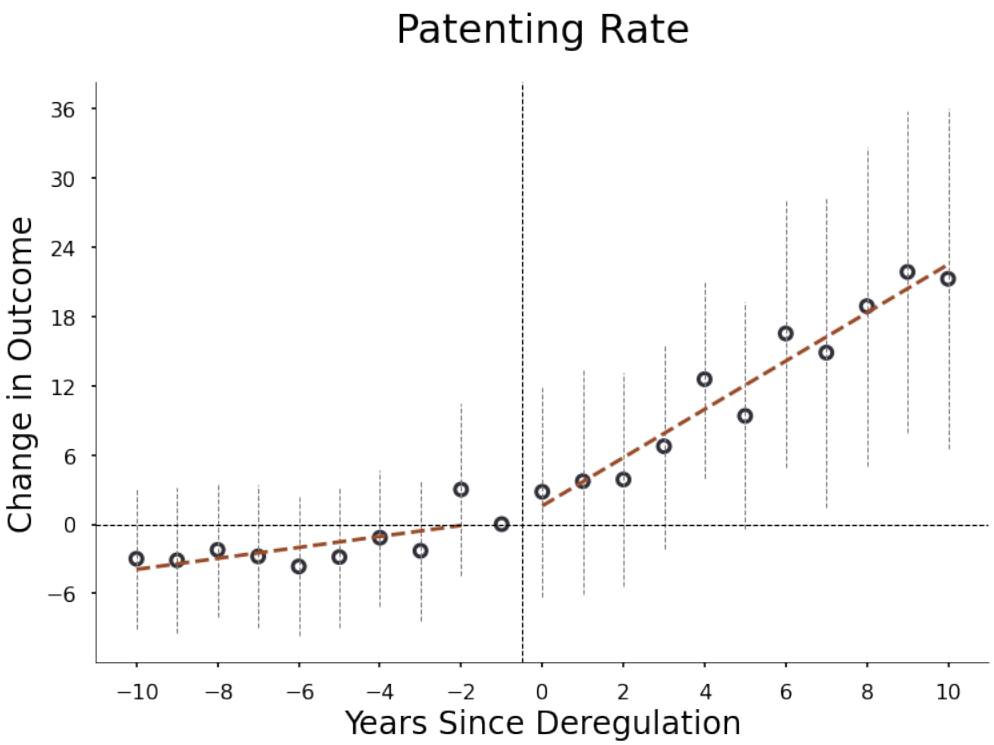
E Supplemental Figures and Tables

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



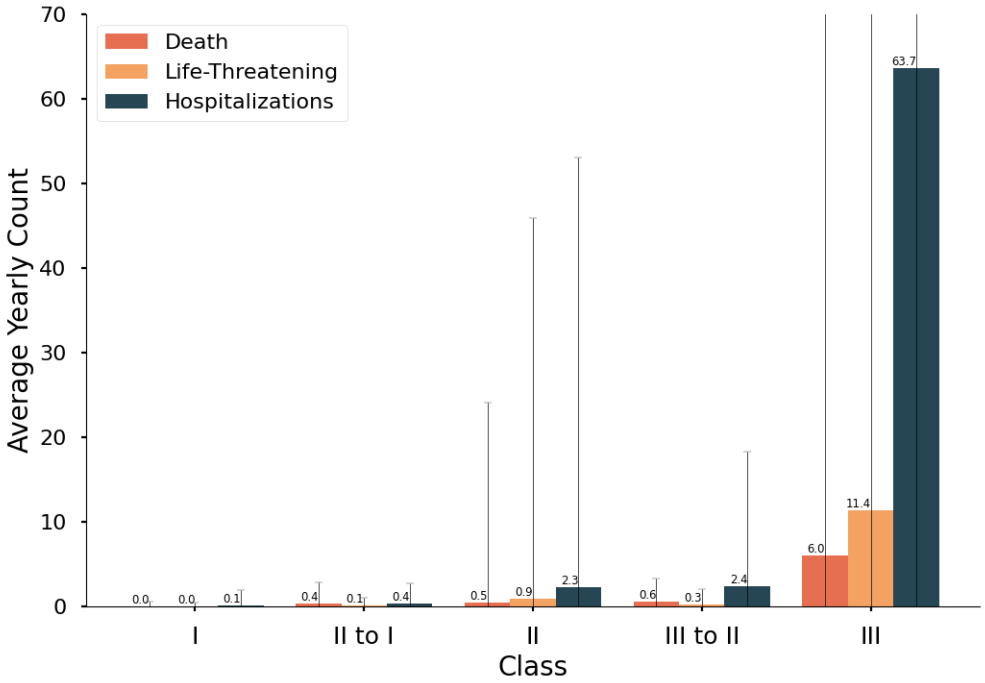
Note: This figure presents a possible change in safety effort after deregulation. This scenario is one in which deregulation could lead to an increase in safety effort, given a sufficient increase in damages, described in section 1. The value x^* represents the optimal level of safety effort after deregulation. The value $\underline{x}$ represents the mandated level of safety effort. Marginal benefits of safety effort under regulation are equal to zero due to preemption. The x-axis indicates the level of safety effort exerted. The y-axis denotes the dollar values of the marginal abatement of damages from safety effort and the marginal cost of safety effort. The counterfactual dotted section of marginal abatement curve under regulation represents the marginal abatement of damages from exerting effort below mandated levels while still achieving FDA approval. Shifts in the marginal benefit curve occur as fewer damages are precluded through federal preemption when regulatory stringency declines.

Appendix Figure E.2: Petitioned Down-Classification Events (Not FDA-Initated)



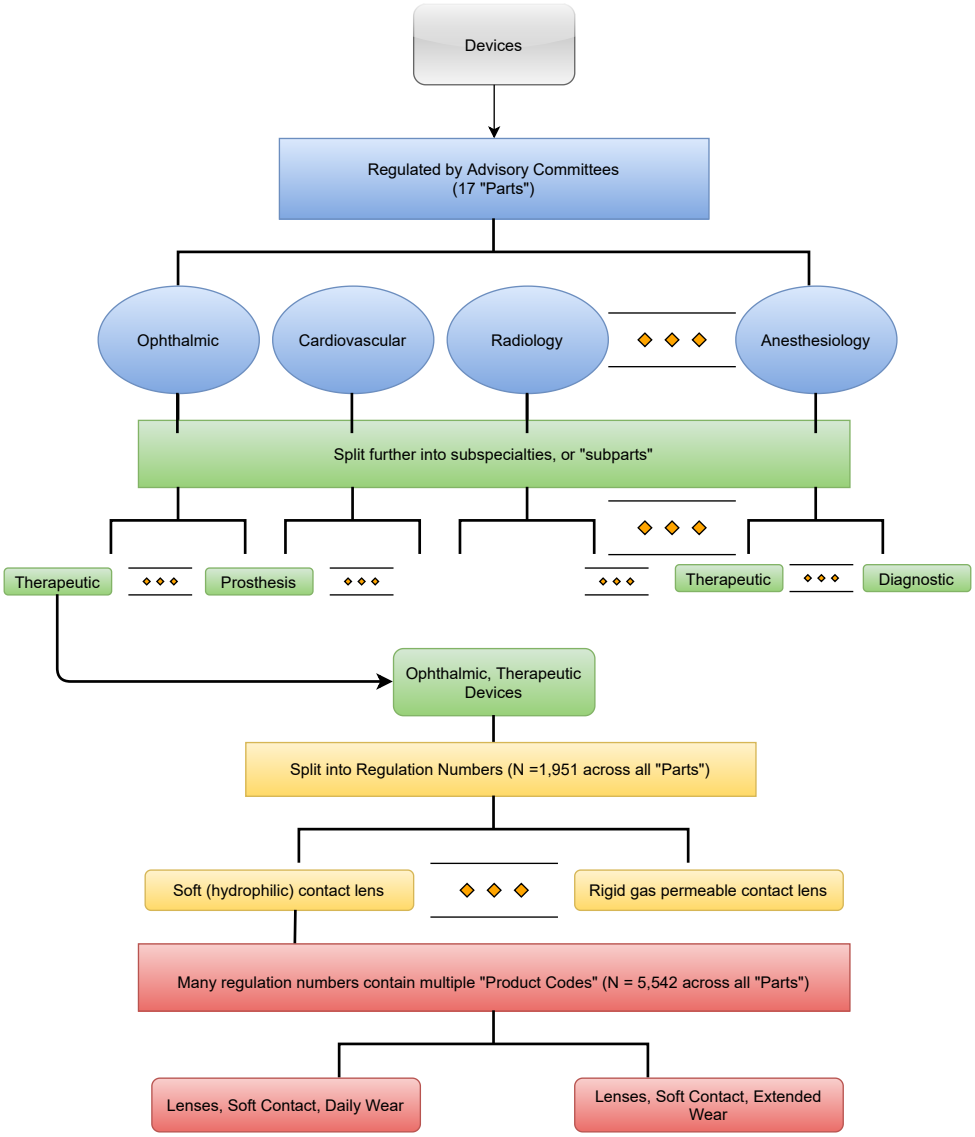
Note: This figure presents the estimates of the β_t coefficients from event-study equation 4 for the patent filing rate measure and illustrates the potential biases that stem from industry petition of down-classification. Outcome data are derived from USPTO patent data. Only Class III to II down-classification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



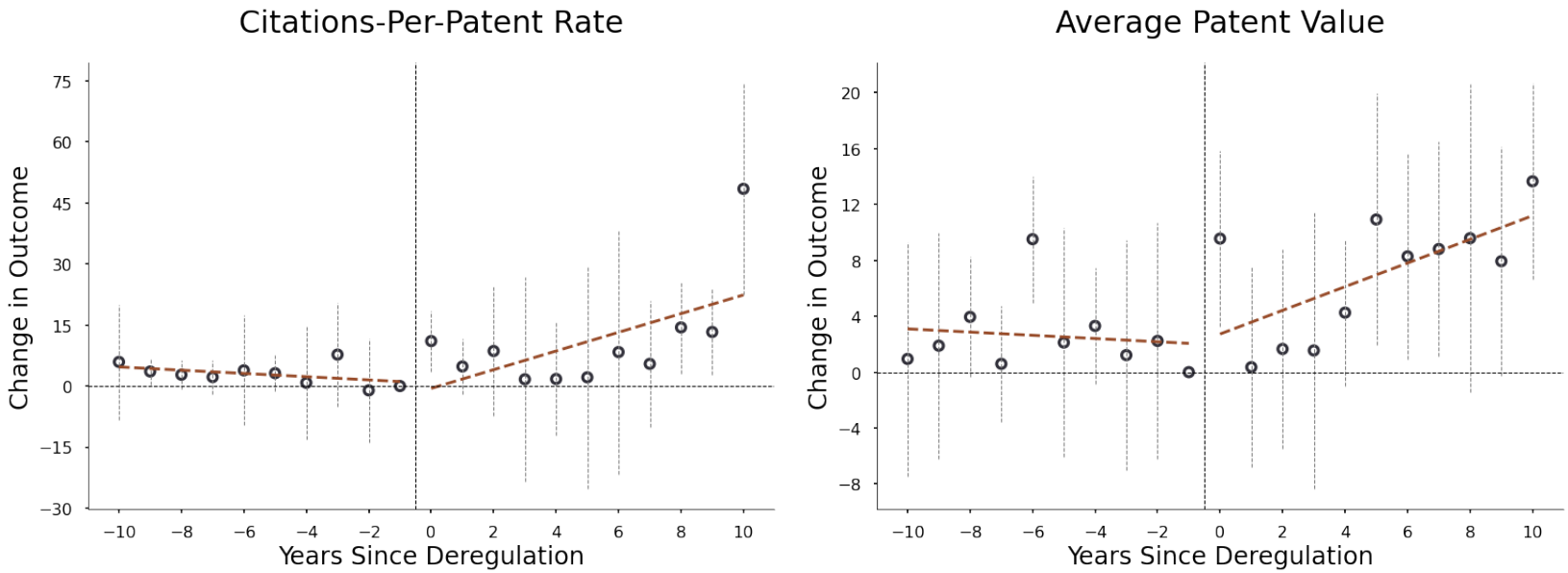
Note: This figure presents the annualized average counts of the specified adverse events for medical device types within the respective classification. The x-axis indicates the device type Class. The x-axis includes down-classified devices from Class III to II and Class II to I events separately. The 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 E.4: FDA Regulatory Hierarchy for Medical Devices



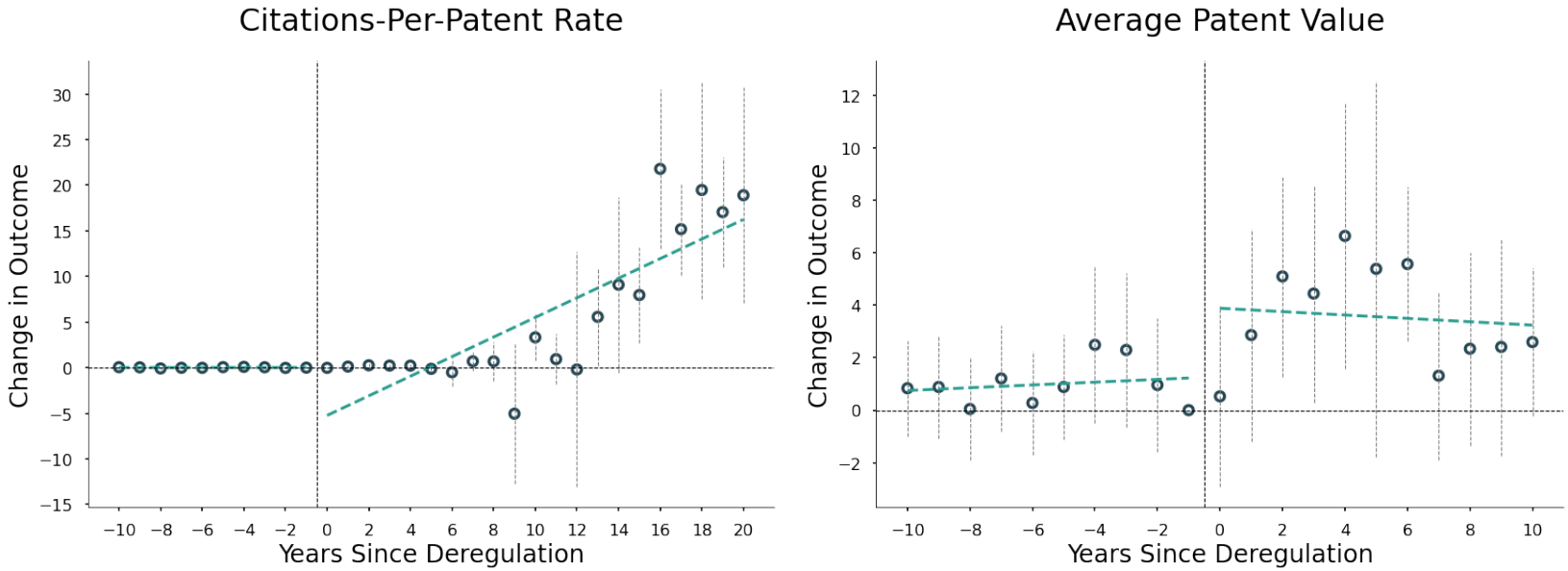
Note: This figure presents the hierarchy with which the FDA regulates medical devices. Devices are regulated at the highest level by "Parts," consisting of 17 advisory committees in distinct areas of medical expertise (e.g., Ophthalmic devices). Within a "Part," devices are categorized into "Subparts,"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

Appendix Figure E.5: Innovation Quality Event-Study Class III to II



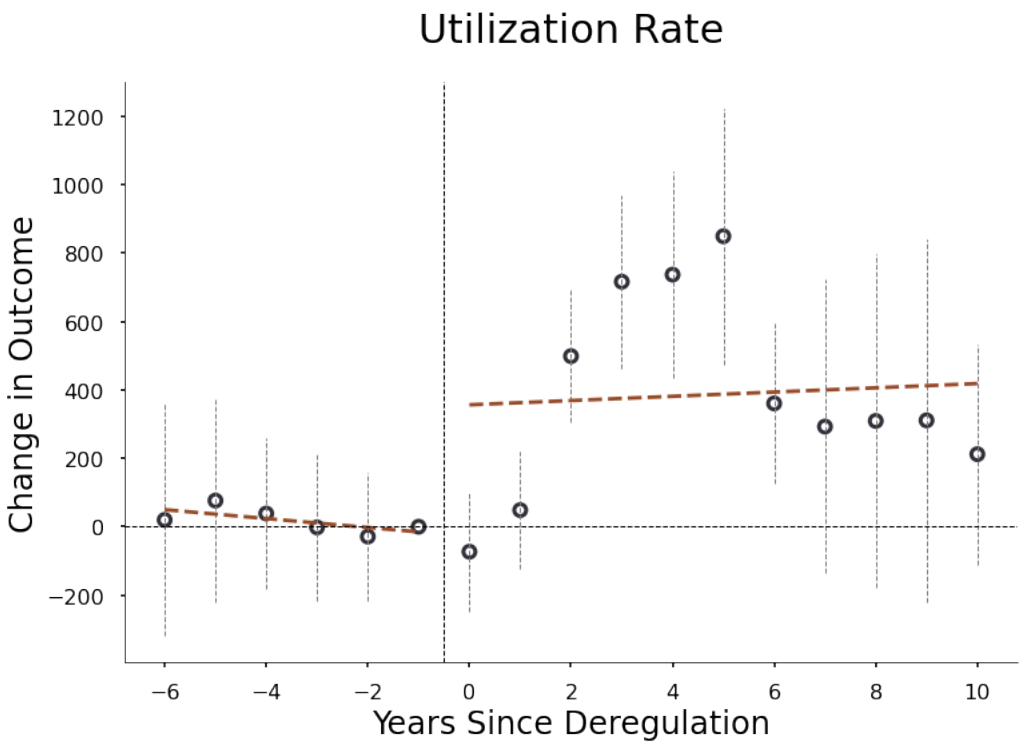
Note: This figure presents the estimates of the β_t coefficients from the event-study equation 4 for the innovation quality outcomes. Only Class III to II down-classification events are considered. Controls are device types matched on baseline averages of the outcome. The coefficient β_{-1} is omitted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

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



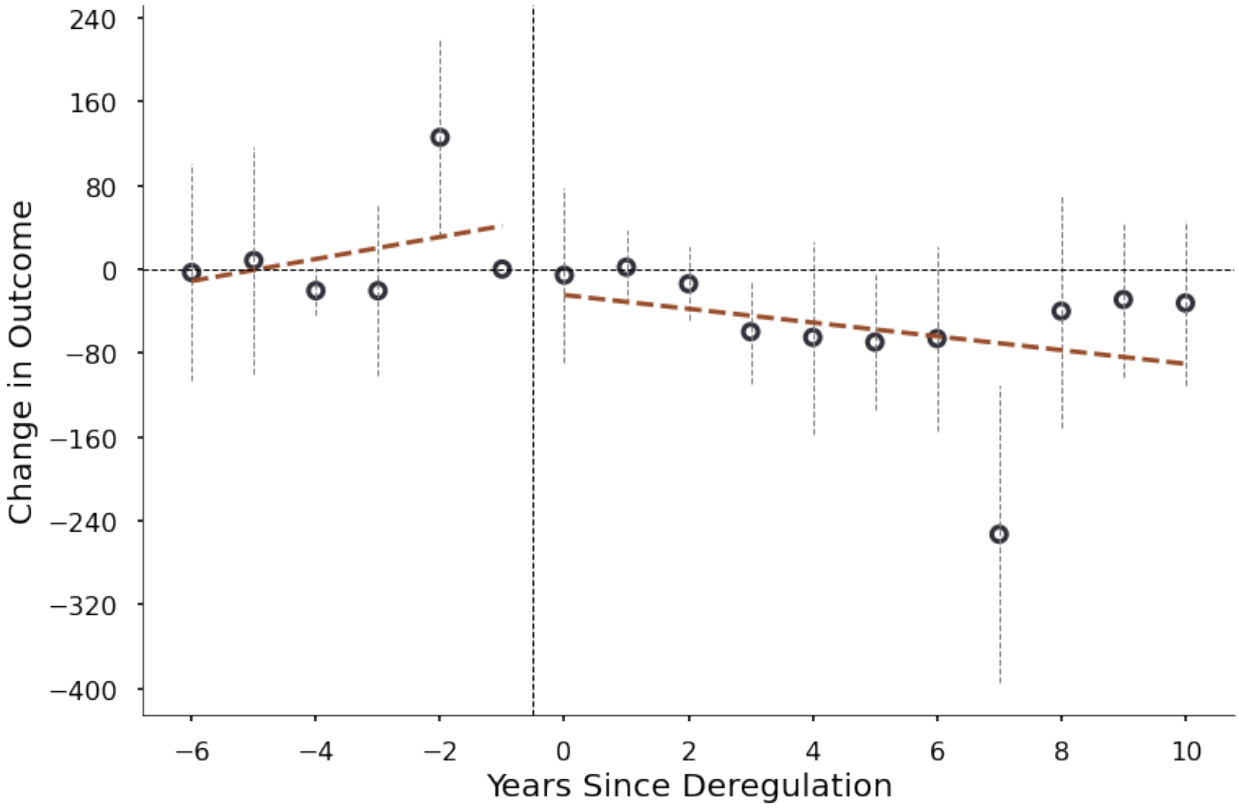
Note: This figure presents the estimates of the β_t coefficients from event-study equation 4 for my innovation quality measures. Only Class II to I down-classification events are considered. Controls are device types matched on baseline averages of the outcome. The coefficient β_{-1} is omitted and serves 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 E.7: Utilization Rates Event-Study



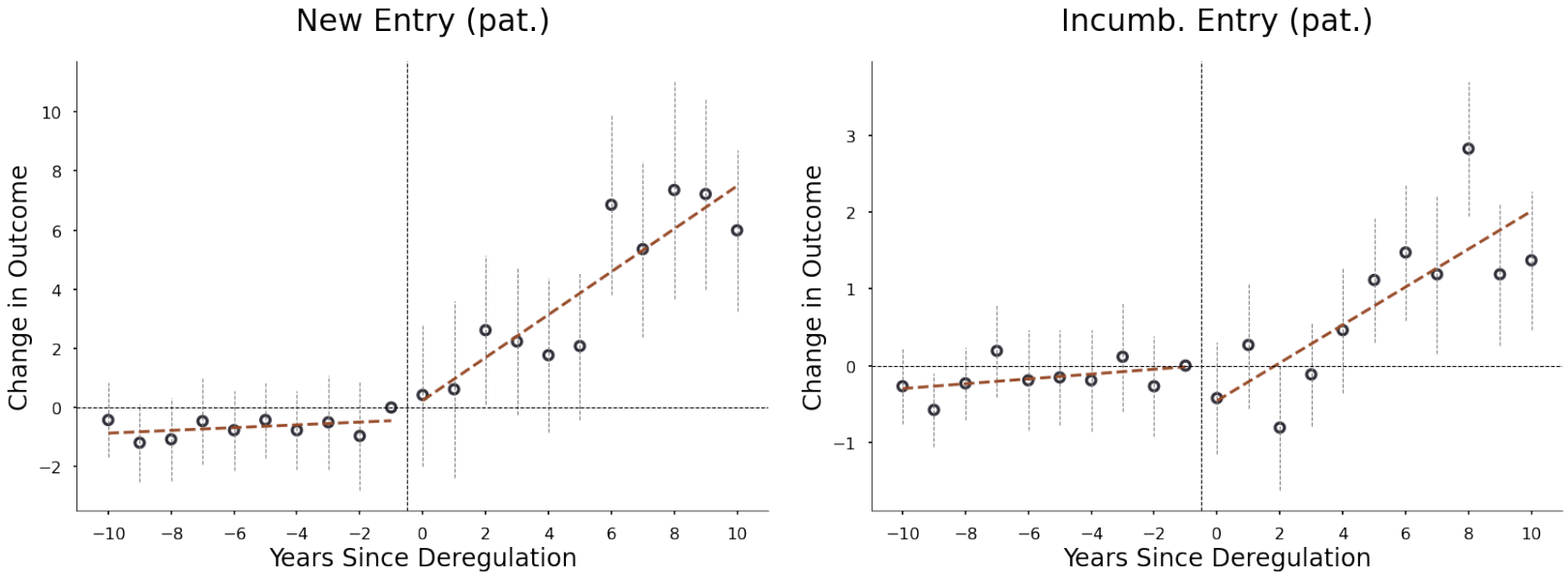
Note: This figure presents the estimates of the β_t coefficients from event-study equation 4 for the utilization rates of procedures that use treated or control medical device types. I do not have claims data before 2005; Thus, I only consider post-2005 Class III to II down-classification events. Controls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

Appendix Figure E.8: Procedure Price Event-Study Class III to II



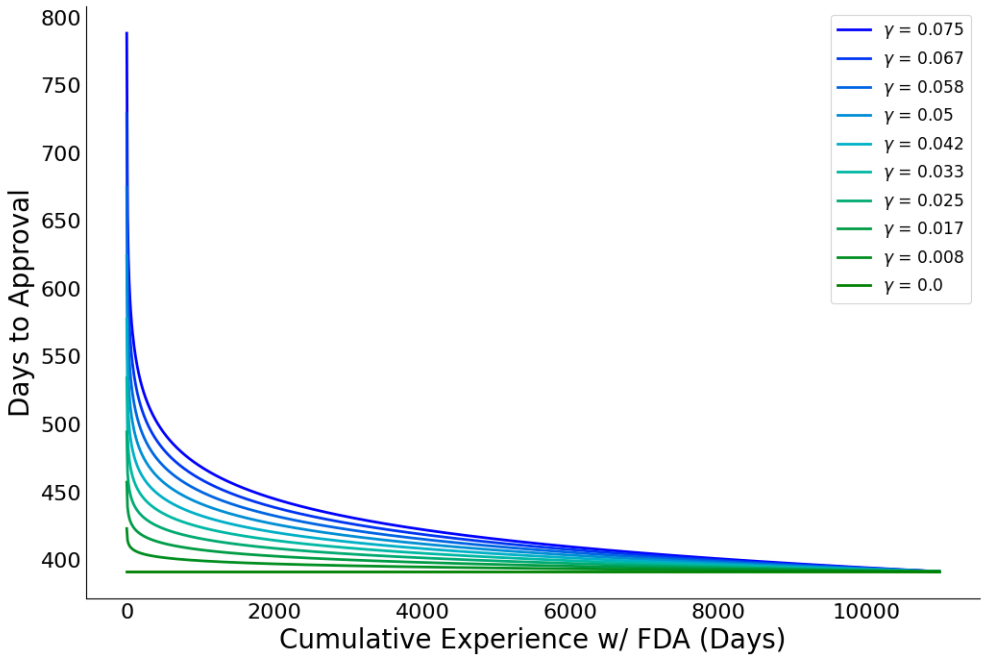
Note: This figure presents the estimates of the β_t coefficients from event-study equation 4 for the price component of my market composition measures. Controls are device types matched on baseline outcome averages. The coefficient β_{-1} is omitted and serves as the reference period. I do not have UCSDH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

Appendix Figure E.9: Market Structure Event-Study Class III to II (Patent Measures)



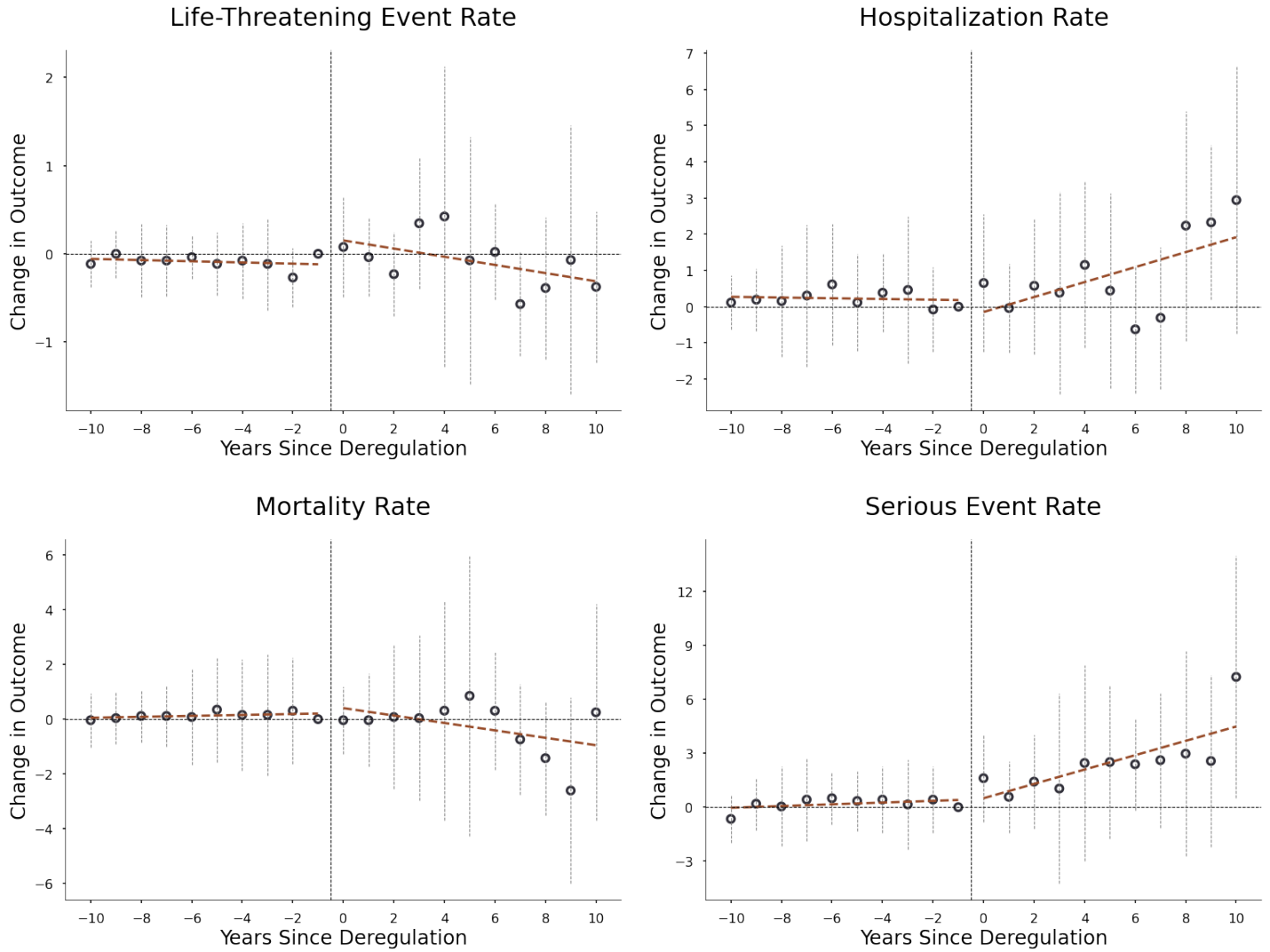
Note: This figure presents the estimates of the β_t coefficients from event-study equation 4 for my market composition measures. Only Class III to II down-classification events are considered. Data are analyzed at an annual frequency. Controls are device types matched on baseline averages innovation rates. The coefficient β_{-1} is omitted and serves as the reference period. The 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 E.10: Flattening the Learning Curve Simulation



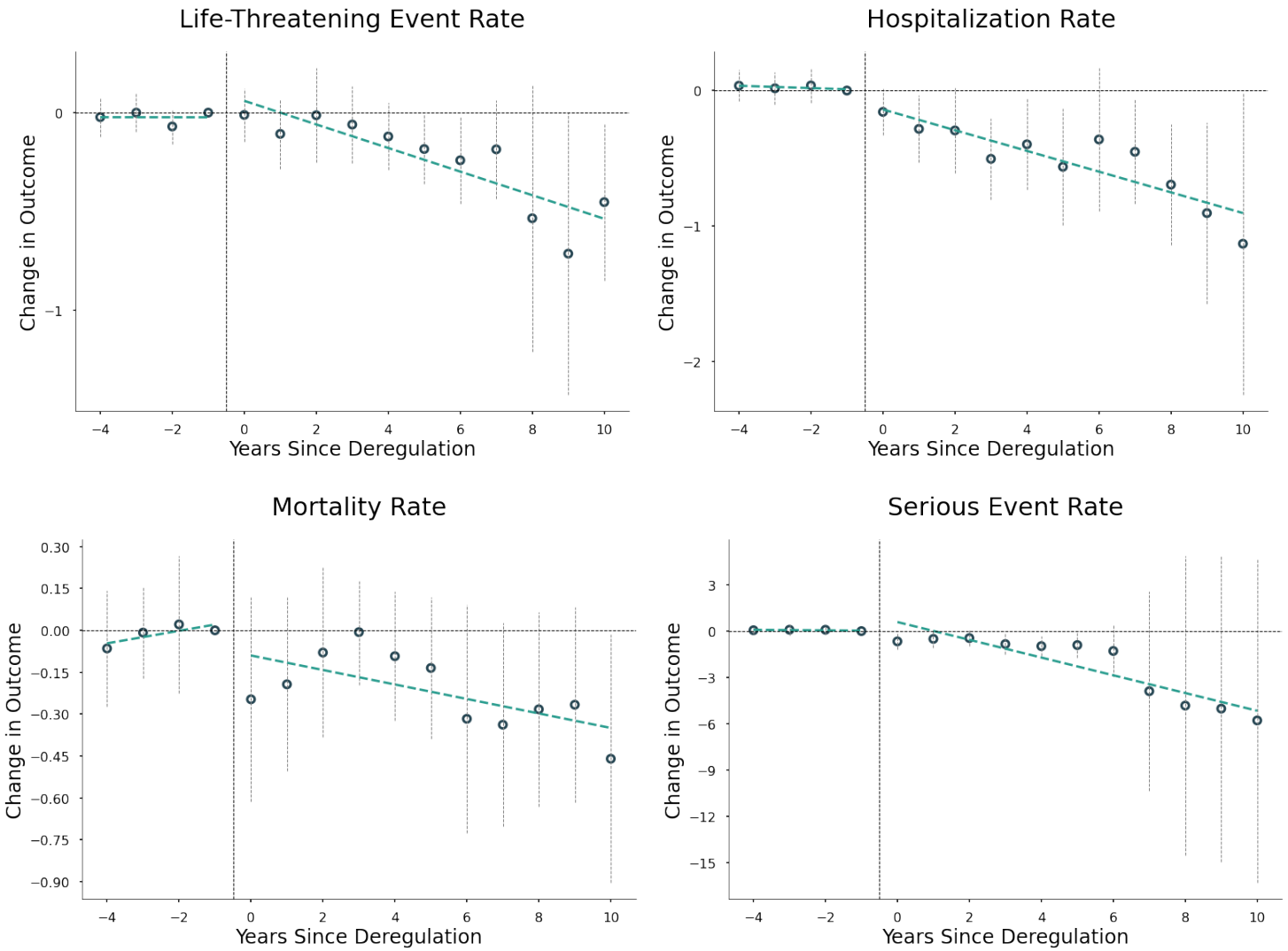
Note: This figure presents the simulation exercise of flattening the Class III learning curve estimated in equation C.1. I flatten the learning curve relative to the most experienced firm. The results of this simulation are provided in table E.13. Above, γ begins at its initial starting point estimated 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 E.11: Adverse Event Event-Study Class III to II



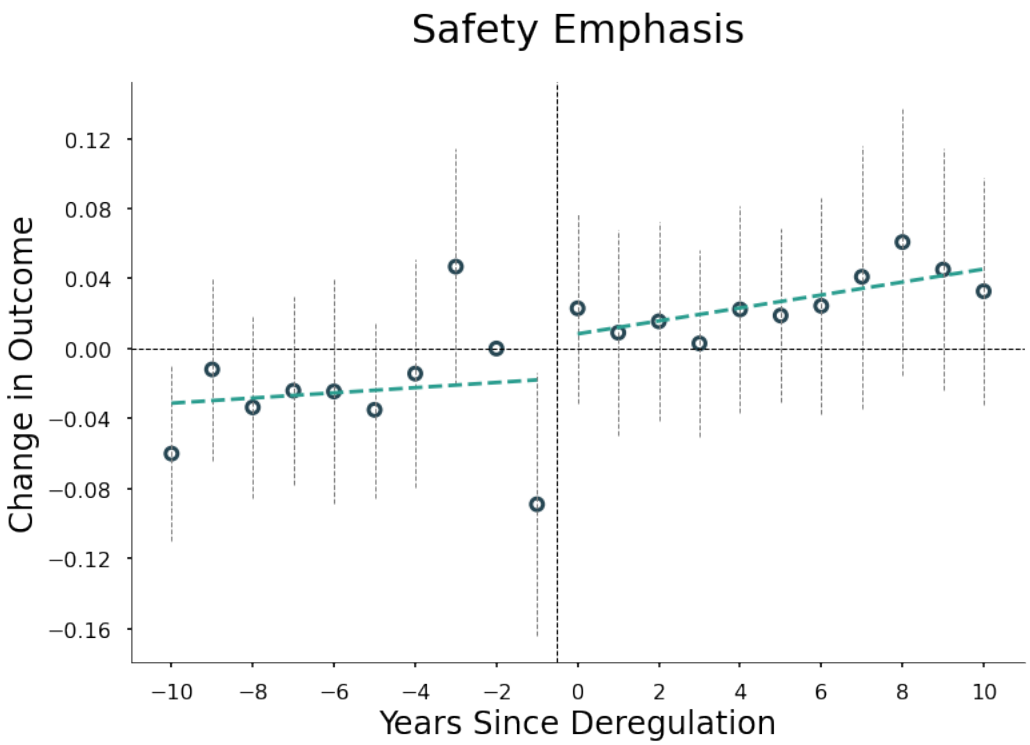
Note: This figure presents the estimates of the β_t coefficients from event-study equation 4 for my adverse event measures. Only Class III to II down-classification events are considered. Data are analyzed at an annual frequency. Controls are device types matched on baseline outcome averages. The coefficient 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 E.12: Adverse Event Event-Study Class II to I



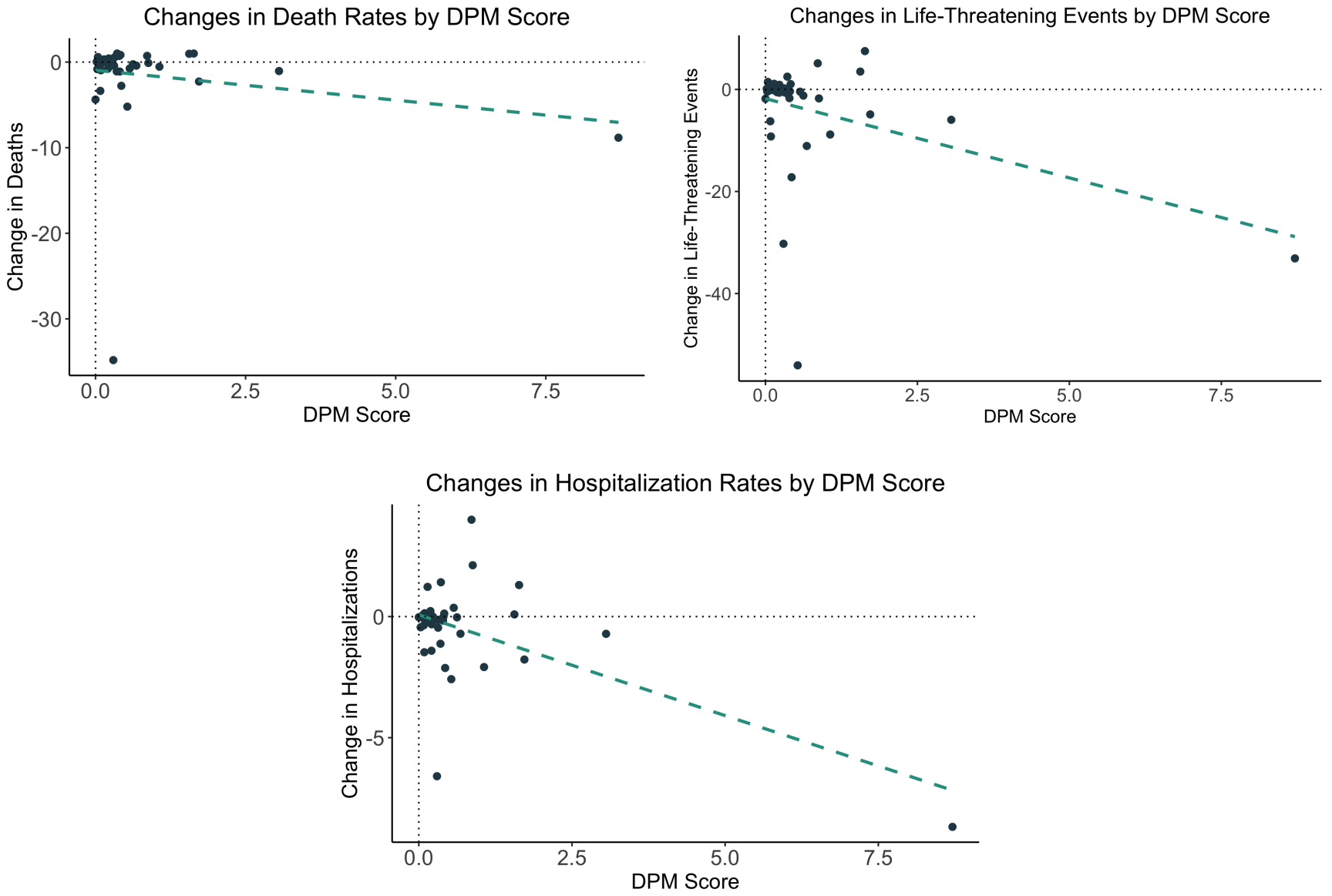
Note: This figure presents the estimates of the β_t coefficients from event-study equation 4 for my adverse event measures. Only Class II to I down-classification events are considered. Only four pre-periods are included because there are no prior adverse event data. Data are analyzed at an annual frequency. 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 E.13: Safety Emphasis Event-Study Class II to I



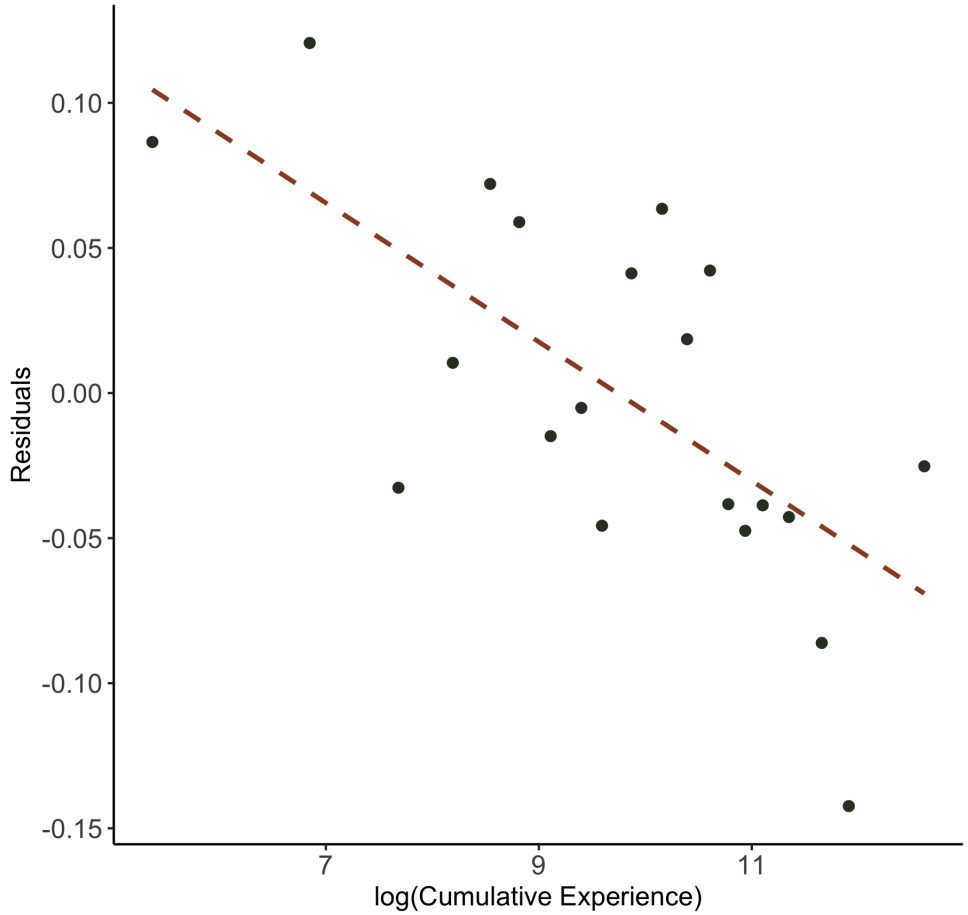
Note: This figure presents the estimates of the β_t coefficients from event-study quation 4 for inventors' emphases on safety. Only Class II to I down-classification events are estimated. Data are analyzed at an annual frequency. Controls are device types matched on baseline outcome averages. The coefficient 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 E.14: Class II to I Changes in Adverse Event Rates at Margin of Decision Rule



Note: This figure presents separate DID estimates of equation 3 for each adverse event measure and each treated device type with a given proxy DPM score relative to matched controls. The DPM score is primarily an increasing function of the baseline average annual incidence of adverse events before deregulation (see appendix D.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 E.15: Binscatter Regression of Log Cumulative Experience vs. Residualized Days to Approval



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

Appendix Table E.1: Reclassification Events Gathered

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

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

Appendix Table E.2: Effect of Down-Classifications on Innovation (Using Borusyak et al. (2021) estimator)

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

Note: The table presents estimates of equation 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 E.3: Effect of Down-Classifications on Market Composition (Using Borusyak et al. (2021) estimator)

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

Note: The table presents estimates of equation 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 E.4: Effect of Down-Classifications on Adverse Events (Using Borusyak et al. (2021) estimator)

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

Note: The table presents estimates of equation 3, which is a difference-in-differences (DID) style OLS regression model. In this analysis, I drop all device types that do not exhibit any positive quantity of the given outcome. Column (1) presents the 5-year baseline average of treated device types for the outcomes listed on the left-hand side. Columns (2)–(5) present DID estimates for the listed outcomes using different control groups. Namely, a matched control group, intuitively similar device types (treat similar diseases), "later treated" device types (treated after sample window), and the full sample, respectively. For column (4), Class III to II, control device types are treated after 2015; thus, all observations after 2015 are dropped. Confidence intervals are calculated using Conley–Taber test statistics. +, *, **, and *** correspond with statistical significance at the 0.10, 0.05, 0.01, and 0.001 levels respectively.

Appendix Table E.5: Down-Classification Spillovers (Innovation)

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

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

Appendix Table E.6: Class III to II Device Types by Broad Device Category: Treated Group versus Intuitive Control Group

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

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

Appendix Table E.7: Class II to I Treated Device Types by Broad Category

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

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

Appendix Table E.8: Class II to I Intuitive Control Device Types by Category

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

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

Appendix Table E.9: Effect of Down-Classifications on Innovation (Drop No Counts)

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

Note: The table presents estimates of equation 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 E.10: Effect of Down-Classifications on Market Composition (Drop No Counts)

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

Note: The table presents estimates of equation 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 E.11: Effect of Down-Classifications on Adverse Events (Drop No Counts)

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

Note: The table presents estimates of equation 3, which is a difference-in-differences (DID) style OLS regression model. In this analysis, I drop all device types that do not exhibit any positive quantity of the given outcome. Column (1) presents the 5-year baseline average of treated device types for the outcomes listed on the left-hand side. Columns (2)–(5) present DID estimates for the listed outcomes using different control groups. Namely, a matched control group, intuitively similar device types (treat similar diseases), "later treated" device types (treated after sample window), and the full sample, respectively. For column (4), Class III to II, control device types are treated after 2015; thus, all observations after 2015 are dropped. Confidence intervals are calculated using Conley–Taber test statistics. +, *, **, and *** correspond with statistical significance at the 0.10, 0.05, 0.01, and 0.001 levels respectively.

Appendix Table E.12: Estimation of Learning Curve Parameters

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

Note: The table presents the estimates of equation 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 E.13: Flattening the Learning Curve Simulation—Unique Devices Approved

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

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

Appendix Table E.14: 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 E.15: Regulation by Approval Type and Class

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

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

Appendix Table E.16: Share of Document Types from Class III Device Types (PMA Required)

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

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