Regulating the Innovators:

Approval Costs and Innovation in Medical Technologies

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Abstract

I examine how FDA regulation shapes innovation, market structure, and product safety by leveraging deregulation events that affected some established medical device types but not others. Linking FDA records, patents, and health insurance claims, I find that deregulation increases the quantity and quality of new technologies—especially among smaller, less-experienced firms—increases entry, and reduces medical procedure prices. Severe adverse events do not increase; for mature technologies and in higher-liability settings, they decline, consistent with postmarket measures (standards and liability) substituting for premarket review. These results clarify when targeted deregulation can expand innovation without sacrificing safety. (JEL I18, L51, O31)

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New technologies can both improve well-being and increase risk. Regulatory agencies such as the U.S. Food and Drug Administration (FDA) manage risk through premarket review—a compelling approach for high-risk, groundbreaking innovations (Grennan and Town, 2020). For lower-risk or mature technologies, where innovation is often incremental, the value of intensive review is less clear. Critics argue that stringent review raises entry costs and chills innovation (Peltzman, 1973); proponents counter that it builds demand and fosters entry (Carpenter et al., 2010). Given that FDA-regulated products comprise a $2.8 trillion market (FDA, 2020b), empirical evidence on these opposing views is important.

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

To estimate the causal effects of reclassification, I employ a stacked difference-in-differences strategy. I compare affected device types to multiple control groups: devices with similar baseline characteristics, devices deregulated at a later time, and devices intuitively resembling the treated group. This approach yields consistent results across controls and finds no evidence of divergent pre-existing trends. These results align with industry consensus that reclassifications are "unpredictable" (Makower et al., 2010; Powell, 2018), often occurring after long delays and opaque decision-making.[1]

In the medical device sector, regulatory changes can reshape market dynamics, even for

[1]For example, the 1994 down-regulation of contact lenses took nearly a decade to materialize, largely due to the FDA's reliance on proprietary data from manufacturers.

mature, low-risk products. Notably, down-regulation facilitated a breakthrough in soft contact lenses, leading to a patent valued at $930 million (US-6478423-B1; Kogan et al. (2017)) and the rise of the market-leading ACUVUE brand.[2] Moreover, the industry's landscape reveals a key tension: ex-ante safety regulation vs. ex-post legal liability. Historically, FDA clearance provided legal protections, while deregulation removes these protections, increasing firms' exposure to litigation, which can claim up to 3.8% of annual revenues (Fuhr et al., 2018) and influence safety investments.[3]

An important contribution of this paper is the assembly of novel, comprehensive data linking regulatory changes to market outcomes. Regulation affects many factors, and data on these factors are siloed, unorganized, and unconnected to medical device types, limiting prior research. I overcome these challenges by combining programmatic online text extraction, text analysis algorithms, and manual linkages to compile, merge, and harmonize the required data. This unified dataset spans four decades of regulatory changes affecting thousands of device types, as well as corroborative measures of innovation quantity and quality, firm characteristics, market structure, device pricing, and product safety.

Analysis of these data shows that down-regulation substantially increases the quantity and quality of innovation. Relative to control groups, moving from Class III (high regulation) to Class II (moderate) requirements increases patent filings and FDA submissions by 140–315%, with no spillover effects on similar device types.[4] Patents filed after down-regulation also garner more citations and higher market valuations, indicating improved technological quality. By contrast, the shift from Class II to Class I (deregulation) spurs a modest increase in the quantity and quality of patent filings. Moreover, the largest increases in innovation come from smaller, less regulatory-experienced firms, which have historically driven radical

[2]These incremental innovations bridge the gap between groundbreaking advances and their widespread adoption, elevating technological impact.

[3]Indeed, legal liability has been shown to alter innovation strategies within the medical device sector (Galasso and Luo, 2017, 2018). The financial toll of liability can be heavy, illustrated by the $1 billion Stryker hip implant settlement or the $3.2 billion Dow Corning breast implant settlement (2023 USD).

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

breakthroughs (Wu et al., 2019).

These regulatory events also reshaped market structure. Down-regulation spurred a 600% increase in new entry (i.e., firms with no prior device submissions) and a fivefold increase in incumbent entry (i.e., firms expanding into newly down-regulated products). Meanwhile, deregulation significantly increased new entrants by 72% without influencing incumbent entry. These market structure changes were associated with increased product variety, with the introduction of, for example, more minimally invasive, biocompatible, modular, and data-driven devices. The heightened competition associated with deregulation, predominantly impacting more generic, low-risk devices, translated to a significant 32% decrease in the prices of outpatient medical procedures utilizing these deregulated devices.

Although proponents of deregulation often emphasize these potential benefits, safety remains a pressing concern. Surprisingly, my findings suggest that deregulation can improve product safety. The yearly count of serious adverse events rose insignificantly following down-regulation but declined significantly after deregulation.[5] A textual analysis of patent documents also reveals a robust increase in safety-related research after deregulation.

Two mechanisms help explain these improvements in product safety. First, a firm-level liability channel: when Class II requirements are lifted—viewed by the Institute of Medicine as insufficient to assure safety (IOM, 2011)—manufacturers lose a regulatory-compliance safe harbor in tort (a legal defense), raising expected liability and strengthening incentives to reduce injury risk. I test this using cross-firm variation in effective liability: smaller firms can more readily cap exposure via bankruptcy and thus face lower effective liability (Shavell, 1986), whereas larger firms cannot. Consistent with this channel, safety gains concentrate among larger firms, and a subsequent deregulation episode—after the compliance defense had already been removed—shows no detectable change in safety. These patterns suggest that tort liability can substitute for formal premarket regulation in promoting safety, especially for generic or low-risk products.

[5] I show, using a subset of devices for which I have claims data, that this finding is robust to normalizing by utilization.

Second, a device-level lifecycle channel: the impact of reclassification depends on technological maturity. Early reclassification, when failure modes are still being discovered, can spur innovation but raise risk; once a device type is mature, reclassification lowers entry costs without compromising safety, enhancing innovation and improving safety. Many device types currently in Class III or II meet these maturity benchmarks, implying that standards-based oversight may outperform premarket authorization in those settings. The channels are complementary: liability pressure predicts where safety improves (across firms), while maturity predicts when it improves (across device types). Similar compliance–liability and lifecycle trade-offs appear in generic drugs, genetically modified foods, aviation, automobiles, and over 15,000 consumer products regulated by the CPSC (Schwartz and Appel, 2020; Schauzu, 2000; Pisani, 2011), suggesting broader relevance.

My findings contribute to several literatures. First, I advance the growing literature on the effects of public policy on medical innovation.[6] While the global medical device market is valued at $500 billion and projected to reach $1 trillion by 2030 (Stewart, 2022), relatively little empirical research has examined how regulation shapes innovation in this industry. Unlike studies that focus on high-risk cardiovascular technologies (Stern, 2017; Grennan and Town, 2020), I exploit quasi-exogenous FDA regulatory shocks that span low- to moderate-risk device types and both high- and low-regulation environments. This design recovers not only innovation responses but also the underexplored safety impacts of regulation.

Second, I contribute to work on regulatory design and liability grounded in classic trade-offs between ex-ante rules and ex-post tort (Coase, 1960; Shavell, 1984, 1986)[7]. Building on theory about when oversight should shift toward legal remedies (Kolstad et al., 1990), and on arguments for moving from rule- to performance-based regimes as information accumulates (Baldwin et al., 2011)[8], with compliance monitoring as an enabling tool (Coglianese and

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

[7] See also Ehrlich and Posner (1974); Glaeser et al. (2001); Kessler (2010); Shavell (2018).

[8] Henry and Ottaviani (2019) also analyzes the conditions under which stringent approval processes are socially optimal.

Lazer, 2003; Viscusi et al., 2018), newer models recommend easing oversight once safety evidence is sufficient (Henry et al., 2022). I provide causal evidence on this trade-off using FDA reclassifications: deregulation need not reduce safety; its effects hinge on firm characteristics, product maturity, and liability risk. In "safe-candidate" categories—those with substantial clinical evidence—firms increase safety-related innovation post-deregulation. More broadly, transitioning to lighter oversight at the right stage can spur innovation while maintaining safety, consistent with liability partially substituting for premarket control (Galasso and Luo, 2017; Philipson et al., 2010).

Finally, my findings relate to the literature on endogenous growth (Romer, 1990). Recent work links labor regulation to innovation, the engine of growth, while other studies show regulation can depress competition and create long-run inefficiencies.[9] I show that product regulation in devices dampens both innovation and market competition. Moreover, deregulation disproportionately benefits firms with less prior regulatory experience, implying that regulatory knowledge remains localized rather than freely diffusing across firms. These frictions raise the effective costs of regulation and advantage experienced multiproduct incumbents across regulated product lines.

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 implications for policy, and Section 7 concludes.

1 Background

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

[9]For studies on labor regulation impacts, see Acharya et al. (2014, 2013); Aghion et al. (2019). For studies on regulation's effects on market competition, see Buettner (2006); Aghion et al. (2009, 2005); Djankov et al. (2006); Hahn and Hird (1991).

1.1 Enactment of Medical Device Regulations

The 1976 Medical Device Amendments (MDA) extended the FDA's oversight to devices and organized products into *generic device types* (e.g., "daily-wear soft contact lenses" vs. "extended-wear soft contact lenses"). The policy variation I study occurs at the level of these generic device types.

Device types fall into a three-tier risk system. Class I (low risk) generally requires facility registration alone. Class II (moderate risk) typically proceeds via the 510(k) "substantial equivalence" pathway; this pathway has been criticized as insufficient to assure safety (IOM, 2011) and, on average, costs firms $24 million and delays commercialization by ten months (Makower et al., 2010).[10] Class III (high risk) generally requires time-intensive premarket approval (PMA) supported by clinical evidence, costing, on average, $75 million (Makower et al., 2010). Figure 1 provides an illustration of these different pathways and Appendix A.4 provides more details.

1.2 Reclassification of Medical Device Types

The FDA may reclassify medical device types to a lower class as postmarket evidence clarifies risks.[11] The FDA regulates new, markedly novel devices in Class III to ensure safety under unknown risks.[12] While it is probable that the FDA will deregulate some lower-risk device types within a class, the specific types affected and the timing of such events are difficult to anticipate (Makower et al., 2010; Powell, 2018).[13] My empirical analysis supports

[10] Estimates in Makower et al. (2010) come from a survey of 204 predominantly early-stage firms reporting their aggregate FDA-related costs (see Appendix A.4).

[11] Additionally, manufacturers can file a petition for reclassification, bringing the FDA's attention to particular device types for further investigation. My analysis, however, focuses on reclassification events explicitly enacted by the FDA's initiative (rather than a petition).

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

[13] Appendix A.1 provides additional details that highlight why these events are difficult to anticipate, while Figure D.1 Panel (a) presents the distribution of these events over time. For example, the deregulation of contact lenses took the FDA a decade to announce after an internal decision was made.

this assessment as I do not find evidence of divergent pre-existing trends when comparing reclassified device types to control groups.

By contrast, Class II to I down-classifications mostly resulted from episodic, statute-driven agency initiatives. For example, following the Safe Medical Devices Act, the FDA reclassified a broad set of Class II types using a previously undisclosed adverse-event cutoff computed from pre-period averages (FDA, 1995) (Appendix A.3; Figure D.1). Because the review was triggered by legislative timing and the cutoff referenced only baseline levels—not contemporaneous technology changes or trends—the timing across device types is plausibly "as-good-as-random." A regression-discontinuity design is infeasible (too few types lie near the cutoff), so I compare treated types with unaffected Class I types—both previously deregulated and always-Class I—selected to have similar pre-period scores under the same rule. Event-study estimates show no differential pre-trends, supporting this identification. These reclassifications occur in established device types; accordingly, the estimates speak to improvements in existing technologies rather than the emergence of radically new ones.

1.3 Regulation versus Litigation: Federal Preemption

U.S. device manufacturers face substantial product-liability exposure—estimated at up to 3.8% of revenues (Fuhr et al., 2018)—which can chill innovation and threaten smaller firms (Galasso and Luo, 2018). The U.S. legal environment (class actions, punitive damages, limited caps) heightens this risk (Guendling, 2016), creating a "powerful incentive for improving product safety" (Bravman v. Baxter Healthcare Corp., 1994).[14]

Regulatory compliance, however, can limit tort exposure. In Riegel v. Medtronic Inc. (2008), the Supreme Court held that PMA (Class III) preempts many state-law claims. Historically, in the 1990s, many 510(k) (Class II) devices also received substantial protection (Flaherty Jr, 2008), whereas Class I devices—lacking FDA approval—do not. Some Class II devices remain protected today; Appendix C.2 documents the evolving litigation

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

environment.

2 Conceptual Framework

I build a two-stage model (formal details in Appendix B) in which firms first invent and finance development, then commercialize and choose safety effort. Reclassification shifts three primitives that govern these choices: the approval delay, the mandated safety level, and effective exposure to tort. Under Class III/II (regulated), firms face positive approval delays, must meet a mandated level of safety effort, and enjoy a regulatory-compliance safe harbor in tort that lowers expected liability. Under Class I (deregulated), firms avoid approval delays, choose safety effort to maximize profits, and lose the compliance defense, raising expected liability.

Delays shorten the effective life of innovations and raise external financing needs, especially for inexperienced and capital-constrained firms. Easing review through deregulation, therefore, increases R&D and entry, with disproportionately strong responses among smaller or less regulatory-experienced firms.

Product safety responds differently across regimes because, historically, effective liability changes only after deregulation. When Class II requirements are lifted, firms lose the compliance defense, and expected liability increases, potentially enhancing safety effort. If deregulation increases safety effort, the magnitude of this response is heterogeneous: when a firm's seizable assets are low relative to worst-case damages (partly "judgment-proof"), the marginal return to safety is attenuated and safety effort increases less, while larger, better-capitalized firms face higher effective exposure and increase safety effort more. By contrast, down-regulation (III to II) leaves the compliance defense in place and, thus, produces little systematic change in safety.

Although not formalized in the model, device-level technological maturity complements this firm-level mechanism. Early in the lifecycle, unknown failure modes make safety effort

hard to target, lowering its marginal return and increasing the informational value of premarket testing. Once failure modes are understood and codified in standards, easing review can reduce delays and financing costs without compromising safety.

This framework delivers three predictions borne out in the data: (i) both forms of reclassification increase innovation and entry via the delay/finance channel, especially among smaller and inexperienced firms; (ii) safety improves after deregulation (II to I) because expected liability rises when the compliance defense disappears, with larger effects at better-capitalized firms; and (iii) these safety gains are most pronounced for mature device types, where the informational value of premarket review is lower.

3 Data

To conduct my empirical analysis, I compile data from eight sources to provide an expansive view of the costs and benefits of medical device regulations. Summary statistics for these data are provided in Table 1, and a data catalog is presented in Figure D.2.

FDA Reclassification Events. To conduct a comprehensive analysis of FDA reclassification events, I compiled a complete record of all reclassifications from 1980 to 2015.[15] For Class III to II events, I also indicate whether the event was motivated by the FDA's "own initiative" or in response to an industry petition, as this distinction is empirically important. Figure D.3 shows that device types subject to a petitioned reclassification demonstrate a notable jump in patent filings in the year of the announcement, with long-run impacts more than double those observed in non-petitioned events.[16] The Class III to II events I consider are those enacted by the FDA's own initiative where the affected device types had at least one PMA submission prior to reclassification.[17] For Class II to I events, I consider affected

[15]Table D.1, Panel A enumerates the device types in my analysis that were down-regulated, including Federal Register citations. Appendices A.1 and A.3 elaborate on the deregulation events and cite sources listing the affected devices.

[16]Table D.1, Panel B enumerates the petitioned device types that were down-regulated, while Appendix A.2 provides more information on the petitioned events.

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

device types with at least one 510(k) submission beforehand.

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

FDA Adverse Event Reports (MAUDE). The FDA's Manufacturer and User Facility Device Experience (MAUDE) database contains roughly 9.7 million device-related reports. I construct a device–type–by–year series of adverse event reports from 1992–2019. I focus on "serious" outcomes—deaths, hospitalizations, and life-threatening events. To study heterogeneity by firm size, I hand-link the top 300 MAUDE-reporting manufacturers to CRSP/-Compustat to obtain asset totals for public firms. I construct three complementary safety measures, each suited to a different purpose in the analysis. First, simple annual counts of serious events retain the full treated sample and avoid denominator noise; I use these for baseline event-study figures as a benchmark, while acknowledging that levels are sensitive to utilization and reporting intensity (see Appendix C.1 for more details and robustness checks). Second, where reliable procedure mappings exist, I normalize by exposure—serious events per linked procedure—so that estimates reflect risk conditional on use rather than shifts in volume or case mix; these exposure-adjusted rates serve as a robustness check for

treated groups that have linked procedures. Third, I report a "severity share"—serious events divided by total MAUDE reports—which absorbs broad shifts in reporting intensity and utilization to the extent they affect both numerator and denominator. Because reductions in serious events must outpace reductions in overall reports to manifest as product safety improvements, this is a conservative metric that I deploy for cross-device-type comparisons (e.g., by device age) to maintain the full treated sample while aiming to account for utilization. Across these measures, the conclusions are consistent.

Dimensions Patent Grants Extract. Patents complement the "unique devices approved" metric as a measure of innovation. Unlike pharmaceuticals, which have the Orange Book to link drugs to patents, no equivalent database exists for medical devices. To construct this linkage, I use *Dimensions*—a tool for programmatic patent text searches (Hook et al., 2018)—to identify relevant USPTO-granted patents. The process involves extracting keywords from FDA device type descriptions and using them to retrieve patents containing these terms. The resulting patent dataset contained over 1.2 million medical device patents from 1976–2019. I then compute annual patent counts per device type (i.e., "patenting rates") based on initial filing dates. This approach yields a panel of yearly patent counts for 5,000 FDA-defined device types from 1976 to 2019. Patents serve as a valuable innovation measure, enabling analysis of how Class II to I deregulation affects innovation—an aspect not captured by the "unique devices approved" metric. They also allow for direct comparisons between down-regulation and deregulation. Moreover, the consistency of results across patent filings and device submissions, as shown in Section 5, reinforces the robustness of the findings, demonstrating that the observed increase in innovation is not dependent on a specific metric. Appendix C.1 provides further details on the patent collection process and robustness checks.

Patent and Patent Applicant Characteristics. I enrich the patent data with measures of innovation quality and applicant characteristics. Patent quality is assessed using forward

citations from other patents and patent market value.[18] Market values, derived from Kogan et al. (2017), are expressed in 2019 million dollars (CPI-deflated) and are based on the increase in a patent assignee's stock price following a USPTO issuance announcement, making them available only for publicly traded firms. I also construct *emphasis on safety*—a device-type-year indicator equal to one if at least one patent filed that year explicitly references safety features—following Clemens and Rogers (2020).[19] This measure allows me to assess how reclassification influences inventors' focus on improving device safety, complementing the adverse event analyses. Lastly, to examine how reclassification affects innovation across firms of different sizes, I link patent applicants to total firm asset holdings from the CRSP/-Compustat database.

Truven Health MarketScan Database ("MarketScan"). MarketScan is a monthly panel of employer-sponsored commercial claims from 1996–2013. Because no nationally representative source reports hospital device purchase prices before 2011,[20] I use MarketScan outpatient paid amounts—adjudicated under the Healthcare Common Procedure Coding System (HCPCS)—as a proxy for device prices, since device costs are typically bundled into the procedure payment.[21] To estimate the price effects of FDA reclassification, I link FDA product codes to outpatient procedures with a large-language model (GPT-5–mini). I instructed the model with strict guardrails, including linking only when the device defines the procedure or materially drives payment.[22] I then benchmark the LLM-based device–procedure concordance against an independently produced medical-coder concordance (two AAPC-certified coders with third-coder reconciliation) and find it more accurate.[23] However, the results

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

[19] Explicit safety mentions are rare, so I code the measure as binary. See Appendix C.1 for details and robustness checks.

[20] ECRI's *PriceGuide* offers a rolling 10-year window of hospital purchase prices, limiting historical coverage.

[21] NIH, *Reimbursement Knowledge Guide for Medical Devices*, pp. 10, 14, `https://seed.nih.gov/sites/default/files/2024-01/Reimbursement-Knowledge-Guide-for-Medical-Devices.pdf`.

[22] Additional guardrails included: (i) outpatient-only scope; (ii) analyte-specific mappings for in vitro diagnostics; and (iii) hard exclusions for E/M, visit/collection/handling, and unlisted/miscellaneous HCPCS families (e.g., 992xx). Each proposed linkage required a brief rationale and supporting source(s).

[23] Accuracy was adjudicated by a three-model panel (GPT-5 Thinking, Gemini 2.5 Pro, Claude Sonnet 4.5)

are robust when using the human encodings. The final concordance (Table D.2) covers 15 deregulated device types (Class II to I)—a subset of the 56 device types deregulated after 1996 used in the main analysis—and 3 of the 12 down-regulated device types (Class III to II); the remaining device types either lack a clear outpatient-procedure mapping or are linked to procedures not observed in the MarketScan claims. For controls, I use (i) CPT procedures matched to treated procedures on pre-event mean prices from the full CPT universe and (ii) a second matched set restricted to procedures tied to device-type controls used in the innovation and market-structure analysis. I then aggregate to an annual panel of mean paid amounts by linked device type to measure price dynamics around reclassification.

4 Empirical Strategy

My strategy for estimating the effects of reclassification includes "stacked" difference-in-differences and event-study designs. After describing each design, I underscore how I address potential issues when generating causal estimates in my context.

The first regression specification uses a staggered difference-in-differences design. I estimate a "stacked" regression, following Cengiz et al. (2019), which avoids potential biases from staggered treatment designs when treatment effects vary within units over time (Goodman-Bacon, 2018; de Chaisemartin and d'Haultfoeuille, 2019). The results are robust to alternative estimators and outcome transformations.[24] This approach assembles event-specific panel data, which includes a given treated unit $r \in \{1, \ldots, N^1\}$ and all admissible controls for that unit. 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

applying the same rules and selecting the better mapping in blinded A/B tests. Across the compared device types, the panel scored GPT-5–mini higher. Estimated accuracy (correct links / total links provided) from Claude Sonnet 4.5: GPT-5–mini = 80%, expert coders = 75%. GPT-5 Thinking judged GPT-5–mini correct on 78/100 items vs. expert coders 43/100; Gemini 2.5 Pro (Spreadsheet 1) judged 85/100 vs. 48/100. I therefore adopt the LLM concordance at baseline and report robustness to human encodings.

[24] I re-estimate the main specifications using the imputation estimator of Borusyak et al. (2021) (in levels), a log-transformed specification for count outcomes ($\log(y+1)$), and a quasi-Poisson model. Robustness results for the three broad outcome categories—Innovation (Table D.3), Market Structure (Table D.4), and Adverse Events (Table D.5)—are reported in Appendix Tables.

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

In Equation 1, 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 reclassification has occurred in device type c. The outcomes of interest are denoted by $Y_{t,c,r}$. Event-by-time fixed effects ($\gamma_{t,r}$) and event-by-device-type fixed effects ($\gamma_{c,r}$) are included. The coefficient of interest, β_1, estimates the differential change in the outcome variable for treated device types relative to control device types after reclassification. I estimate Equation 1 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 ($N^1 = 12$). Thus, I follow Conley and Taber (2011), who provide a method of constructing reliable confidence intervals for difference-in-differences estimates in the presence of a small number of policy changes. This approach uses information from control group residuals to form confidence intervals.[25]

Like all difference-in-differences designs, my specification relies on the assumption that differential trends in the outcomes of interest do not pre-date the reclassification events. To test this assumption, I estimate a stacked event-study design using OLS, given by

$$Y_{t,c,r} = \gamma_{c,r} + \gamma_{t,r} + \sum_{k(t,c)\neq -1} \beta_k 1\{\text{Treated}\}_{c,r} \times I_{k(t,c)} + \varepsilon_{t,c,r}, \tag{2}$$

In Equation 2, $1\{\text{Treated}\}_{c,r}$ is an indicator for whether device type c in event panel r has been subject to reclassification.[26] $I_{k(t,c)}$ are indicators for years relative to the reclassification. I define $k(t,c) = 0$ as the year of reclassification. Thus, coefficients β_k represent the

[25] Conclusions do not hinge on Conley–Taber standard errors; estimates and significance patterns are similar under the Borusyak et al. (2021) imputation and quasi-Poisson specifications (Tables D.3, D.4, D.5).

[26] Note that for treated units, there is only one device-type fixed effect; however, control device types may appear in multiple event panels r, resulting in multiple device-type-event fixed effects. For example, the outcome for the number of patents filed for daily-wear soft contact lenses in 2008 (a treated group) appears once and is associated with one device-type fixed effect, whereas the outcome for extended-wear soft contact lenses in 2008, used as an intuitive control, appears in multiple panels corresponding to different treated events, each with its own device-type-event fixed effect.

difference-in-differences estimate of the change in the outcome in a given period relative to the year before reclassification (i.e., the omitted year $k(t,c) = -1$). Standard errors for each β_k are calculated using Conley and Taber (2011).

Reclassification rulings for Class III to II events are typically announced two years before enactment, while the Class II to I events were announced one year before enactment. Since innovators could respond to a reclassification announcement, $1\{\text{reclass}\}_{t,c}$ is equal to one for all forward-looking outcomes (e.g., patenting) for all device-type-years after an announcement occurs in device type c. However, FDA administrative data will not reflect changes until the year of enactment since firms cannot introduce devices under new regulations before enactment. Thus, for FDA-derived outcome data, the indicator $1\{\text{reclass}\}_{t,c}$ is equal to one for all device-type-years after a reclassification is enacted in device type c. For the event study, the event-time $k(t,c) = 0$ follows accordingly.

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

I construct three distinct control groups to capture different counterfactual scenarios and address various sources of potential bias. The first control group consists of "later-treated" device types that were reclassified only after the treated device types and after the latest sample year.[27] Because the FDA ultimately deemed these later-treated devices suitable for the same kind of reclassification, they can be viewed as "on the margin." By comparing

[27]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, I use device types moved from Class II to I in late 2019. The 21st Century Cures Act drove this Class II to I event and was the first time FDA-initiated reclassifications of Class II devices occurred since 1998 (the year of the event I analyze). Importantly, the FDA used the same explicit reclassification criteria in both events.

earlier-treated devices to these borderline reclassifications, I approximate a scenario in which the earlier-treated devices remained at their higher classification somewhat longer, assuming their outcomes would have evolved similarly.

Second, I include an "intuitive" control group, composed of device types that treat similar ailments and exhibit comparable risk profiles to those in the treatment group. By focusing on devices within the same medical domain, I control for market-level changes (e.g., shifts in demand or clinical practice) that might otherwise confound the effect of reclassification. Although these intuitive controls could plausibly be exposed to reclassification spillovers, I find no evidence of such effects.[28] Tables D.7 and D.8 provide detailed profiles of the intuitive control groups and the treated devices.

Finally, I construct "matched" control groups. For each reclassification pathway, I match each treated product code to its two nearest never-reclassified codes using 5-year pre-event means.[29] Although I do not find evidence of spillovers, I exclude device types that treat the same indications as the treated code. Because many outcomes (e.g., patenting) naturally trend upward over time, aligning pre-event levels via matching improves comparability; accordingly, this matched design is my preferred specification, though results are similar under alternative control groups.[30]

Additionally, some medical device types may never exhibit adverse events or innovative activity and thus would be incomparable to those that do. Thus, I also provide results from analyses that consider only treated and control device types with positive counts of a given outcome in Table D.9. My findings are robust to these restrictions.

[28] See Table D.6 for spillover estimates.

[29] Implementation details: For each treated product code, I compute 5-year pre-event means (relative to its reclassification year) and select the two nearest-neighbor controls from the treated group's pre/post regimes (III to II: 510(k)/PMA; II to I: 510(k)/510(k)-exempt). All matched units have at least one pre-period patent. Distance metrics and covariate sets are: (i) *Adverse-event analysis*—Mahalanobis distance on standardized pre-event means of all considered outcomes; using all outcomes guards against noise in pre-event adverse-event rates. (ii) *Innovation/market-structure analyses*—squared Euclidean distance on raw pre-event means of patent counts and new firms patenting, augmented with device-submission counts for Class III to II. (iii) *Patent-quality analysis*—squared Euclidean distance on raw pre-event means of forward-citation rates and real patent-value measures.

[30] Each event panel contains one treated group and its own matched controls; controls can reappear across panels. In inference, I account for such reuse when clustering standard errors.

As with every non-experimental research design, selection into treatment is a primary concern. Since the FDA's reclassification of medical device types is based on baseline adverse event rates, I cannot ascertain how reclassification would impact adverse event rates for a randomly chosen device type.[31] Consequently, my estimates represent local average treatment effects among lower-risk device types within a given class.

5 Results

This section presents estimates of Equations 1 and 2, which capture the effect of reclassification on various outcomes of interest. Subsection 5.1 presents the effects on the flow and quality of innovation. Subsection 5.2 provides the effects on market structure. Subsection 5.3 details how the effects of reclassification on innovation and market structure differ by firm characteristics. Subsection 5.4 presents the effects on device safety.

5.1 Changes in Innovation

Table 2 reports estimates of Equation 1 for the innovation outcomes.[32] Panel A presents estimates for Class III to II events, and Panel B provides estimates for Class II to I. Column (1) reports the treated group's 5-year pre-event mean. Columns (2)–(4) report estimates of Equation 1 relative to (i) matched controls, (ii) intuitive controls, and (iii) "later-treated" device types, respectively. Conley-Taber standard errors are reported below the coefficients.

Table 2, Panel A indicates that Class III to II events ("down-regulation") led to statistically significant increases in patenting rates, unique device submissions, forward citations per patent, and patent market values across all control comparisons (Cols. 2–4). Depending on the control group, the estimates imply 140%–337% more patents and device submissions

[31] Importantly, the FDA does not choose device types based on innovative potential or the potential for market structure effects. See Appendix A.3 for more details.

[32] Table D.9 displays results for device types with positive outcome counts only. Note that sample sizes differ across Tables 2, 3, and 4 due to variations in the availability of associated patents, medical procedures, and adverse events for each device type.

per device-type-year (baseline means: 8 patents/yr; 1 submission/yr). Post-event patents receive roughly 2–3 times as many forward citations and exhibit double the market value. Panel B reports smaller but economically meaningful responses for Class II to I deregulations: patenting increased by 62%, forward citations by 87%, and market value increased modestly. These effects are statistically significant for the intuitive and later-treated control groups, but not under the preferred matched-control specification.

I study dynamics by estimating the event-study specification in Equation 2. Figure 2 plots the event-time coefficients β_k for down-regulation and deregulation events using the "matched" control groups. The results of this analysis provide several insights for interpreting my findings. First, the estimated leads ($k < 0$) are small and statistically indistinguishable from zero over the decade prior to reclassification. This insight strengthens the identifying assumptions that (i) treatment and control groups would have exhibited similar trends in outcomes absent the policy change,[33] (ii) policies were not anticipated, and (iii) policies were not endogenous to increases in innovative activity. Second, post-event, β_k rises gradually and remains elevated, consistent with reclassification inducing new R&D investment (with gestation lags) rather than merely pulling filings forward in time.

Lastly, Figure 2 demonstrates a nuanced technological response to down-regulation. Panel (a) shows a gradual rise in patenting, whereas Panel (b) shows a sharp, immediate increase in device submissions that reflects both new *and* existing technologies. Several mechanisms can generate the early spike in submissions: (i) firms can quickly commercialize "on-the-shelf" products previously stalled by costly approval; (ii) existing technologies can be repurposed to new indications; (iii) streamlined review lowers frictions for products at various testing stages; and (iv) until recently, more lenient E.U. rules enabled firms to bring previously E.U.-approved devices to the U.S. after reclassification (Grennan and Town, 2020). By contrast, patenting rises slowly, consistent with gestation lags in R&D and the fact that existing technologies are either already patented or not patent-eligible. In particu-

[33]Event study coefficients are similar to those estimated using the intuitive and later-treated controls (not shown).

lar, once a patent application is filed in one jurisdiction, firms generally have 12 months to file in other jurisdictions under the Paris Convention (Popp, 2005). Applying for patents in multiple countries is inexpensive as firms can concurrently file patents in up to 153 countries through the Patent Cooperation Treaty (WIPO, 2020).

5.2 Changes in Market Structure

This section examines how reclassification reshapes market structure through four channels: (i) overall firm entry, (ii) incumbent expansion, (iii) procedure prices, and (iv) product variety.

I begin by estimating Equation 1 on two key outcomes: the number of new firms entering each device category (i.e., "new entry") and the number of incumbent firms expanding into reclassified device types (i.e., "incumbent entry"). Table 3 presents the difference-in-differences estimates.[34]

Panel A shows that down-regulation (Class III to II) leads to a sharp rise in both new and incumbent entry. New-firm entry significantly increases by 600% in the FDA submissions data (baseline: 0.1 firms/yr) and by 164%–284% in the patent data. Incumbents also expand into newly down-regulated device types, though less than the inflow of new entrants.

Panel B indicates that deregulation (Class II to I) generates a more modest but statistically significant 72% increase in new-firm entry in the patent data. Increases in incumbent entry, however, are not statistically significant under the preferred matched-control specification.

Event-study estimates in Figure 3 reinforce these patterns. Effects, when present, are persistent, and pre-treatment coefficients are flat, supporting the identifying assumptions. Panels (a)–(b) highlight a gradual increase in new-firm entry, consistent with R&D and commercialization lags; additional event-study plots are provided in Figure D.4.[35]

[34]Table D.9 restricts to device types with positive counts.

[35]Figure D.4 plots additional event-study coefficients: Panels (a)–(b) show incumbent and new entry for down-regulation using FDA device-submission data (available both pre- and post-event), corresponding to

Having established effects on entry, I turn to medical procedure prices linked to reclassified devices. The top row of each panel in Table 3 reports difference-in-differences estimates for log procedure prices.

Panel A shows no economically meaningful change following down-regulation: the preferred specification yields a 0.06 log-point increase in prices, which is statistically indistinguishable from zero.[36] The event-study in Figure 3, panel (c), plots a possible post-event temporary increase that subsequently fades, consistent with short-run price adjustments rather than a persistent level shift.

By contrast, Panel B indicates a large and statistically significant 32% decline in procedure prices following deregulation.[37] The preferred specification matches treated procedures to control procedures drawn from the full pool of CPT codes ("All CPTs"). Results are robust when re-estimating with the device-type controls used in the innovation and market structure analyses—after restricting those controls to device types that link to procedures ("Matched"). Event-study estimates (Figure 3, panel (d)) show an immediate drop that deepens over time, consistent with price renegotiation dynamics in medical technology markets (Reinhardt, 2006; Grennan and Swanson, 2020). Overall, the evidence suggests that competition induced by deregulation lowers associated procedure prices, whereas down-regulation leaves prices relatively unchanged.

I next ask whether expanded entry widens product variety. Figure D.5 illustrates how inventive effort reallocates across topics within device types after reclassification. For each pathway (Class III to II; Class II to I), I train an LDA topic model on patents linked to treated device types (after standard text preprocessing) and choose the number of topics by

the "Incumb. Entry (dev.)" and "New Entry (dev.)" rows in Table 3, Panel A. Panels (c)–(d) display incumbent entry based on patents for deregulation and down-regulation, respectively (corresponding to "Incumb. Entry (pat.)" in Table 3, Panels A and B).

[36] Similar results are obtained using the human-expert device-type-procedure concordance, with an estimate of 0.06 (SE 0.10).

[37] Using the human-expert device–procedure concordance yields a slightly attenuated yet statistically significant estimate of -0.14 (SE = 0.07). This specification includes 48 treated device types, reflecting less conservative linkages.

maximizing a coherence criterion.[38] Each patent is assigned a dominant topic to construct a topic–device–year panel. For each treated device type and topic, I match to the never-reclassified device type whose pre-event count in that topic is closest, and estimate a topic-level difference-in-differences via Equation 1.

Panel (a)—Class III to II—shows large post-event increases in topics such as "catheter, delivery, sheath, system, assembly" and "polymer, agent, coating, composition," consistent with quality-enhancing advances (e.g., minimally invasive delivery and biomaterials). These shifts align with the citation and market-valuation improvements in Section 5.1. Panel (b)—Class II to I—exhibits disproportionate growth in topics such as "element, portion, configured, connector," suggestive of modular/process innovation and cost-reduction, in line with the documented price declines.

In sum, reclassifying devices from Class III to II induces significant entry by both incumbents and new firms. Procedure prices remain largely unchanged in this pathway. Moving from Class II to I also stimulates new-firm entry and is associated with lower procedure prices. In both settings, product variety widens, indicating a substantive reshaping of technological trajectories following reclassification.

5.3 Heterogeneity by Firm Size and Regulatory Proficiency

Average treatment effects can mask important cross-firm differences. I therefore estimate Equation 1 separately by (i) firm size and (ii) regulatory proficiency, linking results to Section 2 and highlighting design elements that make regulation more accessible to less-experienced producers.

Regulatory Proficiency. I proxy proficiency using firms' cumulative exposure to FDA approval delays up to each event date and form quartiles of this measure. I then re-estimate device submission responses within quartile bins and report percent changes relative to pre-

[38] Preprocessing includes lower-casing, tokenization, stop-word filtering, lemmatization, bigram/trigram detection, and dictionary trimming. "Coherence" summarizes the co-occurrence structure among a topic's highest-probability terms.

event means (Figure D.6, panel (a)).[39] Down-regulation raises new device submissions across all quartiles, but the response is steeply decreasing in proficiency: least-experienced firms exhibit roughly an 850% increase, compared with about 50% for the most experienced.[40] This pattern aligns with Proposition 3 (Appendix B), described in Section 2, which predicts larger gains for firms facing higher ex-ante regulatory delays.

Firm Size. I next examine differential innovation responses by asset terciles, using patenting rates as the outcome. Patents are already linked to firm-level assets via Kogan et al. (2017) and provide a common metric across both reclassification pathways. Figure D.7, Panels (a)–(b) show that both transitions (Class III to II and II to I) result in the smallest firms (lowest asset tercile) displaying the largest post-event increases in patenting, consistent with Proposition 4 in Appendix B: when regulatory and financing frictions fall and expected profits rise, marginal returns to R&D are highest for capital-constrained firms.

While unobserved factors correlated with size or experience could, in principle, confound these patterns, two diagnostics mitigate concern. First, in my data firm size is empirically uncorrelated with FDA experience, allowing the two channels to be distinguished. Second, industry documentation and manufacturer statements repeatedly cite regulatory know-how and financing constraints as pivotal inputs into R&D decisions, reinforcing the interpretation that relaxed requirements disproportionately benefit smaller and less regulation-proficient firms.

5.4 Changes in Device Safety

I examine the impact of reclassification on product safety by re-estimating Equation 1 for two outcomes: (i) serious adverse-event rates (events per year) and (ii) the probability that any patent in a device–year explicitly emphasizes safety. Table 4, Panel A indicates that

[39]Firms in the lowest experience quartile have lower baseline submission rates due to shorter operating histories; percent changes provide a more comparable scale than level changes across quartiles.

[40]To assess whether large incumbents simply created subsidiaries to evade liability, I sampled 20 new spinal-implant manufacturers (a high-innovation segment) submitting 510(k)s after the 2008 down-regulation. Only one was a subsidiary; the remainder were new firms (founded post-2000; median founding year = 2011, mean = 2010). Over the subsequent 13 years, only two of the 20 were acquired; 80% were U.S.-based.

down-regulation (Class III to II) is not associated with consistent, statistically significant changes in adverse-event rates across control groups.[41] The preferred specification does, however, suggest an economically meaningful rise in hospitalizations. The likelihood of any safety–emphasis patent increases under the baseline identification but is not robust to alternative methods for identifying safety innovations (Appendix C.1; Table D.10).

By contrast, Table 4, Panel B shows that deregulation (Class II to I) is associated with marked safety improvements: hospitalization rates, life-threatening incidents, and fatalities fall significantly under most control comparisons, and safety-focused innovation rises. Magnitudes imply a 61–71% reduction in annual hospitalizations and a suggestive 40–70% decline in deaths (pre-mean: 0.2 deaths/yr), relative to counterfactual levels. The probability that any patent emphasizes safety roughly doubles, and this effect is robust to alternative measurement approaches (Appendix C.1; Table D.10), mirroring the pattern in FDA adverse-event data.[42]

Figure 4 plots the event-time coefficients β_k from Equation 2.[43] Panel (a) suggests a possible increase in serious events after down-regulation, consistent with the static point estimate on hospitalizations (though the pooled DiD effect is statistically insignificant). Panel (b) shows a clear post-deregulation decline across serious events. Consistent with increased manufacturer attention to safety, the probability of safety-emphasis in patents rises in tandem (Figure D.8).[44]

What explains safety gains after deregulation? A leading mechanism is legal liability.

[41] Table D.9 reports estimates restricted to device types with positive counts.

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

[43] Event studies disaggregated by serious-event subtypes show no divergent pre-trends between treated and control device types (not shown).

[44] The adverse event rates underlying Figure 4 are raw counts per year and are unadjusted for utilization. To test robustness, I normalize these counts by dividing annual adverse event counts by the volume of medical procedures associated with the device type. This normalization, using claims data available from 1996–2013, is feasible for 15 deregulated and only 3 down-regulated device types that can be linked to outpatient procedure codes. Too few Class III devices are linked to procedures to allow normalization. Figure D.9 compares event studies using this subset of deregulated devices: Panel (a) reports non-normalized counts, while Panel (b) divides events by procedure counts. Both show similar dynamics, though the normalized series yield somewhat stronger and more statistically precise effects.

Removing ex-ante regulation shifts the locus of enforcement to ex-post litigation, potentially improving safety; larger, asset-rich firms face higher collectible damages and thus stronger incentives to invest in safety (Proposition 1–2, Appendix B). Two tests support this mechanism. First, an analysis of heterogeneity by firm assets shows that larger firms exhibit a >150% increase in the probability of at least one safety innovation (Figure 5, panel (a)), whereas smaller firms respond less; correspondingly, reductions in serious adverse events are attenuated among small firms (panel (b)).[45]Figure D.10, Panel (b) illustrates that the share of medical device tort claims culminating in bankruptcy among small firms sharply increases after deregulation. Second, a 2015 deregulation in which devices were *not* liability-exempt prior to policy change yields no post-deregulation safety improvement (Appendix C.2), pointing to liability exposure—rather than competition or innovation alone—as the key driver of safety gains.

Several caveats are in order. First, Class III device types are reclassified when prospective regulation is deemed sufficient to mitigate harm; therefore, the average safety effect for down-regulation should be interpreted as a local average treatment effect for device types meeting that criterion. Second, while regulatory changes could, in principle, influence reporting behavior, stringent enforcement of serious-event reporting and the null findings after the 2015 policy change argue against reporting bias as the main explanation. Additional discussion and robustness appear in Appendix Section C.3.

6 Implications for Regulatory Design

A central policy question is when lighter-touch oversight can safely replace stringent pre-market review. As products mature, failures are observed, guidance is refined, and designs improve. I formalize this idea by linking post-reclassification outcomes to a device's *market age* and translating the estimates into practical thresholds to guide down-classification decisions. Once a device type's risk profile is well understood, targeted special or general

controls can replace more resource-intensive premarket requirements without compromising safety (Baldwin et al., 2011; Coglianese and Lazer, 2003; Viscusi et al., 2018).

Measuring market age. For each device type i, *market age* at reclassification is defined as the reclassification year minus the earliest verifiable introduction. I take the minimum of: (i) the first peer-reviewed clinical study, (ii) the earliest patent filing linked to the device type, or (iii) the first FDA submission.[46]

Device-level effects. I study heterogeneity in two outcomes that summarize safety and innovative activity: (i) the share of serious events among all reported adverse events (a conservative severity-composition measure) and (ii) annual patent counts. For each treated device type, I estimate a difference-in-differences effect relative to a matched control set with similar pre-event levels of the outcome (baseline specification in Section 4). To compare safety effects across maturity, I use the severity share to reduce mechanical differences from heterogeneous post–event utilization paths—newer device types typically ramp up adoption while older types plateau—so level changes in serious events do not simply reflect differential uptake. I find a similar maturity gradient when estimating using log(serious events + 1) counts.

Linking effects to market age. I relate each device-level DiD estimate to market age using OLS, controlling for baseline severity, baseline patenting, and broad device-category fixed effects. For Class III to II transitions, I include an FDA-initiated indicator (whether the reclassification was due to an industry petition); for Class II to I, I include the Device Priority Model score (see Appendix A.3).

Findings. More mature device types become safer post-reclassification. Regressing device-level DiD effects on market age—controlling for baseline outcome levels and broad product-area fixed effects—yields a negative age slope for both transitions (Appendix Tables D.11 and D.12). Linear fits "zero crossings" at roughly 30 years (III to II) and 63 years (II to I), where the fitted post–reclassification change in the serious–event measure

[46]Introduction years are assembled via semi-automated extraction with human verification; in a hold-out validation sample, automated and hand-coded dates align closely ($r = 0.76$).

(relative to matched controls) equals zero; beyond these ages, the fitted effect is negative conditional on covariates (Appendix Figure D.11).[47] Innovation effects are largest at lower ages, with steeper negative slopes in the patent-impact regressions for Class III to II, and remain economically meaningful well beyond the safety thresholds.

Policy implications. Many current Class III and II device types already exceed these market-age thresholds (Figure D.12), indicating a sizable pool that could be down-classified to reduce entry costs and spur innovation without worsening serious adverse events. A back–of–the–envelope calculation—combining the estimated innovation effects with standard values for patent–related surplus—suggests benefits of roughly $53 million per year per reclassified device type (Appendix Table D.13).

Complementary mechanism (liability). Section 5.4 shows that larger, well-capitalized firms improve safety more after reclassification. A natural interpretation is that when damages are collectible, courts effectively discipline safety; for smaller, thinly capitalized firms, this channel is weaker because they are partly judgment-proof. Policymakers can extend liability-based enforcement to these firms by delegating monitoring to insurers—requiring liability coverage below an asset threshold so underwriters, who bear loss risk, price safety and impose conditions (e.g., maintenance and operator-protocol requirements, incident reporting, recall participation). Where such coverage is credible, earlier transitions than the market-age baseline may be justified; where it is not, higher cutoffs may be appropriate.

7 Discussion and Conclusion

This paper quantifies the effect of FDA regulation on innovation, market structure, and safety. Given that FDA-regulated products comprise a $2.8 trillion annual market (FDA, 2020b), understanding these impacts is crucial. By assembling a comprehensive dataset on

[47] Using log(serious events + 1) yields a similar maturity gradient. For Class III to II, the age slope is negative and marginally significant ($\hat{\beta}_{\text{age}} = -0.0197$, s.e. 0.010, $p = 0.076$); for Class II to I it is negative but imprecise ($\hat{\beta}_{\text{age}} = -0.0013$, s.e. 0.001, $p = 0.289$). Innovation shows the following pattern: $\hat{\beta}_{\text{age}} = -0.0369$ (s.e. 0.016, $p = 0.031$) for Class III to II and is near zero for Class II to I ($\hat{\beta}_{\text{age}} = 0.0002$, s.e. 0.001, $p = 0.877$).

innovation, market dynamics, firm profiles, and safety records, I provide causal evidence on the consequences of "down-regulation" (Class III to II) and "deregulation" (Class II to I).

Lighter oversight substantially boosts both the quantity and quality of innovation. Patent filings and unique device submissions increase by as much as 140–315%, with pronounced benefits accruing to less regulation-proficient and smaller firms. These policy transitions increase market entry and widen product variety, underscoring changes in market structure that, in some cases, contribute to lower procedure prices. Product safety does not systematically change after down-regulation, while deregulation yields sizable declines in serious adverse events alongside a robust rise in safety emphasis in patent texts.

A significant contribution of this paper is to demonstrate that two forces—legal liability and device market age—systematically influence how reclassification impacts safety. First, exploiting heterogeneity by firm assets, safety improves more for well-capitalized firms—where damages are collectible—than for smaller, judgment-proof producers, indicating that courts discipline safety when exposure is credible. For small firms, mandated liability coverage can delegate monitoring to insurers. Second, I quantify maturity thresholds at which lighter-touch oversight is predicted not to worsen safety: about 30 years for Class III to II and 63 years for Class II to I. When reclassification occurs beyond these thresholds, serious adverse events decline and innovation rises, implying economically meaningful net benefits from targeted, maturity-contingent deregulation.

These insights extend beyond medical devices. Parallels with E.U. device oversight and adjacent domains—pharmaceuticals, generics, and GM foods[48]—suggest broader value in regulatory designs that (i) tailor requirements to market maturity and (ii) rely on liability–based enforcement where collectible. Future work could refine impacts along the full healthcare supply chain, measure healthcare access and quality responses, and test external validity across sectors and countries. Such efforts will be vital for ensuring that regulatory frameworks remain both flexible and protective in an era of rapid technological advancement.

[48]Tabarrok (2000) offers evidence regarding the optimality of FDA pharmaceutical regulations.

References

Acemoglu, Daron and Joshua Linn, "Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry," *Quarterly Journal of Economics*, 2004, *119* (3), 1049–1090.

Acharya, Viral, Ramin Baghai, and Krishnamurthy Subramanian, "Labor Laws and Innovation," *Journal of Law and Economics*, 2013, *56* (4), 997–1037.

_ , _ , and _ , "Wrongful Discharge Laws and Innovation," *The Review of Financial Studies*, 2014, *27* (1), 301–346.

Aghion, Philippe, Antonin Bergeaud, and John Van Reenen, "The Impact of Regulation on Innovation," *NBER Working Paper 28381*, 2019.

_ , Nick Bloom, Richard Blundell, Rachel Griffith, and Peter Howitt, "Competition and Innovation: An Inverted-U Relationship," *Quarterly Journal of Economics*, 2005, *120* (2), 701–728.

_ , Richard Blundell, Rachel Griffith, Peter Howitt, and Susanne Prantl, "The Effects of Entry on Incumbent Innovation and Productivity," *The Review of Economics and Statistics*, 2009, *91* (1), 20–32.

Argente, David, Salomé Baslandze, Douglas Hanley, and Sara Moreira, "Patents to Products: Product Innovation and Firm Dynamics," 2020.

Arrow, Kenneth J, "The Economic Implications of Learning by Doing," in "Readings in the Theory of Growth," Springer, 1971, pp. 131–149.

Baldwin, Robert, Martin Cave, and Martin Lodge, *Understanding Regulation: Theory, Strategy, and Practice*, Oxford University Press, 2011.

Boomhower, Judson, "Drilling Like There's No Tomorrow: Bankruptcy, Insurance, and Environmental Risk," *American Economic Review*, 2019, *109* (2), 391–426.

Borusyak, Kirill, Xavier Jaravel, and Jann Spiess, "Revisiting Event Study Designs: Robust and Efficient Estimation," 2021.

Bragg, Jennifer L., Maya P. Florence, and Amanda H. Chan, "Failure to Report Adverse Events Results in Criminal Misbranding Settlement and Individual Liability," 2018.

Budish, Eric, Benjamin N Roin, and Heidi Williams, "Do Firms Underinvest in Long-Term Research? Evidence from Cancer Clinical Trials," *American Economic Review*, 2015, *105* (7), 2044–85.

Buettner, Bettina, "Entry Barriers and Growth," *Economics Letters*, 2006, *93* (1), 150–155.

Carpenter, Daniel, "Protection Without Capture: Product Approval by a Politically Responsive, Learning Regulator," *American Political Science Review*, 2004, *98* (4), 613–631.

_ **, Justin Grimmer, and Eric Lomazoff**, "Approval Regulation and Endogenous Consumer Confidence: Theory and Analogies to Licensing, Safety, and Financial Regulation," *Regulation & Governance*, 2010, *4* (4), 383–407.

CDRH, "About Manufacturer and User Facility Device Experience (MAUDE)," 2023.

Cengiz, Doruk, Arindrajit Dube, Attila Lindner, and Ben Zipperer, "The Effect of Minimum Wages on Low-Wage Jobs," *Quarterly Journal of Economics*, 2019, *134* (3), 1405–1454.

Center for Devices and Radiological Health, "Learn if a Medical Device Has Been Cleared by FDA for Marketing," 2018.

Chatterji, Aaron K, "Spawned With a Silver Spoon? Entrepreneurial Performance and Innovation in the Medical Device Industry," *Strategic Management Journal*, 2009, *30* (2), 185–206.

_ **and Kira R Fabrizio**, "Does the Market for Ideas Influence the Rate and Direction of Innovative Activity? Evidence From the Medical Device Industry," *Strategic Management Journal*, 2016, *37* (3), 447–465.

Clemens, Jeffrey and Parker Rogers, "Demand Shocks, Procurement Policies, and the Nature of Medical Innovation: Evidence from Wartime Prosthetic Device Patents," *NBER Working Paper 26679*, 2020.

Coase, Ronald H, "The Problem of Social Cost," in "Classic Papers in Natural Resource Economics," Springer, 1960, pp. 87–137.

Coglianese, Cary and David Lazer, "Management-Based Regulation: Prescribing Private Management to Achieve Public Goals," *Law & Society Review*, 2003, *37* (4), 691–730.

Conley, Timothy G and Christopher R Taber, "Inference with "Difference in Differences" With a Small Number of Policy Changes," *The Review of Economics and Statistics*, 2011, *93* (1), 113–125.

Costello, Kevin and Christopher Pham, "Regulatory Preemption of Medical Devices," 2016.

de Chaisemartin, Clément and Xavier d'Haultfoeuille, "Two-Way Fixed Effects Estimators With Heterogeneous Treatment Effects," *NBER Working Paper 25904*, 2019.

Djankov, Simeon, Caralee McLiesh, and Rita Maria Ramalho, "Regulation and Growth," *Economics letters*, 2006, *92* (3), 395–401.

Dranove, David, Craig Garthwaite, Christopher Heard, and Bingxiao Wu, "The Economics of Medical Procedure Innovation," *Journal of Health Economics*, 2022, *81*, 102549.

Ehrlich, Isaac and Richard A Posner, "An Economic Analysis of Legal Rulemaking," *Journal of Legal Studies*, 1974, *3* (1), 257–286.

Emergo, "Emergo Survey: Regulatory Issues Remain Biggest Challenge for Most Medical Device Companies," May 2019.

_ , "FDA eMDR Adverse Event Reporting for Medical Device Companies," 2022.

Ensign, Lisa Garnsey and K Bretonnel Cohen, "A Primer to the Structure, Content and Linkage of the FDA's Manufacturer and User Facility Device Experience (MAUDE) Files," *eGEMs*, 2017, *5* (1), 12.

FDA, "Medical Devices; Proposed Exemptions From Premarket Notification for Certain Classified Devices; Proposed Rules," *Federal Register*, July 1994, *59*, 37378.

_ , "Medical Devices; Proposed Reclassification and Exemption From Premarket Notification for Certain Classified Devices," *Federal Register*, July 1995, *60*, 38902–38916.

_ , "Medical Devices; Exemptions From Premarket Notification; Class II Devices," *Federal Register*, January 1998, *63*, 3142–3145.

_ , "CFR - Code of Federal Regulations Title 21," 2020.

_ , "Fact Sheet: FDA at a Glance," 2020.

_ , "Medical Device Reporting (MDR): How to Report Medical Device Problems," 2020.

Finkelstein, Amy, "Static and Dynamic Effects of Health Policy: Evidence from the Vaccine Industry," *Quarterly Journal of Economics*, 2004, *119* (2), 527–564.

Fuhr, Ted, Evgeniya Makarova, Steve Silverman, and Vanya Telpis, "Capturing the Value of Good Quality in Medical Devices," Jan 2018.

Gaglani, Shiv, "Investing in Medical Devices: Interview with Venture Capitalist Dave Eichler of Psilos," Jun 2014.

Galasso, Alberto and Hong Luo, "Tort Reform and Innovation," *The Journal of Law and Economics*, 2017, *60* (3), 385–412.

_ **and** _ , "When Does Product Liability Risk Chill Innovation? Evidence from Medical Implants," *NBER Working Paper 25068*, 2018.

Glaeser, Edward, Simon Johnson, and Andrei Shleifer, "Coase versus the Coasians," *The Quarterly Journal of Economics*, 2001, *116* (3), 853–899.

Goodman-Bacon, Andrew, "Difference-in-differences With Variation in Treatment Timing," *NBER Working Paper 25018*, 2018.

Grennan, Matthew and Ashley Swanson, "Transparency and Negotiated Prices: The Value of Information in Hospital-Supplier Bargaining," *Journal of Political Economy*, 2020, *128* (4), 1234–1268.

_ **and Robert J. Town**, "Regulating Innovation with Uncertain Quality: Information, Risk, and Access in Medical Devices," *American Economic Review*, 2020, *110* (1), 120–61.

Guendling, Benjamin L, "Product-Liability Risk Exposure in the U.S. And Europe: Similar but Still Separate and Distinct," *Michigan Bar Journal*, 2016, *95*, 18–21.

Hahn, Robert W and John A Hird, "The Costs and Benefits of Regulation: Review and Synthesis," *Yale Journal on Regulation*, 1991, *8* (1), 233.

Henry, Emeric and Marco Ottaviani, "Research and the Approval Process: The Organization of Persuasion," *American Economic Review*, 2019, *109* (3), 911–55.

_ **, Marco Loseto, and Marco Ottaviani**, "Regulation with Experimentation: Ex Ante Approval, Ex Post Withdrawal, and Liability," *Management Science*, 2022, *68* (7), 5330–5347.

Hook, Daniel, Simon Porter, and Christian Herzog, "Dimensions: Building Context for Search and Evaluation," *Frontiers in Research Metrics and Analytics*, 2018, *3*, 23.

Institute of Medicine, *Public Health Effectiveness of the FDA 510(k) Clearance Process: Balancing Patient Safety and Innovation: Workshop Report*, The National Academies Press, 2010.

_ , *Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years*, The National Academies Press, 2011.

Johnson, Judith Ann, "FDA Regulation of Medical Devices," 2012.

Jr, James M Flaherty, "Defending Substantial Equivalence: An Argument for the Continuing Validity of the 510(K) Premarket Notification Process," *Food & Drug LJ*, 2008, *63*, 901.

Kahan, Jonathan S., "Medical Device Reclassification: The Evolution of FDA Policy," *Food, Drug, Cosmetic Law Journal*, 1987, *42* (3), 288–306.

Kelly, Bryan, Dimitris Papanikolaou, Amit Seru, and Matt Taddy, "Measuring Technological Innovation over the Long Run," *American Economic Review: Insights*, 2021, *3* (3), 303–20.

Kelsey v. Alcon Laboratories, Inc., "Kelsey v. Alcon Laboratories, Inc.," *No. 180902756 [2019] WL 1884225 (Utah Dist. Ct. Apr. 22, 2019).*

Kessler, Daniel P, *Regulation Versus Litigation: Perspectives from Economics and Law*, University of Chicago Press, 2010.

Kogan, Leonid, Dimitris Papanikolaou, Amit Seru, and Noah Stoffman, "Technological Innovation, Resource Allocation, and Growth," *Quarterly Journal of Economics*, 2017, *132* (2), 665–712.

Kolstad, Charles D, Thomas S Ulen, and Gary V Johnson, "Ex Post Liability for Harm vs. Ex Ante Safety Regulation: Substitutes or Complements?," *American Economic Review*, 1990, *80* (4), 888–901.

Makower, Josh, Aabed Meer, and Lyn Denend, "FDA Impact on US Medical Technology Innovation; A Survey of Over 200 Medical Technology Companies," 2010.

Medtronic, Inc. v. Lohr, "Medtronic, Inc. v. Lohr," *518 U.S. 470 (1996).*

Meier, B., "Costs Surge for Medical Devices, but Benefits are Opaque," 2009.

Moses, Mark W, Paola Pedroza, Ranju Baral, Sabina Bloom, Jonathan Brown, Abby Chapin, Kelly Compton, Erika Eldrenkamp, Nancy Fullman, John Everett Mumford et al., "Funding and Services Needed to Achieve Universal Health Coverage: Applications of Global, Regional, and National Estimates of Utilisation of Outpatient Visits and Inpatient Admissions From 1990 to 2016, and Unit Costs From 1995 to 2016," *The Lancet Public Health*, 2019, *4* (1), 49–73.

Mulligan, Casey B, "Peltzman Revisited: Quantifying 21st Century Opportunity Costs of FDA Regulation," *NBER Working Paper 29574*, 2021.

Munford, Luther T., "Next Decade To-Do: Enforce Preemption for Class Ii Devices With Special Controls," July 2018.

Olson, Mary K, "Firm Characteristics and the Speed of FDA Approval," *Journal of Economics & Management Strategy*, 1997, *6* (1), 377–401.

Peltzman, Sam, "An Evaluation of Consumer Protection Legislation: The 1962 Drug Amendments," *Journal of Political Economy*, 1973, *81* (5), 1049–1091.

Philipson, Tomas J, Eric Sun, and Dana Goldman, "The Effects of Product Liability Exemption in the Presence of the FDA," in "Regulation vs. Litigation: Perspectives From Economics and Law," University of Chicago Press, 2010, pp. 137–163.

Pietzsch, Jan B, Marta G Zanchi, and John H Linehan, "Medical Device Innovators and the 510 (K) Regulatory Pathway: Implications of a Survey-Based Assessment of Industry Experience," *Journal of Medical Devices*, 2012, *6* (2).

Pisani, Robert P, "Federal Preemption Defenses in Product Liability Suits: A Continuing Evaluation," *IDC Quarterly*, 2011, *21* (1).

Popp, David, "Using the Triadic Patent Family Database to Study Environmental Innovation," *Environment Directorate Working Paper*, 2005, *2.*

Powell, Spenser F, "Changing Our Minds: Reforming the FDA Medical Device Reclassification Process," *Food & Drug LJ*, 2018, *73*, 177.

Reinhardt, Uwe E, "The Pricing of US Hospital Services: Chaos Behind a Veil of Secrecy," *Health Affairs*, 2006, *25* (1), 57–69.

Riegel v. Medtronic, Inc., "Riegel v. Medtronic, Inc.," *552 U.S. 312, 323-24 (2008).*

Romer, Paul M, "Endogenous Technological Change," *Journal of Political Economy*, 1990, *98* (5, Part 2), S71–S102.

Schauzu, Marianna, "The Concept of Substantial Equivalence in Safety Assessment of Foods Derived From Genetically Modified Organisms," *AgBiotechNet*, 2000, *2* (044), 1–4.

Schwartz, Victor E and Christopher E Appel, "Where's the Beef?: A Guide to Judges on Preemption of State Tort Litigation Involving Branded Drugs," *U. Cin. L. Rev.*, 2020, *89*, 597.

Shavell, Steven, "A Model of the Optimal Use of Liability and Safety Regulation," *The RAND Journal of Economics*, 1984, *15* (2), 271–280.

_ , "The Judgment Proof Problem," *International Review of Law and Economics*, 1986, *6* (1), 45–58.

_ , *Liability for Harm Versus Regulation of Safety*, Routledge, 2018.

Stein, Jeremy C, "Agency, Information and Corporate Investment," *Handbook of the Economics of Finance*, 2003, *1*, 111–165.

Stern, Ariel Dora, "Innovation Under Regulatory Uncertainty: Evidence From Medical Technology," *Journal of Public Economics*, 2017, *145*, 181–200.

Stewart, Conor, "Global Medical Devices Market 2021," Dec 2022.

Tabarrok, Alexander T, "Assessing the FDA via the Anomaly of Off-Label Drug Prescribing," *The Independent Review*, 2000, *5* (1), 25–53.

US Government Accountability Office, "FDA Should Take Steps to Ensure That High-Risk Device Types Are Approved through the Most Stringent Premarket Review Process.," 2009.

Viscusi, W Kip, Joseph E Harrington Jr, and David EM Sappington, *Economics of Regulation and Antitrust*, MIT press, 2018.

WIPO, "WIPO-Administered Treaties," 2020.

Wu, Lingfei, Dashun Wang, and James A Evans, "Large Teams Develop and Small Teams Disrupt Science and Technology," *Nature*, 2019, *566* (7744), 378–382.

Y Combinator, "Introducing Startup FDA," Nov 2016.

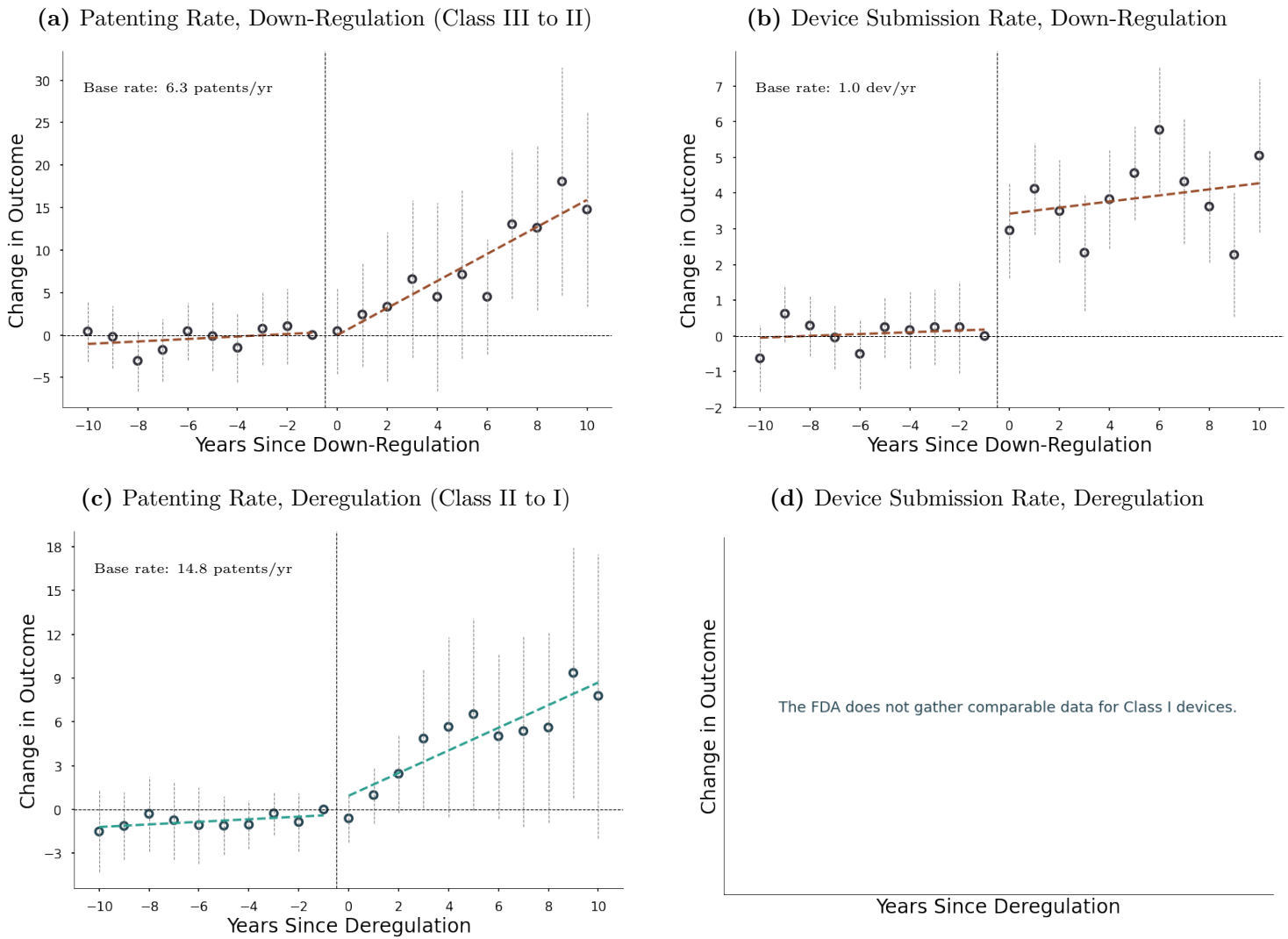
Figures and Tables

Figure 1: Background on Medical Device Regulations

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

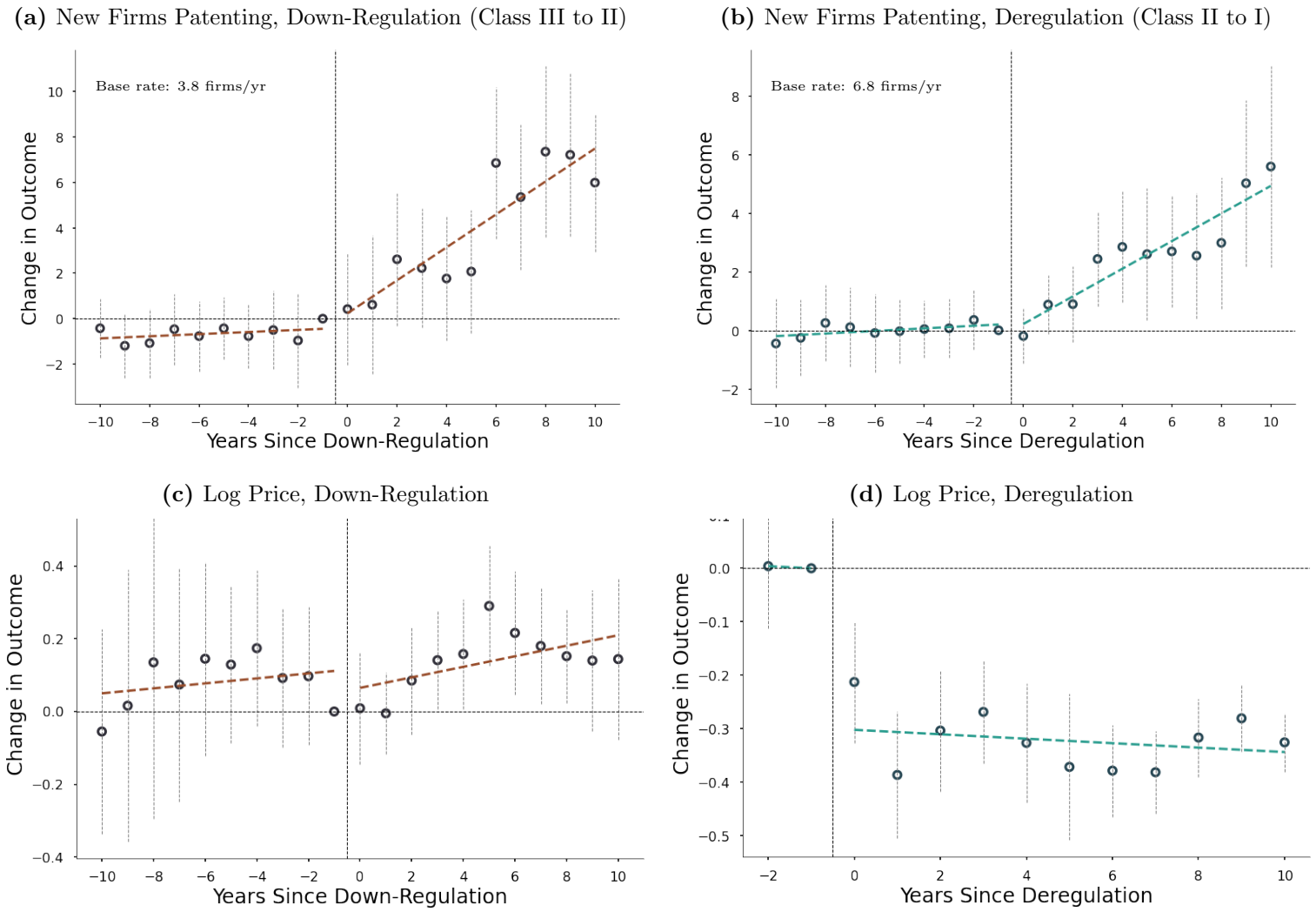
Note: This figure presents background on FDA medical device regulations and the reclassification policy changes I leverage in my analysis. The FDA assigned device types to one of three classes, each corresponding to a level of perceived risk, which requires a certain amount of time spent approving the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

Figure 2: Effect of Reclassification on Innovation



Note: This figure presents the β_k coefficient estimates from the event-study equation (refer to Equation 2) for innovation outcomes. Device types in control groups are matched based on pre-event outcome averages (levels). The coefficient β_{-1} serves as the reference and is therefore omitted. Data is analyzed annually. Every panel traces the trajectory of outcomes in treated groups compared to controls surrounding the reclassification event. Panel (a) depicts the annual patent filing trends before and after down-regulation events (Class III to II). Panel (b) shows the annual evolution of device submissions to the FDA. Panel (c) portrays patenting trends for deregulated device types (Class II to I). For clarity, Panel (d) lacks data on Class I device submissions due to their non-mandatory nature for market entry. Standard errors for down-regulation events follow the methodology of Conley and Taber (2011). 95% confidence intervals are provided.

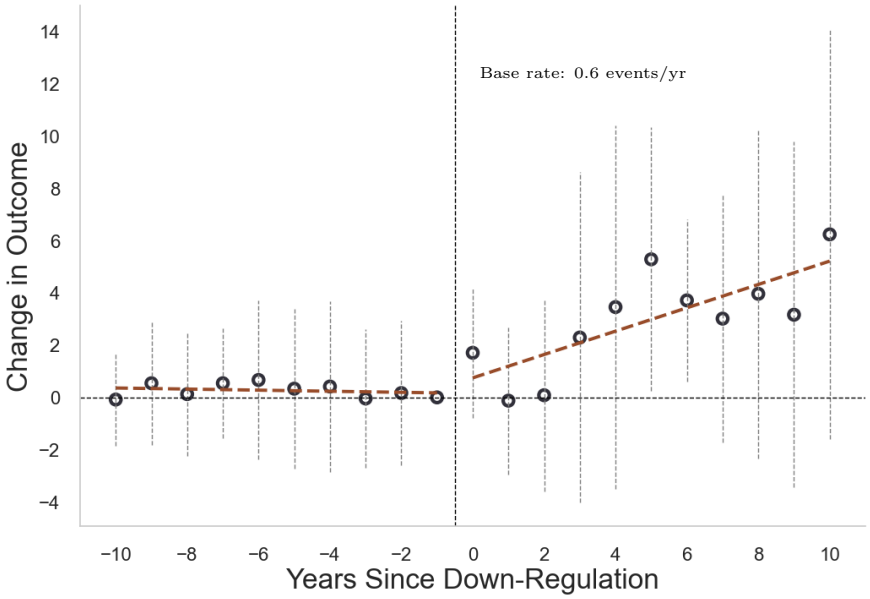
Figure 3: Effects of Reclassification on Market Structure



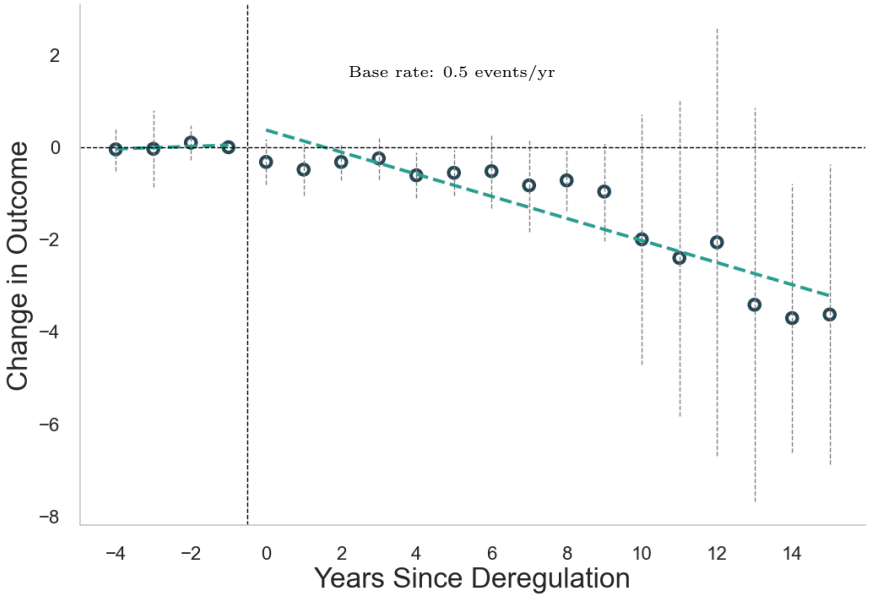
Note: This figure presents the β_k coefficient estimates from the event-study equation (refer to Equation 2) for outcomes related to market structure. Device types in control groups are matched based on pre-event outcome averages. The coefficient β_{-1} serves as the reference and is therefore omitted. Data is analyzed annually. Each panel contrasts the treated groups' outcomes with control groups around the time of the reclassification event. Specifically, Panel (a) depicts the annual count of new firms patenting around the time of down-regulation events (Class III to II). Panel (b) shows the count of new firms patenting around deregulation events (Class II to I). Panel (c) plots estimates of log outpatient payments for device-linked medical procedures associated with down-regulated device types, using MarketScan claims. Panel (d) provides a similar analysis for procedures associated with deregulated device types for which I only have two years of pre-event claims data. Standard errors for down-regulation events follow the methodology of Conley and Taber (2011). 95% confidence intervals are provided.

Figure 4: Effects of Reclassification on Product Safety

(a) Serious Adverse Events, Down-Regulation



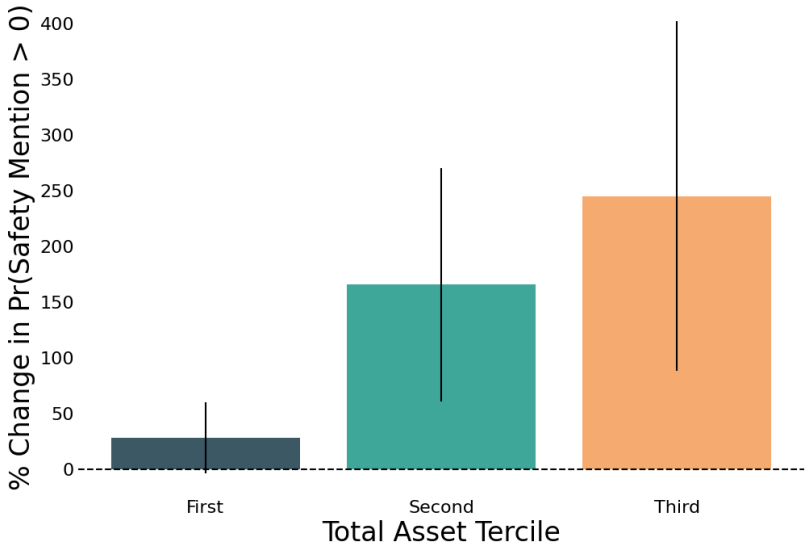
(b) Serious Adverse Events, Deregulation



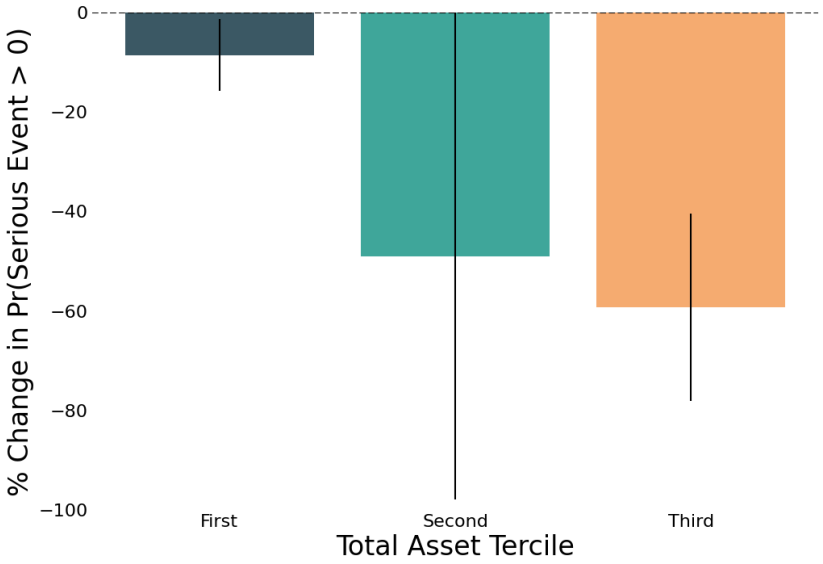
Note: The figure plots event-study estimates β_k from Equation 2 for serious adverse events (life-threatening events, death, hospitalization, disability) using annual data. Controls are device types matched on pre-event outcome averages; β_{-1} is the omitted category. Panel (a): down-regulation vs. matched controls. Panel (b): deregulation vs. matched controls. 95% confidence intervals shown.

Figure 5: Change in Product Safety by Firm Asset Terciles (II to I)

(a) Change in Safety Effort by Firm Assets



(b) Change in Serious Events by Firm Assets



Note: This figure presents separate DiD (Difference-in-Differences) estimates from Equation 1, detailing the change in the probability of firms having at least one instance of specified outcomes within treated device types, categorized by firm asset terciles. Given the low frequency of safety mentions and serious events at the firm level, all non-zero instances are coded as one, thus transforming the analysis into a Linear Probability Model (LPM). Baseline outcome frequencies are similar across asset terciles. Panel (a) examines changes in the probability of safety-related innovations, and Panel (b) addresses changes in the probability of serious adverse events (such as death, hospitalization, or life-threatening incidents). The terciles represent asset sizes of publicly traded firms. The x-axis shows the asset terciles (first, second, or third), while the y-axis reflects the percentage change in likelihood. Bars signifying 95% confidence intervals are also included.

Table 1: Summary Statistics

Variable	N	Mean	SD	Range
I. FDA Administrative Data				
A. PMA/510(k) Submissions	0.169M	-	-	-
Number of Device Types	4,709	-	-	-
Submissions per Device Type	-	35.5	110.8	[1, 2,457]
Total Submitting Firms	14,092	-	-	-
Firms per Device Type	4,703	14.6	33.8	[1, 812]
Firm Regulatory Proficiency†	4,661	18.4 yrs	58.9 yrs	[0, 642.1 yrs]
B. Adverse Event Reports	9.7M	-	-	-
Number of Device Types Reporting	4,111	-	-	-
Adverse Events per Device Type	-	2,353.3	18,939.9	[1, 600,000]
Serious Events per Device Type	2,400	571.7	5,186.8	[1, 149,376]
Assets of Offending Firms	5,706,511	$3.76B	$5.76B	[$542K, $790B]
II. Dimensions Device Patents (N = 1,248,292)				
Number of Device Types	2,113	-	-	-
Patents per Device Type	-	590.8	2,077.3	[1, 23,056]
Citations per Patent	1,248,292	14.6	88.8	[1, 5,817]
Patent Market Valuation	377,465	$13.1M	$30.7M	[$45, $1.9B]
Applicant Assets	359,805	$26.7B	$54.8B	[$66K, $1.1T]
III. MarketScan Claims Data (N = 7.2B procedures)				
Number of Procedure Codes	17,379	-	-	-
Procedures per Code	-	412,871	6,421,877	[11, 61.1M]
Price per Procedure-Year	181,659	$731.9	$1,604.8	[$0, $121,791]

Note: Table D.14 provides summary statistics for each class independently. See Kogan et al. (2017) for more information on the patent market valuation data, which was merged into the patent dataset. The CRSP/Compustat database was used to derive the total assets of firms applying for patent protection as 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 discrepancies between (i) the total FDA device types (5,542) and the number 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 with market valuations and applicant assets; and (iii) the total number of claims and those 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 Reclassification on Innovation

		DiD Estimates		
Reclassification	Pre-mean (1)	Matched (2)	Intuitive (3)	Later (4)
A. Class III to II:				
Patenting Rate	8.25	11.62*	24.93**	23.46*
	(8.98)	(5.04)	(9.10)	(9.26)
Device Submission Rate	0.95	3.00***	3.20**	3.05**
	(1.25)	(0.84)	(1.06)	(1.03)
Citations-Per-Patent Rate	9.06	18.05**	21.39*	26.13**
	(20.65)	(6.31)	(9.65)	(9.28)
Average Patent Value	10.45	10.47+	24.00**	22.95**
	(13.38)	(6.24)	(8.20)	(8.27)
Sample Size		1496	1056	1012
B. Class II to I:				
Patenting Rate	16.46	10.35	32.26*	34.82**
	(37.07)	(7.36)	(12.63)	(10.82)
Citations-Per-Patent Rate	0.66	0.58	7.89***	9.18***
	(0.47)	(1.19)	(1.78)	(1.71)
Average Patent Value	13.45	2.38	8.86***	8.26***
	(28.87)	(1.47)	(2.26)	(2.19)
Sample Size		11704	10648	12232

Note: The table presents estimates of Equation 1, a difference-in-differences (DiD) style OLS model. Outcomes are derived from *Dimensions* patent data, FDA administrative data, and Kogan et al. (2017). Column (1) reports 5-year pre-treatment averages for treated device types. Columns (2)–(4) report DiD estimates using (i) matched controls, (ii) intuitively similar devices (treating similar diseases), and (iii) "later-treated" devices (reclassified after the sample window), respectively. Device submissions are unavailable for Class I devices. For Column (4), Class III to II control device types are treated after 2015; thus, all post-2015 observations are dropped. Confidence intervals use Conley–Taber inference. Symbols +, *, **, and *** denote statistical significance at 0.10, 0.05, 0.01, and 0.001 levels, respectively.

Table 3: Effect of Reclassification on Market Structure

Reclassification	Pre-mean (1)	DiD Estimates: All CPTs (2)	Matched (3)	Intuitive (4)	Later (5)
A. Class III to II:					
Procedure Price	1652.86†	0.06	-0.04	-	-
	(1456.53)	(0.10)	(0.11)	-	-
Sample Size		594	126	-	-
Incumb. Entry (dev.)	0.28	-	1.38***	1.36**	1.25**
	(0.58)	-	(0.39)	(0.45)	(0.44)
New Entry (dev.)	0.07	-	0.42***	0.45***	0.44***
	(0.25)	-	(0.09)	(0.10)	(0.10)
Incumb. Entry (pat.)	1.55	-	0.57	2.84**	2.84**
	(1.73)	-	(0.80)	(1.07)	(1.09)
New Entry (pat.)	3.87	-	6.36**	10.99**	10.80**
	(4.55)	-	(2.16)	(3.86)	(3.97)
Sample Size		-	1496	1056	1012
B. Class II to I:					
Procedure Price	147.28†	-0.32***	-0.23***	-	-
	(343.70)	(0.06)	(0.07)	-	-
Sample Size		1062	1260	-	-
Incumb. Entry (pat.)	2.32	-	0.32	1.64*	2.00***
	(4.37)	-	(0.35)	(0.66)	(0.60)
New Entry (pat.)	7.45	-	5.38**	11.68**	12.71***
	(17.08)	-	(1.97)	(3.92)	(3.38)
Sample Size		-	11704	10648	12232

Note: The table reports estimates from Equation 1, a DiD OLS model. Column (1) reports 5-year pre-event means for treated device types. Columns (2)–(5) show DiD estimates using controls that match on (2) baseline prices across all procedure codes, (3) device outcomes, (4) intuitively similar diseases, and (5) later-treated devices. Price data are available only for 1996–2013, limiting sample size. Due to data constraints, Columns (4)–(5) omit price results. † Pre-mean prices are unlogged, while estimates are logged. Confidence intervals use Conley–Taber inference. +, *, **, and *** denote statistical significance at 0.10, 0.05, 0.01, and 0.001 levels, respectively.

Table 4: Effect of Reclassification on Adverse Events

		DiD Estimates		
Reclassification	Pre-mean (1)	Matched (2)	Intuitive (3)	Later (4)
A. Class III to II:				
Emphasis on Safety	0.08	0.36***	-	-
	(0.25)	(0.045)	-	-
Life-Threatening Event Rate	0.07	0.67	0.89	-0.61
	(0.31)	(0.63)	(0.84)	(0.85)
Hospitalization Rate	0.25	2.97*	3.07	2.86
	(0.84)	(1.19)	(1.97)	(1.97)
Mortality Rate	0.08	0.89+	1.08	0.33
	(0.46)	(0.51)	(0.67)	(0.87)
Sample Size		924	644	616
B. Class II to I:				
Emphasis on Safety	0.046	0.04***	-	-
	(0.25)	(0.01)	-	-
Life-Threatening Event Rate	0.07	-0.65+	-0.14+	-7.08*
	(0.42)	(0.34)	(0.08)	(3.61)
Hospitalization Rate	0.14	-1.77*	-1.12*	-3.39+
	(0.86)	(0.80)	(0.48)	(1.76)
Mortality Rate	0.21	-0.43+	-0.29+	-0.14
	(1.92)	(0.22)	(0.17)	(0.14)
Sample Size		8428	6776	7784

Note: The table presents estimates of Equation 1, a DiD OLS model. Column (1) reports 5-year pre-event means for treated devices. Adverse event outcomes are derived from the FDA MAUDE database. Columns (2)–(4) show DiD estimates using matched, intuitively similar, and "later-treated" control groups, respectively. For Column (4), Class III to II controls are treated after 2015; thus, post-2015 observations are dropped. Confidence intervals use Conley–Taber inference. +, *, **, and *** correspond with statistical significance at the 0.10, 0.05, 0.01, and 0.001 levels, respectively.

Appendix Material: For Online Publication

A Additional Details on FDA Regulations

This appendix provides context on the timing and rationale of FDA reclassification decisions and a concise reference on device classes. First, I summarize agency motivations for selected Class III to II down–regulations, emphasizing that timing typically reflected process–driven steps (statutory directives, evidence accumulation, or piggybacking on related actions) rather than contemporaneous technological developments. Second, I contextualize industry–petitioned down–regulations. Third, I describe how the FDA selected Class II to I deregulations. Finally, I give a brief reference on Class I, II, and III requirements.

A.1 Background on Class III to II Events

The cases below illustrate that Class III to II reclassifications were predominantly process–driven and difficult to anticipate.

Daily–Wear Soft Contact Lenses

FR citation: 62 FR 30988 **Broad area:** Ophthalmic **Year Announced:** 1994

Rationale. The down–classification was primarily based on accumulated PMA evidence over the prior decade, much of it not publicly available at the time of deliberation. As noted in the October 1993 panel minutes, "Key data that were needed to support reclassification were contained in PMAs and were not publicly available for use." This procedural hurdle led to the FDA "waiting ten years to make this [reclassification] announcement." Notably, only *daily–wear* lenses were reclassified; extended–wear lenses remained in Class III (which serves as an "intuitive" control group. The timing therefore reflected evidentiary maturity, not a discrete technology shock.

Vascular Graft Prosthesis

FR citation: 64 FR 12774 **Broad area:** Cardiovascular **Year Announced:** 1999

Rationale. This action formed part of the Food and Drug Administration Modernization Act (FDAMA, 1997) follow–through on legacy (pre–1976) Class III types with substantial clinical history. FDAMA §515(i) directed the agency to resolve the status of pre–amendment Class III devices lacking final regulations or PMA requirements. The reclassification was therefore deadline– and process–driven, leveraging long–run safety/effectiveness experience rather than recent technological advances.

Tacrolimus Test System

FR citation: 67 FR 58329 **Broad area:** Clinical chemistry **Year Announced:** 2002

Rationale. The tacrolimus assay reclassification followed, and was harmonized with, a petition–initiated action for the analogous cyclosporine assay. The FDA identified a common special–controls guidance ("Cyclosporine and Tacrolimus Assays") as sufficient to assure safety and effectiveness for both, citing similarities in mechanism and clinical management. The timing for this reclassification thus materialized from alignment with a related assay rather than a tacrolimus–specific breakthrough.

Vascular Embolization Device

FR citation: 69 FR 77899 **Broad area:** Cardiovascular **Year Announced:** 2002

Rationale. Panel records emphasize that, decades earlier, clinical information was insufficient to set performance standards; only after extended experience did evidence support robust standards and special controls. The reclassification culminated a long evidence–accumulation process rather than a sudden technological shock.

A.2 Background on Industry-Petitioned Class III to II Events

The main analysis focuses on FDA–initiated actions; petitioned cases are informative about strategic incentives. Sponsors sometimes petition to (i) reduce first–entry burden, (ii) facilitate follow–on equivalence–based entry, or (iii) broaden access once evidence is mature. Examples include Alto Development's request to reclassify stainless–steel sutures on the basis of existing materials standards (Kahan, 1987); Centocor's efforts to reclassify tumor–associated antigen tests (e.g., CA125, PSA) following an initial PMA, likely to enable subsequent 510(k) pathways; and a petition by the Orthopaedic Surgical Manufacturers Association (with AAOS support) to reclassify pedicle screws for pediatric deformities (Docket FDA–2009–M–0101), citing accumulated clinical evidence. These illustrate the mix of motives: accelerating initial entry, smoothing iterative innovation, and expanding access when special controls suffice.

A.3 Background on Class II to I Events

Two agency actions—in 1996 and 1998—removed 510(k) requirements for selected Class II devices. The 1996 action was part of a resource–reallocation strategy to focus review on higher–risk submissions (FDA, 1994, 1995). To prioritize candidates, FDA used an internal *Device Priority Model* (DPM) that combined injury frequencies (deaths, serious, less–serious) with expected use, health benefit, and effectiveness (FDA, 1995). Injury components increased the score; higher benefit/effectiveness or lower use reduced it. Because exact cutoffs and some inputs were not public, I proxy the DPM with a weighted index of average annual adverse–event counts,

$$\text{Proxy DPM} \;=\; 0.38 \times \text{Deaths} \;+\; 0.30 \times \text{Serious Injuries} \;+\; 0.12 \times \text{Less–Serious Injuries},$$

which preserves the risk ordering most relevant to the 1996 action. In the data, top–decile

device types have roughly four times the proxy score of the 89th–percentile type, and high–death categories also rank high on serious and less–serious injuries.

The 1998 deregulation implemented FDAMA §510(m)(1) (1997), which directed FDA to list Class II devices no longer needing 510(k) (FDA, 1998). Internal scoring was paired with four criteria: (i) no reported deaths in prior years; (ii) well–understood characteristics for safe/effective performance; (iii) device changes are either readily detectable by users or unlikely to raise risk; and (iv) modifications are unlikely to create a new device type. These criteria did not hinge on short–run technological improvements or outcome trends, and the agency did not publish exact scores.

A.4 Class I, II, and III Device Regulation Reference

Class I (low risk). Subject to general controls.[49] About 41% of product codes are Class I, and roughly 90% of those are exempt from premarket submissions beyond facility registration. New devices may be Class I if intended use and key characteristics match an existing Class I type; novel intended use or technology can trigger a new device type requiring review.[50]

Class II (moderate risk). Subject to special controls and typically the 510(k) pathway, which requires substantial equivalence to a predicate. About 56% of product codes are Class II. While shorter and less intensive than PMA, 510(k) review is not costless in practice; survey evidence puts FDA-related and adjacent costs around $24 million (Makower et al., 2010). If substantial equivalence fails, the sponsor must pursue PMA.

Class III (high risk or insufficient information for special controls). New high-risk types generally require PMA with clinical evidence; some pre-amendment Class III types have historically proceeded via 510(k).[51] Class III codes comprise roughly 2% of prod-

[49] "Low risk" refers to devices that do not support/sustain life and do not present unreasonable risk (e.g., tongue depressors).

[50] Manufacturers can also seek a De Novo classification when appropriate; see FDA (2020a).

[51] A small share of 510(k)s includes limited clinical data; requirements vary by context (Center for Devices and Radiological Health, 2018).

uct codes but a disproportionate share of spending (Meier, 2009). End–to–end premarket testing costs from concept to PMA approval have been estimated at about $94 million, of which roughly $75 million reflects FDA–related activities, with pivotal studies the largest component (Makower et al., 2010). PMA supplements cover many post–approval changes with timelines calibrated to the scope of modification (Johnson, 2012).

B Detailed Conceptual Framework

In this section, I detail the theoretical model mentioned in Section 2 for R&D decisions under regulation and litigation environments.

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

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

B.1 Model Preliminaries

Undirected R&D yields stochastic inventions to a representative, profit-maximizing firm. Upon realizing the new technology, the firm decides if it will allocate capital for directed

R&D to (i) improve the product's safety profile during the development phase and (ii) commercialize the invention. The firm makes this decision in one of two environments: regulation "R" or litigation "L." The model is characterized by the following parameters:

Timing Parameters.—The year a firm realizes and develops an invention is given by t_{invent}, which I normalize to zero. The years it takes to commercialize the product are $t_{comm,f}$. In the medical device industry, FDA approval plays a key role in delaying commercialization (Makower et al., 2010; Pietzsch et al., 2012).[52] Thus, for concreteness, think of $t_{comm,f}$ as the approval delay. Under litigation L, there are no approval delays (i.e., $t_{comm,f,L} = 0$). In the regulated environment, approval delays are positive but decrease with regulatory experience (Olson, 1997; Makower et al., 2010; Chatterji, 2009).[53] Following Arrow (1971), I model this relationship by equating the present delay $t_{comm,f}$ to the learning curve $\beta\ T_f^{-\gamma}$, where T_f is prior experience, β is the delay with no prior experience (i.e., $T = 1$) and $\gamma > 0$. Delay costs are given by $\chi t_{comm,f}$, where χ is the yearly cost of approval delays.[54]

Financing Costs.—Smaller firms must raise external capital to cover the costs of development and commercialization at time t_{invent}.[55] Fundraising can be difficult: 56% of small medical device firms claim funding as a central challenge (Emergo, 2019). Following Stein (2003), I capture these financing frictions by assuming deadweight costs given by $C(e_f)$, where $C(\ )$ is an increasing convex function of external funds e_f (similar to the R&D model of Stern (2017)). External funds e_f are equal to the difference between the non-financing costs and internal capital K_f. I omit other costs of commercialization for simplicity.

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

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

[54]Makower et al. (2010) find an average monthly cost of $1.3 million for Class III approval delays (e.g., clinical trial costs, etc.). I assume $t_{comm,f}$ and several other parameters below are deterministic for simplicity.

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

Regulated and Deregulated Effective Lives.—A successfully commercialized product becomes less relevant over time. For expositional ease, I describe the neoclassical risk-adjusted discount factor of the R&D project as δ, which includes obsolescence and commercialization risk.[56,57] Firms enjoy longer or shorter effective product lives depending on the regulatory environment. Under regulation, I define an invention's *Regulated Effective Life (REL)* as the expected years it will be commercialized and non-obsolete in present value terms as discounted by the regulated firm. The effective life of the regulated product begins at time $t_{comm,f}$, yielding an effective life of $REL_f = \sum_{t_{comm,f}}^{\infty} \delta^t = \delta^{t_{comm,f}}/(1-\delta)$. By contrast, in a deregulated environment N, I define an invention's *Effective Life (EL)* similar to *REL*, except the lifespan of the product starts at t_{invent}, given by $EL = \sum_{t=0}^{\infty} \delta^t = 1/(1-\delta)$. Notice that $REL_f < EL$ by definition, as regulated profit flows are delayed.

Expected Damages and Safety Effort Costs.—Borrowing from Shavell (1986) and Boomhower (2019), if a firm chooses to commercialize its product, it exerts x_f effort to improve product safety, costing ψ per unit, at t_{invent}.[58] Under litigation L, a commercialized product generates stochastic adverse events that yield $\phi(x_f; \vec{Z})$ legal damages per year, a random variable with expected value $D(x_f; \vec{Z})$ and vector $\vec{Z}$ containing other factors that influence damages in expectation (e.g., firm seizable assets K_f, the litigation environment, damage caps). The expected damages function $D(\ )$ is a positive decreasing convex function of safety effort x_f. The firm exerts effort to maximize the returns to commercialization by equating the marginal cost of effort $\psi + C_x(\psi x_f^* - K_f)$ to the present value of its marginal benefits $-EL \cdot D'(x_f^*; \vec{Z})$ (i.e., marginal abatement of expected damages). By contrast, under regulation R, the firm is exposed to no legal damages due to federal preemption. Thus, firms exert the mandated

[56] 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.

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

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

level of safety effort $\underline{x}$, as any further effort yields no return.

Profits.—If the product is successfully commercialized and non-obsolete, it generates profits π per year for the innovating firm. Although regulation can affect profits by altering market structure, I do not model this relationship, focusing instead on motivating my firm composition and product safety results. Thus, for simplicity, I assume that deregulation increases the aggregate level of R&D, consistent with my empirical findings, which implies that deregulation does not cut profits enough to outweigh declines in commercialization costs.[59] I assume only expert regulators can perceive safety effort (i.e., asymmetric information); hence, safety effort does not affect profits once a product is approved.

B.2 Characterization of the Investment Decision

In the regulated environment R, firm f expects to receive profits from commercializing a device for REL_f years. The firm will develop and commercialize its invention if and only if these expected profits exceed the combined delay, safety effort, and financing costs:[60]

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

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

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

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

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

financing costs:[61]

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

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

Notice the key differences between the investment incentives in environments R and L: firms that commercialize in L (i) expect legal damages, (ii) choose and pay for an optimal level of safety effort, (iii) enjoy a longer effective life of their products, and (iv) do not incur delay costs.[62]

B.3 Distortions from Regulation

I focus on model implications related to distortions in firm participation and safety efforts resulting from regulation. Throughout, I assume that deregulation increases the level of R&D activity. This assumption is supported by my empirical results and allows me to more clearly motivate the less intuitive results I find in my analysis.

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

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

This proposition implies that ineffective regulations could make products less safe. I show in Section 5 that Class II regulations may lead to such an outcome. These insights, however,

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

[62]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).

may be specific to the litigious U.S. environment. For example, if a country aggressively caps damages (represented in $\vec{Z}$), firms would face lower expected damages, and safety efforts could drop relative to regulated levels.

Another factor influencing a firm's expected damages is the value of its seizable assets. Following insights on the "judgment proof problem" (Shavell, 1986), when damages exceed the value of a firm's seizable assets, the difference can be discharged through bankruptcy. This option protects small firms from worst-case damages, lowering expected damages and the marginal benefit of exerting safety effort. Thus, if deregulation increases safety efforts, it will do so most for large firms. I state this as follows (and more formally in Appendix B.5):

Proposition 2. *(Deregulation Introduces Bankruptcy Distortion) Assume firm A has fewer assets than firm B (i.e., $K_A < K_B$) and that firm A's assets are insufficient to cover its worst-case damages. Firms A and B are otherwise identical. If deregulation increases both firms' safety efforts above the regulated baseline $\underline{x}$ (i.e., $x_A^*, x_B^* > \underline{x}$), then firm B will increase its safety effort more than firm A, that is, $x_B^* - \underline{x} > x_A^* - \underline{x}$.*

The next distortion I detail arises from regulatory complexity (i.e., the delays from complex regulatory requirements). Complexity distorts the composition of firms that commercialize as inexperienced firms reap lower returns from commercialization. Deregulation removes these distortions and disproportionately increases the returns to commercialization for inexperienced firms. To formalize this claim, I present the following proposition:[63]

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

An example helps illustrate the potentially dramatic implications of proposition 3. Consider firm A has no prior experience, and firm B has one previously commercialized project that was delayed for two years. Firm A must wait out a two-year delay. By contrast, firm

[63]Proofs are presented in Appendix B.4.

B waits out a one-year delay, incurring 50% lower delay costs than firm A and enjoying a longer effective life of its product. Although deregulation removes delay-related costs for both firms, the increase in returns to commercialization is at least twice as large for firm A.

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

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

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

B.4 Proofs

Proof of Proposition 1

Proof. **Claim.** If $\psi + C_x(\psi \underline{x} - K) < -EL \cdot D'(\underline{x})$, then the optimal safety effort under deregulation satisfies $x_f^* > \underline{x}$.

Proof. Suppose, for contradiction, that $x_f^* < \underline{x}$. Since x_f^* is optimal,

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

Because $x_f^* < \underline{x}$ and $C_x(\cdot)$ is strictly increasing,

$$C_x(\psi x_f^* - K) \;\leq\; C_x(\underline{x} - K).$$

Also, $D'(\cdot)$ is strictly increasing, so

$$D'(x_f^*) \;<\; D'(\underline{x}) \quad \Longrightarrow \quad -EL \cdot D'(x_f^*) \;>\; -EL \cdot D'(\underline{x}).$$

Combining these inequalities yields

$$\psi + C_x(\underline{x} - K) \;>\; -EL \cdot D'(\underline{x}), \tag{B.4}$$

contradicting the assumption that $\psi + C_x(\psi\underline{x} - K) < -EL \cdot D'(\underline{x})$. Hence, $x_f^* > \underline{x}$. □

Proof of Proposition 2

Proof. Under deregulation, firm B chooses x_B^* satisfying

$$\psi + C_x(\psi x_B^* - K_B) = -EL \cdot D'(x_B^*),$$

and firm A chooses x_A^* satisfying

$$\psi + C_x(\psi x_A^* - K_A) = -EL \cdot D_T'(x_A^*),$$

where $D_T'(x) > D'(x)$ for all x. (Note that both D_T' and D' are negative, so this inequality implies that, in absolute terms, the marginal benefit of safety effort is lower for firm A.)

Suppose, for the sake of contradiction, that $x_A^* \geq x_B^*$. Since $C_x(\cdot)$ is strictly increasing in its argument and because $K_A < K_B$, it follows that

$$\psi + C_x(\psi x_A^* - K_A) > \psi + C_x(\psi x_B^* - K_B).$$

By the first-order conditions, we have

$$\psi + C_x(\psi x_A^* - K_A) = -EL \cdot D_T'(x_A^*) \quad \text{and} \quad \psi + C_x(\psi x_B^* - K_B) = -EL \cdot D'(x_B^*).$$

Since $D_T'(x_A^*) > D'(x_B^*)$ and $EL > 0$, we obtain

$$-EL \cdot D_T'(x_A^*) < -EL \cdot D'(x_B^*).$$

Thus, we deduce that

$$\psi + C_x(\psi x_A^* - K_A) < \psi + C_x(\psi x_B^* - K_B),$$

which is a contradiction. Therefore, the assumption $x_A^* \geq x_B^*$ must be false, implying that

$$x_A^* < x_B^*,$$

and consequently,

$$x_B^* - \underline{x} > x_A^* - \underline{x}.$$

□

Proof of Proposition 3

Proof. **Claim.** If Firm A has less regulatory experience than Firm B ($T_A < T_B$), then deregulation increases A's returns to commercialization more than B's.

Sketch of Proof. Under regulation R, the more stringent *effective* delays imply

$$\text{Returns}_{A,R} < \text{Returns}_{B,R}.$$

Under a purely litigious environment L, we assume no complexity delays, so

$$\text{Returns}_{A,L} = \text{Returns}_{B,L}.$$

The difference-in-differences is

$$(\text{Returns}_{A,L} - \text{Returns}_{A,R}) \; - \; (\text{Returns}_{B,L} - \text{Returns}_{B,R}) \; =$$

$$\big(\text{Returns}_{A,L} - \text{Returns}_{B,L}\big) \; - \; \big(\text{Returns}_{A,R} - \text{Returns}_{B,R}\big).$$

Since $\text{Returns}_{A,L} = \text{Returns}_{B,L}$, this becomes

$$-\big(\text{Returns}_{A,R} - \text{Returns}_{B,R}\big) \; > \; 0.$$

Thus, deregulation increases returns for A more than for B. □

Proof of Proposition 4

Proof. **Claim.** Suppose Firm A is smaller than Firm B ($K_A < K_B$) and has nonzero financing costs only under regulation (i.e., $K_A < \chi t_{comm,A} + \psi \underline{x}$, but $K_A \geq \psi x_A^*$ under deregulation). Then deregulation increases A's commercialization returns more than B's.

Sketch of Proof. Under regulation, A must raise external capital (and thus pay financing costs) because

$$K_A < \chi t_{comm,A} + \psi \underline{x}.$$

By contrast, B may not need to raise external capital if $K_B \geq \chi t_{comm,B} + \psi \underline{x}$. Hence,

$$\text{Returns}_{A,R} < \text{Returns}_{B,R}.$$

After deregulation, assume $K_A \geq \psi x_A^*$. Now A does not incur financing costs for its higher

(optimal) safety effort. Its returns thus rise more than B's from deregulation:

$$(\text{Returns}_{A,L} - \text{Returns}_{A,R}) \ > \ (\text{Returns}_{B,L} - \text{Returns}_{B,R}).$$

Therefore, A's deregulated returns increase the most. If smaller firms also have lower expected damages due to bankruptcy, that effect further amplifies A's gains. □

B.5 Bankruptcy Protection Model Extension

Following insights from the literature on the "judgment proof problem" (see Shavell (1986); Boomhower (2019)), when damages exceed the value of a firm's seizable assets, the difference can be discharged through bankruptcy. To reflect the bankruptcy option, I augment the model above to include expected damages that differ by firm assets K_f. I define the unspent capital available to cover damages as u_f. Unspent capital includes the capital not spent on commercialization costs $(K_f - c_f)$ and profits from the current period, given by $u_f = \pi + K_f - c_f$. This term incorporates the simplifying assumption that net profits from the last period are distributed as dividends.[64] The upper bound of legal damages is given by $\bar{\phi}$.

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

$$\text{Expected Damages} \ = \ \begin{cases} D(x_f^*; \vec{Z}) & \text{if } u \geq \bar{\phi}, \\ \underbrace{\left[\int_0^u \nu f(\nu; x_f^*, \vec{Z}) d\nu + \int_u^{\bar{\phi}} K f(\nu; x_f^*, \vec{Z}) d\nu\right]}_{D^T(x_f^*; \vec{Z})} & \text{else.} \end{cases} \tag{B.5}$$

In words, if the firm's capital stock is at least as high as worst-case damages, the expected

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

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

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

PROPOSITION 5. *(Deregulation introduces bankruptcy distortion)* Assume firm A has fewer assets than:

(i) firm B (i.e., $K_A < K_B$), and

(ii) its worst-case damages $\bar{\phi}$ (i.e., $K_A < \bar{\phi}$).

Firms A and B are otherwise identical. Suppose deregulation leads to an increase in both firms' safety efforts relative to a regulated baseline $\underline{x}$, that is, $x_A^*, x_B^* > \underline{x}$ (as in Proposition 1). Then

$$x_B^* > x_A^*, \quad \text{and equivalently} \quad x_B^* - \underline{x} > x_A^* - \underline{x}.$$

In other words, the larger-capital firm B increases its safety effort *more* than the smaller-capital firm A under deregulation.

C Data and Variable Construction and Validation

C.1 Patent Data Collection

This section describes how I link patents to device types, validate the linkage, and assess robustness to alternative patent samples.

Construction. For each of over 5,000 FDA device types, I construct a keyword string from (i) the regulation–number description and (ii) the device–name description, removing stopwords, punctuation, and duplicates. For example, "Implantable pacemaker pulse generator" and "Leadless Pacemaker" become "implantable pacemaker pulse generator leadless." I then search the full text of all U.S. patent documents in *Dimensions* and keep patents that contain *all* keywords. The process is repeated for every device type. When a patent is returned for multiple types, I keep a single, randomly chosen assignment to avoid double-counting.

Validation and error modes. Keyword linkages can admit complementary (non-device) technologies and, less often, spurious linkages. Drug-related patents are the most frequent complements under Cooperative Patent Classification (CPC) labels. Some are economically relevant complements rather than errors: e.g., MRI platform growth can raise demand for imaging agents detailed in the linked patent US-10,428,030-B2; Searching for "cyclosporine test system" returns US-10,011,612-B2, CPC-labeled as a drug but describing administration that is routinely monitored by cyclosporine tests. In other cases, links are more tenuous (e.g., a contact-lens query capturing a drug patent because of the drug's contact-lens delivery mechanism). Below, I show results are robust to excluding such patents.

Restricted samples and robustness. According to the USPTO,[65] which tags medical-device patents by technology classes, 210,992 patents were designated medical-device–related during 1995–2015. My keyword method yields 875,324 patents over a comparable period,

[65] See https://www.uspto.gov/web/offices/ac/ido/oeip/taf/meddev.htm.

likely reflecting inclusion of complementary technologies. I validate the main findings using two restricted samples.

First, I limit to CPC "A61" (Medical or Veterinary Science; Hygiene) and exclude "A61P" (drugs), yielding 171,682 patents in 1996–2015. I report the top three CPC labels by device type for Class III and Class II devices at this link and this link; the primary CPC codes align well with device descriptions.

Second, I screen all USPTO patents with the Large-Language Model GPT-4o. For each patent, I supply title, abstract, and primary CPC and ask whether it describes an FDA-regulated device and, if so, to suggest a product code. The prompt, with two calibrating examples, is as follows:

> As an expert in patents and FDA medical devices, assess the following patent—provided with its title, abstract, and CPC codes—to determine whether it describes a medical device that is regulated by the FDA Center for Devices and Radiological Health. If it does, identify the corresponding FDA product code.
>
> Return your response in the following list format:
>
> [Is Device (0 or 1); FDA Product Code (if applicable); Short Description (if applicable)]
>
> Examples:
>
> - Patent 1:
>
> Title: Compositions and methods for inhibiting protein on surfaces; Abstract: The use of NIPAM polymers to prevent or reduce the formation of protein deposits on the surfaces of medical devices is described. The invention is particularly directed to the reduction of the adsorption of proteins on surfaces of contact lenses and other medical prosthetics.; Primary CPC: A61L12/08
>
> Response: [1; LPN; Accessories, soft lens products]
>
> - Patent 2:
>
> Title: Gene therapy vector system and prodrug genes; Abstract: The present invention relates to a replication retrovirus vector system comprising thymidine kinase (HSV-TK) gene and cytosine deaminase (CD) gene which make gene transfer to cancer cell tissue for the efficient treatment of cancer. This system of the invention can be advantageously used as a pharmaceutical composition for the treatment of cancer.; Primary CPC: A61K48/0058
>
> Response: [0; ;]

Although suggested product codes are often inaccurate, the device/not-device flag is informative. Restricting to patents flagged as devices narrows the sample to 302,140 patents

during 1996–2015. I also use this screened set to calibrate the patent-topic model so that non-device patents do not drive topics.

Table D.15 re-estimates Equation 1 using these samples. Panel (a) shows that, for Class III to II events, both GPT-4o and A61 restrictions yield effects that are larger relative to pre-means and more precisely estimated than the unrestricted Column (2) of Table 2. For the GPT-4o restriction, the absolute effect is about two-thirds of baseline, suggesting roughly one-third of the baseline reflects spillovers into complementary technologies. Figure D.13 shows the corresponding event study under the A61 restriction; the main pattern remains. For Class II to I events (Panel (b)), the GPT-4o restriction implies a large increase in patenting, whereas the A61 restriction yields an economically and statistically insignificant effect. These results indicate that innovation gains for II to I are smaller and more sensitive than for III to II.

Patents are an imperfect innovation measure. Many patents are not commercialized, and large firms may file strategically. As shown by Argente et al. (2020), a substantial share never produces marketable products. My analysis of device-submission rates in the main text, however, complements these patent measures of innovation and yields consistent results.

Additional patent quality measure. I use the novelty/radicalness index of Kelly et al. (2021) to proxy for "breakthrough" patents. The indicator identifies patents that are textually novel relative to prior art and similar to subsequent patents. The distribution is highly skewed in the device–type–year panel (2,112 observations): ≈75% zeros; right tail up to 44; mean 0.58; s.d. 2.30. DiD estimates in Table D.16 broadly mirror the main patent-quality results: breakthrough counts rise post-reclassification, especially for Class III to II. Quasi-Poisson estimates are similar but imprecise because Conley–Taber standard errors are unavailable for non-linear models and treated units are few; linear specifications with Conley–Taber errors yield tighter intervals.

Identifying Patents Emphasizing Safety Advancements. To capture safety-directed innovation, I analyze patent text for safety content. I train a Word2Vec model on all titles and abstracts and select terms closest to "safety" in the embedding space; the resulting set includes "safety," "safe," "safer," "endangering," "precautions," "unsafe," "hazardous," "failsafe," "safely," "dangerous," "hazard," "danger," "risking," "harming," "injuring," "injury," "jeopardizing," "risk," "complication," and "life-threatening." A patent is flagged if its title or abstract contains at least one of these terms. Because only about two percent of patents include such terms, I aggregate to the device-type–year level and create an indicator for whether any patent in that cell mentions safety. The measure rises after Class II to I reclassifications. Typical examples include US-10045712-B2 (FDA product code FRZ), which describes an MRI-compatible neonatal table with a safety barrier and automated checks to avoid ferromagnetic objects, and US-10247362-B2 (BXH), which adds over-pressure alarms to medical gas gauges to reduce explosion risk.

Robustness of the safety-mention analysis. To confirm that the safety-mention measure is not overly dependent on a single detection method, I compare two alternative definitions. First, a literal-keyword approach flags any occurrence of the string "safety" in the title or abstract. Second, an embedding-distance approach computes the cosine similarity between each patent's embedding and the centroid of five short sentences describing device safety in different contexts. These five sentences are:

i. "The device incorporates multiple safety mechanisms to prevent accidents."

ii. "Safety protocols must be strictly followed in all operational procedures."

iii. "Ensuring user safety is paramount in the design of this system."

iv. "The material is certified for safety under international standards."

v. "Safety features include automatic shut-off and emergency alerts."

Using the 99th similarity percentile as the threshold (results are similar at the 95th), Table D.10 shows statistically significant post–Class II to I increases under both methods, consistent with Table 4; no robust increase appears for Class III to II.

C.2 Validation of Class II to I Product Safety Results

I corroborate the product safety findings and the role of liability using (i) device recalls and (ii) a 2015 Class II to I event that did not materially change liability exposure.

Device recalls. Recalls directly address serious defects, are supervised/mandated by the FDA, are less sensitive to utilization, and are difficult to conceal. Recall data begin in 2000, whereas the primary II to I events occur in 1996 and 1998, so I focus on long-run dynamics. Administrative recall data by device type from 2000–2022 show patterns consistent with the adverse-event and safety-text analyses. Figure 2, panel (b), shows an immediate rise in available technologies after reclassification; Figure 4 shows a small, immediate decline in serious events (with hospitalizations significantly lower), followed by a larger decline five to seven years later as patents in Figure 2, panel (c), diffuse.

Figure D.14 compares average recalls per year for affected device types with the same matched controls used in the adverse-event analysis. Trends (and levels) are similar through about seven years post-event and subsequently diverge, with a persistent decline in recalls for reclassified devices over the subsequent two decades. An event-study specification, with zeros imputed for the years immediately around the events when recall data are unavailable, shows no pre-trend or early effects by construction, no divergence at event times 4–6 when data exist, and a significant decline beginning around year 7 that grows thereafter. The decline of about 0.5 recalls per device-type-year represents roughly a 50 percent reduction relative to the control mean.

2015 Class II to I event with no change in liability. More than 200 Class II device types were reclassified in 2015 without materially altering tort exposure while removing

510(k) requirements.[66] Before Medtronic Inc. v. Lohr (1996), 510(k) often preempted state tort claims (Flaherty Jr, 2008); Medtronic Inc. v. Lohr (1996) weakened preemption for Class II; later, Riegel v. Medtronic Inc. (2008) restored some protection, but primarily where FDA imposed device-specific special controls (Costello and Pham, 2016).[67] Most 2015 Class II devices lacked such controls and thus remained exposed.[68] Using the main matching/estimation strategy, I find no significant changes in hospitalizations, life-threatening events, deaths, or the composite serious-events measure (Figure D.15, Panel (a)); recalls likewise do not change meaningfully for up to eight years (Figure D.15, Panels (b)–(c)). These null results support liability exposure—not market structure or innovation alone—as the driver of the earlier safety gains. Notably, entry and patenting responses appear larger in 2015 (Figure D.16): new-entrant patenting nearly doubles within two years (base 11.9 entrants/yr), versus a statistically insignificant 13.7% rise within two years after the 1996/8 events.[69] Because 2015 reduced regulatory costs without raising litigation exposure, innovation benefits may be larger than they were historically.

C.3 Adverse Event Data: Examples, Coverage, and Limitations

MAUDE reports include severity labels such as life-threatening (L), hospitalization (H), disability (S), and death (D). An illustrative spinal-fusion report (H) reads: "It was reported that a [spinal fusion] device has broken whilst implanted... The representative has confirmed the revision has now taken place and that he has retrieved the device."

The FDA cautions against naïvely using adverse-event counts as a safety measure because utilization is unobserved, reporting can be incomplete, and reports are unverified (CDRH,

[66]The 2015 event was the first major Class II reclassification since the 1996/8 events analyzed in the main specification.

[67]See, for example, Kelsey v. Alcon Laboratories Inc. (2019), involving a contact-lens disinfectant subject to special controls; the court found preemption barred design-defect claims. Similar outcomes have been found for latex gloves, contact lenses, tampons, condoms, angioplasty catheters, wound dressings, tissue adhesive with wound-closure devices, a hemorrhoid-prevention wedge, and electrical-stimulation devices (Munford, 2018).

[68]Special controls are typically issued for Class III to II reclassifications.

[69]Data limit the horizon to two years post-policy. The 2015 event adds about five new firms per year relative to pre-event means; the 1996/8 events add about one.

2023). I address each concern:

First, unobserved utilization can bias adverse event levels as increases in adverse events may reflect increases in utilization rather than changes in product safety. The DiD design partly addresses this issue, which nets out any time-invariant rates of under-reporting. Additionally, to further mitigate this potential bias, for a subset of device types that map to procedures, I normalize by procedure volumes and re-run the product safety analysis, finding that the impact of deregulation is robust, if not stronger, to normalization.

Second, only serious events and manufacturer reports are mandatory. Under-reporting of non-serious events could increase after deregulation, but serious manufacturer reports, the focal product safety outcome, are legally required and subject to enforcement with financial and criminal penalties (FDA, 2020c; Bragg et al., 2018; Emergo, 2022). Moreover, the 2015 II to I event (no liability change) shows no change in product safety, suggesting reporting rates do not mechanically change after deregulation.

Third, reports are not adjudicated. The absence of safety impacts following the 2015 event, the focus on closely monitored serious outcomes, and concordant evidence from safety-focused patent text and recalls mitigate this concern.

Lastly, adverse event data coverage expanded over time. Manufacturer reports entered MAUDE in 1996, coinciding with early II to I events (Ensign and Cohen, 2017). This expansion likely contributes to large relative declines immediately after deregulation in Table 4, panel (b), as reporting rose in both treated and control groups. However, splitting adverse events by reporter type shows non-manufacturer serious reports—without the same data coverage shock—also fall after deregulation (Figure D.17, Panel (a)). Analyzing manufacturer reports alone reproduces the main pattern with wider later confidence intervals, consistent with greater variance as reporting increased (Panel (b)).

C.4 Device Market Age Construction

This subsection details the construction of the *market age* variable used in Section 6. I identify the introduction year using hand coding supplemented by GPT-4o adjudication for Class II devices. GPT-4o was provided with a prompt instructing it to report the earliest introduction date and a plausible source (e.g., a patent filing or an early academic study). I then cross-validated GPT-4o encodings with a subset of 25 down–regulated device types for which I independently determined introduction years. The correlation coefficient between the hand-coded and GPT-4o measures was 0.76 ($p < 0.001$), lending credibility to the automated approach. The prompt appears below.

> *"You are an expert in medical devices and have knowledge of when the first device of a given type was introduced. This could be through the earliest academic study that presented the device or the first patent filed by its inventor, whichever came first. I will provide you with a specific medical device, and I would like you to report back the year it was introduced, along with the relevant source.*
>
> *Here are a few examples:*
>
> *User: 'Sterilizer, Soft-Lens, Thermal, Ac-Powered, Soft (hydrophilic) contact lens care products.' Response: ['Year: 1974', 'source: first patent filed by Cybron Corp. likely used some time before.']*
>
> *User: 'Stimulator, Salivary System, Electrical salivary stimulatory system.' Response: ['Year: 1986', 'source: first submitted PMA. Weiss 1986. subsequent study in 1988 by Steller M.']*
>
> *User: 'Device, Vascular, For Promoting Embolization, Vascular embolization device.' Response: ['Year: 1975', 'Wooly tail embolization coil invented by Cesare Gianturco.']*
>
> *User: 'Intervertebral Fusion Device With Bone Graft, Lumbar, Intervertebral body fusion device.' Response: ['Year: 1953', 'source: The Treatment of Ruptured*

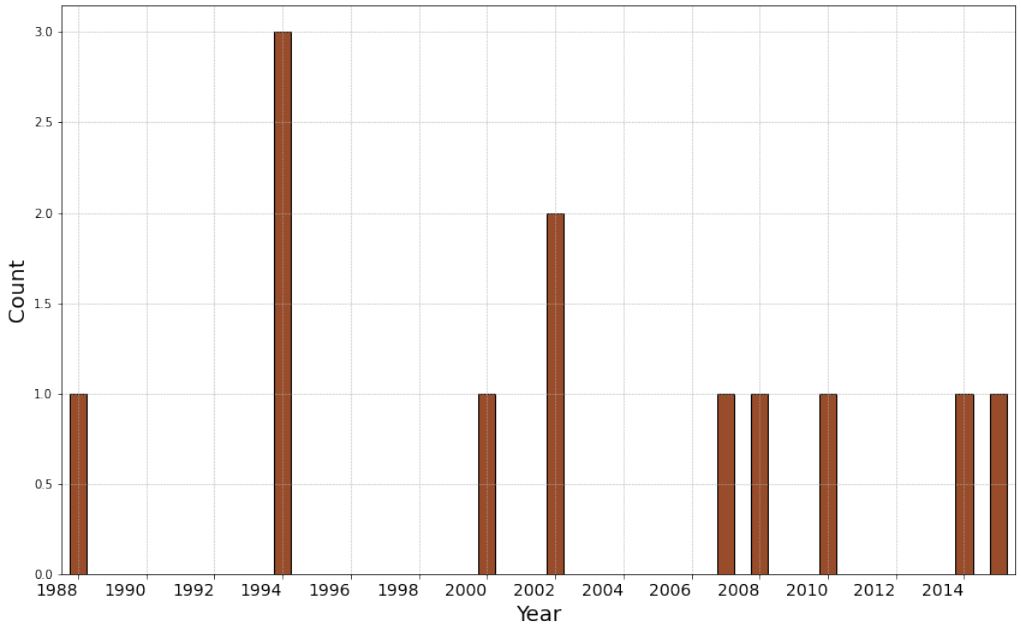
Lumbar Intervertebral Discs by Vertebral Body Fusion: I. Indications, Operative Technique, After Care.']"

The resulting market-age measure proxies the depth of knowledge about a device's failure modes and risk profile. Higher values indicate that regulators and manufacturers can rely more on targeted (special or general) controls in lieu of intensive premarket evaluation.

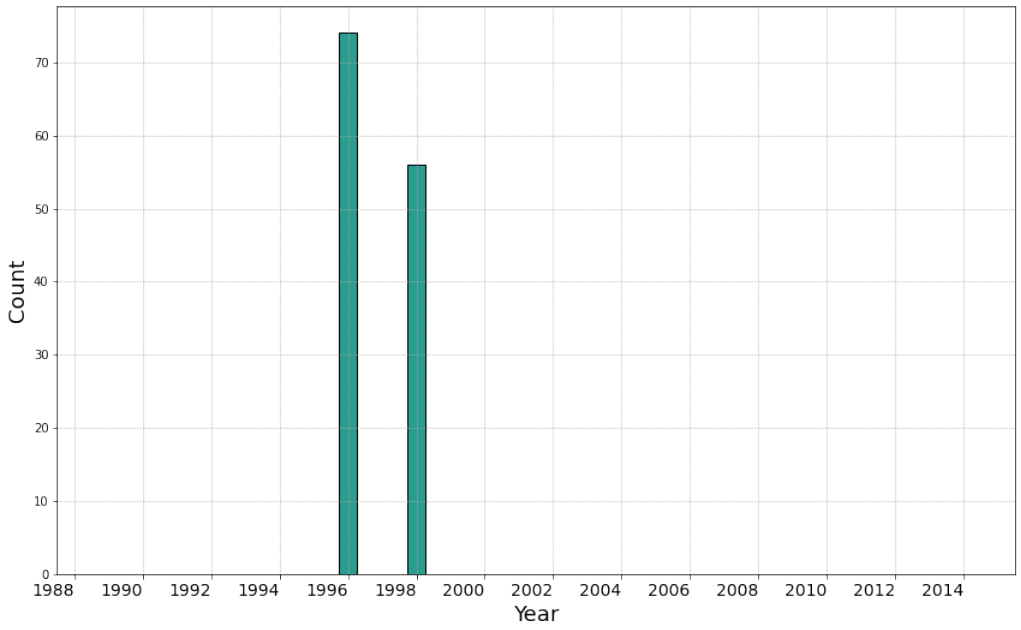
D Supplemental Figures and Tables

Appendix Figure D.1: Temporal Distribution of Reclassification Events

(a) Down-Regulation Events

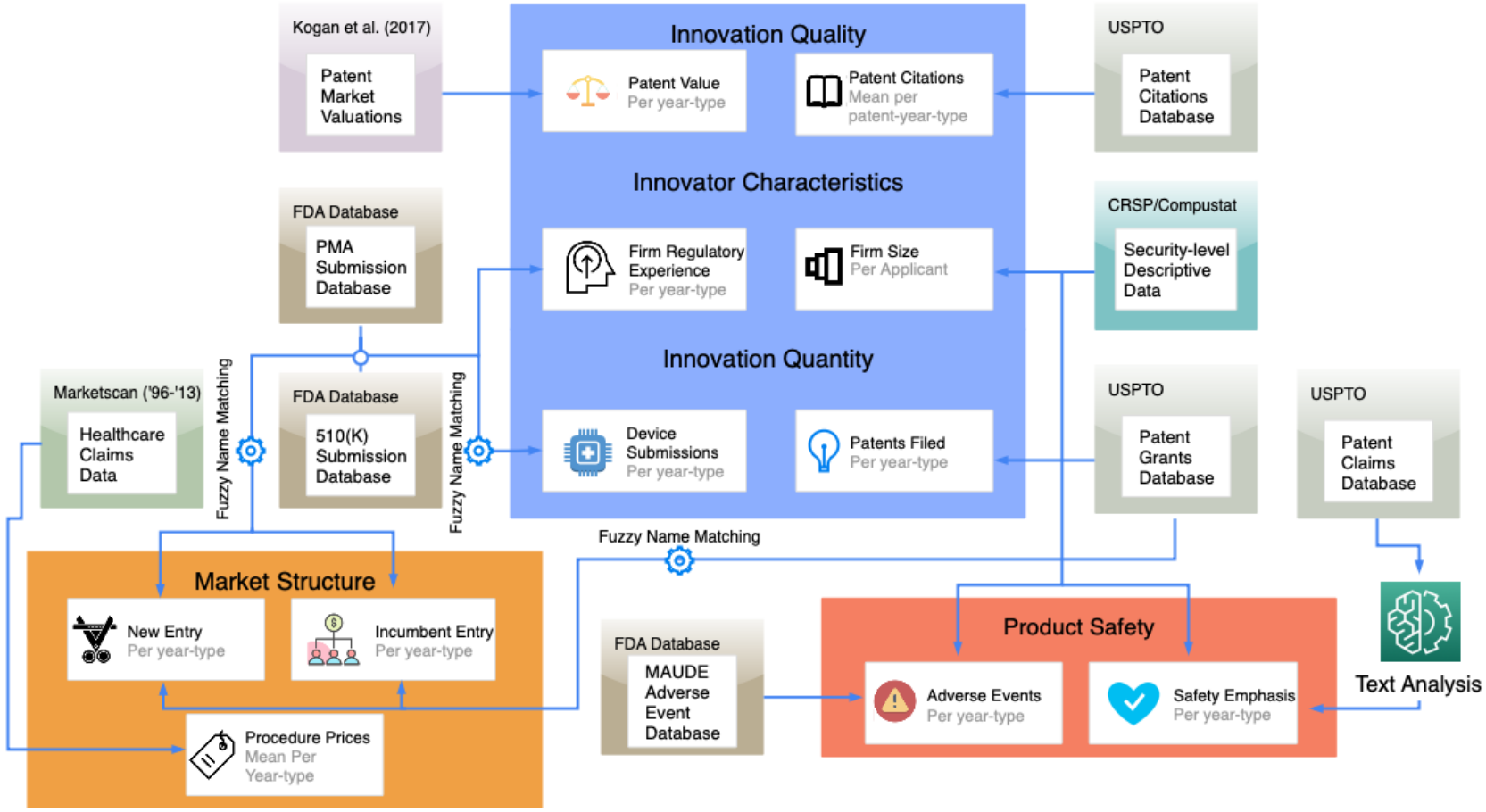


(b) Deregulation Events



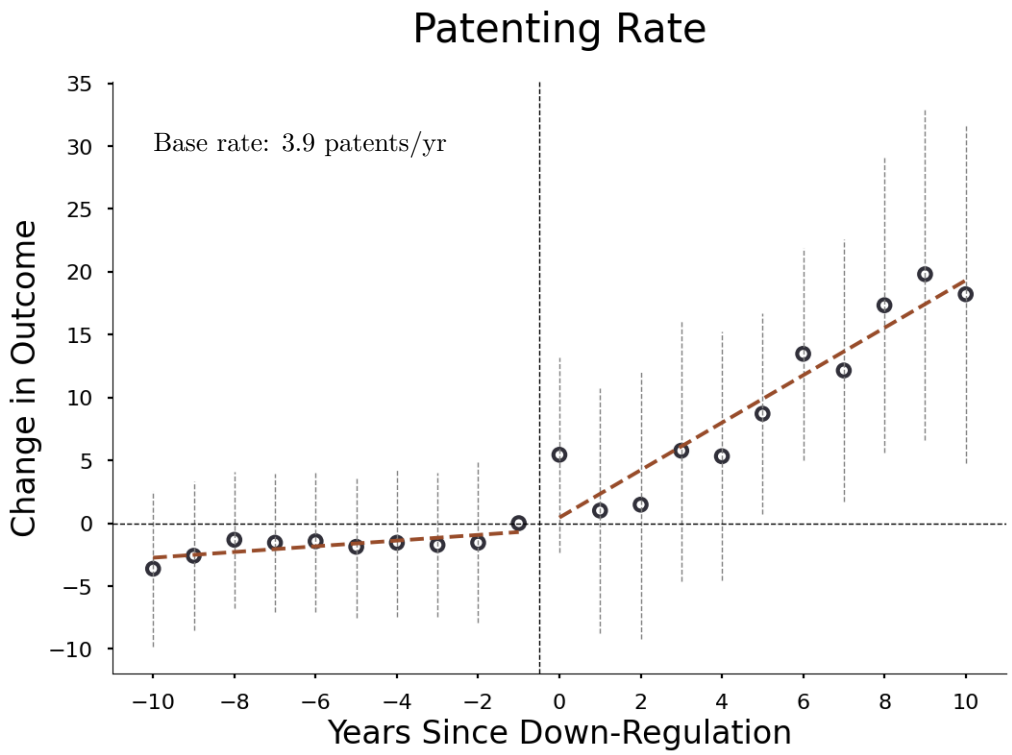
Note: These histograms depict the distribution of down-regulation and deregulation events over time. Panel (a) presents the yearly counts of down-regulation events, while Panel (b) displays the yearly counts of deregulation events.

Appendix Figure D.2: Data Catalog



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

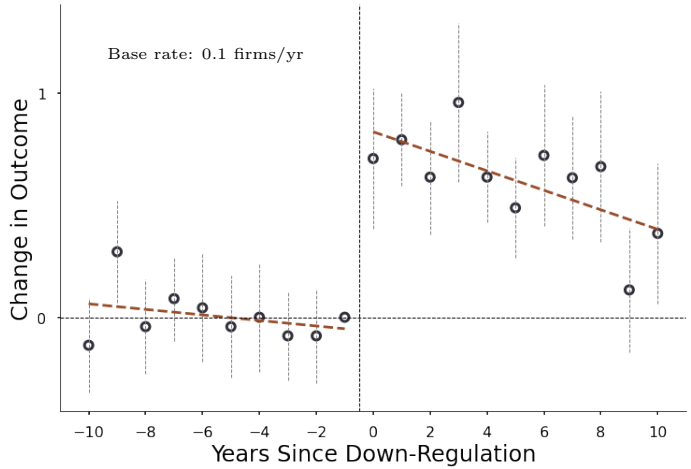
Appendix Figure D.3: Petitioned Down-Regulation Events (Not FDA Initiative)



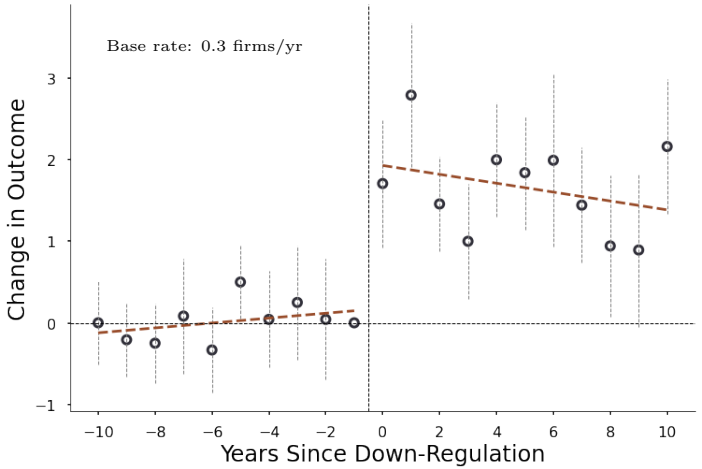
Note: This figure presents the estimates of the β_k coefficients from event-study Equation 2 for the patent filing rate measure and illustrates the potential biases that stem from industry petition of reclassification. Outcome data are derived from *Dimensions* patent data. Only Class III to II reclassification 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 D.4: Reclassification and Market Structure (Incumbent Entry and Other Measures)

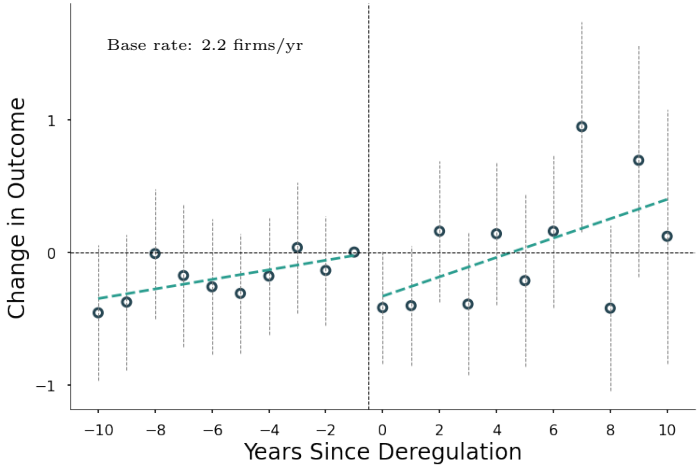
(a) New Entry (Device Data), Down-Regulation (III to II)



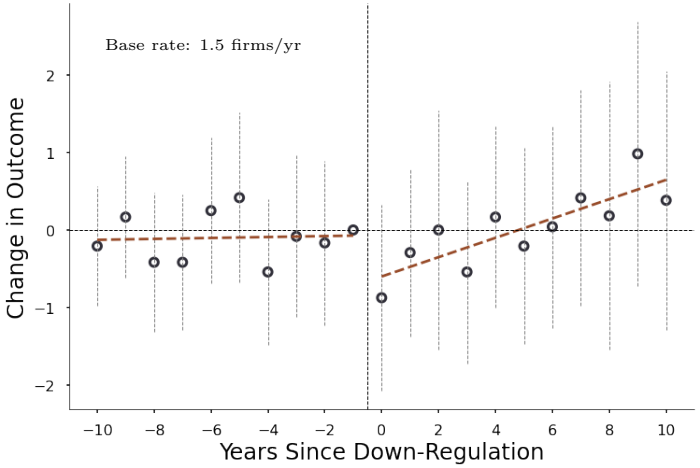
(b) Incumbent Entry (Device Data), Down-Regulation



(c) Incumbent Entry (Patent Data), Deregulation (II to I)



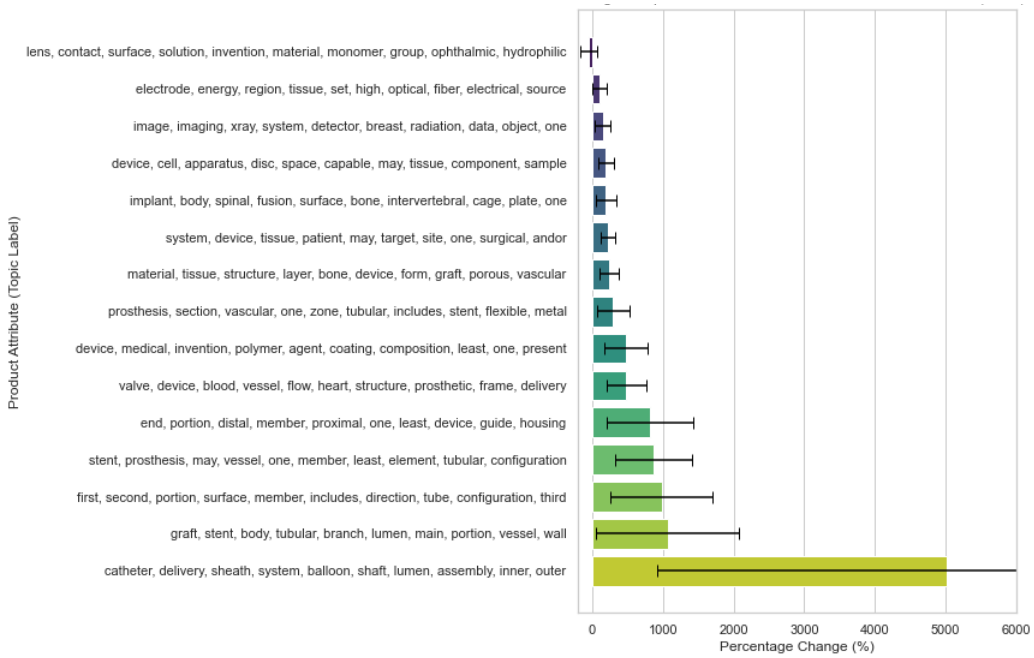
(d) Incumbent Entry (Patent Data), Down-Regulation



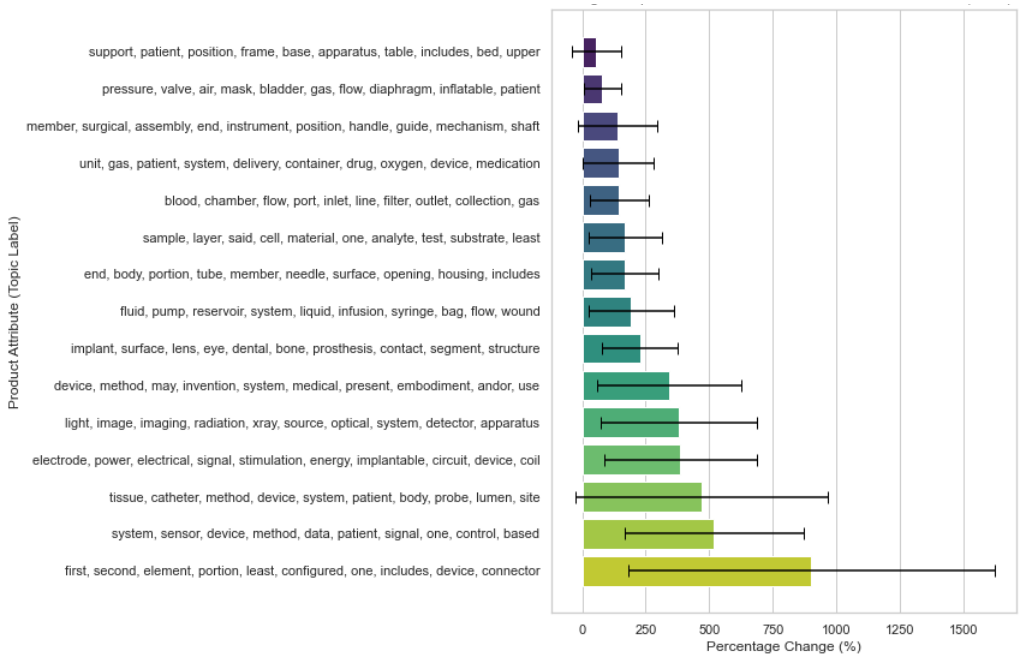
Note: The figure displays the estimates of the β_k coefficients from the event-study equation (see Equation 2) for incumbent entry and new entry using patent or FDA device submission data. Control groups comprise device types matched on pre-event outcome averages. The β_{-1} coefficient is the reference and thus excluded. Analyses utilize annual data. Panel (a) traces new entry among down-regulated devices, measured using FDA device submission data, against matched controls. Panel (b) does the same for incumbent entry. Panel (d) plots changes in incumbent entry after down-regulation using patent data. Panel (c) plots changes in incumbent entry among deregulated device types, measured using patent data. Confidence intervals are set at 95%.

Appendix Figure D.5: Product Variety, Complexity, and Quality

(a) Change in Patent Topics, Down-Regulation

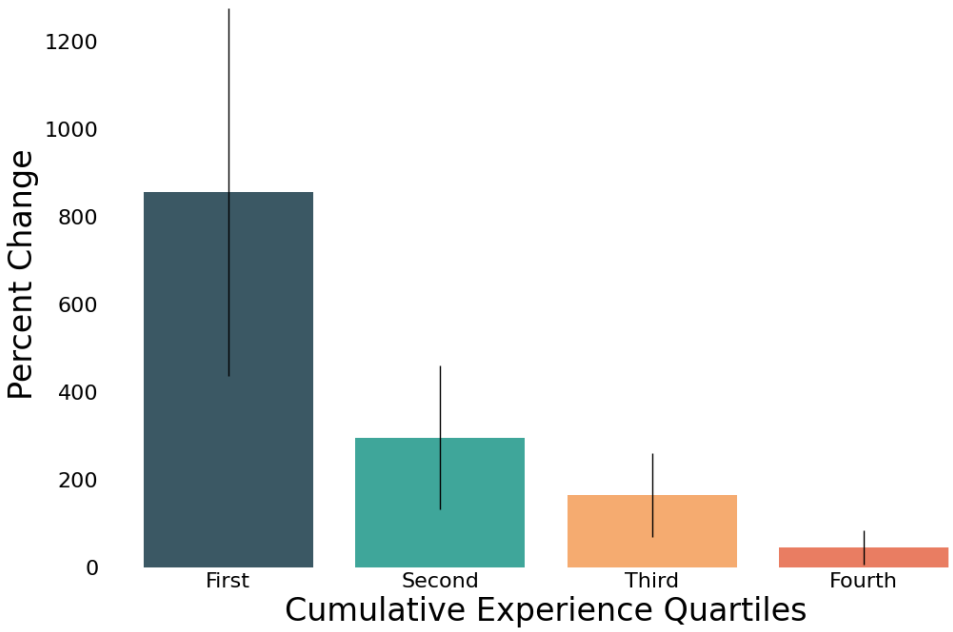


(b) Change in Patent Topics, Deregulation



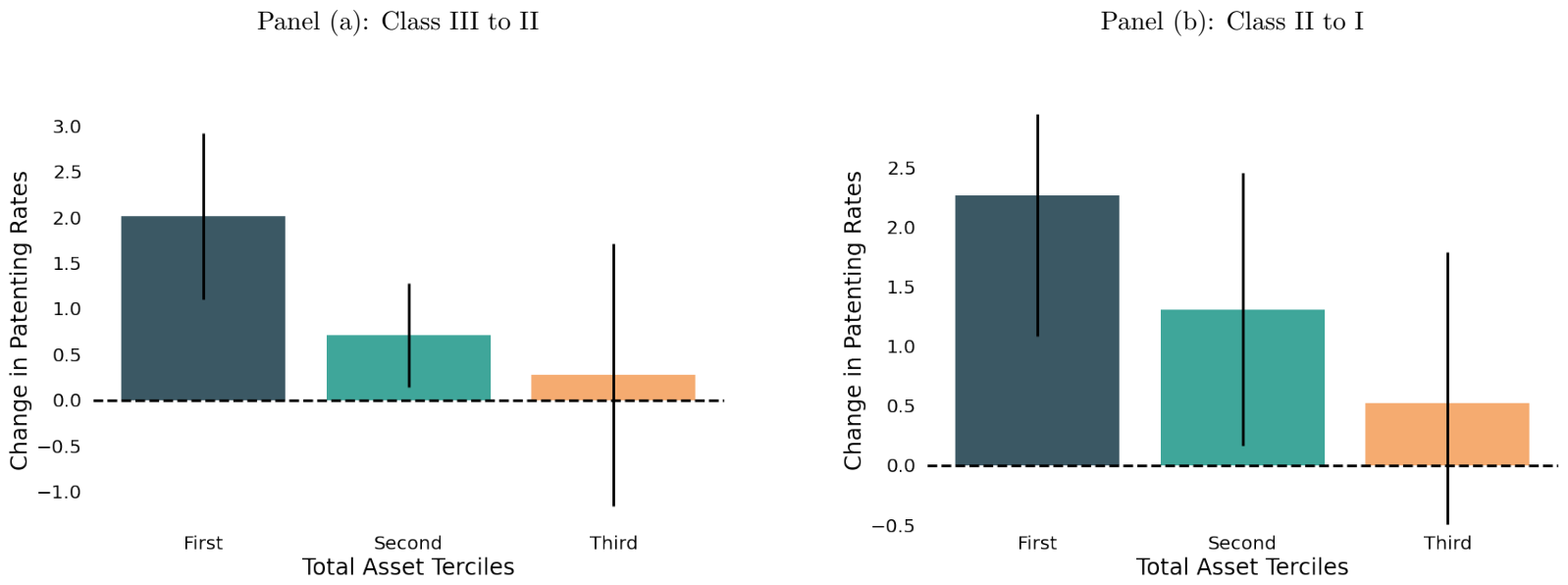
Note: The figure shows estimated percent changes in patents by topic following reclassification, using Equation 1 estimated separately for each topic cluster. Panel (a) shows the effects of down-regulation; Panel (b) shows the effects of deregulation. DiD estimates compare changes in topic emphasis between treated and matched control units before and after reclassification. 95% confidence intervals shown.

Appendix Figure D.6: Effects on Innovation by Experience



This figure illustrates how Class III to II reclassification impacts the rates of new device submissions, segmented by firm experience. DiD estimates show the percent changes in new device marketing rates for treated device types relative to controls, categorized by experience quartiles. Firm experience is assessed by totaling each firm's time complying with FDA regulations before submitting a given device for approval. Notably, baseline new device submission rates from newer firms in the lowest experience quartile are inherently smaller due to their shorter operational history and limited scale for innovating high-tech products. Therefore, analyzing percent changes enables meaningful cross-quartile comparisons, emphasizing growth over absolute innovation levels. The estimation excludes no-experience observations to avoid undefined outcomes and biases from extensive margin (entry) decisions. Confidence intervals are set at 95%.

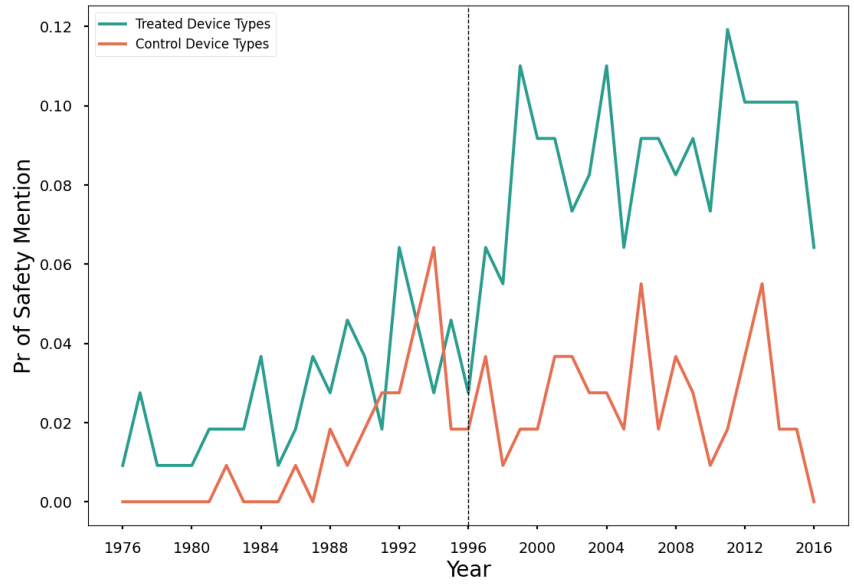
Appendix Figure D.7: Effect of Reclassification on Patenting Rates by Asset Terciles



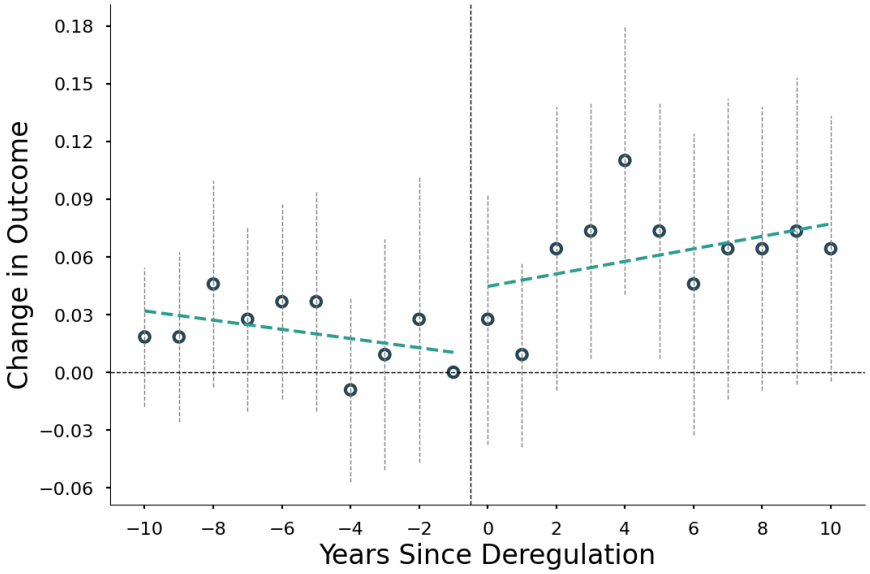
Note: This figure presents the DiD estimates from Equation 1 for the patenting rate across reclassification types and firm asset terciles. For the empirical estimates, I exclude patent data for private firms since I only observe firm asset data for publicly traded firms. Panel A presents the change in patenting rates in my Class III to II treated medical device types, relative to matched control groups, across asset terciles. The first tercile represents the bottom 33rd percentile of assets, the second represents the 33rd–66th percentile and the third represents the 66-100th percentile. Panel B presents the change in patenting rates in my Class II to I treated medical device types, relative to matched control groups, across asset terciles. 95% confidence intervals overlay the estimates. Simulated confidence intervals are calculated using a Monte Carlo procedure. This procedure produces estimates across repeated random draws from the empirical distribution of firm characteristics.

Appendix Figure D.8: Impact of Class II to I Events on Safety Emphasis

(a) Safety Emphasis, Raw Trends



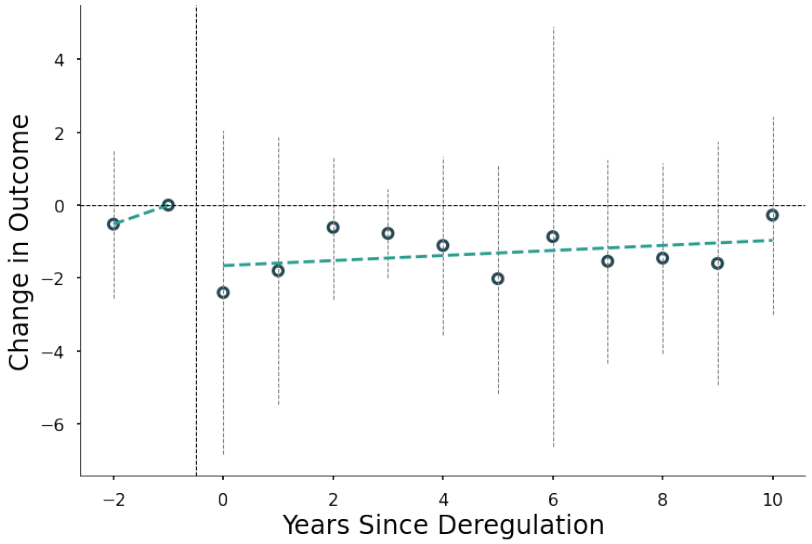
(b) Safety Emphasis, Event Study



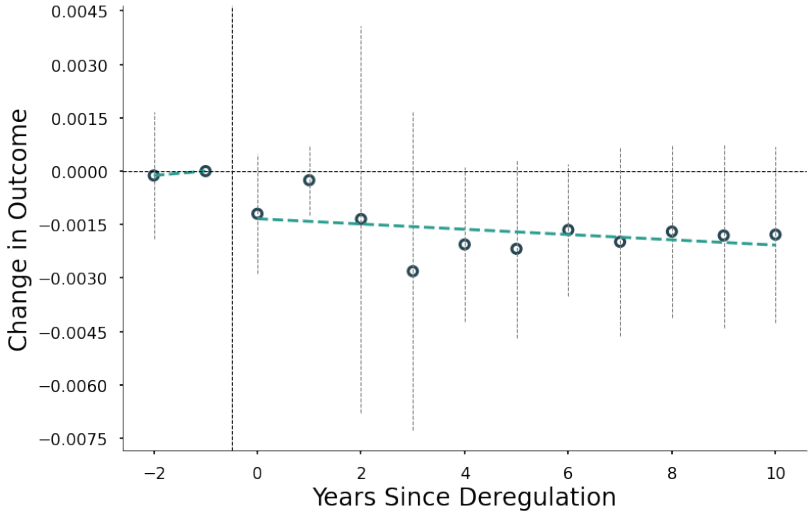
Panel (a) displays raw trends in the average probability of observing mentions of safety in patents for treated device types compared to control device types. Panel (b) presents estimates of the β_k coefficients from the event-study Equation 2, capturing inventors' emphasis on safety. The analysis focuses exclusively on Class II to Class I reclassification events, using annual data. Control device types are matched based on baseline averages of the innovation outcome variables. The coefficient β_{-2} is omitted and serves as the reference period due to noise in the pre-event data. The figure illustrates the evolution of the proportion of patents emphasizing safety in their text, with 95% confidence intervals included.

Appendix Figure D.9: Impact of Class II to I Events on Product Safety: Normalizable Subset (Raw Counts vs. Normalized)

(a) Serious Events



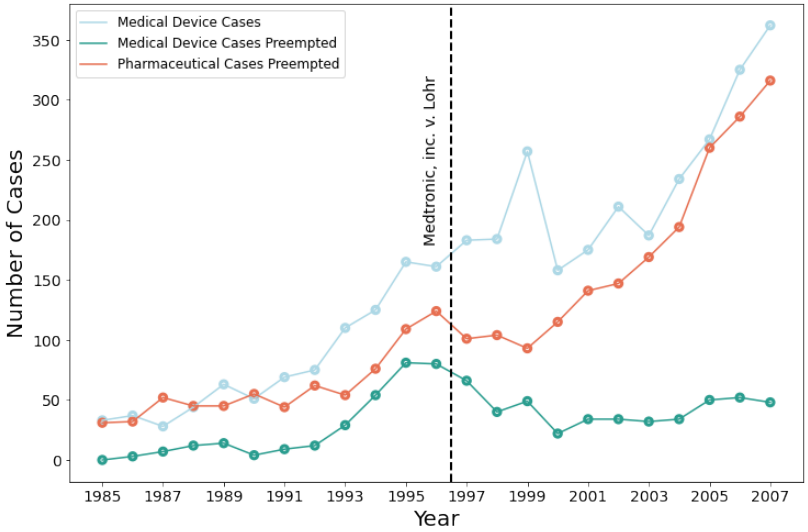
(b) Serious Events, Normalized by Procedure Volume



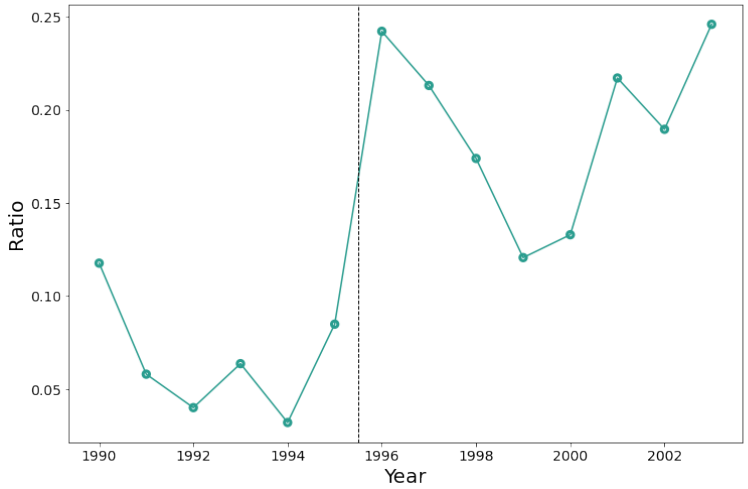
Note: This figure presents estimates of the β_k coefficients from Equation 2 for serious adverse events (life-threatening incidents, deaths, hospitalizations, or disabilities). The sample is limited to device types linked to medical procedures in MarketScan claims, with outcomes measured annually. Controls are device types matched on baseline averages. β_{-1} is omitted as the reference period. Panel (a) reports estimates for the normalizable subset of deregulated devices prior to normalization; Panel (b) shows estimates from the same subset after normalization by procedure volume. The sample mean of the treatment groups in the years prior to deregulation is 0.002 serious events per procedure. Conley–Taber 95% confidence intervals are reported. Too few Class III devices were linked to procedure codes to allow a comparable normalization analysis.

Appendix Figure D.10: Evolution of Medical Device Legal Environment

(a) Medical Device and Drug Tort Cases



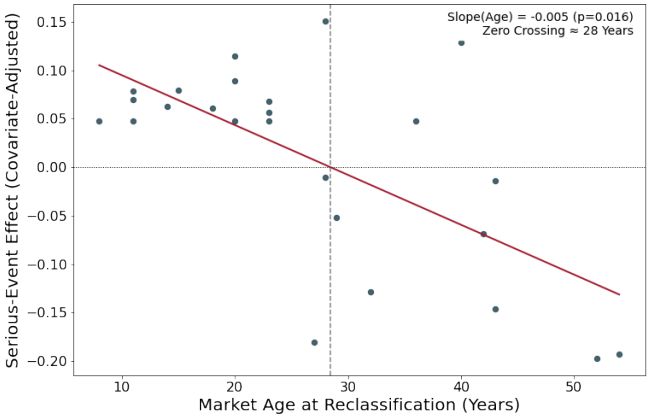
(b) Ratio of Bankruptcy Cases to Tort Claims for Medical Device Firms



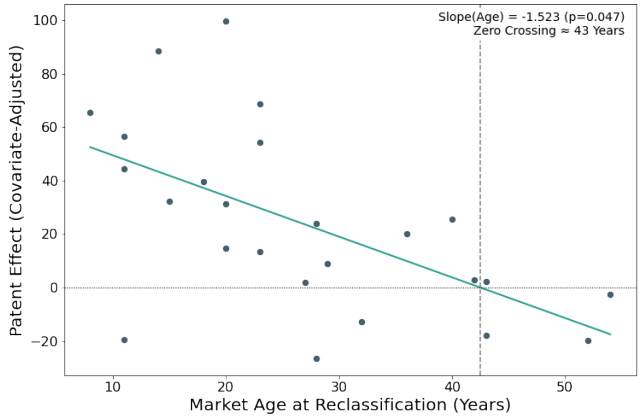
Note: Panel (a) depicts yearly counts of medical device tort claims and highlights those referencing "preemption." It also includes counts for pharmaceutical tort cases mentioning "preemption." Data for this panel is sourced from Nexis Uni and is based on searches for "Medical device tort," "medical device tort preempt," and "pharmaceutical tort preempt." The vertical dotted line marks 1996, the year of the Supreme Court's Medtronic, Inc. v. Lohr decision, which significantly impacted the regulatory environment by withdrawing legal protections for Class II devices. Panel (b) plots the ratio of bankruptcy case counts to tort claim counts in the medical device industry by year. Data for this panel is sourced from Nexis Uni and is based on searches for "medical device Chapter 11 bankruptcy."

Appendix Figure D.11: How Impacts Vary with Device Market Age

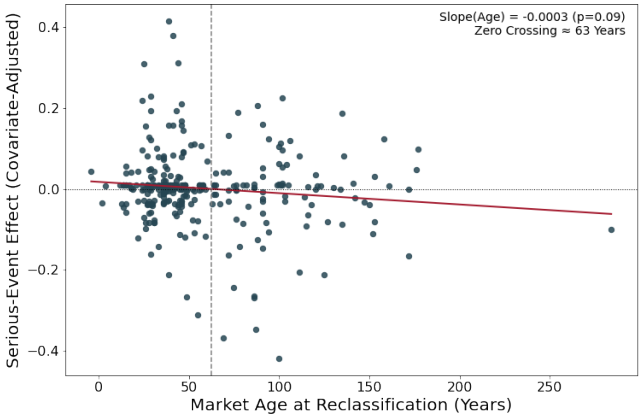
(a) Down-regulation: Serious-Event Effect



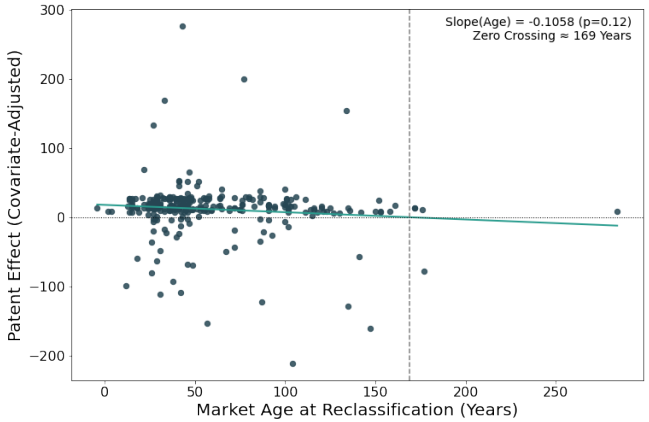
(b) Down-regulation: Patenting Effect



(c) Deregulation: Serious-Event Effect



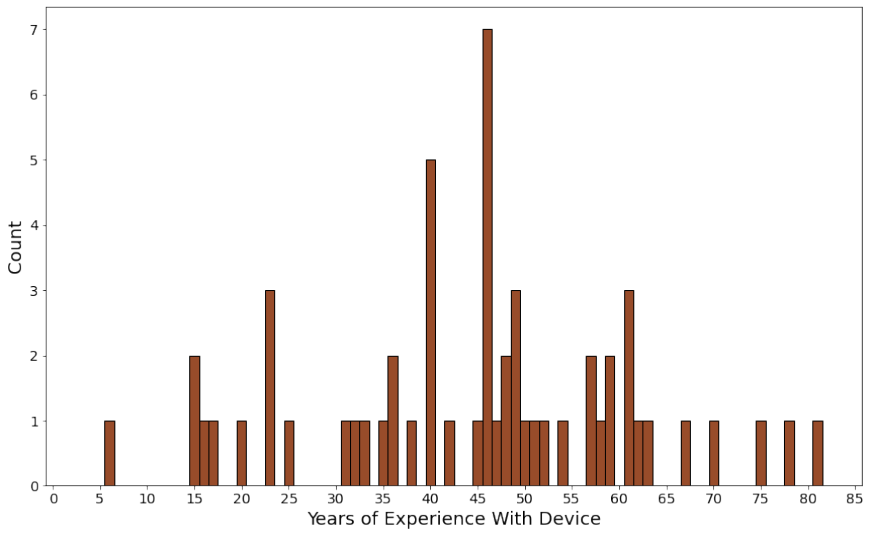
(d) Deregulation: Patenting Effect



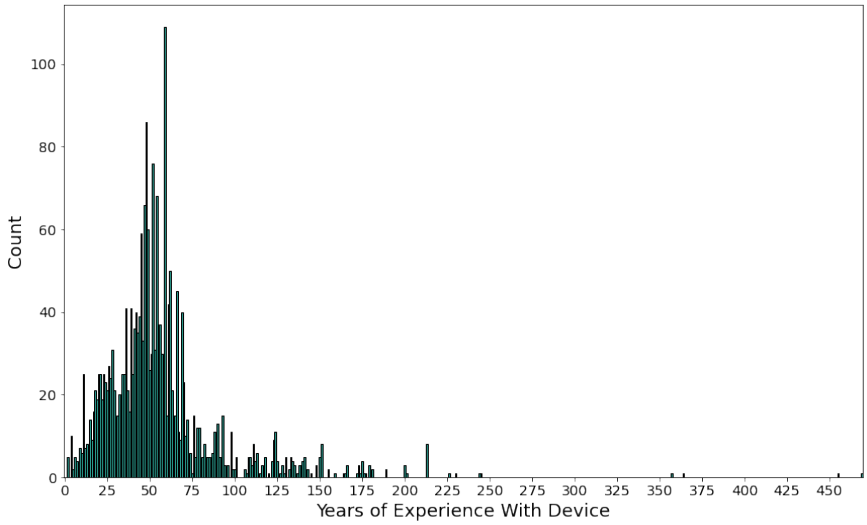
Note: Each panel plots device-level DiD estimates against market age at reclassification. Points are covariate-adjusted predictions in the original units, evaluated at representative values for other regressors (continuous controls at sample means; indicators at sample shares; reference product area). Curves show the conditional OLS fit. The dashed vertical line marks the policy-relevant cutoff—the age at which the fitted safety effect equals zero. Panels (a)–(b) show down-regulation (Class III to II); panels (c)–(d) show deregulation (Class II to I).

Appendix Figure D.12: Histogram, Years of Experience With Current Class III and II Devices

(a) Class III Devices

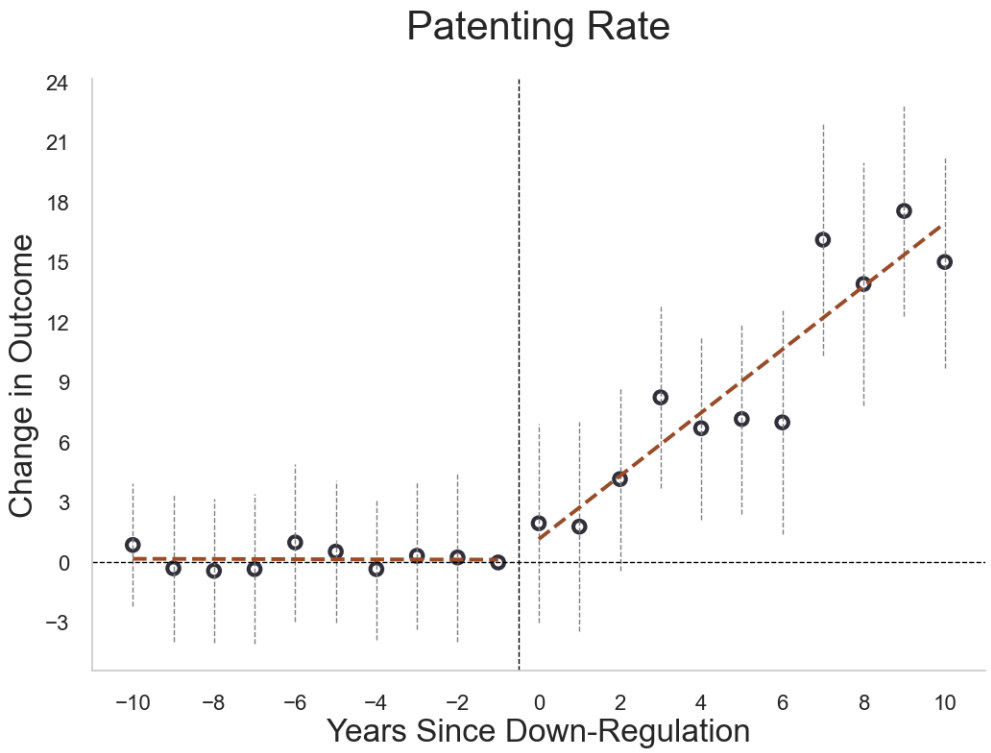


(b) Class II Devices



Panel (a) illustrates the distribution of years of experience for current Class III medical devices, displaying the frequency of devices based on their years of use. Panel (b) presents a similar distribution for Class II medical devices. The data were collected using GPT-4o to gather invention dates for each device. The correlation coefficient between device experience determined through a hand-coded correspondence of all down-regulated device types (N = 25) and that generated by GPT-4o is 0.76, with $p < 0.001$, indicating a strong positive relationship between the two methods.

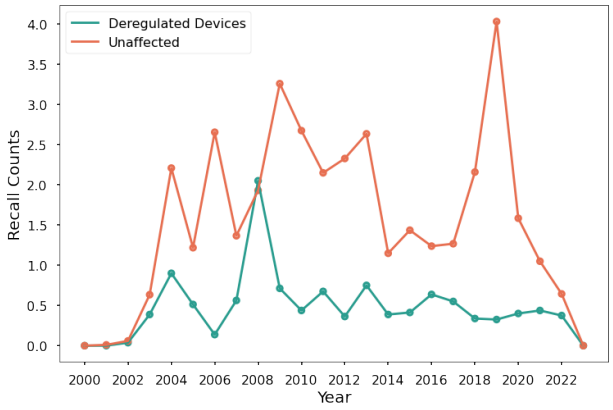
Appendix Figure D.13: Effects of Class III to II Events on Patenting Rates: Restricted Patent Sample



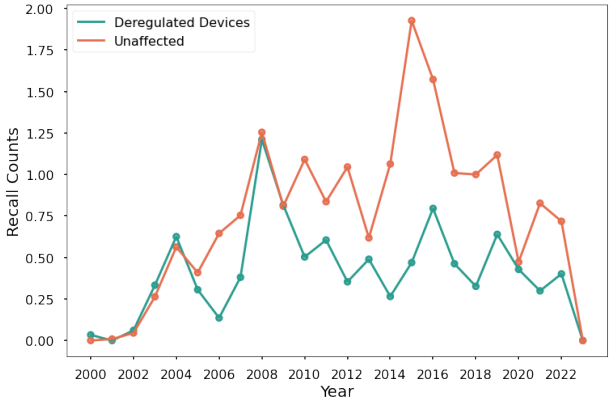
Note: This figure presents the estimates of the β_k coefficients from event-study Equation 2 for patenting rates using the restricted patent sample described in Appendix C.1. Compare to Figure 2, Panel (a). Controls are device types matched on baseline average innovation rates. The coefficient β_{-1}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

Appendix Figure D.14: Device Recall Analysis—Class II to I

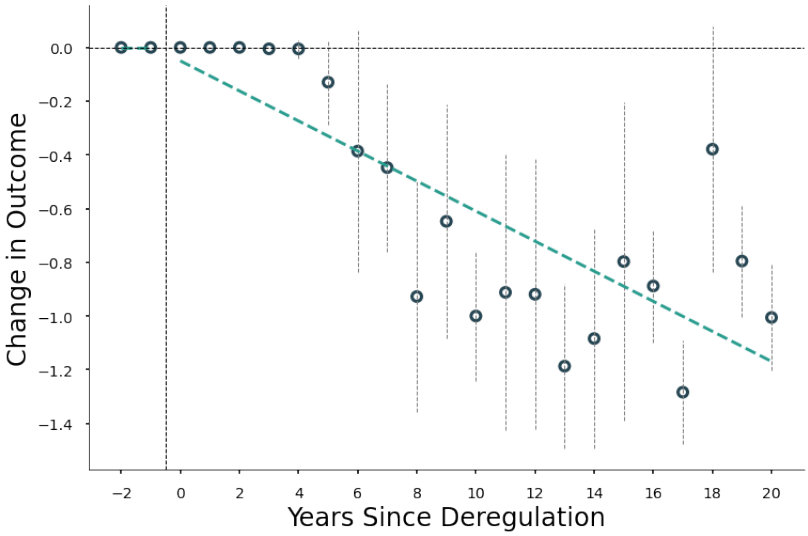
(a) Raw Trend—Matched Controls



(b) Raw Trend—Intuitive Controls



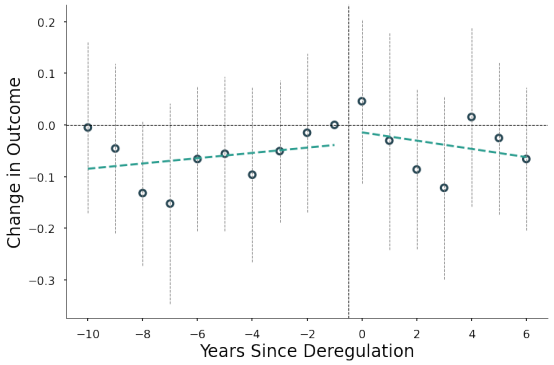
(c) Recall Count Event Study, Matched Controls



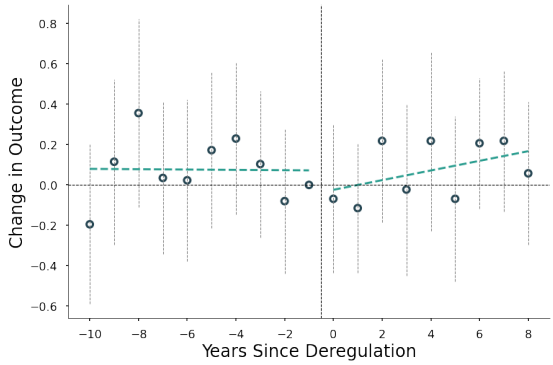
Note: This figure illustrates the device recall analysis for the Class II to I events. Panels (a) and (b) display the average device recall counts by treatment status from 2000 to 2023 for the matched and intuitive control groups, respectively. Panel (c) shows the event-study estimates of the change in device recalls over time. Recall counts for event times $-2 \leq t \leq 3$ are constant at zero due to the missing recall data for those specific years.

Appendix Figure D.15: Safety and Recalls After Deregulation—Class II to I (2015)

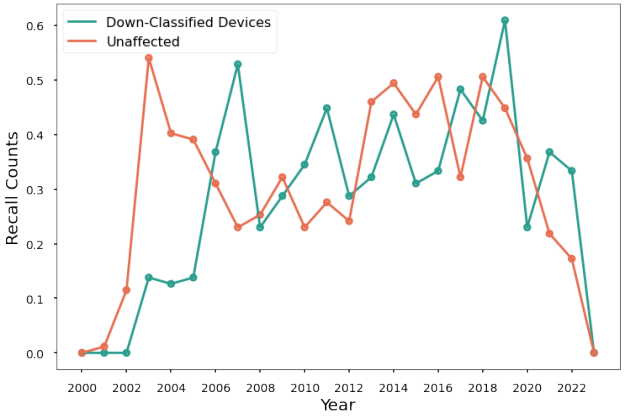
(a) Serious adverse events (event study)



(b) Device recalls (event study)

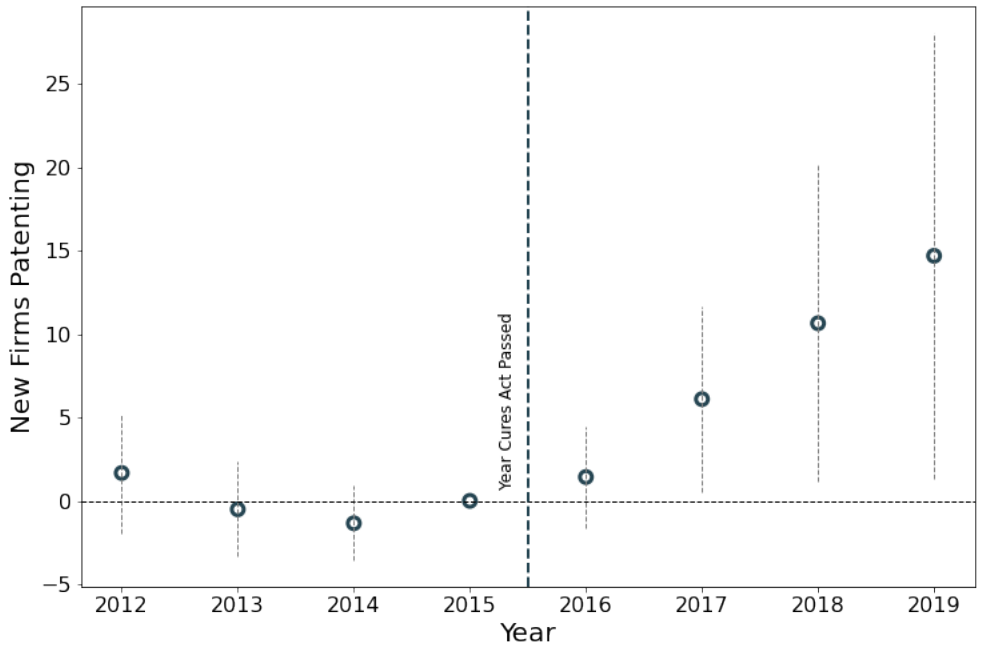


(c) Device recalls (raw mean trends by treatment status)



Note: Panels (a)–(b) report event-study coefficients β_k from Equation 2 for the 2015 Class II to I reclassification; β_{-1} is omitted (reference). Outcomes are annual. Treated device types are compared to matched controls based on pre-event baseline outcome averages. Panel (a) shows serious adverse events—life-threatening, death, hospitalization, and disability—from FDA's MAUDE database. Panel (b) shows device recalls. Panel (c) plots raw mean recall counts by treatment status (2000–2023). 95% confidence intervals are shown on Panels (a)–(b).

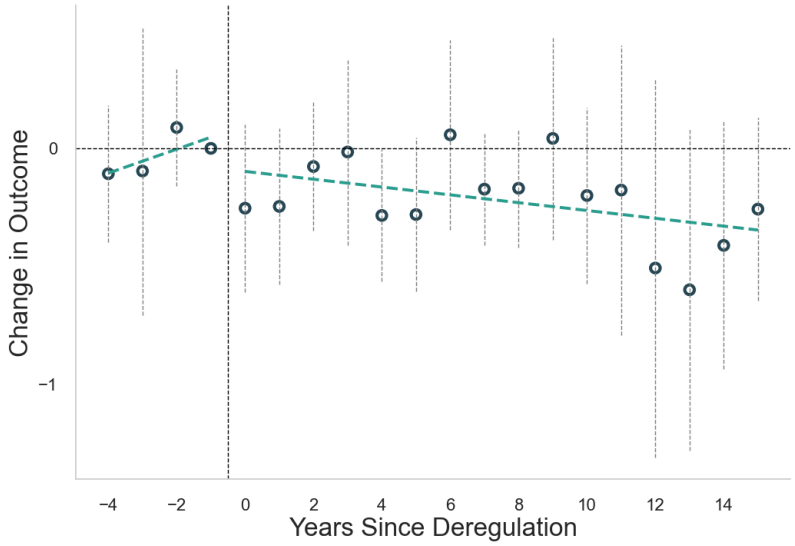
Appendix Figure D.16: Effects of 2015 Class II to I Event on New Entry



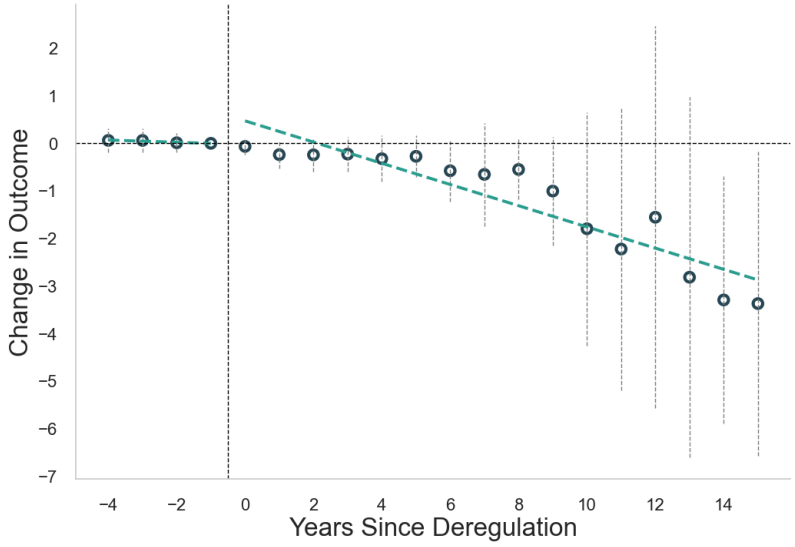
Note: This figure presents the estimates of the β_k coefficients from event-study. Controls are device types matched on baseline average innovation rates. The coefficient β_{-1} is omitted and serves as the reference period. Data are analyzed at an annual frequency. The entry rate is measured by the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

Appendix Figure D.17: Serious Adverse Event Changes by Reporter Type—Class II to I

(a) Serious Adverse Events, Excluding Manufacturers



(b) Serious Adverse Events, Manufacturers



Note: The figure displays the estimates of the β_k coefficients from the event-study equation (see Equation 2) for serious adverse events, encompassing life-threatening incidents, mortality, hospitalizations, and disability, differentiated by the source of the adverse event report. Results are presented separately for manufacturer reports and reports from all other sources. Control groups consist of device types matched on pre-event outcome averages. The β_{-1} coefficient is the reference and thus excluded. Analyses utilize annual data. Panel (a) traces serious adverse events for down-regulated devices against matched controls based on reports from non-manufacturer sources. Panel (b) offers a parallel analysis but exclusively considers serious adverse event reports originating from manufacturers. Confidence intervals are set at 95%.

Appendix Table D.1: Class III to II Down-Regulated Device Types (FDA-Initiated and Petitioned)

A. Down-Regulated Device Types Considered (FDA-Initiated; Main Sample)

Device Type Description	Part	Year Announced	FR Citation
Tacrolimus test system.	Clinical Chemistry...	2002	67 FR 58329
DNA-based TB diagnostic devices.	Immunology And..	2014	79 FR 31027
Electrical salivary stimulatory system.	Dental Devices	2015	80 FR 72586
Extracorporeal shock wave lithotripter.	Gastroenterology-Urology Devices	2000	65 FR 48612
Rigid gas permeable contact lens.	Ophthalmic Devices	1994	59 FR 10284
Soft contact lens.	Ophthalmic Devices	1994	59 FR 10284
Bone sonometer.	Radiology Devices	2008	73 FR 40969
Full-field digital mammography system.	Radiology Devices	2010	75 FR 68203
Vascular embolization device.	Cardiovascular Devices	2002	69 FR 77899
Cutaneous carbon dioxide (PcCO2) monitor.	Anesthesiology Devices	1988	54 FR 27160
Vascular graft prosthesis.	Cardiovascular Devices	1994	66 FR 18542
Intervertebral body fusion device.	Orthopedic Devices	2007	72 FR 32172

B. Petitioned Down-Regulated Device Types

Device Type Description	Part	Year Announced	Petitioning Entity	FR Citation
Cyclosporine test system.	Clinical Chemistry And Clinical Toxicology Dev...	2001	Dade Behring, Inc., and Microgenics, Inc.	67 FR 58329
Bone grafting material (dental bone repair).	Dental Devices	2003	Bicon, Inc.	70 FR 21949
Nonabsorbable stainless-steel suture.	General And Plastic Surgery Devices	1986	Alto Development Corp.	68 FR 32984
Absorbable synthetic suture; polyglycolic acid).	General And Plastic Surgery Devices	1990	Advanced Bioresearch Associates	68 FR 32984
Nonabsorbable synthetic polyester suture.	General And Plastic Surgery Devices	1990	Advanced Biosearch Associates	68 FR 32984
Nonabsorbable silk suture.	General And Plastic Surgery Devices	1990	Advanced Biosearch Associates	68 FR 32985
Tissue adhesive (topical skin approximation).	General And Plastic Surgery Devices	2007	Regulatory & Clinical Research Institute, Inc....	73 FR 31033
Tumor-associated antigen test system (alpha-fetoprotein).	Immunology And Microbiology Devices	1996	Centocor, Inc.,	62 FR 66005
Tumor-associated antigen test system (epithelial ovarian).	Immunology And Microbiology Devices	1996	Centocor, Inc.,	62 FR 66005
Tumor-associated antigen test system (prostate-specific antigen).	Immunology And Microbiology Devices	1996	Centocor, Inc.,	62 FR 66005
Automated antimicrobial susceptibility test system (short-term).	Immunology And Microbiology Devices	2000	BioMerieux Vitek, Inc.	68 FR 5827
Hepatitis A serological assays (antibody and IgM).	Immunology And Microbiology Devices	2004	Beckman Coulter, Inc	71 FR 6679
Home uterine activity monitor.	Obstetrical And Gynecological Devices	1999	GE Marquette Medical Systems, Inc.	66 FR 14076
Bone cement (PMMA).	Orthopedic Devices	1999	OSMA	67 FR 46855
Hip joint metal/polymer constrained prosthesis.	Orthopedic Devices	2001	OSMA	67 FR 21173
Stair-climbing wheelchair.	Physical Medicine Devices	2013	DEKA Research & Dev. Corp.	79 FR 20782
Nuclear Magnetic resonance diagnostic device.	Radiology Devices	1988	Thomson-CGR Medical Corp.	53 FR 5078

Note: Panel A lists device types down-regulated from Class III to II by FDA initiative; Panel B lists device types down-regulated via reclassification petitions. In Panel B, the device description consolidates the original "Broad" and "Narrow" descriptions: if the narrow term adds specificity, it appears as a brief parenthetical qualifier; if it is redundant, the broad term alone is used. Entries include regulatory part, announcement year, petitioning entity (Panel B), and Federal Register citation. All rows correspond to device types with at least one prior PMA submission.

Appendix Table D.2: Treated Device Type to Procedure Linkages

Product Code	Device Name	CPT (L1)	HCPCS L2	Procedure
A. Class III to II				
LNS	Lithotriptor, Extracorporeal Shock-Wave, Urological	50590		Extracorporeal shock wave lithotripsy (ESWL) for renal calculi (kidney stones).
MAX	Intervertebral Fusion Device With Bone Graft, Lumbar	22558		Anterior lumbar interbody fusion (ALIF).
MLM	Enzyme Immunoassay, Tacrolimus	80197		Therapeutic drug assay of tacrolimus (FK506) in blood.
B. Class II to I				
CEK	Biuret (Colorimetric), Total Protein	84155		Total protein, serum – quantitative biuret colorimetric assay.
CER	2,4-Dinitrophenylhydrazine, Lactate Dehydrogenase	83615		Lactate dehydrogenase (LDH) quantitative assay.
CFH	Tetrazolium Int Dye-Diaphorase, Lactate Dehydrogenase	83615		Lactate dehydrogenase (LDH) quantitative assay.
CFJ	NAD Reduction/NADH Oxidation, Lactate Dehydrogenase	83615		Lactate dehydrogenase (LDH) quantitative assay.
DAD	Haptoglobin, Antigen, Antiserum, Control	83010		Haptoglobin assay (quantitative immunologic serum haptoglobin test).
FFL	Dislodger, Stone, Basket, Ureteral, Metal	52352		Ureteroscopy with removal of ureteral calculus (stone extraction using basket device).
FNL	Bed, AC-Powered Adjustable Hospital		E0260	Hospital bed, semi-electric (head and foot adjustment), with any type side rails, with mattress.
FNM	Mattress, Air Flotation, Alternating Pressure		E0277	Powered pressure-reducing air mattress (alternating/low air loss) furnished as DME.
IKK	System, Isokinetic Testing And Evaluation	97750		Physical performance test or measurement with written report, each 15 minutes.
ILO	Pack, Hot Or Cold, Water Circulating	97010		Application of hot or cold packs (superficial thermal modality).
JCA	Device, Bleeding Time	85002		Bleeding time test.
JGP	Lowry (Colorimetric), Total Protein	84155		Measurement of total protein concentration in blood (serum, plasma, or whole blood).
JGQ	Turbidimetric, Total Protein	84155		Total protein; quantitative assay (serum/-plasma) – turbidimetric method.
JPI	Device, Hematocrit Measuring	85014		Hematocrit (microhematocrit) test – measurement of packed cell volume.
KSX	Substance, Blood Grouping Of Non-Human Origin For In Vitro Diagnostic Use	86900, 86901		Blood grouping (ABO) and Rh(D) typing immunohematology tests.

Note: The table provides the device-to-procedure linkages for the two reclassification pathways where (i) procedures are linked to the device, (ii) the reclassification event occurred after 1996 (the earliest year in my data), and (iii) there are outpatient claims attributable to that procedure. Procedure code description text is abbreviated; code descriptors were verified against published references.

Appendix Table D.3: Robustness Matrix: Innovation (All estimators)

A. Class III to II

Borusyak et al.

	Pre-mean	Matched	Intuitive	Later
Patenting Rate	8.25	16.55+	29.62***	28.16**
	(8.98)	(9.94)	(8.45)	(8.59)
Device Submission Rate	0.95	2.69***	2.98***	2.84***
	(1.25)	(0.56)	(0.56)	(0.56)
Citations-Per-Patent Rate	9.06	19.20*	23.13*	28.05***
	(20.65)	(7.48)	(9.00)	(7.37)
Average Patent Value	10.45	13.69*	28.39***	27.23***
	(13.38)	(6.62)	(6.12)	(6.22)
Sample Size		1496	1056	1012

Log(+1)

	Pre-mean	Matched	Intuitive	Later
Patenting Rate	8.25	0.82***	1.62***	1.52**
	(8.98)	(0.19)	(0.45)	(0.48)
Device Submission Rate	0.95	0.58***	0.69***	0.64***
	(1.25)	(0.13)	(0.18)	(0.17)
Citations-Per-Patent Rate	9.06	0.77***	1.64***	1.60**
	(20.65)	(0.15)	(0.49)	(0.49)
Average Patent Value	10.45	0.78***	1.49***	1.37**
	(13.38)	(0.21)	(0.45)	(0.45)
Sample Size		1496	1056	1012

Quasi-Poisson

	Pre-mean	Matched	Intuitive	Later
Patenting Rate	8.25	0.60*	0.94**	0.72**
	(8.98)	(0.24)	(0.29)	(0.22)
Device Submission Rate	0.95	1.78**	2.62***	2.20**
	(1.25)	(0.62)	(0.72)	(0.71)
Citations-Per-Patent Rate	9.06	0.74**	0.67+	0.70+
	(20.65)	(0.26)	(0.35)	(0.38)
Average Patent Value	10.45	0.70+	1.05*	0.52
	(13.38)	(0.40)	(0.45)	(0.44)
Sample Size		1496	1056	1012

B. Class II to I

Borusyak et al.

	Pre-mean	Matched	Intuitive	Later
Patenting Rate	16.46	11.37	33.78**	36.69***
	(37.07)	(13.19)	(12.11)	(10.86)
Citations-Per-Patent Rate	0.66	0.34	7.93***	9.26***
	(0.47)	(3.28)	(1.85)	(1.80)
Average Patent Value	13.45	2.64	8.38***	8.11***
	(28.87)	(2.43)	(2.18)	(2.15)
Sample Size		11704	10648	12232

Log(+1)

	Pre-mean	Matched	Intuitive	Later
Patenting Rate	16.46	0.08	0.40***	0.50***
	(37.07)	(0.05)	(0.11)	(0.10)
Citations-Per-Patent Rate	0.66	0.09**	0.47***	0.56***
	(0.47)	(0.03)	(0.08)	(0.08)
Average Patent Value	13.45	0.09	0.42***	0.50***
	(28.87)	(0.06)	(0.11)	(0.10)
Sample Size		11704	10648	12232

Quasi-Poisson

	Pre-mean	Matched	Intuitive	Later
Patenting Rate	16.46	0.18	-0.11	0.01
	(37.07)	(0.19)	(0.26)	(0.20)
Citations-Per-Patent Rate	0.66	0.11	0.41*	0.44*
	(0.47)	(0.24)	(0.17)	(0.18)
Average Patent Value	13.45	0.18	0.13	0.05
	(28.87)	(0.12)	(0.15)	(0.14)
Sample Size		11704	10648	12232

Note: Panel A shows Class III to II reclassifications; Panel B shows Class II to I. Column (1) reports the 5-year pre-event mean for treated device types ("Pre-mean"). Columns (2)–(4) report difference-in-differences estimates using three control sets: (i) *Matched* controls, (ii) *Intuitive* (device types treating similar conditions), and (iii) *Later-treated* device types (treated after the analysis window). Estimation is reported three ways: *Borusyak et al. (2021)* imputation estimator (levels), *Log(+1)* where count outcomes are transformed by $\log(y+1)$, and *Quasi-Poisson* for overdispersed counts. Confidence intervals are based on Conley–Taber test statistics; $+, *, **, ***$ denote statistical significance at the 0.10, 0.05, 0.01, and 0.001 levels, respectively. Where present, a "Sample Size" row refers to the estimation sample used in Columns (2)–(4).

Appendix Table D.4: Robustness Matrix: Market Structure (All estimators)

A. Class III to II

Prices (Borusyak et al. only)

		DiD Estimates			
	Pre-mean	All CPTs	Matched	Intuitive	Later
Procedure Price	1652.86†	0.06	-0.03	-	-
	(1456.53)	(0.04)	(0.07)	-	-
Sample Size		594	126	-	-

Market composition — Borusyak et al.

		DiD Estimates			
	Pre-mean	All CPTs	Matched	Intuitive	Later
Incumb. Entry (dev.)	0.28	-	1.02***	1.09***	0.97***
	(0.58)	-	(0.13)	(0.12)	(0.11)
New Entry (dev.)	0.07	-	0.38***	0.42***	0.40***
	(0.25)	-	(0.11)	(0.11)	(0.11)
Incumb. Entry (pat.)	1.55	-	1.49+	3.49***	3.49***
	(1.73)	-	(0.81)	(0.54)	(0.54)
New Entry (pat.)	3.87	-	7.99+	12.50***	12.31***
	(4.55)	-	(4.15)	(3.70)	(3.70)
Sample Size		-	1496	1056	1012

Market composition — Log(+1)

		DiD Estimates			
	Pre-mean	All CPTs	Matched	Intuitive	Later
Incumb. Entry (dev.)	0.28	-	0.44***	0.45***	0.38***
	(0.58)	-	(0.10)	(0.12)	(0.11)
New Entry (dev.)	0.07	-	0.21***	0.23***	0.22***
	(0.25)	-	(0.04)	(0.05)	(0.05)
Incumb. Entry (pat.)	1.55	-	0.28*	0.75**	0.75**
	(1.73)	-	(0.13)	(0.24)	(0.25)
New Entry (pat.)	3.87	-	0.72***	1.28***	1.22***
	(4.55)	-	(0.16)	(0.35)	(0.35)
Sample Size		-	1496	1056	1012

Market composition — Quasi-Poisson

		DiD Estimates			
	Pre-mean	All CPTs	Matched	Intuitive	Later
Incumb. Entry (dev.)	0.28	-	2.19**	3.21***	2.32**
	(0.58)	-	(0.73)	(0.80)	(0.81)
New Entry (dev.)	0.07	-	1.68**	2.44***	1.89**
	(0.25)	-	(0.58)	(0.66)	(0.61)
Incumb. Entry (pat.)	1.55	-	0.42*	0.24	0.43
	(1.73)	-	(0.20)	(0.32)	(0.28)
New Entry (pat.)	3.87	-	0.71*	1.26***	1.21***
	(4.55)	-	(0.31)	(0.36)	(0.27)
Sample Size		-	1496	1056	1012

B. Class II to I

Prices (Borusyak et al. only)

		DiD Estimates			
	Pre-mean	All CPTs	Matched	Intuitive	Later
Procedure Price	147.28†	-0.32**	-0.23*	-	-
	(343.70)	(0.11)	(0.11)	-	-
Sample Size		1062	1260	-	-

Market composition — Borusyak et al.

		DiD Estimates			
	Pre-mean	All CPTs	Matched	Intuitive	Later
Incumb. Entry (pat.)	2.32	-	0.38	1.69**	2.08***
	(4.37)	-	(0.74)	(0.62)	(0.58)
New Entry (pat.)	7.45	-	5.81	12.12**	13.25***
	(17.08)	-	(4.01)	(3.74)	(3.36)
Sample Size		-	11704	10648	12232

Market composition — Log(+1)

		DiD Estimates			
	Pre-mean	All CPTs	Matched	Intuitive	Later
Incumb. Entry (pat.)	2.32	-	0.02	0.15*	0.24***
	(4.37)	-	(0.03)	(0.06)	(0.06)
New Entry (pat.)	7.45	-	0.10*	0.32***	0.39***
	(17.08)	-	(0.04)	(0.09)	(0.08)
Sample Size		-	11704	10648	12232

Market composition — Quasi-Poisson

		DiD Estimates			
	Pre-mean	All CPTs	Matched	Intuitive	Later
Incumb. Entry (pat.)	2.32	-	0.02	-0.31*	-0.10
	(4.37)	-	(0.11)	(0.14)	(0.11)
New Entry (pat.)	7.45	-	0.23	-0.09	-0.04
	(17.08)	-	(0.17)	(0.24)	(0.15)
Sample Size		-	11704	10648	12232

Note: Panel A shows Class III to II; Panel B shows Class II to I. Each block reports the 5-year pre-event mean for treated device types (Column 1) and DiD estimates by control set: *All CPTs* (matching baseline prices among all procedure codes), *Matched* (matching outcomes to medical-device controls), *Intuitive* (similar device types), and *Later-treated*. The *Prices* blocks are available only for the Borusyak et al. estimator, as the price outcome is continuous and positive; thus, the log price is always the outcome used; some control-set columns (e.g., Intuitive/Later) are blank for price estimations, as the procedure linkage was not comprehensive enough to facilitate these control groups. For prices, pre-event means are reported in levels, while estimates are on the log scale. The *Market composition* estimation is reported three ways: *Borusyak et al. (2021)* imputation estimator (levels), *Log(+1)* where count outcomes are transformed by $\log(y+1)$, and *Quasi-Poisson* for overdispersed counts. Confidence intervals use Conley–Taber test statistics; $+, *, **, ***$ mark 0.10, 0.05, 0.01, and 0.001 significance. Any "Sample Size" rows refer to the estimation sample for the corresponding control-set columns.

Appendix Table D.5: Robustness Matrix: Adverse Events (All estimators)

A. Class III to II

Borusyak et al.

	Pre-mean	Matched	Intuitive	Later
Life-Threatening Event Rate	0.07	0.46	0.82+	-0.57
	(0.31)	(0.52)	(0.43)	(1.21)
Hospitalization Rate	0.25	3.17**	3.42**	3.25**
	(0.84)	(1.18)	(1.15)	(1.17)
Mortality Rate	0.08	0.85+	1.06*	0.48
	(0.46)	(0.49)	(0.47)	(0.65)
Sample Size		924	644	616

Log(+1)

	Pre-mean	Matched	Intuitive	Later
Life-Threatening Event Rate	0.07	0.14	0.21+	-0.02
	(0.31)	(0.11)	(0.11)	(0.13)
Hospitalization Rate	0.25	0.55**	0.51+	0.46+
	(0.84)	(0.17)	(0.26)	(0.24)
Mortality Rate	0.08	0.22*	0.29*	0.14
	(0.46)	(0.10)	(0.12)	(0.14)
Sample Size		924	644	616

Quasi-Poisson

	Pre-mean	Matched	Intuitive	Later
Life-Threatening Event Rate	0.07	0.35	2.89**	0.94
	(0.31)	(0.66)	(0.95)	(0.61)
Hospitalization Rate	0.25	1.33**	1.55*	1.09+
	(0.84)	(0.41)	(0.75)	(0.59)
Mortality Rate	0.08	1.81+	3.02***	1.34
	(0.46)	(0.94)	(0.48)	(0.83)
Sample Size		924	644	616

B. Class II to I

Borusyak et al.

	Pre-mean	Matched	Intuitive	Later
Life-Threatening Event Rate	0.07	-0.68*	-0.14+	-7.04
	(0.42)	(0.33)	(0.08)	(6.22)
Hospitalization Rate	0.14	-1.65*	-1.16*	-3.43
	(0.86)	(0.69)	(0.53)	(2.11)
Mortality Rate	0.21	-0.44*	-0.32+	-0.16
	(1.92)	(0.21)	(0.17)	(0.18)
Sample Size		8428	6776	7784

Log(+1)

	Pre-mean	Matched	Intuitive	Later
Life-Threatening Event Rate	0.07	-0.06*	-0.04+	-0.06
	(0.42)	(0.03)	(0.02)	(0.04)
Hospitalization Rate	0.14	-0.08*	-0.16**	-0.06
	(0.86)	(0.04)	(0.06)	(0.05)
Mortality Rate	0.21	-0.04+	-0.06+	-0.01
	(1.92)	(0.02)	(0.04)	(0.02)
Sample Size		8428	6776	7784

Quasi-Poisson

	Pre-mean	Matched	Intuitive	Later
Life-Threatening Event Rate	0.07	-1.41**	-0.74+	-3.59***
	(0.42)	(0.47)	(0.38)	(1.07)
Hospitalization Rate	0.14	-1.49***	-1.17**	-1.56*
	(0.86)	(0.40)	(0.42)	(0.74)
Mortality Rate	0.21	-1.25***	-1.07***	-1.10***
	(1.92)	(0.31)	(0.31)	(0.23)
Sample Size		8428	6776	7784

Note: Panel A shows Class III to II; Panel B shows Class II to I. Column (1) reports the 5-year pre-event mean for treated device types. Columns (2)–(4) report DiD estimates using *Matched*, *Intuitive*, and *Later-treated* control sets. For the Later-treated specification in the Class III to II case, control device types are treated after 2015; consequently, post-2015 observations are excluded by construction. Estimation is shown using the *Borusyak* imputation estimator (levels), *Log(+1)* ($\log(y+1)$), and *Quasi-Poisson*. Confidence intervals follow Conley–Taber; significance codes are $+, *, **, ***$ for 0.10, 0.05, 0.01, and 0.001 levels. "Sample Size" rows, where present, refer to the estimation sample for Columns (2)–(4).

Appendix Table D.6: Reclassification Spillovers (Innovation)

		DiD Estimates
	Pre-mean	Matched
Reclassification	(1)	(2)
A. Class III to II:		
Patenting Rate	0.4	-2.38
	(1.24)	(1.58)
Device Submission Rate	0.38	-0.06
	(0.76)	(0.23)
Sample Size		1056
B. Class II to I:		
Patenting Rate	4.89	-2.89
	(14.16)	(6.60)
Sample Size		10296

Note: The table presents estimates of Equation 1, 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. Column (2) presents my OLS estimates of reclassifications on device types closely related to treated device types using matched controls. Confidence intervals for my estimates in Column (2) are calculated using Conley–Taber test statistics. 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 D.7: Class III to II Device Types by Broad Device Category: Treated Group versus Intuitive Control Group

Device Description	Broad Description	Treatment	Implantable
Compensated thorpe tube flowmeter.	Anesthesiology Devices—Monitoring Devices	0	0
Cutaneous carbon dioxide (PcCO2) monitor.	Anesthesiology Devices—Monitoring Devices	1	0
Pacemaker repair or replacement material.	Cardiovascular Devices—Cardiovascular Prosth...	0	1
Vascular embolization device.	Cardiovascular Devices—Cardiovascular Prosth...	1	1
Vascular graft prosthesis— < 6mm diameter.	Cardiovascular Devices—Cardiovascular Prosth...	0	1
Vascular graft prosthesis—Synthetic/Biologic Composite	Cardiovascular Devices—Cardiovascular Prosth...	1	1
Blood specimen collection device.	Clinical Chemistry And Clinical Toxicology Dev...	0	0
Tacrolimus test system.	Clinical Chemistry And Clinical Toxicology Dev...	1	0
Electrical salivary stimulatory system.	Dental Devices—Therapeutic Devices	1	0
Intranasal Expiratory Resistance Valve (Sleep Apnea)	Dental Devices—Therapeutic Devices	0	0
Extracorporeal shock wave lithotripter.	Gastroenterology-Urology Devices—Therapeutic...	1	0
Hemodialysis system and accessories.	Gastroenterology-Urology Devices—Therapeutic...	0	0
Mycobacterium tuberculosis immunofluorescent reagents	Immunology And Microbiology Devices—Serologi...	0	0
Nucleic acid-based in vitro diagnostic devices...	Immunology And Microbiology Devices—Serologi...	1	0
Rigid gas permeable contact lens (daily wear)	Ophthalmic Devices—Therapeutic Devices	1	0
Rigid gas permeable contact lens (extended wear)	Ophthalmic Devices—Therapeutic Devices	0	0
Soft (hydrophilic) contact lens (daily wear)	Ophthalmic Devices—Therapeutic Devices	1	0
Soft (hydrophilic) contact lens (extended wear)	Ophthalmic Devices—Therapeutic Devices	0	0
Intervertebral body fusion device.	Orthopedic Devices—Prosthetic Devices	1	1
Wrist joint carpal lunate polymer prosthesis.	Orthopedic Devices—Prosthetic Devices	0	1
Bone sonometer.	Radiology Devices—Diagnostic Devices	1	0
Emission computed tomography system.	Radiology Devices—Diagnostic Devices	0	0
Full-field digital mammography system.	Radiology Devices—Diagnostic Devices	1	0
Mammographic X-ray system.	Radiology Devices—Diagnostic Devices	0	0

Note: The table presents the devices and their broad categories used in the treatment and intuitive control groups. No "life-sustaining" devices are considered in the treatment and control groups. The column "Implantable" indicates the devices that are implantable.

Appendix Table D.8: Class II to I Device Types by Broad Category, with Intuitive Controls

Category Description	Treated: Count	Treated: Implants	Control: Count	Control: Implants
Anesthesiology—Diagnostic Devices	2	0	3	0
Anesthesiology—Miscellaneous	2	0	3	0
Anesthesiology—Monitoring Devices	6	0	11	0
Anesthesiology—Therapeutic Devices	17	0	23	0
Cardiovascular—Monitoring Devices	5	0	5	0
Cardiovascular—Prosthetic Devices	2	0	2	1
Cardiovascular—Surgical Devices	0	0	2	0
Clinical Chemistry/Toxicology—Test Systems	6	0	6	0
Clinical Chemistry/Toxicology—Laboratory Instruments	3	0	3	0
Dental—Diagnostic Devices	1	0	2	0
Dental—Miscellaneous Devices	1	0	1	0
Dental—Surgical Devices	1	0	2	0
Ear, Nose, and Throat—Diagnostic Devices	0	0	2	0
Ear, Nose, and Throat—Surgical Devices	2	0	6	0
Gastroenterology–Urology—Diagnostic Devices	4	0	20	0
Gastroenterology–Urology—Monitoring Devices	1	0	1	0
Gastroenterology–Urology—Surgical Devices	2	0	10	0
Gastroenterology–Urology—Therapeutic Devices	2	0	19	1
General & Plastic Surgery—Surgical Devices	0	0	1	0
General Hospital & Personal Use—Miscellaneous	7	0	14	0
General Hospital & Personal Use—Monitoring	4	0	5	0
General Hospital & Personal Use—Therapeutic	4	0	7	0
Hematology & Pathology—Manual Devices	0	0	4	0
Hematology & Pathology—Used by Blood Manufacturer	0	0	4	0
Immunology & Microbiology—Diagnostic Devices	0	0	1	0
Immunology & Microbiology—Immunological Test Systems	4	0	14	0
Immunology & Microbiology—Microbiology Devices	0	0	1	0
Immunology & Microbiology—Serological Reagents	12	0	47	0
Neurological—Diagnostic Devices	0	0	1	0
Neurological—Therapeutic Devices	1	0	1	0
Obstetrical & Gynecological—Diagnostic Devices	0	0	1	0
Obstetrical & Gynecological—Surgical Devices	0	0	6	0
Obstetrical & Gynecological—Therapeutic Devices	0	0	2	0
Ophthalmic—Diagnostic Devices	2	0	4	0
Ophthalmic—Prosthetic Devices	5	2	4	4
Ophthalmic—Surgical Devices	0	0	3	0
Orthopedic—Diagnostic Devices	0	0	1	0
Orthopedic—Surgical Devices	0	0	1	0
Physical Medicine—Diagnostic Devices	3	0	5	0
Physical Medicine—Prosthetic Devices	4	0	6	0
Physical Medicine—Therapeutic Devices	12	0	19	0
Radiology—Diagnostic Devices	5	0	9	0
Radiology—Therapeutic Devices	1	0	12	0

Note: The table reports counts of broad device *categories* in the *Treated* set and in the *Intuitive Control* set, alongside how many of those within-category device types are implantable (*Implants*). No life-sustaining devices are included in any set. Category labels are harmonized for readability (minor punctuation/capitalization differences consolidated).

Appendix Table D.9: Effects of Reclassification on Innovation, Market Structure, and Adverse Events (Zero-Count Units Excluded)

I. Innovation

A. Class III to II

		DiD Estimates		
	Pre-mean	Matched	Intuitive	Later
Patenting Rate	8.25	11.62*	22.97*	21.68*
	(8.98)	(4.85)	(10.15)	(10.09)
Device Submission Rate	0.95	3.00***	3.20**	3.05**
	(1.25)	(0.83)	(1.04)	(1.00)
Citations-Per-Patent Rate	9.06	18.05**	-4.78	22.81*
	(20.65)	(6.09)	(13.39)	(9.01)
Average Patent Value	10.45	11.47+	20.38*	20.25*
	(13.38)	(6.16)	(9.37)	(8.97)
Sample Size		1408	660	748

B. Class II to I

		DiD Estimates		
	Pre-mean	Matched	Intuitive	Later
Patenting Rate	16.46	10.35	32.26**	34.82**
	(37.07)	(7.41)	(12.29)	(10.86)
Citations-Per-Patent Rate	0.66	0.58	7.89***	9.18***
	(0.47)	(1.25)	(1.80)	(1.81)
Average Patent Value	13.45	2.44	8.07**	6.90**
	(28.87)	(1.61)	(2.51)	(2.49)
Sample Size		10868	8976	9944

II. Market Structure

A. Class III to II

			DiD Estimates		
	Pre-mean	Price	Matched	Intuitive	Later
Incumb. Entry (dev.)	0.28	-	1.38***	1.38**	1.27**
	(0.58)	-	(0.39)	(0.46)	(0.44)
New Entry (dev.)	0.07	-	0.31***	0.54***	0.52***
	(0.25)	-	(0.07)	(0.13)	(0.13)
Incumb. Entry (pat.)	1.55	-	0.57	2.25+	2.60*
	(1.73)	-	(0.80)	(1.21)	(1.27)
New Entry (pat.)	3.87	-	6.96***	11.54*	11.56*
	(4.55)	-	(2.11)	(4.63)	(4.51)
Sample Size		-	1408	616	748

B. Class II to I

			DiD Estimates		
	Pre-mean	Price	Matched	Intuitive	Later
Incumb. Entry (pat.)	2.32	-	0.35	1.50*	1.96**
	(4.37)	-	(0.35)	(0.70)	(0.65)
New Entry (pat.)	7.45	-	5.57**	11.37**	12.40***
	(17.08)	-	(2.05)	(4.01)	(3.74)
Sample Size		-	11484	9856	10912

III. Adverse Events

A. Class III to II

		DiD Estimates		
	Pre-mean	Matched	Intuitive	Later
Life-Threatening Event Rate	0.07	1.50*	1.64	-1.25
	(0.31)	(0.67)	(1.10)	(1.69)
Hospitalization Rate	0.25	2.63	5.32*	4.40
	(0.84)	(1.69)	(2.62)	(2.70)
Mortality Rate	0.08	2.59**	2.78*	1.06
	(0.46)	(0.85)	(1.40)	(1.80)
Sample Size		420	196	252

B. Class II to I

		DiD Estimates		
	Pre-mean	Matched	Intuitive	Later
Life-Threatening Event Rate	0.07	-2.01*	-0.29	-35.10*
	(0.42)	(0.87)	(0.18)	(17.26)
Hospitalization Rate	0.14	-5.20***	-2.01*	-11.46*
	(0.86)	(1.52)	(0.89)	(5.49)
Mortality Rate	0.21	-1.33*	-0.63	-0.96
	(1.92)	(0.65)	(0.41)	(0.61)
Sample Size		2912	2660	2128

Note: Each panel reports estimates from Equation 1, a difference-in-differences (DiD) OLS specification. Device types with only zero counts for a given outcome over the sample are excluded (*Zero-Count Units Excluded*). Column (1) in every subpanel reports the 5-year pre-event mean for treated device types. For the Innovation and Adverse Events blocks, Columns (2)–(4) report DiD estimates using three control sets: *Matched*, *Intuitive* (treat similar diseases), and *Later-treated*. For the Market Structure block, Columns (2)–(5) report DiD estimates using *Price-matched* controls, *Matched* controls (matched on baseline innovation and adverse-event levels), *Intuitive* controls, and *Later-treated* controls, respectively. For the Later-treated specification in the Class III to II case, control device types are treated after 2015; accordingly, post-2015 observations are dropped by construction. Confidence intervals are computed using Conley–Taber test statistics. Significance codes: +, ∗, ∗∗, and ∗ ∗ ∗ denote 0.10, 0.05, 0.01, and 0.001 levels, respectively.

Appendix Table D.10: Effect of Reclassification on Probability of Any Safety Mention (Robustness Across Alternative Approaches)

Outcome	Approach	Pre-Mean	Estimate
A. Class II to I			
Pr of any Safety Mention	Embedding Distance	0.009	0.027***
		(0.096)	(0.008)
Pr of any Safety Mention	"Safety" Only	0.023	0.009***
		(0.150)	(0.005)
B. Class III to II			
Pr of any Safety Mention	Embedding Distance	0.000	-0.059***
		(0.096)	(0.022)
Pr of any Safety Mention	"Safety" Only	0.000	-0.004***
		(0.150)	(0.014)

Note: This table presents the estimated effects of reclassification events on the probability of safety mentions, analyzed through two distinct approaches. Panel A reports results for Class II to I reclassifications (sample size: 1,584), while Panel B reports results for Class III to II reclassifications (sample size: 11,748). The "pre-mean" column indicates the average outcome prior to reclassification. The estimates are rounded to three decimal places, with standard errors (SE) shown in parentheses directly below the estimates. For the Safety-Only Approach, the outcome measures the probability of observing any mention of the keyword "safety" within a device type-year pair. For the Embedding Distance Approach, the outcome measures whether any patent was identified as semantically similar to a set of five safety-related reference sentences using the BERT embedding model, within the same device type-year pair. Statistical significance is denoted as follows: + ($p < 0.10$), * ($p < 0.05$), ** ($p < 0.01$), and *** ($p < 0.001$).

Appendix Table D.11: Relationship Between Impacts and Device Experience (III to II)

Variable	(1)	(2)
Device Experience (years)	-0.0051*	-1.5231*
	(0.0020)	(0.7130)
Intercept	0.2379*	82.2241+
	(0.1080)	(40.7090)
Baseline Serious Adverse Events	-0.0005	-1.7597
	(0.0040)	(1.4960)
FDA's Own Accord	0.0128	-21.9656
	(0.0400)	(15.2210)
Orthopedic Devices	0.0736	5.5511
	(0.0950)	(35.3210)
Other Devices	-0.1523+	-52.1829+
	(0.0760)	(27.9670)
Plastic Surgery, Gastro-Urology Devices	0.0419	-24.7850
	(0.0930)	(34.7250)
Baseline Patent Count	—	2.1629***
	—	(0.0830)
N	25	25
Serious-Event Estimate	Yes	No
Patenting Estimate	No	Yes

Note: The regression relates device-level DiD estimates for (1) serious adverse events and (2) patenting activity to each device type's market age (FDA years of experience) and other covariates, including baseline patenting rates. "—" indicates variables excluded from a given specification. Due to limited data, fixed effects are included only for higher-risk device categories (each with ≥ 2 observations); cardiovascular devices are the omitted group. To increase power, FDA-initiated reclassifications (own accord = 0) are included with a corresponding fixed effect. +, *, **, *** denote significance at 0.10, 0.05, 0.01, 0.001 levels.

Appendix Table D.12: Relationship Between Impacts and Device Experience (II to I)

Variable	(1)	(2)
Device Experience (years)	-0.0003+	-0.1058
	(0.0000)	(0.0680)
Intercept	0.0151	-11.0335
	(0.0190)	(8.3490)
Baseline Serious Adverse Events	-0.0107	-0.3645
	(0.0070)	(3.1030)
Device Priority Model Score	0.0347	4.2559
	(0.0440)	(18.4000)
Cardiovascular Devices	-0.0111	16.3702
	(0.0370)	(15.4030)
Clinical Chemistry and Clinical Toxicology Devices	0.0035	-22.6099
	(0.0370)	(15.6070)
Dental Devices	0.0203	2.6410
	(0.0480)	(19.9890)
Ear, Nose, and Throat Devices	-0.0799*	18.6166
	(0.0390)	(16.4120)
Gastroenterology-Urology Devices	0.0040	15.6506+
	(0.0210)	(9.2680)
General and Plastic Surgery Devices	-0.1454	5.3584
	(0.1040)	(43.0700)
General Hospital and Personal Use Devices	0.0333	12.8009
	(0.0260)	(11.1150)
Hematology and Pathology Devices	0.0051	3.9180
	(0.0390)	(16.3570)
Immunology and Microbiology Devices	-0.0071	2.0850
	(0.0210)	(9.0570)
Neurological Devices	0.0351	15.9746
	(0.0730)	(30.2830)
Obstetrical and Gynecological Devices	0.0406	21.0217
	(0.0380)	(15.9460)
Ophthalmic Devices	-0.0041	20.8907
	(0.0340)	(14.5630)
Orthopedic Devices	-0.0294	16.9783
	(0.0730)	(30.2300)
Physical Medicine Devices	0.0383	13.2064
	(0.0240)	(10.2630)
Radiology Devices	-0.0070	10.6918
	(0.0270)	(11.6080)
Baseline Patent Count	—	2.1629***
	—	(0.0830)
N	293	293
Serious-Event Estimate	Yes	No
Patenting Estimate	No	Yes

Note: The regression relates device-level DiD estimates for (1) serious adverse events and (2) patenting activity to each device type's market age (FDA years of experience) and other covariates, including baseline patenting rates. "—" indicates variables excluded from a given specification. To increase power, all deregulated device types with at least one submission are included. Fixed effects for part descriptions are included, with anesthesiology devices as the omitted group. +, *, **, *** denote significance at 0.10, 0.05, 0.01, 0.001 levels.

Appendix Table D.13: Costs and Benefits of Reclassification

Assumptions

-Cost of mortality is EPA's VSL of $10 million ($2019).
-Average inpatient hospital stay costs $22,000 (Moses et al., 2019). No other costs.
-Attribute 80% of patent value to business stealing/creative destruction (Kogan et al., 2017).
-Do not consider private firm patent values.
-Do not consider scientific value of innovation.
-No value of efficacy information from regulations.
-No value from firm entry (e.g., not considering the value of new jobs).

		Outcome	Estimate	95% C.I.	Value	Total	95% C.I.
Class III to II	Costs	Mortality	1.08	[-0.3,2.4]	$10M	$10.8M	[-$3M, $24M]
		Hospitalizations	2.38	[-0.1,4.9]	$0.02M	$.05M	[$0M, $0.1M]
						$10.9M	[-$3M, $24M]
	Benefits	Patented Innovation	5	[3.2,8.1]	$32M/5	$32M	[$20.5M, $51.8M]
Class II to I	Costs	Mortality	-0.43	[-0.7, -0.16]	$10M	-$4.3M	[-$7M, -$1.6M]
		Hospitalizations	-2.1	[-3.3, -0.9]	$0.02M	-$0.04M	[-$0.06M, $0]
						-$4.3M	[-$7M, -$1.6M]
	Benefits	Patented Innovation	9	[3.1, 14.9]	$27M/5	$48.6M	[$16.7M, $80.5M]

Note: The table offers back-of-the-envelope cost-benefit analyses for Class III to II and Class II to I reclassification events, with assumptions outlined in the table header. Patenting rate increases are estimated using data from publicly traded companies for which I can obtain patent values as calculated in Kogan et al. (2017). These estimates, categorized by firm asset terciles, are presented in Figure D.7. Patent values are deflated to 2019 (million) dollars using the CPI. I include 95% confidence intervals for both costs and benefits, which are annualized and averaged across treated device types. "Value" in the column represents the per-unit value of each estimate. "Patented Inn." refers to patented innovations by public firms, while "Hospital." refers to hospitalizations.

Appendix Table D.14: Summary Statistics by FDA Class

Panel A: FDA Administrative Data	**Class I**	**Class II**	**Class III**
Device submissions			
Total submissions (N)	30,797	118,820	3,395
Number of device types (N)	1,560	2,496	59
Submissions per device type	19.74	47.60	57.54
	[78.13]; [1, 1,927]	[131.24]; [1, 2,457]	[148.08]; [1, 795]
Total submitting firms (N)	3,876	9,129	80
Firms per device type	10.52	19.26	6.64
	[29.80]; [1, 812]	[38.49]; [1, 622]	[10.86]; [1, 47]
Firm regulatory proficiency*	6.79 yrs	11.90 yrs	54.67 yrs
	[23.80 yrs]; [0, 409]	[39.17 yrs]; [0, 642]	[87.78 yrs]; [0, 640]
Adverse event reports (AERs)			
Total AERs (N)	475,782	4,510,435	976,693
Device types reporting (N)	1,264	1,975	101
Adverse events per device type	376.41	2,283.76	9,670.23
	[2,550.82]; [1, 52,526]	[162,560.00]; [1, 409,685]	[32,432.58]; [1, 228,892]
Serious events per device type	25.64	344.30	2,871.03
	[107.30]; [1, 1,547]	[2,402.00]; [1, 46,502]	[13,442.19]; [1, 115,097]
AERs with matched firm assets (N)	475,779	4,510,430	976,693
Assets of offending firms	$3.6B	$2.21B	$620.61B
	[$12.8B]; [$0.59M, $721.40B]	[$3.36B]; [$0.54B, $6.25T]	[$4.69B]; [$0.57B, $77.21B]
Panel B: Dimensions Device Patents	**Class I**	**Class II**	**Class III**
Total patents (N)	671,665	567,204	9,423
Patents per device type	698.92	515.64	181.21
	[2,453.44]; [1, 23,056]	[1,732.32]; [1, 17,559]	[453.66]; [1, 2,536]
Citations per patent	10.57	19.23	21.62
	[56.42]; [1, 5,067]	[115.75]; [1, 5,817]	[97.71]; [1, 4,265]
Patent market valuation	$12.50M	$13.80M	$16.70M
	[$30.00M]; [$48, $1.70B]	[$31.50M]; [$45, $1.90B]	[$30.50M]; [$45, $440M]
Applicant assets	$26.10B	$27.50B	$15.50B
	[$53.50B]; [$0.07M, $1.1T]	[$56.60B]; [$0.17M, $0.70T]	[$33.60B]; [$1.18M, $0.90T]

Note: For rows with distributional stats, the first line shows the *mean*; the second line lists *SD* and *range* in brackets. Panel A reports FDA administrative aggregates; Panel B reports Dimensions patent statistics. Patent market valuation data are from Kogan et al. (2017). Firm total assets are from CRSP/Compustat (proxy for firm size); market values and applicant assets are observed only for patents filed by public firms (∼25% of patents). *"Regulatory proficiency" indicates the total number of days a firm has experienced approval delays across all its submitted devices.

Appendix Table D.15: Impact of Reclassification on Patenting Rates: Restricted Samples

	Patenting Rate	
Restriction	Pre-mean	DiD Estimate
(a) Class III to II:		
GPT-4o Identified Devices	5.02	7.80**
	(6.17)	(2.52)
Health Patents (No Drugs)	4.55	11.71**
	(6.06)	(3.60)
(b) Class II to I:		
GPT-4o Identified Devices	3.40	4.46***
	(12.91)	(1.21)
Health Patents (No Drugs)	3.88	0.34
	(13.40)	(1.85)

Note: The table presents estimates of Equation 1, a difference-in-differences (DiD) OLS regression model analyzing patenting rates for restricted patent samples described in Appendix C.1. Panel (a) examines reclassifications from Class III to II, while Panel (b) examines Class II to I. *GPT-4o Identified Devices* refers to patents determined as devices by GPT-4o, and *Health Patents (No Drugs)* refers to patents classified under the CPC system as "health" (A61) excluding drug patents (not A61P). The "Pre-mean" column presents the 5-year baseline average of treated device types for the restrictions listed on the left-hand side. The "DiD Estimate" column provides DiD estimates when the treated groups are compared to matched controls for the restrictions listed on the left-hand side. Confidence intervals are calculated using Conley–Taber test statistics. Standard errors are presented in parentheses below the estimates. Significance levels are denoted as follows: * p<0.05, ** p<0.01, *** p<0.001.

Appendix Table D.16: Effect of Reclassification on Breakthrough Patents

Outcome	Pre-mean	Q-Poisson	OLS	Log
A. Class III to II				
Breakthrough Patents	0.98	0.54	0.68***	0.10**
		(0.44)	(0.21)	(0.03)
B. Class II to I				
Breakthrough Patents	2.98	0.19	0.66***	0.05***
		(0.26)	(0.00)	(0.00)

Note: This table presents the estimated effects of reclassification events on the yearly count of breakthrough patents across multiple models (Quasi-Poisson, OLS linear model, and OLS log outcome). Panel A corresponds to down-regulation (III to II) with a sample size of 1,584, and Panel B corresponds to deregulation (II to I) with a sample size of 11,748. Estimates are rounded to two decimal places, and standard errors (SE) are presented in parentheses directly below the corresponding estimates.