Regulating the Innovators: Approval Costs and Innovation in Medical Technologies

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Motivation

New technologies can improve well-being, but they can also cause harm

Mitigate harm w/ ex-ante regulation. Compelling for high-risk, radical technologies (GT, 2020)

For established and/or low-risk technologies, benefit less clear

- Critics: Chills innovation and competition
- Proponents: Improves safety, innovation, and competition with quality signal

FDA is a focal point of this debate

- FDA regulates $2.8T worth of goods—I focus on medical devices (e.g., x-ray machines)

Research Question

Question: How does FDA medical device regulation affect innovation, market structure, and product quality of well-established medical device types?

- Broad: How does strict product regulation compare to lenient regulation and no regulation?

How: Examine unpredictable events: strict Class III $\rightarrow$ moderate Class II ("down-regulation"), or II $\rightarrow$ I ("deregulation")

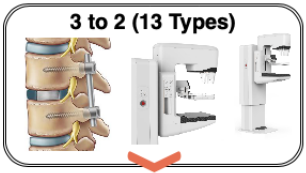
Preview of Results

My analysis of these events leads to the following three results:

1. **Innovation**—Patents and submitted devices ↑ 200%. $32B or 20% of market
   - Outsized increases at small and inexperienced firms (complexity and financing frictions)
   - Innovativeness ↑ 200% w/ deregulation. Small firm increase plausible driver (Wu et al., 2019)
2. **Market structure**—10-fold↑ firm entry. ↓ 25% in prices after deregulation (commodities), but not after down-regulation (high-tech differentiated products). All reasonable magnitudes (Busso and Galiani, 2019; JanBen et al. 2022)
3. **Product safety**—Safety emphasis ↑ 100% and ↓ 25% in severe adverse events after deregulation, even at margin ($10.8B). Mechanism: Legal liability risk

Background – Policy Changes

Down-Classification



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

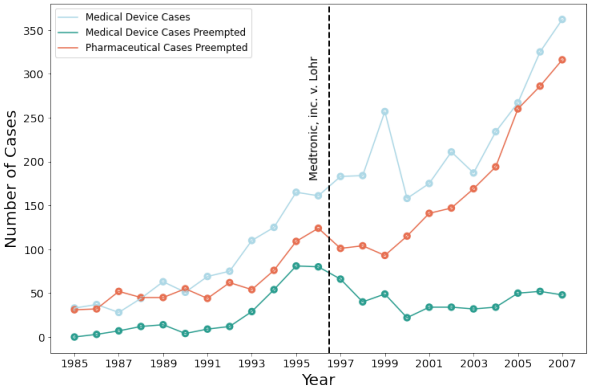
Congressional Mandate • Adverse Event History • **Unpredictable**

(Powell, 2018)

Timing "as-good-as-random", candidates selected using observable crude measure of safety. Measure unknown beforehand

▸ Class II Preemptions

Background – Legal Liability in Medical Device Context



- "It must be recognized that state tort actions...remain a powerful incentive for improving product safety." (Bravman v. Baxter Healthcare Corp.)
- Litigation drains 3.8% of annual revenues, chills innovation (Galasso and Luo, 2018)
- Examples: $1 billion (2014 Stryker hip) and $3.2 billion (1998 Dow Corning breast)
- Before 1996, "virtually every court" held that Class III and II protected from injury tort (Flaherty, 2008). After, only III

Background – Meaningful Incremental Innovation after Down-Regulation

United States Patent (10) **Patent No.: US 6,478,423 B1**
Turner et al. (45) **Date of Patent: Nov. 12, 2002**

(54) **CONTACT LENS COATING SELECTION AND MANUFACTURING PROCESS**

Assignee: **Johnson & Johnson Vison Care, Inc.**, Jacksonville, FL (US)

ABSTRACT

The invention is a method of making a coated contact lens with desirable physiological performance.

$1 billion value (2023 USD). Retains shape and moisture. Led to top-two ACUVUE OASYS
Most innovation not radical (Acemoglu et al., 2022). Incremental increases tech adoption

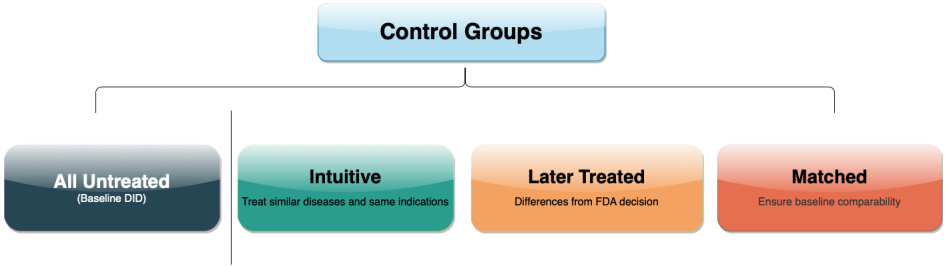
Data

I compiled data on innovation, market structure, and product safety

1. FDA Admin: Adverse events, device approval submissions (innovation and firm activity)
2. USPTO Patents: Filed patents in medical device categories, citations, innovation direction, firm activity
3. Marketscan (1996–2013): Health insurance claims data on procedure prices and usage
4. CRSP/Compustat: Firm size
5. Kogan et al. 2017: Patent market valuations

Methodology: Stacked Difference-in-Differences and Event Studies

- Staggered adoption bias (Goodman-Bacon, 2018; etc.)
- Use "stacked estimators." Only compares treated groups to untreated groups



- No divergent pre-trends across all outcomes and event types

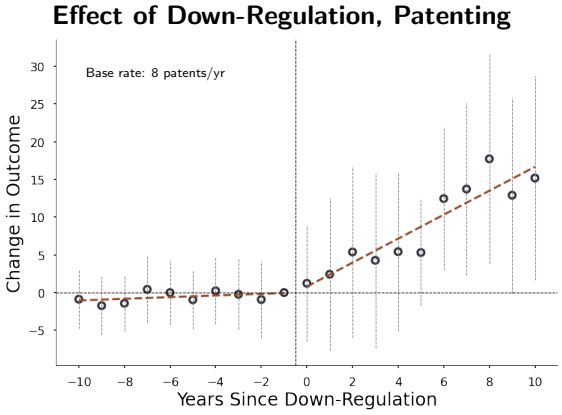
Results

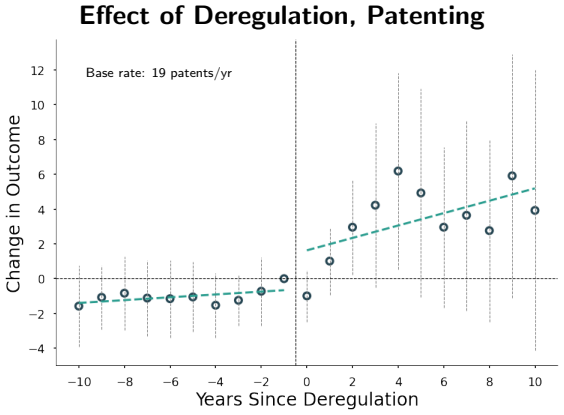
Three core findings: (1) innovation, (2) market structure, (3) product safety

Result 1: Innovation

- How do these events affect patenting rates and device submission rates?
- Do firm traits shape these effects?

Down-Regulation Boosts Innovation, Deregulation to a Lesser Extent





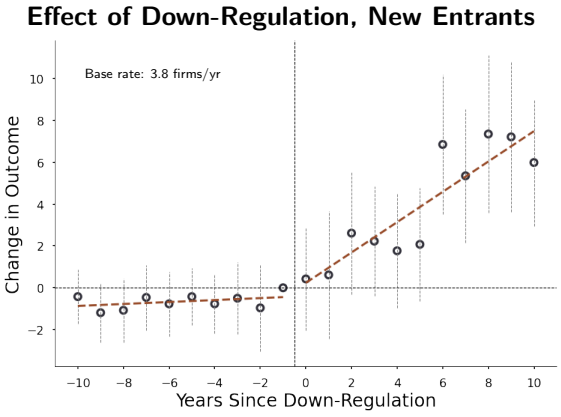
Innovation increases most for small and inexperienced firms. FDA device submission measures are consistent. Patent quality also increases

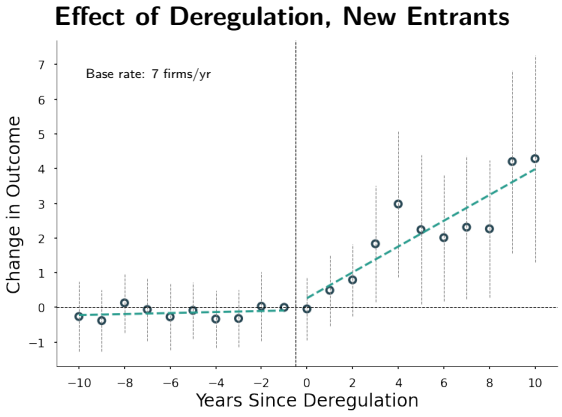
▸ FDA Submissions ▸ Innovation Quality

Result 2: Market Structure

How do these events affect firm entry and prices?

Down-Regulation and Deregulation Increase Firm Entry



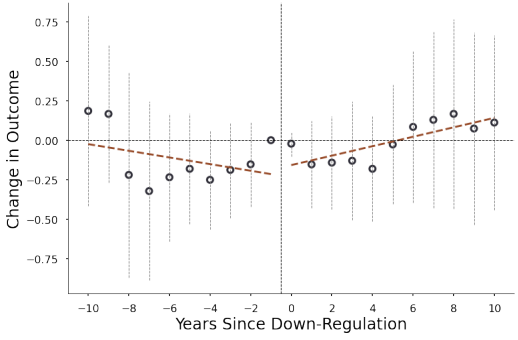


Similar estimates for using FDA admin data

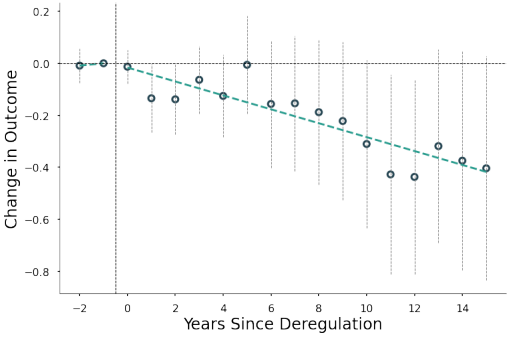
▸ FDA Measure

Deregulation Drives Down Prices, While Down-Regulation Does Not

Effect of Down-Regulation, Log Average Price



Effect of Deregulation, Log Average Price

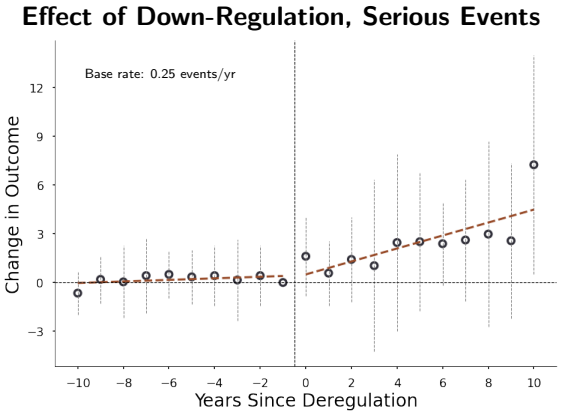


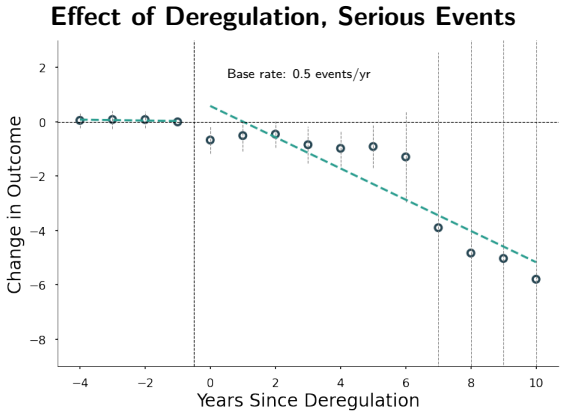
Commodities vs. differentiated products, innovation increases dramatically, so quality improves as well, higher-risk devices are smaller share of procedure costs

Result 3: Product Safety

Large innovation and market structure effects. What about product safety?

Down-Regulation May Decrease Product Safety, Deregulation Improves It





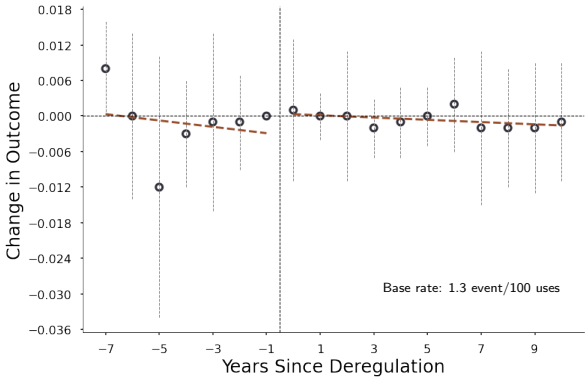
Inventors also focus more on safety in patent texts

Product Safety: Robust to Normalizing by Utilization

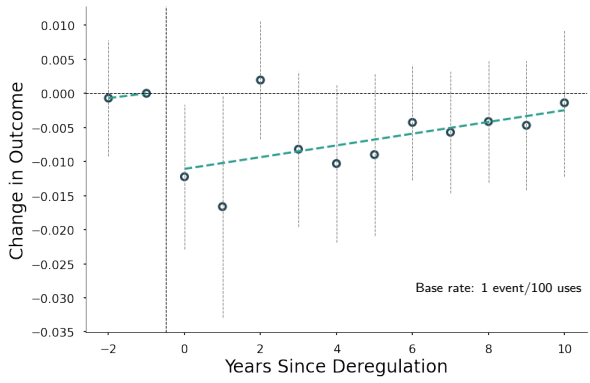
Using subset of 46 product categories (out of 123) for which I have pre-event claims data:

$$\text{Rate}_{j,t} = \frac{\#\text{ of serious events}_{j,t}}{\#\text{ of medical procedures}_{j,t}}:$$

Down-Regulation, Rate of Serious Events



Deregulation, Rate of Serious Events

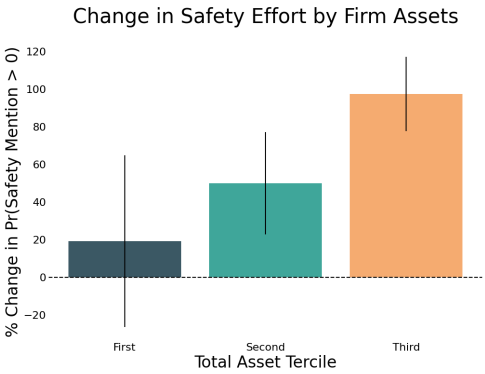


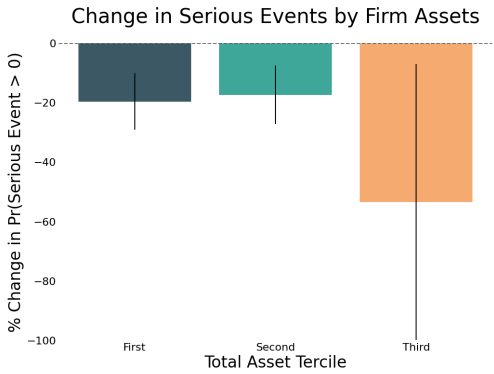
▸ Non-Normalized Subset

Product Safety: Firms w/ Highest Liability Exposure Improve Safety Most

(Bankruptcy distortion)

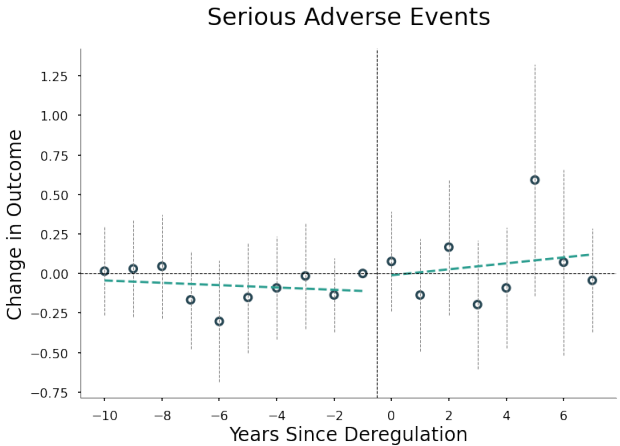
Identify liability mechanism using differences in ex-post exposure to legal liability from bankruptcy





Product Safety: No Improvement if Liability Does Not Change

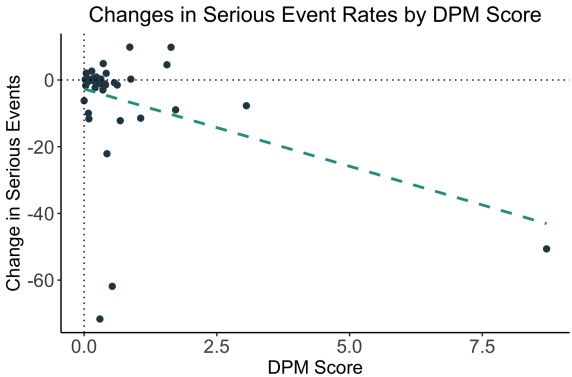
2015 Deregulation: Impacted 66 medical device categories; Class II devices already exposed to liability

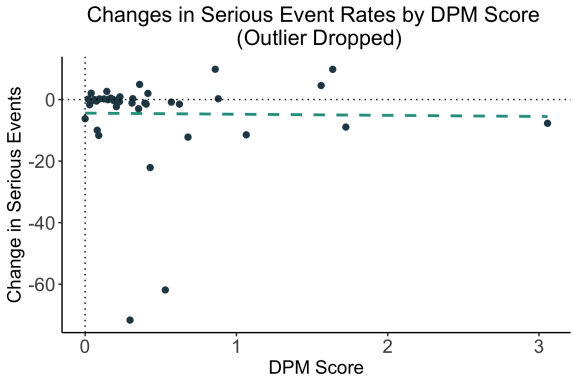


But larger innovation and entry effects than the 1996 events

Generalizing Potential Effects to Untreated Class II Device Types

Higher DPM score means more marginal (i.e., more dangerous pre-event)



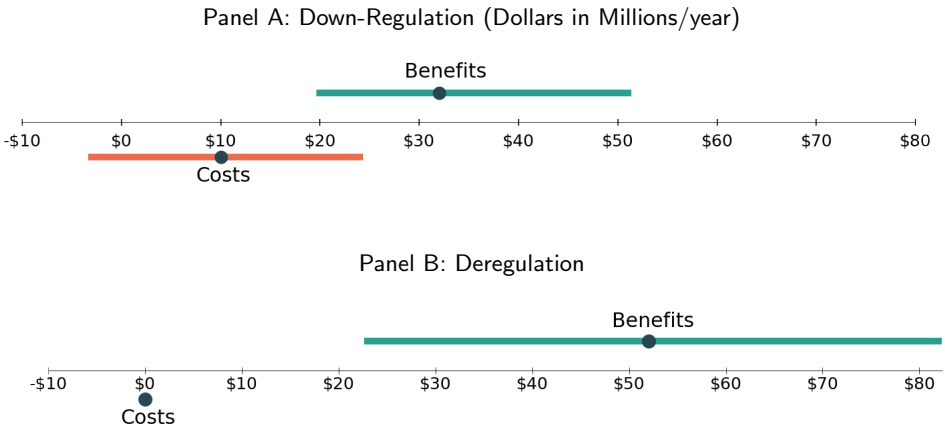


Interpreting These Findings

Back-of-the-envelope calculation and discussion

Back-of-the-Envelope Calculations

By appraising additional patents, lives saved, and cost savings:



Deregulating all Class II $\rightarrow$ \$132 billion (77% of mkt). Not surprising (NAM)

Discussion: Importance of Considering Innovation and Market Structure

- Important effects of public policy on innovation and market structure (Finkelstein, 2004; Budish, Roin, and Williams, 2015; Clemens and Rogers, 2020)

- Medical device deregulation increases innovation and market competition. Frictions magnify costs
  - Large innovation and entry effects. Consistent w/ Grennan and Town (2020)
  - Supply-side, industrial policies vs. demand-side policies (Finkelstein, 2004; BKS, 2013)

- Litigation as alternative in established markets (Coase, 1960; Kolstad et al., 1990; Kessler, 2010)

- Results may generalize to other regulated markets (Acharya et al., 2014; Aghion et al., 2019)
  - Class III similar to brand-name drug regulation
  - Class II similar to regulations for generics and GM foods/crops
  - Liability protection: aircraft, automobiles, 15,000 products by Consumer Product Safety Commission

Appendix

Class II to I Details

Congress forced FDA to deregulate. Underresourced, they used a mechanical/crude evaluation measure:

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

- I cannot measure RHS variables perfectly
- But I can get close with adverse event reports
- Can match controls with same score
- Find no pre-trends

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Class III to II Details

Following criteria based on safety (much less mechanical):

- Health risks identified and Class II will ensure safety
- Medical literature (DMIST study)
- Premarket approvals, recalls, adverse events
- Clinical experiences (safety)
- Example: Panel cites study, digital as good as film mammography (no additional harm)

Timing of these events is as-good-as-random (contact lenses)

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Class II Preemptions

I found the following cases in which Class II approval barred legal claims:

- Latex gloves
- Contact lenses
- Angioplasty catheters
- Wound dressing
- Tampons
- Tissue adhesive with wound closure device
- Condoms
- Hemorrhoid prevention pressure wedge
- Electrical stimulation devices

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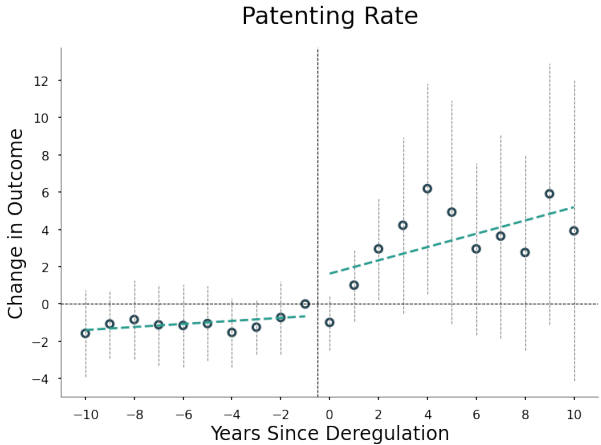
Class II to I Results

Base rate: 16 patents per year (no device submission data available)



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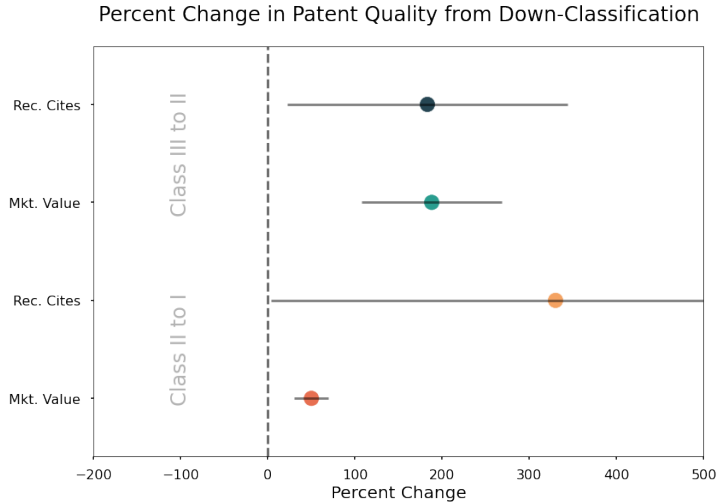
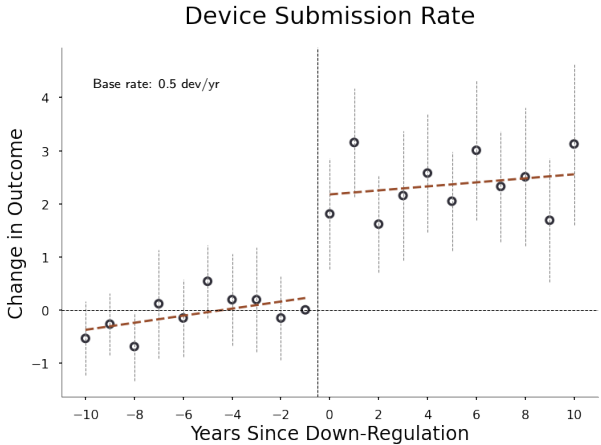
Change in Innovation Quality



Change in Innovation — FDA Submissions



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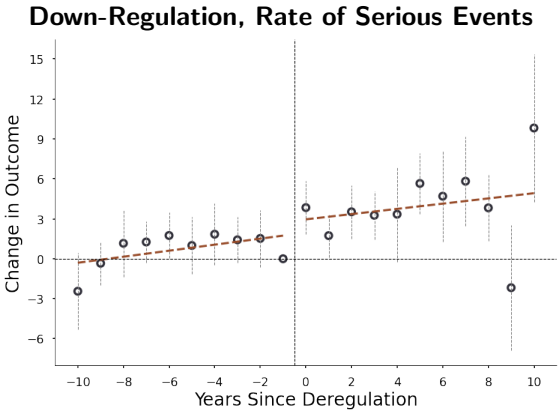
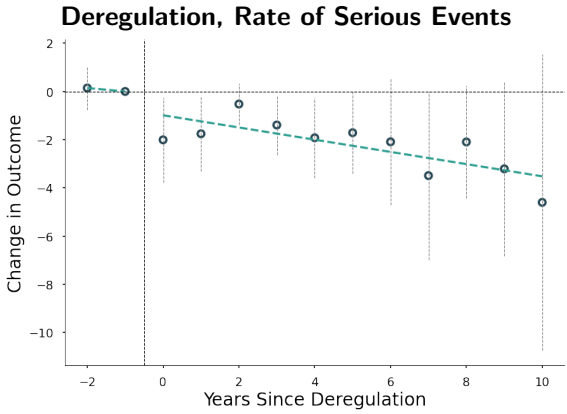
Product Safety: Non-Normalized Outcomes for Subset w/ Claims

Using subset of 46 product categories (out of 123) for which I have pre-event claims data:





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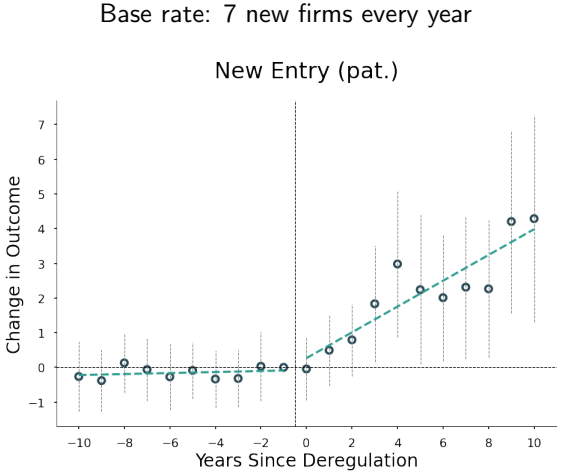
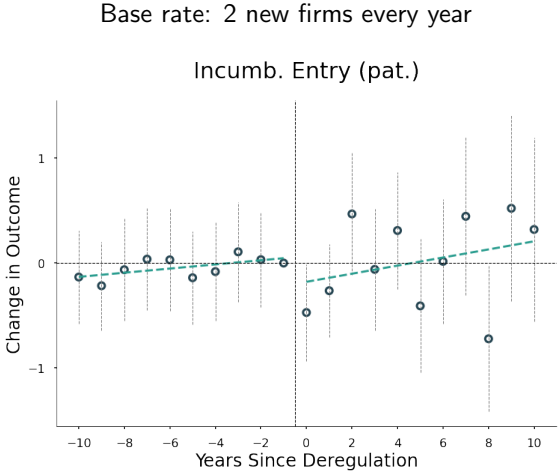
Class II to I Entry Results (Patents)

Base rate: 7 new firms every year



No price data

Base rate: 2 new firms every year



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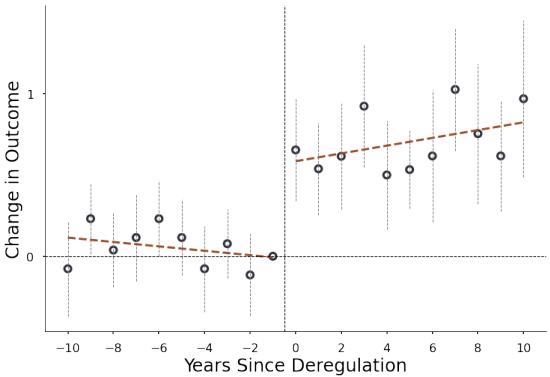
Firm Entry Results Measured by FDA Submissions (Class III to II)

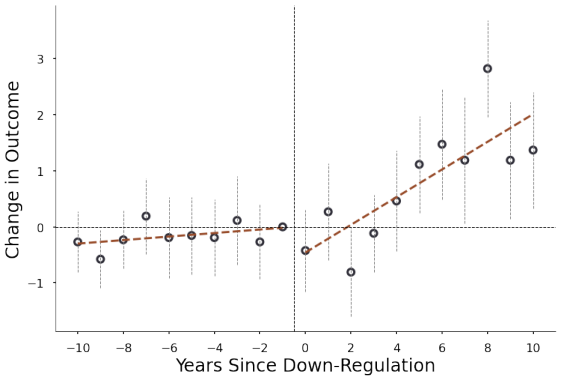
Base rate: 1 firm every ten years

New Entry (dev.)



Base rate: 1.5 firms every year

Incumb. Entry (pat.)



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