Negative Product Disclosure and Innovation*

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Abstract

This paper studies how the disclosure of negative product quality information impacts innovation. In the United States, medical device firms must report device malfunctions and injuries to the FDA and to a public adverse events regulatory database. However, historically, firms could exclude certain adverse events reported to the FDA from the public database. Beginning in 2019, this option was eliminated and the historical private data became accessible to the public. We show how this disclosure of negative information shifted the rate and direction of subsequent medical innovation. In exploring mechanisms, we highlight the dual role of disclosure: it prevents incumbents from withholding negative product quality information and expands learning opportunities for competitors. Additionally, we consider spillovers effects within firms and across product markets, revealing how disclosure of negative information drives firm responses and market outcomes.

JEL Classifications: O310; D830; L640
Keywords: Innovation; Disclosure; Learning; Medical Devices

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1 Extended Abstract

Firms' innovation choices depend on available information. This necessity generates a tension. On the one hand, successful innovation requires being able to learn from others, including the directions of their efforts and both positive and negative outcomes. Yet, on the other hand, profiting from innovation requires some control over information emanating from one's own effort (Teece, 1986). The patent system attempts to remedy this tension for technological information by mandating disclosure of patented technologies but guaranteeing time-limited exclusivity of use. An active literature in strategy and economics continues to grapple with the relationship between disclosure and innovation (Chondrakis et al., 2021; Baruffaldi et al., 2023; Furman et al., 2021; Kankanhalli et al., 2024; Kim and Valentine, 2021; Lück et al., 2020; Gross, 2022).

In this paper, we examine how negative product-related disclosure relates to innovation. In particular, we explore how the elimination of a channel through which innovating firms could withhold information about adverse product events affects subsequent innovation. We theorize two potential channels through which such effects could materialize. First, firm choosing subsequent innovation effort, since they are no longer able to withhold any potential future negative product information, may decrease their innovative effort in the affected product markets. We call this channel the "withholding effect." We expect this channel to decrease innovation in product markets most exposed to information withholding pre-shock. We also expect the withholding effect to be strongest in for incumbent firms, who were the firms able to withhold adverse events pre-shock. A second channel through which inability to withhold negative product information could affect innovation is via a "learning effect". That is, firms may change their innovation choices because they have more information post-shock about the negatives relating to particular products made by other firms. Again, this should decrease innovation in affected product markets, but here we would expect this effect to be most salient for entrant firms.

We investigate this relationship using data from the U.S. medical device industry, focusing on products first marketed from 2003 to 2023. We identify a exogenous decrease in firms' ability to withhold negative product information using the public release and simultaneous discontinuation of the Alternative Summary Report (ASR) data, a selected set of medical device adverse events that were not publicly disclosed, in June 2019. Our core datasets include the ASR data, which allows us to identify product markets exposed to the shock, the publicly disclosed adverse events data, MAUDE (Manufacturer and User Facility Device Experience), and, to track innovation, the Premarket Approvals data (PMA) and 510(k) Premarket notification datasets, which collectively track all new medical devices approved or cleared for marketing by the FDA. We supplement the FDA datasets with data available from Evaluate Medtech to capture additional innovation outcomes and firm dynamics (e.g., mergers and acquisitions) and link in patent data at the firm-product market level.

The ASR program was started in 1999 ostensibly as a way to relieve administrative burden for firms and the FDA owing to high volumes of adverse events.[1] It allowed firms to submit summary reports on a quarterly basis for adverse events in selected product markets, which were then withheld from the public adverse events database (MAUDE). In June 2019, the ASR program was eliminated and the historial ASR data were released following a Kaiser Health News (KHN) report in March 2019. The KHN report made the existence of the ASR database public knowledge. By the time it was eliminated, ASR included some adverse event information for 102 product markets (or FDA "product codes"), compared to more than 4,000 in MAUDE. ASR included 5.8 million reports from its initiation in 1999 until its termination in June 2019, compared with the 8.2 million events in the public database MAUDE over the same time period (Galasso and Luo, 2024). One example of a product market in ASR is medical staplers. Figure 1 details the number of adverse events in MAUDE (public) and ASR (private) for 2000-2023. Figure 2 outlines MAUDE and ASR adverse events for another ASR-present product market, pacemaker electrodes.

[1] See the sparse, archived details here and here. This law blog provides some additional details here.

We include in our sample the set of firm-product markets with at least one product prior to 2019. Our core treatment measure is at the product market level, where we classify a product market as having "High Exposure" if it had at least one adverse event in the ASR database. The motivation behind this measure is that product markets with adverse events in ASR are likely to be more affected by the public release of this information compared to those without any ASR adverse events. We further disaggregate exposure into focal firm ASR adverse events versus other firm. Our final dataset includes 3,377 firms and 4,720 product markets, and 35,143 firm-product markets. Our unit of observation is the firm-product market-year. Our analytical sample is 696,946 observations. We observe (Table 1) that on average 7 percent of firm-product market-years have High Exposure and 5 percent have at least one new medical device approval.

To examine how the ASR shock affected innovation, we implement a DID specification which compares firm-product markets with High Exposure to those without any adverse events in ASR before and after 2019. Our main regressions are OLS and include firm-product market and year fixed effects and firm-product market clustered standard errors.

We find that the ASR release is associated with a decline in new medical devices. Column 1 in Table 3 shows that among affected firm-product markets, there is a 0.02 percentage point (or 41 percent) decrease in the likelihood of any medical device approval. We further estimated an event study version of this result. Figure 5 shows that the likelihood of any medical device associated any given firm-product market declines following the ASR's shutdown and public release.

Beyond direct effects on treated product markets, we also investigate if there are spillover effects to related product markets. To do so, we used data on predicate devices.[2] If devices

[2]The US FDA regulates medical devices and categorizes them into three classes: *Class I* are low-risk devices, mainly subject to basic controls and typically not subject to FDA notification before marketing; *Class II* are medium-risk devices, often requiring a Pre-Market Notification process (known as 510(k)), in which manufacturers need to show that their device is substantially equivalent to a device that is already on the market; and *Class III* are high-risk devices which have to undergo a more stringent Pre-Market Approval (PMA) process, i.e., clinical trials to prove safety and effectiveness. Most devices are Class II, where manufacturers are required to demonstrate that their proposed device is "substantially equivalent" to a previously approved device, known as a "predicate" device.

in one product market serve as predicates for the other—that is, if they are "substantially equivalent" enough in technology or design per the FDA to serve as the basis for regulatory clearance—we consider the product markets as related. Using this measure, we document the presence of meaningful spillover effects: exposure to ASR can lead firms to lower their level of innovation in related but not-directly-exposed markets.

The decline in new medical device innovation following ASR's public release could result from two effects: the inability of incumbents to withhold negative product quality information (the "withholding effect") and resulting shift in learning opportunities for entrants (the "learning effect"). To investigate these two effects, we conduct two analyses: first, we leverage the phased shutdown of the ASR program, which began winding down in 2017. Products codes with adverse events that could still be included in ASR after 2017 may be more affected by the withholding effect. Second, we examine differences across entrants and incumbents, with the motivation that entrants may be more responsive to learning opportunities and incumbents may be more impacted by the inability to withhold negative information. Across both sets of analyses, we find evidence highlighting the importance role of "withholding effects"—i.e., firm concerns about being unable withhold negative information for a medical device in a product code may lower firms' incentives to invest further in that product code.

In the next iteration of our ongoing work on this project, we plan to bring increased rigour to our existing sets of analysis, using a more carefully constructed control group (i.e., better accounting for any selection into treatment) and exploring different sources of variation in exposure to treatment, as well as providing additional tests of the disclosure and learning effects of the ASR shock on innovation in medical devices.

In sum, we find that firms decrease their innovative efforts after they can no longer expect to withhold negative information and an associated public release of negative information. Our research thus contributes to the larger literature on the relationship between disclosure, and in particular the ability to withhold negative information, and innovation.

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8 Figures and Tables

Figure 1: Differences in ASR and MAUDE: Stapler Example

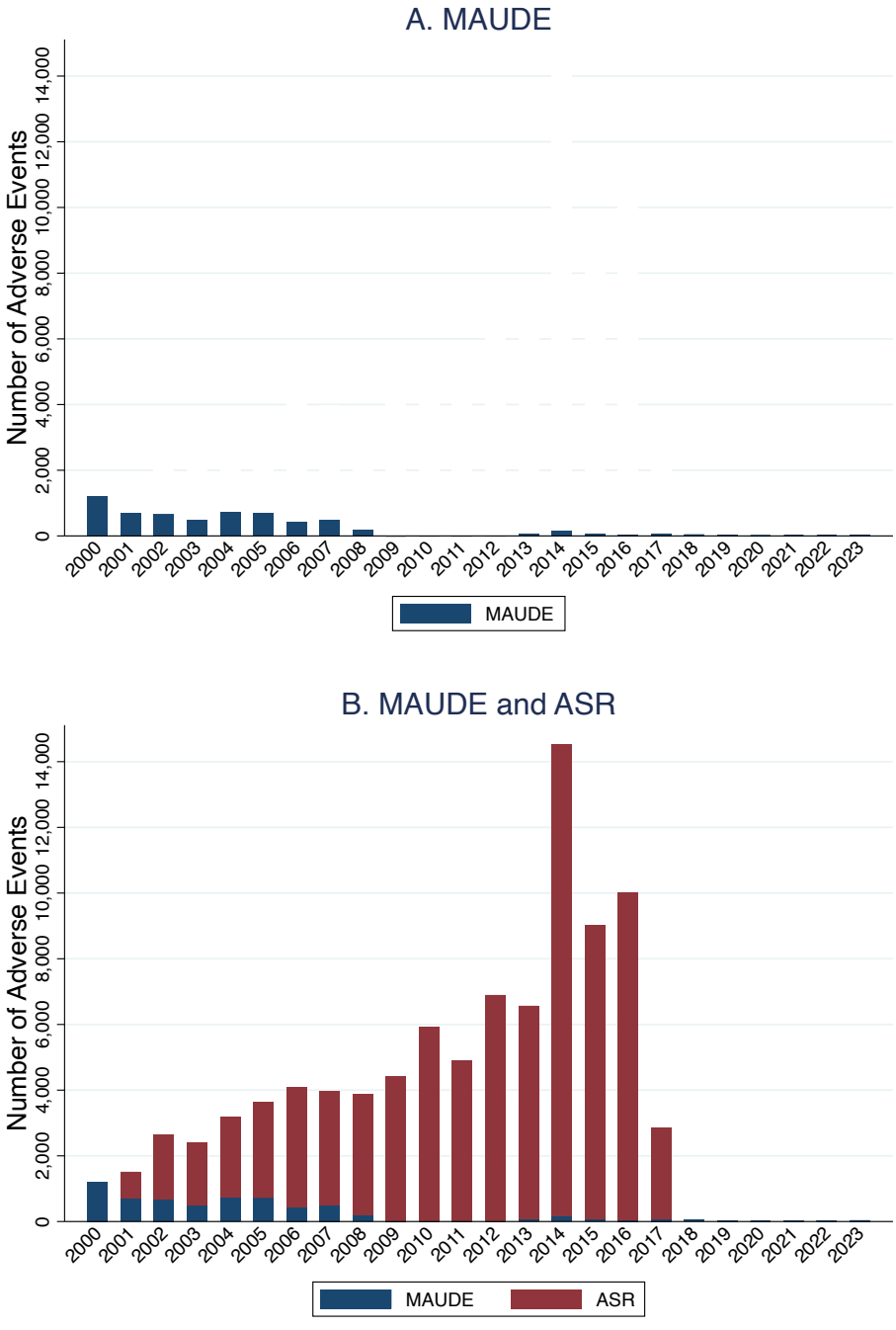
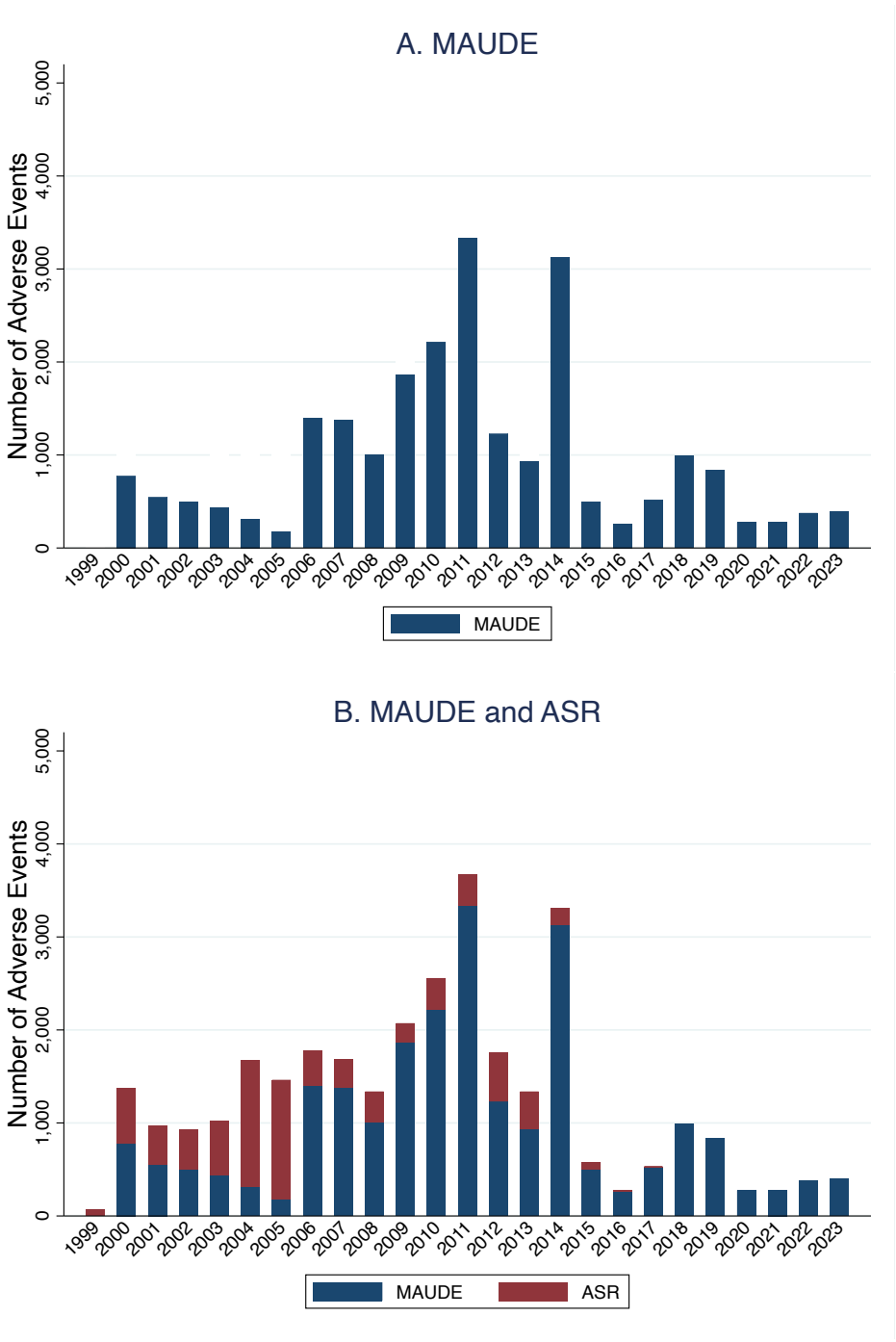


Figure 2: Differences in ASR and MAUDE: Pacemaker Electrode Example



8.1 Firm-Product Market Descriptives

Table 1: Summary Statistics: Firm-Product Market-Year Level

	mean	sd	min	max
High Exposure	0.07	0.25	0	1
High Exposure (Focal Firm)	0.01	0.07	0	1
High Exposure (Non-Focal Firm)	0.06	0.24	0	1
Any Application	0.05	0.22	0	1
Nb. Application	0.07	0.36	0	20
Year	2013.31	6.02	2003	2023

Note: Observations at the firm-market-year level.

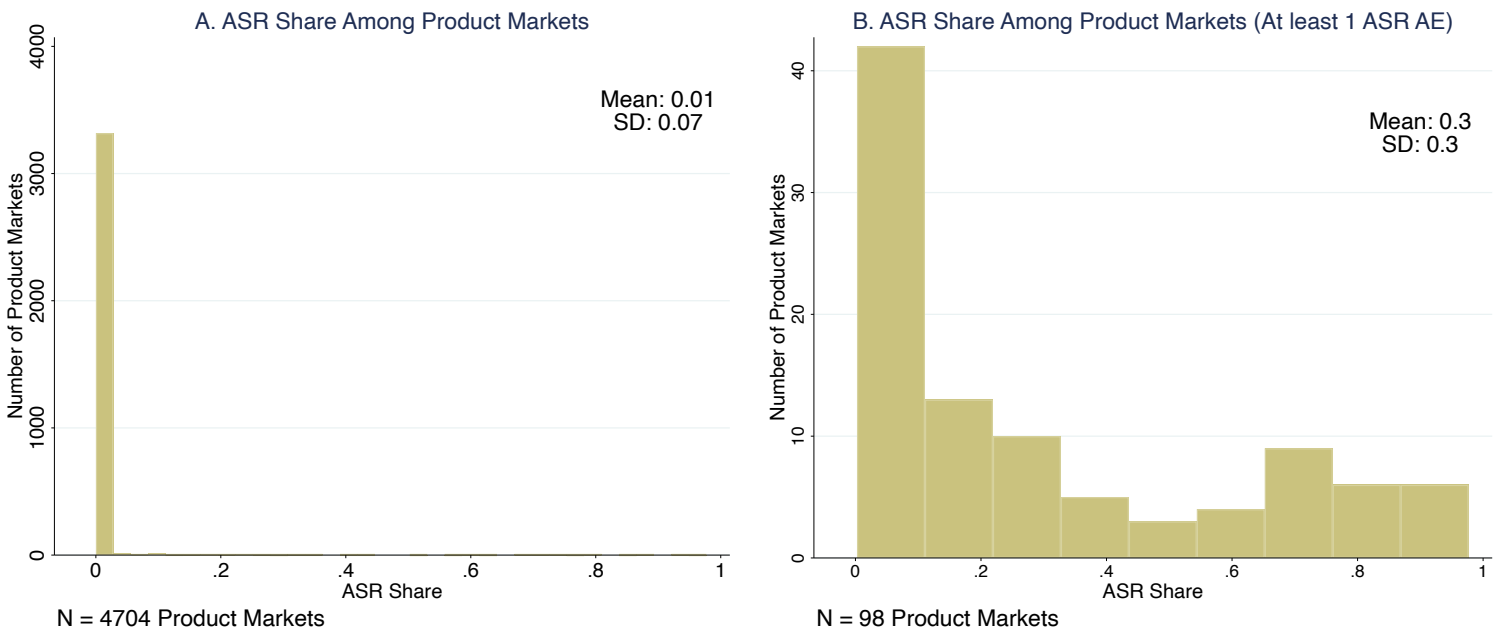
8.2 Product Market Descriptives

Table 2: Comparison of Product Markets with ASR vs. no ASR

	in_ASR			
	0	1	Total	Test
N	5,883 (98.3%)	102 (1.7%)	5,985 (100.0%)	
N MAUDE AEs	1,884.407 (30,198.771)	74,468.510 (236,225.224)	3,121.429 (43,892.424)	<0.001
A ASR AE	0.000 (0.000)	56,552.137 (322,878.003)	963.796 (42,581.162)	<0.001
N Apps pre2019	12.056 (57.563)	76.686 (155.344)	13.157 (61.109)	<0.001
N Apps 2014-2018	2.346 (13.651)	14.510 (33.000)	2.553 (14.284)	<0.001
N PMAs pre2019	0.170 (1.266)	2.147 (6.926)	0.204 (1.566)	<0.001
N PMAs 2014-2018	0.028 (0.302)	0.118 (0.568)	0.030 (0.309)	0.004
N 510ks pre2019	11.886 (57.538)	74.539 (156.082)	12.953 (61.083)	<0.001
N 510ks 2014-2018	2.318 (13.651)	14.392 (33.047)	2.523 (14.285)	<0.001
Anesthesiology	0.041 (0.197)	0.010 (0.100)	0.040 (0.196)	0.119
Chemistry	0.073 (0.260)	0.050 (0.218)	0.073 (0.259)	0.367
Cardiovascular	0.061 (0.239)	0.297 (0.459)	0.065 (0.247)	<0.001
Dental	0.056 (0.230)	0.030 (0.171)	0.056 (0.229)	0.252
Ear Nose Throat	0.039 (0.193)	0.030 (0.171)	0.038 (0.192)	0.644
Gastro Uro	0.090 (0.287)	0.129 (0.337)	0.091 (0.288)	0.186
Hematology	0.040 (0.197)	0.000 (0.000)	0.040 (0.195)	0.039
Hospital	0.057 (0.233)	0.109 (0.313)	0.058 (0.234)	0.029
Immunology	0.041 (0.198)	0.000 (0.000)	0.040 (0.197)	0.038
Microbiology	0.078 (0.268)	0.000 (0.000)	0.076 (0.265)	0.004
Neurology	0.044 (0.205)	0.040 (0.196)	0.044 (0.204)	0.839
ObGyn	0.040 (0.195)	0.010 (0.100)	0.039 (0.194)	0.127
Ophthalmic	0.050 (0.217)	0.040 (0.196)	0.049 (0.217)	0.644
Orthopedic	0.056 (0.230)	0.040 (0.196)	0.056 (0.230)	0.474
Pathology	0.039 (0.193)	0.000 (0.000)	0.038 (0.191)	0.044
Physical Med	0.034 (0.180)	0.010 (0.100)	0.033 (0.179)	0.187
Radiology	0.034 (0.181)	0.000 (0.000)	0.033 (0.180)	0.059
Surgery	0.084 (0.277)	0.208 (0.408)	0.086 (0.281)	<0.001
Toxicology	0.044 (0.206)	0.000 (0.000)	0.044 (0.204)	0.031
Device Class I	0.358 (0.479)	0.150 (0.359)	0.354 (0.478)	<0.001
Device Class II	0.562 (0.496)	0.580 (0.496)	0.563 (0.496)	0.725
Device Class III	0.080 (0.271)	0.270 (0.446)	0.083 (0.277)	<0.001

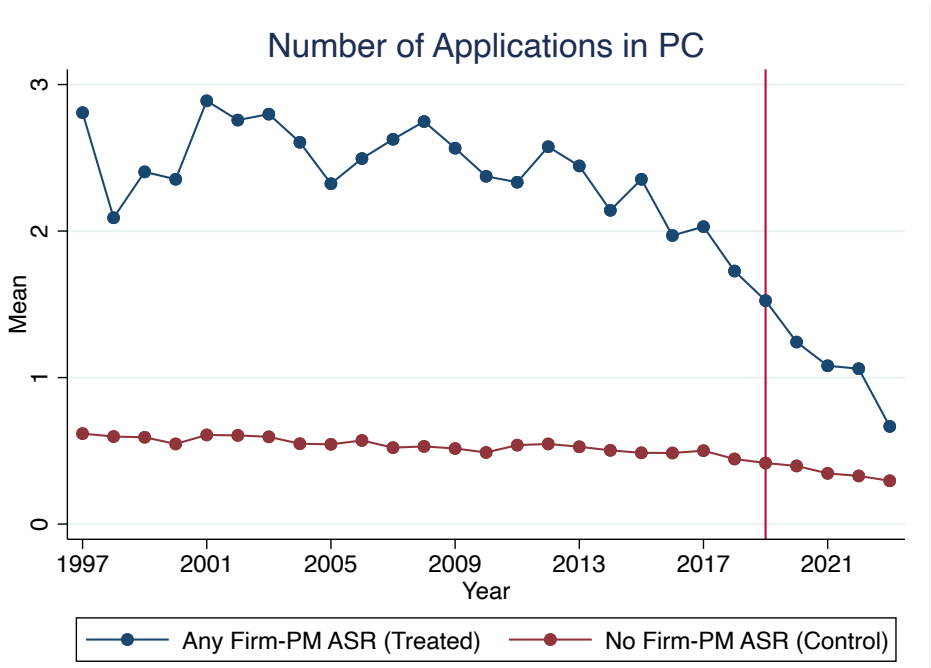
Note: Product Markets in above tabulations represent all product codes in FDA data.

Figure 3: Distribution of Pre-Shock ASR Share (Product Code Level)



Note: Product Markets in figure represent those in our analytical dataset.

Figure 4: Trend in Applications Among Treated and Non-Treated Product Markets



Note: Treated Product Markets have any ASR.

8.3 Firm-Market-Year Analysis

8.3.1 Main Effects

Table 3: Impact of ASR Release on Medical Device Approvals

VARIABLES	(1) 1(App)	(2) 1(App)	(3) 1(App)
Post x High Exposure	-0.0198***		
	(0.00557)		
Post x High Exposure (Focal Firm)		-0.0134	
		(0.00929)	
Post x High Exposure (Non-Focal Firm)			-0.0201***
			(0.00553)
Observations	696,946	696,946	696,946
R-squared	0.219	0.219	0.219
Year FE	YES	YES	YES
Firm-PC FE	YES	YES	YES
Mean of Dep. Var.	0.0487	0.0487	0.0487

Robust standard errors in parentheses
*** p<0.01, ** p<0.05, * p<0.1

Table 4: Impact of ASR Release on Ln Medical Device Approvals

VARIABLES	(1) Ln(App)	(2) Ln(App)	(3) Ln(App)
Post x High Exposure	-0.0177***		
	(0.00543)		
Post x High Exposure (Focal Firm)		-0.0131	
		(0.0130)	
Post x High Exposure (Non-Focal Firm)			-0.0180***
			(0.00525)
Observations	696,946	696,946	696,946
R-squared	0.283	0.283	0.283
Year FE	YES	YES	YES
Firm-PC FE	YES	YES	YES
Mean of Dep. Var.	0.0395	0.0395	0.0395

Robust standard errors in parentheses
*** p<0.01, ** p<0.05, * p<0.1

Table 5: Impact of ASR Release on PMA Medical Device Approvals

VARIABLES	(1) 1(PMA App)	(2) 1(PMA App)	(3) 1(PMA App)
Post x High Exposure	-0.000834** (0.000384)		
Post x High Exposure (Focal Firm)		-0.00417** (0.00180)	
Post x High Exposure (Non-Focal Firm)			-0.000535* (0.000323)
Observations	696,946	696,946	696,946
R-squared	0.075	0.075	0.075
Year FE	YES	YES	YES
Firm-PC FE	YES	YES	YES
Mean of Dep. Var.	0.000739	0.000739	0.000739

Robust standard errors in parentheses
*** p<0.01, ** p<0.05, * p<0.1

Table 6: Impact of ASR Release on 510K Medical Device Approvals

VARIABLES	(1) 1(510k App)	(2) 1(510k App)	(3) 1(510k App)
Post x High Exposure	-0.0189*** (0.00562)		
Post x High Exposure (Focal Firm)		-0.00921 (0.00922)	
Post x High Exposure (Non-Focal Firm)			-0.0196*** (0.00560)
Observations	696,946	696,946	696,946
R-squared	0.222	0.222	0.222
Year FE	YES	YES	YES
Firm-PC FE	YES	YES	YES
Mean of Dep. Var.	0.0479	0.0479	0.0479

Robust standard errors in parentheses
*** p<0.01, ** p<0.05, * p<0.1

8.3.2 Main Effects: Robustness

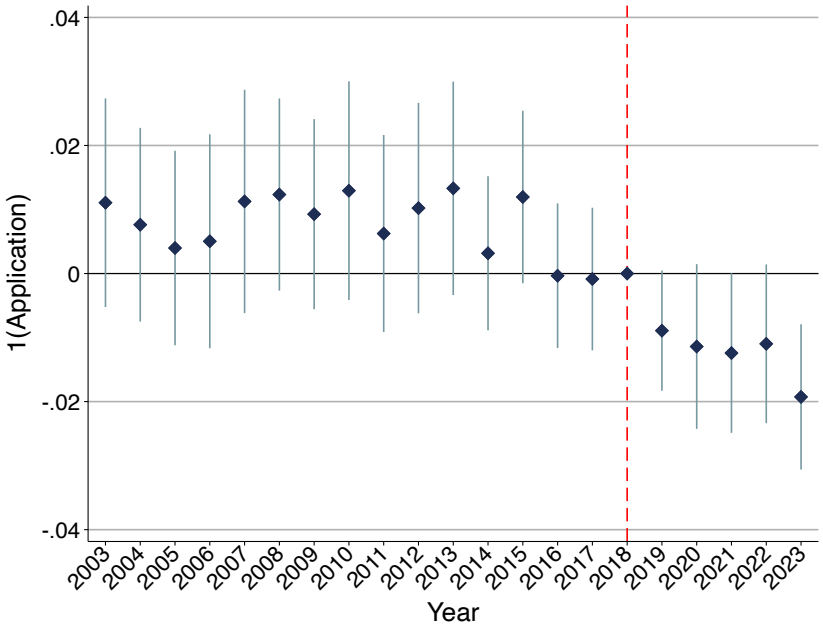
Table 7: Impact of ASR Release on Medical Device Approvals, Detailed FE

VARIABLES	(1) 1(App)	(2) 1(App)	(3) 1(App)	(4) 1(App)	(5) 1(App)	(6) 1(App)	(7) 1(App)
Post x High Exposure	-0.00287	-0.0134***	-0.0355***	-0.0201***	-0.0198***	-0.0201***	-0.0198***
	(0.00207)	(0.00203)	(0.00225)	(0.00231)	(0.00219)	(0.00279)	(0.00557)
Observations	696,946	696,946	696,946	696,946	696,946	696,946	696,946
R-squared	0.001	0.032	0.060	0.083	0.219	0.083	0.219
Year FE	YES	NO	NO	YES	YES	YES	YES
Firm FE	NO	YES	NO	YES	NO	YES	NO
PC FE	NO	NO	YES	YES	NO	YES	NO
Firm-PC FE	NO	NO	NO	NO	YES	NO	YES
Cluster SE	NO	NO	NO	NO	NO	FIRM	FIRM and PC
Mean of Dep. Var.	0.0487	0.0487	0.0487	0.0487	0.0487	0.0487	0.0487

Standard errors in parentheses
*** p<0.01, ** p<0.05, * p<0.1

Note: Observations at the firm-market-year level.

Figure 5: Impact of ASR Release on Medical Device Approvals



Note: Controls include Firm-Market FE, Year FE. SE clustered at the Firm-Market level.