Negative Product Disclosure and Innovation*

Colleen Cunningham
University of Utah

Jennifer Kao
UCLA

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Abstract

This paper studies how the disclosure of negative product quality information impacts firm innovation. There exists a core tension in innovation-related disclosure: firms would like to access product quality-related information from others while managing information about their own products. This tension implies the relationship between mandated disclosure and innovation is complex. Focusing on negative product disclosure, we leverage the unique features of the U.S. medical device industry, where regulations historically allowed device manufacturers to withhold certain adverse events from the public adverse events regulatory database. In 2019, such exemptions were eliminated, making millions of historically private adverse event records publicly available and terminating firms' ability to withhold future negative events. We show how this disclosure of negative product quality information shifted the rate and direction of subsequent medical innovation. We examine the dual role of disclosure: it prevents withholding while also expanding learning. Additionally, we consider spillover effects within firms and across product markets, revealing how disclosure of negative information shapes firm responses and market dynamics.

JEL Classifications: O310; D830; L640
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1 Introduction

Firms' product development decisions depend on the set of available information. This creates an inherent 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. On the other hand, profiting from innovation necessitates a degree of 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. While an active literature in economics and strategy explores the relationship between intellectual property-related invention 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), there has been less work on the effects of negative product quality disclosure of information that emerges after a product's launch. This post-launch data is crucial as it offers insights into a product's performance in real-world settings.

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 examine the interactions between two potential channels that could drive these effects. The first channel, which we term the "withholding effect," suggests that firms may reduce their innovation efforts in markets where they previously withheld negative information. We expect this channel to be strongest for incumbent firms, as they were able to withhold adverse events information before the disclosure change. The second channel, referred to as the "learning effect," clarifies how firms, now equipped with more comprehensive information about the shortcomings of products from other firms, may adjust their innovation decisions. We expect that this effect would lead to lower innovation in affected product markets, with this effect being most pronounced among 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 leverage an 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, Manufacturer and User Facility Device Experience (MAUDE), 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 burdens for firms and the FDA owing to high volumes of adverse events.[1] The program 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, following a report by Kaiser Health News (KHN) report in March 2019 that made the existence of the program publicly known, the ASR program was eliminated and the historical ASR data were released. At the time of its discontinuation, ASR included adverse event information for 102 product markets (or FDA "product codes"), compared to more than 4,000 in MAUDE. From its initiation in 1999 until its termination in June 2019, ASR included 5.8 million reports, compared with the 8.2 million events in the public database MAUDE over the same time period (Galasso and Luo, 2024).

To examine the causal impact of the ASR data release on innovation, we leverage a difference-in-differences (DID) design, utilizing cross-product market variation in exposure to the release. Our core treatment measure is at the product market level, where we classify

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

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 compare firm-product markets with High Exposure to those without any adverse events in ASR before and after 2019. Our findings suggest that the information release meaningfully shifted device development. In particular, we find that the ASR release is associated with a 41 percent decline in new medical devices.

Beyond direct effects on treated product markets, we also investigate if there are spillover effects to related product markets. To do so, we use newly collected data on predicate devices.[2] If devices 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 be driven by two effects: the inability of incumbent firms to withhold negative product quality information (the "withholding effect") and the resulting shift in learning opportunities for entrant firms (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 between incumbents and entrants, with the motivation that incumbents may be more impacted by the inability to withhold negative information and that entrants may be more responsive

[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.

to learning opportunities. Across both sets of analyses, we find evidence highlighting the important role of "withholding effects"—i.e., firm concerns about being unable to withhold negative information for a medical device in a product code may lower firms' incentives to invest further in that product code.

Taken together, this study highlights a more nuanced understanding of how disclosure can influence innovation. While prior research has often focused on the impact of disclosing positive pre-market information (e.g., the existence of an invention), our findings emphasize the important role of post-market disclosure of product quality information in shaping firms' innovation decisions. We also explore the key mechanisms driving these responses and shed light on the importance for firms of controlling the information associated with their own products. Our research thus contributes to the larger literature on disclosure, and in particular, the inability to withhold negative product quality information, and innovation.

The paper proceeds as follows: Section 2 introduces the data and descriptive facts. Section 3 presents the paper's main results regarding the causal impact of negative product market disclosure on innovation. Section 4 explores the mechanisms and provides additional heterogeneity analyses. Section 5 examines responses at the market and firm level. Finally, Section 6 concludes.

2 Data

To study the relationship between negative information and innovation, we use data from the U.S. medical device industry. Our analytical dataset is built from several datasets linked at the firm-product market-time period level, including data on publicly disclosed adverse events (MAUDE), non-publicly disclosed adverse events (ASR), medical device approvals (PMAs), and medical device clearances (510k). We analyze the relationship between ASR exposure and device approvals/clearances (which we refer to as approvals for brevity) from 2003 to 2023, but also leverage earlier years of data to measure the firm's portfolio of products and experience.

2.1 Adverse Events and ASR Exposure

We collect data on MAUDE and ASR adverse events from the FDA. For a given firm-product market, we measure exposure to the ASR shock (the closure of the program and release of the database) by identifying whether the focal product market had adverse events in ASR prior to the database's release in 2019. We classify product markets as having "High Exposure" if it has at least one adverse event in ASR. We further examine whether the exposure was local to the focal firm or another firm.

2.2 Medical Device Approvals

Our primary measure of innovation is new medical device. Medical device application and approval data comes the FDA and Evaluate Medtech. For each new medical device, we have information on the device name, manufacturer firm, medical device class (I, II, III), year of application and approval, product market, and specialty.

To identify the set of firm-product market pairs that are likely to co-occur, we restrict our sample of to set of firm-product market to those with at least one device present. Our final dataset includes: 3,377 firms; 4,720 product markets; and 35,143 firm-product markets. We examine how the instance, level, composition, and quality of new medical devices changes between 2003 (or the focal firm's founding year if it occurs after 2003) to 2023 for a total of 696,946 firm-product market-year observations.

2.3 Descriptive Statistics

2.3.1 Product Market Descriptives

Table 1 compares FDA product markets that are in ASR to those that are not. Overall, ASR product markets are larger (have a larger portfolio of devices), and have more publicly available adverse events (in MAUDE). While the distribution across medical specialties is

fairly even, ASR product markets are more common in Cardiovascular and Surgery specialty-related devices. Further, ASR product codes are also more commonly Class III devices, which are the riskiest per FDA classifications.

Figure 1 highlights the share adverse events in ASR (versus MAUDE, the publicly available database), across product markets in our analytical sample. This figure shows that most product markets are not in ASR (Panel A). Further, there is some variance in the share in ASR across product markets that are in ASR (Panel B), which is also reflected in our sample product markets in Figures 2 and 3.

Providing suggestive evidence for our main empirical strategy, Figure 4 depicts the trend in number of applications at the product market-level for ASR and non-ASR markets, highlighting the relative decrease at the market level for ASR markets.

2.3.2 Firm-Product Market Descriptives

Turning to firm-product market descriptives, Table 2 shows that the 7 percent of average firm-product market-year have High Exposure. For a given firm-product market, 5 percent of firm-product market-year observations have at least one new medical device approval. Figure 5 shows a relative decrease in device applications for the ASR exposed firm-product markets after 2019.

3 Impact of Negative Product Disclosure on Innovation

3.1 Empirical Strategy

We begin by empirically examining the release of adverse events in ASR on innovation among firms. Our baseline DID specification compares firm-product markets with at least one to those without any adverse event in ASR, before and after the database's release in 2019. For firm-product market-year *f,p,t*, we estimate the following:

$$Y_{f,p,t} = \alpha + \beta Post_t \times HighExposure_{f,p,t} + \delta_{f,p} + \delta_t + \epsilon_{f,p,t} \quad (1)$$

where $Y_{f,p,t}$ is an indicator for any medical device approval, $Post_t$ is an indicator for years after 2019, and $HighExposure$ is an indicator for whether the focal product market has an adverse event in ASR prior to 2019. Our main regressions include firm-product market fixed effects ($\delta_{f,p}$) and year fixed effects (δ_t). We estimate ordinary least squares models with hetereoskedasticity-robust standard errors clustered at the firm-product market level.

3.2 Baseline Results

Column 1 in Table 3 show that the disclosure of negative medical device information in ASR is associated with a decline in new medical devices. Among affected firm-product markets, there is a 1.98 percentage point (or a 41 percent) decrease in the likelihood of any new medical device.

In Table 4 though Table 6 we explore variations on the dependent variable, including logged count of applications (Table 4), and then breaking out new devices into an indicator for any PMA device (Table 5), and an indicator for any 510(k) cleared device (Table 6). Notably, PMA devices (i.e., those for the riskiest devices requiring new clinical evidence) are much rarer that 510(k) devices, which make up over 95% of new devices regulated by the FDA in any year.

3.3 Robustness Checks

In our preferred specification of our main analyses, we include year and firm-product market fixed effects and cluster our standard errors and the firm-product market level. In Table 7, we include our main results on the outcome of any new device across a range of different fixed effects and S.E. clustering. We see the results are similarly significant for all that include at least some controls for firm differences, which is expected given ASR-exposed firms tend to be larger than non-ASR firms.

To explore the timing of our main effects, we estimate an event study version of Equation 1 where $Post_t$ is replaced with a vector of indicator variables for each year before and after the

disclosure of ASR. Providing support for our identification strategy, Figure 6 shows that the likelihood of any medical device associated any given firm-product market declines following the ASR's public release.

We also explored heterogeneity across device types, in Figure 7 and Table 8. We see the results are driven by class II devices, which is the largest device class. We find no significant difference by product market age.

4 Mechanisms and Heterogeneity

4.1 Withholding and Learning Effects

The observed decline in new medical device innovation following the public release of ASR may be due to two factors: the "withholding effect," where incumbent firms can no longer hide negative product quality information, and the "learning effect," where entrant firms gain new learning opportunities. To assess the relative importance of each channel, we leverage specific institutional details about the timing of the ASR closure and characteristics of the firms involved.

4.1.1 Timing of ASR Closure

The official end of the ASR program was June 2019, when the database was posted by the FDA and adverse events could no longer be submitted to the FDA through the program.[3] However, in closing down ASR, the FDA reported that the program had been winding down since 2017, and already that only a subset of markets (product codes) remained eligible. Reviewing the number of active markets in ASR by year, in Figure 8, we see that about half of the markets had no ASR events by 2018.

While imperfect, this staggered shutdown potentially allows us to separate out the withholding and learning effects. Specifically, for those markets that dropped out of ASR pre-2018, the effect of the 2019 shock should be largely learning related (as the ability to withhold

[3]Details in Press Release

already expired). Comparatively, for the markets that were still in ASR post-2018, the effect of the 2019 shock would be both to withholding and to learning.

To explore this, in Table 9 and Table 10, we split the expose effect into product markets that left ASR pre-2018 and post-2018. The results highlight some evidence for a withholding effect: first, the post-2018 coefficients are larger, and second, for focal firms, we see a significant effect only for the post-2018 period.

4.1.2 Entrants vs. Incumbents

To further examine withholding and learning effects, we analyze variation across firm types: entrants and incumbents. Firms are classified into two mutually exclusive categories based on their pre-2019 device experience. "Entrants" are firms with relatively less device experience, defined as having devices below the 90th percentile in the focal product market prior to 2019 (approximately four devices). "Incumbents" are firms with more device experience, defined as having devices above the 90th percentile.

Figure 9 presents coefficients from regressions that are fully saturated with controls. The figure indicates that the impact of ASR's public release is noticeably different for the two firm types: entrants experience little change in the likelihood of a medical device approval, while incumbents are significantly more likely to lower their level of new device innovation. These findings are consistent with the view that firm concerns about no longer being able to withhold negative information (which may dampen current and future demand) may lead firms to withhold investment in additional new devices.

4.2 Spillovers

ASR's shutdown and public release of negative product information may also have spillover effects across product markets. For example, the presence of ASR adverse events in a product market may lead firms to change their innovative activity markets that are technologically similar to the affected markets. To explore if there are spillovers across product markets, we

incorporate data on predicates to identify linked product markets.

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 (over 95% of FDA regulated 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. If devices in one product market serve as predicates for the other—that is, if the devices 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.

Table 11 documents the presence of meaningful spillover effects: Column 1 shows that the use of adverse events in ASR in different, but technologically similar product markets can lead firms to lower their level of device innovation.

4.3 Additional Innovation Outcomes

4.3.1 Recalls

Turning to additional innovation outcomes at the firm-product market level, we examine if ASR-exposed product markets had differential outcomes in terms of product recall events. Recall events mean the device is defective in some way, and the manufacturer must notify patients and clinicians and take corrective action (Liebel et al., 2021). We exclude from our analyses recalls due to labeling issues. In Table 12, we find overall no change in recalls due to ASR exposure; however, the incidence of recalls increased for focal firms while decreasing for non-focal firms.

4.3.2 Patents

We then examine if there were any associated changes in patent filings as a consequence of ASR shock. The challenge in building these analyses is to create a link between patent classes (i.e., CPCs) and product markets (FDA product codes). To link patents to markets, we adapt the Algorithmic Links with Probabilities (ALP) method developed by Lybbert and Zolas (2014). We use ALP to link detailed patent classes to medical product markets.[4]

We observe a decrease in filing of any patent within exposed product markets following ASR's shutdown and public release of negative product information, in Table 13. The event study figure shows the estimates are increasingly noisy with time (Figure 10), which is likely due to the recency of the end of our panel and lags associated with patent grant.

5 Market and Firm Level Effects

5.1 Product-market Level Responses

Our main results are at the firm-product market level for firms with products already in the market. However, the effect of ASR may be affect firm entry and exit from product markets, and thereby the the level of innovation at the product market level beyond that of firms already in the market at the time of the shock.

To explore this, we examine responses at the product market level. Much like at the firm-product market level, we find exposed product markets have fewer subsequent device applications, as shown in Columns 1 and 2 of Table 14. We also found the number of firms in affected markets significantly decreased (Column 3), which is depicted in the Figure 11. Interestingly, when we break out the trends in firms into new firms, in Figure 12, and old

[4]The ALP process involves 3 broad steps: (1) identifying 3-5 keywords for each market (which we did using machine learning, research assistant checks, and leveraging the UMLS metathesaurus for medical synonyms), (2) searching for those keywords in patents and aggregating counts to patent class level, and (3) creating probabilistic linkages between patent classes and product markets. One example: the CFR code *§ 870.2100 Cardiovascular blood flowmeter* is matched to patent classes (CPC) *A61B8/06 Measuring blood flow* with weight of 0.932 and *A61B8/02 Measuring pulse or heart rate* with weight of 0.068. We use these weights to select the CFR and associated product code (which is a slight aggregation of CFR).

firms, in Figure 13, we see the decline is coming from existing firms leaving, while entry rates for new firms are not significantly lower (though the pre-trends show some decline in both groups).

5.2 Firm Level Responses

If affected firms are decreasing new product applications in affected markets, a natural question to ask is: what they are doing instead? To explore this, we conduct several firm level analyses using an ASR exposure variable that reflects the share of a firm's adverse events that are in ASR. These analyses include firm and year fixed effects, and standard errors are clustered at the firm level. We focus on both applications and product recalls.

Table 15 explores the impact of ASR exposure on firm-level product development. We observe decreases in overall applications (Column 1), and both for those in formerly ASR categories (Column 2) and in categories not formerly in ASR for exposed firms (Column 3). Further, more exposed firms are less likely to enter new markets (product codes, or PCs, Column 4), and again that this is true for both markets that were previously in ASR (Column 5) and previously not in ASR (Column 6). These findings suggest that exposed firms are generally decreasing their efforts, overall, rather than reallocating them.

Table 16 highlights that firms more exposed to ASR are less likely to have a product recall after the end of the shock. These preliminary findings suggest the products of exposed firms may be safer post-shock. Together with the findings in Table 15, this suggests that firms are strategically reacting to increased scrutiny of their products by reducing their product output and improving product quality.

6 Conclusion

Firms' product development decisions are shaped by their access to and control over product quality information. Using detailed data from the medical device industry, we show that firms significantly reduce their innovative efforts when they are unable to withhold nega-

tive product quality information. Although this corresponds to an aggregate decline in the introduction of new products in affected markets, preliminary evidence suggests that firms may instead be focusing on fewer, but higher quality products. Our study contributes to the broader body of literature examining the interplay between disclosure–specifically, the ability to withhold negative product quality information–and innovation.

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Figures and Tables

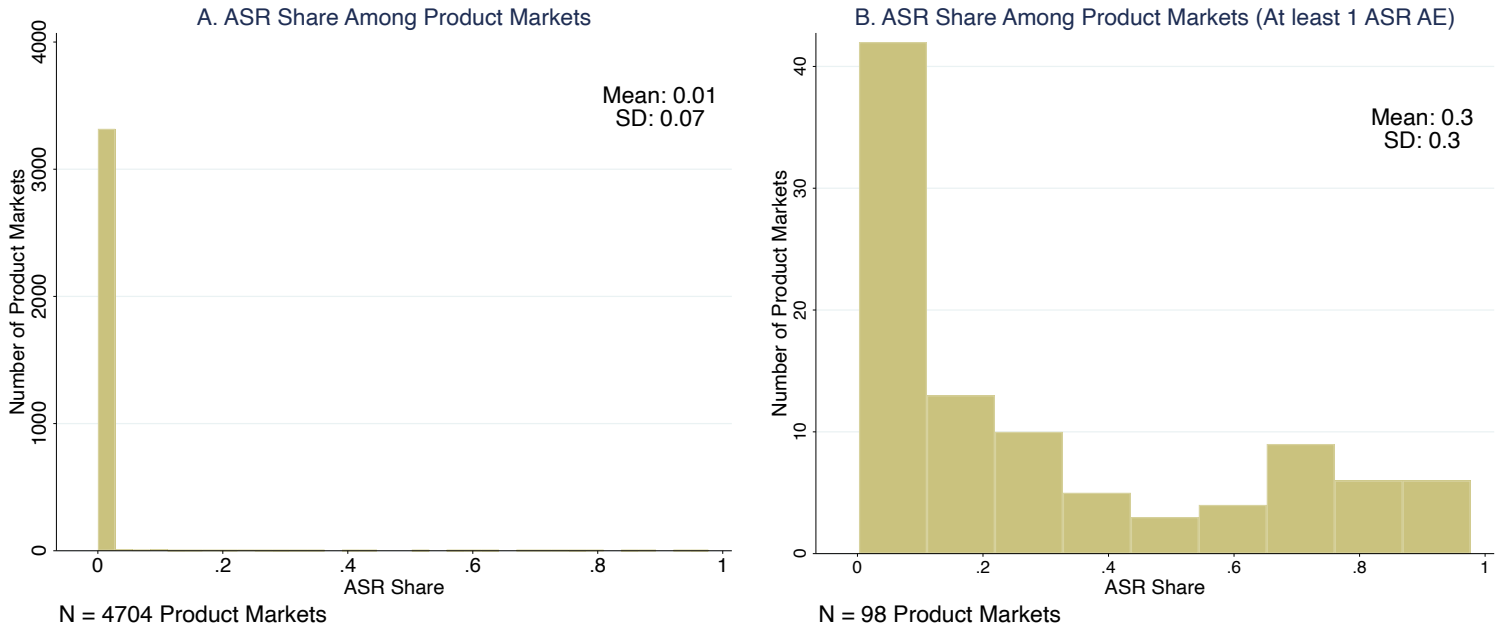
Product Market Descriptives

Table 1: Comparison of Product Markets with ASR vs. no ASR

	No ASR	With ASR	Total	Test
N	4,687 (97.9%)	99 (2.1%)	4,786 (100.0%)	
N MAUDE AEs	2,274.599 (33,626.195)	74,182.040 (237,781.851)	3,762.028 (48,683.413)	<0.001
A ASR AE	0.000 (0.000)	48,558.616 (283,579.326)	1,004.451 (41,167.640)	<0.001
N Apps pre2019	15.255 (64.652)	70.737 (150.137)	16.402 (67.952)	<0.001
N Apps 2014-2018	2.980 (15.360)	13.000 (31.297)	3.187 (15.911)	<0.001
N PMAs pre2019	0.205 (1.410)	2.212 (7.021)	0.247 (1.743)	<0.001
N PMAs 2014-2018	0.035 (0.338)	0.121 (0.576)	0.037 (0.345)	0.014
N 510ks pre2019	15.049 (64.632)	68.525 (150.835)	16.156 (67.932)	<0.001
N 510ks 2014-2018	2.945 (15.362)	12.879 (31.343)	3.150 (15.913)	<0.001
Anesthesiology	0.044 (0.206)	0.010 (0.101)	0.044 (0.204)	0.101
Chemistry	0.067 (0.249)	0.051 (0.221)	0.066 (0.249)	0.539
Cardiovascular	0.072 (0.259)	0.286 (0.454)	0.077 (0.266)	<0.001
Dental	0.056 (0.231)	0.031 (0.173)	0.056 (0.230)	0.271
Ear Nose Throat	0.036 (0.187)	0.031 (0.173)	0.036 (0.187)	0.767
Gastro Uro	0.099 (0.299)	0.133 (0.341)	0.100 (0.300)	0.272
Hematology	0.034 (0.182)	0.000 (0.000)	0.033 (0.180)	0.063
Hospital	0.061 (0.240)	0.112 (0.317)	0.062 (0.242)	0.039
Immunology	0.038 (0.191)	0.000 (0.000)	0.037 (0.189)	0.050
Microbiology	0.069 (0.254)	0.000 (0.000)	0.068 (0.251)	0.007
Neurology	0.047 (0.212)	0.041 (0.199)	0.047 (0.212)	0.763
ObGyn	0.042 (0.200)	0.010 (0.101)	0.041 (0.199)	0.118
Ophthalmic	0.044 (0.204)	0.041 (0.199)	0.043 (0.204)	0.897
Orthopedic	0.067 (0.250)	0.041 (0.199)	0.067 (0.249)	0.302
Pathology	0.028 (0.165)	0.000 (0.000)	0.027 (0.163)	0.094
Physical Med	0.034 (0.181)	0.010 (0.101)	0.033 (0.179)	0.198
Radiology	0.034 (0.181)	0.000 (0.000)	0.033 (0.179)	0.064
Surgery	0.093 (0.290)	0.204 (0.405)	0.095 (0.294)	<0.001
Toxicology	0.034 (0.182)	0.000 (0.000)	0.033 (0.180)	0.063
Device Class I	0.317 (0.465)	0.144 (0.353)	0.313 (0.464)	<0.001
Device Class II	0.598 (0.490)	0.577 (0.497)	0.597 (0.490)	0.684
Device Class III	0.085 (0.279)	0.278 (0.451)	0.090 (0.286)	<0.001

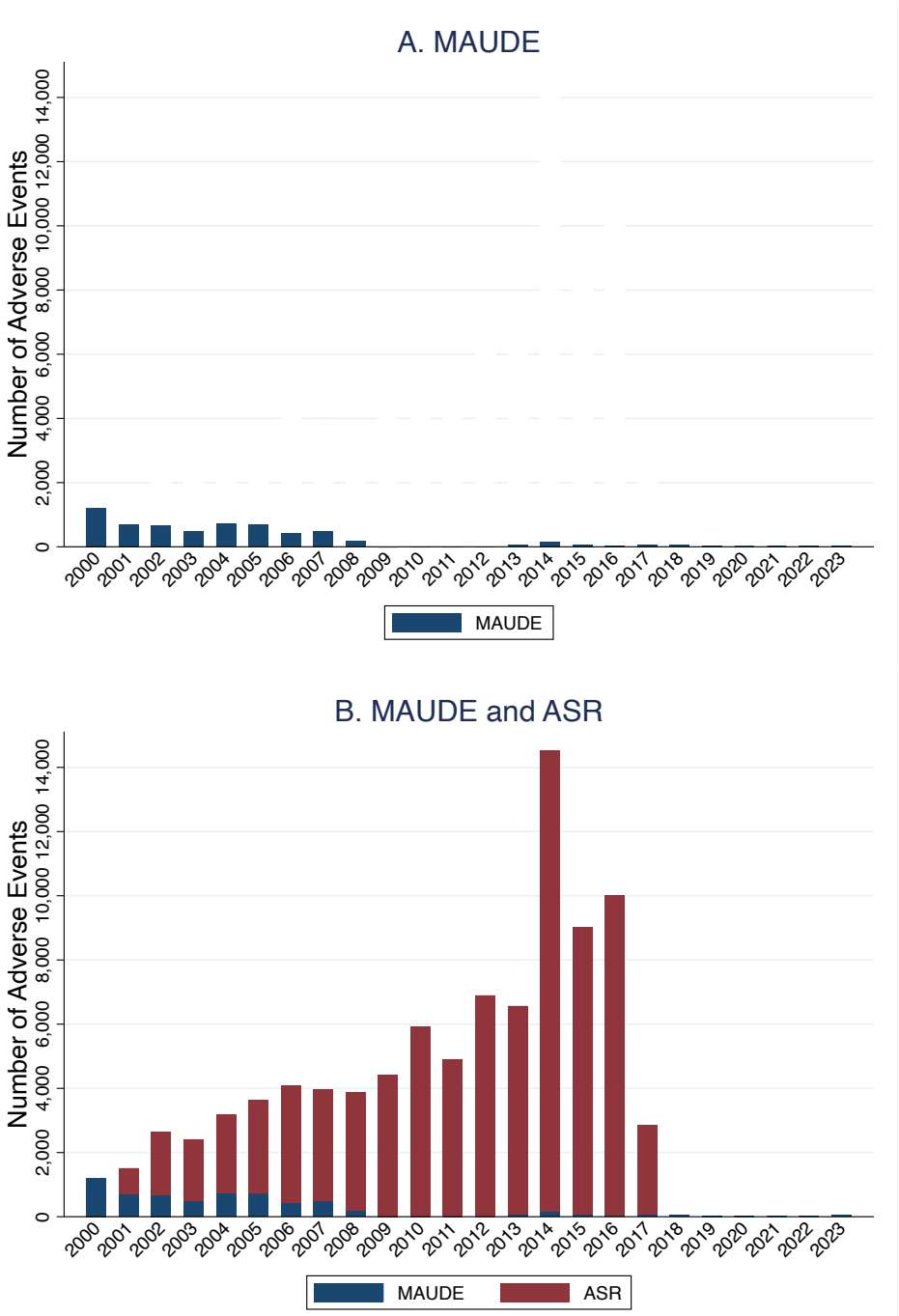
Note: Product market in this table represent all product codes in FDA data. This table compares FDA product markets that are in ASR to those that are not.

Figure 1: Distribution of Pre-Shock ASR Share (Product Code Level)



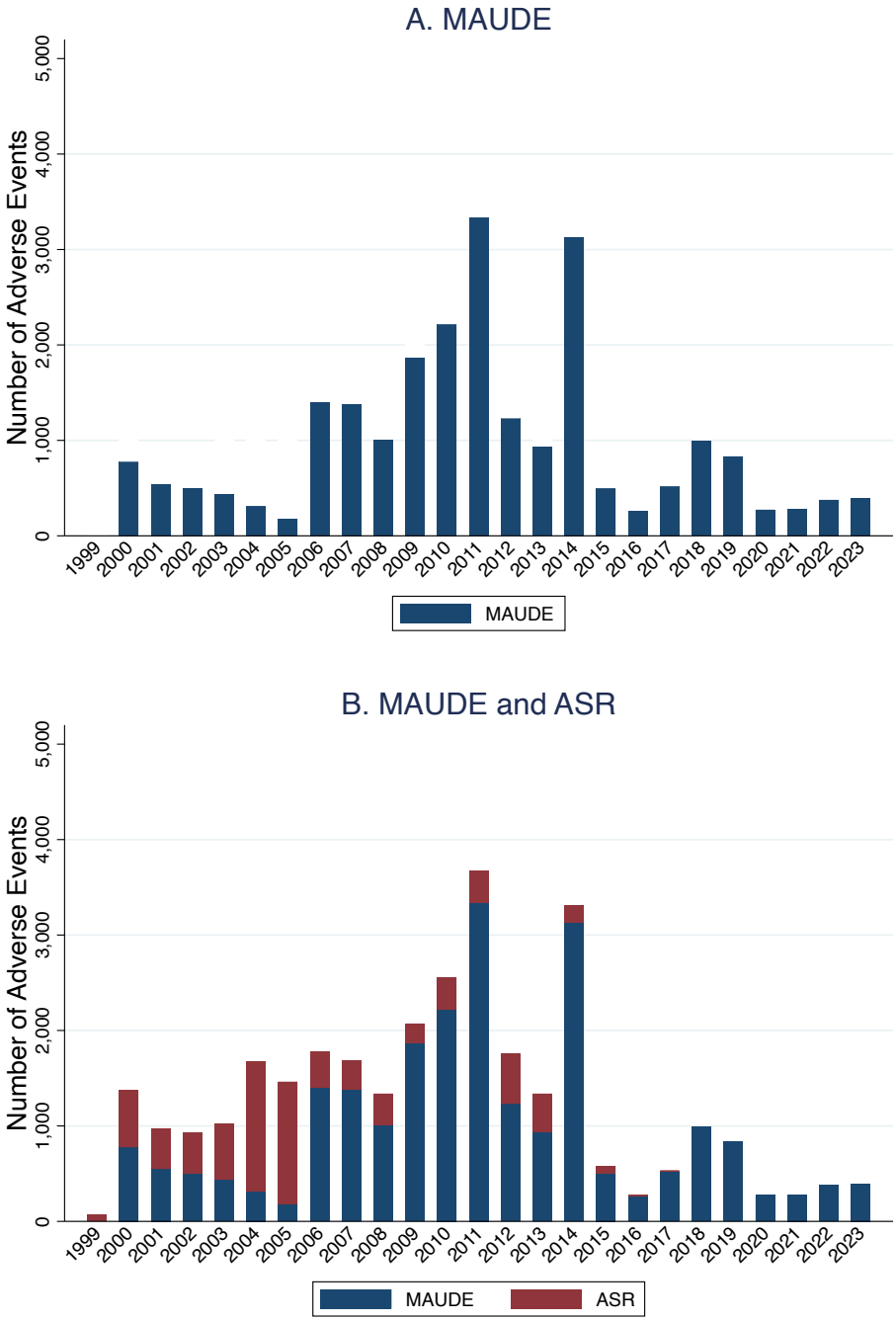
Note: This figure shows the distribution of ASR among product markets in our analytical dataset.

Figure 2: Differences in ASR and MAUDE: Stapler Example



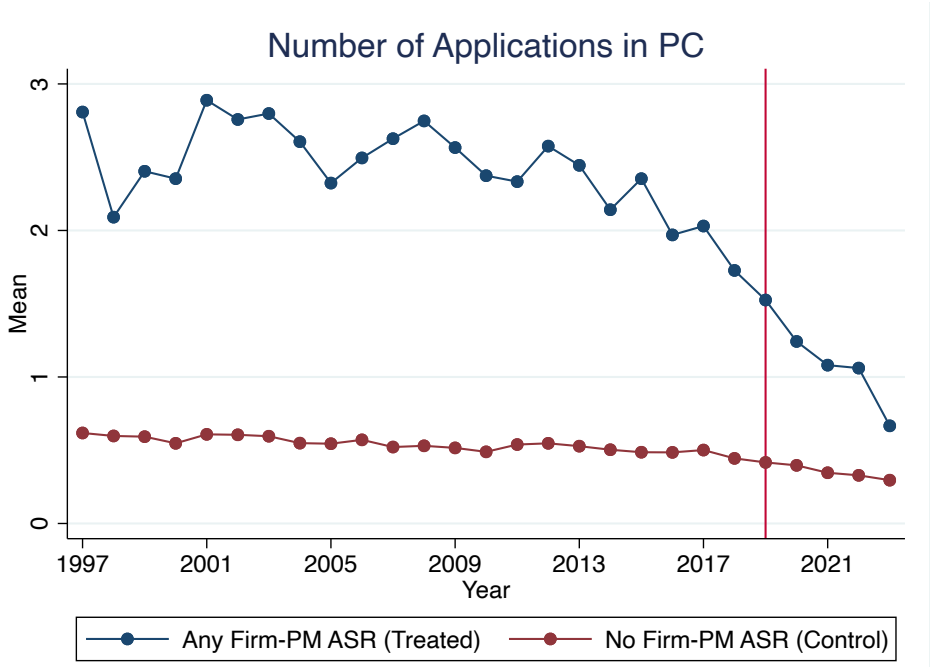
Note: These figures shows the distribution of MAUDE and ASR adverse events among the surgical stapler product market.

Figure 3: Differences in ASR and MAUDE: Pacemaker Electrode Example



Note: These figures shows the distribution of MAUDE and ASR adverse events among the pacemaker electrode product market.

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



Note: This figure shows trends in product markets with any ASR (High Exposure) to those without ASR (non-High Exposure) over time.

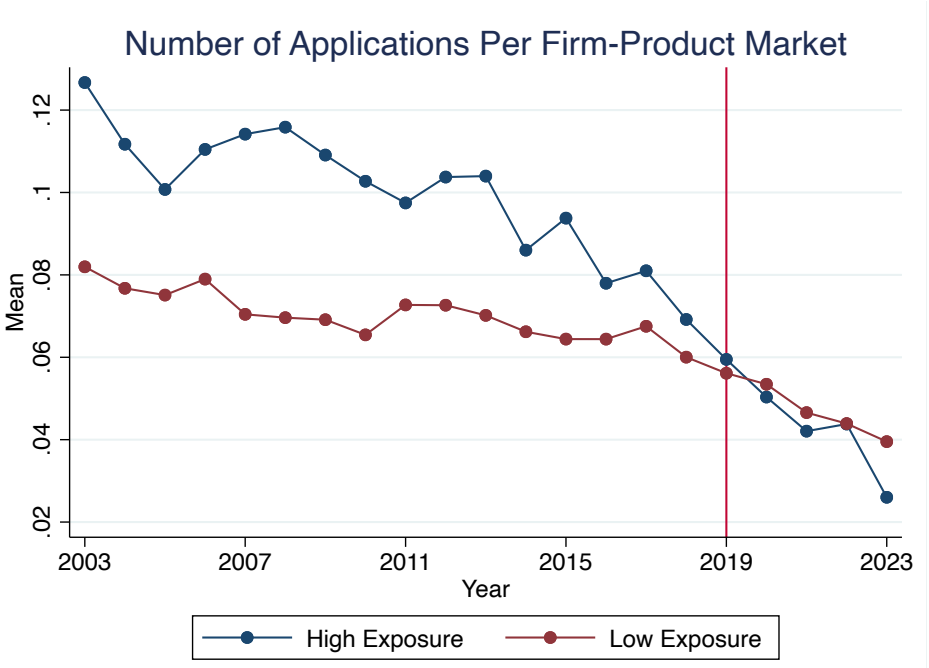
Firm-Product Market Descriptives

Table 2: 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: This table provides summary statistics at the firm-product market level.

Figure 5: Trend in Applications Among Treated and Non-Treated Product Markets



Note: This figure shows trends in firm-product markets with any ASR (High Exposure) to those without ASR (non-High Exposure) over time.

Firm-Market-Year Analysis

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

Note: This table reports DiD estimates of the effect of the ASR data release on the likelihood of a medical device approval. Observations at the firm-market-year level. Estimates are from OLS models. Robust standard errors, clustered at the firm-product market level, are shown 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

Note: This table reports DiD estimates of the effect of the ASR data release on log number of medical device approvals. Observations at the firm-market-year level. Estimates are from OLS models. Robust standard errors, clustered at the firm-product market level, are shown 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

Note: This table reports DiD estimates of the effect of the ASR data release on the likelihood of a PMA medical device approval. Observations at the firm-market-year level. Estimates are from OLS models. Robust standard errors, clustered at the firm-product market level, are shown 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

Note: This table reports DiD estimates of the effect of the ASR data release on the likelihood of a 510k medical device approval. Observations at the firm-market-year level. Estimates are from OLS models. Robust standard errors, clustered at the firm-product market level, are shown in parentheses. ***p<0.01, **p<0.05, *p<0.1.

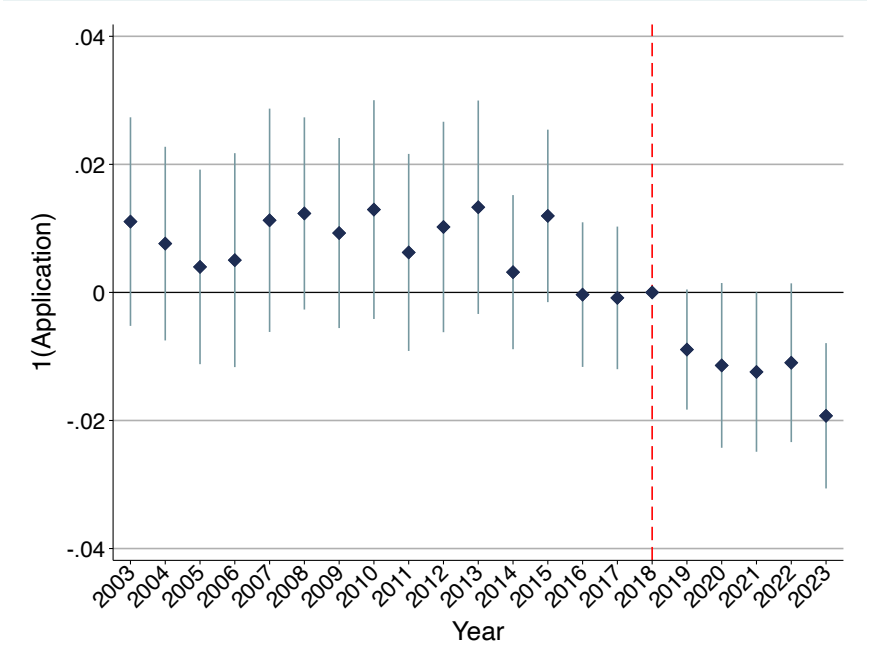
Main Effects: Robustness

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

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

Note: This table reports DiD estimates of the effect of the ASR data release on the likelihood of any medical device approval. Each column reports different combinations of fixed effects. Observations at the firm-market-year level. Estimates are from OLS models. Robust standard errors, clustered at the firm-product market level, are shown in parentheses. ***p<0.01, **p<0.05, *p<0.1.

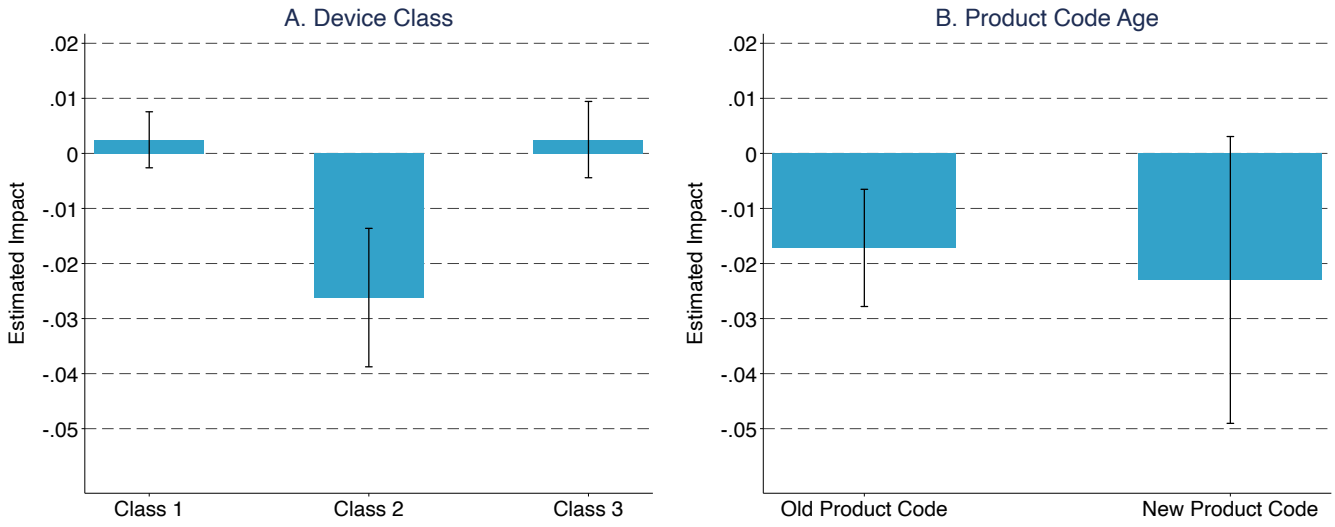
Figure 6: Event Study Estimates–Impact of ASR Release on Medical Device Approvals



Note: This figure plots the change in the likelihood of a medical device approval following the ASR data release. OLS regressions include firm-product market fixed effects and year fixed effects. Standard errors are clustered at the firm-product market level.

Heterogeneity Across Device Types

Figure 7: Impact of ASR Release on Medical Device Approvals, Heterogeneity by Device Type



Note: This figure plots the change in the likelihood of a medical device approval following the ASR data release across different device classes (Panel A) and product market ages (Panel B). Coefficients are estimated from OLS regressions at the firm-product market level and include firm-product market fixed effects and year fixed effects. Standard errors are clustered at the firm-product market level.

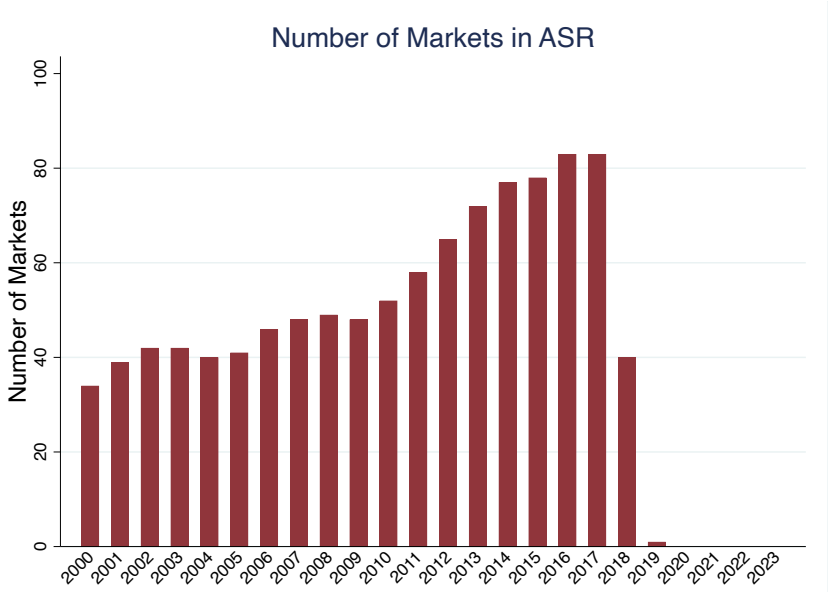
Table 8: Impact of ASR Release on Medical Device Approvals, Heterogeneity by Device Type

	(1)	(2)	(3)	(4)	(5)
VARIABLES	Old Product Code (On/before 1984)	New Product Code (After 1984)	Device Class 1	Device Class 2	Device Class 3
Post x Any Firm-PC ASR	-0.0172***	-0.0230*	0.00247	-0.0262***	0.00251
	(0.00543)	(0.0133)	(0.00260)	(0.00642)	(0.00353)
Observations	448,055	248,891	160,596	468,942	39,262
R-squared	0.231	0.199	0.156	0.214	0.121
Year FE	YES	YES	YES	YES	YES
Firm-PC FE	YES	YES	YES	YES	YES
Cluster SE	FIRM and PC	FIRM and PC	FIRM and PC	FIRM and PC	FIRM and PC
Mean of Dep. Var.	0.0471	0.0514	0.00937	0.0660	0.0151

Note: This table reports DiD estimates of the effect of the ASR data release on the likelihood of any medical device approval. Observations at the firm-market-year level. Estimates are from OLS models. Robust standard errors, clustered at the firm-product market level, are shown in parentheses. ***p<0.01, **p<0.05, *p<0.1.

Mechanisms

Figure 8: Product Markets Actively in ASR by year



Note: This figure shows the number of product markets in ASR over time.

Table 9: Impact of ASR Release on Medical Device Approvals, Split by ASR Exit pre- vs. post-2018

VARIABLES	(1) 1(App)	(2) 1(App)	(3) 1(App)
Post x High Exposure (pre18)	-0.0133**		
	(0.00594)		
Post x High Exposure (post18)	-0.0283***		
	(0.00923)		
Post x High Exposure (pre18 Focal Firm)		5.32e-05	
		(0.00790)	
Post x High Exposure (post18 Focal Firm)		-0.0324**	
		(0.0165)	
Post x High Exposure (pre18 Non-Focal Firm)			-0.0144**
			(0.00622)
Post x High Exposure (post18 Non-Focal Firm)			-0.0278***
			(0.00901)
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

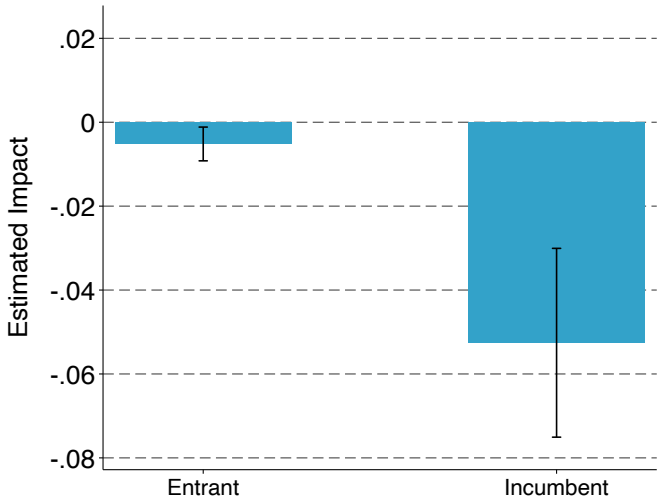
Note: This table reports DiD estimates of the effect of the ASR data release on the likelihood of any medical device approval, split by ASR exit before and after 2018. Observations at the firm-market-year level. Estimates are from OLS models. Robust standard errors, clustered at the firm-product market level, are shown in parentheses. ***p<0.01, **p<0.05, *p<0.1.

Table 10: Impact of ASR Release on Medical Device Approvals, Split by ASR Exit pre- vs. post-2018

VARIABLES	(1) Ln(App)	(2) Ln(App)	(3) Ln(App)
Post x High Exposure (pre18)	-0.0113*		
	(0.00599)		
Post x High Exposure (post18)	-0.0261***		
	(0.00890)		
Post x High Exposure (pre18 Focal Firm)		0.0104	
		(0.0123)	
Post x High Exposure (post18 Focal Firm)		-0.0461**	
		(0.0216)	
Post x High Exposure (pre18 Non-Focal Firm)			-0.0132**
			(0.00627)
Post x High Exposure (post18 Non-Focal Firm)			-0.0245***
			(0.00837)
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

Note: This table reports DiD estimates of the effect of the ASR data release on the likelihood of log number of medical device approvals, split by ASR exit before and after 2018. Observations at the firm-market-year level. Estimates are from OLS models. Robust standard errors, clustered at the firm-product market level, are shown in parentheses. ***p<0.01, **p<0.05, *p<0.1.

Figure 9: Impact of ASR Release on Medical Device Approvals, Split by Incumbent and Entrants



Note: This table reports DiD estimates of the effect of the ASR data release on the likelihood of any medical device approval, split by incumbent and new entrant firms. Coefficients are estimated from OLS regressions at the firm-product market level that include firm-product market fixed effects and year fixed effects. Standard errors are clustered at the firm-product market level.

Table 11: Impact of ASR Release on Medical Device Approvals, ASR Linked by Predicate

VARIABLES	(1) 1(App)
Post x Any ASR in Linked PC	-0.0322*** (0.00394)
Observations	696,946
R-squared	0.219
Year FE	YES
Firm-PC FE	YES
Mean of Dep. Var.	0.0487

Note: This table reports DiD estimates of the effect of the ASR data release on the likelihood of any medical device approval, in a product market linked by a predicate. Observations at the firm-market-year level. Estimates are from OLS models. Robust standard errors, clustered at the firm-product market level, are shown in parentheses. ***p<0.01, **p<0.05, *p<0.1.

Table 12: Impact of ASR Release on Medical Device Recalls

VARIABLES	(1) 1(Recall Device No Label)	(2) 1(Recall Device No Label)	(3) 1(Recall Device No Label)
Post x High Exposure	-0.000565		
	(0.00153)		
Post x High Exposure (Focal Firm)		0.0264**	
		(0.0107)	
Post x High Exposure (Non-Focal Firm)			-0.00291**
			(0.00145)
Observations	696,946	696,946	696,946
R-squared	0.186	0.186	0.186
Year FE	YES	YES	YES
Firm-PC FE	YES	YES	YES
Mean of Dep. Var.	0.00938	0.00938	0.00938

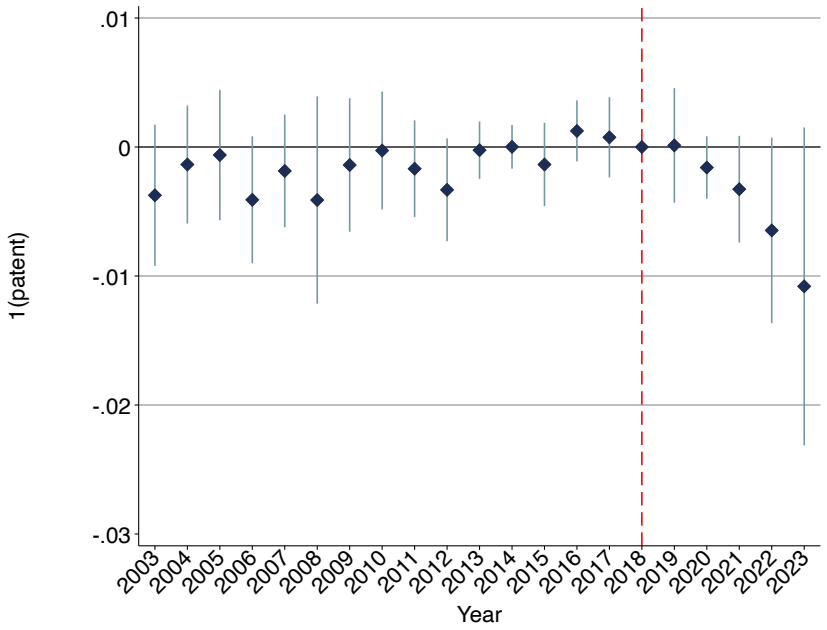
Note: This table reports DiD estimates of the effect of the ASR data release on the likelihood of any recall. Observations at the firm-market-year level. Estimates are from OLS models. Robust standard errors, clustered at the firm-product market level, are shown in parentheses. ***p<0.01, **p<0.05, *p<0.1.

Table 13: Impact of ASR Release on Patent Applications

VARIABLES	(1) 1(Patent)	(2) 1(Patent)	(3) 1(Patent)
Post x High Exposure	-0.00310*		
	(0.00171)		
Post x High Exposure (Focal Firm)		-0.00184	
		(0.00138)	
Post x High Exposure (Non-Focal Firm)			-0.00318*
			(0.00177)
Observations	696,946	696,946	696,946
R-squared	0.600	0.600	0.600
Year FE	YES	YES	YES
Firm-PC FE	YES	YES	YES
Mean of Dep. Var.	0.00118	0.00118	0.00118

Note: This table reports DiD estimates of the effect of the ASR data release on the likelihood of any patent application. Observations at the firm-market-year level. Estimates are from OLS models. Robust standard errors, clustered at the firm-product market level, are shown in parentheses. ***p<0.01, **p<0.05, *p<0.1.

Figure 10: Impact of ASR Release on Patent Applications



Note: This figure plots the change in the likelihood of a patent application following the ASR data release. OLS regressions include firm-product market fixed effects and year fixed effects. Standard errors are clustered at the firm-product market level.

Product Market-Year level analysis

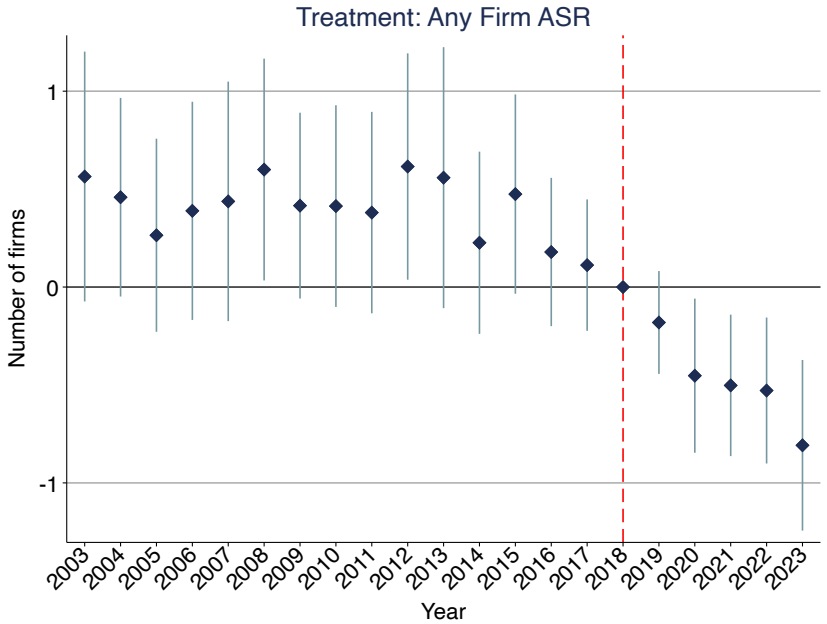
Table 14: Market-level Impact of ASR Release

VARIABLES	(1) 1(App)	(2) Nb. App	(3) Nb. Firms
Post x Any Firm-PC ASR	-0.0798***	-1.140***	-0.945***
	(0.0195)	(0.287)	(0.218)
Observations	123,520	123,520	123,520
R-squared	0.460	0.733	0.753
Year FE	YES	YES	YES
PC FE	YES	YES	YES
Cluster SE	PC	PC	PC
Mean of Dep. Var.	0.155	0.542	0.471

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

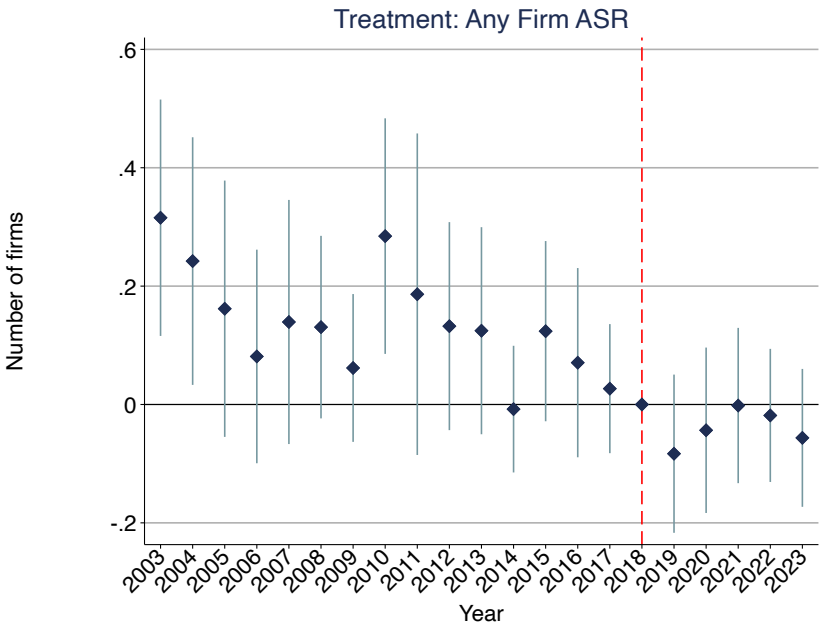
Note: This table reports DiD estimates of the effect of the ASR data release on medical device approvals and firms at the product market level. Observations at the market-year level. Estimates are from OLS models. Robust standard errors, clustered at the product market level, are shown in parentheses. ***p<0.01, **p<0.05, *p<0.1.

Figure 11: Market-level Impact of ASR Release on the Number of Firms



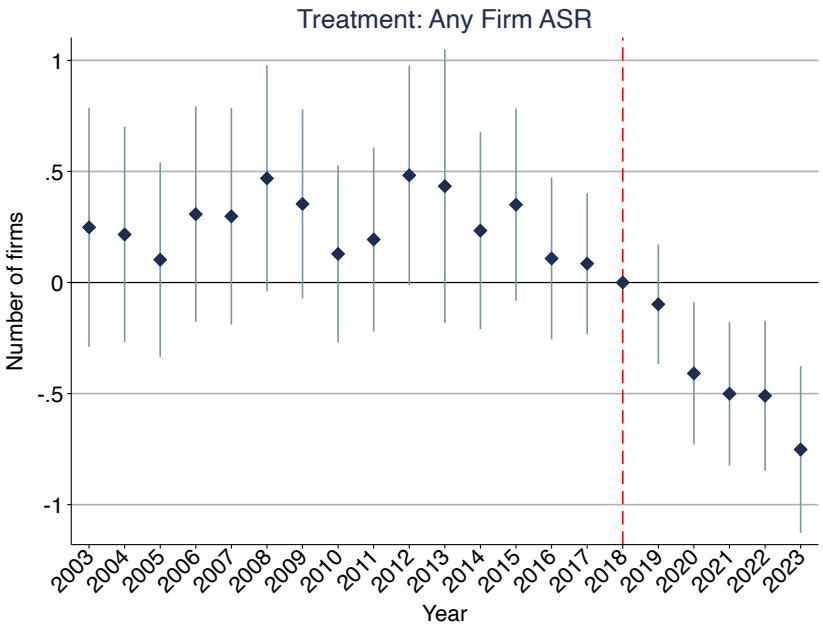
Note: This figure plots the change in number of firms following the ASR data release, at the product market level. OLS regressions include product market fixed effects and year fixed effects. Standard errors are clustered at the firm-product market level.

Figure 12: Market-level Impact of ASR Release on the Number of New Firms



Note: This figure plots the change in number of new firms following the ASR data release, at the product market level. Firms that have an approval in the focal PC for the first time are considered "new firms." OLS regressions include product market fixed effects and year fixed effects. Standard errors are clustered at the firm-product market level.

Figure 13: Market-level Impact of ASR Release on the Number of Old Firms



Note: This figure plots the change in number of non-new firms following the ASR data release, at the product market level. Firms that have an approval in the focal PC for the first time are considered "new firms." OLS regressions include product market fixed effects and year fixed effects. Standard errors are clustered at the firm-product market level.

Firm-year level analysis

Table 15: Firm-level Impact of ASR Release on Medical Device Approvals

VARIABLES	(1) Ln(App)	(2) Ln(App ASR)	(3) Ln(App nonASR)	(4) Nb PCs new	(5) Nb ASR PCs new	(6) Nb nonASR PCs new
Post x High Exposure (Share)	-0.287**	-0.204**	-0.253*	-0.920***	-0.0901***	-0.830***
	(0.134)	(0.0834)	(0.131)	(0.309)	(0.0257)	(0.292)
Observations	61,988	61,988	61,988	61,988	61,988	61,988
R-squared	0.636	0.559	0.633	0.493	0.125	0.489
Year FE	YES	YES	YES	YES	YES	YES
Firm FE	YES	YES	YES	YES	YES	YES
Mean of Dep. Var.	0.244	0.0282	0.231	0.175	0.00905	0.166

Note: This table reports DiD estimates of the effect of the ASR data release at the firm-level. Observations at the firm-year level. Estimates are from OLS models. Robust standard errors, clustered at the firm level, are shown in parentheses. ***p<0.01, **p<0.05, *p<0.1.

Table 16: Firm-level Impact of ASR Release on Recalls

VARIABLES	(1) 1(Recall Device No Label)
Post x High Exposure (Share)	-0.0865*
	(0.0460)
Observations	61,988
R-squared	0.548
Year FE	YES
Firm FE	YES
Mean of Dep. Var.	0.0317

Note: This table reports DiD estimates of the effect of the ASR data release on the likelihood of a recall, at the firm-level. Observations at the firm-year level. Estimates are from OLS models. Robust standard errors, clustered at the firm level, are shown in parentheses. ***p<0.01, **p<0.05, *p<0.1.