

Negative Product Disclosure and Innovation*

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Abstract

We investigate how mandated negative product disclosure, which forces firms to reveal information about their own products while providing information about competitor products, shapes the rate and direction of subsequent innovation. In 2019, the U.S. Food and Drug Administration (FDA) terminated an adverse event reporting exemption for selected medical device product markets and released 6 million previously withheld adverse events. Using a difference-in-differences design, we find that device innovation in directly exposed markets declined by 19 percent. The decline was primarily driven not by firms decreased ability to withhold their own negative information, but by firms updating beliefs in response to increases in disclosed product information. While overall innovation declined, entrants into exposed markets introduced more novel, safer, and higher quality devices. Incumbent firms in exposed markets shifted R&D to less exposed markets. The number of R&D active firms in exposed also declined, drive by incumbent exit. These findings show that mandatory negative product disclosure can reshape not only the rate of innovation but also its direction, i.e., where firms invest, what they develop, and overall market structure.

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1 Introduction

Firms’ research and development (R&D) decisions are shaped, in part, by what they can observe and withhold about their innovations once on the market. How should firms respond when they—and their competitors—are required to disclose negative information about their product innovations? Mandated disclosure removes firms’ ability to control whether and when to reveal product quality information. For firms, this shift can both reduce and redirect subsequent R&D activity. On the one hand, disclosure may increase the salience of product risks and thereby public scrutiny, potentially leading firms to decrease innovation. On the other hand, disclosure increases information about competitor products, enabling firms’ to update their R&D investment decisions accordingly. The result may not simply be a change in the rate of innovation, but a broader process of adaptation where firms reallocate their R&D investments across markets, change product attributes, and enter and exit product markets.

Despite the importance of information in shaping R&D, there is limited empirical evidence on how the mandated disclosure of product quality information (particularly negative information) shapes the rate and direction of firms’ R&D decisions. Prior research has focused on settings where disclosure is endogenous and has largely examined competitors’ responses (e.g., [Ball et al. 2018](#); [Krieger 2021](#)), overlooking how firms adapt in response to the public disclosure of their own negative information and how such transparency shapes the direction of R&D activity. We address these gaps by leveraging the unique features of the U.S. medical device industry, which includes the mandatory disclosure of millions of adverse events (AEs) and newly constructed data on regulatory “predicate” relationships linking new devices to previously approved, technologically similar products. Against this backdrop, we examine how the mandated disclosure of negative product quality information shapes firm innovation, by analyzing (i) its effect on the overall rate of R&D, (ii) the underlying mechanisms (i.e., loss of withholding and access to competitors’ information), and (iii) how firms

adapt their R&D investments, ultimately shifting the direction of innovation.

In June 2019, the U.S. Food and Drug Administration (FDA) discontinued and released historical data from the Alternative Summary Report (ASR) database, a selected set of medical device AEs that were not publicly disclosed.¹ The termination of the ASR database led to the release of 6 million reports on AEs including deaths, serious injuries, and malfunctions.² Using a difference-in-differences (DID) design, we compare changes in product markets that are differentially exposed to the ASR database release. At the market-year level, we see that firms reduce the level of new device applications by 19 percent in markets more exposed to the data release.

To shed light on the drivers of this decline, we investigate two mechanisms: (i) firms' responses to losing the ability to withhold their own negative product quality information and (ii) their responses newly disclosed information about their competitors. Several findings indicate that the broader release of competitor information played an important role. First, the timing aligns with the full release of ASR data in 2019, not with an earlier wind-down period when firms began losing their ability to withhold information. Second, we show that these effects are driven by firms reducing device applications in response to the release of competitors' AEs. Third, using newly-constructed data based on predicate relationships, which offers a more precise and dynamic measure of technological relatedness across device markets than standard regulatory classifications, we show that innovation also declines in technologically related, but not directly exposed, markets. These patterns highlight how disclosure can shape innovation by shifting firms' R&D decisions in response to new information about competitors.

While negative information disclosure may lead to an aggregate decline in the rate of innovation, firms may also adapt to the changed information environment. These adaptation responses will have implications for not only the overall rate, but also the direction of R&D.

¹In contemporary work, Galasso and Luo (2024) use the same empirical setting to examine the specific role of litigation on subsequent innovation.

²By way of comparison, the public AEs database contained 9 million events over the same time period that ASR database was in use.

Leveraging our empirical setting, we distinguish between “ASR aware” firms that were more likely to be directly affected by the loss of withholding and “ASR naive” firms that were more likely to be surprised by newly revealed competitor information. We find that ASR aware firms respond by reallocating R&D investment away from newly scrutinized markets. In contrast, ASR naive firms respond by shifting toward more novel, safer, and higher quality product. The disclosure also reshapes market dynamics: the number of research-active firms declines overall, driven largely by incumbent withdrawal. Taken together, these findings show that mandated disclosure of negative product information shapes not only the rate of R&D, but also its direction by shifting the markets in which firms choose to compete, the types of products developed, and the types of firms that continue to innovate.

A key managerial implication is that firms do not simply reduce R&D activity in response to negative product disclosure; they can adapt by shifting the markets they choose to compete and the types of products they choose to develop. This underscores the importance of investing in capabilities that enable adaptation, such as . For policymakers, these findings highlight that transparency regulations can meaningfully reshape the level and direction of subsequent R&D activity.

This paper is related to the literature on the relationship between product quality disclosure and innovation (see, e.g., [Dranove and Jin, 2010](#); [Ball et al., 2018](#); [Krieger, 2021](#); [Hsu et al., 2022](#)), which highlights the importance of product quality information in shaping firms’ R&D decisions. We build on this work by not just examining the effect of disclosure on overall R&D levels, but how firms adapt their R&D activity in response to newly revealed negative product information and ultimately shift the direction of subsequent R&D. We contribute in at least four ways.

First, we focus on the disclosure of post-market product quality information, rather than pre-market disclosure related to early-stage failures such as unsuccessful clinical trials ([Krieger, 2021](#); [Hsu et al., 2022](#)). While pre-market information may inform firms’ initial R&D decisions, they are often generated in controlled settings. In contrast, post-market

disclosures provide insights into how products perform in real-world settings over longer time horizons. As a result, they may more directly shape expectations about demand (by firms, rivals, and other stakeholders) and lead to broader adaptations in not only in whether firms invest in R&D, but how and where they do so.

Second, our study focuses on mandated disclosure, rather than the effects of voluntary or strategic disclosure decisions (Kao, 2024; Cunningham and Kapacinskaite, 2025). Prior studies have largely focused on endogenous disclosure choices, limiting the focus to competitors’ responses (Ball et al., 2018; Krieger, 2021). By leveraging a large-scale, policy-driven release, we can examine firms responses to both (i) the loss of their ability to withhold negative product quality information and (ii) the availability of information about competitors’ products.³ This approach provides a more comprehensive view of how disclosure shapes firms’ R&D decisions.

Third, we move beyond aggregate R&D measures, such as whether firms initiate, continue, or terminate projects (Ball et al., 2018; Krieger, 2021), to examine how firms adapt their R&D decisions in response to mandatory disclosure. By analyzing shifts in portfolio allocation, product attributes, and market entry, we show how disclosure shapes the direction of R&D activity both across and within firms and markets.

Finally, we contribute a novel methodological approach to measuring technological relatedness and product novelty that extends beyond traditional measures, such as patent classifications and citations (Trajtenberg et al., 1997; Fleming et al., 2007; Bloom et al., 2013). Patent classifications are often broad and may combine technologies that may not be functionally similar, while patent citations are firm-driven and may reflect citation norms rather than true technological similarity. In contrast, we leverage FDA predicate relationships (i.e., regulatory linkages that require firms to reference prior, technologically similar products). These references are reviewed by regulators, providing a validated and more precise measure

³This complements the literature on invention (not product) disclosure which primarily examines changes in patent policies (see, e.g., Chondrakakis et al., 2021; Furman et al., 2021; Kim and Valentine, 2021; Lück et al., 2020; Hegde et al., 2023).

of functional similarity across products, even when they span multiple patent classes. Predicate linkages often capture relationships that may be missed by patent-based measures, such as changes in product design or function not reflected in patents. More broadly, this approach offers a framework for studying innovation and adaptation in other regulated settings where firms must demonstrate technological equivalence to related, but distinct products. For example, in the U.S. aerospace industry, parts manufacturers must obtain Federal Aviation Administration approval by showing equivalence to previously certified components (Federal Aviation Administration, 2025). These regulated equivalence relationships provide an alternative lens to study spillovers and innovation beyond what traditional measures, such as patents, can reveal.

The paper proceeds as follows: Section 2 describes the setting and conceptual framework. Section 3 introduces the data and presents descriptive facts. Section 4 presents the paper’s baseline results regarding the causal impact of negative product market disclosure on the overall rate of innovation and explores mechanisms. Section 5 examines how firms and markets adapt. Finally, Section 7 concludes.

2 Setting and Conceptual Framework

2.1 Medical Device Regulation

The U.S. medical device industry is an economically significant, research-intensive sector where spending is expected to reach \$800 billion by 2030 (van den Heuvel et al., 2018). The FDA regulates U.S. medical devices, both pre- and post-market. Pre-market devices are classified based on risk into three categories with varying evidentiary requirements for market entry. Low risk devices are subject to basic controls and typically not subject to FDA notification before marketing (i.e., Class I).⁴ Medium risk devices typically are required to follow a Pre-Market Notification (PMN) process (known as 510(k) clearance) in which

⁴Because low-risk devices do not require FDA clearance or approval pre-market, there is no FDA database of such devices. Our analyses therefore necessarily exclude such devices/markets.

manufacturers need to show that the device is substantially equivalent to a device that is already marketed, known as a “predicate” device, to be cleared for marketing (Class II). High risk devices typically have to undergo a more stringent Pre-Market Approval (PMA) process, i.e., clinical trials to prove safety and effectiveness. Of devices regulated by the FDA pre-market, i.e., medium and high risk, most (95%+) are medium risk. The FDA publicly posts information about each cleared or approved device, including summary reports of the basis for approval (i.e., evidence of substantial equivalence to predicate or clinical trial evidence.)

2.2 Negative Product Disclosure: Adverse Event Reports

In addition to pre-market regulation, the FDA has required manufacturers (since 1984) and device user facilities, e.g., hospitals and nursing facilities (since 1990), to report AEs involving marketed medical devices. AEs are unwanted outcomes from medical device use, including death, life-threatening injury, hospitalization, or other serious negative outcomes. AE reporting helps with post-market safety monitoring, consumer decision-making and ideally helps to improve device safety over time. Since the mid-1990s, AE reports have been housed by the FDA in a publicly accessible database known as the Manufacturer and User Facility Device Experience (MAUDE).⁵ Manufacturers are required to report AEs to the FDA within 30 days of becoming aware of them. User facilities must report device-related deaths or serious injuries to manufacturers and the FDA within 10 days, and provide summary reports to the FDA every six months. Approximately 95% of AEs in MAUDE come from manufacturer firm reports (Everhart et al., 2025).

2.2.1 The (Private) Alternative Summary Reporting Program

Against this backdrop of pre-market regulation and mandated, public disclosure of post-market AEs, in 1999, the FDA implemented the Alternative Summary Reporting (ASR) program. The ASR program allowed manufacturers to submit adverse event reports on a

⁵For additional details, see U.S. Food and Drug Administration (2025).

quarterly basis in summary format, rather than on an individual basis and based on the 30-day window mentioned above. The program was intended to ease administrative burdens for firms and the FDA amid rising report volumes.⁶ ASR AEs were excluded from being included in MAUDE because they “were not submitted in a form compatible with the public MAUDE database” (U.S. Food and Drug Administration, 2025). Further, while it is unclear from available documents if it was intended from the outset, AEs in the ASR database were not made public *in any form* before ASR was terminated in 2019.

The program started with 12 explicitly listed product markets (including, for example, pacemaker electrodes, breast implants, and heart valves), with the FDA sending the program initiation announcement to manufacturers of devices in these markets, on July 31, 1997 (U.S. Food and Drug Administration, 1997).⁷ The ASR program was subsequently expanded to additional product markets, though public details on this expansion are unavailable.⁸

Knowledge of the program was quite limited before it was terminated in 2019. The ASR database was created without any public notice or regulations (Jewett, 2019). According to former industry insiders, ASR using firms were very “tight-lipped” about it. Sales representatives could credibly ignore ASR AEs to make devices seem safer (Jewett, 2019). Many safety experts, physicians, and former FDA officials, including former FDA deputy commissioner Dr. Robert Califf, were unaware of ASR’s existence (Jewett, 2019).

In March 2019, a Kaiser Health News investigation publicly revealed the existence of the ASR program (Jewett, 2019). Quickly thereafter, in June 2019, the FDA officially terminated the program and released its historical data covering 1999 to 2019. The ASR dataset includes

⁶The administrative effort-related issues of adverse event data are foreshadowed in a 1997 US GAO (U.S. Government Accountability Office, 1997). See also the sparse, archived details in U.S. Food and Drug Administration (1997) and U.S. Food and Drug Administration (2000). Additional details can be found in the law blog, Beck (2023).

⁷The full list of 12 initial product markets (product code) includes: Permanent Pacemaker Electrode (DTB); Diagnostic IV Catheter (DQO); Endosseous Implant (DZE); Mechanical/Hydraulic Incontinence Device (EZY); Mechanical/Hydraulic Impotence Device (FHW); IV Catheter (FOZ); IV Administration Set (FPA); Silicone Breast Prosthesis (FTR); Saline Breast Prosthesis (FWM); Urological Catheter (KOD); Implanted Subcutaneous IV Catheter (LJT); Mechanical Heart Valve (LWQ).

⁸Since all of the historical ASR data were made publicly available in 2019, we can, however, observe all firms that used the ASR database, in which product markets, and starting when.

6 million reports on AEs in 102 product markets over that period. In contrast, MAUDE contained 9 million events covering more than 4,000 product markets over the same time period.

The ASR database release increased the amount of AEs known to the public for exposed markets. Figure 1, Panel A highlights this increase across all product markets. Some device markets such as surgical staplers (Panel B) and dental implants (Panel C), saw large increases in reported historical events after ASR data became public, while others, like pacemakers (Panel D), had more minimal increases. While our main treatment measure compares markets with any AEs in ASR to those with none, we leverage this variation in our robustness tests in Section 4.4. The nature of AEs also differs somewhat in MAUDE and ASR. While death-associated events are relatively rare in the ASR database (compared to the public database, MAUDE), serious (but non-fatal) outcomes are more common in the ASR database (Appendix Table A1). The events in both MAUDE and ASR represent serious and informative AEs.

2.3 Conceptual Framework

To guide our empirical analyses, we outline a conceptual framework for how firms plausibly adjust their R&D decisions in response to the termination of ASR, i.e., disclosure mandates for negative product information.

2.3.1 Impact of Negative Disclosure on the Rate of Innovation

Terminating a program that allowed firms to selectively withhold negative product information while also releasing all previously withheld negative product information affects firms' R&D investment choices through two mechanisms: a *withholding effect* and an *information effect*.

First, mandating disclosure removes firms' abilities to withhold negative information about new products.

In product markets where withholding was previously permitted, this ability to withhold information may have spurred firm R&D investment in more novel or higher-risk projects by allowing firms to maintain favorable perceptions of product quality and, therefore, demand even if their products were associated with AEs. Removing the ability to withhold information increases scrutiny from external stakeholders (consumers, investors) and may reduce expected demand for current and future products in the affected product market (Dranove and Jin, 2010; Jin and Leslie, 2003). As a result, firms may reassess the expected returns to innovation associated with products in newly exposed markets, leading to a decline in the rate of R&D investment in those markets.

Second, disclosure also publicly releases information about competitors' products in the affected market that were previously unavailable or privately held. This allows firms to update their beliefs about the technological risks and the commercial potential in the product market (Hegde and Luo, 2018; Chondrakis et al., 2021). The net effect of such competitor disclosure on the rate of firms' R&D investment is theoretically ambiguous. Some firms may scale back investment after learning that a market is riskier or less profitable than previously believed, while others may increase R&D investment if they expect that disclosure will lead to reduced competition. However, recent work suggests that the former learning effects tend to dominate, suggesting that firms may reduce R&D investment in response to negative signals about the product market (Bloom et al., 2013; Krieger, 2021).

Importantly, the effects of both mechanisms may extend beyond directly affected product markets (i.e., those where negative information requirements directly led to the release of previously withheld negative information). A large literature documents the importance of information spillovers across markets (see, e.g., Harhoff, 1996; Alcácer and Chung, 2007; Bloom et al., 2013; Bai et al., 2024; Deore et al., 2024). When product markets are technologically related, negative information disclosed in one market may lead firms to update beliefs about technologically related products. We therefore expect spillovers across technologically related markets.

2.3.2 How Firms Adapt to Negative Information Disclosure

While negative information disclosure may lead to an aggregate decline in the rate of innovation, firms may also adapt to the changed information environment. These adaptation responses will have implications for not only the overall rate, but also the direction of R&D. In particular, it may shape several dimensions, including (i) how firms reallocate their R&D portfolios, (ii) how they shift the characteristics of new products, (iii) how these choices translate into market-level changes.

Before discussing each dimension, it is important to note that firms’ adaptation responses likely depend on their prior ability to withhold information. In our setting, we distinguish between firms that previously had approvals in product markets included in the ASR database (“ASR aware” firms) and those that did not (“ASR naive” firms). ASR aware firms, which include incumbents, were more likely to have withheld information in the ASR database and thus directly affected by the loss of withholding. These firms may respond by reallocating R&D investments away from newly exposed markets that now face greater scrutiny. Indeed, how firms allocate their R&D portfolios across markets is a critical strategic decision. Prior work shows that firms frequently reallocate innovation investments in response to changes in perceived risk, competition, or regulatory conditions (Bloom et al., 2013; Krieger, 2021).

In contrast, ASR naive firms (which are less affected by the ability to withhold and more affected by the ability to learn from competitors disclosures) may continue to invest in affected product markets, but shift the attributes of the products they develop. For example, these firms may seek to differentiate themselves from newly exposed rivals by increasing the novelty, safety, or perceived quality of their products. The decision to adapt product attributes is consistent with prior work showing that firms adapt to increased transparency by investing in higher quality products to differentiate themselves and signal reliability (Jin and Leslie, 2003; Lee et al., 2021).

2.3.3 Testable Predictions

This conceptual framework yields two sets of testable predictions.

First, we expect that, on average, mandatory disclosure negative product information will reduce the aggregate rate of R&D in affected markets. This aggregate effect is driven by both the loss of firms’ ability to withhold negative information and the public release of competitors’ negative information. These effects are not restricted to directly exposed markets, but will spill over to technologically related markets.

Second, we expect firms to adapt differently based on prior exposure to the disclosure regime. ASR aware firms are more likely to reallocate R&D away from newly exposed markets. In contrast, ASR naive firms may shift toward developing safer, higher-quality, or more novel products to differentiate from weakened competitors. These adaptations may reshape market structure, driven by reductions in incumbent participation.

We now turn to the empirical analysis to examine these predictions.

3 Data and Descriptives

To study the relationship between negative information and innovation, we use data on product markets (e.g., surgical staplers), firms (e.g., Medtronic), and years to link together several datasets. We supplement these datasets by constructing novel measures of technological similarity across markets and product novelty.

3.1 Adverse Events and Exposure to the ASR Disclosure

We collect FDA data on AEs from two sources: the newly-public AE database, the ASR database (from 1999 to 2019) and the long-standing public AEs database, the MAUDE database. Figure 2 shows how the number of product markets with ASR AEs changed over time. There are two important features to note. First, ASR participation expanded gradually. While, the program began with 12 FDA-approved markets in 1997 (“Original

ASR”), it ultimately covered 102 distinct product markets.⁹ Second, although the program officially ended in June 2019, when the data was publicly released and AE submissions to the ASR database ceased, the FDA had already begun phasing out the program in 2017 such that only a subset of product markets remained eligible.¹⁰ Figure 2 shows that by 2018, half of the product markets active in 2017 no longer contained ASR AEs. We leverage this gradual wind-down in our empirical analyses to isolate mechanisms driving the aggregate effect.

Our primary measure of exposure to the ASR shock (i.e., the closure of the program and data release) is constructed at the product market level. We classify product markets as having “High Exposure” if it has at least one AE in the ASR database.

3.2 Medical Device Innovation

Our primary measure of innovation is a medical device application. To identify new devices, we use device application data for 1997 to 2023 from the FDA and Evaluate Medtech, for both pre-market approvals and 510(k) device clearances. For each new device application, we have information on the device name, manufacturer firm, medical device class (I, II, III), approval type (510(k) or PMA), year of application and approval, and product market. Appendix Figure B1 provides an example of an approved device application.

3.2.1 Measuring Technological Similarity Across Markets

Given the potential for spillovers across markets, we would like to identify product markets technological similar to High Exposure product markets. A key challenge is that existing classifications (e.g., FDA specialty classifications, patent classes) are broad and may group together devices that serve similar functions or regions of the body, but rely on different technologies. For example, the FDA dental specialty includes both floss and dental x-ray machines. To overcome this challenge, we exploit a unique feature of the regulatory system

⁹One of the original ASR product market had no AEs in the ASR data: Diagnostic IV Catheter (DQO).

¹⁰Additional details can be found in [U.S. Food and Drug Administration \(2019\)](#)

to trace technological similarity across product markets: as described in Section 2.1, manufacturers of devices that have to go through the 510(k) approval process are required to demonstrate that their proposed device is “substantially equivalent” to a previously approved “predicate” device. Equivalence is based on intended use, materials, and efficacy. We link product markets if at least one device in a product market references a predicate in another product market (or vice versa). With this approach, approximately 40% of product markets are linked. See Appendix B.1 for more details.

3.2.2 Measuring Device Attributes

We construct measures of device novelty, safety, and quality.

We supplement the FDA datasets with data on patents from PatentsView. Specifically, we include U.S. patent applications for eventually granted patents that we link to our data at the product market level. To proxy for safety and quality, we use the share of safety-related patents and the average age of backward citations.

A challenge in incorporating patent data in our analyses, in which exposure is by product market, is to be able to link patent classes (i.e., CPCs) and product markets. We leverage the link created by [Cunningham and Hall \(2025\)](#). They link patent classes (CPC subgroups) to medical product markets (FDA regulatory groups). Their linkage involves: (i) identifying 3-5 keywords for each market (using machine learning, research assistant checks, and leveraging the UMLS metathesaurus for medical synonyms), (ii) 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.

3.3 Analytic Dataset

Due to the nature of the ASR shock (which primarily occurs at the product market level), our main analyses is conducted at the product market-year level. We begin by identifying the all product markets with at least one device approval between 1960 (the earliest approval in our dataset) and 2023 (the last full year). We then construct a balanced product market-year panel that follows each product market from 2003 to 2023. The final product market-year dataset includes 5,180 product markets and 108,780 product market-year observations.

Table 1 presents summary statistics for key variables at the product market-year level. Between 2003 and 2019, the average product market-year had 18 more AEs in the MAUDE database relative to the ASR database. Roughly one percent of product market-year observations are classified as High Exposure, while three percent are technologically similar to a High Exposure market. Device applications are rare with 0.42 applications in the average product market-year. Product attributes vary substantially across observations (e.g., 0.05 product market-years have a novel predicate but the standard deviation is 0.22). On average, there are 15 firms active in a given product market-year, the majority of which have prior approvals in that market.

While our primary analysis focuses on the product market-year level, we also analyze outcomes at the firm-product market-year and firm-year levels to explore mechanisms and to examine how firms adapt. We discuss the underlying datasets and specification in their respective sections.

4 Baseline Impact on Innovation

4.1 Empirical Strategy

We begin by empirically examining the baseline impact of the ASR shock on innovation among firms. Our baseline DID specification compares product markets with at least one adverse event in ASR to those without any adverse event in the ASR database, before and

after the database’s release in 2019. For product market-year p, t , we estimate the following:

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

where $Y_{p,t}$ is a measure of R&D activity (e.g., the log number of device applications) in product market p and year t , $Post_t$ is an indicator for years after 2019, and $HighExposure$ is an indicator for whether the focal product market has an adverse event in the ASR database prior to 2019. Our main regressions include product market fixed effects (δ_p) and year fixed effects (δ_t). We estimate ordinary least squares models with heteroskedasticity-robust standard errors clustered at the product market level.

Descriptive evidence provides support for our empirical strategy. Panel A of Appendix Figure A1 plots the average number of device applications in product markets with ASR AEs (i.e., markets with relatively high exposure to the ASR shock) and markets without ASR AEs (i.e., those with relatively low exposure to the ASR shock). Prior to 2019, product markets with ASR AEs were associated with significantly more research activity. However, after the ASR program is terminated and the data released, there is significant convergence in the number of device applications across the two groups. Notably, there is some convergence that occurs as early as 2017. As we discussed in Section 3.1, this coincides with the start of a wind-down period where the FDA began winding down the use of the program, but had not yet released the data. In subsequent analyses, we exploit this institutional feature to parse out mechanisms.

4.2 Effect on the Rate of Innovation

Panel A in Table 2 shows that the ASR shock (closure of the program and release of its data) leads to a significant and negative impact on the likelihood of a device application for a given firm-product market-year. Column 2 presents estimates from regressions that are fully saturated with both year fixed effects and product market fixed effects. It shows that

the ASR leads to a 19 percent ($e^{-0.207} - 1$) decline in the number of device applications in product markets that are more highly exposed to the ASR shock relative to those that are less exposed.

To explore the timing of the estimated effect, we estimate a dynamic version of Equation (2). Panel A of Figure 3 shows that the difference in the likelihood of a device application between firm-product markets in high versus low exposure product markets prior to 2019 is statistically indistinguishable from zero. After the ASR shock, we observe an immediate decline in the likelihood of a device application in High Exposure product markets.¹¹ The post-ASR shock decline remains large, negative, and statistically significant. The fairly quick response is consistent with the idea that firms may be withholding seeking applications of devices that are already “on the shelf.”

To examine changes within markets, we extend our analysis from the product market-year level to the firm-product market-year level. We construct a firm-product market-year dataset that includes only firm-product market pairs where the firm has at least one device approval, ensuring the sample reflects likely R&D activity and avoids mechanically inflating statistical significance.¹² We then adapt equation (2) to the firm-product market-year level, estimating the effect of the ASR shock using a specification that includes firm-product market and year fixed effects, with standard errors clustered at both the firm and product market levels. Given the relative rarity of device applications at this level, we estimate the effect of the shock on the likelihood of a device application within the focal firm and product market.¹³ The results, shown in Panel B of Table 2 and Figure 3, confirm that the ASR shock leads to a significant decline in the likelihood a device application at the firm-product market-year level.

¹¹Indeed, though the difference is statistically indistinguishable from zero, the number of device applications begin to converge around the phased wind-down of the program in 2017. We discuss this point further in Section 4.3.

¹²The resulting dataset includes 3,413 firms and 5,180 product markets, for a total of 782,474 firm-product market-year observations.

¹³In particular, for firm-product market-year f, p, t , we estimate $Y_{f,p,t} = \alpha + \beta Post_t \times HighExposure_{p,t} + \delta_{f,p} + \delta_t + \epsilon_{f,p,t}$. The trends shown in Panel B of Appendix Figure A1 provides support for this specification.

4.3 Mechanisms: Withholding and Information Effects

The decline in device applications following the ASR shock may reflect two distinct mechanisms: (i) the loss of firms’ ability to withhold their own negative information, and (ii) the disclosure of negative information about competitors’ products. Understanding these distinctions is important because they have different implications for how transparency policies shape firm innovation: the first mechanism operates through direct constraints on firms’ disclosure decisions, while the second mechanism operates through updating in response to shifts in the information environment. In this section, we leverage unique institutional details to shed further light on the relative importance of each mechanism.

4.3.1 ASR Program Wind-down and Public Disclosure

As described in Section 3.1, the ASR program officially ended in June 2019, when the FDA publicly released the full ASR database. However, the program began winding down in 2017, as the FDA gradually revoked exemptions for certain product markets and firms. This staggered rollback allows us to distinguish between the effects of losing the ability to withhold information (beginning in 2017) from the effects of the public information release of competitors’ information (beginning in 2019).

Panel A of Table 3 shows that, at the product market-year level, the decline in the number of device applications is significantly larger following the 2019 ASR data release than following the initial wind-down of the program. Panel B shows similar patterns at the firm-product market-year level following the 2019 release compared to the initial wind-down period. While the decline following the wind-down period is statistically significant, the decline following the data release is significantly larger. Together, these results suggest that, while the loss of withholding may matter, the broader release of competitor information plays a more salient role, on average, in shaping firms’ R&D decisions, on average.

4.3.2 Own Adverse Events and Competitor Disclosures

The results in Section 4.3.1 highlight the important role of changes in the information environment, particularly the public release of competitor information, in shaping firms' R&D decisions. However, this average effect may mask important heterogeneity in how firms respond, depending on whether they are directly affected by the loss of withholding or by newly available information about others. To provide further context, we examine whether firms respond differently depending on whether the disclosed AEs are their own or from competitors.

To do so, we conduct a firm-product market-year level analysis where we exploit variation in the source of ASR AE.¹⁴ Table 4 reports estimates from a firm-product market-year specification that interacts the source of the AE with the timing of the ASR policy change (wind-down vs. data release). Column 1 shows that when the disclosed AE originates from the focal firm, device applications decline significantly following the ASR program wind-down. This is consistent with firms responding to the inability to withhold their own negative information. In contrast, Column 2 shows that firms primarily respond to competitor AEs after the public release of ASR data in 2019, when that information becomes widely available.

Taken together, these results suggest that while public disclosure of competitor information is the primary driver of firms' R&D decisions, on average, the loss of withholding also matters, particularly for firms whose own AEs are newly exposed.

4.3.3 Spillovers Across Markets

While the previous section examines spillovers within the same product market, we now explore whether the effects of competitor disclosure extend to technologically related markets. If newly disclosed risks in one market shift expectations about products in about technologically similar markets, firms may reduce R&D investment even in markets not directly

¹⁴A product market-year level analysis would not allow us to separately identify the effects of an ASR AE from a given firm vs. those of another firm.

exposed to the ASR data release.

Table 5 provides evidence for such cross-market spillover effects. Panel A reports results at the product market-year level. Column 1 shows that device applications significantly decline in technologically similar product markets (as measured by predicate linkages). The effects are similar to the direct effects in Table 2, Panel A, Column 1, because a given product market may be linked to multiple product markets directly exposed to the ASR shock (i.e., High Exposure product markets). Column 2 confirms that these spillover effects persist even when High Exposure product markets are excluded. Panel B shows that patterns are similar at the firm-product market-year level.

Together with the results in Section 4.3.2, these results support the view that broader shifts in the information environment, within and across markets, play an important role in shaping firms' R&D decisions.

4.4 Robustness Checks and Heterogeneity

Online Appendix C presents a series of robustness checks and extensions to our baseline analyses. Below, we present a brief summary of our main findings.

In Appendix Table C1, we demonstrate the robustness of our results across different specifications and samples. Column 1 uses a continuous measure of product market level exposure to the ASR shock, as measured by the share of pre-2019 AEs in the ASR database relative to all AEs. Column 2 restricts the sample to product markets within the same device specialties as those represented in the ASR database. Column 3 implements a matched regression where we match product markets based on pre-2019 research intensity (above or below the median number of device applications) and device specialty.

We also address confounding from concurrent events, namely the Covid-19 pandemic. Although the ASR shock occurs before the pandemic and it is unclear whether Covid-19 would differentially affect product markets in the ASR database, we conduct two tests. First, in Column 4, we exclude product markets authorized for emergency use during the Covid-19

pandemic (e.g., ventilators and respiratory assistance devices) . Second, in Column 5, we address the possibility that firms with products in Covid-related product markets may have experienced broader firm-level shocks that could influence their R&D decisions across all product markets. To account for this, we exclude all devices from firms that had at least one product in a Covid-related product market. The results continue to hold.

To further characterize the nature of the ASR shock, we leverage differences in the size and composition of the the newly released AEs. In Online Appendix Table C2, Column 1 shows that that product markets with a larger absolute increase in publicly available AEs experience a significant decline in device applications. Column 2 examines whether the shock was greater in markets where ASR disclosure increased the product market’s relative share of total AEs (and therefore worsens external stakeholder perceptions of safety). We find that markets with larger increases in AE share also experienced a greater decline in applications, although this effect is not statistically significant at the product market level.

As firms’ responses likely depend on expected demand, we next examine whether the ASR shock has a larger effect in markets with more available substitutes. As a proxy for device-level substitutability, we first use the cumulative number of approved devices in the product market before 2019. While this captures potential alternatives, it may also reflect broader competition. To address this, we also use the cumulative number of firms with approved products before 2019, using total firms for product market–year regressions and rival firms (excluding the focal firm) for firm–product market–year regressions. In both cases, product markets below the median are classified as having low substitutability; those above are classified as high. Appendix Table C3 shows that the decline in device applications is significantly larger in markets with a high number of substitutes, consistent with firms being more willing to shift R&D investments when alternatives are available.

Finally, we examine heterogeneity by device type. Appendix Table C4 show the overall decline is devices with 510(k) approval, rather than PMA approval. The relatively moderate level of regulatory scrutiny for 510(k) devices may lead to greater variation in device quality,

potentially making firms more responsive to newly disclosed safety information in these markets.

5 Firm Adaptation

Having shed light on the immediate impact of the ASR shock on firms’ R&D investments and the underlying mechanisms, we now examine how firms adapt to a new information environment that mandates the disclosure of negative product information. We focus on three key dimensions: (i) portfolio reallocation, (ii) product attribute adaptation, and (iii) market entry.

As described in Section 2.3, firms’ adaptation responses likely depend on their awareness of the ASR program prior to the database’s release: Firms that were more aware likely respond both to the loss of withholding and to newly available information about competitors, while less aware firms may be more influenced by competitor disclosures. We proxy for awareness by defining “ASR aware” firms as those with device approvals in any ASR product market before the program ended and the database was released in 2019. As discussed in Section 2.2.1, firms active in product markets first associated with the ASR database in 2017 may have been notified of the program’s initiation. Given this and the typical two-year device lifecycle (Gelijns et al., 1991), we define ASR awareness as having approvals in product markets associated with the ASR database between 1997 and 2018.¹⁵ All other firms are considered “ASR naive.” Note that as defined, “ASR aware” firms are likely to encompass product market incumbents, while “ASR naive” firms are likely to encompass new entrants to a product market. Appendix Table D1 shows that ASR aware firms tend to have more device applications and more AEs.

¹⁵Our results are similar when using a significantly broader window for defining awareness, such as classifying firms as aware if they had approvals at any point before 2019.

5.1 Portfolio Reallocation

In response to the ASR shock, firms may respond by reallocating R&D investments in their portfolios. This may be particularly salient among ASR aware firms, who, given potential prior withholding behavior, may face heightened scrutiny and have incentives to shift R&D activity toward less exposed product markets. Alternatively, adjustment frictions may limit their ability to reallocate, leading firms to persist in existing markets despite increased risk.

To examine how firms reallocate their R&D investments across product markets, we restrict the sample to ASR aware firms and conduct firm-year analyses. The firm-year specification allows us to assess how a give firm reallocates R&D investments across different types of product markets. In particular, we estimate:

$$Y_{f,t} = \alpha + \beta Post_t \times HighFirmExposure_{f,t} + \delta_f + \delta_t + \epsilon_{f,t} \quad (2)$$

where $Y_{f,t}$ is a measure of R&D activity (e.g., indicator for any device application, number of device applications) for firm f in year t , $Post_t$ is an indicator for years after 2019, and $HighFirmExposure$ is an indicator for whether the focal firm has an adverse event in ASR in a product market prior to 2019. We include firm fixed effects (δ_f) and year fixed effects (δ_t) and estimate ordinary least squares models with heteroskedasticity-robust standard errors clustered at the firm level.

Table 6 presents results across four mutually exclusive product market types: all product markets (Column 1), High Exposure product markets (i.e., product markets with ASR AEs) (Column 2), other markets that are technologically similar to High Exposure product markets (Column 3), and other remaining markets (Column 4). Column 1 shows that ASR aware firms reduce their overall device applications following the ASR shock. Columns 2 and 3 reveal that these reductions are concentrated in High Exposure product markets and, to a lesser degree, in other markets that are technologically similar to High Exposure product markets, which is consistent with the existence of direct effects and cross-market spillover

effects of disclosure. Notably, Column 4 shows no significant decline in other markets, consistent with targeted reallocation rather than a uniform decline in activity.

Taken together, these findings suggest that ASR aware firms do not reduce their R&D investments uniformly across markets. Instead, they strategically reallocate investment in response to changes in scrutiny and perceived risk.

5.2 Product Attribute Adaptation

The decline in R&D investments by some firms may have created opportunities for other firms that were those less reliant on withholding and likely to be more responsive to changes in the information environment (i.e., ASR naive firms). In particular, as ASR aware firms reallocate their R&D investments away from High Exposure product markets and technologically similar markets, such markets may become less competitive and more attractive to new entrants who might invest in more novel, safer, and higher quality devices. However, these opportunities may be dampened if the ASR shock may have broadly discouraged R&D investments in High Exposure product markets, regardless of any potential product attributes.

To examine this, we focus on ASR naive firms. We conduct a product market-year analysis that allows us to examine how new and existing firms change the nature of their products in response to changed information environment.¹⁶

We begin by examining product novelty using predicate characteristics. Column 1 of Appendix Table 7 shows that, following the ASR shock, in High Exposure product markets, device applications from ASR naive firms are more likely to reference a novel predicate. Column 2 suggests that, conditional on using a predicate, such firms typically rely on newer predicates, suggesting that they may be developing devices based on more novel technologies.

Next, we examine whether firms shift towards safer devices. Column 3 shows share of safety-related patents from ASR naive firms increases in High Exposure product markets,

¹⁶In contrast, a firm-product market-year or firm-year analysis requires that a firm exist prior to the ASR shock.

suggesting a shift toward products with improved safety profiles. Finally, we characterize device quality using forward citations within two years of the patent grant date.¹⁷ Column 4 shows that following the ASR shock, the number of citations per patents from ASR naive firms increases in High Exposure product markets.

Taken together, the results suggest that ASR naive firms respond to the ASR shock by improving the nature of their devices through developing more novel, safety-oriented, and higher-quality products.

Before proceeding, a natural question might be: in addition to reallocating their R&D investments, do ASR aware firms also shift their product attributes?¹⁸ Appendix Table D2 shows among ASR aware firms experience a significant decline in the likelihood of referencing a novel predicate. This pattern is consistent with the idea that the ability to engage in withholding may have led such firms to previously invest in more novel, riskier products.

5.3 Market Entry

Having established that the closure of the ASR program and the release of its data lead to a shift in product reallocation and attribute adaptation, we now examine how it reshaped broader market dynamics. Using a product market-level panel, we analyze changes in the number of firms types, which differ in how they relate to the focal market: (i) market incumbents (i.e., firms with prior applications in the focal market), (ii) firms entering a new market within the industry, and (iii) firms entering the medical device industry for the first time.¹⁹

Column 1 of Table 8 shows that there is an overall decline in the number of research-active firms among affected product markets. Column 2 shows that this decline is driven primarily

¹⁷The citation window is limited by the timing of our analysis.

¹⁸As indicated by Appendix Table D1, there are important differences across ASR firms aware and naive firms. For example, within the average product market-year, ASR aware firms submit 0.25 510(k) device applications (i.e., the type of applications that require a predicate, while ASR naive firms submit 0.16.

¹⁹While conceptually related to our earlier definitions of ASR aware and ASR naive firms, these classifications are distinct: they are based on a firm’s relationship to the focal market (e.g., incumbent or entrant) regardless of the firm’s prior use of product markets with AEs in ASR.

by market incumbents reducing reinvestment in the focal market. In contrast, Column 3 shows that entry by existing firms into new markets also falls, and Column 4 shows a smaller but significant decline in new-to-industry entrants.

Together, this shows how disclosure reshapes R&D activity across the broader market landscape by deterring reinvestment by incumbents and slowing entry into High Exposure product markets. However, it is important to note that these are relatively short-term effects. As a result, while our prior results suggest that non-ASR aware firms (which include new entrants) respond by developing more novel, safer, and higher-quality products, these responses may initially be outweighed by the exit of incumbents. However, over time, the influence of new entrants may grow, potentially shifting the long-term trajectory of innovation in these product markets.

6 Alternative Explanations

In this section, we address several potential explanations that would be consistent with our main results.

6.1 Role of Firm Reputation

One alternative explanation for our results is that shifts in firms' R&D decisions are primarily driven by reputational concerns rather than strategic decision making. However, if this were the case, firms might reduce their overall R&D activity following the ASR shock. However, our analysis of firms' reallocation decisions (in Table ??) indicates a more nuanced response: there is substantial heterogeneity in the extent to which they decrease their R&D activity across product markets. This pattern suggests that firms are not broadly retreating from R&D activity but are reallocating their efforts toward markets perceived as lower risk. Our main results are therefore unlikely to be primarily driven by shifts in firm reputation.

6.2 Role of Regulatory Scrutiny

Since we only able to observe accepted device applications, an alternative explanation for the observed decline in device applications is that it reflects increased risk aversion by the regulator . However, this concern is mitigated by the fact that most regulators were already aware of the ASR program before its termination and data disclosure. Further, shows an aggregate decline in patenting activity (an activity that takes place well before FDA review and approval of devices). While firms may take regulatory scrutiny into account while making their R&D decisions, the decline in patenting suggests that regulatory risk is unlikely to be a key driver of the observed patterns in post-ASR R&D activity.

7 Conclusion

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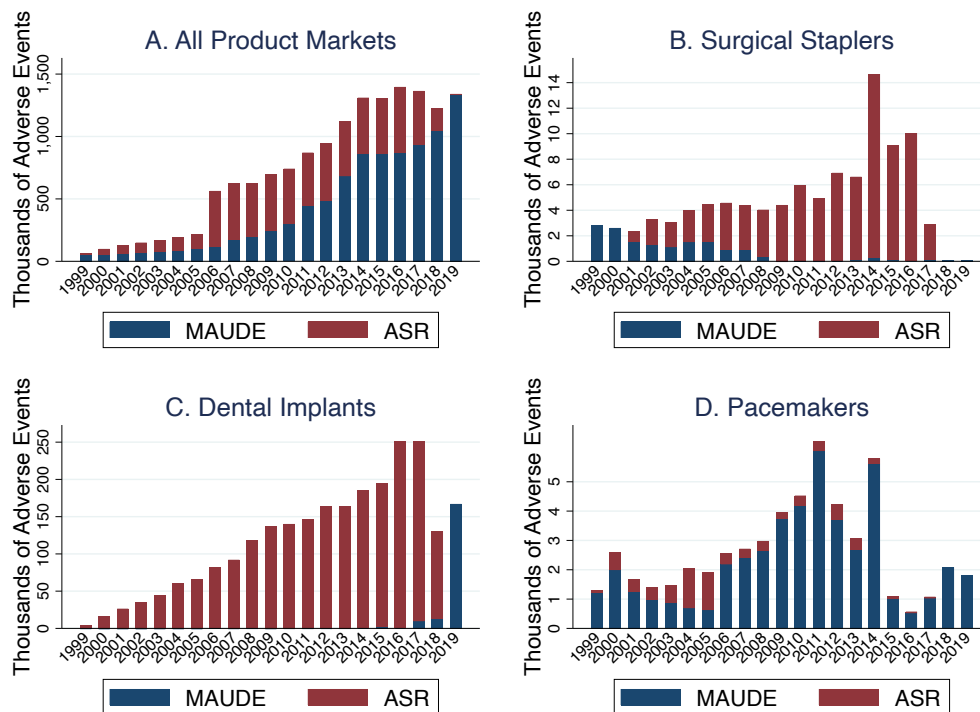
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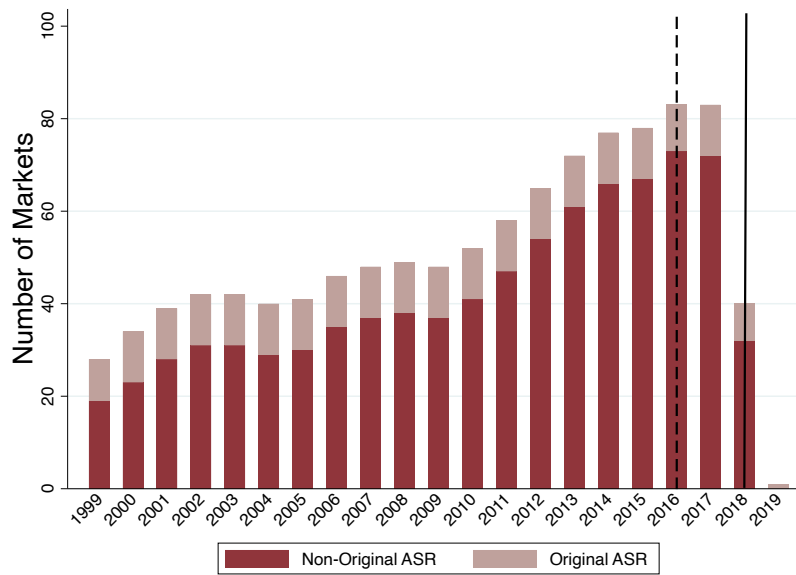
Figures and Tables

Figure 1: TRENDS IN THE NUMBER OF ADVERSE EVENTS IN ASR AND MAUDE



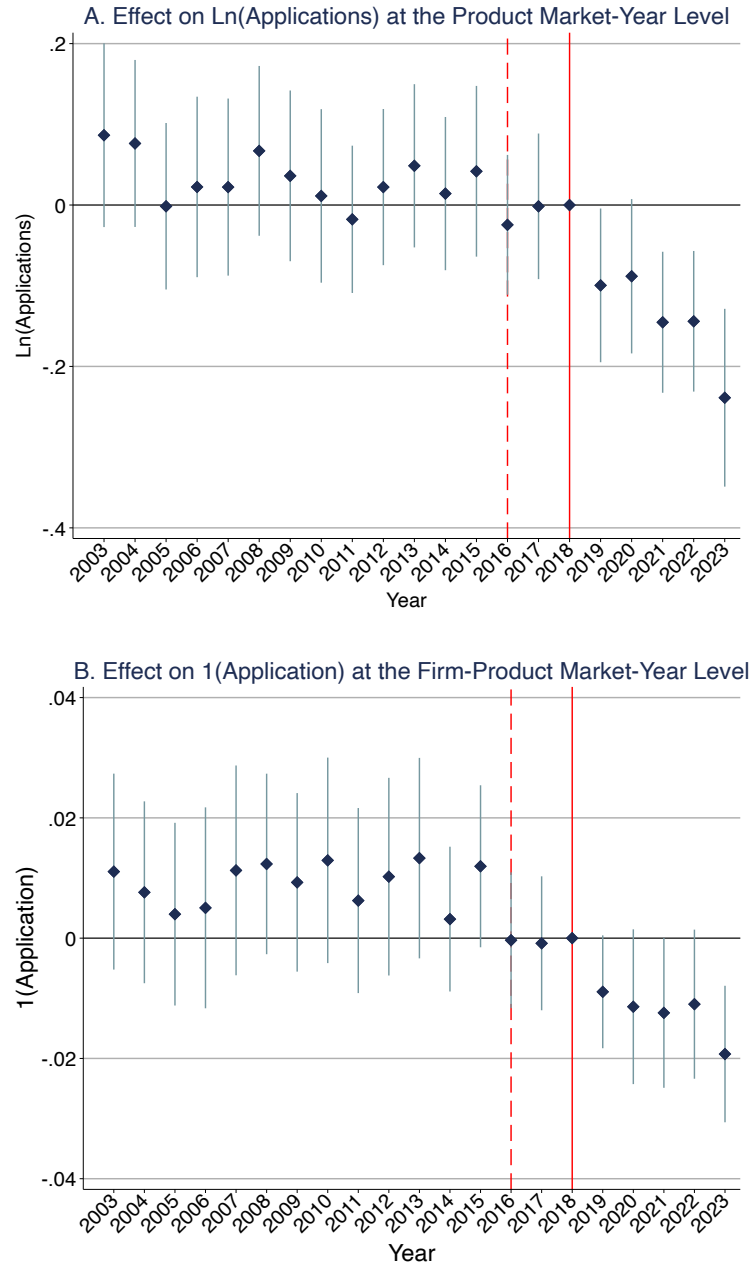
NOTE: This figure shows the trends in the number of MAUDE and ASR adverse events. The sample includes all adverse events submitted to either database between 1999 and 2019.

Figure 2: TRENDS IN PRODUCT MARKETS IN ASR



NOTE: This figure shows the number of product markets associated with adverse events in the ASR database. “Original ASR” refers to product markets that the FDA approved for participation in the ASR program in 1997, when the program originated. All other product markets in ASR are categorized as “Non-Original ASR.” The dotted vertical line reflects the year before the FDA began winding down the program. The solid vertical line indicates the year of the program was fully terminated and its data was publicly released.

Figure 3: EFFECT OF ASR RELEASE ON DEVICE APPLICATIONS



NOTE: This figure plots the change in device applications following the closure of the ASR program and public release of its data. Panel A documents product market-year level estimates of the effect on the log number of device applications. Estimates from OLS regressions with product market and year fixed effects. Standard errors are clustered at the product market level. Panel B presents firm-product market-year level estimates of the the effect on the likelihood of a device application. Estimates from OLS regressions with firm-product market and year fixed effects. Standard errors are clustered at the firm and product market level. The dotted vertical line reflects the year before the FDA began winding down the program. The solid vertical line indicates the year of the program was fully terminated and its data was publicly released.

Table 1: SUMMARY STATISTICS AT THE PRODUCT MARKET-YEAR LEVEL

	Count	Mean	SD	Min	Max
# MAUDE AEs (2003 to 2019)	88,060	66.00	1,072.47	0	161,787
# ASR AE (2003 to 2019)	88,060	47.52	2,746.12	0	302,826
High Exposure Market	108,780	0.01	0.12	0	1
Tech. Similar to High Exposure Market	108,780	0.03	0.18	0	1
# Applications	108,780	0.42	2.25	0	73
1(Novel Predicate)	108,780	0.05	0.22	0	1
Predicate Age (Years)	11,855	3.64	4.84	0	42
Share of Safety Patents	35,094	0.03	0.09	0	1
# Patent Citations Per Patent	35,094	2.02	7.67	0	171
# Firms	108,780	14.52	137.60	0	7,372
# Firms with Prior Approval in Market (Market Incumbents)	108,780	11.12	110.31	0	6,014
# Firms with No Prior Approval in Market (New to Market)	108,780	2.33	20.74	0	1,099
# Firms with No Prior Approval in Industry (New to Industry)	108,780	1.07	16.92	0	1,670

NOTE: This table shows summary statistics of key characteristics at the product market level. The number of observations is smaller for “Predicate Age (Years)” and “# Patent Citations Per Patent” because these measures are only defined for product market-years with at least one 510(k) device application or one patent, respectively.

Table 2: EFFECT OF ASR RELEASE ON DEVICE APPLICATIONS

	(1)	(2)
<i>A. Product market-year level, dependent variable: $\ln(\text{applications})$</i>		
Post Release x High Exposure	0.273*** (0.0722)	-0.207*** (0.0421)
Mean of Dep. Var.	0.147	0.147
Observations	108,780	108,780
Year FE	YES	YES
Market FE	NO	YES
<i>B. Firm-product market-year level, dependent variable: $1(\text{application})$</i>		
Post Release x High Exposure	0.00149 (0.00657)	-0.0251*** (0.00646)
Mean of Dep. Var.	0.0433	0.0434
Observations	782,474	782,441
Year FE	YES	YES
Firm-Market FE	NO	YES

NOTE: This table reports DID estimates of the change in device applications following the closure of the ASR program and the public release of its data. Estimates are from OLS models. Panel A documents product market-year level estimates of the effect on the log number of device applications. Standard errors are clustered at the product market level. Panel B presents firm-product market-year level estimates of the effect on the likelihood of a device application. Standard errors are clustered at the firm and product market level. *** $p < 0.01$, ** $p < 0.05$, * $p < 0.1$.

Table 3: EFFECT OF ASR WIND-DOWN AND DATA RELEASE

	(1)
<i>A. Product market-year level, dependent variable: $\ln(\text{applications})$</i>	
Post WindDown x High Exposure	-0.0294 (0.0437)
Post Release x High Exposure	-0.182*** (0.0425)
Mean of Dep. Var.	0.147
Observations	108,780
Year FE	YES
Market FE	YES
<i>B. Firm-product market-year level, dependent variable: $1(\text{application})$</i>	
Post WindDown x High Exposure	-0.0112** (0.00553)
Post Release x High Exposure	-0.0155*** (0.00533)
Mean of Dep. Var.	0.0434
Observations	782,441
Year FE	YES
Firm-Market FE	YES

NOTE: This table reports DID estimates of the change in device applications following the closure of the ASR program and the public release of its data, and separately accounts for the wind-down of the ASR program. The effect of the initial (not publicly announced) policy wind-down, which started in 2017, is separately estimated using *Post WindDown*. The effect of the ASR full closure and data release is estimated using *Post Release*. Estimates are from OLS models. Panel A documents product market-year level estimates of the effect on the log number of device applications. Standard errors are clustered at the product market level. Panel B presents firm-product market-year level estimates of the effect on the likelihood of a device application. Standard errors are clustered at the firm and product market level. ***p<0.01, **p<0.05, *p<0.1.

Table 4: OWN ADVERSE EVENTS AND COMPETITOR DISCLOSURES

	Dependent variable: 1(application)	
	(1)	(2)
Post WindDown x High Exposure (ASR Event from Same Firm)	-0.0346* (0.0194)	
Post WindDown x High Exposure (ASR Event from Different Firm)		-0.00949* (0.00576)
Post Release x High Exposure (ASR Event from Same Firm)	-0.00753 (0.0169)	
Post Release x High Exposure (ASR Event from Different Firm)		-0.0160*** (0.00562)
Mean of Dep. Var.	0.0434	0.0434
Observations	782,441	782,441
Year FE	YES	YES
Firm-Market FE	YES	YES

NOTE: This table reports firm-product market-year level DID estimates of the change in the likelihood of a medical device application following the closure of the ASR program and the public release of its data, and separately accounts for whether the ASR AE comes from the focal firm or a different firm. Estimates are from OLS models. Standard errors are clustered at the firm and product market level. *** $p < 0.01$, ** $p < 0.05$, * $p < 0.1$.

Table 5: EFFECT ON TECHNOLOGICALLY RELATED MARKETS

	Full Sample (1)	Excl. High Exposure Markets (2)
<i>A. Product market-year level, dependent variable: $\ln(\text{applications})$</i>		
Post Release x Tech. Similar to High Exposure Market	-0.258*** (0.0364)	-0.220*** (0.0401)
Mean of Dep. Var.	0.147	0.141
Observations	108,780	107,247
Year FE	YES	YES
Market FE	YES	YES
<i>B. Firm-product market-year level, dependent variable: $1(\text{application})$</i>		
Post x Tech. Similar to High Exposure Market	-0.0232*** (0.00378)	-0.0196*** (0.00385)
Mean of Dep. Var.	0.0434	0.0424
Observations	782,441	746,310
Year FE	YES	YES
Firm-Market FE	YES	YES

NOTE: This table reports DID estimates of the change in device applications following the closure of the ASR program and the public release of its data, in technologically related product markets. Estimates are from OLS models. Panel A documents product market-year level estimates of the effect on the log number of device applications. Standard errors are clustered at the product market level. Panel B presents firm-product market-year level estimates of the effect on the likelihood of a device application. Standard errors are clustered at the firm and product market level. ***p<0.01, **p<0.05, *p<0.1.

Table 6: PRODUCT REALLOCATION ACROSS MARKETS, AMONG ASR AWARE FIRMS

	Dependent variable: Ln(applications)			
	All Markets	High Exposure Markets	Other Markets Tech-Similar High Exposure Markets	Other Markets
	(1)	(2)	(3)	(4)
Post Release x High Firm Exposure	-0.312** (0.121)	-0.231*** (0.0767)	-1.054*** (0.189)	-0.170 (0.122)
Mean of Dep. Var.	0.733	0.185	0.274	0.515
Observations	7,956	7,956	7,956	7,956
Year FE	YES	YES	YES	YES
Firm FE	YES	YES	YES	YES

NOTE: This table reports DIDestimates of the change in device applications allocation across mutually-exclusive product market types, following the closure of the ASR program and the public release of its data. The sample is restricted to ASR aware firms. Observations at the firm-year level. “High Firm Exposure” is an indicator for whether the firm has an AE in the ASR database. 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 7: PRODUCT ATTRIBUTE ADAPTATION, AMONG ASR NAIVE FIRMS

	1(Novel Predicate) (1)	Ln(Predicate Age) (2)	Share of Safety Patents (3)	Citations Per Patent (4)
Post Release x High Exposure	0.0147*** (0.00543)	-0.292*** (0.0536)	0.0527** (0.0235)	0.400* (0.226)
Mean of Dep. Var.	0.0210	0.707	0.0335	0.787
Observations	108,780	6,077	9,018	9,018
Year FE	YES	YES	YES	YES
Market FE	YES	YES	YES	YES

NOTE: This table reports DIDestimates of the change in medical device attributes following the closure of the ASR program and the public release of its data. The sample is restricted to ASR naive firms. Observations at the product market-year level. Estimates are from OLS models. Robust standard errors, clustered at the product market level, are shown in parentheses. The sample in Column 2 is restricted to product market-years with at least one 510(k) device application (which references predicates). The sample in Columns 3 and 4 is restricted to product market-years with at least one patent. ***p<0.01, **p<0.05, *p<0.1.

Table 8: EFFECT OF ASR RELEASE ON NUMBER OF FIRMS

	Ln(All Firms)	Ln(Market Incumbents)	Ln(New to Market)	Ln(New to Industry)
	(1)	(2)	(3)	(4)
Post Release x High Exposure	-0.415*** (0.0936)	-0.366*** (0.0949)	-0.279*** (0.0745)	-0.200*** (0.0744)
Mean of Dep. Var.	0.432	0.334	0.170	0.0618
Observations	108,780	108,780	108,780	108,780
Year FE	YES	YES	YES	YES
Market FE	YES	YES	YES	YES

NOTE: This table reports DID estimates of the change in the number of firms following the closure of the ASR program and the public release of its data. Observations at the product 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.

Negative Product Disclosure and Innovation

Appendix

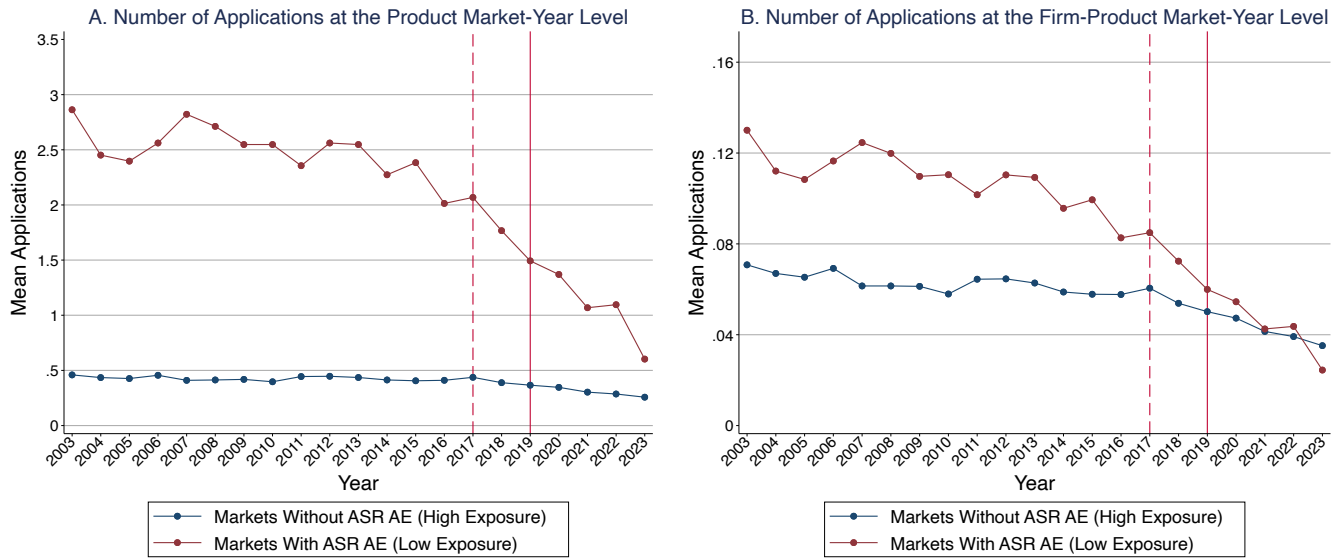
Appendix A Additional Summary Statistics

Table A1: DIFFERENCES IN ADVERSE EVENTS

	MAUDE		ASR		T-Test <i>p</i> -value
	Mean	SD	Mean	SD	
Total	54.26	965.67	38.91	2,471.68	0.06*
Death (%)	2.52	10.54	0.08	0.93	0.00***
Serious (%)	10.59	24.54	37.49	46.36	0.00***
Other (%)	46.63	41.53	62.41	46.41	0.00***
Unknown (%)	48.91	40.71	0.01	0.13	0.00***

NOTE: This table compares the number and composition of adverse events in the MAUDE and ASR databases, within each year. The sample includes all adverse events submitted to either database between 1999 and 2019. “Other” refers to events that are not classified as leading to deaths and serious events (e.g., events that required interventions, malfunctions). *** $p < 0.01$, ** $p < 0.05$, * $p < 0.1$.

Figure A1: TRENDS IN DEVICE APPLICATIONS



NOTE: This figure shows the average number of device applications in markets with adverse events in the ASR database and those without, over time. Panel A shows the average number of applications in a product market over time. Panel B shows the average number of applications in a firm-product market over time.

Appendix B Data Construction

Figure B1: EXAMPLE: DRUG APPLICATION K182561

Device Classification Name	<u>System, Image Processing, Radiological</u>	
510(k) Number	K182561	
Device Name	UroNav (Version 3.0)	
Applicant	Invivo Corporation	
	3545 SW 47th Ave. Gainesville, FL 32608	
Applicant Contact	Kenneth M. Revennaugh	
Correspondent	REGULATORY TECHNOLOGY SERVICES, LLC 1000 Westgate Drive, Suite 510k Saint Paul, MN 55114	
Correspondent Contact	Mark Job	
Regulation Number	<u>892.2050</u>	
Classification Product Code	LLZ	
Date Received	09/18/2018	Product market = Medical imaging management system
Decision Date	10/19/2018	
Decision	Substantially Equivalent (SESE)	
Regulation Medical Specialty	Radiology	
510k Review Panel	Radiology	
Summary	<u>Summary</u>	
Type	Traditional	
Reviewed by Third Party	Yes	
Combination Product	No	
Predetermined Change Control Plan Authorized	No	

NOTE: This is a device application record for device application K182561.

Appendix B.1 Linking Product Markets Using Predicates

Figure B2: EXAMPLE: IDENTIFYING PREDICATE DEVICES IN APPLICATION SUMMARY DOCUMENT

images of the target organ and the current and the projected future path of the interventional instrument taking into account patient movement. Other software features include patient data management, multi-planar reconstruction, segmentation, image measurements and 2D/3D image registration.

UroNav is intended for treatment planning and guidance for clinical, interventional and/or diagnostic procedures. The device is intended to be used in interventional and diagnostic procedures in a clinical setting. Example procedures include, but are not limited to image fusion for diagnostic clinical examinations and procedures, soft tissue biopsies, soft tissue ablations and placement of fiducial markers.

Predicate Device Information & Comparison

Predicate Devices Name	Predicate 510(k) Submission References
UroNav (Version 2.0)	K153073 (Primary)
PercuNav	K121498 (Reference)

**Product market =
Computed
tomography x-ray
system**

The design, function, and specifications of UroNav 3 are similar to the identified legally marketed predicate devices. Similar to UroNav (Version 2.0) and PercuNav, UroNav 3 provides image-guided interventional planning and navigation for prostate procedures, the ability to view and capture live 2D ultrasound data to create reconstructed 3D ultrasound images/models and the ability to fuse and register these images with those acquired and imported from other DICOM-based imaging devices. Similar to all of the above listed predicate devices, UroNav also performs other viewing and image-processing functions such as image registration, multi-planar reformats and includes tools to segment, measure and annotate images. Each of the devices can also output selected image views, processed data and user-defined reports.

NOTE: This is an excerpt of a summary document (for device application K182561, as shown in Figure B1) that lists the applicant device's predicate devices. Device application is associated with product market LLZ ("Medical Image Management System"). One of its predicate devices, K121498, is associated with product market JAK ("Computed tomography x-ray system").

Appendix C Robustness Checks and Heterogeneity

Table C1: IMPACT OF ASR RELEASE ON DEVICE APPLICATIONS,
ALTERNATIVE SPECIFICATIONS AND SAMPLES

	Continuous Treatment	Restricted Specialties	Matched Regression	Excl. Covid Product Markets	Excl. Covid Product Markets and Firms
	(1)	(2)	(3)	(4)	(5)
<i>A. Product market-year level, dependent variable: $\ln(\text{applications})$</i>					
Post Release x High Exposure Share	-0.310*** (0.0944)				
Post Release x High Exposure		-0.206*** (0.0422)	-0.197*** (0.0506)	-0.204*** (0.0421)	-0.178*** (0.0390)
Mean of Dep. Var.	0.147	0.154	0.269	0.152	0.128
Observations	108,780	85,604	90,874	105,363	105,363
Year FE	YES	YES	YES	YES	YES
Market FE	YES	YES	YES	YES	YES
<i>B. Firm-product market-year level, dependent variable: $1(\text{application})$</i>					
Post Release x High Exposure Share	-0.0461*** (0.0177)				
Post Release x High Exposure		-0.0253*** (0.00646)	-0.0228*** (0.00699)	-0.0251*** (0.00646)	-0.0220*** (0.00594)
Mean of Dep. Var.	0.0434	0.0426	0.0491	0.0434	0.0461
Observations	782,441	662,032	727,975	781,292	609,379
Year FE	YES	YES	YES	YES	YES
Market FE	YES	YES	YES	YES	YES

NOTE: This table reports DID estimates from alternative specifications and samples of the change in device applications following the closure of the ASR program and the public release of its data. Estimates are from OLS models. Panel A documents product market-year level estimates of the effect on the log number of device applications. Standard errors are clustered at the product market level. Panel B presents firm-product market-year level estimates of the effect on the likelihood of a device application. Standard errors are clustered at the firm and product market level. Column 1 uses a continuous measure of product market level exposure to the ASR shock, as measured by the share of pre-2019 AEs in the ASR database relative to all AEs. Column 2 restricts the sample to product markets within the same device specialties as those represented in the ASR database. Column 3 implements a matched regression where we match product markets based on pre-2019 research intensity (above or below the median number of device applications) and device specialty. Column 4 excludes product markets authorized for emergency use during the Covid-19 pandemic. Column 5 exclude all devices from firms that had at least one product in a Covid-related product market (in Panel A, the outcome includes only applications from firms without any devices in Covid-related product markets; in Panel B, we drop all observations linked to firms with at least one device in a Covid-related product market.). *** $p < 0.01$, ** $p < 0.05$, * $p < 0.1$.

Table C2: IMPACT OF ASR RELEASE ON DEVICE APPLICATIONS,
BY CHANGING AE LEVELS AND RELATIVE SHARES

	(1)	(2)
<i>A. Product market-year level, dependent variable: Ln(applications)</i>		
Post Release x Difference in AE Levels/1000000	-0.481*** (0.0216)	
Post Release x Difference in AE Share Across Markets		-1.196 (3.100)
Mean of Dep. Var.	0.147	0.147
Observations	108,780	108,780
Year FE	YES	YES
Market FE	YES	YES
<i>B. Firm-product market-year level, dependent variable: 1(application)</i>		
Post Release x Difference in AE Levels/1000000	-0.0623*** (0.00457)	
Post Release x Difference in AE Share Across Markets		-0.499*** (0.186)
Mean of Dep. Var.	0.0434	0.0434
Observations	782,441	782,441
Year FE	YES	YES
Firm-Market FE	YES	YES

NOTE: This table reports DID estimates of the effect of the ASR data release on device applications and directly examines the effect of changing AE levels and relative shares. *Difference in AE Levels/1000000* is the number of ASR AEs (in millions). *Difference in Share of AEs Across PCs* is the change in a product market's share of adverse events (across all product markets) before and after incorporating ASR events. Estimates are from OLS models. Panel A documents product market-year level estimates of the effect on the log number of device applications. Standard errors are clustered at the product market level. Panel B presents firm-product market-year level estimates of the effect on the likelihood of a device application. Standard errors are clustered at the firm and product market level. ***p<0.01, **p<0.05, *p<0.1.

Table C3: IMPACT OF ASR RELEASE ON DEVICE APPLICATIONS,
HETEROGENEITY IN SUBSTITUTABILITY

	Device Substitutability		Firm Substitutability	
	Low (1)	High (2)	Low (3)	High (4)
<i>A. Product market-year level, dependent variable: Ln(applications)</i>				
Post Release x High Exposure	-0.0222*** (0.00222)	-0.153*** (0.0443)	-0.0230*** (0.00239)	-0.163*** (0.0443)
Mean of Dep. Var.	0.0167	0.316	0.0194	0.285
Observations	61,383	47,397	56,490	52,290
Year FE	YES	YES	YES	YES
Market FE	YES	YES	YES	YES
<i>B. Firm-product market-year level, dependent variable: 1(application)</i>				
Post Release x High Exposure	-0.0124*** (0.00214)	-0.0193*** (0.00651)	-0.00702*** (0.00267)	-0.0219*** (0.00752)
Mean of Dep. Var.	0.0105	0.0509	0.0205	0.0656
Observations	146,633	635,808	386,106	396,335
Year FE	YES	YES	YES	YES
Firm-Market FE	YES	YES	YES	YES

NOTE: This table reports DID estimates of the effect of the ASR data release on device applications, across product markets with varying levels of substitutability. Panel A documents product market-year level estimates of the effect on the log number of device applications. Standard errors are clustered at the product market level. Panel B presents firm-product market-year level estimates of the effect on the likelihood of a device application. Standard errors are clustered at the firm and product market level. Product markets whose cumulative number of device applications before 2019 is below (above) the median is considered to have low (high) substitutability. Product markets whose research active firms (in Panel A) or research active rivals (in Panel B) before 2019 is below (above) the median is considered to have low (high) substitutability. ***p<0.01, **p<0.05, *p<0.1.

**Table C4: IMPACT OF ASR RELEASE ON DEVICE APPLICATIONS,
HETEROGENEITY BY DEVICE APPROVAL TYPE**

	510k Applications (1)	PMA Applications (2)
<i>A. Product market-year level, dependent variable: $\ln(\text{applications})$</i>		
Post Release x High Exposure	-0.194*** (0.0428)	-0.0139*** (0.00496)
Mean of Dep. Var.	0.144	0.00319
Observations	108,780	108,780
Year FE	YES	YES
Market FE	YES	YES
<i>B. Firm-product market-year level, dependent variable: $1(\text{application})$</i>		
Post Release x High Exposure	-0.0242*** (0.00651)	-0.000897** (0.000411)
Mean of Dep. Var.	0.0427	0.000658
Observations	782,441	782,441
Year FE	YES	YES
Firm-Market FE	YES	YES

NOTE: This table reports DID estimates of the effect of the ASR data release on device applications, across devices with different approval types. Panel A documents product market-year level estimates of the effect on the log number of device applications. Standard errors are clustered at the product market level. Panel B presents firm-product market-year level estimates of the effect on the likelihood of a device application. Standard errors are clustered at the firm and product market level. *** $p < 0.01$, ** $p < 0.05$, * $p < 0.1$.

Appendix D Firm Adaptation

Table D1: SUMMARY STATISTICS: FIRMS WITH AND WITHOUT APPROVALS IN MARKETS WITH ASR AEs

	ASR Naive Firms		ASR Aware Firms		T-Test <i>p</i> -value
	Mean	SD	Mean	SD	
# MAUDE AEs	3.20	83.59	1,039.69	10,816.16	0.00***
# ASR AE	0.00	0.00	381.06	7,491.46	0.00***
# Applications	0.32	0.99	3.65	10.39	0.00***

NOTE: This table compares firms with approvals without pre-2019 approvals in markets with ASR AEs (“ASR Naive firms”) and firms with pre-2019 approvals in markets with ASR AEs (“ASR Aware firms”).

Table D2: PRODUCT ATTRIBUTE ADAPTATION, AMONG ASR AWARE FIRMS

	1(Novel Predicate) (1)	Ln(Predicate Age) (2)	Share of Safety Patents (3)	Citations Per Patent (4)
Post Release x High Exposure	-0.0930*** (0.0226)	0.114 (0.0956)	0.00649 (0.00630)	-0.609 (0.811)
Mean of Dep. Var.	0.0320	0.790	0.0252	2.103
Observations	108,780	7,854	33,749	33,749
Year FE	YES	YES	YES	YES
Market FE	YES	YES	YES	YES

NOTE: This table reports DIDestimates of the effect of the ASR data release on changes in product attributes. The sample is restricted firms with prior applications in a product market with adverse events in ASR. Observations at the product market-year level. Estimates are from OLS models. The sample in Columns 1 and 2 are restricted to product market-years with at least one 510(k) device application (which reference predicates). The sample in Columns 3 and 4 is restricted to product market-years with at least one patent. Robust standard errors, clustered at the product market level, are shown in parentheses. *** $p < 0.01$, ** $p < 0.05$, * $p < 0.1$.