Negative Product Disclosure and Innovation*

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Abstract

Disclosure mandates force firms—and their rivals—to reveal information. We investigate how mandated negative product disclosure shapes the rate and direction of subsequent medical 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 affected device innovation declined by 17 percent, driven primarily by information effects rather than withholding effects. While the overall rate of innovation declined, new entrants introduced more novel and higher quality devices. Incumbent firms introduced safer, higher quality devices and shifted their innovation efforts to unaffected markets. The number of R&D active firms in affected markets also declined. These findings show that mandatory negative product disclosure may decrease the rate of innovation but also re-direct it towards more novel, safer, and higher quality new products.

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1 Introduction

Firms' research and development (R&D) decisions are shaped by available product information (Arrow, 1962; Nelson, 1982; Cohen and Levinthal, 1989). There are two sides to this. First, their choices depend on what they can withhold about their own innovations once on the market. Second, their choices depend on what they observe about others marketed innovations, including when things go wrong. How will firms respond when they—and their competitors—are required to disclose negative information about their products?

Governments often mandate negative product information disclosure—for instance, timely and comprehensive disclosure of any adverse events associated with medical devices—in the public interest. Such mandates decreased a firm's ability to withhold their own adverse events while increasing information about those of others. While withholding effects on innovation are somewhat straightforward—i.e., decreased expectations of withholding negative information increase the costs of generating novel and potentially risky new products—informational effects are more complex. Increased negative information may increase public scrutiny in general, leading firms to decrease innovation. At the same time information about the problems with rivals' products may cause firms' to learn and improve their innovations and thereby impact R&D decisions. The overall result may not simply be a decrease in the rate of innovation, but have broader effects including firms adapting product attributes, reallocating their R&D investment, and entering and exiting differentially affected 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. Prior research has focused on endogenous negative disclosure of typically pre-market information, and has largely examined competitors' responses (e.g., Ball et al. 2018; Krieger 2021). We therefore know relatively little about how firms change their R&D investment decisions in response to public disclosure of their own negative information, and the effects on overall innovation. To investigate this

question, we leverage the unique features of the U.S. medical device industry, including an exogenous increase in mandatory disclosure of negative product information alongside the release of millions of historical adverse events (AEs). We examine how this shock, which eliminated discretion in withholding and increased negative product information shaped firm innovation, by analyzing (i) its effect on the rate of innovation, (ii) the underlying mechanisms (i.e., loss of withholding and increased access to competitors' information), and (iii) how firms adapt their R&D investments, i.e., changes in the direction of innovation.

Beginning in 1999, the U.S. Food and Drug Administration (FDA), implemented the Alternative Summary Report (ASR) program, which allowed AEs from a selected set of medical device markets to not be publicly disclosed.[1] In June 2019, the FDA ended the ASR program, and and released all historical AE data, covering 6 million reports including deaths, serious injuries, and malfunctions.[2] Using a difference-in-differences (DID) design, we compare innovation outcomes across product markets differentially exposed to the ASR program cessation and associated AE data release. At the market-year level, we find a reduction in new device applications of 17 percent.

To shed light on the drivers of this decline, we investigate two mechanisms: (i) loss of the ability to withhold own negative product quality information, or the *withholding effect* and, (ii) newly disclosed information about their rivals' AEs, or the *information effect*. While we find evidence of the presence of both mechanisms, several findings indicate that much of the decline was driven by information effects. First, the bulk of the decrease aligns with the release of ASR data in 2019, not with an earlier wind-down period beginning in 2017 when firms began losing their ability to withhold information. Second, the post-2019 negative effects are driven by firms responding to the release of competitors' AEs, that is, those that had not used the ASR program themselves. Third, innovation also declines in technologically

[1] In contemporary work, Galasso and Luo (2024) use the ASR program termination as an instrument for litigation in estimating the effects on subsequent innovation.

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

related, but not directly exposed, markets.[3] 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 leads to a decline in the rate of innovation, firms may also adapt their R&D investments in response to the changed disclosure and information environment. These adaptation responses will have implications for not only the overall rate, but also the nature and direction of innovation. To explore firm-level adaptation, we distinguish between "ASR aware" firms–incumbents in ASR product markets—that are likely to experience both *withholding* and *information* effects, and "ASR naive" firms that are likely to be primarily affected by *information*. We find that ASR aware firms shift towards safer and higher quality R&D investments in exposed markets, and also reallocate R&D investment away from exposed markets. In contrast, ASR naive firms—those who entered ASR product markets after the shock—introduce more novel products in exposed markets. The disclosure also reshapes markets: the number of research-active firms in exposed markets declines overall, driven largely by incumbent exit.[4] Taken together, these findings show that mandated disclosure of negative product information shapes not only the rate of innovation, but also its direction, including the types of new products developed, the markets in which firms choose to compete, and market structure.

This paper adds to growing literature on the relationship between R&D quality disclosure and innovation (see, e.g., Dranove and Jin, 2010; Ball et al., 2018; Krieger, 2021; Hsu et al., 2022). We contribute in several ways.

First, we focus on the disclosure of post-market negative product quality information, rather than pre-market disclosure of early-stage failures such as unsuccessful clinical trials (Krieger, 2021; Hsu et al., 2022). While pre-market information may inform firms' initial

[3]To identify technologically related markets, we use 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. More details in the data section.

[4]Note that our setting is one where mandated disclosure is the norm, which likely explains why we do not see larger reallocation effects. In other words, the exposed markets are going from a world of selective discretion to full disclosure whereas the control markets are already in the full disclosure world.

R&D decisions, they are often generated in controlled settings. In contrast, post-market information reflects 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 the its nature and direction.

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 to gain empirical traction (Ball et al., 2018; Krieger, 2021). By leveraging a large-scale, policy-driven change and data 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.[5] This approach allows for a more comprehensive view of how disclosure shapes innovation.

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 investments in response to mandatory disclosure. By analyzing shifts in product attributes, portfolio allocation, 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 approach to measuring both technological relatedness (across product markets) 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). While useful and detailed, patent classifications are often broad and may combine technologies that may not be functionally similar. Further, patent citations may reflect citation norms rather than true technological similarity. In contrast, to measure technology relatedness, we leverage FDA predicate relationships (i.e., regulatory linkages

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

that require firms to reference prior, technologically similar products). These references are reviewed by regulators, providing a validated and more precise measure of functional similarity across products, even when they span multiple patent classes. Predicate linkages often capture relationships that may 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 based on 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 a research-intensive, economically significant 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 with varying evidentiary requirements for market entry. Low risk devices (e.g., scalpels, stethoscopes) are subject to basic controls and typically not

subject to FDA notification before marketing.[6] Medium risk devices (e.g., catheters, infusion pumps) typically are required to follow a Pre-Market Notification (PMN) process (known as 510(k) clearance) in which 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. High risk devices (e.g., joint or heart implants) typically have to undergo a more stringent Pre-Market Approval (PMA) process, including clinical trials to prove safety and effectiveness.[7] 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. Medical device AEs involve unwanted outcomes from medical device use, ranging from death and life-threatening injury, to hospitalization or other serious negative health 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).[8] 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).

[6] Because 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.

[7] Low risk devices are designated as Class I by the FDA; Medium risk are Class II; and high risk are Class III.

[8] For additional details, see U.S. Food and Drug Administration (2025).

2.2.1 The (Private) Alternative Summary Reporting Program

Against this backdrop of pre-market regulation and mandated reporting with public disclosure of post-market AEs, in 1999, the FDA implemented the Alternative Summary Reporting (ASR) program. The ASR program allowed manufacturers to submit AE reports on a quarterly basis in summary format, rather than the 30-day/individual format mentioned above. The program was intended to ease administrative burdens for firms and the FDA amid rising AE report volumes.[9] ASR AEs were subsequently excluded from MAUDE (i.e., from public disclosure) 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 publicly available *in any form* before ASR was terminated in 2019.

The ASR program initially included 12 explicitly listed product markets (including, for example, pacemaker electrodes, breast implants, and heart valves). The FDA sent the program announcement to manufacturers of devices in these markets (only) on July 31, 1997 (U.S. Food and Drug Administration, 1997).[10] The ASR program was subsequently expanded to additional product markets, though public details on this expansion are unavailable.[11]

Knowledge of the ASR program was scarce. It was created without any public notice (Jewett, 2019). According to former industry insiders, ASR using firms were very "tight-lipped" about it, in part as it meant sales representatives could ignore ASR AEs to make devices appear safer (Jewett, 2019). Most industry safety experts, physicians, and several former FDA officials, including former FDA deputy commissioner Dr. Robert Califf, were

[9]The 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).

[10]The full list of 12 initial product markets (product code) includes: Permanent Pacemaker Electrode (DTB); Diagnostic IV Catheter (DQO); Endosseous (Dental) 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).

[11]Since 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.

unaware of the ASR program's existence (Jewett, 2019).

In March 2019, a Kaiser Health News investigation publicly revealed the existence of the ASR program (Jewett, 2019). In June 2019, the FDA officially terminated the program and released all historical ASR AE data covering 1999 to 2019. The ASR dataset includes 6 million AEs in 102 product markets over that period. In contrast, the public database MAUDE contained 9 million AEs covering more than 4,000 product markets over the same time period. Notably, the ASR program had apparently begun winding down in 2017, as the FDA gradually revoked exemptions for certain product markets, though, like the ASR program itself, this wind-down was not widely known outside of firms using the ASR.

The 2019 ASR database release substantially increased the amount of AEs known to the public. Figure 1, Panel A highlights this increase across all product markets. Some device markets in ASR, such as surgical staplers (Panel B) and dental implants (Panel C), saw large increases in reported historical AEs 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 simple conceptual framework for how firms plausibly adjust their R&D investments in response to disclosure mandates for negative product information and the release of 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. Removing the ability to withhold negative information increases scrutiny from external stakeholders (e.g., consumers and investors) and may reduce expected demand for current and future products (Dranove and Jin, 2010; Jin and Leslie, 2003). As a result, firms may expect lower returns to innovation, leading to a decline in the rate of R&D investment and innovation. Notably, these effects would be for firms and in markets where withholding was previously possible.

Second, increased information about competitors' products allows firms to update their beliefs about the technological risks and the commercial potential in the relevant product market (Hegde and Luo, 2018; Chondrakis et al., 2021). The net effect of competitor disclosure of negative product information on the rate of firms' R&D investment is theoretically ambiguous. Some firms may scale back investment after learning that current innovations are riskier than previously believed, while others may increase R&D investment if they expect that increased expectations of disclosure will lead to reduced competition. Recent work suggests that the learning effects tend to dominate, which would imply information effects (for negative product information) will reduce R&D investment (Bloom et al., 2013; Krieger, 2021).

Importantly, informational effects on R&D investment likely extend beyond directly affected product markets. 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 existing products in technologically related (but not directly exposed) markets. To the degree information effects are present, we expect them to spillover into these indirectly exposed product markets.

2.3.2 How Firms Adapt to Negative Information Disclosure

Beyond effects on innovation rate, firms may also adapt to the changed information environment created by disclosure mandates, changing the direction and nature of innovation. These broader adaptation responses are important to consider as they help us understand the full picture of how mandated disclosure of negative product information on innovation. We thus also consider how disclosure mandates may lead to changes in product attributes in affected markets (as a means of differentiation), in firm re-allocation of R&D across markets (as firms frequently reallocate innovation investments in response to changes in perceived risk, competition, or regulatory conditions (Bloom et al., 2013; Krieger, 2021).) We also consider how these choices translate into changes in market composition.

How firms adapt likely depends on their exposure to *withholding* and *informational* effects. In our setting, we distinguish between firms that previously had approvals in product markets included in the ASR database (which we call "ASR aware" firms) and those that did not ("ASR naive" firms). ASR aware firms are likely to be affected both by the loss of withholding and by information. In contrast, ASR naive firms are exposed solely to information effects.

Prior work shows 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). We investigate if ASR naive firms use this increased (negative information) to differentiate themselves as they enter these markets, for instance by increasing the novelty,

safety, or perceived quality of their products. We also consider if ASR aware firms reallocate efforts away from exposed markets and towards less exposed markets as they lose the comparative ability to withhold. Finally, we investigate how mandated disclosure relates to firm entry and exits.

3 Data and Descriptives

To study the relationship between negative product information disclosure and innovation, we build data on medical device product markets (e.g., surgical staplers), including approvals, adverse events, and linked patents, linked to cleaned firm data (e.g., Medtronic) for 2003-2023.[12]

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, which we use as a benchmark and in various robustness tests. Figure 2 shows how the number of product markets with AEs in ASR changed over time. There are two important features to note. First, the ASR program expanded gradually. While, ASR began with 12 FDA-approved markets in 1997 ("Original ASR"), it ultimately covered 102 distinct product markets.[13] 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 winding down the program in 2017.[14] Figure 2 shows that by 2018, half of the product markets active in 2017 no longer had AEs added to the ASR. We leverage this gradual wind-down in our empirical analyses to isolate the role of the withholding mechanism in driving the aggregate effect.

Our primary measure of exposure to the ASR shock is constructed at the product market

[12]Cleaning and linking firm data across various FDA datasets and to patent data involved both algorithmic and manual cleaning steps, including leveraging Evaluate Medtech's data to identify deals.

[13]One of the original ASR product markets had no AEs in the ASR data: Diagnostic IV Catheter (DQO).

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

level. We classify a product market as "High Exposure" if it has at least one AE in the ASR database and "Low Exposure" if it is never present in the ASR database.

3.2 Medical Device Innovation

Our primary measure of innovation are new medical device applications as reflected in device application data for 1997 to 2023 from the FDA supplemented by Evaluate Medtech, including both pre-market approvals (PMAs) and 510(k) device clearances. For each (eventually cleared or approved) new device application, we have information on the device name, applicant manufacturer firm, device approval type (510(k) or PMA), application and approval dates, and associated product market. Appendix Figure B1 provides an example of an approved device application.

3.2.1 Measuring Technological Relatedness Across Markets

To test for potential information spillovers across markets, we identify product markets technological related to High Exposure product markets. A key challenge in identifying technological relatedness is that existing structural classifications that aggregate related product markets (e.g., by FDA specialty classification or patent classes) are both quite broad and may link devices that serve similar diseases or conditions, but rely on different technologies, and therefore for which there is unlikely to be informational spillovers. For example, the FDA dental specialty includes product markets from floss to dental x-ray machines. To overcome this challenge, we exploit a unique feature of medical device pre-market regulations to link technologically similar product markets: as described in Section 2.1, manufacturers of devices that go through the 510(k) process must demonstrate "substantially equivalence" to a previously approved "predicate" device. This equivalence is based on intended use, materials, and efficacy. Leveraging this, we consider product markets as technologically related if at least one device in a product market references a predicate device in another product market

(or vice versa). Using this approach, approximately 40% of product markets are linked.[15] We use predicate links to identify product markets that are technologically related to High Exposure markets and thus to test for informational effects.

3.2.2 Measuring Device Attributes

Beyond measuring effects on the rate of innovation, we construct measures of device novelty (using predicate information), and R&D quantity, safety, and quality (using linked patent data) to estimate changes to the nature and direction of innovation.

For device novelty, we use two measures based on the predicate device(s) referenced by the focal device. First, does the device reference a "novel" predicate? We consider a device's predicate to be novel if the focal device use a predicate from a product market that no prior device in the focal device's product market has referenced before. Second, at the time of application of the focal device, how old is the predicate device? We measure predicate age based on the time (in years) since the predicate device was applied for at the time of focal device application. We use both novel predicate and predicate age to capture the technological novelty of the focal device.

To measure R&D quantity, safety, and quality, we use patent-based measures, which provide a better representation of investment choices than device applications, which measure innovation, i.e., commercialization. A challenge in incorporating patent data in our analyses, in which exposure varies across product markets, is linking patents to product markets. To accomplish this, we leverage the link patent-class-to-medical-device-product-market link created by Cunningham and Hall (2025). In short, their linkage involves: (i) identifying 3-5 keywords that define each market (using machine learning, research assistant checks, and leveraging the UMLS metathesaurus for medical synonyms), (ii) searching for those keywords in patents, (iii) aggregating counts to patent class level, and (iv) creating probabilistic linkages between patent classes and product markets. One example: the product market

[15] See Appendix B.1 for more details.

Cardiovascular blood flowmeter (FDA CFR § 870.2100) is linked to patent classes (CPC) *A61B8/06 Measuring blood flow* with linkage probability of 0.932 and *A61B8/02 Measuring pulse or heart rate* with probability 0.068. We count patents in product markets if they have a higher than 5% linkage probability.

To measure R&D quantity, we count all (eventually granted) patent applications (using Patentsview data) in a product-market year. Given a patent can fall into multiple product markets via the probablistic linkage, we inverse weight a patent by the number of linked product markets. To proxy for R&D safety, we identify safety-related patents—that is, patent applications whose abstracts contain mention of safety-related words. We use Galasso and Luo (2024)'s keyword list to flag patents that are safety- and/or reliability-related.[16] To proxy for R&D quality, following much prior research, we examine forward citations to the patent within 2 years of grant. Because our data are quite recent (i.e., our Post period is 2019-2023 inclusive), which truncates forward citation counts, we use an indicator for any forward citations.

3.3 Analytic Dataset

Due to the nature of the ASR shock (which 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 two percent of product market-year observations are classified as High Exposure, while four percent are technologically related to

[16]Specifically, we flag instances of the following word roots in patent abstracts: safe*, reliab*, integrit*, error*, fail*, problem*, and vulnerab*.

a High Exposure market. Device applications are relatively 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 is at the product market-year, we also analyze outcomes at the firm-product market-year and firm-year levels to explore mechanisms and to examine adaptation. We discuss the specific datasets and specifications in their respective sections.

4 Baseline Impact on Innovation

4.1 Empirical Strategy

We begin by empirically examining the baseline impact of the 2019 ASR shock on innovation rates. Our baseline DID specification compares product markets with at least one adverse event in ASR to those without any adverse events in the ASR database, pre- and post-2019. We estimate the following:

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

where $Y_{p,t}$ is a measure of innovation (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 both product market (δ_p) and year fixed effects (δ_t). We estimate ordinary least squares models with hetereoskedasticity-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 High and Low Exposure product markets. Prior to 2019, High Exposure product markets were associated with significantly

more new device applications. However, after the ASR program was terminated and the data released, there is movement towards convergence in the number of device applications across the two groups. At the firm-product market-year level, we see the likelihood of a new device application converges across High and Low Exposure markets post-2019. Notably, the relative decrease in both descriptive analyses begins as early as 2017. As we discussed in Section 3.1, this coincides with the start the FDA winding down ASR, but before data release (or public acknowledgment of the program). In subsequent analyses, we exploit this institutional feature to help parse out mechanisms.

4.2 Effect on the Rate of Innovation

Panel A in Table 2 shows that the 2019 ASR shock has a significant and negative effect on the number of device applications in a given product market-year. Column 2 presents estimates from regressions that are fully saturated with both year and product market fixed effects. The ASR shock leads to a 17 percent ($e^{-0.188} - 1$) decline in new device applications in High Exposure product markets.

We also estimate a dynamic version of Equation (3). Panel A of Figure 3 shows that the difference in number of device applications between product markets in High versus Low Exposure product markets prior to 2019 is statistically indistinguishable from zero in the fully saturated model. After the ASR shock, we observe an immediate decline in device applications in High Exposure product markets.[17] The post-ASR shock decline remains large, negative, and statistically significant throughout the post-period. The fairly quick response is consistent with the idea that firms may be withholding seeking applications of devices that are already "on the shelf."[18]

To set a baseline for later analyses that examine changes within markets, we include a ver-

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

[18]This is supported by evidence in Table C4 that shows the overall declines are driven by 510(k) applications, i.e., medium-risk devices the require clearances rather than (more stringent and time-consuming) approval for marketing.

sion of these analyses at the firm-product market-year level. Our firm-product market-year dataset includes only firm-product markets with at least one device approval, to ensure the sample reflects firm-markets with some likelihood of R&D activity and to avoid mechanically inflating statistical significance.[19] We adapt equation (3) 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 predict the likelihood of a device application in a firm-product market-year. In particular, we estimate:[20]

$$Y_{f,p,t} = \alpha + \beta Post_t \times HighExposure_{p,t} + \delta_{f,p} + \delta_t + \epsilon_{f,p,t} \tag{2}$$

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, of 2.4 percentage points. This finding also helps to show our product market-level results are not driven by just a few firms.

4.3 Mechanisms: Withholding and Information Effects

The decline in device applications following the ASR shock may reflect two distinct firm-level mechanisms: (i) anticipation of a loss of ability to withhold negative information, a *withholding effect*, and (ii) response to the disclosure of negative information about competitors' products, an *information effect*. Distinguishing the effects of each mechanism is important because they have different implications for how mandated disclosure 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 some helpful institutional details to

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

[20] The trends shown in Panel B of Appendix Figure A1 provides support for this specification.

unpack 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, according to industry insiders, the program had already began winding down in 2017, as the FDA gradually revoked exemptions for certain product markets and firms. This staggered wind-down gives us some traction to distinguish between the effects of losing the ability to withhold information (which began in 2017) from the effects of the public information release of competitors' information (in 2019).

Panel A of Table 3 shows that, at the product market-year level, the decline in device applications is significantly larger following the 2019 ASR data release than following the initial wind-down of the program. While there is a decline that begins during the wind-down period, the additional decline following the data release is both large significant. Panel B shows similar patterns at the firm–product market–year level following the 2019 release compared to the initial wind-down period. Notably, in these results the wind-down period shows significant declines, yet we still see significant additional declines post release. Together, these results suggest that, while the loss of withholding may matters, the broader release of competitor information plays a larger role, on average, in shaping firm innovation.

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, the average effect across firms likely conceals firm heterogeneity in whether they are affected by the loss of withholding (i.e., they have used ASR in now are facing the withholding loss) and information, or are mainly affected by newly available information about others.

To split apart these effects, we conduct a firm-product market-year level analysis where we exploit variation in the source of ASR AEs: the *Same* firm (meaning the focal firm itself has used ASR in the product market) versus a *Different* firm (the focal firm did not use ASR in the product market).[21] Table 4 reports estimates from a firm–product market–year specification that interacts these firm distinctions with the elements of the ASR shock (wind-down vs. data release). Column 1 shows that when the firm has previously used ASR in that product market, device applications decline significantly following ASR wind-down, and there is no additive effect of the release. This result is consistent with firms responding to the inability to (continue to) withhold negative information. In contrast, Column 2 shows that firms who did not use ASR in the product market respond more strongly after the public release of ASR data in 2019, when that information becomes widely available.

Notably, we find that firms who did not use ASR also decreased their innovation in High Exposure markets during the wind-down period. There are a few potential reasons for such a result, even though such firms did directly face a decrease in the ability to withholding in the focal product market. First, such firms may be aware of the existence of ASR. In additional analysis (in Appendix Table C5) we split out such firms into those that used ASR in a different product market (Column 2) and those who never used ASR (Column 3). We see awareness of ASR predicts a strong wind-down decrease. Yet, even for firms seemingly unaware of ASR, we still see some evidence of a significant wind-down effect. One additional factor that could be relevant for such declines is that the wind-down of ASR across markets would have led to more publicly listed AEs as firms could no longer use ASR. Even for firms unaware of ASR, the increase in public AE disclosure may have caused some decreases in the relative rate of innovation in High Exposure markets.

Taken together, these results suggest that the loss of withholding also matters, particularly for firms who participated directly in ASR and further that information effects are a key driver the overall patterns.

[21] Note that a product market-year level analysis does not allow us to separately identify the effects of an ASR AE from a given firm vs. those of another firm.

4.3.3 Spillovers Across Markets

To dig further into informational effects, we now explore whether the effects of competitor disclosure extend to technologically related markets. If changes in mandated disclosure provides valuable information about technologies, firms may reduce innovation even in markets not directly exposed to the ASR shock. Notably, these markets are not changing in their withholding effects.

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

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).[22] 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,

[22]See the FDA on COVID-19 and Medical Devices

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 Adaptation

Our results to this point focus on the immediate impact of the ASR shock on the rate of innovation and investigation the underlying mechanisms. Given we observe declines due to (negative) information, an obvious question is what do firms do to adapt their innovation strategies beyond these immediate responses? To investigate this, we examine on three key dimensions: (i) product attribute adaptation, (ii) portfolio reallocation, and (iii) market exit/entry.

As described in Section 2.3, firms' adaptations likely depend on their awareness of the ASR program prior to the database's release: Firms that were aware of ASR pre-shock respond both to the loss of withholding and to newly available information about competitors, while less ASR-aware firms may be more influenced by information effects. 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 1997 were notified of the program's initiation. We cannot know if this is also true for later product markets, but we are defining potential awareness broadly, i.e., erring on the side of including unaware firms in the aware sample. Given this and the typical two-year

device lifecycle (Gelijns et al., 1991), we define ASR awareness as having approved devices any High Exposure product market (in ASR database) between 1997 and 2018.[23] All other firms are considered "ASR naive." Note that as defined, "ASR aware" firms likely encompass product market incumbents, while "ASR naive" firms are likely to encompass new entrants to a product market. Consistent with this, Appendix Table D1 shows that ASR aware firms tend to have more devices and more AEs.

5.1 Product Attribute Adaptation

As increased negative information about existing products led to a decline in the rate of innovation, they also potentially lead to changes in the nature and direction of innovation. To examine this, we conduct a product market-year analysis that allows us to differentially examine how ASR aware and ASR naive firms change the nature of their products in response to changed information environment, in Table 6.[24]

Both firms are likely to be affected in terms how they adapt their product attributes to the new information environment. For ASR aware firms, beyond reducing expectations of withholding the information shock generates increased negative information about existing products in the market, including most notably their own products in the focal market. Thus, beyond reducing innovation, we might expect them to focus on improving the safety and quality of their new devices. For ASR naive firms, the information shock for existing products in High Exposure markets and the decrease in the rate of innovation of ASR aware firms (i.e., market incumbents) provides opportunities for them to compete by introducing different and more innovative alternative products.

To examine changes to the nature and direction of innovation, we examine device novelty, and R&D quantity, safety focus, and quality.

Starting with ASR aware firms, in Panel A of Table 6, we see that they are less likely

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

[24]In contrast, a firm-product market-year requires that a firm exist in the market prior to the ASR shock.

to introduce novel devices (as proxied by having a *Novel Predicate*). However, they appear also reduce their patenting while focusing on both safety and quality of their patents in High Exposure Markets. For ASR naive firms, in Panel B of Table 6, we they tend to introduce more novel devices in High Exposure product markets post-2019, as measured both by *Novel Predicate* and *Predicate Age* suggesting, conditional on using a predicate, such firms typically rely on newer technology in these markets. Further, while there are no detectable effects on patenting rates or safety, the quality of their patents (measured by having any forward citations within 2 years of grant) in High Exposure markets increases significantly.[25]

Taken together, the results suggest that ASR aware firms (i.e., incumbents) respond by investing in less novel but safer and higher quality devices and device R&D, and reduce their R&D investments, while ASR naive firms (i.e., entrants) respond by investing in more novel and higher quality devices and device R&D.

Before proceeding, it is worth emphasizing that ASR aware and ASR naive firms are different, as indicated by Appendix Table D1. 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. This fact is also apparent in the differences in the dependent variable means across Panel A and B of Table 6. While we see ASR aware firms experience a significant decline in the likelihood of referencing a novel predicate, they had higher rates of novelty pre-2019. 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.

[25]In Appendix Table D2 we run the product attribute analyses for all firms combined, and the results largely mimic those of the ASR Aware Firms (which make up the majority of the firms in our sample). Further, while our main patent analyses are for eventually granted patent applications, we also tried to explore results for published (pre-grant) patent applications, given the recency of our time window. Because the assignee data is more missing than not for that sample, we couldn't run the firm-based analyses. However, we do observe an increase in safety-related patenting for High Exposure markets in that data.

5.2 Portfolio Reallocation

In response to the ASR shock and associated declining investments in exposed markets, 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.

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:

$$Y_{f,t} = \alpha + \beta Post_t \times HighFirmExposure_{f,t} + \delta_f + \delta_t + \epsilon_{f,t} \tag{3}$$

where $Y_{f,t}$ is a measure of innovation (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 hetereoskedasticity-robust standard errors clustered at the firm level.

Table 7 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 reallocate investment in response to changes in scrutiny and perceived risk.

5.3 Market Entry

The prior results show that ASR naive firms, i.e., product market entrants, create more novel, safer, and higher quality products. A natural question then is about firm entry and exit dynamics. Using a product market-level panel, we analyze changes in the number of firms types, split into: (i) market incumbents (i.e., firms with devices 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.[26]

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 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

[26]While 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.

in these product markets.

6 Alternative Explanations

In this section, we address potential alternative explanations that would be consistent with our main results, i.e., that explain why the ASR program termination and data release would lead to a decrease in innovation.

6.1 Role of Firm Reputation

One alternative explanation for our results is that decreased innovation are primarily driven by reputational concerns rather than strategic decision making. For instance, firms previously using ASR may face increased litigation that decreases firm resources for innovation (Galasso and Luo, 2024) or incur organization stigma that leads employees to decrease their innovative efforts (Zhou et al., 2024). If this were driving our results, we would expect the negative effects to be only for firms using ASR, and that said firms would reduce their overall R&D investments following the ASR shock. Two of our analyses suggest this is not the case. First, we find declines in innovation from firms without AEs in ASR (in Table 4). Second, our analysis of firms' product attribute allocation (in Table 6) and reallocation decisions (in Table 7) indicates a more nuanced response: ASR aware firms are not simply retreating from R&D activity and innovation across the board but are reallocating their efforts toward markets less exposed to the shock. Our main results are therefore unlikely to be solely driven by firm reputational effects.

6.2 Role of Regulatory Scrutiny

Since we only able to observe accepted device applications, a plausible alternative explanation for the observed decline in device applications is that it reflects increased risk aversion by the FDA (the regulator). Put starkly, the rate of device applications by firms may not have decreased, but instead FDA may be approving/clearing fewer devices as a consequence of

the public release of ASR and its implications for the FDA's reputation. This alternative explanation is mitigated by a few key features of our results. First, our core results (in Table 2) are not driven by overall declines, but those specific to ASR-exposed markets, suggesting the results are not simply due overall FDA scrutiny increases post-ASR release. Further, we find significant negative effects of ASR on innovation for technologically-related but not directly exposed markets (in Table 5), which suggests this is not driven solely by localized ASR-related scrutiny. This pattern—neither totally general nor totally localized to ASR markets—is not consistent with FDA scrutiny driven behavior. Further, we find descriptive evidence of a relative decline in patenting activity (an activity that takes place before FDA review and approval of devices), as depicted in Figure E1, and for ASR aware firms in Table 6. While firms may take regulatory scrutiny into account while making their R&D and innovation decisions, the decline in patenting suggests that regulatory risk is unlikely to be a key driver of the observed innovation declines and firm adaptations post-ASR.

7 Conclusion

We find mandated negative product disclosure significantly reshapes both the rate and direction of innovation. We use the 2019 termination of the FDA's ASR program and the associated release of withheld adverse events, we find a 17 percent decline in device innovation.

This decline was largely driven by information effects, where firms adapted their innovation and R&D decisions in response to newly available negative information about their competitors' products, rather than solely by the loss of their ability to withhold (own) negative information. These informational effects also extended to technologically related, but not directly exposed, markets.

Beyond the overall rate, we highlight crucial adaptive responses among firms. Specifically, we find that incumbent firms (those who are ASR aware) reallocated their R&D investments

away from exposed markets to less exposed ones, while new entrants (ASR naive firms), in contrast, introduced more novel, safer, and higher-quality devices into the exposed markets. Ultimately, the disclosure reshaped market structure, leading to a decline in the number of R&D active firms in exposed markets, largely due to incumbent exit.

These findings underscore that mandatory negative product disclosure has complex implications, leading to a decrease in overall innovation quantity but also fostering a shift towards qualitative improvements and safer products from new market entrants.

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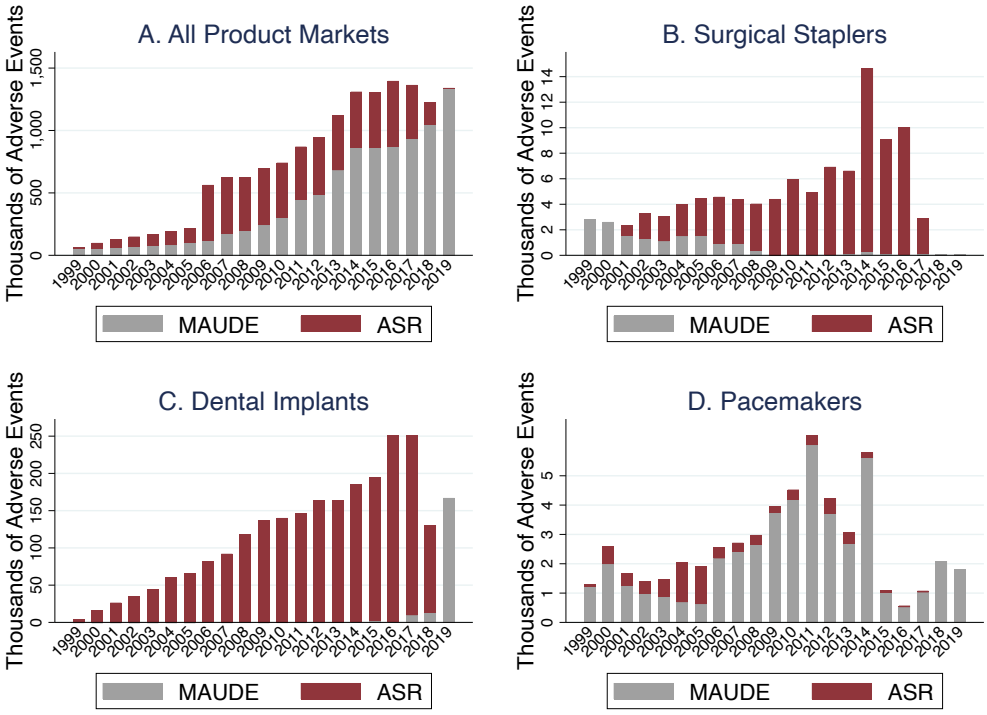
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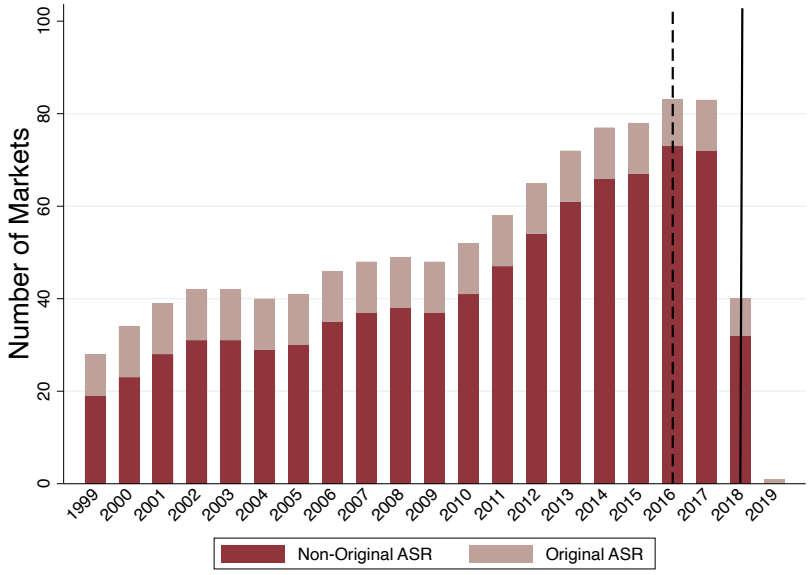
Figures and Tables

Figure 1: Trends in the Number of Adverse Events in ASR and MAUDE



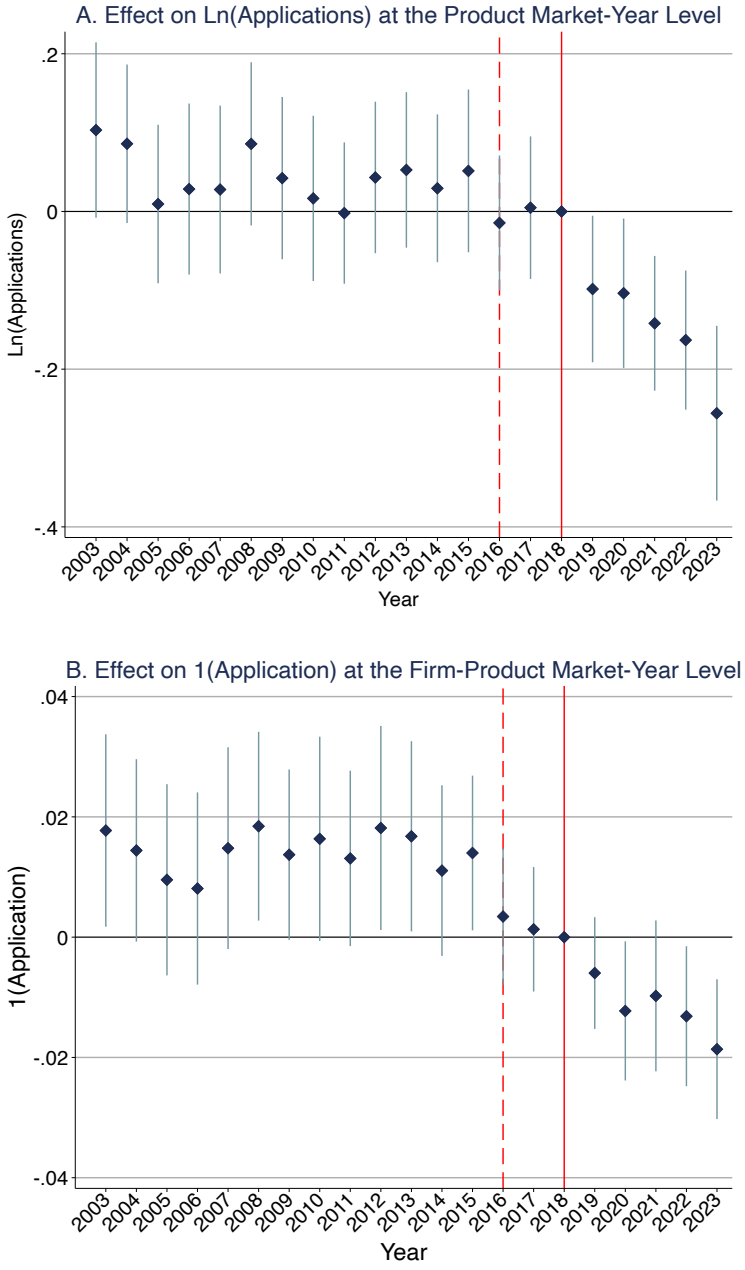
Note: This figure shows the trends in the number of MAUDE and ASR adverse events. The sample includes all adverse events submitted to either database between 1999 and 2019.

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	85.02	1,391.82	0	132,709
# ASR AE (2003 to 2019)	88,060	66.55	3,240.65	0	305,047
High Exposure Market	108,780	0.02	0.14	0	1
Tech. Similar to High Exposure Market	108,780	0.04	0.19	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
# Patents (PC weighted)	108,780	0.40	2.54	0	158
1(Safety Patent)	36,378	0.33	0.47	0	1
1(Patent Citations)	36,378	0.64	0.48	0	1
# Patent Citations Per Patent	36,378	2.00	7.64	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)
A. Product market-year level, dependent variable: Ln(applications)		
Post Release x High Exposure	0.280***	-0.188***
	(0.0653)	(0.0335)
Mean of Dep. Var.	0.147	0.147
Observations	108,780	108,780
Year FE	YES	YES
Market FE	NO	YES
B. Firm-product market-year level, dependent variable: 1(application)		
Post Release x High Exposure	0.00394	-0.0236***
	(0.00598)	(0.00520)
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 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)
A. Product market-year level, dependent variable: Ln(applications)	
Post WindDown x High Exposure	-0.0376
	(0.0357)
Post Release x High Exposure	-0.155***
	(0.0345)
Mean of Dep. Var.	0.147
Observations	108,780
Year FE	YES
Market FE	YES
B. Firm-product market-year level, dependent variable: 1(application)	
Post WindDown x High Exposure	-0.0128***
	(0.00473)
Post Release x High Exposure	-0.0126***
	(0.00458)
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 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)		-0.0116**
		(0.00484)
Post Release x High Exposure (ASR Event from Same Firm)	-0.00753	
	(0.0169)	
Post Release x High Exposure (ASR Event from Different Firm)		-0.0128***
		(0.00481)
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	Excl. High Exposure Markets
	(1)	(2)
A. Product market-year level, dependent variable: Ln(applications)		
Post Release x Tech. Similar to High Exposure Market	-0.257***	-0.209***
	(0.0351)	(0.0398)
Mean of Dep. Var.	0.147	0.139
Observations	108,780	106,658
Year FE	YES	YES
Market FE	YES	YES
B. Firm-product market-year level, dependent variable: 1(application)		
Post x Tech. Similar to High Exposure Market	-0.0229***	-0.0179***
	(0.00374)	(0.00381)
Mean of Dep. Var.	0.0434	0.0419
Observations	782,441	731,853
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 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 Attribute Adaptation

	Device Novelty		R&D Quantity	R&D Safety	R&D Quality
	1(Novel Predicate)	Ln(Predicate Age)	Ln(Patent Count)	1(Safety Patent)	1(Patent Citations)
	(1)	(2)	(3)	(4)	(5)
A. ASR Aware Firms					
Post Release x High Exposure	-0.0889***	0.0930	-0.0433*	0.0684*	0.0633**
	(0.0189)	(0.0870)	(0.0258)	(0.0350)	(0.0259)
Mean of Dep. Var.	0.0327	0.814	0.147	0.334	0.647
Observations	108,780	7,980	108,780	35,064	35,064
Year FE	YES	YES	YES	YES	YES
Market FE	YES	YES	YES	YES	YES
B. ASR Naive Firms					
Post Release x High Exposure	0.0171***	-0.165***	0.0155	0.0285	0.173***
	(0.00516)	(0.0419)	(0.0161)	(0.0477)	(0.0654)
Mean of Dep. Var.	0.0201	0.711	0.0146	0.174	0.412
Observations	108,780	5,783	108,780	9,061	9,061
Year FE	YES	YES	YES	YES	YES
Market FE	YES	YES	YES	YES	YES

Note: This table reports DID estimates of the change in medical device attributes 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. 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 4 and 5 is restricted to product market-years with at least one patent. ***p<0.01, **p<0.05, *p<0.1.

Table 7: 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	-0.334***	-0.298***	-0.988***	-0.193
	(0.121)	(0.0800)	(0.177)	(0.122)
Mean of Dep. Var.	0.642	0.214	0.205	0.438
Observations	9,657	9,657	9,657	9,657
Year FE	YES	YES	YES	YES
Firm FE	YES	YES	YES	YES

Note: This table reports DID estimates 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 8: Effect of ASR Release on Number of Firms

	Ln(All Firms) (1)	Ln(Market Incumbents) (2)	Ln(New to Market) (3)	Ln(New to Industry) (4)
Post Release x High Exposure	-0.343***	-0.325***	-0.249***	-0.173***
	(0.0721)	(0.0747)	(0.0621)	(0.0618)
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

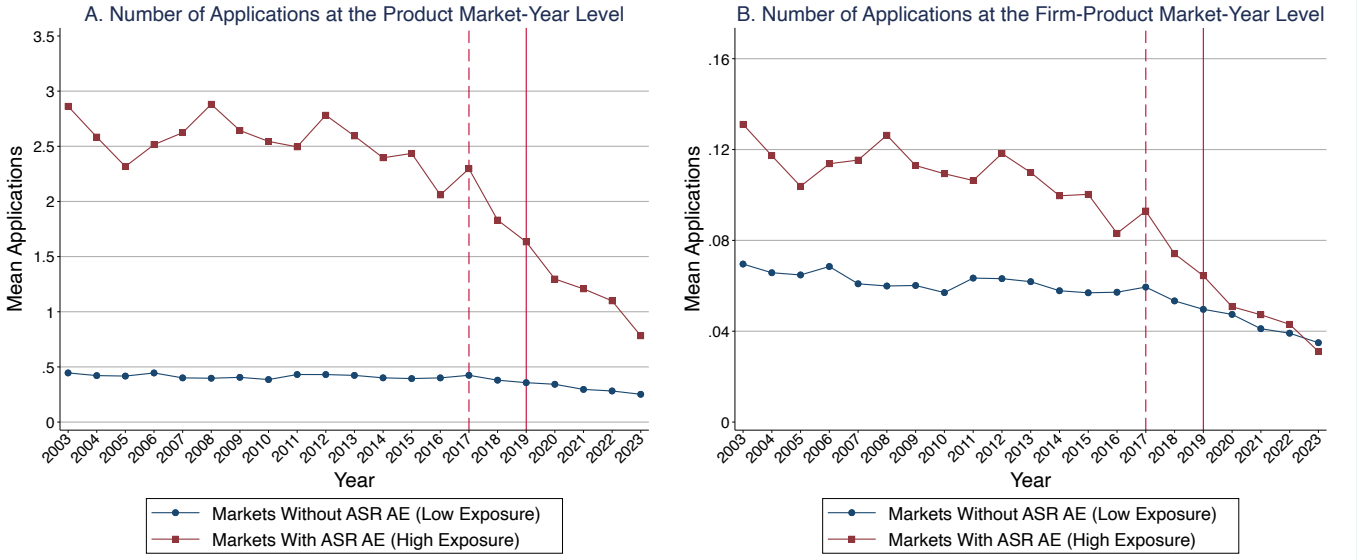
Appendix A Additional Summary Statistics

Table A1: Differences in Adverse Events

	MAUDE		ASR		T-Test p-value
	Mean	SD	Mean	SD	
Total	70.97	1,253.99	55.71	2921.10	0.11
Death (%)	2.50	10.9	.08	0.88	0.00***
Serious (%)	11.76	27.79	16.97	32.00	0.00***
Other (%)	47.08	41.34	34.27	43.04	0.00***
Unknown (%)	48.09	41.76	0.02	0.25	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

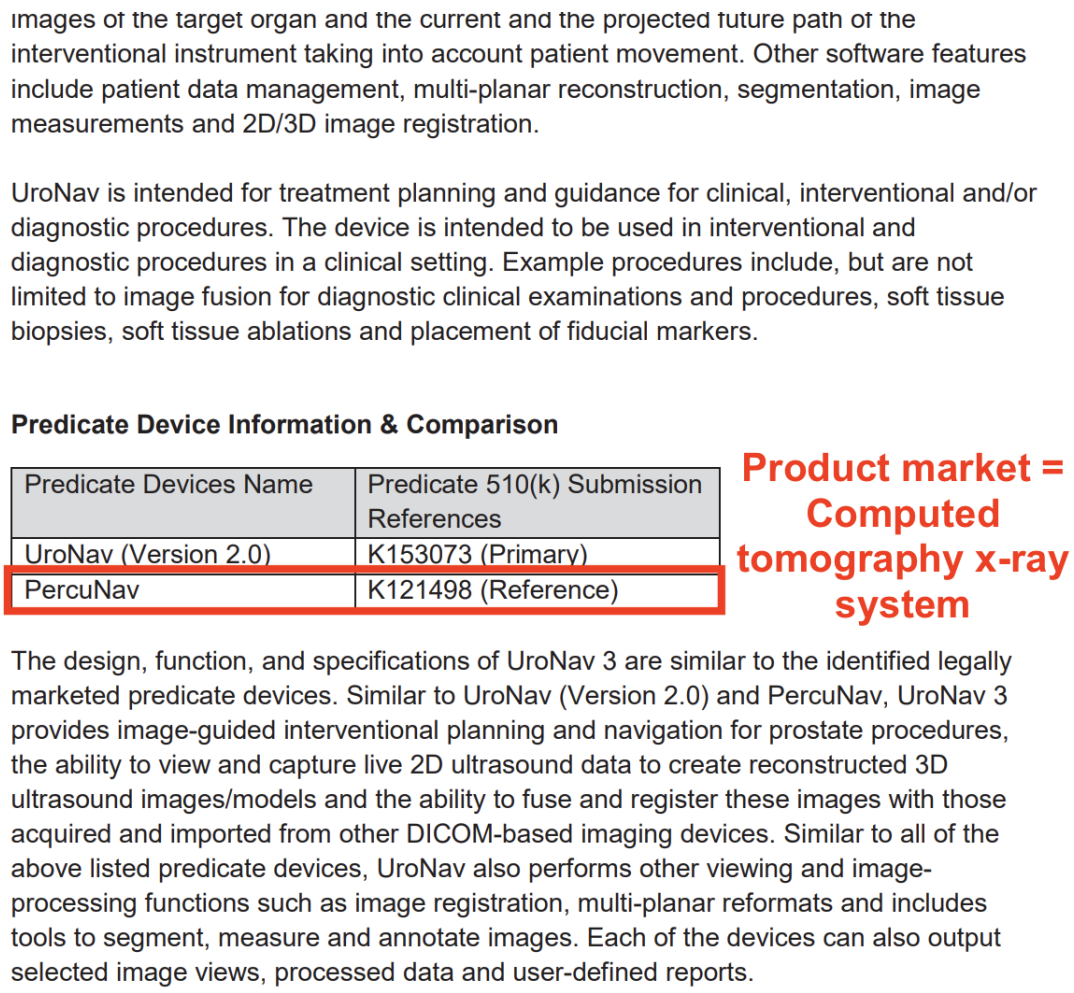
Figure B1: Example: Drug Application K182561



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 Specialities	Matched Regression	Excl. Covid Product Markets	Excl. Covid Product Markets and Firms
	(1)	(2)	(3)	(4)	(5)
A. Product market-year level, dependent variable: Ln(applications)					
Post Release x High Exposure Share	-0.301***				
	(0.0852)				
Post Release x High Exposure		-0.187***	-0.187***	-0.185***	-0.163***
		(0.0336)	(0.0413)	(0.0335)	(0.0316)
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
B. Firm-product market-year level, dependent variable: 1(application)					
Post Release x High Exposure Share	-0.0407**				
	(0.0163)				
Post Release x High Exposure		-0.0238***	-0.0226***	-0.0236***	-0.0212***
		(0.00519)	(0.00582)	(0.00520)	(0.00479)
Mean of Dep. Var.	0.0442	0.0426	0.0486	0.0434	0.0461
Observations	720,554	662,032	727,975	781,292	609,379
Year FE	YES	YES	YES	YES	YES
Firm-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 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)
A. Product market-year level, dependent variable: Ln(applications)		
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
B. Firm-product market-year level, dependent variable: 1(application)		
Post Release x Difference in AE Levels/1000000	-0.0470***	
	(0.0133)	
Post Release x Difference in AE Share Across Markets		-4.70e-08***
		(1.33e-08)
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 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	High	Low	High
	(1)	(2)	(3)	(4)
A. Product market-year level, dependent variable: Ln(applications)				
Post Release x High Exposure	-0.0246***	-0.157***	-0.0143*	-0.158***
	(0.00931)	(0.0382)	(0.00861)	(0.0368)
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
B. Firm-product market-year level, dependent variable: 1(application)				
Post Release x High Exposure	-0.0130***	-0.0189***	-0.00608***	-0.0204***
	(0.00293)	(0.00531)	(0.00224)	(0.00605)
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 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	PMA Applications
	(1)	(2)
A. Product market-year level, dependent variable: Ln(applications)		
Post Release x High Exposure	-0.176***	-0.0120***
	(0.0339)	(0.00419)
Mean of Dep. Var.	0.144	0.00319
Observations	108,780	108,780
Year FE	YES	YES
Market FE	YES	YES
B. Firm-product market-year level, dependent variable: 1(application)		
Post Release x High Exposure	-0.0228***	-0.000771**
	(0.00523)	(0.000367)
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 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 C5: Own Adverse Events and Competitor Disclosures by Firm Types

	Dependent variable: 1(application)			
	Mkt incmbnt	Mkt incmbnt, diff mkt ASR	Mkt incmbnt, never ASR	Mkt entrant
	(1)	(2)	(3)	(4)
Post WindDown x High Exposure (ASR Event from Same Firm)	-0.0318*			
	(0.0193)			
Post WindDown x High Exposure (ASR Event from Different Firm)		-0.0370**	-0.0134*	0.00120*
		(0.0168)	(0.00808)	(0.000619)
Post Release x High Exposure (ASR Event from Same Firm)	0.0143			
	(0.0170)			
Post Release x High Exposure (ASR Event from Different Firm)		-0.0110	-0.0153*	-0.0138***
		(0.0116)	(0.00880)	(0.00404)
Mean of Dep. Var.	0.0646	0.0697	0.0625	0.00715
Observations	493,435	114,768	376,422	289,006
Year FE	YES	YES	YES	YES
Firm-Market FE	YES	YES	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. 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.

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 p-value
	Mean	SD	Mean	SD	
# MAUDE AEs	2.89	82.62	871.83	9,901.06	0.00***
# ASR AE	0.00	0.00	318.83	6,853.97	0.00***
# Applications	0.32	1.00	3.12	9.59	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").

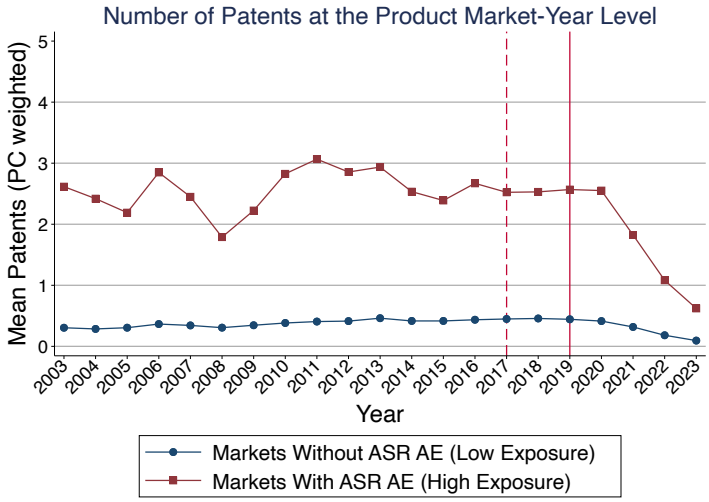
Table D2: Product Attribute Adaptation, All Firms Combined

	Device Novelty		R&D Quantity	R&D Safety	R&D Quality
	1(Novel Predicate)	Ln(Predicate Age)	Ln(Patent Count)	1(Safety Patent)	1(Patent Citations)
	(1)	(2)	(3)	(4)	(5)
Post Release x High Exposure	-0.0760***	0.160**	-0.0288	0.0650*	0.0569**
	(0.0189)	(0.0742)	(0.0244)	(0.0352)	(0.0255)
Mean of Dep. Var.	0.0490	1.145	0.155	0.335	0.643
Observations	108,780	11,338	108,780	36,290	36,290
R-squared	0.243	0.435	0.918	0.531	0.479
Year FE	YES	YES	YES	YES	YES
Market FE	YES	YES	YES	YES	YES

Note: This table reports DID estimates of the change in medical device attributes 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. 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 4 and 5 is restricted to product market-years with at least one patent. ***p<0.01, **p<0.05, *p<0.1.

Appendix E Patenting Rates

Figure E1: Trends in Patents



Note: This figure shows the average number of (eventually granted) patent applications linked to markets with adverse events in the ASR database and those without, over time. Because patents can be assigned to multiple product markets, counts are based on inverse weights which split a patent across all linked markets.