Negative Product Disclosure and Innovation*

Colleen Cunningham
University of Utah

Jennifer Kao
UCLA

PRELIMINARY DRAFT

Abstract

We investigate how negative product disclosure affects the rate and direction of subsequent innovation. In 2019, the U.S. Food and Drug Administration (FDA) terminated an adverse event reporting exemption for a subset of medical device product markets and released 6 million previously withheld adverse events. We find that innovation in affected device markets declined by 17 percent, primarily driven by firms' responses to information about competitors' products rather than by the loss of their own ability to withhold information. The decline was attenuated in markets without close substitutes. Despite the overall reduction in innovation, firms introduced safer, higher quality devices and reallocated R&D toward unaffected markets. The number of R&D active firms in affected markets also fell. Taken together, these findings show how large-scale negative product disclosure can reshape the allocation of innovative effort towards safer and higher quality products.

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1 Introduction

Firms' research and development (R&D) decisions are shaped by available information about preceding R&D activity and existing products (Arrow, 1962; Nelson, 1982; Mokyr, 2002; Scotchmer, 1991; Rosenberg, 1976). Much of this information is negative, ranging from failures, defects, and harms, and is common across the economy: from smartphone, laptop, and electric vehicle battery fires, to toy malfunctions, to unexpected side effects in pharmaceuticals, to surgical robot arms colliding during surgery. Despite the salience and prevalence of such negative product information, we know relatively little about how it shapes firms' subsequent R&D decisions.

On the one hand, negative information about existing products can reveal new opportunities, spurring additional entrepreneurial energy and innovation investment (Krieger et al., 2022; Ball et al., 2022). On the other hand, they may cause firms to update their beliefs about expected demand as well as technical and regulatory challenges associated with developing novel products in that market, leading to declines in related innovation (Hsu et al., 2025; Krieger, 2021). Beyond shaping the rate of innovation, the disclosure of negative product information may drive firms to adapt in ways that shift the direction of innovation and the allocation of innovative activity across markets and firms.

We leverage the unique features of the U.S. medical device setting to shed light on this issue. Against a backdrop of public disclosure of adverse events (AEs) via the Manufacturer and User Facility Device Experience (MAUDE) database, 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] The existence of this program was not made public. In June 2019, following the public exposure of the program's existence, the FDA ended the ASR program, and released all historical AE data, covering 6 million reports including deaths, serious injuries,

[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.

and malfunctions.[2] Using a difference-in-differences (DID) design that exploits this industry-wide exogenous increase in disclosure of adverse events, we provide three sets of results.

First, we show that the release of negative product information reduced the rate of innovation. The ASR data release led to a 17 percent decline in new device applications. The decline is immediate and persistent, lasting years after the data release. The decline is largely driven by medium-risk devices that can still present meaningful harm but do not require the stringent and time-consuming pre-market approvals required for high-risk devices. As a result, post-market information is particularly informative for firms and consumers.

Second, we shed light on the mechanisms through which mandatory disclosure of negative product information shapes innovation. The termination of ASR operated through two channels: it revealed new information about competitors' products (an *information effect*) and removed firms' ability to withhold negative product quality information about their products going forward (a *withholding effect*). While we find evidence of both mechanisms, we show that the decline is largely driven by information effects. First, the FDA began winding down the ASR program in 2017, allowing us to empirically separate information and withholding effects. The bulk of the decrease aligns with the release of ASR data in 2019, not with the earlier 2017 wind-down period when firms began losing their ability to withhold AEs. Second, the post-2019 decline is largely driven by firms responding to the release of competitors' AEs, that is, firms that had not used the ASR program themselves. Consistent with informational effects, we find evidence of information spillovers: innovation also declines in technologically related markets that were directly exposed to the ASR information shock (Harhoff, 1996; Alcácer and Chung, 2007; Bloom et al., 2013; Bai et al., 2024; Deore et al., 2024).[3] These patterns highlight how the revelation of competitor information via mandated disclosure can have a chilling effect on innovation. These declines are largest in markets with

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

[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. We provide more details in the data section.

more substitutes where the degree of unmet need is lower.

Third, we show that firms adapt their R&D investments in response to the changed information environment. We find that firms shift towards less novel, safer, and higher quality R&D investments in exposed markets, and also reallocate their portfolios to shift investment away from exposed markets. The disclosure also reshapes markets: the number of research-active firms in exposed markets declines overall, driven largely by incumbent exit. Taken together, these findings show that mandated disclosure of negative product information shapes not only the rate of new product introductions, the types of products developed, which markets firms choose to compete in, and the set of firms that innovate.

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., 2022; Krieger, 2021; Kao, 2024; Cunningham and Kapacinskaite, 2025; Hsu et al., 2025). We contribute in several ways.

One stream of prior research has focused on endogenous disclosure of negative pre-market information (e.g., trial failures (Krieger, 2021)), or on product-specific, temporally exogenous negative product disclosure events (e.g., drug relabeling, toy recalls) affect demand (Higgins et al., 2021; Freedman et al., 2012), divert firm resources and attention (Natividad and Sorenson, 2015; Macher and Wade, 2016). When there are specific complementary resources, R&D failures can lead to increases in own R&D (Krieger et al., 2022). One-off product failures are also associated with competitor new product introductions (Ball et al., 2022). Yet, we know relatively little about the effect of exogenous disclosure of product quality information that permanently alters the information environment across an industry, thus shifting firms' expectations about demand and about technological and regulatory feasibility.

A second stream of recent research focuses on the effects of *mandated* pre-market disclosures (e.g., clinical trial results) finding peer learning may lead to fewer new projects (Hsu et al., 2025) and to firms waiting to learn and thereby slowing innovation (Cunningham et al., 2025). However, such mandates involve a mixture of changes to withholding and information and the information environment changes are more diffuse, which make it difficult to

isolate the mechanisms by which mandated disclosure of negative information shapes innovation. 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.

We build off of these two streams by focusing on the exogenous disclosure of post-market negative information, combining the effects of changes to demand for existing products (per the literature that focuses on product-level failures) and changes to the information environment which allow for technology-related learning, and separate from withholding effects. Related to this, we move beyond considering innovation rate (Ball et al., 2022; Krieger, 2021), to examine how firms adapt, i.e., shifts in product attributes, portfolio allocation, and market entry.

Finally, we contribute a novel approach to identifying information spillovers across markets that extends beyond traditional measures, such as patent classifications and citations (Trajtenberg et al., 1997; Fleming et al., 2007; Bloom et al., 2013). To do so, we leverage FDA predicate relationships (i.e., regulatory linkages that require firms to reference prior, technologically similar products as a basis for marketing approval). As such links are reviewed by regulators, they provide a validated and precise measure of functional similarity across products. Predicate linkages often capture relationships that may be missed by other similarity measures (including patent class groupings), such as changes in product design or function. This approach also could be applied in other regulated settings where firms must demonstrate technological equivalence to related, 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).

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 discusses managerial implications and 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.[4] Medium risk devices (e.g., catheters, infusion pumps) typically are required to follow a Pre-Market Notification 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.[5] 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, such as evidence of substantial equivalence to predicate or clinical trial evidence.

[4]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.

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

2.2 Negative Product Disclosure: Adverse Events

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. 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. 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).[6] Public disclosure of AEs helps with post-market safety monitoring, consumer decision-making and ideally helps to improve device safety over time. Approximately 95% of AEs in MAUDE come from manufacturer firm reports (Everhart et al., 2025). Importantly, firms use publicly available AE databases (i.e., MAUDE) to learn about rival product usage and product failures (Maslach et al., 2018).

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.[7] AEs reported via the ASR were subsequently excluded from MAUDE, and thus from public disclosure, because they "were not submitted in a form compatible with

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

[7]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).

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).[8] The ASR program was subsequently expanded to additional product markets, though public details on this expansion are unavailable.[9]

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 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. 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 B1).

[8]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).

[9]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.

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. For simplicity, our main treatment measure compares markets with any AEs in ASR to those with none. However, we leverage this variation in our robustness tests in Section 4.4.

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. In subsequent sections, we exploit this staggered wind-down to shed light on underlying mechanisms.

2.3 Conceptual Motivation

To motivate our empirical analysis, in this section, we consider how negative product disclosure might affect the rate and direction of subsequent innovation. Fundamentally, innovation is cumulative (Scotchmer, 1991). Previous inventive activity—both successes and failures–lays the foundation for subsequent technological development (Rosenberg, 1969, 1976). Yet, for innovation to effectively cumulate, relevant information must be disclosed in an accessible way (Mokyr, 2002; Murray and O'Mahony, 2007; Gross, 2023; Hegde et al., 2023).

2.3.1 Impact of Negative Disclosure on the Rate of Innovation

In the innovation context, negative disclosure suggests a particular innovation may not work as intended. It can include failures in pre-market tests or post-market adverse events, and vary in both severity and scale.

Because innovation is cumulative, increases in disclosure of negative information change the information environment for subsequent innovation. Negative information plausibly affects firm innovation decisions through two information channels: (1) changes to beliefs about

market opportunities, as increases in negative information may decrease consumer demand for affected, and closely related, products, and (2) changes in beliefs about the quality of affected (and related) technologies, as increases in negative information reveal issues with if and how such products work.

In terms of market opportunities, the direction of the effect on subsequent related innovation is not immediately clear. After a negative disclosure event, demand for the focal product likely decreases, as previous research has demonstrated (Higgins et al., 2021; Freedman et al., 2012). Decreased demand for the focal product may lead the focal firm to increase marketing spending and R&D and acquisition activity in the focal product market to fill newly unmet demand and utilize complementary resources (Macher and Wade, 2016; Krieger et al., 2022). Beyond the focal product and firm, negative demand effects can spillover to highly similar products of other firms (Freedman et al., 2012; Zavyalova et al., 2012), which, may also thereby lead such firms to increased R&D efforts and innovation in affected markets (Ball et al., 2022). Such reasoning would imply an increase in innovation. However, this logic implicitly assumes the negative disclosure creates an unmet need to fill via innovation, i.e., a positive shock to demand. If there are viable substitutes, negative information may not create demand.

Further, in terms of technological information, increases in negative disclosure suggest focal and similar technologies may not work as well as previously believed. Related empirical evidence finds when disclosure mandates increase negative disclosure, firms are more able to learn from peer failures, and subsequently slow down their new product development (Cunningham et al., 2025), shut down related inventive projects (Krieger, 2021), and start fewer related inventive projects (Hsu et al., 2025).

Taken together, these two information channels imply that the information effects of negative disclosure on the rate of innovation are not clear.

In addition to these information effects, when disclosure is mandated, firms may also respond to the loss of their ability to selectively withhold negative information for past and

future products. A large literature on selective disclosure shows that when firms are able to withhold information, they tend to withhold negative product quality information from consumers, investors, and competitors (Dranove and Jin, 2010). When firms can no longer withhold evidence of low product quality, they may expect less demand and investment, or additional scrutiny (Jin and Leslie, 2003; Dranove and Jin, 2010; Bernstein, 2015). As a result, under the withholding effect, firms expect lower returns to innovation, leading to a decline in the rate of innovation.

The relative size of withholding and information effects likely depends on the relative number of firms that have access to opportunities to withhold information. In contrast, information effects are potentially valuable to all firms that are operating in or considering entry to, affected and technologically-related markets. Therefore, empirically, withholding effects should be most salient when the ability to withhold information is removed and should occur among previously withholding firms. In contrast, information effects should be strongest when the information is publicly released and should also extend to firms and markets that were previously not able to withhold.

2.3.2 How Firms Adapt to Disclosure Mandates

In addition to affecting the overall rate of innovation, the disclosure of negative product quality can lead to firm adaptation, which has implications for the direction of innovation as well as the allocation of research activity across markets and firms.

First, firms may adjust product attributes in response to the disclosure of negative product quality information. When negative information changes beliefs about market opportunities, firms expect that demand will shift towards safer and more reliable products. Previous work on product quality disclosure has shown that firms will invest in quality improvements when poor performance becomes disclosed (e.g., in hospitals, restaurants) (Jin and Leslie, 2003). At the same time, negative product disclosure changes beliefs about the riskiness of certain product attributes. Firms can use information about competitors' failures to adapt

their own product attributes by emphasizing features that mitigate newly revealed risks (Maslach, 2016; Lee et al., 2021). Against this backdrop, firms that can no longer withhold negative product quality information and face heightened scrutiny or reputational risk, may reduce risk-taking and emphasize safer, more incremental projects. Taken together, we would expect that the disclosure of negative product quality information would shift the direction of innovation towards safer, higher quality, and more incremental products.

Second, firms may reallocate their R&D portfolios across markets in response to shifts in exposure. Prior work has shown that firms' reallocate their R&D portfolios across markets in response to differences in regulatory scrutiny and costs. As a result, firms that previously benefited from selective withholding may strategically reallocate R&D resources away from markets with high exposure–where scrutiny and perceived risk are greatest–toward less-exposed markets.

Third, disclosure mandates may alter market structure by changing the distribution of information-related advantages and incentives across firms. Incumbents that may have previously benefited from opportunities to withhold information may have experienced reduced advantages, while entrants can exploit newly available information to identify opportunities. This shift in the information environment may lead to shifts in market structure (Kim et al., 2023).

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.[10]

[10]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 M&A activity.

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, it ultimately covered 102 distinct product markets.[11] 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.[12] Figure 2 shows that by 2018, half of the product markets active in 2017 no longer had AEs added to the ASR. In a subsequent analysis, 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 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.[13]

3.2 Medical Device Innovation

Our primary measure of innovation is new medical device applications as reflected in device application data for 1997 to 2023 from the FDA supplemented by Evaluate Medtech, including both 510(k) device clearances and pre-market approvals (PMAs). 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 A1 provides an example of

[11] One of the original ASR product markets had no AEs in the ASR data: Diagnostic IV Catheter (DQO).
[12] Additional details can be found in U.S. Food and Drug Administration (2019)
[13] Robustness checks Appendix C indicate that our effects are robust to continuous treatment measures.

an approved device application.

3.2.1 Measuring Technological Relatedness Across Markets

To test for potential information spillovers across markets, we identify product markets technologically 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 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 spillovers from negative information release. 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 "substantial equivalence" to a previously approved "predicate" device. This equivalence is based on intended use, materials, and efficacy. Further, empirical evidence suggests information spillovers across predicate links (Everhart et al., 2023; Hsu et al., 2024). Using predicate links between devices, we consider product markets as technologically related if at least one device in a product market references as a predicate a device in another product market (or vice versa). Using this approach, approximately 40% of product markets are linked.[14] 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 and R&D 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 of innovation.

[14] See Appendix A.1 for more details.

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 uses 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.

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 patent-class-to-medical-device-product-market link created by Cunningham and Hall (2025). This 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 *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 probabilistic 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.[15] 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 are conducted at the product market-year level. We begin by identifying 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 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 ensure our product market level results are not driven by just a few firms, to explore mechanisms, and to examine adaptation. We discuss the specific datasets and specifications in their respective sections.

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

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 heteroskedasticity-robust standard errors clustered at the product market level.

Descriptive evidence provides support for our empirical strategy. Panel A of Appendix Figure B1 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 of 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 (1). 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.[16] 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 withhold seeking applications of devices that are already "on the shelf." This is supported by evidence in Table C4 that shows the overall declines are driven by 510(k) applications, i.e., medium-risk devices that require clearances rather than (more stringent and time-consuming) approval for marketing.

To account for firm-level heterogeneity within product markets, we also conduct a firm-product market-year analysis. 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.[17] We adapt equation (1) 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

[16] 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.

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

application in a firm-product market-year. In particular, we estimate:[18]

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

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*. In this section, we leverage unique institutional details of the device setting to unpack the relative importance of each mechanism by exploiting variation across time, firms, and markets.

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 begun winding down in 2017, as the FDA gradually revoked exemptions for certain product markets and firms. This staggered wind-down provides an opportunity 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

[18]The trends shown in Panel B of Appendix Figure B1 provides support for this specification.

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 and 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 matter, 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

To investigate these mechanisms further, 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) in a firm-product market-year level analysis.[19] 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 firms with prior use of ASR in a given product market experience a significant decline following the ASR wind-down, with no additional decline following the information release. This result is consistent with the withholding effect, where 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, consistent with the information effect where firms respond to newly available information.

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 not directly face a decrease in the ability to withholding

[19]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.

in the focal product market. First, such firms may be aware of the existence of ASR. In an additional analysis (in Appendix Table C7) 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.

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 provide 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 firm innovation.

4.3.4 Substitutability

Our results suggest that, largely driven by information effects, firms decrease their innovation in response to negative product disclosure. The direction of these effects was not ex ante obvious. Prior research suggests a tension between the opportunity for innovation, i.e., for new products to fill potential unmet needs, which would suggest increased innovation, and the revelation of increased technological and regulatory costs of innovation in affected markets, which suggests decreases.

To explore this tension, we examine whether the ASR shock has a larger effect in markets with more available substitutes, and thus a lower degree of unmet need. We measure available substitutes as both *within market* and *across market*.

Within market: We measure within market substitutability at both the device- and firm-level. 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. Table 6 shows that the decline in device applications is significantly larger in markets with a high number of substitutes.

Across market: To proxy for across market substitutability, we use the FDA's regulatory classification structure of different product markets (i.e., "product codes"). Specifically, the FDA device regulatory structure situates product codes within regulatory groups of closely related (and regulated) devices. For instance, *Permanent pacemaker electrodes*

(DTB) and *Temporary pacemaker electrodes (LDF)* are grouped together in *CFR § 870.3680 Cardiovascular permanent or temporary pacemaker electrode*. Some product codes have such related product codes, i.e., close substitutes; others do not. In Table 7 we separate out markets with close substitutes from those without (single market). We find our results are confined to markets with close substitutes (per Column 1 and 3). Further, we split out the High Exposure markets into those with a non-ASR substitute market and those with no non-ASR substitute market (including both ASR markets without any substitute market and those in which the only substitute market(s) are also in ASR). We find, in Column 4, that our results are driven by those with close, non-ASR substitutes.

Overall, these results suggest that when the potentially positive demand-related effects of negative disclosure are less evident, firms decrease innovation in response to negative information shocks.

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 restricts the sample to product markets within the same device specialties as those represented in the ASR database. Column 2 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 3, we exclude product markets authorized for emergency use during the Covid-19 pandemic (e.g., ventilators and respiratory assistance devices).[20] Second, in Column 4, we

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

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 ASR shock, we leverage differences in the size and composition of the newly released AEs to show that product markets exposed to larger information releases experienced greater declines in device innovation. Online Appendix Table C2 reports three exposure measures. 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 shows that product markets with a larger absolute increase in publicly available AEs experience a significant decline in device applications. Column 3 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.

The degree to which the ASR release affects firms should depend on how actionable the disclosed information is. We proxy for actionability using the recency of the AEs: if AEs were deposited more recently, they are more likely to reflect safety issues that remain relevant for current products. We therefore classify product codes into those with relatively old ASR (below the median AE age) and relatively recent ASR (above the median AE age) based on when their AEs were placed in ASR. Table C3 shows that the decline in applications is concentrated in product codes with more recent ASR exposure.

Finally, we examine heterogeneity by device type. Appendix Table C4 shows the overall decline is in 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 investigating 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 three key dimensions: (i) product attribute adaptation, (ii) portfolio reallocation, and (iii) market exit/entry.

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 quality of innovation. To examine this, we conduct a product market-year analysis that allows us to examine changes in the nature and quality of new devices in response to changed information environment, in Table 8.

The information shock generates increased negative information about existing products in the market, likely reducing demand for existing products and those perceived to be similar. As such the information shock provides opportunities for firms to compete by introducing different and more innovative alternative products. Further, we might expect firms to focus on improving the safety and quality of their new devices, given the negative focus of the information.

To examine changes to the nature and quality of innovation, we examine device novelty, safety focus, and quality. Table 8 presents these results. We find devices tend to be less novel: they are less likely to reference a novel predicate device (new-to-the-market) and the predicate devices they reference tend to be older. In terms of R&D investments, the patents in High Exposure markets become more safety-focused and, the quality of their patents (measured

by having any forward citations within 2 years of grant) in High Exposure markets increases significantly.[21]

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 firms plausibly aware of ASR before it was widely revealed, i.e., firms with device approvals in any ASR product market pre-2019. Such firms, who, given potential prior withholding behavior, may face heightened scrutiny and have incentives to shift R&D activity toward less exposed product markets. Further, it is only for such firms that we can credibly identify changes in portfolio allocation involving ASR 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 given 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 heteroskedasticity-robust standard errors clustered at the firm level.

[21] In Appendix Table D2 we split the results by ASR Aware and ASR Naive firms. "ASR aware" firms are defined as those with device approvals in any ASR product market before the program ended and the database was released in 2019 (between 1997 and 2018.) 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. We see that for ASR aware firms, even R&D quantity, as measured by patent filings, decreased in High Exposure markets.

Table 9 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 firm 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. 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) not just the firm's prior use of product markets with AEs in ASR.

Column 1 of Table 10 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 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 is 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 organizational 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 D2) and reallocation decisions (in Table 9) 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 are 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 to 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 D2. 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.

6.3 Role of Selection

An additional alternative explanation for our results is selection. For instance, perhaps the markets in ASR (and/or the firms in those markets) are less promising or otherwise less amenable to innovation. If these markets are more likely to be treated (i.e., have ASR AEs),

it would be plausible that such selection is driving the decline in innovation post-ASR shock.

A few features of the policy and shock lessen this concern. First, there is significant (often long) temporal separation between a product market's inclusion in ASR and the 2019 information shock, suggesting the drop in innovation in these categories was not a result of anticipatory effects. Second, much of the ASR effects we find are from firms who did not themselves have AEs in ASR, as per Table 3, suggesting the decreases are not due to something specific about the firms (or firm-markets) that opted into ASR.

Third, when ASR was first initiated, it was not clear that the AEs submitted through the program would not be disclosed publicly, thus lessening the concern that such markets were chosen to minimize disclosure-related innovation effects. Yet, it is true that when later markets were added to ASR (for which we are unable to observe the process) firms could reasonably assume such AEs would not be publicly disclosed. If our results were driven by these later-added markets, we might conclude some form of market selection is driving our results. However, when we split out the effects by *Original* versus *Non-Original* ASR markets, in Appendix Table C9, we see both categories of ASR markets have significant negative effects.

Finally, to assess whether product markets associated with ASR differed in their underlying propensity for innovation, we follow Williams (2013) and compare pre-1999 trends in device applications across product markets with different levels of ASR use before our study period. We consider two comparison types: (i) *Original* versus *Non-Original* ASR markets and (ii) product markets with any ASR AE (i.e., High Exposure) to those without. Figure C1 shows that in both cases, the difference is relatively flat over time. This suggests that research propensity is not evolving differentially prior to our study period and that product code fixed effects likely capture differences across product markets.

7 Conclusion

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We find mandated negative product disclosure significantly reshapes both the rate and nature of innovation. Using 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, focusing on safer and higher quality development, while new entrants (ASR naive firms), in contrast, introduced more novel devices and focused on higher-quality R&D in 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 some initial shifts towards qualitative improvements and safer products.

[22]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.

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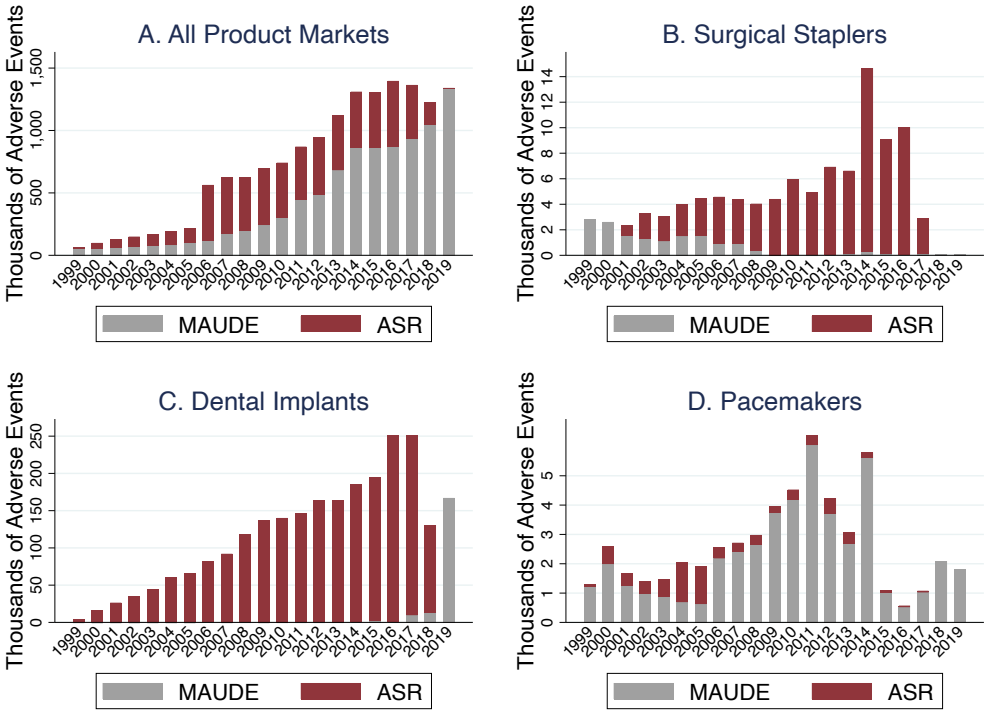
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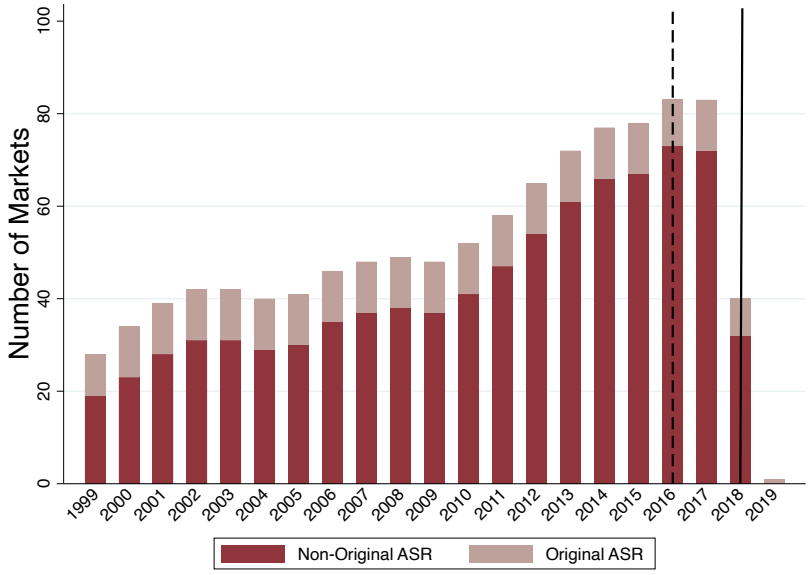
Figures and Tables

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



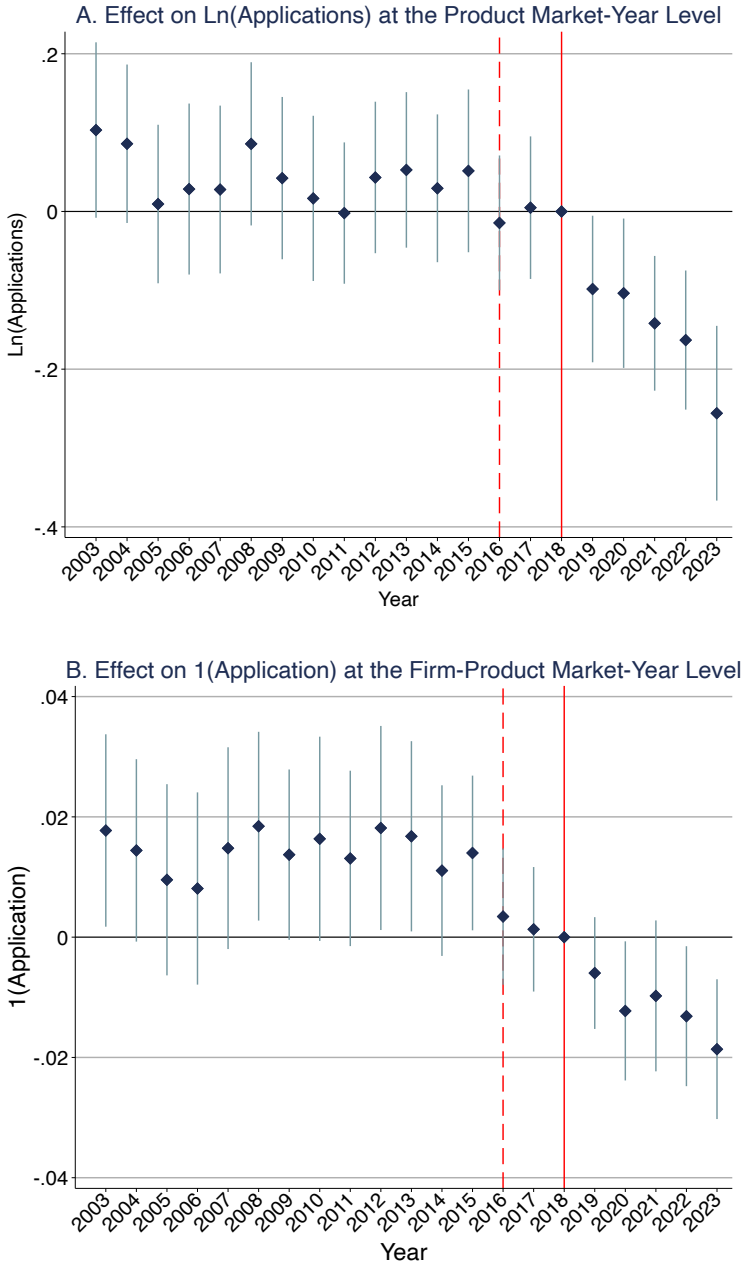
Note: This figure shows the trends in the number of MAUDE and ASR adverse events. The sample includes all adverse events submitted to either database between 1999 and 2019.

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 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 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 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 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: Impact of ASR Release on Device Applications, Heterogeneity in Within Market 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 *within market* 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 7: Impact of ASR Release on Device Applications, Heterogeneity in Across Market Substitutability

	Single Market			ASR mkt split
	No	Yes	Int.	
	(1)	(2)	(3)	(4)
A. Product market-year level, dependent variable: Ln(applications)				
Post Release x High Exposure	-0.219***	-0.0800	-0.217***	
	(0.0489)	(0.0527)	(0.0488)	
Post Release x High Exp X Single mkt			0.132*	
			(0.0712)	
Post Release x High Exp (non-ASR sub mkt)				-0.248***
				(0.0531)
Post Release x High Exp (no non-ASR sub mkt)				-0.0557
				(0.0417)
Mean of Dep. Var.	0.225	0.185	0.213	0.213
Observations	47,124	18,858	65,982	65,982
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	-0.0243***	-0.00764	-0.0246***	
	(0.00591)	(0.00610)	(0.00584)	
Post Release x High Exp X Single mkt			0.0180**	
			(0.00820)	
Post Release x High Exp (non-ASR sub mkt)				-0.0260***
				(0.00604)
Post Release x High Exp (no non-ASR sub mkt)				-0.00483
				(0.00498)
Mean of Dep. Var.	0.0491	0.0363	0.0457	0.0457
Observations	495,188	178,545	673,733	673,733
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 *across market* 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. There are two sets of analyses. In Columns 1-3, we flag whether the product market has any close substitute medical device product markets. If not, we consider it a *single market*. In Column 4, we split ASR markets into those with a non-ASR market as a close substitute and those without a non-ASR close substitute market. ***p<0.01, **p<0.05, *p<0.1.

Table 8: 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)
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.

Table 9: 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 10: 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	-0.343***	-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 Data Construction

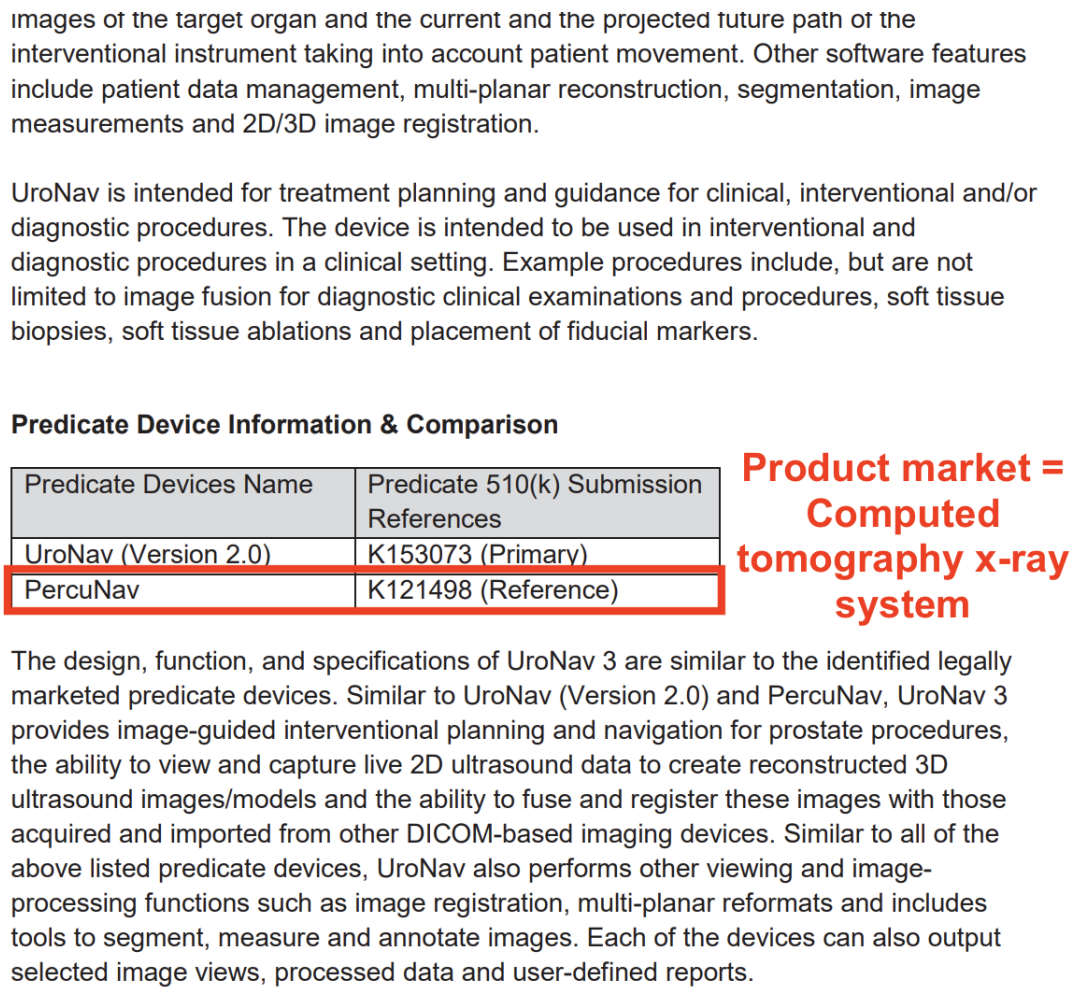
Figure A1: Example: Device Application K182561



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

Appendix A.1 Linking Product Markets Using Predicates

Figure A2: 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 A1) 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").

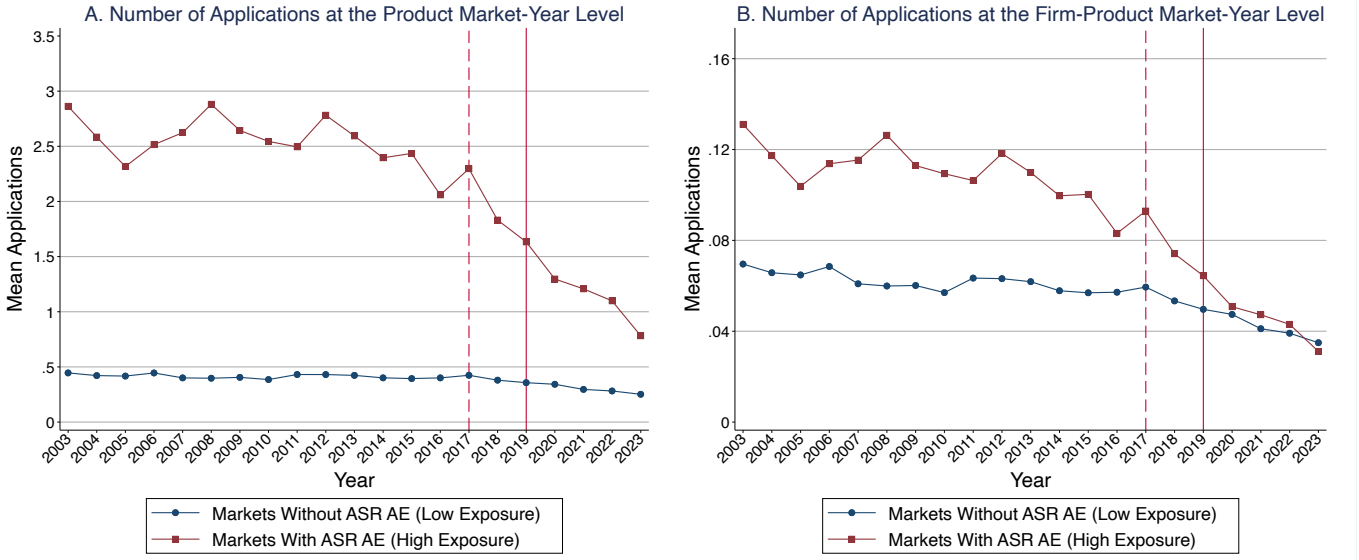
Appendix B Additional Summary Statistics

Table B1: 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 B1: 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 C Robustness Checks and Heterogeneity

Table C1: Impact of ASR Release on Device Applications, Alternative Specifications and Samples

	Restricted Specialities	Matched Regression	Excl. Covid Product Markets	Excl. Covid Product Markets and Firms
	(1)	(2)	(3)	(4)
A. Product market-year level, dependent variable: Ln(applications)				
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.	0.154	0.269	0.152	0.128
Observations	85,604	90,874	105,363	105,363
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	-0.0238***	-0.0226***	-0.0236***	-0.0212***
	(0.00519)	(0.00582)	(0.00520)	(0.00479)
Mean of Dep. Var.	0.0426	0.0486	0.0434	0.0461
Observations	662,032	727,975	781,292	609,379
Year FE	YES	YES	YES	YES
Firm-Market FE	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 restricts the sample to product markets within the same device specialties as those represented in the ASR database. Column 2 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 3 excludes product markets authorized for emergency use during the Covid-19 pandemic. Column 4 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 Varying Exposure Size Measures

Exposure Size Measure:	Continuous Exposure Share	Difference in AE Levels/1000000	Difference in AE Share Across Markets
	(1)	(2)	(3)
A. Product market-year level, dependent variable: Ln(applications)			
Post Release x Exposure Measure	-0.301***	-0.481***	-1.196
	(0.0852)	(0.0216)	(3.100)
Mean of Dep. Var.	0.147	0.147	0.147
Observations	108,780	108,780	108,780
Year FE	YES	YES	YES
Market FE	YES	YES	YES
B. Firm-product market-year level, dependent variable: 1(application)			
Post Release x Exposure Intensity	-0.0407**	-0.0470***	-4.70e-08***
	(0.0163)	(0.0133)	(1.33e-08)
Mean of Dep. Var.	0.0442	0.0434	0.0434
Observations	720,554	782,441	782,441
Year FE	YES	YES	YES
Firm-Market FE	YES	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 varying exposure size measures. *Continuous Exposure Share* is the 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. *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, by Old vs. Recent ASR Exposure

	(1)
A. Product market-year level, dependent variable: Ln(applications)	
Post Release x High Exposure x Old ASR	-0.164***
	(0.0418)
Post Release x High Exposure x Recent ASR	-0.223***
	(0.0547)
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 Release x High Exposure x Old ASR	-0.0162***
	(0.00555)
Post Release x High Exposure x Recent ASR	-0.0283***
	(0.00883)
Mean of Dep. Var.	0.0352
Observations	782,441
Year FE	YES
Firm-Market FE	YES

Note: This table reports DID estimates of the effect of the ASR data release on device applications, by varying ASR Age. *Old ASR* is an indicator for product codes whose most recent ASR AE is below the median (in years) among product codes with ASR AEs. *Recent ASR* is an indicator for all other product codes with ASR AEs. 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 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 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: Impact of ASR Release on Device Applications, Heterogeneity by Market Device Type

	Diagnostic/ Monitoring	Prosthetic	Surgical	Therapeutic
	(1)	(2)	(3)	(4)
A. Product market-year level, dependent variable: Ln(applications)				
Post Release x High Exposure	-0.470***	-0.0203	-0.136**	-0.219**
	(0.151)	(0.0435)	(0.0636)	(0.0856)
Mean of Dep. Var.	0.344	0.335	0.125	0.210
Observations	10,185	9,009	15,645	11,151
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	-0.0310***	-0.00713	-0.0140*	-0.0220**
	(0.0104)	(0.0124)	(0.00725)	(0.00863)
Mean of Dep. Var.	0.0621	0.0775	0.0280	0.0397
Observations	129,839	106,053	147,491	109,338
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 device markets with different types of use. 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 C6: 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.

Table C7: 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.

Table C8: Effect of ASR Wind-down and Data Release on Public AEs

	(1)
A. Product market-year level, dependent variable: Ln(Maude AE)	
Post WindDown x High Exposure	1.087***
	(0.189)
Post Release x High Exposure	0.232**
	(0.108)
Mean of Dep. Var.	0.585
Observations	108,780
R-squared	0.805
Year FE	YES
Market FE	YES
B. Firm-product market-year level, dependent variable: Ln(Maude AE)	
Post WindDown x High Exposure	0.0952***
	(0.0362)
Post Release x High Exposure	0.0348
	(0.0219)
Observations	782,441
Mean of Dep. Var.	0.181
R-squared	0.694
Year FE	YES
Firm-Market FE	YES

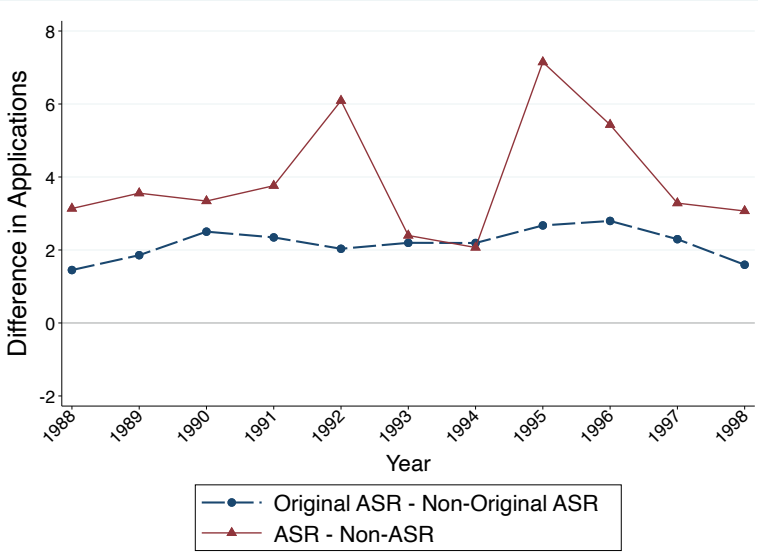
Note: This table reports DID estimates of the change in MAUDE AEs following the closure of the ASR program and the public release of its data, and separately accounts for the wind-down of the ASR program. The effect of the initial (not publicly announced) policy wind-down, which started in 2017, is separately 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 maude AEs. Standard errors are clustered at the product market level. Panel B presents firm-product market-year level estimates of the effect on the log number of maude AEs. Standard errors are clustered at the firm and product market level. ***p<0.01, **p<0.05, *p<0.1.

Table C9: Impact of ASR Release on Device Applications, Heterogeneity by Original versus non-Original ASR Market

	(1)
A. Product market-year level, dependent variable: Ln(Applications)	
Post Release x High Exp (Original ASR)	-0.325***
	(0.106)
Post Release x High Exp (Non-Original ASR)	-0.171***
	(0.0348)
Mean of Dep. Var.	0.147
Observations	108,780
Year FE	YES
Market FE	YES
B. Firm-product market-year level, dependent variable: 1(Applications)	
Post Release x High Exp (Original ASR)	-0.0275***
	(0.00869)
Post Release x High Exp (Non-Original ASR)	-0.0228***
	(0.00590)
Mean of Dep. Var.	0.0434
Observations	782,441
Year FE	YES
Firm-Market FE	YES

Note: This table reports DID estimates of the effect of the ASR data release on device applications, splitting the ASR effect into *Original* ASR markets, those included in the program by the FDA at it's outset, and *Non-Original* ASR markets. 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.

Figure C1: Differences in Device Applications Across Device Types



Note: This figure shows the average difference in device applications across product markets in the pre-analysis period. The dashed blue line reflects the average difference between *Original* ASR markets (those included in the program by the FDA at it's outset) and *Non-Original* ASR markets. The solid red line reflects the average difference between those with any ASR AE (i.e. High Exposure markets) to those without any ASR AE.

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").

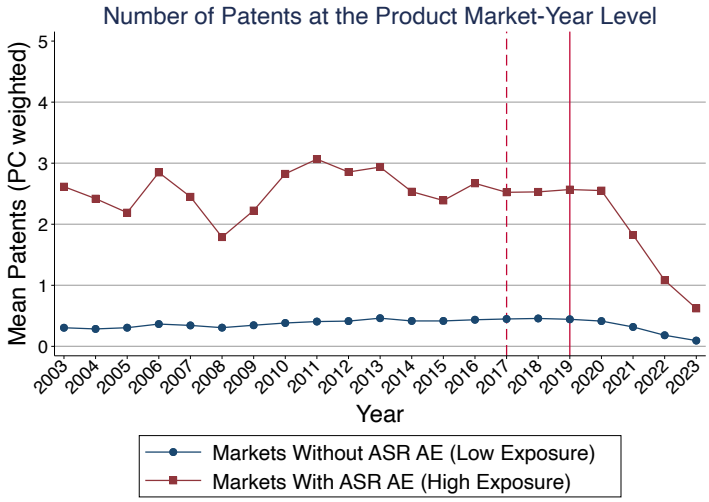
Table D2: Product Attribute Adaptation

	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			0.0155	0.0285	0.173***
			(0.0161)	(0.0477)	(0.0654)
Mean of Dep. Var.			0.0146	0.174	0.412
Observations			108,780	9,061	9,061
Year FE			YES	YES	YES
Market FE			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.