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PRODUCT LIABILITY LITIGATION AND INNOVATION: EVIDENCE FROM MEDICAL DEVICES

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ABSTRACT

We examine the relationship between product liability litigation and innovation by systematically combining data on product liability lawsuits with data on new product introductions in a panel dataset of leading medical device firms. We first document a decline in the propensity to introduce new products for both defendant firms and other firms operating in litigated device categories. This decline, however, does not spill over to other device categories, and we also do not find any slowing down in firms' patenting activities. We then show that changes in two features of the regulatory environment---(1) the availability of public information regarding adverse events and (2) federal law taking precedence over state law---substantially affect the likelihood of litigation. These changes also provide quasi-exogenous variations in litigation that confirm our baseline findings. Finally, we show that litigation appears to induce firms to develop safer devices. Overall, our findings suggest that product liability litigation affects the rate and direction of technological progress, and that safety regulation and liability regimes interact with one another in significant ways.

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1 Introduction

Risk and uncertainty create immense challenges with respect to firms' investment decisions (Bloom, 2009). In many sectors, a major risk stems from product liability lawsuits for harms that defective products cause (Viscusi, 2012; Hua and Spier, 2020). The volume of product liability cases has risen substantially in recent decades, reaching about 60,000 filings across U.S. courts in 2019 (Lex Machina, 2020). The salient nature of the human suffering associated with these cases also tends to attract extensive media coverage and public attention, which may significantly damage firms' reputations and reduce the perceived safety of their underlying technologies (Galasso and Luo, 2021). While the relationship between liability and innovation has long been contentious (Porter, 1990), advances in artificial intelligence and sophisticated robotics have further intensified this debate. As the European Union begins to modernize its product liability directive to account for these new technologies, the biggest opposition from the business sectors rests on the potential detrimental effects on innovation and the competitiveness of the region (AFNUM et al., 2023).

Despite the high stakes of these issues, empirical evidence regarding the liability-innovation relationship remains scarce. A small number of studies have investigated either the effect of an increase in the expected liability risk before any lawsuits are realized (Viscusi and Moore, 1993; Galasso and Luo, 2017) or the impact of a single significant litigation event that targeted a large upstream supplier rather than the producer of the defective product (Galasso and Luo, 2022). The present paper offers the first large-sample evidence examining the innovation impact of realized product liability litigation directly targeting the producers.

The net impact of product liability litigation on firms' incentives to introduce new products is theoretically ambiguous. In a canonical model, firms introduce a new product when the present value of its expected profits (net development and commercialization costs) exceeds the profits from its existing products. Seen through this lens, a firm may accelerate new product introductions once it becomes the target of litigation for two reasons. First, litigation reduces the profitability of existing products due to a greater risk of lawsuits and higher damage payments, consistent with viewing new and safer products as "remedial actions" in the law and economics literature (Chen and Hua, 2012). Second, litigation may increase consumers' willingness to pay for safety, thereby increasing the expected profits for new, safer products (Galasso and Luo, 2022).

Whereas the above arguments suggest that litigation would increase the rate of new product introductions, several opposing effects are also at play. Most directly, the litigation process, which is often lengthy and stressful, may impose significant financial costs on firms and divert their time and attention away from research and development (R&D) (Hunziker and Jones, 1994). Such costs may overwhelm the positive, accelerating effect of litigation, especially if safer products require significant resources and are techno-

logically challenging. In addition, uncertainty regarding potential new safety standards before litigation is resolved may also delay firm investment. Particularly concerning to industry observers, litigation may have substantial spillover effects far beyond a specific product or firm (Foote, 1988). These factors all underlie Porter's (1990) recommendation for "*a systematic overhaul of the U.S. product liability system*," in which he argues that "*product liability [in the U.S.] is so extreme and uncertain as to retard innovation*."

This theoretical ambiguity highlights the importance of empirical research. We investigate this issue by systematically combining data on product liability lawsuits with data on new product introductions. Our empirical context is the medical device sector, which is research-intensive and highly impactful on social welfare (Chatterji and Fabrizio, 2014; Stern, 2017; Grennan and Town, 2020). Medical device firms also account for a large fraction of product liability lawsuits (Lex Machina, 2020).[1] Moreover, the medical device industry is subject to both safety regulation and product liability, thus allowing us to examine how these policies interact. Empirical evidence on such interactions provides useful inputs to studies of the optimal mix of these two policies, which is relevant to both theory and policy (Shavell, 1984; Henry, et al., 2022).

The core dataset we construct includes information on both new product introductions and litigation for 45 leading medical device firms between 1995 and 2020. For each firm, we use application data provided by the U.S. Food and Drug Administration (FDA) to measure new product introductions to a given product category in a given year. We also obtain litigation data from the Judicial Panel on Multidistrict Litigation, which provides a complete list of multi-district litigation (MDL) cases—the predominant way in which significant product liability lawsuits are litigated in the medical device and pharmaceutical industries.

We present three sets of findings. First, we find that defendant firms' likelihood of submitting an FDA application in the litigated product categories declines by about 40% during active litigation, which on average takes about seven years. We also find a negative but smaller effect for non-defendant firms operating in the litigated product categories. This decline in new product introduction, however, is localized in that it does not spill over to other product categories, even those that are technologically adjacent. In addition, the decline is not permanent: New product introductions recover shortly after the litigation has concluded. Moreover, we do not find any evidence that the firms' patenting activities slow down due to litigation.

Our second set of results, which is based on two regulatory changes, demonstrates important ways in which the regulatory environment interacts with product liability litigation, which, in turn, affects innovation. These regulatory changes also provide quasi-exogenous variations in the likelihood of litigation,

[1] Data from LexMachina indicate that 55 percent of the federal product liability cases pending between 2015 and 2020 are related to the medical/pharmaceutical sector.

further confirming our baseline findings.

The first regulatory change regards the reporting of adverse events after a product is marketed. Because it is difficult to uncover all device-related problems before entry, the FDA collects information on adverse events associated with using a device from manufacturers and healthcare providers. Generally, the FDA has made these events searchable in a publicly accessible database. However, the FDA implemented an alternative system that collected adverse event reports associated with 100 product categories between 1999 and 2019 but never disclosed this repository to the public. We use this undisclosed database to show that the availability of public information on adverse events significantly affects the likelihood of litigation. We further leverage this setting to identify quasi-exogenous variations in litigation driven by the differential availability of public adverse-event information, which itself is related to differential awareness of the existence of this undisclosed reporting system. A two-stage least square analysis with instrumental variables confirms the negative association between litigation and the introduction of new products.

The second regulatory change is a regime shift after which federal law takes precedence over state law (known as federal preemption). Whether products that have passed a pre-market review by the federal agency should again be subject to product liability lawsuits governed by state law has long been a contentious issue. The 2008 Supreme Court's ruling in Riegel v. Medtronic clarified that federal preemption applies for devices that have already satisfied the FDA's most stringent approval process. We find that litigation against these types of devices indeed dropped after 2008. Moreover, leveraging this ruling as a source of quasi-exogenous variation in the rate of litigation, we again confirm our baseline results.

Our final set of results concerns whether litigation induces safer device development. In one analysis, we use the adverse event type information to examine whether devices introduced after litigation are less likely to be associated with death and injuries (the most severe outcomes). We then use medical device patent texts to assess whether litigation induces firms to file more patents related to safety. With both approaches, we find that devices introduced during and after litigation are safer than those introduced beforehand.

Taken together, our results show that the introduction of new products by both defendant firms and firms operating in the litigated product categories declines during periods of active litigation. We also find that the negative effect disappears after litigation concludes; it does not spill over beyond the relatively narrow technology areas, and there is no evidence that firms' patenting activities slow down. Product liability litigation also appears to be associated with an increase in device safety. These results provide valuable inputs into the debates regarding the role of product liability in innovation.They show that, in the U.S. medical device industry, contrary to the concerns of widespread chilling effects, the negative effect of product liability litigation on new product introductions is very much localized. They also suggest that features of the regulatory

environment—such as the transparency policy of adverse event information—and the legal process need to be considered in this conversation.

2 Related Literature

The present paper is related to the extensive law and economics literature, which is mostly theoretical, on how product liability affects firms' incentives to invest in safety.[2] Because firms respond to consumers' demand for safety and quality, an important theme of earlier studies was to find conditions under which product liability was socially desirable: for example, when consumers underestimate or do not observe product risks (Daughety and Reinganum, 1995); when consumers who place a higher value on the product are also those suffering accidents more frequently (Hua and Spier, 2020); and when intense competition diminishes firms' incentives to maintain their reputation (Chen and Hua, 2017). Related to our focus on realized lawsuits rather than the expected liability risk, Chen and Hua (2012) distinguished between ex-ante and ex-post effects of product liability. They allowed firms to increase product safety through ex-ante investment and by fixing problems when they arose after sales. They showed that higher liability created a trade-off between these two incentives and had a U-shaped impact on ex-ante investment in safety.

While the literature recognizes that product liability can have positive effects on product safety, several studies identified mechanisms through which liability may deter investment in new products that impose novel risks. Several of these mechanisms are rooted in behavioral biases involving novelty. One bias is ambiguity aversion: for example, Viscusi (1999) showed experimentally that judges preferred older products with well-known hazards over new products with uncertain risks, even if the latter were safer in expectation. Parchomovsky and Stein (2008) argued theoretically that the heavy reliance on the custom of tort laws biases firms against novel innovation even if it is potentially safer. Another bias is hindsight bias; that is, when someone gets injured, it may cause people to believe that the risk should have been anticipated ex-ante (Viscusi, 2012). Moreover, the substantial uncertainty of litigation outcomes, such as the size of the punitive awards, which could be exacerbated when the judges and jurors assess novel products, could also deter innovation (Sunstein et al., 2002). Finally, Dawid and Muehlheusser (2022) considered a market-size reason: When product liability is stringent, product entry is delayed, which reduces sales and ultimately discourages investment in safety or deters investment in the new technology in the first place.

Despite the extensive theoretical literature, large-sample empirical evidence on the relationship between liability and innovation is scarce. In a seminal article, Viscusi and Moore (1993) found a significant positive correlation between liability insurance premiums and R&D investments in a cross-sectional sample of large

[2] An extensive empirical literature exists on the link between legal liabilities and medical practice, as well as healthcare costs (e.g., Kessler and McClellan, 1996; Currie and MacLeod, 2008; Frakes, 2013).

U.S. firms in the 1980s. Galasso and Luo (2017) found that states changing laws to reduce the liability risk for medical practitioners, who are the users of medical technologies, experienced a significant decline in medical device patenting compared to states without such law changes. Thus, both studies found evidence against the dominant narrative that liability chills innovation (Porter, 1990). These results suggest the positive effect of greater liability on investment in risk-mitigating technologies and safer product designs may dominate potential chilling effects. Galasso and Luo (2022) examined the effects of a mass tort litigation against DuPont, an upstream material supplier, after a producer of jaw implants filed for bankruptcy. They showed that this litigation, while not affecting DuPont's innovation activities, had a large, negative effect on innovation in a variety of downstream permanent implant markets. This study suggested that misallocation of liability costs across the value chain may have had a substantial negative impact (Hay and Spier, 2005). In this case, upstream suppliers faced disproportionately high liability costs compared to their expected profits, which resulted in a market-wide withdrawal of large material suppliers and, in turn, led to a substantial decline in downstream innovation. The present paper contributes to this literature by adding new, systematic evidence on the impact of product liability lawsuits directly targeting the producers of new products.

An important aspect of our paper is how safety regulation interacts with product liability. This is related to the theoretical literature on the conditions under which either liability, regulation, or a mix of both should be used (e.g., Shavell, 1984; Kolstad, Ulen, and Johnson, 1990). More recently, Henry et al. (2022) highlighted the uncertainty and information acquisition in the innovation process and study when regulation is preferred to liability or vice versa. Our findings on how these two regimes may interact could provide valuable input to further theoretical investigations of the optimal mix of different policy tools.

Finally, our paper contributes to the literature on innovation in life sciences (see Kyle, 2022, for a recent survey for drugs). Two streams of research are especially relevant. The first relates to the impact of regulation. Notably, Peltzman (1973) argued that efficacy requirements beyond safety deters innovation; Rogers (2023) showed that deregulation was associated with more new medical technologies; and Stern (2017) investigated how regulatory uncertainty may create a disadvantage for first movers. For a positive case of more stringent quality requirements, Grennan and Town (2020) showed that it was important to induce adoption by mitigating quality concerns, at least in the case of coronary stents. Our paper contributes to this literature by studying how regulation may affect innovation through interacting with the product liability system. The second relevant stream is about the impact of product failures on innovation. Ball et al. (2019) showed a positive relationship between product recalls and innovation of the recalling firms' rivals; Krieger et al. (2022) found that drug withdrawals had a positive effect on focal firms' number of projects but a negative effect on rival firms; and Galasso and Luo (2021) showed that mass media coverage of CT

scanner accidents increased innovation of the entire industry, particularly in features that mitigate radiation risk. The paper contributes new evidence on the impact of product liability litigation.

3 Theoretical Considerations

Firms strategically choose when to introduce new products. In a canonical model of product innovation, it is optimal to replace an existing product with a new product if the present value of the expected profits from the new product (net of development and commercialization costs) exceeds the profits from the existing product on the market. Building on this simple idea, the industrial organization literature has identified several factors affecting product introduction decisions. These factors include competitive pressure, the presence of network externalities, and the role of intellectual property rights (inter alia see Katz and Shapiro, 1992; Waldman, 1993; Fishman and Rob, 2000; and Argente et al., 2020).

This simple insight can be used to link product liability litigation with a firm's product introduction decisions. Specifically, two effects of such litigation may increase a firm's incentive to introduce new products. First, litigation may make the existing product less profitable to the firm because it inflicts greater litigation costs than a new, safer product. Keeping the old product on the market is likely to lead to more litigation and greater damage awards or settlement payments than replacing it with a new product. From this perspective, introducing new products is one potential remedial action firms can take when facing product liability lawsuits (Chen and Hua, 2012).

Second, litigation may also incentivize new product introductions because it shifts demand. Aware of the litigation, consumers may perceive the old products as more harmful, and, at the same time, their willingness to pay for safety may increase. As a result, consumer demand for the old products will decrease whereas their demand for new, safer products will increase. In other words, product liability may create a demand-pull force that incentivizes firms to develop risk-mitigating technologies and replace old products with safer ones (Galasso and Luo, 2021).

While the aforementioned effects may encourage new product introduction, whether this is realized depends on other factors. One important consideration is the technological feasibility and the costs associated with developing and commercializing safer products. It is possible that improving safety is costlier and takes longer than improving along other quality dimensions. If such challenges are significant, we may see a slowing down of new product introductions among firms involved in product liability litigation despite the preceding positive effects. In the Online Appendix, we present a model, which builds on Waldman (1993), to formalize the prior discussion. The model, while simple, clarifies that the net effect of product liability litigation on new product introductions is theoretically ambiguous, highlighting the importance of empirical

investigations.

Product liability litigation may reduce the firm's incentives to introduce new products through other channels that are not considered in our simple model in the Appendix. First, litigation may cause disruptions at the defendant firm, financially and otherwise. Mass liability lawsuits, as we have seen in recent decades, can inflict significant financial costs on firms, potentially crowding out resources to develop new products. Corporate executives also stress the non-monetary costs of litigation, including the distractions and stress that firm employees experience during the process (Hunziker and Jones, 1994).

Moreover, legal considerations may delay new product introductions because changes to a product's design may be compelling evidence that the original product was defective. Whereas the admissibility of such evidence varies from state to state, the plaintiff's attorneys may use it in other ways to the disadvantage of the defendant firm. For this reason, legal professionals recommend giving careful consideration before redesigning products during litigation (Beck, 2022; Rudman and Winchell, 2023).

Lastly, mass tort cases may generate substantial regulatory and legal uncertainty that delay innovation investments. In some extreme cases, policymakers may even consider banning an entire product category, which happened in 1992 during the silicone breast implant litigation (Angell,1996). More typically, the discovery process, trial proceedings, and court decisions may reveal crucial information on product safety and design failures (Sieg, 2000). This information helps clarify what the new safety standards might be from a legal liability perspective and how the regulators may revise their approval criteria. Firms may want to wait for sufficient resolution of such uncertainty before making any significant investments.

The forgoing discussion focuses on how product liability litigation may affect the defendant firm's likelihood of introducing new products in litigated product markets. Product liability litigation may have other effects, for example, on other product markets in which the defendant firm operates, as well as on other non-litigated firms in the litigated markets (Jarrell and Peltzman, 1985; Nocke and Strausz, 2023). Moreover, as the discussion suggests, products introduced after litigation should improve upon the previous products in terms of safety and reduce consumer harm. We examine these effects empirically in Sections 8 and 9. Finally, whereas our paper focuses on the (ex-post) effect of realized lawsuits, firms are likely to adjust their innovation strategies even in the absence of litigation, if they perceive a change in the (ex-ante) litigation risk. We discuss the distinction between the ex-ante and ex-post effects of litigation in light of existing empirical evidence in Section 10.

4 Background

Medical device safety is governed by two types of public policies: regulation and product liability. While the present paper focuses on product liability litigation, we describe device regulation because understanding device regulation clarifies the empirical context and the data we use. Moreover, an important part of our analysis investigates changes in the regulatory environment that interact with the liability system.

4.1 Medical device regulation

In 1976, Congress passed the Medical Device Amendments (MDA), authorizing the FDA to regulate all medical devices to ensure the safety and efficacy of these products. The FDA's core functions include regulating the approval process before a device is marketed, as well as monitoring product performance and responding to newly discovered risks after a device is marketed.

The approval process depends on the risk level of a device. The FDA assigns devices into three classes. Class III devices pose the most significant risks to patients and are subject to Premarket Approval (PMA), the most stringent process. PMA requires scientific evidence, through nonclinical and clinical studies, that assures that the device is safe and effective for its intended uses. Examples of PMAs include implanted defibrillators and pacemakers. Class II devices pose moderate to high risks and are governed by Premarket Notice (510(k)), a much less involved process than PMA. The applicant needs to only provide proof that the device is substantially equivalent—with the same intended use and the same technological characteristics—as a legally marketed device that is not subject to PMA. Examples of 510(k) devices include x-ray machines, fetal monitors, and muscle stimulators. Class I devices pose minimal risks and are largely exempt from the regulatory screening process.

Because it is difficult to uncover all device-related problems before entry, it is critical for the FDA to acquire information on potential device-related safety issues after a product is marketed. Manufacturers, importers, and device user facilities are required to report certain device-related adverse events and product problems to the FDA. Healthcare professionals, patients, and other consumers are encouraged to voluntarily report adverse events. These reported events are hosted in the Manufacturer and User Facility Device Experience (MAUDE) database on the FDA's website and are searchable by the public.

When systematic patterns of safety issues arise, federal statutes mandate that firms initiate recalls to remove or correct violative products. While firms undertake most recalls voluntarily, the FDA has the authority to order recalls when a firm's remedial actions are inadequate. The FDA classifies recalls into three classes. Class I is the most severe and refers to a situation in which the use of the product has a reasonable probability of causing serious adverse health consequences or death. An example is potential battery issues

of devices that help hearts pump blood. Class II refers to a situation in which using a product may cause temporary or medically reversible adverse health consequences. An example is software malfunctioning that may lead to inappropriate dose changes of an insulin pump. Class III recalls are the least severe and are unlikely to cause adverse health consequences, such as product mislabeling.

4.2 Product liability litigation

Product liability operates through the court system, whereby patients harmed by design, manufacturing, or marketing defects of a product can bring lawsuits against the product's producer. The primary goal of product liability is to compensate the victims for their economic losses such as medical expenses and lost wages, as well as non-economic losses such as pain and suffering. In addition, product liability laws seek to deter the production of unsafe products that cause harm. This deterrence is achieved by punishing the defendant firm through punitive damages beyond the compensation purposes. Product liability is generally governed by state laws. However, because many lawsuits tend to involve plaintiffs from multiple states, the multidistrict litigation (MDL) procedure used in the federal court system has become a dominant way to litigate product liability cases, especially for medical devices and pharmaceutical products.[3]

Federal statute established the MDL procedure in 1968 and has since been governed by the Judicial Panel on Multidistrict Litigation (JPML). Under this procedure, cases pending in different federal districts involving one or more common issues (e.g., injuries involving the same medical device) may be transferred to a single federal district court for pre-trial proceedings.[4] The purposes of such consolidations are "*to avoid duplication of discovery, to prevent inconsistent pre-trial rulings, and to conserve the resources of the parties, their counsel, and the judiciary*."[5] Although the MDL procedure relates to pre-trial management, nearly 96% of the individual cases consolidated in MDLs are terminated (through either dismissal or settlement) by the transferee judges responsible for the pre-trial proceedings (Smith, 2020). Cases that are not terminated are returned to their originating districts for further legal action.

We focus on MDL cases in the present paper for two reasons. The first reason is practical. Data on cases filed at state courts are fragmented and difficult to access. By contrast, comprehensive data on cases filed at federal courts are readily available. Whereas it is difficult to assess precisely how many non-MDL product liability cases involve medical device firms, the available evidence suggests that this number is small. For example, LexMachina, a leading legal analysis database, reported that in 2018, 34,448 new

[3]Even though the majority of MDL cases (about 76%, according to the data available in LexMachina) relate to product liability, the MDL procedure is used in other areas such as antitrust, securities fraud, and IP infringement. According to a recent report, at the end of 2018, the 248 pending MDL dockets accounted for 52% of all pending federal civil cases (Fuchsberg and Dang, 2019).

[4]Some MDL-associated cases might initially be filed in state courts. These cases may be removed from state courts to federal district courts and then transferred to the designated transferee court that is responsible for the pre-trial proceedings.

[5]https://www.jpml.uscourts.gov/about-panel.

product liability cases were filed in federal district courts involving defendants in the Medical Equipment and Supplies Manufacturing (NAICS 3391) sector and that 97% were consolidated in MDLs. By contrast, an estimate based on the 2018 Court Statistics Project (CSP) report suggests that about 525 product liability cases involving medical devices were filed in (non-MDL) state courts in the same year.[6] Second, non-MDL litigations tend to involve relatively few plaintiffs in limited geographic locations. Relative to these individual, non-consolidated lawsuits, MDL litigations tend to amass a larger number of plaintiffs and are significantly more costly for the defendant firms.

Industry reports and commentators have noticed a dramatic increase in the number of filings in product liability MDLs. Cohen and Thompson (2020) commented that this rise has largely "*been prompted by plaintiff's attorney advertising and social media, which have skyrocketed over the last decade—particularly with respect to drug and device product liability cases, advertised by plaintiffs firms that aggregate hundreds or even thousands of cases.*" AdvaMed, a medical device industry association, published several articles on the potential role of third-party litigation financing in boosting plaintiff attorneys' ability to turn litigation into long-term business ventures via advertising to find clients. They claim that "*the vast majority of product liability litigation against them is driven by litigation financing,...*" and "*overall, financing litigation against medtech companies only compromises patient interests and chills innovation"* (White, 2023).

5 Data, Variables, and Methods

5.1 Sample construction

Our sample includes 45 leading medical device firms that we identified from the following sources. First, we looked for firms in Compustat, a comprehensive database of publicly traded firms, with primary 4-digit Standard Industrial Classification codes in the broader 3-digit code 384 "Surgical, Medical, and Dental Instruments and Supplies." Following Gaonkar and Moeen (2023), we also included firms whose primary code is 5047, "Medical, Dental, and Hospital Equipment and Supplies." Within this set of firms, we selected the top 30 based on their average annual sales between 2000 and 2020. These firms account for about 80% of the total sector sales during this time window reported in Compustat.[7] Second, because the previous step

[6] To the best of our knowledge, precise statistics on state court cases and their case type breakdowns are not available. The number 525 is derived as follows. According to the CSP (2018) report, the total number of incoming civil caseloads at all state courts in 2018 is 16.4 million. About 4% of civil cases are tort cases, and about 1% of tort cases are product liability (the vast majority of state tort cases are auto torts). This implies that about 6,560 of the 2018 state caseloads are product liability cases. The CSP (2018) report does not provide data on the industry breakdown. However, according to the LexMachina data, about 8% of federal product liability cases are medical device cases. This suggests that about 525 cases in 2018 were product liability cases related to medical devices.

[7] We dropped firms that were active for fewer than 5 years in the 2000s and consolidated entities that changed names during the sample period.

might miss large private firms or public firms such as J&J and GE whose primary sectors are not medical devices but nonetheless are important players in this industry, we further identified medical device firms from rankings available from three industry trade magazines. We first added firms that were not captured by the first step but were featured as the top 30 largest medical device firms by MPO (Medical Product Outsourcing) Magazine's annual report at least 10 times during the period 2005-2020. We then added several additional top-ranked firms in product categories that are associated with high liability risks: orthopedic implants and cardiac pacemakers.[8]

A complication of the medical industry is that acquisitions are common. Because the FDA databases often list the acquired firms rather than the parent firms, we might miss new product introductions and important events without addressing these acquisitions. In the Online Appendix, we provide a detailed description of how we collected the acquisition data and cleaned firm names in the FDA databases. Ultimately, we identified 254 firms that were acquired by the 45 firms in our sample and their acquisition dates. For all of the variables of interest (e.g., new product introductions and litigation events), we assigned the values associated with the acquired firms to the acquiring firms starting from the year of the acquisition. While not common, there are also divestitures. We collected divestiture dates and removed the values of our variables of interest from the parent firm after the year of the divestiture. Data associated with these acquired firms before their acquisition (and the spun-off firms after the divestiture) were removed from our sample. In other words, our sample still consists of 45 firms, but their innovation activities and events data were adjusted by the acquisitions and divestitures.

With the help of the new product application data provided by the FDA (which we introduce in detail in the next section), we organized our sample as a panel at the firm-product category-year level, where product categories were defined by the product code data assigned by the FDA. A product code distinguishes a generic type of device, for example, pulmonary valves. We defined the beginning of a firm's presence in a product category (code) as the year in which the firm applied for its first application in this product code or acquired a firm that had pre-existing products in this code. We used 1995 as the start of our sample. Thus, a firm-product code starts either from its beginning year of code presence or 1995. In the baseline analysis, we assumed that a firm operates in a product code until the end of our sample, which is 2020, except if the firm was acquired by another firm before 2020. The final sample includes 86,741 firm-product code-year observations between 1995 and 2020, with 45 unique firms and 2,089 unique product codes.

[8]For orthopedics, we included firms that are featured in the top 10 orthopedic device producers ranked by the leading industry publication ODT (Orthopedic Design & Technology) Magazine at least 10 times during the period 2005-2020. For cardiac pacemakers, we included firms in the top 10 list ranked by the leading industry intelligence company "Meticulous Research" in 2020.

5.2 Variables

We construct the variables of interest at the firm-product code-year level.

5.2.1 New product introductions

Our key outcome of interest is new product introductions, which are based on the PMA and 510(k) databases that the FDA maintains. There are 86,856 unique new 510(k) applications between 1995 and 2020, 88% of which are Class II devices. The PMA dataset includes the original and supplemental applications (e.g., design changes or production process changes). Between 1995 and 2020, there were 888 unique new PMA applications, 90% of which were Class III devices, and 38,289 supplemental applications.

In most regressions, our dependent variable is the count of original PMA applications and 510(k) applications in a firm-product code-year. Note that a 510(k) application is much less costly than a PMA application (in terms of R&D investments, trial costs, and approval time). Thus, the same number of new product introductions in a 510(k) code will carry a different economic significance from a PMA code. This is less concerning because we control for firm-product code fixed effects and, hence, the estimated effects of litigation are based on comparisons within a specific product code. Our findings are robust to the inclusion of 3,421 PMA supplemental applications for significant design changes in the total count of new product introductions for PMA codes.[9]

5.2.2 Product liability litigation

The Judicial Panel on Multidistrict Litigation (JPML) website provides the complete list of 1,596 MDLs that are terminated by September 30, 2021, as well as 245 MDLs that are pending as of September 30, 2021.[10] The caption of each MDL allows us to detect the product sector and lawsuit type (e.g., product liability, patent infringement, or antitrust). For example, the caption of MDL #2158 is "Zimmer Durom Hip Cup PL," where Zimmer is the defendant firm, hip cup is a type of implant, Durom is the trademark of the product, and PL indicates product liability. Using MDL captions, we identified 45 unique product liability MDLs involving medical devices. For each MDL, the JPML reports provide information on the cumulative number of cases that are filed locally and transferred into the governing district court of that particular MDL at the end of a (fiscal) year.[11] Thus, the difference in the number of cumulative cases filed between two

[9] The PMA dataset provided by the FDA indicates the supplement type; for example, "Normal 180 Day Track" and "Panel Track" are for substantial changes in designs and processes, whereas "30-Day Notice" and "Real-Time Process" are minor changes. There is also information on the reason for change such as "Process Change - Manufacturer/Sterilizer/Packager/Supplier" and "Change Design/Components/Specifications/Material." We define significant design changes as supplement reason being "Change Design/Components/Specifications/Material" and supplement type being "Normal 180 Day Track" and "Panel Track."

[10] https://www.jpml.uscourts.gov/statistics-info

[11] A fiscal year at JPML starts from October in the previous year to September in the current year. In our analysis, we merge the litigation events in a fiscal year to new product introductions in a calendar year. Thus, the effect of litigation should be interpreted

adjacent years is the number of newly filed cases in a given year.

To match the litigation data to our sample, we need to identify the defendant firms and the product codes that are litigated. We identify the defendant firms using court documents obtained through the leading legal analytics database LexMachina, as well as from the Federal Judicial Center's Integrated Database.[12] To identify the product codes of the medical devices litigated, we manually identify the device names from the court documents and search for the original 510(k) or the PMA applications of these products based on the information on the product name, the brand name, and the defendant firms. We then assign the associated product codes to an MDL. Multiple product codes might be affected by an MDL. Ultimately, we found 215,483 total cases (associated with 37 MDLs) that were filed in 1995-2020 against 16 firms in our sample.

5.2.3 Adverse events and recalls

We also collect information on the number of adverse events and the number of product recalls a firm experienced within a product code in a given year. For the adverse events data, the primary database is the MAUDE database, which is publicly searchable. We use adverse events in this database starting from 1997, which was when the database started including manufacturer reports.[13] A total of 10.7 million adverse events were reported between 1997 and 2020. Thirty-five percent of these reports involve serious injuries, 1.48% involve deaths, and the remainder are device malfunctioning without any serious injuries or death.

We append MAUDE data with adverse events data from the Device Experience Network (DEN) reporting system, which hosts publicly available reports between 1984 and 1996. We also collect adverse events data from the Alternative Summary Reporting (ASR) database. As we explain in detail in Section 7.1, these adverse events were submitted to the FDA between 1999 and 2019 but were not released to the public. There are a total of 5.8 million event reports, 39% of which involve injuries and deaths. All of these adverse event datasets contain information on the manufacturing firms (whose names need cleaning and standardization) and the product codes of the medical devices. Using this information, we calculate the total number of adverse events associated with a firm-product code-year, as well as separately the number of events that were released to the public versus hidden events that were not.

The recall data are downloaded from openFDA.[14] There are 44,140 recall events between 1995 and

with this slight lag in mind.

[12]The Federal Judicial Center's Integrated Database provides information on civil cases filed and terminated from 1970-1987 and pending from SY 1988 to the present.

[13]The downloadable MAUDE data files consist of voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996. Because the manufacturer reports comprise the majority of the reports, we started using MAUDE in 1997. Earlier adverse events data are hosted in the Device Experience Network (DEN) reporting system from 1984 to 1996.

[14]These bulk-downloaded data contain information on the recall dates, firm identities, and the 510(k) and PMA numbers of the recalled product but not the recall class. We separately collect the recall-class information on the FDA recall website and merge it

2020. Seven percent are Class I recalls, and 63% are Class II recalls. Following Ball et al. (2019), we focus on Class I and II recalls in our empirical analysis, as these recalls present the most significant patient health risks and are more disruptive to firms than Class III recalls. We identify the product codes affected by a recall based on the 510(k) and PMA numbers included in the recall database. This allows us to construct the total number of Class I and Class II recalls a firm experienced in a product code in a given year.

5.3 Descriptive statistics

Table 1 provides summary statistics for the main sample. There is at least one FDA application for 11% of the firm-product code-year observations, and the average number of FDA applications is 0.176. While a sizable share of our sample firms (16 out of 45 firms) has experienced litigation, these events only occur in a small number of product codes (28 out of 2,089 unique codes). Across all observations, the probability of having active litigation is only 0.4%. Conditional on having active litigation, however, the number of new cases filed per year is high at 913 per year.

Figure 1 plots the annual likelihood of having at least one FDA application in firm-product code combinations that have been ever litigated. The figure distinguishes between the period before (and after) litigation and the period during litigation.[15] The figure provides a first look at our main result showing that there are significantly fewer new product introductions during litigation relative to before and after litigation.

5.4 Empirical methods

Our regression analyses rely on the following model:

$$Y_{c,f,t} = \alpha + \beta Litigation_{c,f,t} + \gamma X_{c,f,t} + \delta_t + \theta_{c,f} + \varepsilon_{c,f,t}. \quad (1)$$

The unit of observation is a firm-product code-year and the dependent variable, $Y_{c,f,t}$, captures the introduction of new devices by firm f in product code c and year t. The treatment variable, $Litigation_{c,f,t}$ equals to one in the years in which firm f is actively involved in product liability litigation over its devices in product code c. The term $X_{c,f,t}$ captures a series of time-varying controls such as adverse events or product recalls. The terms δ_t and $\theta_{c,f}$ are year and firm-product code fixed effects. The coefficient β identifies the effect of product liability litigation on new device introductions. The baseline regressions are estimated by OLS, with standard errors clustered at the firm-product code level. In Section 6.1.3 and 7, we discuss potential endogeneity concerns and how we address this concern, to the extent we can; specifically, we saturate our model with time-varying trends in firm-specific broader technology areas, and we also leverage two

with the bulk-downloaded data using the unique recall event identifier.

[15] Not all MDLs are concluded in our sample period. Conditional on concluded cases, the median MDL takes about 7 years.

quasi-exogenous regulatory changes.

6 Baseline Results

Table 2 presents the first set of estimates quantifying the relationship between product liability litigation and new product introductions. For all regressions, the dependent variable is a dummy indicating that at least one application is filed by the firm in a product code in a given year, and the variable of interest is a dummy indicating that the firm experiences active litigation for devices in this product code. Column 1 controls for firm-code and year fixed effects. Column 2 controls for the underlying risk level by including the total number of adverse event reports associated with this firm-product code-year. Column 3 further controls for the type of adverse events reported by including the fraction of reports involving deaths and injuries. Column 4 adds firm-year effects that help control for time-varying effects at the firm level. All of these regressions show a statistically significant negative association between litigation and new product introductions. The magnitude is large. Considering that the mean value of the dependent variable for firm-product codes experiencing litigation is 0.370 in years with no active litigation, our estimated coefficients correspond to about a 40% drop in the propensity to introduce new products during active litigation years.

6.1 Robustness to the baseline results

In this section, we first provide several robustness checks using alternative measurements or specifications, which are presented in Appendix Table A1, and then describe three results that require an explanation of the institutional context. In Table A1, we first show that the results are robust to adjusting the dependent variable by taking into account, in acquisition years, the applications filed by the acquired firms in the five-year window preceding the acquisition. This adjustment reflects the notion that firms can innovate through both internal R&D and external acquisitions. We also confirmed that our findings are robust to adjusting the dependent dummy variable considering the supplemental PMA applications that significantly change the designs of pre-existing PMA products. We then confirm our results with a fixed-effects Poisson estimator, using the number of applications as the dependent variable.[16] In Column 4, we show that the results hold when controlling for knowledge stock defined as the logarithm of the discounted sum of applications filed by the firm in the previous five years, with the annual depreciation rate set at 0.15 as is in Hall et al. (2005). In Column 5, we show that the results are similar if we capture litigation with the logarithm of the number of new cases filed in a year rather than with a dummy variable. In Column 6, we show that our results are

[16]This estimator isolates the within firm-code variation in applications and drops firm-codes in which there is no filing for our entire sample period. In an unreported specification, we also show that the results are similar in an OLS model with the total applications as the dependent variable. We also confirm the baseline finding with a (more conservative) double clustering of the standard errors at the firm and code level rather than the firm-code level as in the baseline.

robust to using the "imputation estimator" developed by Borusyak, Jaravel, and Spiess (2023) who aimed to address the potential biases of a staggered roll-out of the treatment.[17] In Column 7, we show that the results hold when we control for the average time the FDA takes to approve applications submitted in a specific product code in a year.[18] Finally, we confirm that the negative effect is not driven by a complete exit by the litigated firm from the litigated product code.[19]

6.1.1 Device recalls

When systematic problems arise, firms often conduct product recalls, either voluntarily or mandated by the FDA. We want to control for product recalls because these actions may also negatively affect firm's product introduction decisions. We shorten our sample period because data on product recalls are systematically available only after 2003. Recalls are much more frequent than litigation; 4% of the firm-code-year observations in the 2003-2020 subsample are associated with at least one Class-I or Class-II recall. We show, in Column 1 of Appendix Table A2, that the coefficient of litigation is similar to our baseline results when controlling for the log of the total number of recalls in a firm-product code-year. This remains the case for the subsample of firm-codes that experience at least one recall during 2003-2020 and when controlling as well for the number of recalls in previous years.

6.1.2 Case resolution

Another issue to address is whether the negative effect estimated is driven exclusively by cases in which the defendant firm lost and was required to pay damage awards. To address this concern, we collect data on case outcomes from Lex Machina and supplemental sources. Almost all MDLs in our data involve some sort of global settlement, but in some cases, the settlement is preceded by court findings that are in favor of the defendant or the plaintiff. We use this information to code litigation outcomes. Specifically, if we see that more than 20% of the filed cases are still unresolved at the time of our analysis, we code the MDL as pending. For non-pending MDLs, we code about 21% of the MDLs as won by the defendant (when court

[17] The "imputation estimator" computes unit and period fixed effects using only untreated observations and generates imputed outcomes to estimate the treatment effect. We also address the potentially biased estimates due to the staggered roll-outs of treatment by decomposing the two-way fixed effects estimator following the procedure developed in Goodman-Bacon (2021). The decomposition shows that the timing variation accounts for less than 1% of the estimated effect, which implies that essentially all the identifying variation comes from comparison to firm-code units not litigated during our sample period.

[18] It is possible that litigation may have alerted the FDA to increase the stringency level of the approval process for products in the litigated categories. Unreported results, based on a dataset of individual applications, show that applications submitted in the litigated product codes during active litigation years do not take a longer time to be approved than other applications.

[19] We define "exit" by inactivity of five years following the last filing of the firm in the code. To account for truncation, if the last filing of a firm-code happens after 2017, no exit is defined. If the last filing happens before 2017, we impute exit five years after the last recorded filing. In unreported regressions, we re-estimated the exit regression using a proportional hazard survival model with a Weibull distribution. If anything, the estimated hazard is less than one (equal to 0.895) suggesting lower likelihood of exit during (and after) litigation, but the standard error is large and we cannot reject that the exit rate is independent of litigation. Overall, this analysis suggests that litigation does not induce firms in our sample to permanently exit the technology area.

findings are in favor of the defendant and no damages are awarded) and 8% as lost (when findings are in favor of the plaintiffs and damages are awarded). The remaining 47% are coded as settled. These are the cases for which Lex Machina shows no court findings or damages.

In the last column of Appendix Table A2, we examine whether cases coded as won or lost are associated with differential impacts on the likelihood of new products in comparison to cases settled or still pending. The results show that our baseline finding is not driven by the handful of cases in which the defendant firms lost. The estimated effects appear slightly stronger for lost cases and slightly milder for cases that are won by the defendant firms. However, these differences are not statistically significant from the default pool of settled and pending cases that constitute the majority of our sample MDLs.

6.1.3 Controlling for time-varying changes at the level of broader technology areas

A natural concern is that the negative association between innovation and litigation identified in the previous analysis may be biased due to unobservable variation over time, which is correlated with both new product introductions and litigation. One can think of several channels through which this may happen, and the implied biases may go in different directions. For example, one may expect that increasing trends in product sales may stimulate innovation but also increase the likelihood of litigation, as more patients may be injured. In this case, not controlling for product sales would lead to an underestimation of the effect of litigation. Alternatively, media coverage of adverse events may also relate to both variables; negative coverage may spur litigation and chill adoption, which in turn chills innovation. In this case, not controlling for media coverage would lead us to overestimate the effect of litigation.

It is generally challenging to control for product sales, as detailed device sales data provided by vendors such as ECRI typically cover only five to seven years of our sample period and only a subset of the devices (Grennan and Swanson, 2020). Although it may be possible to get longer and more complete coverage based on publicly available procedure data, such data are typically coarse and cannot distinguish different producers. Media coverage may have a similar problem in that it often mentions only firm names and general device names. This may lead readers to infer negative information at a level that is broader than the specific litigated devices. Due to these data challenges, we take a different approach by saturating the model with time-varying fixed effects for a firm and a broader technology area. The idea is to mimic the level of time-varying factors as if we could access broader-level sales or media coverage data.

We use the Code of Federal Regulations (CFR) to define broader technology areas. The CFR uses a hierarchical classification system. At the highest level, we have 16 medical specialties. Take "888.331 - Hip joint metal/polymer constrained cemented or uncemented prosthesis" as an example. The medical specialty,

orthopedics, is indicated by the first three digits 888. Within a specialty, the first decimal digit (in the example above, 888.3) defines 73 subgroups. These subgroups typically categorize the devices into diagnostic, monitoring, and therapeutic devices within each specialty. Using the two decimals (in the example 888.33), we get 371 narrower categories that are related to specific types of devices such as hip-joint prosthesis or knee-joint prosthesis. This level of classification is roughly equivalent to controlling for detailed time-varying measures (e.g. sales, market share, media mentions, etc.). The narrowest level of classification (938 classes) may describe differences in technologies, materials, or more detailed components. For example, a different parallel class to the above example is "888.332 - Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis."

On average, each of the 16 medical specialties contains about 130 product codes in our sample; each of the 73 subgroups contains 29 product codes; each of the 372 categories includes 5.6 codes; and the narrowest classification includes about 2.2 codes each. Appendix Table A3 presents a series of regressions that include firm-broader technology area-year effects, where the broader technology areas are defined at different levels. The estimated coefficient of litigation remains negative and significant in most of the regressions. In Column 4, where we use the finest level (938 different groups), while the magnitude of the estimate drops in half, it remains negative and statistically significant at the 10% level. Overall, this analysis suggests that the negative association between litigation and new product introduction uncovered in our baseline model is unlikely to be driven primarily by time-varying omitted variables.[20]

6.2 Dynamic effects of litigation

In this subsection, we conduct time-specific analyses to examine both the pre-trends and potential dynamics of the effect of litigation. We first estimate a dynamic specification of our baseline model in which the coefficients β_τ capture the differences between the treatment and control firm-codes in year τ relative to the year when litigation starts. Figure 2 plots the estimates from this model, where the year before litigation is the baseline (i.e., β_{-1} is normalized as 0). The lagged coefficients are statistically insignificant, small in magnitude, and bounce around zero. This supports the common trend assumption. The figure also shows that the decline in new product introductions takes place relatively quickly, and remains somehow constant during the litigation span.

In Appendix Table A4, we extend the baseline model to separate the time period during active litigation

[20] We also conduct the test proposed by Oster (2019) to evaluate the robustness of our results to potential omitted variables. The test uses the changes in the coefficients and R-squared after the inclusion of controls to construct bias-adjusted treatment effects. Specifically, we compare our baseline model (Column 2 of Table 2) to the most saturated specification in Table A3 (Column 4). The bias-adjusted coefficients are bounded above from zero. This provides additional support for the conclusion that our findings are not entirely driven by omitted variable bias.

and the period after the litigation has concluded.[21] The estimates show that the decline is not permanent; indeed, the rate of new product introductions recovers to the pre-litigation level, starting around the second year after the litigation has ended. Additional analysis suggests that the end of litigation seems to have a specific effect, other than the simple passage of time, that may be necessary to develop safer products. Specifically, we show that the pattern—the drop in the likelihood of new product introductions is relatively quick and stays stable over the entire litigation spell—holds regardless of the length of active litigation.[22] These results suggest that the defendant firms might be waiting for the litigation to conclude. As discussed in Section 3, this may happen if firms are concerned about their remedial actions, such as product redesigns, being used against them in court. This worry is further confirmed by our conversations with industry insiders.

7 Regulatory Environment and Litigation

This section investigates two regulatory changes that shed light on how features of safety regulation may affect product liability litigation and, in turn, new product introductions. We also exploit the quasi-exogenous variations in litigation resulting from these regulatory changes to confirm our baseline findings.

7.1 Public availability of adverse event information

As mentioned, the FDA continues its benefit-risk assessment of a product after it is marketed, and an important means to achieve this goal is to collect adverse events from device firms and healthcare providers. The FDA generally makes these reports publicly searchable through the MAUDE database. The public availability of such information is relevant for us because it affects the likelihood of litigation. Industry reports have documented ways in which plaintiff attorneys leverage such information to identify potential cases and find clients. For example, Lockard (2007) wrote, "*Plaintiffs' counsel are becoming more skilled at using regulatory agencies and public health authorities to identify their targets and to lay the framework for their suits. They scour FDA databases and state agencies for adverse-event reports and news of potential recalls.*" According to Medmarc (2022), "*plaintiffs' attorneys know that even without a single 'strong' case, life sciences companies may be amenable to settling when faced with a multitude of potential lawsuits and the expense and bad publicity that necessarily accompany such suits*."

[21] Cases can be returned to state courts for trial after the MDL process, which is for pre-discovery, has concluded. However, because the vast majority of MDLs end in settlement and because we do not systematically observe state cases, we define the concluding year of an MDL as the concluding year of the litigation in this study.

[22] We run three regressions for this analysis. In the first two regressions, we separate firm-codes with litigation spells longer than (and including) seven years from those shorter than six years. For both sets of litigations, we include two dummy variables indicating the two years before the end of litigation. Both show that the recovery does not start before the litigation. In the last regression, presented in Column 4 of Appendix Table A4, we included ten dummy variables indicating each year after the beginning of the litigation until 9 plus years, as well as a single dummy variable indicating the post-litigation period. While the post-litigation variable has a positive and significant coefficient, the coefficients of all the dummies during active litigation are consistently negative and similar in their magnitudes.

The quasi-exogenous shock we examine in this section results from a program the FDA implemented that incidentally kept a large number of adverse events hidden from the public between 1999 and 2019. Since 1984, the FDA Medical Device Reporting regulations have required firms to file a separate report for each adverse event (FDA, 2018). As the number of adverse events grew in the 1990s, the FDA was overwhelmed by the costs of reviewing these reports. According to former FDA official Larry Kessler, "*thousands of injury and malfunction reports poured into the agency each month, with about 15 staff members dedicated to reviewing them*" (Jewett, 2019). To reduce this administrative burden, the FDA implemented an Alternative Summary Reporting (ASR) program, which enabled manufacturers of certain devices to submit quarterly summary reports instead of individual reports (FDA, 2019). Device manufacturers in 12 product codes were informed about the ASR program in 1997, and reporting into this database started in the fourth quarter of 1999. Over time, the ASR program expanded to 102 product codes and received 5.8 million reports until June 2019 when the program was terminated.[23] In comparison, the total number of reports received by the MAUDE database is 8.2 million in the same time period, covering 4,102 product codes.[24]

A crucial feature of the ASR program, which is central to our analysis, is that these reports were not made public until after the Kaiser Health News (KHN) reported about this program in March 2019. The FDA stated that the main reason for not publicly releasing the information was that the format of the ASR submissions was not compatible with the public database (FDA, 2019). Industry accounts also claim that the existence of the ASR program was not well-known to the medical community, including the medical device companies, medical practitioners, and plaintiff lawyers. According to KHN, the ASR was "*so obscure that it is unknown to many of the doctors and engineers dedicated to improving device safety. Even a former FDA commissioner said he knew nothing of the program*" (Jewett, 2019).

In this section, we first show that the public disclosure of adverse event information indeed matters for litigation. Specifically, Column 1 of Table 3 regresses the litigation dummy on the number of hidden reports (included in ASR) and the total number of adverse event reports, which is the sum of reports included in the MAUDE and ASR databases, associated with a firm-code-year. We find a strong positive correlation between the total number of reports and the likelihood of litigation. Notable is that the number of hidden (ASR) reports is also strongly associated with litigation, but the correlation is negative, and the magnitude exactly offsets that of the total number of reports. These results suggest that only public reports drive litigation, and

[23] There was no clear official information about the criteria for the eligibility of reporting into the program. The initial communication targeted manufacturers operating in 12 product codes with adverse events "well known to the FDA" (FDA, 1997). A revision to the guidelines published in 1999 did not specify the set of products for which the reporting exemption could apply.

[24] The sharp contrast in the number of reports per product code between ASR and MAUDE (56,862 vs. 1,999) is consistent with the fact that the 102 product codes included in the ASR program are significantly more likely to be implants and Class-III devices (the highest-risk devices).

additional adverse events reported to the hidden database do not increase the likelihood of litigation. Column 2 confirms this finding in a specification that regresses the litigation dummy on $log(\text{total events})$ and $log(\text{total events}/\text{public events})$.[25] Column 3 further excluded the 12 product codes that the FDA initially included before the formal roll-out of the ASR program. It is possible that the device problems in these 12 product codes were sufficiently well known that plaintiff lawyers might already be working on litigation regardless of whether the events are reported in the hidden database or not.

The second exercise we conducted is to delve deeper into the drivers of ASR reporting within a firm-code. Appendix Table A5 focuses on the codes outside the 12 codes that were originally included in the program during the period 2003-2018 so that we can also control for recalls. The first regression shows that the number of hidden reports increases with the total number of adverse reports, but it decreases with the number of serious events (deaths and injuries). The positive correlation with the total reports is intuitive and is confirmed by our conversations with industry insiders familiar with the ASR program, which they use for efficiency purposes because it allows for bulk-reporting. The FDA's guidelines forbid reporting events involving deaths, and serious injuries under specific cases to the ASR program. This partly explains the negative correlation between the number of ASR reports and the number of serious events.[26]

Because the existence of the ASR program was not widely known in the industry, we separately investigate firms that might be more likely to be aware of the program and those that are less aware. Intuitively, firms operating in the original 12 codes around the time when the FDA initiated the program (specifically, 1995–1999) were informed by the FDA about the program. In contrast, firms that were not active in any of these original 12 codes around that time are less likely to be aware of the ASR. Indeed, the second and third columns in Appendix Table A5 show that the associations between adverse events and the use of ASR are driven exclusively by firms that were more likely to be aware of the program. Less-aware firms are significantly less likely to use the ASR in the first place, and the little use of the program is not correlated with the adverse-event volume.

Finally, building on the aforementioned results, we examine whether our baseline result is robust to exploiting the quasi-exogenous variation in litigation driven by the differential availability of public information on adverse events. Column 1 of Table 4 presents the estimates of a 2-stage least square (2SLS) regression in which litigation is instrumented by a measure of the number of adverse events hidden in the

[25] Notice that $b_1 log(\text{total events}) + b_2 log(\text{total events}/\text{public events}) = \beta_1 log(\text{total events}) + \beta_2 log(\text{public events})$, where $\beta_1 = b_1 + b_2$, and $\beta_2 = -b_2$. Then, $b_2 = -0.006$ implies $\beta_2 = 0.006$, and $b_1 + b_2 = -0.006 + 0.006 = 0$ implies $\beta_1 = 0$. Thus, conditional on the same number of public events, the variation in the number of total events (which comes from the hidden events) does not matter.

[26] Our conversations with industry insiders also suggest that while they know that the ASR reports are not made public, they do not believe that the motive to use the program to hide serious incidences is common. This account is consistent with the data in that we do not observe a positive relationship between the number of ASR reports and the number of serious events.

ASR database. The regression confirms the negative association between litigation and new product introductions. Column 2 of Table 4 presents a similar analysis using instrumental variables constructed using information on: (1) whether the firm was likely to be aware of the ASR program and (2) the number of total and non-serious adverse events associated with a firm-code-year. This approach adds an additional layer of exogeneity, as it does not rely on a firm's actual reporting decision. This regression also confirms the negative association between litigation and new product introductions. With both IV approaches, the estimated negative effect is larger than our baseline estimate in magnitude, suggesting a potential underestimation of the OLS estimates.

7.2 Federal preemption: Riegel v. Medtronic, Inc.

The second regulatory change we study relates to the extent under which federal regulation of medical devices supersedes state law; specifically, whether product liability lawsuits against devices that the FDA has deemed safe and effective after a full review should be precluded. The rationale for such liability exemption is that the FDA, which has extensive expertise, has assessed that the device is "safe enough" to be marketed based on substantial evidence during the approval process. As explained by Glantz and Annas (2008), such assessments should not be challenged on a case-by-case basis by courts and nonexpert juries who see the negative effects of a device on one person but not the benefits of a device to society as a whole. Even though the original regulation (MDA of 1976) included language that could be interpreted to preempt state tort law, the scope of federal preemption was unclear until the 2008 Riegel v. Medtronic Supreme Court decision (Gentry and McMichael, 2020). The Court held that medical devices approved under the PMA process were exempt from state liability claims for aspects of the products that the FDA has already reviewed (typically product designs). Furthermore, the language in the court decision clarified that 510(k) devices were not subject to federal preemption.[27]

For our purposes, this ruling provided a significant shift, in theory, in the likelihood of litigation faced by PMA devices relative to 510(k) devices. The first step of our analysis is to confirm empirically that this is indeed the case, because according to legal practitioners, plaintiffs' lawyers attempted various tactics after 2008 to circumvent federal preemption so that they could continue to bring lawsuits. One example of such tactics was to argue for manufacturing defects, as some language in the Riegel case suggests that manufacturing defect claims might escape preemption (Gentry and McMichael, 2020). For sharper results, we focus on comparing PMA devices to a set of relatively high-risk 510(k) devices (specifically, firm-code

[27]The rationale for not exempting 510(k) devices, as seen from the Supreme Court decision in the Medtronic v Lohr (1996), is that the 510(k) process, which requires only substantial equivalence, did not impose device-specific federal requirements ensuring safety. Source: "Re-visiting Medtronic v. Lohr After the Safe Medical Devices Act: The Argument for Express Preemption for 510(k) Devices," by James M. Beck and Kevin Hara, RX for the Defense, 2017, Volume 25 Issue 3.

combinations with more than 1,200 adverse event reports during our entire sample period, corresponding to the top decile of the sample distribution). Column 1 of Table 5 shows a significant decline in the litigation rate for PMA devices after 2008, compared to high-risk 510(k) devices.

We then zoom in on PMA devices and examine whether the effect of litigation has changed before and after Riegel. Column 2 of Table 5 shows that for PMA devices, the negative association between litigation and the propensity to introduce new products disappears after Riegel. One interpretation is that the surviving PMA lawsuits after 2008 are less likely to rely on design defect claims and instead focus on manufacturing defects or other claims. The latter types of claims are less likely to influence product innovations.

Finally, Column 3 of Table 5 exploits the variation in litigation caused by the Riegel case and uses the interaction between 'PMA' and 'after 2008' as an instrument for litigation. The 2SLS estimates confirm the negative effect of litigation on the introduction of new devices. Consistent with the ASR analysis, the magnitude of the IV estimate is significantly larger than the one obtained with OLS, suggesting a potential underestimation of our OLS estimates.

8 Spillover Effects of Litigation

The results so far show that product liability litigation leads to a significant decline in new product introductions by defendant firms in the litigated product categories. A big concern about liability litigation is that the negative effect spills over to other product areas or firms. We examine this question in this section.

8.1 Within-firm spillovers

We first examine the spillover effects on non-litigated areas of defendant firms; we do this according to the technological or functional distance. The regression in Column 1 of Table 6 adds a dummy variable that indicates product codes that are not litigated but are in the same category (5-digit CFR, e.g., all hip implants) as the litigated product codes. The coefficient of this dummy variable is small and statistically insignificant, indicating that the chilling effect does not spill over to the closest product categories. Column 2 adds another dummy variable indicating the remaining product codes in the broader subgroup (4-digit CFR, e.g., all therapeutic devices in orthopedics) as the litigated product codes. Also, in this case, there is no evidence of a spillover effect. Column 3 adds yet another dummy capturing the remaining product codes within the (3-digit) medical specialty (e.g., orthopedics). Here, we actually find a positive spillover effect of litigation. Finally, Column 4 adds a dummy indicating product codes outside the litigated medical specialty, and it shows no change in the propensity to introduce new products.

Overall, the results show no negative spillover effects on other product areas for the defendant firms. They suggest that firms in our sample are able to manage and contain the consequences of product liability

shocks within the narrow product categories that are directly implicated by litigation. There seems to be some resource reallocation going on, increasing innovation intensities in areas that are furthest away from the litigated products but still in the same medical specialty. This is consistent with our discussion with industry practitioners that in many large corporations, human and financial resource allocation tends to be divisionalized.

8.2 Cross-firm spillovers

Column 1 of Table 7 compares the effect of litigation on the defendant firm and other firms operating in the same product code. The results show that the other non-litigated firms also experience a decline in their likelihood of introducing new products, but the magnitude of the decline is half as much as that of the defendant firms. Column 2 confirms this spillover effect on other firms in the litigated product codes using a sample of firm-codes that have never experienced litigation directly during the entire sample period. Columns 3 and 4 increasingly expand the analysis by technological distance of non-litigated firms. We find no spillover effects in non-litigated product codes for these non-litigated firms.

It is interesting to compare our results with those in Ball et al. (2019) who found a positive effect of product recalls on rival firms in the same product codes. In their paper, Ball et al. (2019) found that the positive effect comes from the competition effect: a firm's product recalls reduce competition for its rivals. Although litigation is often accompanied by recalls, it is much rarer and is associated with other disruptions and uncertainties. For the rival firms, the negative spillover effects seem to dominate the potential positive effect of reduced competition. That said, it is important to note that the chilling effect for non-litigated firms is significantly localized to the specific product codes in which litigation takes place.

9 Device Safety and Patenting

An important objective of the product liability system is to incentivize safety. In this section, we investigate whether products introduced after litigation are safer. We measure safety in two ways: one is to use the adverse events data to characterize the safety profile of a device, and the other is to leverage patent texts to directly measure investments in new technologies related to safety. Although each approach has limitations, together they open a window into the effect of litigation on product safety. In addition, we use patent data to investigate whether firms slow down their invention activities, which is the early stage of the innovation process, during litigation.

9.1 Device safety

9.1.1 Measured with adverse event data

Our first approach uses adverse events data, especially injuries and deaths, to characterize the safety profile of a new device. Ideally, we would like to use the ratio of the number of injuries and deaths over the total volume of products used, because the ratio indicates the likelihood of harm. This is not possible without usage data. Instead, we use the ratio of the number of injuries and deaths over the total number of adverse events, which indicates the severity of harm. A reduction in this ratio is consistent with the idea that, in relative terms, there is a decline in the most severe incidents. A concern about this measure is that it can be driven by an increase in severe incidents that is slower than the increase in all incidents. Again, it is difficult to distinguish between these two interpretations without usage data. To partially mitigate this concern, we examine whether the absolute number of severe events, as well as all events, changes after litigation. We recognize that all of these measures are far from perfect without usage data. Moreover, they rely on the assumption that physicians do not avoid using a device in the litigated product categories on the sickest patients. The following results should be interpreted with these caveats in mind.

In Column 1 of Table 8, the dependent variable is the sum of all future adverse events (including product malfunctions, injuries, and deaths) associated with devices a firm plans to introduce in a product code in a given year; Column 2 counts only injuries and deaths; and Column 3 uses the ratio of serious events to all events; that is, (injuries + deaths)/(malfunctions + injuries + deaths). All of the regressions use firm-code combinations with at least one future adverse event in the entire sample period, and we drop observations for which no new products are introduced in a given year. All regressions control for the total number of devices introduced in that year. The results show that all of these indicators drop significantly for devices introduced during litigation, and the reductions are even greater after the end of litigation. With the caveats mentioned above, the adverse events data are consistent with the idea that litigation is associated with an increase in device safety.

9.1.2 Measured with patent texts

A separate approach we take is to directly measure firm investment in device safety using patent data, collected from the United States Patent and Trademark Office (USPTO). Patent data contain rich textual information that allows us to examine the specific nature of a new technology. This measure avoids the flaw of the previous adverse-event measures, because it does not need usage data. That said, it is important to recognize potential measurement errors in identifying the litigated patent classes and safety-related patents.

The USPTO classifies each patent using the cooperative patent classification (CPC) scheme, which is a

detailed hierarchical scheme.[28] We use patents in the CPC A61 class, which covers medical technologies, to construct a panel at the firm-technology class (defined by the finest level of the CPC scheme)-year level from 1995 to 2020. We manually map the litigated FDA product codes to relevant patent classes based on their official descriptions on the FDA and USPTO websites as well as other supplementary information. When a higher classification level in the CPC scheme is identified as litigated, all of the hierarchically lower levels are also defined as litigated. We classify a patent as safety-related if its title or abstract includes keywords about either safety (e.g., safe, reliable, integrity) or problems (e.g., error, failure, problem, vulnerability). The idea behind using problem keywords is that a patent is unlikely to include such words in prominent places such as the title and abstract unless this technology is meant to address these problems. Out of 114,000 medical device patents filed by our sample firms, 6.58% are identified as safety-related patents.

Columns 4 and 5 of Table 8 present regression results on safety-related patents: the dependent variable of Column 4 is a dummy variable indicating that the firm filed at least one safety-related patent in a technology field-year, and that of Column 5 is the ratio between safety-related patents and total patents. These two regressions use active patent classes (i.e., patent classes with more than 25 patents from all firms and all years in our sample, which is the top 20th percentile of all patent classes). We find that during litigation, there is not only a greater likelihood of filing at least one safety-related patent but also a shift towards safety-related research relative to the firm's overall research activities. This increase in safety research, however, does not persist; both measures revert to the pre-litigation level when litigation ends. The lack of persistence here differs from the results in the previous section, which shows better safety performance for devices introduced when litigation ends than those introduced during litigation. This difference can be explained by distinguishing invention activities from product performance. While the increase in safety-related research does not persist, the new inventions created during litigation may help improve and sustain the safety performance of generations of products.

9.2 Overall patenting intensity

Finally, we examine the intensity of a firm's overall patenting activities during litigation. The results, presented in Appendix Table A6, actually show an increase in patenting intensities during this period. These results should be interpreted with caution because the mapping between litigated product codes and patent classes may be imprecise. This said, the lack of decline in patenting activities also highlights the difference between invention and commercialization. Firms appear to continue to invest in research during litigation,

[28] For example, temporo-mandibular joints (artificial jaws) are classified in the CPC group A61F 2/3099 which is part of section A (Human Necessities), class 61 (medical or veterinary science; hygiene) Subclass F (Filters implantable into blood vessels and Prostheses).

especially on safety-related technologies, even if they slow down their introductions of new products.

10 Discussion

Our results provide valuable evidence-based input to the debate over the role of product liability in technological progress, which is an important but complex policy question. First, the concentrated nature of mass litigation, the lack of significant spillover effects beyond the specific litigated product categories, and the absence of any slowdown in patenting all show that litigation activities in the medical device industry do not generate widespread chilling effects on innovation. These findings mitigate concerns about a significant externalization of litigation costs to many other products of the defendant firms (Foote, 1988).[29] If anything, we have found some small positive effects on commercialization for other product areas by the defendant firms, which do not support substantive financial disruptions at these companies. Moreover, it is encouraging to see that the rate of new product introductions recovered shortly after the litigation is concluded and there is a re-direction towards safer products and technologies.

The present paper, which adds evidence to the existing literature regarding the impacts of realized litigations, helps provide a more complete picture of the relationship between product liability and innovation. It highlights the importance of distinguishing between the ex-ante and the ex-post effects of product liability (Chen and Hua, 2012). The negative ex-post effect of product liability litigation does not necessarily imply a negative effect ex-ante. In fact, both of the existing empirical studies on the ex-ante effect of product liability find that it is positively associated with R&D and patenting (Viscusi and Moore, 1993; Galasso and Luo, 2017). Moreover, the negative consequences for firms that experience lawsuits make sense in that the product liability regime would otherwise lose its deterrence effect that incentivizes ex-ante safety investment. Contrary to the worries of many industry observers, the ex-post effect of litigation does not seem to be too disruptive and widespread, at least in the medical device industry. These results, taken together, seem to shift the weight of the evidence toward the view that, generally, the current product liability regime in the U.S. does *not* substantially chill innovation investment.

This said, we do find a significant slowdown in the introduction of new devices in the litigated markets. While new product introductions do recover, the recovery does not happen until the litigation concludes. This delay can be significant, as a typical litigation takes about seven years and the longest can be over ten years. Conversations with industry experts, as well as our data, suggest that this delay is not exclusively

[29] Such an argument was also noted by Fleming and Sugarman (1980): "*[I]n the case of a dangerous drug, not only would the drug in all likelihood be totally withdrawn from the market after its risks have been discovered but the cost of compensation would in any event probably be spread among all or most other products of the particular manufacturer, with the result that the consumers of the safe drugs would in effect be bearing the accident costs of the dangerous drug. In a theoretical free market, this 'externalizing' of the cost might be blocked, but often -and prescription drugs is a good example- such a hypothesis is wholly unrealistic*."

driven by the necessary time taken to improve safety. This may happen if firms are concerned about their product redesigns being used against them in court. Thus, reforms that shorten the litigation time, such as the fixed timeframe of an MDL proceeding that Goodwin (2021) proposed, may not only improve the efficient use of legal resources but also lead to a faster recovery of new product introductions.

Finally, our findings on how the regulatory environment matters for litigation suggest that the effect of one policy may depend on how other policies are designed. In our context, the impact of the liability system depends, in part, on whether the public has access to the adverse event information regulated by the FDA. Because the FDA relies on individual healthcare professionals and device producers to report adverse events, it seems an important policy question to assess whether public transparency affects their incentives to share information.[30] More broadly, whether the government should promote public transparency of adverse events of medical products, even if it collects such information, is an interesting, standalone policy question. While the FDA has generally been abiding by the principle of transparency, European Union regulators have been gathering rapidly rising numbers of injury and malfunction reports each year but refuse to publish the data (ICIJ, 2018). The policy differences appear to hinge on different assessments of the tradeoffs between the potential benefits of transparency against harms such as giving away confidential commercial information and unnecessarily scaring the public. Our finding suggests that this question needs to consider also the tradeoffs related to the litigation mechanism.

11 Conclusion

In this paper, we examine the relationship between product liability litigation and new product introductions in an economically and socially important and research-intensive sector: medical devices. Our main result is that product liability litigation is associated with a substantial decline in new product introductions by defendant firms and other firms in the litigated product categories during periods of active litigation. However, the negative effect disappears after litigation is concluded, it does not spill over beyond the relatively narrow technology areas, and firms do not seem to slow down their patenting activities. Moreover, we find that product liability litigation is associated with an increase in device safety. These results suggest that the negative effect of litigation on innovation is much smaller than what many industry observers feared. As discussed in the previous section, while most of the evidence provided by large-sample studies comes from a single industry, what we have observed in the literature seems to favor the view that the current product liability regime in the U.S. does not substantially chill innovation investments.

[30] Concerns of a disincentive to disclose adverse events is also why the statute generally disallows the use of mandatory reports in civil litigation, including barring their admission as evidence. Separately, the FDA's regulation prohibits the FDA or other parties from divulging any information in a voluntary report that could be used to identify a subject or reporter (Scheetz, 2011).

Future research is desirable in several directions. First, research outside the medical device sector and outside the United States would be valuable for assessing whether the localized nature of litigation's impact holds more generally. Second, it is important to detect specific situations in which the liability laws have a substantial chilling effect on innovation. For example, Galasso and Luo (2022) showed significant negative consequences when liability costs are misallocated across the supply chain. Another example is the exit of vaccine producers in the 1970s and 1980s, which is likely be driven by the vaccine producers' limited ability to profit from their inventions, making their liability exposure disproportionately large (Finkelstein, 2004). Identifying these situations could help inform targeted policy responses such as liability exemption policies and industry level compensation funds. Finally, while the product liability regime does not seem detrimental to the overall innovation investment, it does shift the direction towards safer products, possibly at the expense of new technologies that impose novel risks. It would be valuable for future research to quantify the impact of liability on such novel products and inform policies that could mitigate any potential negative effects (Acemoglu, 2021; Gans, 2024).

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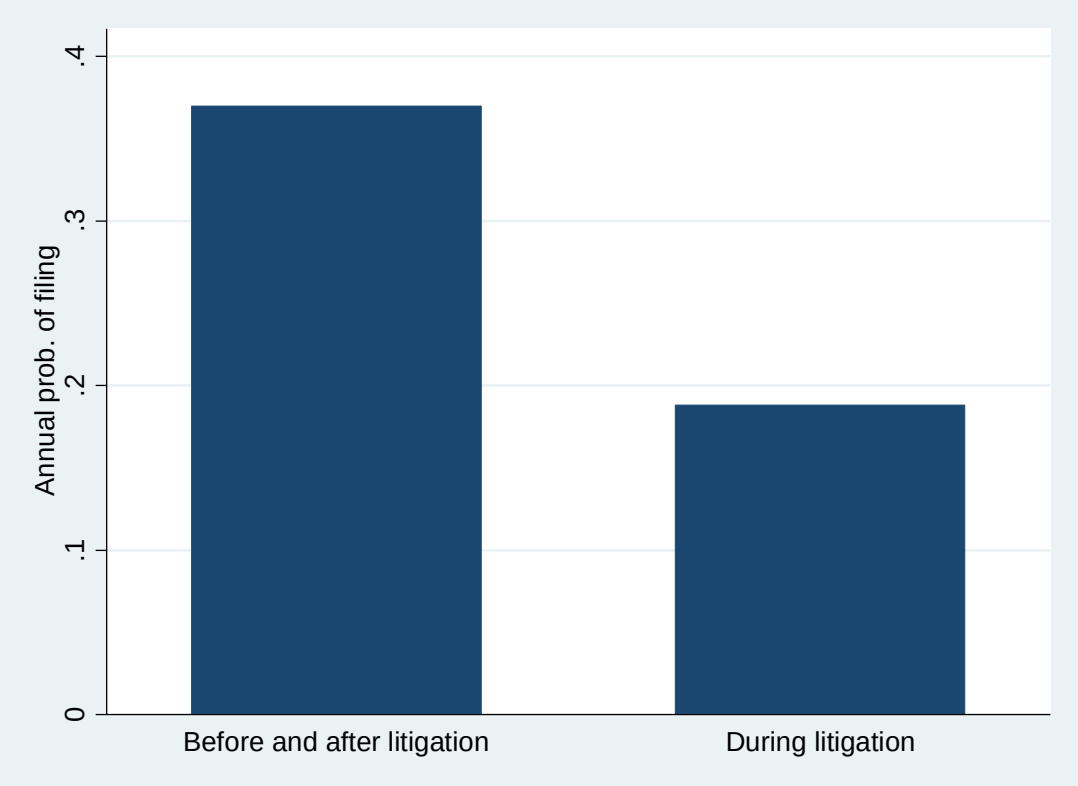

Figure 1: New product introduction before/after litigation versus during litigation

Notes: This figure plots the average likelihood of filing for at least one FDA application for firm-product code combinations that have ever been litigated in our sample. The figure distinguishes between the years during active litigation and the year before and after litigation.

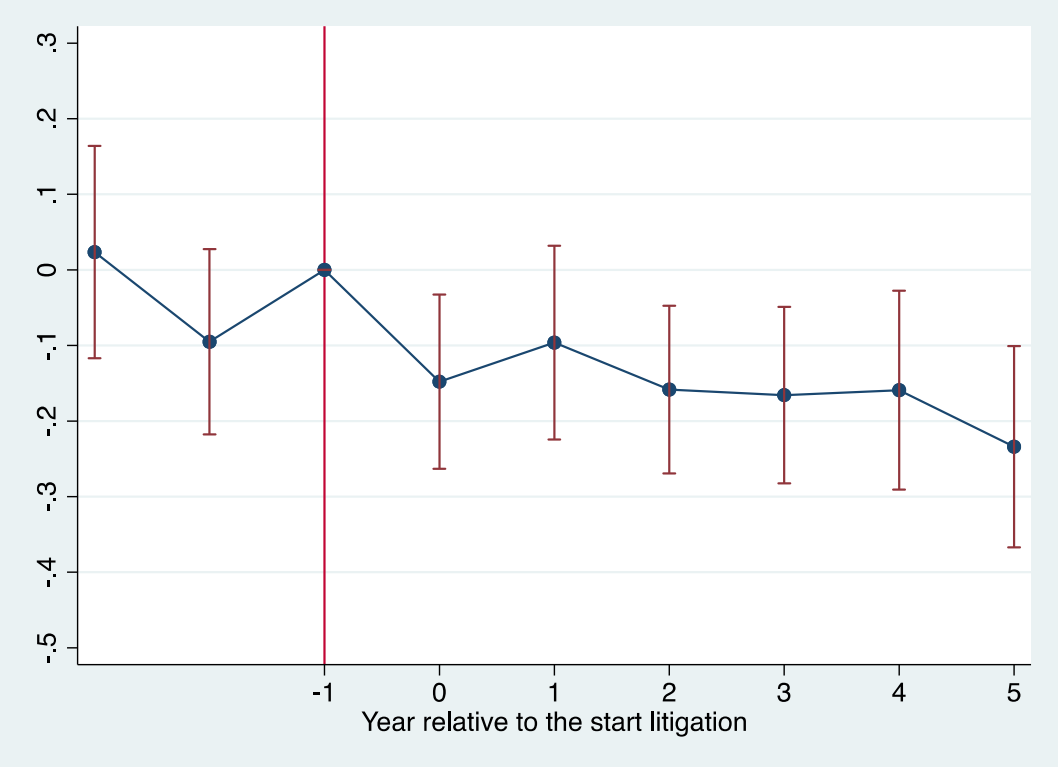

Figure 2: Annual treatment effects

Notes: This figure plots the estimated coefficients (and the 95% confidence intervals) of a dynamic version of our baseline regression in Equation (1). The effect for the year before litigation is the normalized to be the baseline.

Table 1: Summary Statistics

	Observations	Mean	Std. Dev.	Min	Max
Applications	86,741	0.176	0.653	0	28
Application Dummy	86,741	0.113	0.316	0	1
Cases Filed	86,741	3.245	119.773	0	12,450
Litigation (dummy)	86,741	0.004	0.060	0	1
Adverse Events	86,741	111.278	2947.599	0	304,508
Year	86,741	2010.208	6.964	1995	2020

Notes: Applications = the total number of applications submitted by the firm in a product code in a year. Application Dummy = 1 if the firm submits at least one application in a product code and a year. Cases Filed = the number of new cases filed against the firm in a year involving devices in a product code. Litigation = 1 if there is active litigation against the firm in a year involving devices in a product code. Adverse Events = the total number of adverse events reported associated with a firm's devices in a product code and a year. Year = calendar year.

Table 2: Baseline Regressions

	(1) Application Dummy	(2) Application Dummy	(3) Application Dummy	(4) Application Dummy
Litigation	-0.132*** (0.046)	-0.155*** (0.046)	-0.154*** (0.046)	-0.162*** (0.045)
log(Adverse Events + 1)		0.010*** (0.002)	0.011*** (0.002)	0.010*** (0.002)
Fraction of serious events			-0.011* (0.007)	
Firm-code effects	YES	YES	YES	YES
Year effects	YES	YES	YES	YES
Firm-year effects	NO	NO	NO	YES
Observations	86,741	86,741	86,741	86,551

Notes: OLS regressions with robust standard errors clustered at the firm-code level. * significant at 10%, ** significant at 5%, and *** significant at 1%. Application Dummy = 1 if the firm submits at least one application in a product code and a year. Adverse Events = the total number of adverse events reported associated with a firm's devices in a product code and a year. Fraction of serious events = the number of adverse events involving deaths and injuries divided by the total number of adverse events. Litigation = 1 if there is active litigation against the firm in a year involving devices in a product code.

Table 3: Public Availability of Adverse Event Information and Litigation

	(1)	(2)	(3)
	Litigation	Litigation	Litigation
Hidden Events	-0.004**		
	(0.002)		
Adverse Events	0.004**		
	(0.002)		
log(Adverse Events/Public Events)		-0.004***	-0.006***
		(0.001)	(0.002)
log(Adverse Events + 1)		0.006***	0.006***
		(0.001)	(0.001)
log(Recalls + 1)			0.002
			(0.003)
Firm-code effects	YES	YES	YES
Year effects	YES	YES	YES
Sample	Full	Full	2003-2018, excluding origional 12 ASR codes
Observations	86741	86741	60144

Notes: OLS regressions with robust standard errors clustered at the firm-code level. * significant at 10%, ** significant at 5%, and *** significant at 1%. Litigation = 1 if there is active litigation against the firm in a year involving devices in a product code. Adverse Events = the total number of adverse events reported associated with a firm's devices in a product code and a year (in thousands). Hidden Events = the total number of adverse events reported in the ASR database that are associated with a firm's devices in a product code and a year (in thousands). Public Events = the total number of adverse events reported in the MAUDE database that are associated with a firm's devices in a product code and a year (in thousands). Recalls = the number of Class I and Class II recalls by a firm in a product code in a year.

Table 4: Instrumental Variable Regressions

	(1) Application Dummy	(2) Application Dummy
Litigation (instrumented)	-3.530*	-1.092***
	(1.867)	(0.390)
log(Adverse Events + 1)	0.021*	0.006**
	(0.011)	(0.003)
log(Recalls + 1)	0.013	0.008
	(0.011)	(0.007)
Firm-code effects	YES	YES
Year effects	YES	YES
Instruments	log(Adverse Events/Public Events)	Aware*log(Adverse Events + 1), Aware*log(Non-serious Events + 1)
First stage F-stat	21.408	19.433
Sample	2003-2018, excluding origional 12 ASR codes	2003-2018, excluding origional 12 ASR codes
Observations	59863	59863

Notes: 2SLS regressions with robust standard errors clustered at the firm-code level. * significant at 10%, ** significant at 5%, and *** significant at 1%. Application Dummy = 1 if the firm submits at least one application in a product code and a year. Litigation = 1 if there is active litigation against the firm in a year involving devices in a product code. Adverse Events = the total number of adverse events reported associated with a firm's devices in a product code and a year. Public Events = the total number of adverse events reported in the MAUDE database that are associated with a firm's devices in a product code and a year. Non-serious Events = the total number of adverse events involving product malfunctions (not deaths or injuries) associated with a firm's devices in a product code and a year. Aware = 1 if the firm operated, during 1995-1999, in the original 12 codes selected by the FDA as the agency initiated the ASR program. Recalls = the number of Class I and Class II recalls by a firm in a product code in a year.

Table 5: Riegel v. Medtronic

	(1) Litigation	(2) Application Dummy	(3) Application Dummy
Estimation method	OLS	OLS	2SLS
PMA x After 2008	-0.031***		
	(0.012)		
Litigation x Before 2008		-0.120***	
		(0.042)	
Litigation x After 2008		0.004	
		(0.067)	
Litigation (instrumented)			-1.411**
			(0.564)
log(Adverse Events + 1)	0.006***	-0.004	0.015***
	(0.002)	(0.004)	(0.005)
log(Recalls + 1)	0.001		0.013
	(0.005)		(0.009)
Firm-code effects	YES	YES	YES
Year effects	YES	YES	YES
First stage F-stat			38.82
Sample	PMA codes and high-risk 510(k) codes	PMA codes	PMA codes and high-risk 510(k) codes
Observations	12412	9438	12398

Notes: Robust standard errors clustered at the firm-code level. *significant at 10%, ** significant at 5%, and *** significant at 1%. Application Dummy = 1 if the firm submits at least one application in a product code and a year. Litigation = 1 if there is active litigation against the firm in a year involving devices in a product code. Before 2008 = 1 for years before 2008, and After 2008 = 1 for years after 2008. PMA = 1 if the product code is subject to the Premarket Approval review requirement. High-risk 510(k) are 510(k) product codes with more than 1,200 adverse reports filed during the entire sample period. In Column 3, Litigation is instrumented by PMA × After 2008. Adverse Events = the total number of adverse events reported associated with a firm's devices in a product code and a year. Recalls = the number of Class I and Class II recalls by a firm in a product code in a year.

Table 6: Spillovers within Firms

	(1) Application Dummy	(2) Application Dummy	(3) Application Dummy	(4) Application Dummy
Litigation	-0.158*** (0.046)	-0.159*** (0.046)	-0.155*** (0.046)	-0.153*** (0.046)
Other codes in category	-0.024 (0.021)	-0.025 (0.021)	-0.021 (0.021)	-0.018 (0.021)
Other codes in sub-group		-0.010 (0.013)	-0.005 (0.013)	-0.003 (0.013)
Other codes in specialty			0.048*** (0.008)	0.050*** (0.008)
Codes outside specialty				0.006 (0.004)
log(Adverse Events + 1)	0.010*** (0.002)	0.010*** (0.002)	0.010*** (0.002)	0.010*** (0.002)
Firm-code effects	YES	YES	YES	YES
Year effects	YES	YES	YES	YES
Observations	86741	86741	86741	86741

Notes: OLS regressions with robust standard errors clustered at the firm-code level. * significant at 10%, ** significant at 5%, and *** significant at 1%. Application Dummy = 1 if the firm submits at least one application in a product code in the year. Litigation = 1 if there is active litigation against the firm in a year involving devices in a product code. Specialty (16 groups in total) is defined using the first three digits of the CFR classification, subgroup (73 groups in total) is defined using the first four digits of the CFR classification, and category (372 in total) is defined using the first five digits of the CFR classification. Other codes in category = 1 for other product codes in the same category as the litigated product code in a given year; Other codes in sub-group = 1 for product codes outside the category but within the same subgroup as the litigated product code in a given year; Other codes in specialty = 1 for product codes outside the subgroup but within the same specialty as the litigated product code in a given year; and Other codes outside specialty = 1 for product codes outside the specialty of the litigated product code in a given year. These dummy variables are all mutually exclusive. Adverse Events = the total number of adverse events reported associated with a firm's devices in a product code and a year.

Table 7: Spillovers Across Firms

	(1)	(2)	(3)	(4)
	Application Dummy	Application Dummy	Application Dummy	Application Dummy
Litigation	-0.164***		-0.160***	-0.161***
	(0.046)		(0.046)	(0.046)
Other firms in code	-0.061**	-0.054**	-0.059**	-0.059**
	(0.025)	(0.027)	(0.024)	(0.024)
Other firms in category			0.015	0.015
			(0.016)	(0.016)
Other firms in sub-group			0.006	0.006
			(0.010)	(0.010)
Other firms in specialty				-0.002
				(0.007)
log(Adverse Events + 1)	0.010***	0.010***	0.010***	0.010***
	(0.002)	(0.002)	(0.002)	(0.002)
Firm-code effects	YES	YES	YES	YES
Year effects	YES	YES	YES	YES
Sample	Full	Never litigated firm-codes	Full	Full
Observations	86741	85787	86741	86741

Notes: OLS regressions with robust standard errors clustered at the firm-code level. * significant at 10%, ** significant at 5%, and *** significant at 1%. Application Dummy = 1 if the firm submits at least one application in a product code in the year. Litigation = 1 if there is active litigation against the firm in a year involving devices in a product code. Other firms in code = 1 for non-defendant firms in the litigated product code in a given year. Specialty (16 groups in total) is defined using the first three digits of the CFR classification, subgroup (73 groups in total) is defined using the first four digits of the CFR classification, and category (372 in total) is defined using the first five digits of the CFR classification. Other firms in category = 1 for non-defendant firms in non-litigated product codes in the same category as the litigated codes in a given year. Other firms in sub-group = 1 for non-defendant firms in product codes that are in the same subgroup but the same category as the litigated codes in a given year. Other firms in specialty = 1 for non-defendant firms in product codes that are in the same specialty but the same subgroup as the litigated codes in a given year. These dummy variables for non-defendant firms are all mutually exclusive. Adverse Events = the total number of adverse events reported associated with a firm's devices in a product code and a year.

Table 8: Litigation and Device Safety

	(1) log (Future Adverse Events+1)	(2) log (Future Serious Adverse Events+1)	(3) Future Serious Adverse Events/Future Adverse Events	(4) Safety Patent Application Dummy	(5) Safety Patent Applications/ Total Patent Applications
During Litigation	-0.915**	-1.375***	-0.212***	0.031*	0.017**
	(0.416)	(0.461)	(0.042)	(0.018)	(0.009)
After Litigation	-2.556*	-3.733**	-0.473***	0.003	0.002
	(1.527)	(1.674)	(0.107)	(0.023)	(0.010)
log(Applications + 1)	0.703***	0.660***	0.005		
	(0.082)	(0.075)	(0.011)		
log(Patent Applications + 1)				0.113***	
				(0.003)	
No adverse events (dummy)	-2.846***	-1.795***	-0.442***		
	(0.052)	(0.047)	(0.012)		
Firm-code (patent subclass) effects	YES	YES	YES	YES	YES
Year effects	YES	YES	YES	YES	YES
Observations	7961	7961	7961	121039	121039

Notes: OLS regressions with robust and clustered standard errors. * significant at 10%, ** significant at 5%, and *** significant at 1%. Future Adverse Events = the total number of future adverse events reported for all the applications submitted by a firm in a product code in a given year. Future Serious Adverse Events = the total number of future adverse events involving injuries and deaths reported for all the applications submitted by a firm in a product code in a given year. No Future Adverse Events = 1 if devices applied for this year are associated with zero future adverse events. Safety Patent Application Dummy = if there is at least one safety-related patent application in its title or abstract. Columns 1-3 consider only firm-codes with at least one application in the entire sample period. Columns 4-5 use relatively active patent classes; that is, classes with more than 25 patents applied by all of our sample firms in the entire sample period.

ONLINE APPENDIX

Product Liability Litigation and Innovation: Evidence from Medical Devices

by Alberto Galasso and Hong Luo

A. Theoretical model

Our modeling approach follows Waldman (1993) and considers a monopoly producer in a market that lasts two periods. We first present the basic model consistent with Waldman (1993) and then extend it by adding considerations of product liability litigation.

A.1. The Basic Model

In the first period, the firm sells products of type A. The products are perfectly durable and provide utility to consumers in periods 1 and 2. In the second period, the firm decides whether to introduce a new version of the product, which we refer to as type B. Each unit of the product is produced at marginal cost c. There are two groups of consumers. Consumers of group 1 are present in the market in periods 1 and 2. Consumers of group 2 are present in the market only in the second period. Each group has a size of N. Consuming technology $k = A, B$ in period $t = 1, 2$ gives consumers utility $V_k + N_k^t$, where the term N_k^t captures network effects linked to the total number of individuals using product k in period t. These network externalities are not necessary to derive our results, but we include them in the model for consistency with Waldman's framework. As does Waldman (1993), we assume that the firm can perfectly price discriminate and that there is no discounting.

In this setting, if the firm sells product A to all N consumers of group 1 in period 1, the following surplus is generated in the first period: $(V_A + N - c)N$. Still following Waldman (1993), we assume that all individuals of group 1 consume in the first period and focus on the decision to introduce the new version of the product in period 2. We assume that the firm can offer a lower price to group 1 consumers if they trade in their version of product A and purchase version B.

Consider first the case in which the firm chooses not to offer product B and simply continues to sell product A in the second period. If all N consumers of group 2 buy the product, the firm generates the following second-period surplus by trading with group 2: $(V_A + 2N - c)N$. Under the assumption of perfect price discrimination, this formula also captures the second-period profits the firm generated in the absence of product upgrades.[1]

Consider then the case in which the firm switches to product B. Waldman (1993) shows that this generates second-period profits from group 1 equal to $(V_B - V_A + N - c)N$. To see this, notice that in the second period, group 1 consumers obtain gross utility equal to $V_B + 2N$ if they purchase B and $V_A + N$ if they keep consuming A. This implies that the maximum price, p, that the firm can charge to induce them to

[1] Waldman (1993) shows that these profits are consistent with a Perfectly Coalition Proof Nash equilibrium. Notice that trading to consumers of group 2 also increases the utility of group 1 but this does not translate into a second-period profit flow as there are no transactions with these consumers in period 2.

switch is obtained by solving $V_B + 2N - p = V_A + N$ which yields $p = V_B - V_A + N$. The profits obtained from group 2 consumers by purchasing product B are $(V_B + 2N - c)N$.[2]

The above analysis leads to the following condition for keeping the initial product on the market:

$$V_A > V_B + (N - c)/2. \tag{1}$$

Notice that the inequality is more likely to be satisfied if $V_A - V_B > 0$ (i.e., the alternative version of the product is strictly inferior) and if $N - c < 0$ (the network effects are small relative to the production costs).

A.2. Adding Product Liability Litigation

We now extend the basic model to consider the case in which the firm, when deciding to offer a new version of the product, faces product liability lawsuits against the old product. Such litigation adds several additional considerations, which may influence the likelihood of new product introduction in different directions.

We first consider two effects that would increase the likelihood of introducing the new product. The first is that keeping the old product A on the market would result in greater litigation costs than introducing the new product B (under the assumption that B is safer than A). Specifically, we assume that the baseline litigation cost is L, which the firm needs to pay regardless of product switching. Switching to product B does not add additional costs, but keeping product A on the market results in a total litigation cost of $L + \rho L2N$. Intuitively, we can think of the extra term $\rho L2N$ as the total variable cost of litigation in that each of the $2N$ consumers of the old product may join the litigation with probability ρ and incur a cost of L.[3] The second effect is a reduction in the perceived value of the old product, which becomes $V_A - \Delta$. The term Δ captures consumers' lowered willingness to pay because they know that the product may cause them harm.

With these two effects, the condition required to keep product A on the market becomes:

$$(V_A - \Delta + 2N - c)N - L(1 + \rho 2N) > (V_B - V_A + \Delta + N - c)\, N + (V_B + 2N - c)N - L, \tag{2}$$

which is simplified to:

$$V_A > V_B + (N - c)/2 + \Delta + L\rho. \tag{3}$$

Notice that compared to equation (1), litigation increases the likelihood of introducing product B through

[2]Notice that in both cases the computation relies on the assumption that consumers expect all other consumers to switch to B. This is also consistent with the Perfectly Coalition Proof equilibrium concept.

[3]Here, we implicitly assume that before the litigation, the firm expects a litigation cost for the old product lower than $\rho L2N$. Otherwise, the firm would have introduced the safer product in the first place. This is plausible as the litigation event per se may increase the firm's perception of the safety profile of its old product. Alternatively, the litigation may make the court more likely to hand out tougher judgments.

two channels. First, as captured by Δ, litigation increases consumers' value for product B relative to product A. Second, as captured by $L\rho$, introducing the new product protects the firm from an increase in the scope of litigation and the associated costs.

The above analysis assumes that product B is safer than product A without extra R&D investment. This may not be the case. Assuming that extra investment is necessary to make product B safer and that the investment is R. Adding R to the right-hand side of equation (2), the condition for keeping the old product on the market becomes:

$$V_A > V_B + (N - c)/2 + \Delta + L\rho - \frac{R}{2N}. \tag{4}$$

Comparing (1) and (4) shows that, in this more generalized extension, the effect of product liability litigation on innovation is ambiguous. Specifically, the likelihood of new product introduction increases when $2N(\Delta + L\rho) > R$ and decreases otherwise. On the one hand, litigation may increase the relative profitability of new products because consumers perceive them as safer and because the new products provide greater protection against additional liability litigation. These benefits need to be balanced against the costs associated with developing a safer version of the product.

B. Data on Mergers and Acquisitions

A complication in linking data on the various variables (e.g., new product applications) to our sample firms comes from the fact that mergers and acquisitions are common in the medical device industry. Furthermore the firm names that show up in the FDA databases (e.g., the applicant of a new device) are often those of the acquired firms even after their acquisitions. For our analysis, we want to count an acquired firm's new product applications as those by the parent firm during the years in which the parent firm owns it. This requires information on the ownership period, which starts from the year of the acquisition. Less frequently, a firm may divest an independent entity or sell it to another firm. For these cases, the spin-off year is the end of an ownership period.

We went through the following three steps to identify firms acquired and spun off by our sample firms and the ownership spells:

1. We first identified the names of firms that were acquired by our sample firms during the sample period. This information was drawn from three different sources: the WRDS Company Subsidiary Data file, Refinitiv (formerly Thomson Financial) M&A data, and the FDA establishment registration

databases.[4] Excluding subsidiaries that bear their parents' names (e.g., Abbott Molecular for Abbott), these databases yielded 4,363 unique subsidiary names associated with our sample firms. The vast majority of these names are alternative spellings or misspellings of the same firms rather than distinct firms.

2. Because finding the information on the starting and ending years of an ownership period requires manual work, we restricted the subsidiary names for further cleaning to a subset of the relatively important ones. We define the importance using the number of times these names show up in the various FDA databases (e.g., whether a subsidiary has applied for a PMA application). Specifically, using a fuzzy matching algorithm, we matched the subsidiary names to four FDA databases—the two application databases (510(k) and PMA) and the two adverse event databases (MAUDE and ASR)—separately. Because there are relatively few unique firms in the PMA and the ASR databases, we kept a subsidiary name for further cleaning provided it was matched to a name in these databases with a similarity score greater than 0.85. Because many more entity names exist in the MAUDE and 510(k) databases, we first dropped names that are not the most active (i.e., the number of times the name shows up in the database is below the 75th percentile). We kept subsidiary names for further cleaning if they were matched to at least one name in the MAUDE or the 510(k) database with a similarity score greater than 0.85. This step yielded 420 unique subsidiary names for further cleaning. Note that many of these are still different spellings of the same firms.

3. For each of the 420 names, we did two things: first, we manually identified the acquisition and spin-off dates using the WRDS Company Subsidiary Data file, the Refinive M&A database, as well as various publicly available news sources. Second, we standardized the spellings of the subsidiary names. Ultimately, we ended up with 254 unique firms that were acquired or spun off by our 45 sample (parent) firms.

Apart from firms acquired by our sample firms, we also manually collected two additional sets of ownership relationships. One is the ownership relationships among the subsidiary firms in our sample. The other is the ownership relationships among the parent firms in our sample. We also collected information on the founding years of firms in our sample. With all of this information in hand, we accounted for these ownership relationships as we created our analysis panel dataset at the parent firm-product code-year level.

[4]The FDA databases contain information on the owner-operators of all registered establishments (which include a firm's subsidiaries as well as related entities such as importers or manufacturers). The two databases that we used are the "Owner Operator" and "Registration" datasets, which are available at https://www.fda.gov/medical-devices/device-registration-and-listing/establishment-registration-and-medical-device-listing-files-download.

Finally, we wanted to note that apart from acquisitions, a firm may also have independent subsidiaries that are recorded as the relevant entity names in the FDA databases. These subsidiaries often bear their parent companies' names and are much easier to identify within the FDA databases. We allocated their applications (and other variables such as adverse events) to the parent firms.

References

Waldman, Michael (1993) "A new perspective on planned obsolescence," *Quarterly Journal of Economics* 108: 273-283

Table A1. Robustness Checks

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	Application Dummy (adjusted for acquire patents)	Application Dummy (adjusted for PMA supplements)	Applications	Application Dummy	Application Dummy	Application Dummy	Application Dummy	Exit
Estimation method	OLS	OLS	Poisson	OLS	OLS	Imputation	OLS	OLS
Litigation	-0.135***	-0.173***	-0.608**	-0.160***		-0.165***	-0.129***	0.009
	(0.048)	(0.049)	(0.271)	(0.047)		(0.039)	(0.042)	(0.052)
log(Adverse Events + 1)	0.013***	0.016***	0.159***	0.011***	0.010***		0.008***	-0.054***
	(0.002)	(0.002)	(0.014)	(0.002)	(0.002)		(0.002)	(0.002)
log(Application Stock + 1)				-0.026***				
				(0.008)				
log(Cases Filed + 1)					-0.024***			
					(0.008)			
FDA Avg Approval Time							-0.002***	
							(0.001)	
Firm-code effects	YES	YES	YES	YES	YES	YES	YES	YES
Year effects	YES	YES	YES	YES	YES	YES	YES	YES
Observations	86741	86741	54108	86741	86741	86642	86741	86741

Notes: OLS regressions with robust standard errors clustered at the firm-code level. * significant at 10%, ** significant at 5%, and *** significant at 1%. Application Dummy = 1 if the firm submits at least one application in a product code and a year. Application Dummy (adjusted for acquired patents) considers applications submitted by the acquired firms in the five years preceding the acquisition. Application Dummy (adjusted for PMA supplements) considers PMA supplemental applications based on significant design changes submitted by the firm in a product code in a year. Applications = the total number of applications submitted by the firm in a product code in a year. Litigation = 1 if there is active litigation against the firm in a year involving devices in a product code. Adverse Events = the total number of adverse events reported associated with a firm's devices in a product code and a year. Application Stock = discounted sum of applications filed by the firm in the previous five years in a product code. Cases Filed = the number of new cases filed against the defendant firms in the litigated product code in a given year. FDA Avg Approval Time = the average number of months the FDA takes to approve an application submitted in a product code in a given year. This variable is replaced with zero when no applications are filed in this code-year. A dummy indicating that no applications are filed is also included in this regression. Exit = 1 if at least five years of inactivity subsequent to the last filing.

Table A2. Device Recalls and Case Resolution

	(1)	(2)	(3)	(4)
	Application Dummy	Application Dummy	Application Dummy	Application Dummy
Litigation	-0.168***	-0.197**	-0.171***	-0.160***
	(0.048)	(0.079)	(0.055)	(0.052)
log(Recalls + 1)	0.007	0.007	0.006	
	(0.007)	(0.007)	(0.007)	
log(Recalls t-1 + 1)			0.009	
			(0.007)	
log(Recalls t-2 + 1)			0.009	
			(0.007)	
log(Recalls t-3 + 1)			-0.002	
			(0.007)	
log(Recalls t-4 + 1)			-0.011	
			(0.007)	
Litigation X Won				0.083
				(0.109)
Litigation X Lost				-0.081
				(0.076)
log(Adverse Events + 1)	0.004*	0.011***	0.013***	0.010***
	(0.002)	(0.003)	(0.002)	(0.002)
Firm-code effects	YES	YES	YES	YES
Year effects	YES	YES	YES	YES
Sample	After 2002	After 2002 and at least one recall	After 2002 and with lags	Full
Observations	71465	16762	57133	86741

Notes: OLS regressions with robust standard errors clustered at the firm-code level. *significant at 10% ** significant at 5%, and *** significant at 1%. Application Dummy = 1 if the firm submits at least one application in a product code in a year. Litigation = 1 if there is active litigation against the firm in a year involving devices in a product code. Adverse Events = the total number of adverse events reported associated with a firm's devices in a product code and a year. Recalls = the number of Class I and Class II recalls by a firm in a product code in a year. Recalls t-x = the number of Class I and Class II recalls by a firm in a product code in year t-x. Won = 1 if by the end of the sample period less than 20% of the cases in an MDL are unresolved and there are findings in favor of the defendant and no damages. Lost = 1 if by the end of the sample period less than 20% cases in an MDL are unresolved, and there are findings in favor of the plaintiffs and damages awarded.

Table A3. Controlling for Firm-Technology Area-Specific Time Trends

	(1) Application Dummy	(2) Application Dummy	(3) Application Dummy	(4) Application Dummy
Litigation	-0.166***	-0.197***	-0.177***	-0.096*
	(0.046)	(0.058)	(0.064)	(0.055)
log(Adverse Events + 1)	0.008***	0.012***	0.011***	0.015***
	(0.002)	(0.002)	(0.003)	(0.004)
Firm-technology-year effects	16 tech areas	73 tech areas	371 tech areas	938 tech areas
Firm-code effects	YES	YES	YES	YES
Year effects	YES	YES	YES	YES
Observations	84620	74223	58820	34445

Notes: OLS regressions with robust standard errors clustered at the firm-code level. *significant at 10% ** significant at 5%, and *** significant at 1%. Application Dummy = 1 if the firm submits at least one application in a product code and a year. Litigation = 1 if there is active litigation against the firm in a year involving devices in a product code. Adverse Events = the total number of adverse events reported associated with a firm's devices in a product code and a year. Column 1 defines tech areas by the first three digits of the CFR classification scheme, Column 2 defines tech areas by the first four digits of the CFR classification scheme, Column 3 defines tech areas by the first five digits of the CFR classification scheme, and Column 4 defines tech areas by the finest level (all seven digits) of the CFR classification scheme.

Table A4: Dynamic Analysis

	(1)	(2)	(3)	(4)	(5)
	Application Dummy	Application Dummy	Application Dummy	Application Dummy	Application Dummy
Litigation	-0.161***	-0.161***	-0.124**	-0.198**	
	(0.049)	(0.050)	(0.053)	(0.083)	
After Litigation	-0.041		-0.018	-0.089	0.121*
	(0.064)		(0.063)	(0.182)	(0.066)
After litigation year 1		-0.118*			
		(0.066)			
After litigation year 2		-0.041			
		(0.085)			
After litigation years 3+		-0.001			
		(0.081)			
Year 1 before end of litigation			0.033	-0.064	
			(0.069)	(0.073)	
Year 2 before end of litigation			-0.023	0.049	
			(0.057)	(0.067)	
Year 1 since start of litigation					-0.154***
					(0.058)
Year 2 since start of litigation					-0.109
					(0.067)
Year 3 since start of litigation					-0.172***
					(0.062)
Year 4 since start of litigation					-0.177***
					(0.066)
Year 5 since start of litigation					-0.191***
					(0.068)
Year 6 since start of litigation					-0.219***
					(0.066)
Year 7 since start of litigation					-0.139*
					(0.083)
Year 8 since start of litigation					-0.219***
					(0.073)
Years 9+ since start of litigation					-0.141**
					(0.065)
Litigation spells included	all	all	less than 7 years	more than 7 years	all
Observations	86741	86741	86382	86146	86741

Notes: OLS regressions with robust standard errors clustered at the firm-code level. * significant at 10%, ** significant at 5%, and *** significant at 1%. All regressions include firm-code and year effects and control for log(Adverse Events + 1). Application Dummy = 1 if the firm submits at least one application in a product code and a year. Litigation = 1 if there is active litigation against the firm in a year involving devices in a product code. After Litigation = 1 for years after litigation is concluded. After litigation year × dummies capture the xth year after the end of the litigation spell. Year × before end of litigation captures xth year before the end of the litigation spell. Year × since start of litigation captures the xth year since the beginning of litigation.

Table A5: Drivers of the Number of Hidden Reports

	(1) Hidden Reports	(2) Hidden Reports	(3) Hidden Reports
Adverse Events	0.889***	0.895***	0.005
	(0.094)	(0.090)	(0.004)
Serious Events	-1.635***	-1.716***	-0.005
	(0.371)	(0.394)	(0.005)
log(Recalls + 1)	-0.061***	-0.063*	0.000
	(0.023)	(0.033)	(0.000)
Firm-code effects	YES	YES	YES
Year effects	YES	YES	YES
Sample	2003-2018 non 12 ASR codes	2003-2018 non 12 ASR codes, more-aware firms	2003-2018 non 12 ASR codes, less-aware firms
Observations	60144	39449	20695

Notes: Robust standard errors clustered at the firm-code level. * significant at 10%, ** significant at 5%, and *** significant at 1%. Hidden Reports = the total number of adverse events reported in the ASR database that are associated with a firm's devices in a product code and a year. Adverse Events = the total number of adverse events associated with a firm's devices in a product code and a year (in thousands). Serious Events = the total number of adverse events involving injuries and deaths associated with a firm's devices in a product code and a year (in thousands). More-aware firms = 1 if the firm operated, during 1995-1999, in the original 12 codes selected by the FDA as the agency initiated the ASR program. Less-aware firms = 1 if the firm didn't operate, during 1995-1999, in the original 12 codes selected by the FDA as the agency initiated the ASR program.

Table A6: Litigation and Patenting

	(1)	(2)	(3)
	Patent Application Dummy	Patent Applications	Patent Applications
Estimation method	OLS	OLS	Poisson
Litigation in Subclass	0.094***	0.688***	0.494***
	(0.029)	(0.194)	(0.108)
Year effects	YES	YES	YES
Firm-subclass effects	YES	YES	YES
Observations	121039	121039	105514

Notes: Robust standard errors clustered at the firm-patent technology class level. * significant at 10%, ** significant at 5%, and *** significant at 1%. These regressions use relatively active patent classes; that is, classes with more than 25 patents applied by all of our sample firms in the entire sample period. Application Dummy = 1 if the firm submits at least one patent application in a patent class in a given year. Patent Applications = the number of patent applications filed by the firm in the patent class in a given year. Litigation in Subclass = 1 if there is active litigation against the firm in a year involving the focal patent class.