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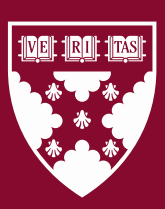

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RESPONDING STRATEGICALLY TO COMPETITORS' FAILURES: EVIDENCE FROM MEDICAL DEVICE RECALLS & NEW PRODUCT SUBMISSIONS

Abstract: Medical device firms operate at the frontiers of innovation. When functioning properly, innovative medical devices can prolong and improve lives; when malfunctioning, the same devices may harm patients and lead to product recalls. Product recalls create significant challenges for firms, but simultaneously generate potentially lucrative opportunities for their competitors. Using the U.S. medical device industry as an empirical setting, we develop predictions and provide evidence that competitor recalls increase unaffected firms' new product submission activities, establishing a previously unexamined relationship between product failures and product submissions. To tease out potential mechanisms, we examine how the number of competitors in a specific product market influences this relationship. We find that firms increase new product submissions after competitor firm failures in markets that have fewer competitors and, as such, represent the greatest opportunities to increase revenues and profits and capture vulnerable market share. Recalls thus not only create internal problems for firms, but also incentivize their competitors.

Keywords: New product submissions, Recalls, Product Failures, Medical Devices, FDA, Health Care

1. INTRODUCTION

New products are critical for firms in several research and development (R&D)-intensive industries, including software, microprocessors, automobiles, and pharmaceuticals. The incentives of firms to innovate in these industries are large, given that new products drive profitability and survival. Nevertheless, the impact of faulty or dangerous products can be ruinous for firms and customers: for instance, software bugs can compromise sensitive customer data; automobile defects can create passenger safety concerns; and, in our empirical setting, malfunctioning medical devices can lead to patient injuries and deaths. Such "first-order" effects of compromised products are salient: they directly harm customers and negatively affect firm performance (Shah *et al.* 2016; Liu and Shanker 2015). But other "second-order" effects, which have been relatively unexplored in research, may present additional challenges, including the potential that product failures impact competitors' new product submission activities and thereby change the product market landscape.

The extant literature often examines product recalls as a phenomenon internal to affected firms. For instance, a well-documented product recall effect is lost revenue (Thirumalai and Sinha 2011; Haunschild and Rhee 2006); when products are found to be unsafe and recalled, sales and distribution are reduced or halted completely (Krumholz *et al.* 2007). Related research discusses the ways in which recalls are difficult for firms to manage, given the negative publicity generated that amplifies sales downturns and shareholder losses (Jarrell and Peltzman 1985; Rhee and Haunschild 2006). Still other research examines how recalls affect internal operations, as resources must be redirected to identify problems and implement solutions (Ball *et al*. 2018).

We propose theoretical reasons and present empirical evidence that recalls also influence a relatively unexplored but important phenomenon that is external to affected firms. In particular, we consider whether and how competitor recalls create market opportunities that incentivize firms to adjust or alter their own subsequent new product submissions in the same product market (KC *et al*. 2013; Krieger 2021). We examine this phenomenon by developing predictions and providing empirical evidence of how firms' new product submissions in a given product market change in response to significant product recalls by their competitors in the U.S. medical device ("med-tech") industry. By leveraging novel, comprehensive medical device submission and recall data from the U.S. Food and Drug Administration (FDA), we examine the following research question: *Do competitor recalls influence new product submissions?* Because we theorize that competitor recalls incentivize firms to increase their new product submission activity in efforts to capitalize on the

market opportunities presented, we then examine how this relationship is moderated by the number of competitors in the product market. In other health care settings, such as the pharmaceutical industry, product markets with fewer competitors can attract more entrants (Kyle 2002; Ball *et al.* 2018); in our setting, fewer competitors in a product market suggest that greater opportunities exist for firms seeking to capitalize on competitor firm mistakes.

A key feature of our empirical setting is the ability to examine well-defined product types (i.e., product markets) using FDA-assigned categories based upon product comparability. When a medical device submission is considered high risk or dissimilar to any previously approved and marketed product, it receives a Pre-Market Approval (PMA) designation. These products are novel and innovative, but comprise a small fraction of total regulated devices. We instead focus on the largest category of regulated medical devices: 510(k) products. These products are of moderate risk, justifiably similar to a previously cleared and marketed product, and are regulated via the FDA's "510(k) clearance process." 510(k) clearances are categorized into distinct product types that precisely define individual product markets. We then use this categorization to examine the relationship between competitor recalls and new product submissions within a given product market.

We examine our hypothesized relationships using 510(k) submissions for three reasons: First, the vast majority (more than 99 percent) of FDA medical device submissions are regulated via the 510(k) clearance process. Second, 510(k) submissions are more "nimble" than PMA submissions—i.e., both shorter in duration and lower in resource requirements (Sall, 2008)—suggesting that they are more "adjustable" to product market dynamics, which may include competitor recalls. Third, data from the 510(k) clearance process are well-suited to examining these phenomena without confounding explanations: the nature of well-established product markets creates settings where there is negligible uncertainty around the technical viability of devices but clear certainty on firm mistakes. Recalls that occur in 510(k) product markets thus constitute actionable information about competitor firm mistakes and potential market opportunities for unaffected firms because the products under consideration are already proven safe. Focusing on this set of products allows us to thoroughly and cleanly test predictions in a large and appropriate sample.

We collect comprehensive FDA regulatory data on all new product submissions and recalls over 2004-2020, inclusive. Using matching software and novel algorithms, we assign all submissions and recalls to a set of standardized firm names and FDA-designated product markets and

then construct detailed histories that provide precise definitions of the relevant set of firms and competitors in each product market and across flexible time intervals. We incorporate these detailed histories into count models to determine how prior competitor recalls, as well as the moderating effect of product market competition, shape firms' subsequent new product submission activities.

Our empirical findings are both informative and in-line with the hypotheses developed. Prior competitor recalls significantly increase subsequent new product submissions. In particular, estimates suggest that a single competitor firm recall increases new product submissions in the following half-year by 10.7 percent. Our models indicate, moreover, that prior competitor recalls increase subsequent new product submissions more significantly in product markets with fewer competitors. These findings suggest that market opportunities motivate firms to augment new product submission activities following competitor firms' mistakes but that such opportunistic approaches are less likely in "crowded" product markets. In other words, competitor recalls provide the opportunity and the willingness to respond but product market competition moderates the ability to succeed. Several robustness checks support these findings.

We offer two key theoretical contributions. First, we contribute to product recall research by establishing novel recall consequences that predict future new product development activity. While prior research identifies several important implications of recalls, such as firm learning (Haunschild and Rhee 2004), market share losses (Jarrell and Peltzman 1985), and consumer confidence reductions (Rhee and Haunschild 2006), no study of which we are aware connects product recalls to subsequent new product submissions. Second, we contribute to the new product development literature (Brown and Eisenhardt 1995) by examining a largely overlooked but important determinant of new product submission activity: product failures—in particular, product recalls.

Our theoretical predictions and empirical results also have implications for industry practitioners. We demonstrate that recalls have consequences that extend beyond a directly affected firm, by motivating competitors to increase new product submissions, especially in those product markets with fewer competitors.

2. RESEARCH SETTING

Medical devices are regulated by the FDA's Center for Devices and Radiological Health (CDRH) via two primary approaches: (1) pre-market gatekeeper and (2) post-market regulator. In its role as pre-market gatekeeper, CDRH reviews new product submissions to determine whether these

devices are safe and effective for use in and by patients. Federal statutes make it illegal to market and sell a medical device in the United States without regulatory approval/clearance.

In the process of clearing 510(k) devices for market release, CDRH assigns medical devices into "product codes" (viz., our product markets) based upon function. As an example, nephrostomy catheters are assigned to product code "LJE" and cardiac ablation catheters are assigned to product code "LPB". While these two catheters are similar in design, they serve very different functions and thus are given different product codes. The FDA clearance process indicates products in the same product code as effective substitutes because they serve the same function, are used in identical ways, and are reviewed by the same group of regulators. Our theorizing and empirical analyses are therefore based on categorical measures of product similarity. In particular, we examine whether and how competitor recalls influence new product submissions in those cases where both occur in the same product market.

In its role as post-market regulator, the FDA ensures that cleared devices perform in a safe and effective manner and present no unnecessary patient risk. During the post-market period, CDRH performs ongoing product surveillance for continued safety and effectiveness, overseeing conformance quality problems (Gray *et al*. 2015; Sousa and Voss 2002). When a systematic pattern of product defects or safety issues arises, firms must initiate voluntary recalls that are overseen by the FDA.

In cases where product safety concerns emerge, federal statutes mandate devices that "present a risk of injury, gross deception, or are otherwise defective" be recalled and removed from the market by the infringing firm.[1] The FDA's recall classifications range from Class I (most severe) to Class II (moderately severe) and Class III (least severe). Class I recalls are for what FDA terms "violative" medical device failures that have a reasonable probability of serious adverse health consequences or death. An example is a faulty implantable heart valve. Class II recalls occur when the use of a device may cause detrimental but medically reversible adverse health consequences, such as a malfunctioning hearing aid. Class III recalls occur when a quality problem is unlikely to cause adverse health consequences but should nevertheless be corrected, such as a product labeling error. Because prior recall research categorizes Class III medical product recalls as "discretionary" due to their low severity (Wowak *et al.*, 2021), our theory and empirical models focus on how

[1] While the recalls in our data are all voluntarily-initiated, FDA maintains the legal authority to mandate recalls but seldom does.

more severe and less discretionary (Class I and II) recalls influence new product submissions. These recall classifications are better proxies for actual product quality problems, are difficult for firms to avoid recalling, and are the most operationally disruptive.[2]

3. LITERATURE REVIEW AND HYPOTHESES

We first hypothesize that competitor recalls influence new product submission activity. To explore a key mechanism that shapes this response, we then consider whether and how the degree of product market competition alters this hypothesized relationship.

COMPETITOR RECALLS

A majority of empirical product recall research investigates either recall effects or recall causes. Most of the research to-date resides in the former category and predominately examines stock market, market share, and customer loyalty effects. For example, Jarrell and Peltzman (1985) provide the first major empirical study: using a nine-year panel of automotive and pharmaceutical industry recalls, the authors determine that the costs incurred by shareholders following recalls exceed the costs incurred by firms to rework or replace defective products. Similar findings related to recall costs are documented by Davidson and Worrell (1992) in the automotive industry; by Cheah *et al*. (2007) in the pharmaceutical industry; and by Chen *et al*. (2009) in the consumer products industry. Empirical research has also found that past recalls influence future recalls (Thirumalai and Sinha 2011), especially when recalls are voluntarily-initiated by firms (Haunschild and Rhee 2004). A small but growing research stream examines whether firm-level factors are predictive of future recalls, including firms with high R&D-intensity (Thirumalai and Sinha 2011), firms with more product and plant variety (Shah *et al*. 2016; Ball *et al*. 2018), and firms facing adverse inspection outcomes (Ball *et al*. 2017).

The extant literature is largely silent, however, on whether a relationship between product recalls and new product submissions exists. Some research suggests that firms learn from their own recalls and make quality improvements, which could hypothetically influence new product development efforts (Haunschild and Rhee 2004). Other research shows that under certain circumstances, firms observe and learn from the pre-market product development activities and R&D failures of their competitors, which may, in turn, influence subsequent new product development

[2] We examine Class III recalls in empirical robustness tests and confirm consistent findings.

projects (Krieger 2021). Our empirical setting differs from these studies in that we examine the impact from the post-market product recalls of competitor firms on new product submission efforts. Our approach is thus similar to research that examines the determinants of firm performance once new products are already commercialized (Haunschild and Sullivan 2002; Baum and Dahlin 2007; Kim and Miner 2007), but is distinct in that it considers competitor firm failures as predictors of new product development activity.

As articulated above, med-tech firms operate in well-defined product markets. Not surprisingly, there are limited information asymmetries within and across these markets. Firms are well-informed with respect to the product status—i.e., successes and failures—of competitors (Porter and Heppelmann 2014; Wu 2013; Thirumalai and Sinha 2011). We suggest that this information awareness influences subsequent firm activities: in particular, it shapes how firms respond via new product submissions to competitor recalls.

This argument has strong analogs to research in pharmaceuticals, a similarly R&D-intensive and regulated health care product setting. Several empirical studies demonstrate product market demand shocks that increase profitability generally lead to more new product development. Examples include exogenous patient population increases (Acemoglu and Linn 2004; Dubois *et al*. 2015), regulatory rule changes (Finkelstein 2004), and reimbursement modifications (Blume-Kohut and Sood 2013; Krieger *et al.* 2022). In a similar vein, we consider competitor recalls as "demand shocks", given the defective products are removed from the market for significant (e.g., indefinite or permanent) periods of time and thereby provide opportunities and shape incentives for other firms to enter. These demand shocks are both direct and indirect. The direct demand shock is that defective products are removed from the market. But this does not necessarily affect the entire product line as recalls generally impact only specific production lots as opposed to all products in a product line (complete product market removals do occur, but these are the rare exception and not the rule). The indirect demand shock comes in the form of a substantial reputational loss in the marketplace (Rhee and Haunschild 2004). When competitor firms announce serious recalls, even for a limited subset of products, it opens a window of opportunity for unaffected firms to potentially sway customers to shift to what can be viewed as more reliable manufacturers.

These direct and indirect demand shocks are particularly salient in the med-tech industry, given its market size and growth and its historic profit margins: many product markets exceed tens of billions in annual (USD) revenue with gross margins around 80-95 percent and net margins around

20-30 percent on average.[3] Such market characteristics—combined with the fact that devices regulated via the 510(k) clearance process represent product areas already proven safe—suggest a relatively low-risk but high-reward approach is to increase new product submissions when and where competitors stumble. In other words, competitor firm mistakes create substantial revenue and profit opportunities—with the potential rewards of increasing new product submission activities likely greater than any inherent product quality risks. We therefore hypothesize that, *ceteris paribus*, med-tech firms will increase new product submissions when competitor firms experience product recalls:

H1: Competitor recalls *increase* new product submissions.

PRODUCT MARKET COMPETITION

Firm incentives to bring new products to market are myriad and include factors such as internal pay schemes (Yanadori and Cui, 2013), complementary assets (Wu *et al.* 2014), demand conditions (Fabrizio and Thomas 2011), and competitive heterogeneity (Leiblein and Madsen 2009; Boudreau *et al*. 2011), among others. We consider a single and readily observable factor that potentially affects firms' incentives for new product submissions that also helps tease out the underlying dynamics of the above hypothesized recall-submission relationship: the number of active competitors in a given product market.

A large literature examines how product market competition shapes firms' R&D, innovation and technology adoption, and new product development activities. We provide a brief overview here, but refer interested readers to insightful literature reviews (e.g., Cohen and Levin, 1989; Gilbert, 2006; and Cohen, 2010). Empirical studies that examine product market competition and firm R&D and new product development activities are mixed: negative, positive, and even inverted-U relationships are found (Cohen, 2010). For instance, Macher *et al.* (2021) find cement plants are more likely to adopt fuel-efficient technology if proximate competitors are few; Polidoro and Theeke (2012) find that pharmaceutical firms facing more competition in drug products under development increase publishing efforts in top medical journals to facilitate FDA assessments and improve market positioning; Aghion *et al.* (2005) find an inverted-U relationship between the industry Lerner index and citation-weighted patents across

[3] See https://www.forbes.com/sites/liyanchen/2015/09/23/the-most-profitable-industries-in-2015/#1c3bf8216b73 and https://www.mddionline.com/three-medical-device-manufacturers-highest-profit-margins.

17 two-digit SIC code industries. Scholars have not surprisingly come to recognize that this relationship is nuanced and shaped by particular industry, product, and technological mechanisms and characteristics. For instance, opportunity can create the potential for innovation but industry appropriability conditions might determine ultimate success; bold innovations or novel products, respectively, might present firm complexities that incremental innovations or established products do not. As Gilbert (2006: 187) notes, "the details matter." Single-industry and narrow-product market examinations better allow for these mechanisms and characteristics to be considered and addressed.

In our empirical setting, the product markets considered have negligible uncertainty regarding technical viability but clear certainty around competitor firm mistakes. In other words, the organizational, market and regulatory difficulties that recalls impart to one firm does not necessarily spill over to all firms. While we theorize in Hypothesis H1 that more competitor recalls will lead to an increase in new product submissions, this may be impacted by how competitive the product market is. In "thick" product markets—i.e., those with many competitors—the large number of firms competing can more easily and more readily "fill the void" left by the recall-affected firms, suggesting that any gains in revenue and profit are relatively *de minimis*. Competitor recalls thus provide the opportunities, but crowded product markets limit the abilities for firms to successfully capitalize on the product recalls of their rivals, *ceteris paribus*. As a corollary, "thin" product markets offer greater opportunities for firms to capitalize on the recalls of rivals, *ceteris paribus*. A smaller number of product market competitors suggest greater abilities via new product submissions to increase revenue and profit and capture the market share left vacated by the recall-affected firms. We view this relationship as one that touches both the "willingness to respond" as well as the "ability to succeed". In particular, while competitor recalls constitute actionable information and provide opportunities for firms to respond via new product submission activities (i.e., the willingness to respond), the extent of product market competition represents a mechanism that moderates the ultimate success (i.e., the ability to succeed). We therefore examine the following moderating hypothesis:

H2: More product market competition *weakens* the relationship between competitor recalls and new product submissions.

EMPIRICS

DATA

We download FDA recall data and 510(k) device submission data over 2004-2020—covering all years in which these data were digitized through the most recent complete calendar year available. We assign each recall and submission to a standardized firm name based on the information included. We clean and standardize firm names in each database and then link firms across databases using the unique 510(k) number of each product (which links back to a specific regulatory clearance application).[4]

New Product Submissions – The 510(k) submission data provide detailed information, including unique identification numbers, submission and clearance dates, applicant firm identities, and device class and product market details.

Recalls – The recall data include recall event numbers, severity classifications, the unique 510(k) number of the recalled product, event dates, and firm identities. We use a digital text-scraping program to identify and collect the 510(k) numbers from free text data included in publicly available documents to precisely identify the device(s) associated with each recall. This direct link between submissions and recalls specific to a unique product is not included in the pre-formatted (structured) recall data available on the FDA website. Scraping and cleaning this information from the recall database text allows recalls to be directly linked to individual submissions within each product market. We utilize Class I and II recalls in our baseline empirical analysis, as these are the least discretionary, constitute the most significant patient health risks, and represent the largest firm disruptions. We consider Class III recalls in robustness tests.

VARIABLES

Our empirical analysis examines how prior competitor recalls affect subsequent new product submissions. Our analyses require that firms have a submission or a recall in the same product market and within a relevant time window in order to be considered "active" in that market.[5] In other

[4] Firm names are cleaned and matched using *matchIT*, a software package for "fuzzy matching" of text strings. *matchIT* creates match keys to search for duplicates and grades matching records. Submission data: https://www.fda.gov/medical-devices/510k-clearances/downloadable-510k-files. Recall data: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm.

[5] We utilize five-year windows because the average med-tech device life cycle is roughly three years and the average product development cycle is roughly two to three years (Wizemann 2010; Nazarian 2009).

words, the set of competitors varies across product markets and over time within a product market in our analyses, as we explain below.

Dependent Variable – The dependent variable, *New Product Submissions*, measures the number of new product submissions made by the firm in a product market and time window. We utilize a six-month window as a baseline, but consider alternative windows in robustness tests and can confirm consistent results.

Independent Variables— Research on innovative activity in health care examines myriad determinants of new product development patterns, including how potential market size positively predicts innovation in pharmaceutical markets (Acemoglu and Linn 2004; Dubois *et. al*. 2015) and how expected time-to-market shapes R&D activities and new drug commercialization (Budish *et. al*. 2015). In the specific context of FDA regulatory approval processes, Carpenter *et al*. (2010) examine FDA review times for new pharmaceutical products and Stern (2017) examines these dynamics in the context of new high-risk medical devices. In the tradition of using "demand shocks" to examine health care new product development effects (Blume-Kohout and Sood 2013; Krieger *et al*. 2022; and Krieger 2021), we consider competitor recalls as positive demand shocks.

The key independent variable, *Competitor Recalls*, represents a lagged count of recalls by competitor firms. To align with the time window of the dependent variable, we count competitor recalls in the six months prior to the new product submission count. In other words, we use the prior six-month window to count competitor recalls in a product market to predict new product submissions in the current six-month window. We explore variations in the number of six-month time window lags that may predict submissions in robustness checks, in order to determine persistence in the competitor firm recall and new product submission relationship. This allows us to determine when the relationship is strongest, when it is weakest, and when it begins to dissipate.

Moderating Variable – # of Competitors is the number of active competitor firms in the same product market in the prior six-month window.

Control Variables – Research suggests that new product development and recall propensities can be partially explained by products, firms, and changes over time (Thirumalai and Sinha 2011; Wowak *et al*. 2015; Shah *et al*. 2016; Ball *et al*. 2017). We therefore include product, firm and year fixed effects in all estimations. We also include several firm-level controls that may be associated with new product sumissions. *Public* is an indicator variable of whether the firm is publicly traded. Public firms may have more access to capital, more formal policies and structures in place,

and greater external market pressures and thus have more new product submissions, in comparison to private firms (Wu, 2012). *Firm Experience* represents the age (measured in logged time window increments) that the firm has been active in the product market. *# of Products* is a count of the number of product markets that the firm is active in. *Firm Recalls* is a count of internal recalls facing the firm and helps control for the influence that these shocks may have on new product submissions. We also include several product market-level control variables that may drive new product submissions. 510(k) products are assigned by the FDA to three regulatory classifications based on risk: Class I medical devices (e.g., stethoscopes, bandages, bedpans) are considered the lowest risk; Class II medical devices (e.g., catheters, blood pressure cuffs, syringes) are considered moderate risk; and Class III medical devices (e.g., implants, pacemakers, stents) are considered the highest risk.[6] We use two indicator variables—*Class II* and *Class III*—treating Class I as the reference category. We use three indicator variables that represent FDA-assigned descriptions of product use and risk to the customer: *Implantable*, *Life Sustaining*, and *Significant Risk*. For example, cardiac stents and hip implants are both implantable medical devices, but only the cardiac stent is considered life sustaining and of significant risk. Finally, *Product Age* represents the age (measured in logged time window increments) that the product code has been on the market.

EMPIRICAL METHODOLOGY

We panelize our data at the firm, product code, and six-month time window level in our baseline analysis. This panelization faciltates the use of count variables—in particular, we model submission counts in the current six-month period based on competitor recalls in the prior six-month period. We explore the empirical robustness of our results by considering alternative panelized versions at the quarter- and year-level of analysis. As our dependent variable is a non-negative count measure, we use negative binomial regession model estimation. In such estimation models, the dependent count variable is believed to be generated by a Poisson-like process. Variation in the dependent variable, however, is allowed to be greater than that of a true Poisson distribution; such extra variation is referred to as overdispersion (Wooldridge 2010).

[6] See https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device

DESCRIPTIVE STATISTICS

Tables 1 and 2 respectively provide descriptive statistics and correlation statistics for the variables in the main estimation. All Variance Inflation Factors (VIF) are below the threshold level of ten, helping to alleviate concerns that multi-collinearity bias influences our results.

4. EMPIRICAL RESULTS

INTERPRETING COEFFICIENTS

The interpretation of estimated coefficients in negative binomial models is as follows: a one unit change in recall count is associated with a ($\exp^{\beta}$-1) percentage change in the number of new product submissions (Wooldridge 2010).

MAIN RESULTS

Table 3 presents the main negative binomial model estimation results. All models include product, firm, and year fixed effects: Model (1) includes the firm- and product market-level control variables; Model (2) adds *Competitor Recalls*; Model (3) adds *# of Competitors*; and Model (4) incorporates a *Competitor Recalls* and *# of Competitors* interaction. The Model (1) results indicate that firms that are publicly traded, have more product market experience, are active across more product markets, and incur more product market recalls have more new product submissions. Product markets that involve implantable and significant risk devices experience more new product submissions, while older product markets experience less new product market submissions.

The Model (2) results indicate that *Competitor Recalls* are positive and statistically significant predictors of new product submissions (β = 0.102; p<0.001), supporting Hypothesis H1. The results indicate that each competitor recall in the prior six-month window is associated with a 10.7 percent increase in new product submissions in the current six-month window.[7] Model (3) adds *# of Competitors* and indicates that "thick" product markets (i.e., those with more competitors) experince more submissions—an unsurprising and mechanical result. Model (4), however, adds the *Competitor Recalls* × *# of Competitors* interaction, which is negative and significant (β = -0.055; p<0.001). This result suggests that the positive relationship between competitor recalls and new product submissions is attenuated in more competitive markets, supporting Hypothesis H2.

[7] $\text{Exp}^{0.102}$-1 = 10.7

Figure 1 presents the economic significance of these results using margins analysis. *Competitor Recalls* varies mostly over its entire range,[8] while *# of Competitors* is held constant at two levels: "thin" product markets (i.e., the 10th percentile of *# of Competitors*) and "thick" product markets (i.e., the 90th percentile of *# of Competitors*). All other variables are held at their respective means. Confidence intervals are reported at the 95th percentile. Figure 1 shows a strong moderating influence of *# of Competitors* on the relationship between *Competitor Recalls* and *New Product Submissions*. In "thick" product markets, there is a subtle but positive relationship between competitor recalls and new product submissions. In "thin" product markets, however, there is a prominent and positive relationship between competitor recalls and new product submissions, especially when the number of competitor recalls in the prior time window exceeds six, which is when the respective confidence intervals no longer overlap. In aggregate, Figure 1 provides strong support for Hypothesis H2, indicating that firms increase new product submissions when competitors stumble but substantially less so in those product markets with many competitors. Competitor recalls provide the opportunity and shape the *willingness to respond* via new product submissions, but the extent of product market competition determines the *ability to succeed* in these endeavors.

ROBUSTNESS RESULTS

We undertake several empirical robustness tests of our main estimation results to demonstrate consistency and to explore mechanisms that may explain our findings. These include endogeneity bias, expansion of our six-month time window, and several verifications of consistency across additional measures and methods.

First, we examine potential endogeneity bias in our model. In particular, the premise of our hypothesized relationship between competitor recalls and new product submissions is that the former serve as exogenous, external shocks that stimulate the latter. However, competitor recalls are only exogenous as measured in our study if firms are unaware that competitors are experiencing product quality problems. Recall "awareness" occurs when competitor recalls are officially initiated as recorded on the FDA website.[9] If competitior firm quality issues that may eventually lead to recalls are observable to firms prior to a recall being initiated, however, than this "pre-recall

[8] We vary the number of competitor firm recalls from zero to fifteen, given the relatively small number of observations (and large standard errors) in the right-hand tail above this maximum.

[9] Our recall dates are the dates in which the public was made aware of the recall, this is what is reported by the FDA in their recall data.

quality problem awareness" would constitute an omitted variable and lead to potential endogeneity concerns. In particular, it is likely to influence competitor recalls and new product submissions. We address this potential source of endogeneity by exploiting an additional and relatively novel source of FDA-available regulatory information.

In the medical device industry, product quality problems are reported in a publicly-available and FDA-maintained system called the Manufacturer and User Facility Device Experience (MAUDE) database. MAUDE is a open-source, user complaint database that collects medical device performance feedback from patients, physicians, and firms. Medtech firms are known to monitor MAUDE data for information related to product quality problems in their respective product markets.[10] Thus, if a MAUDE complaint precedes a competitor recall, then that recall may represent a less than exogenous external shock to unaffected firms. Conversely, competitor recalls that have no prior MAUDE association are exogeneous shocks, as no firm possesses knowledge of competitors' quality problems until those recalls are initiated. Indeed, there are a significant number of recalls that have no prior MAUDE complaints associated with them. This is expected, however, as recalls can be initiated due solely to internal knowledge of the recalling firm, such as from product, process, or materials changes or product safety issues that were not publicly known until the time of the recall in quesiton. To identify the purely exogenous subset of recalls, we focus on those recalls where there are no MAUDE complaints associated with a product prior to its recall. We stipulate in this robustness check that if our results hold in the subset of competitor recalls that have no MAUDE complaints reported prior to the recall initiation date, then endogeneity is unlikely to be biasing our main estimation results.

To associate MAUDE complaints with recalls, we first downloaded all 12.8 million complaint records from the database.[11] We then use FDA submission number information included in the MAUDE database to directly link to the submission number associated with each submission and recall in our dataset. We create an adjusted competitor recall count: *Competitor Recalls-No MAUDE*, which represents those competitor recalls that never appear in the MAUDE complaint database. Roughly two-thirds of our *Competitor Recalls* measure are not associated with any MAUDE complaint. Table 4 presents the estimation results using the adjusted competitor recall

[10] https://www.greenlight.guru/blog/medical-device-reporting-mdr

[11] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm

measure: Models 1-4 examines the entire sample (i.e., all submissions but MAUDE-exempt recalls); Models 5-8 examines a sub-sample (i.e., MAUDE-exempt submissions and recalls). In both sets of estimations, the results closely follow the baseline results presented in Table 3: *Competitor Recalls-No MAUDE* and *# of Competitors* remain positive and statistically significant predictors of new product submissions; and the interaction of these variables remains negative and significant. The Table 4 results thus suggest that the risk of endogeneity biasing our main findings is reasonably low and that the relationship between competitor recalls and new product submissions is reasonably exogenous.

We next consider earlier recall time window lags beyond the main estimation measure of six months. By doing so, we can potentially determine how and when in the new product development process competitor recalls influence new product submissions. For example, if we find that the relationship dissipates quickly—e.g., in the second six-month lag window—then competitor recalls are most influential over new product submissions in the time period just prior to the firm submitting to the FDA. In this case, competitor recalls incent firms to finalize products that are nearly completed. However, if the effect continues for multiple six-month lag windows, the relationship is active throughout the entire new product development cycle—including early on in the new product development project. Finally, this robustness test allows us to qualitatively examine coefficient effect sizes in each time window lag, which can determine where the relationship is the strongest—i.e., close-in or far-out from when the firm submits to the FDA. We include the regression results in Appendix Table A1 and plot the coeffiicents of each six-month window lag from Appnedix Table A1 in Figure 2. Two conclusions from Figure 2 are readily apparent. First, the competitor recall effect weakens as the lag increases, becoming statistically insignificant in the ninth time window lag. Second, because the average product development project for 510(k) medical devices is two to three years (Wizemann 2010; Nazarian 2009), recalls throughout the entire product development project appear to influence submissions—albeit with a stronger effect the closer the relevant competitor product is to its FDA submission date. In other words, new product development projects appear to be most sensitive to competitor recalls in the immediate months before submission, but remain influenced by these recalls as far back as eight six-month time window lags, or approximately four years. This may indicate that competitor recalls influence new product submissions not only during all product development process phases (albeit weakening

with time), but also before the new product development project even starts. In such cases, competitor recalls may help create the necessary momentum to initiate new product development projects.

Finally, we include four additional robustness tests that demonstrate our results are not artifacts of model assumptions and level of analysis choices. In Appendix Table A2, we present results using quarter-year time window and year time window interval and lag structures. In both time window analyses, the hypothesized results remain consistent with the main estimation results. In Appendix Table A3, we implement logistic regression analysis expressing new product submissions as a dichotomous measure. Again, all of the main empirical results continue to hold.[12] In Appendix Table A4, we replace Class I and II recalls with All Class (i.e., I-III) recalls. Again, the results remain consistent with the main estimation. Finally, in Appendix Table A5, we include a model that segregates competitor firm recall counts into those announced by publicly traded firms and those announced by private firms. We do so because it is likely that public firm recalls receive greater awareness and media attention, and may therefore stimulate new product submissions more than private firm recalls. We observe very similar results when comparing both the main and the interaction effects using public and private firm recalls, suggesting our results are robust to these two categories of recalls.

DISCUSSION

This study examines how prior competitor recalls influence subsequent product submissions in the medical device industry. Exploring whether and how competitor recalls stimulate new product submissions not only provides depth to the recall and new product development literature streams, but also suggests important implications for recalling firms.

First, we demonstrate that competitor recalls influence new product submissions. Each additional competitor recall in the prior six months is associated with a 10.7 percent increase in new product submissions. This effect is strongest in the most immediate six-month time window, but continues in a statistically significant manner for approximately four years. As the average 510(k) new product development process is approximately two to three years in length, these results sug-

[12] Note that for Table A3, the coefficients are odds ratios. A positive effect leads to an odds ratio greater than one, and a negative effect leads to an odds ratio less than one. Thus for the interaction term of *Competitor Recall x # of Competitors*, the 0.955 odds ratio is consistent with the negative beta coefficient on the same term from Table 3.

gest that competitor recalls have a persistent and positive relationship with new product submissions throughout the entirety of the new product development process, although Figure 2 indicates that this effect weakens with longer time lags.

Second, we find that these results are contingent upon the competitive landscape in which the specific product exists. For product markets with few competitors, firms have strong incentives, in terms of willingness to respond and ability to succeed, to submit new products. For product market with many competitors, however, the ability to succeed is moderated. Hence, new product submissions following competitor firm recalls in "thick" product markets is weakened.

These findings enhance the body of literature that examines the consequences of recalls (Haunschild and Rhee 2004; Thirumalai and Sinha 2011; Jarrell and Peltzman 1985) by unpacking a highly relevant but largely understudied ramification: recalls by competitor firms impact future new product submissions. Our findings also expand upon previous studies that explore factors that influence new product submissions and their incentives in health care product markets (Acemoglu and Linn 2004; Dubois *et. al.* 2015; Budish *et. al*. 2015; Carpenter *et al*. 2010; Stern 2017).

Our results also have important implications for firms. This study suggests a double penalty associated with product failures: recalls not only create internal challenges via significant recall costs, unwanted negative attention from the media and regulators, and lost income, but also external concerns by incenting competitors to increase their new product submissions—ostensibly to capture vulnerable market share. These results highlight an additional reason why firms should seek to avoid product failures in the first place, indicating that product failure prevention and remediation activities are more valuable for managers than previously thought.

LIMITATIONS

Certain limitations and caveats related to our empirical setting, variables, and econometric analysis are worth noting. First, we examine a single industry and its new product submission- and recall-related activities. While such focus potentially limits the generalizability of our findings and implications, it simultaneously offers greater precision in our measures and estimation, especially given the exhaustive and comprehensive nature of FDA databases. Additionally, many R&D-intensive industries are subject to product failures and recalls, which suggests that our findings likely have broader applicability. Second, our primary predictor is product recalls, but other negative shocks exist within the med-tech industry. These include non-recall-related malfunctions and manufacturing compliance issues, although recalls remain one of the most significant and salient ways

in which firms experience product failure. Third, our recall measures may not capture other relevant features that are unavailable in our data, such as media coverage or financial costs. We nevertheless find the recall characteristics that we do observe are of substantial importance in predicting the forward-looking new product submission activities of med-tech firms. Fourth, we examine new product submissions for those devices that receive regulatory clearance but do not consider those that are denied clearance. The 510(k) submissions that are not cleared by FDA are not made public, however, and actual rejection rates for these submissions are reportedly quite low. Fifth, although we undertake steps to address it, endogeneity may still be present. Other methods, such as instrumental variable analysis, may help further address endogeneity but identifying valid instruments in our particular context is quite challenging and may create other sources of bias.

Notwithstanding these limitations, our results suggest that there are additional externalities associated with product recalls that are unlikely to be fully captured in the existing literature related to estimating the product failure costs. In fact, no studies of which we are aware explore the new product submission consequences of product recalls as we do, highlighting an important contribution that bridges two important literatures streams in the high-innovation and high-risk medical device industry.

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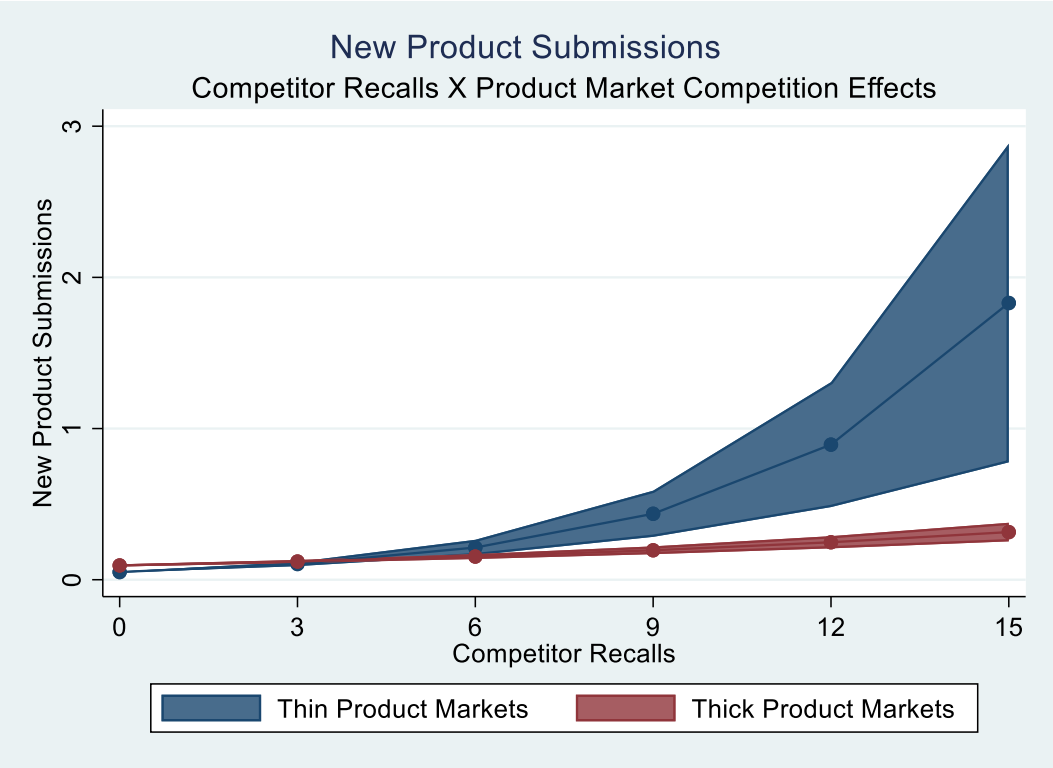
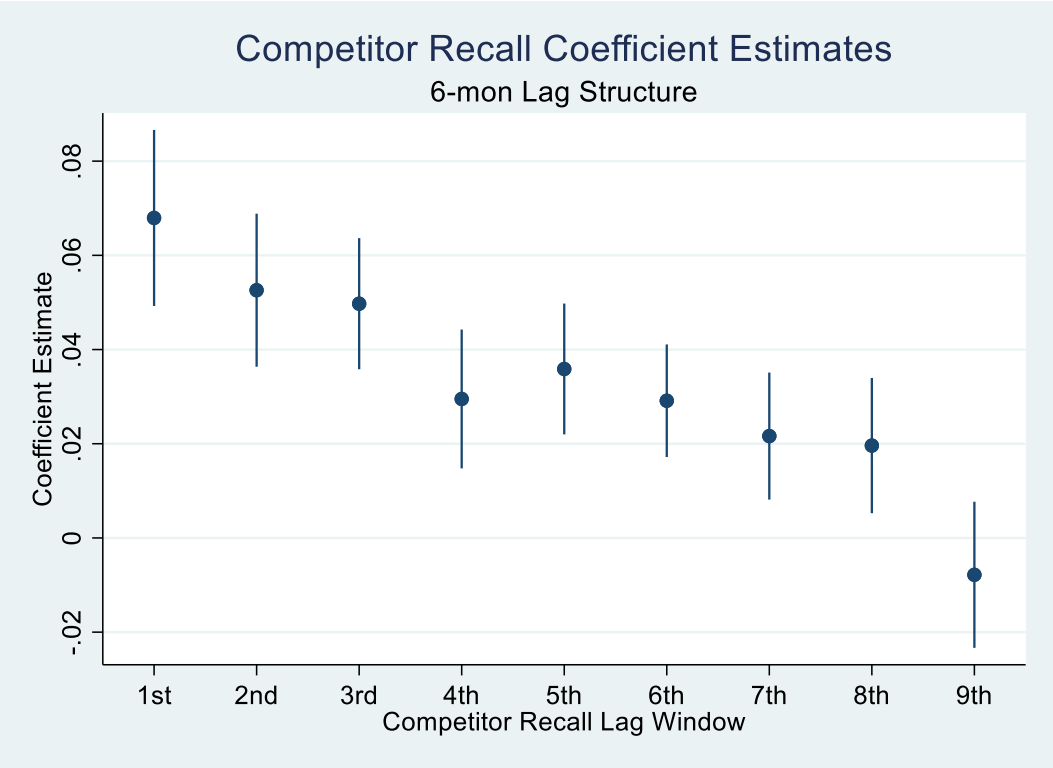
Figure 1: Economic Significance



Notes: (1) Figure uses the Model 4 estimation results in Table 3. (2) *Competitor Recalls* varies from zero (0) to 15 recalls. (3) *# Competitors* is set at two levels: the 10th percentile (i.e., "thin" product markets) and the 90th percentile (i.e., "thick" product markets). (4) All other variables are held at their respective means. (5) Confidence intervals are reported at the 95th percentile.

Figure 2: Competitor Recall Window Lags



Notes: (1) Figure uses the Model 9 estimation results in Appendix Table A1. (2) All variables are held at their respective means. (3) Coefficient estimates and standard errors are reported for Competitor Recalls lagged over successive six-month windows. For example, the 1st lag represents the most prior six-month window, the 2nd lag represents the second prior six-month window, and so on.

Table 1: Descriptive Statistics

VARIABLE	OBS	MEAN	ST DEV	MIN	MAX
New Product Submissions	138,945	0.084	0.341	0.000	13.000
Public	138,945	0.198	0.399	0.000	1.000
Firm Experience	138,945	7.535	5.644	1.000	31.000
# of Products	138,945	8.425	17.399	1.000	120.000
Firm Recalls	138,945	0.019	0.198	0.000	28.000
Regulatory Classification	138,945	1.936	0.255	1.000	3.000
Implantable	138,945	0.246	0.431	0.000	1.000
Life Sustaining	138,945	0.029	0.168	0.000	1.000
Significant Risk	138,945	0.105	0.306	0.000	1.000
Product Age	138,945	53.186	19.264	1.000	81.000
# of Competitors	138,945	40.712	47.761	0.000	237.000
Competitor Recalls	138,945	0.277	1.570	0.000	44.000

Notes: (1) Variables are in raw form (i.e., no transformations). (2) Descriptive statistics are calculated from observations in estimation requirements: (a) at least one recall in PC over the sample timeframe; (b) at least one competitor firm submission in PC over sample timeframe; and (c) PC has some activity (e.g., recall or submission) in the most prior five-year window.

Table 2: Correlation Statistics

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
(1) New Product Submissions	1.00											
(2) Public	0.09	1.00										
(3) Firm Experience	0.05	0.08	1.00									
(4) # of Products	0.07	0.45	0.12	1.00								
(5) Firm Recalls	0.03	0.04	0.09	0.09	1.00							
(6) Regulatory Classification	0.03	0.04	0.03	0.04	0.02	1.00						
(7) Implantable	0.05	-0.01	0.03	0.03	0.00	0.15	1.00					
(8) Life Sustaining	-0.01	0.00	0.01	0.02	0.03	0.05	-0.04	1.00				
(9) Significant Risk	0.05	0.02	0.03	0.05	0.01	0.09	0.34	0.04	1.00			
(10) Product Age	-0.05	-0.05	0.15	-0.08	0.01	0.00	-0.22	0.04	-0.39	1.00		
(11) # of Competitors	0.02	-0.11	-0.01	-0.17	-0.02	-0.05	0.06	-0.11	0.04	0.10	1.00	
(12) Competitor Recalls	0.07	0.01	-0.05	-0.01	0.12	0.05	0.00	-0.01	0.01	0.05	0.20	1.00

Notes: (1) Variables are in raw form (i.e., no transformations). (2) Correlation statistics based upon observations in estimation requirements: (a) at least one recall in PC over the sample timeframe; (b) at least one competitor firm submission in PC over sample timeframe; and (c) PC has some activity (e.g., recall or submission) in the most prior five-year window.

Table 3: Main Estimation Results

	(1)	(2)	(3)	(4)
Public	0.491***	0.480***	0.477***	0.470***
	(0.062)	(0.059)	(0.058)	(0.057)
Firm Experience	0.156***	0.191***	0.183***	0.188***
	(0.032)	(0.031)	(0.031)	(0.030)
# of Products	0.320***	0.308***	0.362***	0.351***
	(0.077)	(0.072)	(0.073)	(0.071)
Firm Recalls	0.232***	0.117*	0.139**	0.090*
	(0.049)	(0.048)	(0.051)	(0.046)
Class II	0.320**	0.301*	0.315*	0.311*
	(0.120)	(0.120)	(0.123)	(0.123)
Class III	-0.272	-0.480+	-0.444+	-0.660**
	(0.291)	(0.258)	(0.258)	(0.248)
Implantable	0.214**	0.220**	0.273***	0.279***
	(0.069)	(0.068)	(0.069)	(0.069)
Life Sustaining	-0.143	-0.146	-0.043	-0.051
	(0.104)	(0.103)	(0.109)	(0.109)
Significant Risk	0.187***	0.163**	0.072	0.054
	(0.055)	(0.055)	(0.057)	(0.057)
Product Age	-0.183***	-0.218***	-0.306***	-0.322***
	(0.041)	(0.040)	(0.042)	(0.042)
Competitor Recalls		0.102***	0.088***	0.335***
		(0.008)	(0.007)	(0.030)
# of Competitors			0.203***	0.220***
			(0.024)	(0.024)
Competitor Recalls x # of Competitors				-0.055***
				(0.006)
Constant	-3.275***	-3.153***	-3.589***	-3.551***
	(0.496)	(0.472)	(0.475)	(0.468)
Observations	138945	138945	138945	138945
Pseudo R-squared	0.033	0.037	0.040	0.042
Wald chi2	12009.397	10167.688	10423.100	9652.370

Notes: (1) All models use negative binomial model regression estimation with half-year interval and lag structures. (2) All models examine Class I or II recalls. (3) All models include: (a) year controls, (b) regulatory medical specialty (RMS) controls, and (c) firm controls based upon ranges of active product codes. (4) Firm Recalls, Competitor Recalls, and # of Competitors are lagged. (5) Firm Experience, Firm # of Products, Product Age, and # of Competitors are logged. (6) Estimation requirements: (a) at least one recall in PC over the sample timeframe; (b) at least one competitor firm submission in PC over sample timeframe; and (c) PC has some activity (e.g., recall or submission) in the most prior five-year window.

Table 4: Robustness Test (No MAUDE Competitor Recalls)

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
Public	0.491***	0.482***	0.479***	0.473***	0.496***	0.489***	0.486***	0.481***
	(0.062)	(0.060)	(0.059)	(0.058)	(0.079)	(0.077)	(0.076)	(0.075)
Firm Experience	0.156***	0.176***	0.169***	0.171***	0.096*	0.121**	0.113**	0.116**
	(0.032)	(0.031)	(0.031)	(0.031)	(0.038)	(0.038)	(0.038)	(0.037)
# of Products	0.320***	0.313***	0.369***	0.361***	0.287**	0.285**	0.328**	0.320**
	(0.077)	(0.073)	(0.074)	(0.073)	(0.106)	(0.105)	(0.107)	(0.106)
Firm Recalls	0.232***	0.181***	0.197***	0.176***	-0.001	-0.092	-0.067	-0.079
	(0.049)	(0.051)	(0.054)	(0.052)	(0.198)	(0.198)	(0.191)	(0.195)
Class II	0.320**	0.315**	0.329**	0.328**	0.310*	0.306*	0.333*	0.332*
	(0.120)	(0.120)	(0.122)	(0.122)	(0.132)	(0.132)	(0.134)	(0.134)
Class III	-0.272	-0.318	-0.305	-0.357	-0.441	-0.457	-0.360	-0.379
	(0.291)	(0.282)	(0.286)	(0.273)	(0.596)	(0.598)	(0.588)	(0.595)
Implantable	0.214**	0.215**	0.271***	0.274***	0.121	0.120	0.129	0.132
	(0.069)	(0.068)	(0.069)	(0.069)	(0.092)	(0.092)	(0.092)	(0.092)
Life Sustaining	-0.143	-0.146	-0.039	-0.042	-0.597**	-0.592**	-0.513**	-0.505**
	(0.104)	(0.104)	(0.110)	(0.111)	(0.188)	(0.188)	(0.187)	(0.188)
Significant Risk	0.187***	0.174**	0.078	0.068	0.197*	0.192*	0.134	0.124
	(0.055)	(0.055)	(0.058)	(0.058)	(0.090)	(0.090)	(0.092)	(0.092)
Product Age	-0.183***	-0.200***	-0.293***	-0.300***	-0.229***	-0.245***	-0.312***	-0.320***
	(0.041)	(0.040)	(0.043)	(0.043)	(0.061)	(0.062)	(0.064)	(0.064)
Competitor Recalls-No MAUDE		0.270***	0.226***	0.858***		0.217***	0.188***	0.814***
		(0.022)	(0.023)	(0.102)		(0.031)	(0.031)	(0.151)
# of Competitors			0.210***	0.220***			0.154***	0.165***
			(0.025)	(0.025)			(0.029)	(0.029)
Competitor Recalls-No MAUDE x # of Competitors				-0.137***				-0.132***
				(0.022)				(0.032)
Constant	-3.275***	-3.239***	-3.680***	-3.664***	-3.498***	-3.473***	-3.817***	-3.788***
	(0.496)	(0.474)	(0.478)	(0.474)	(0.710)	(0.698)	(0.703)	(0.699)
Observations	138945	138945	138945	138945	93116	93116	93116	93116
Pseudo R-squared	0.033	0.035	0.039	0.040	0.024	0.026	0.028	0.028
Wald chi2	12009.397	10957.042	11267.365	9593.830	803.581	791.218	710.196	719.911

Notes: (1) All models use negative binomial model regression estimation with half-year interval and lag structures. (2) All models examine Class I or II recalls. (3) All models include: (a) year controls, (b) regulatory medical specialty (RMS) controls, and (c) firm controls based upon ranges of active product codes. (4) Firm Recalls, Competitor Recalls, and # of Competitors are lagged. (5) Firm Experience, Firm # of Products, Product Age, and # of Competitors are logged. (6) Models 1-4 use entire submission but MAUDE-exempt recall sample; Models 5-8 use MAUDE-exempt submission and recall sample.Estimation requirements: (a) at least one recall in PC over the sample timeframe; (b) at least one competitor firm submission in PC over sample timeframe; and (c) PC has some activity (e.g., recall or submission) in the most prior five-year window.

Appendix Table A1: Robustness Test (Time Lag Measure Analysis)

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
Public	0.477***	0.496***	0.483***	0.477***	0.459***	0.432***	0.432***	0.431***	0.417***
	(0.058)	(0.057)	(0.058)	(0.057)	(0.059)	(0.058)	(0.060)	(0.063)	(0.065)
Firm Experience	0.183***	0.202***	0.312***	0.433***	0.563***	0.686***	0.830***	0.906***	0.954***
	(0.031)	(0.036)	(0.043)	(0.052)	(0.061)	(0.070)	(0.079)	(0.086)	(0.097)
# of Products	0.362***	0.333***	0.302***	0.301***	0.285***	0.287***	0.309***	0.293***	0.274**
	(0.073)	(0.070)	(0.072)	(0.074)	(0.076)	(0.079)	(0.084)	(0.088)	(0.092)
Firm Recalls	0.139**	0.038	-0.007	-0.027	-0.029	-0.025	-0.025	-0.024	-0.029
	(0.051)	(0.043)	(0.027)	(0.022)	(0.020)	(0.020)	(0.021)	(0.023)	(0.024)
Class II	0.315*	0.366**	0.367*	0.335*	0.283+	0.243	0.196	0.132	0.074
	(0.123)	(0.133)	(0.146)	(0.152)	(0.156)	(0.167)	(0.178)	(0.185)	(0.190)
Class III	-0.444+	-0.625*	-0.820**	-0.980***	-1.256***	-1.314***	-1.731***	-1.643***	-1.942***
	(0.258)	(0.255)	(0.268)	(0.264)	(0.268)	(0.285)	(0.303)	(0.305)	(0.506)
Implantable	0.273***	0.260***	0.245***	0.216**	0.174*	0.131	0.101	0.075	0.045
	(0.069)	(0.071)	(0.073)	(0.076)	(0.079)	(0.081)	(0.085)	(0.088)	(0.092)
Life Sustaining	-0.043	-0.051	-0.107	-0.096	-0.095	-0.064	-0.112	-0.197	-0.236
	(0.109)	(0.113)	(0.121)	(0.127)	(0.135)	(0.129)	(0.135)	(0.156)	(0.162)
Significant Risk	0.072	0.074	0.092	0.099	0.100	0.086	0.099	0.107	0.105
	(0.057)	(0.058)	(0.060)	(0.063)	(0.066)	(0.069)	(0.073)	(0.079)	(0.084)
Product Age	-0.306***	-0.339***	-0.354***	-0.370***	-0.375***	-0.392***	-0.375***	-0.391***	-0.380***
	(0.042)	(0.044)	(0.047)	(0.050)	(0.054)	(0.058)	(0.062)	(0.066)	(0.072)
Competitor Recalls (1st lag)	0.088***	0.127***	0.113***	0.103***	0.093***	0.087***	0.082***	0.074***	0.068***
	(0.007)	(0.010)	(0.010)	(0.009)	(0.009)	(0.009)	(0.009)	(0.010)	(0.010)
Competitor Recalls (2nd lag)		0.069***	0.096***	0.085***	0.077***	0.067***	0.060***	0.055***	0.053***
		(0.006)	(0.009)	(0.008)	(0.008)	(0.008)	(0.008)	(0.008)	(0.008)
Competitor Recalls (3rd lag)			0.056***	0.074***	0.067***	0.062***	0.056***	0.054***	0.050***
			(0.005)	(0.007)	(0.007)	(0.007)	(0.007)	(0.007)	(0.007)
Competitor Recalls (4th lag)				0.046***	0.055***	0.050***	0.042***	0.035***	0.030***
				(0.005)	(0.008)	(0.008)	(0.008)	(0.008)	(0.008)
Competitor Recalls (5th lag)					0.040***	0.048***	0.044***	0.038***	0.036***
					(0.005)	(0.007)	(0.007)	(0.007)	(0.007)
Competitor Recalls (6th lag)						0.026***	0.034***	0.031***	0.028***
						(0.006)	(0.006)	(0.006)	(0.006)
Competitor Recalls (7th lag)							0.017**	0.024***	0.022**
							(0.006)	(0.007)	(0.007)
Competitor Recalls (8th lag)								0.010	0.020**
								(0.006)	(0.007)
Competitor Recalls (9th lag)									-0.008
									(0.008)
# of Competitors	0.203***	0.177***	0.161***	0.145***	0.135***	0.145***	0.143***	0.139***	0.148***
	(0.024)	(0.024)	(0.025)	(0.025)	(0.026)	(0.027)	(0.028)	(0.030)	(0.031)
Constant	-3.589***	-3.866***	-3.764***	-4.206***	-4.092***	-4.980***	-5.331***	-5.579***	-5.844***
	(0.475)	(0.423)	(0.452)	(0.436)	(0.463)	(0.477)	(0.532)	(0.543)	(0.622)
Observations	138945	126370	114042	102059	90402	79119	68160	57571	47357
Pseudo R-squared	0.040	0.047	0.053	0.058	0.060	0.064	0.067	0.067	0.065
Wald chi2	10423.100	19817.817	17990.222	7736.222	4483.462	3274.578	2904.009	2560.630	2113.730

Notes: (1) All models use negative binomial model regression estimation with half-year interval and lag structures. (2) All models examine Class I or II recalls. (3) All models include: (a) year controls, (b) regulatory medical specialty (RMS) controls, and (c) firm controls based upon ranges of active product codes. (4) Firm Recalls, Competitor Recalls, and # of Competitors are lagged. (5) Firm Experience, # of Products, Product Age, and # of Competitors are logged. (6) Firm Recalls are summed over the lag structure implemented; # of Competitors are averaged over the lag structure implemented; Each successive model adds a Competitor Recall lag to the prior model. (7) Estimation requirements: (a) at least one recall in PC over the sample timeframe; (b) at least one competitor firm submission in PC over sample timeframe; and (c) PC has some activity (e.g., recall or submission) in the most prior five-year window.

Appendix Table A2: Robustness Test (Quarter and Year Interval Analysis)

	QTR-INTERVAL ANALYSIS				YR-INTERVAL ANALYSIS			
	(1)	**(2)**	**(3)**	**(4)**	**(5)**	**(6)**	**(7)**	**(8)**
Public	0.481***	0.475***	0.473***	0.469***	0.511***	0.499***	0.496***	0.478***
	(0.060)	(0.059)	(0.058)	(0.057)	(0.061)	(0.058)	(0.057)	(0.055)
Firm Experience	0.151***	0.166***	0.161***	0.163***	0.147***	0.212***	0.198***	0.216***
	(0.027)	(0.026)	(0.026)	(0.026)	(0.041)	(0.039)	(0.039)	(0.038)
# of Products	0.326***	0.319***	0.379***	0.372***	0.317***	0.301***	0.347***	0.328***
	(0.076)	(0.074)	(0.075)	(0.074)	(0.080)	(0.075)	(0.076)	(0.073)
Firm Recalls	0.295***	0.186**	0.211***	0.171**	0.215***	0.123***	0.143***	0.095**
	(0.058)	(0.059)	(0.060)	(0.060)	(0.035)	(0.034)	(0.035)	(0.035)
Class II	0.290*	0.283*	0.294*	0.293*	0.366**	0.330**	0.348**	0.339**
	(0.117)	(0.117)	(0.120)	(0.120)	(0.127)	(0.126)	(0.128)	(0.129)
Class III	-0.197	-0.269	-0.256	-0.303	-0.170	-0.436	-0.391	-0.659**
	(0.294)	(0.285)	(0.292)	(0.280)	(0.302)	(0.272)	(0.277)	(0.252)
Implantable	0.215**	0.219**	0.280***	0.282***	0.205**	0.213**	0.255***	0.260***
	(0.069)	(0.068)	(0.069)	(0.069)	(0.070)	(0.069)	(0.069)	(0.069)
Life Sustaining	-0.148	-0.148	-0.036	-0.038	-0.127	-0.140	-0.052	-0.072
	(0.103)	(0.102)	(0.109)	(0.109)	(0.103)	(0.103)	(0.109)	(0.109)
Significant Risk	0.192***	0.181***	0.079	0.071	0.173**	0.138*	0.063	0.033
	(0.055)	(0.055)	(0.057)	(0.057)	(0.056)	(0.055)	(0.058)	(0.058)
Product Age	-0.169***	-0.184***	-0.277***	-0.283***	-0.224***	-0.289***	-0.369***	-0.401***
	(0.039)	(0.038)	(0.041)	(0.040)	(0.046)	(0.045)	(0.046)	(0.046)
Competitor Recalls		0.162***	0.139***	0.462***		0.055***	0.048***	0.209***
		(0.013)	(0.012)	(0.062)		(0.004)	(0.003)	(0.017)
# of Competitors			0.223***	0.230***			0.176***	0.205***
			(0.025)	(0.025)			(0.025)	(0.025)
Competitor Recalls x # of Competitors				-0.073***				-0.035***
				(0.013)				(0.003)
Constant	-4.063***	-4.001***	-4.410***	-4.387***	-2.964***	-2.725***	-3.155***	-3.080***
	(0.494)	(0.480)	(0.483)	(0.478)	(0.451)	(0.425)	(0.429)	(0.415)
Observations	280577	280577	280577	280577	68182	68182	68182	68182
Adjusted R-squared	0.030	0.031	0.035	0.036	0.036	0.043	0.046	0.048
Wald chi2	6230.571	6221.450	6646.480	6575.208	3136.931	3737.021	4056.776	4431.583

Notes: (1) All models use negative binomial model regression estimation with either quarter-year interval and lag structures (models 1-4) or year interval and lag strctures (models 5-8). (2) All models examine Class I or II recalls. (3) All models include: (a) year controls, (b) regulatory medical specialty (RMS) controls, and (c) firm controls based upon ranges of active product codes. (4) Firm Recalls, Competitor Recalls, and # of Competitors are lagged. (5) Firm Experience, # of Products, Product Age, and # of Competitors are logged. (6) Estimation requirements: at least one recall in PC over the sample timeframe; (b) at least one competitor firm submission in PC over sample timeframe; and (c) PC has some activity (e.g., recall or submission) in the most prior five-year window.

Appendix Table A3: Robustness Test (Logistic Regression Analysis)

	(1)	(2)	(3)	(4)
Public	1.542***	1.537***	1.538***	1.533***
	(0.087)	(0.085)	(0.084)	(0.083)
Firm Experience	1.174***	1.214***	1.209***	1.217***
	(0.034)	(0.035)	(0.035)	(0.035)
# of Products	1.385***	1.379***	1.453***	1.440***
	(0.098)	(0.095)	(0.102)	(0.100)
Firm Recalls	1.272***	1.166*	1.184*	1.132*
	(0.083)	(0.075)	(0.081)	(0.063)
Class II	1.577***	1.554***	1.575***	1.568***
	(0.152)	(0.150)	(0.156)	(0.156)
Class III	0.921	0.780	0.810	0.626+
	(0.271)	(0.212)	(0.220)	(0.172)
Implantable	1.221**	1.228**	1.295***	1.306***
	(0.081)	(0.081)	(0.088)	(0.088)
Life Sustaining	0.863	0.860	0.943	0.937
	(0.090)	(0.089)	(0.103)	(0.102)
Significant Risk	1.204**	1.181**	1.082	1.060
	(0.068)	(0.067)	(0.064)	(0.063)
Product Age	0.809***	0.788***	0.723***	0.712***
	(0.030)	(0.028)	(0.028)	(0.028)
Competitor Recalls		1.086***	1.076***	1.327***
		(0.007)	(0.007)	(0.037)
# of Competitors			1.210***	1.228***
			(0.028)	(0.028)
Competitor Recalls x # of Competitors				0.955***
				(0.006)
Constant	0.030***	0.032***	0.022***	0.023***
	(0.013)	(0.014)	(0.010)	(0.010)
Observations	138945	138945	138945	138945
Pseudo R-squared	0.038	0.041	0.045	0.046
Wald chi2	36591.769	29776.802	14823.498	12778.112

Notes: (1) All models use logistic regression estimation and all coefficients are expressed as odds ratios, with half-year interval and lag structures. (2) All models examine Class I or III recalls. (3) All models include: (a) year controls, (b) regulatory medical specialty (RMS) controls, and (c) firm controls based upon ranges of active product codes. (4) Firm Recalls, Competitor Recalls, and # of Competitors are lagged. (5) Firm Experience, # of Products, Product Age, and # of Competitors are logged. (6) Estimation requirements: at least one recall in PC over the sample timeframe; (b) at least one competitor firm submission in PC over sample timeframe; and (c) PC has some activity (e.g., recall or submission) in the most prior five-year window.

Appendix Table A4: Robustness Test (All Recall Classes)

	(1)	(2)	(3)	(4)
Public	0.492***	0.480***	0.477***	0.470***
	(0.061)	(0.059)	(0.058)	(0.057)
Firm Experience	0.152***	0.187***	0.179***	0.185***
	(0.031)	(0.031)	(0.030)	(0.030)
# of Products	0.317***	0.306***	0.359***	0.348***
	(0.076)	(0.071)	(0.073)	(0.071)
Firm Recalls	0.249***	0.133**	0.156**	0.108*
	(0.047)	(0.047)	(0.049)	(0.046)
Class II	0.329**	0.308**	0.324**	0.319**
	(0.118)	(0.118)	(0.120)	(0.120)
Class III	-0.260	-0.476+	-0.436+	-0.654**
	(0.290)	(0.256)	(0.255)	(0.248)
Implantable	0.230***	0.235***	0.284***	0.290***
	(0.068)	(0.067)	(0.068)	(0.067)
Life Sustaining	-0.151	-0.155	-0.050	-0.059
	(0.104)	(0.103)	(0.109)	(0.109)
Significant Risk	0.192***	0.167**	0.078	0.060
	(0.055)	(0.054)	(0.057)	(0.057)
Product Age	-0.176***	-0.212***	-0.298***	-0.314***
	(0.040)	(0.039)	(0.042)	(0.041)
Competitor Recalls		0.104***	0.089***	0.335***
		(0.008)	(0.007)	(0.030)
# of Competitors			0.203***	0.220***
			(0.024)	(0.024)
Competitor Recalls x # of Competitors				-0.055***
				(0.006)
Constant	-3.307***	-3.189***	-3.632***	-3.595***
	(0.493)	(0.469)	(0.472)	(0.464)
Observations	141853	141853	141853	141853
Pseudo R-squared	0.033	0.037	0.041	0.042
Wald chi2	8902.491	8865.331	9221.752	8935.145

Notes: (1) All models use negative binomial model regression estimation with half-year interval and lag structures. (2) All models examine All Class (I–III) recalls. (3) All models include: (a) year controls, (b) regulatory medical specialty (RMS) controls, and (c) firm controls based upon ranges of active product codes. (4) Firm Recalls, Competitor Recalls, and # of Competitors are lagged. (5) Firm Experience, # of Products, Product Age, and # of Competitors are logged. (6) Estimation requirements: (a) at least one recall in PC over the sample timeframe; (b) at least one competitor firm submission in PC over sample timeframe; and (c) PC has some activity (e.g., recall or submission) in the most prior five-year window.

Appendix Table A5: Robustness Test (Public vs. Private Competitor Recalls)

	(1)	(2)	(3)	(4)
Public	0.487***	0.476***	0.473***	0.466***
	(0.061)	(0.059)	(0.057)	(0.057)
Firm Experience	0.155***	0.189***	0.181***	0.186***
	(0.031)	(0.031)	(0.030)	(0.030)
# of Products	0.320***	0.309***	0.362***	0.351***
	(0.077)	(0.072)	(0.073)	(0.071)
Firm Recalls	0.231***	0.118*	0.140**	0.094*
	(0.050)	(0.048)	(0.052)	(0.044)
Class II	0.321**	0.301*	0.315**	0.310**
	(0.118)	(0.118)	(0.120)	(0.120)
Class III	-0.179	-0.373	-0.342	-0.558*
	(0.284)	(0.251)	(0.255)	(0.247)
Implantable	0.214**	0.217**	0.271***	0.275***
	(0.069)	(0.068)	(0.069)	(0.068)
Life Sustaining	-0.146	-0.150	-0.047	-0.055
	(0.103)	(0.103)	(0.109)	(0.108)
Significant Risk	0.188***	0.166**	0.076	0.058
	(0.055)	(0.055)	(0.057)	(0.057)
Product Age	-0.182***	-0.217***	-0.304***	-0.319***
	(0.041)	(0.040)	(0.042)	(0.042)
Public Competitor Recalls		0.087***	0.082***	0.385***
		(0.012)	(0.012)	(0.066)
Private Competitor Recalls		0.116***	0.094***	0.313***
		(0.012)	(0.011)	(0.052)
# of Competitors			0.202***	0.218***
			(0.024)	(0.024)
Public Competitor Recalls x # of Competitors				-0.073***
				(0.016)
Private Competitor Recalls x # of Competitors				-0.045***
				(0.012)
Constant	-3.277***	-3.161***	-3.590***	-3.555***
	(0.497)	(0.474)	(0.476)	(0.469)
Observations	138953	138953	138953	138953
Pseudo R-squared	0.033	0.037	0.040	0.042
Wald chi2	8120.897	7741.212	7885.551	7542.402

Notes: (1) All models use negative binomial model regression estimation with half-year interval and lag structures. (2) All models examine Class I or II recalls. (3) All models include: (a) year controls, (b) regulatory medical specialty (RMS) controls, and (c) firm controls based upon ranges of active product codes. (4) PC Firm Recalls, PC Competitor Recalls, and PC Competitors are lagged. (5) Firm PC Experience, Firm Active Products, PC Age, and PC Competitors are logged. (6) Estimation requirements: (a) at least one recall in PC over the sample timeframe; (b) at least one competitor firm submission in PC over sample timeframe; and (c) PC has some activity (e.g., recall or submission) in the most prior five-year window.