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Abstract: Product recalls create significant challenges for R&D intensive firms, but simultaneously generate potentially lucrative opportunities for competitors. Using the U.S. medical device industry as an empirical setting, we develop predictions and provide evidence that own firm recalls slow new product development activities, while competitor firm recalls accelerate them. We also examine two firm-level moderators that influence the recall and new product development relationship: product scope and ownership. We find that own firm recalls slow new product development for all firm types: a single own firm recall slows new product development up to 43 days, equating to more than $10 million in revenue lost in this high-margin and highly competitive setting. We also find that competitor firm recalls are associated with accelerated development times, but only for broad (vs. narrow) product scope firms and public (vs. private) firms. A one standard deviation increase in competitor firm recalls for these firm types slows new product development by more than two weeks. Organizational resources and financial incentives thus emerge as key determinants of whether firms can effectively capitalize on the potential market opportunities created by competitor recalls. In post-hoc analyses, we explore whether future product quality is predicted by post-recall submission times, but find no evidence that safer products result from post-recall submission timing. This result suggests that new product development delays following recalls are more likely driven by organizational distractions than by product quality learning, and that firms react strategically and rationally by speeding new products to market after competitor recalls.

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

1. INTRODUCTION

New product development is the lifeblood of firms in a wide range of research and development (R&D)-intensive industries, including software, microprocessors, automobiles, and pharmaceuticals. Firm incentives to innovate in these industries are substantial, given the benefits new products bring to profitability and survival. Nevertheless, the impact of faulty or dangerous products can be ruinous: software bugs can compromise sensitive customer data while automotive manufacturing failures can result in passenger injury and death. Such "first-order" effects of compromised products are salient: they harm customers and negatively affect firm financial performance (Shah *et al.* 2017; Liu & Shanker 2015). But other "second-order" effects also present challenges. For instance, product failures are heavily publicized and scrutinized events (Jarrell & Peltzman 1985) and may influence subsequent new product development activities by firms and their competitors.

A well-documented effect of product recalls is lost revenue (Thirumalai & Sinha 2011; Haunschild & Rhee 2006): when products are found to be unsafe and recalled, sales and distribution are reduced or halted completely (Krumholz *et al.* 2007). Recalls can also be costly to manage with external stakeholders, as negative publicity can amplify sales downturns and generate shareholder losses (Jarrell & Peltzman 1985; Rhee & Haunschild 2006). Recalls also affect operations, as internal resources must be redirected to correct recall-related problems (Ball *et al*. 2018). We propose that recalls also influence a previously unexplored but crucial firm activity: new product development. We consider whether and how own firm recalls create internal disruptions that slow subsequent new product development and whether and how competitor firm recalls create market opportunities that accelerate subsequent new product development (KC *et al*. 2013; Krieger 2017).

We explore these phenomena by developing predictions and providing empirical evidence of how new product development changes in response to the most severe types of product recalls in the U.S. medical device ("med-tech") industry. By leveraging comprehensive and novel medical device submission and recall data from the U.S. Food and Drug Administration (FDA), we examine the following primary research question: *Do own firm and competitor firm recalls influence the speed of future new product development?* We then examine how these relationships are influenced by two firm-level moderators: product scope and ownership. We do so because differences in product portfolios and in ownership structures are likely to create resource and incentive heterogeneity among firms that influence how new product development timing is influenced by own firm and competitor firm recalls.

A key feature of our empirical setting is the ability to examine distinct new product development types. The FDA categorizes new medical devices using the concept of product similarity. When a new device is of moderate risk and highly similar to a previously approved and marketed product by the same or another firm, it receives a "510(k)" submission-type designation. Alternatively, when a new device is of extremely high risk or dissimilar to any previously approved and marketed product, it receives a Pre-Market Approval (PMA) designation. 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 510(k) products. Second, 510(k) new product development projects are more "nimble" than PMA new product development projects—i.e., both shorter in duration and lower in resource requirements (Sall 2008)—suggesting that this type of new product development is more likely to respectively slow down or speed up following own and competitor firm recalls. Third, 510(k) data are well-suited to examining these phenomena without confounding explanations: well-established product types create settings where there is limited uncertainty around the technical viability of new products but clear certainty around firm mistakes. Competitor firm failures in 510(k) product areas thus constitute information about potential market opportunities and not about product viability (where accelerating new products to market might otherwise be risky). By focusing on 510(k) submissions, we are thus able to more thoroughly and cleanly test predictions that explain these relationships. In particular, we ground our theory in organizational resource allocation and firm incentives more so than learning from failures because we examine new product development in product areas that are already proven safe. This approach allows us to generalize to other recall-intensive industries (e.g., automobiles, consumer products) where market opportunities are driven more by resources and incentives than by product area viability—thereby broadening the generalizability of our findings to other settings.

We collect comprehensive data on all new product submissions and recalls over 2003-2015. Using matching software and novel algorithms, we assign all submissions and recalls to a set of standardized firm names and FDA-designated product areas and then construct detailed new product development and recall histories that provide precise definitions of the relevant set of firms and competitors in each product area and across time. We incorporate these detailed histories into recurrent-event accelerated failure time (AFT) models to determine how recall source—as well as the firm-level moderating effects of product scope and ownership—affect the timing of firms' subsequent new product development activities.

Our empirical findings are informative and largely in-line with the hypotheses presented below. Own firm recalls *slow* subsequent new product development for all firm types that we examine: "focused" or "broad" in product scope; and privately-held or publicly-listed. In other words, this previously undocumented relationship between own firm recalls and slower new product development is persistent and reasonably impervious to firm-level heterogeneity. In particular, our estimates suggest that a single own firm recall slows new product development by as much as 43 days—a significant delay that can cost as much as $10 million in this high margin industry.[1] We also find that the ability to flex new product development timing after a competitor's recall is more context-specific. Our empirical models suggest that competitor firm recalls *accelerate* subsequent new product development, but this relationship is found only for broad product scope firms and for public firms. A one standard deviation increase in competitor firm recalls for broad or public firms accelerates new product submissions by roughly 16 days. This finding suggests that organizational resources and incentives may motivate firms to accelerate new product development activities following competitors' quality mistakes. Several robustness checks support own and competitor firm recall findings.

In post-hoc analysis, we explore two juxtaposing mechanisms that help tease out this recall and new product development timing relationship: product quality learning vs. recall-related distractions. On the one hand, slowing new product development after own firm recalls may be beneficial if it subsequently improves new product quality via enhanced learning around product design, process design or manufacturing. On the other hand, new product development delays following own firm recalls may simply represent recall-related distractions that have no association with subsequent new product quality. In a similar vein, accelerating new product development after competitor firm recalls may mean rushing to market to the detriment of product quality, or it may represent attempts to capitalize on new market opportunities without any tangible product quality downsides. By using post-recall new product submission timing as a predictor of future recalls for each new product post-market entry, we discern which mechanism is more likely. We find that post-recall new product development timing has no association with subsequent product quality as measured by product recalls. This result indicates that delays from own firm recalls are

[1] Other studies have shown that a 30-day delay in new med-tech product introduction can cost firms more than $10 million in lost revenue. See, e.g., https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/the-growth-imperative-for-medical-device-companies

more likely due to distractions and less likely due to product quality learning. Further, and perhaps more critically, this result suggests that accelerating new product development following competitor firm recalls is rational and strategic given the limited discernable quality risk.

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

Our theoretical predictions and empirical results have implications for industry and public policy. For managers, we offer evidence that own firm recalls crowd out new product development activity without providing discernable product quality benefits down the road. Moreover, firms experiencing recalls face two distinct challenges: (1) internal recall distractions which *delay* own firm new product development efforts; and (2) external new market opportunities which *accelerate* competitor firm new product development efforts. Recall prevention and response are thus more important than extant research suggests. For regulators, such as the FDA, our results document that—at least within med-tech—prior recalls and subsequent new product development activity are closely related. Greater coordination and information exchange between product review activities and quality surveillance activities are thus likely to provide benefits that are not fully internalized at present by these largely independent regulatory activities.

2. RESEARCH SETTING

New product development and product recalls in the med-tech industry have both increased in recent years. Against this background, understanding how product failures potentially impact future new product development efforts in this setting is not only critical for managers and firms, but also important for investors, regulators, policy makers, health care providers, and patients.

Medical devices are regulated by the Center for Devices and Radiological Health (CDRH) within the FDA via two primary approaches: pre-market gatekeeper and 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 U.S. without regulatory approval. During the review process, CDRH assigns medical devices to product areas based on intended use and to regulatory approval pathways based primarily on approved product similarity. Devices are also categorized into product types based on their function. Examples of product types include bare metal coronary artery stents and implantable cardioverter defibrillators. Products that share the same product type are effective substitutes as they serve the same function, are used in identical ways, and are reviewed by the same group of regulators. Our theorizing and primary econometric tests are therefore based on categorical measures of product type similarity. In particular, we examine whether and how recalls influence new product development in those cases where recalls and subsequent new products are in the same product type.[2]

In its role as post-market regulator, the FDA ensures that approved and marketed devices perform in a safe and effective manner and present no unnecessary patient risk. During the post-market period, CDRH performs ongoing surveillance of approved products for continued safety and effectiveness. When medical devices are defective or pose health risks, med-tech firms and health care facilities (e.g., hospitals and physicians' offices) are required to report this information to CDRH. 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.[3] The FDA 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"

[2] We examine recall and new product development associations for non-shared product types in post-hoc analyses.

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

due to their extremely low severity (Ball *et al.* 2018), our theory and econometric models focus on how the most severe (Class I and II) recalls influence new product development, as these recall classifications better proxies for actual product quality problems, are difficult to avoid recalling, and are the most operationally disruptive.[4]

The structure of med-tech firms also plays an important role in our study. Our detailed review of the top-ten U.S. medical device firms by revenue indicates that each is organized by product and/or technological discipline: that is, separate strategic business units (SBUs) comprised of related product types (e.g., cardiovascular devices in one SBU; orthopedic devices in another SBU) given technology, product and process, and resource overlap.[5] This organizational approach suggests that when a recall occurs in a certain product type, technical expertise to assist in recall resolution is likely to draw upon a common set of resources. We further substantiate this claim via discussion with a med-tech industry executive, who described the cardiac device division of her firm as organized into discrete teams with each team focused on a specific product type, including pacemakers, implantable defibrillators, stents, and cardiac catheters. She discussed a situation in which a severe and complex pacemaker recall diverted R&D engineers from another pacemaker new product development project for several months because manufacturing engineers required assistance in identifying the root cause of the product failure. She confirmed that this organizational practice was typical within the industry, suggesting that resolving product failures most directly impacts those resources that are most closely-related.[6]

3. LITERATURE REVIEW AND HYPOTHESES

We first hypothesize that recall source—own firm or competitor firm—influences firms' new product development activity but in opposite directions. We then consider whether and how product scope and ownership affect these hypothesized relationships as firm-level moderators.

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[4] We incorporate Class III recalls in robustness checks and confirm all our results remain consistent.

[5] See https://www.proclinical.com/blogs/2018-5/the-top-10-medical-device-companies-2018 for a top-10 list of U.S. medical device firms by revenue. We used this list and the corporate websites of each firm to verify their organizational structure by product and/or technological similarity.

[6] Some empirical support for this proposition is found in the banking industry. Kim and Miner (2007) suggest that banks learn vicariously from failures, but the impact depends on local geographic and industry origin conditions: local failure-related experience provides survival-enhancing learning value in comparison to non-local failure-related experience. Similar findings are seen in Desai (2015), Aranda *et al*. (2017), and Kalnins and Mayer (2004). It is therefore logical that the net effect of operational disruptions caused by product recalls are experienced most profoundly in innovation activities within the product code in which recalls occur.

RECALL SOURCE

Empirical product recall research is largely divided into two categories: effects and 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 the 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 & Sinha 2011), especially when recalls are voluntarily-initiated by firms (Haunschild & Rhee 2004). A small but growing research stream examines whether industry conditions are predictive of future recalls, including those with high R&D-intensity (Thirumalai & Sinha 2011), more product and plant variety (Shah *et al*. 2016; Ball *et al*. 2018), and adverse inspection outcomes (Ball *et al*. 2017).

The extant literature is largely silent, however, on whether a relationship between product recalls and future new product development exists. Some research suggests that firms learn from their own recalls and make quality improvements, which could accelerate or decelerate subsequent new product development (Haunschild & Rhee 2004). Other research suggests that firms observe and learn from the *pre-market* product development activities and failures of their competitors, which may also influence subsequent new product development efforts (Krieger 2017). Our empirical setting differs from these studies in that we examine the impact of *post-market* product recalls from both own firm and competitor firm perspectives. Our approach is thus similar to research that examines the determinants of firm performance once new products are already commercialized (Haunschild & Sullivan 2002; Baum & Dahlin 2007; Kim & Miner 2007), but is distinct in that it considers own and competitor firm failures as predictors—rather than consequences—of new product development activity.

Operations and supply chain management research examines both the sources—e.g., supply-chain problems (Demirel *et al*. 2017; Yang *et al*. 2009), natural disasters (Kim *et al*. 2010)—and the potential solutions—e.g., insurance (Serpa & Krishnan 2016), buffer inventory (Dong & Tom-

lin 2012)—to operational disruptions. In aggregate, these studies unsurprisingly find that operational disruptions are harmful to firm performance and discuss mitigation strategies. A more narrow research stream examines disruption effects on new product development: Sterman *et al*. (1997) finds that when firms focus on quality improvement initiatives, new product development speed suffers; Benner and Tushman (2002) reach similar conclusions.

We propose that product recalls constitute significant operational disruptions within firms and that these, in turn, negatively affect new product development efforts. Beyond managing customers and legal concerns, firms must identify the root causes of recalls and correct these problems. Technical and operational resources are often redirected and repurposed to implement the requisite product or process changes. As one med-tech industry executive we interviewed explained, "recalls are a shock to the system. Everyone tries to avoid them. But when they happen—and, in particular, when they are severe—everyone works together to recover as quickly as possible. Recall is the preeminent 'four-letter word' in the med-tech industry." We therefore expect resources and attention to be diverted away from new product development activities following own firm recalls. This diversion should increase the time to subsequent new product development activity, *ceteris paribus*, leading to the following hypothesis:

H1A: Own firm recalls *delay* the time to new product submission.

Med-tech firms operate in well-defined product areas, with limited information asymmetries within and across these areas. Firms are well informed with respect to the product status—both 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 new product development activities respond to competitor firm recalls.

This argument has strong analogs to research in pharmaceuticals, a similarly R&D-intensive and FDA-regulated health care product setting. Pharmaceutical new product development studies have shown 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). In a similar vein, "demand shocks" are experienced by firms as the defective products of competitor firms are removed from the market for some period of time.

These shocks are particularly salient in the med-tech industry, given its market size and growth and its historic profit margins: many product type markets exceed tens of billions in (USD) revenue, with gross margins around 80-95 percent and net margins around 20-30 percent on average.[7] Such potential market opportunities—combined with the fact that our research setting of 510(k) products only include product areas already proven safe—may tend to overwhelm any quality concerns of rushing new product to market. In other words, competitor firm mistakes create substantial revenue and profit opportunities—with the potential rewards of accelerating new product development likely greater than any inherent product quality risks. We therefore expect that, *ceteris paribus*, med-tech firms will accelerate new product development activity when competitors experience product recalls, leading to the following hypothesis:

H1B: Competitor firm recalls *accelerate* the time to new product submission.

PRODUCT SCOPE

Scope economies exist when performance benefits are realized from conducting multiple activities jointly in comparison to conducting these activities separately (Panzar and Willig, 1981). The standard analysis of production suggests scope economies result when activities share inputs with limited additional cost. Henderson and Cockburn (1994) identify internal spillovers of knowledge as another source of returns that results from greater product scope: in particular, knowledge developed and accumulated in one R&D activity can be transferred to other activities at little cost but with significant performance benefits.

Scope economies from knowledge spillovers are found in a variety of R&D-intensive industry settings, including pharmaceutical development (Macher and Boerner 2006; Arora et al. 2009), beverage production (Brahm et al. 2017), microcomputer software development (Cottrell and Nault 2004), and semiconductor process development (Macher, 2006), among others. Knowledge generated in one technology area is not only informative, but also beneficial to the development of other technology areas. For instance, Nerkar and Roberts (2004) find that firms with more diverse market experience produce higher quality new products and Desai (2015) suggests hospitals more effectively learn from failures with broad origin distributions. Such activities may require

[7] 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.

marshalling a large volume of product development resources, however, which subsequently create capacity constraints and limit overall effectiveness (Levinthal and Wu 2010). As Eggers (2012) notes, broad versus focused product experience at the firm level may shape the temporal dimensions of new product development.

We suggest that knowledge spillovers resulting from product scope should similarly affect the pattern and pace of new product development activities with respect to own firm recalls. In general, firms with broad product portfolios are likely to require more corrective effort than their more focused brethren, because own firm recalls in one product area may have spillover effects into other related product areas (e.g., in the form of quality testing, remedial updating, etc.). If problem containment is a concern across multiple product areas, then broad firms may necessarily slow new product submissions *more* in response to own firm recalls to ensure that any recall issue in a particular product area is not endemic across other related product areas.

We also suggest that knowledge spillovers resulting from product scope should affect new product development activities following competitor firm recalls. Broad product scope firms can more readily shift organizational resources in attempts to accelerate new product development to capitalize on potential market opportunities that result from competitor firm recalls, in comparison to firms with focused product portfolios. Given their resource and organizational advantages that scope economies provide, the ability to respond rapidly to competitor firm failures is arguably greatest among those firms with broad product portfolios. Focused firms are arguably less able to marshal the requisite organizational resources in a timely manner. Such organizational resource shifting from one product area to other product areas may have implications for subsequent new product development efforts. However, the potential revenue and profit opportunities available and the limited concerns around technical viability suggest broad product scope firms have strong incentives to accelerate new product development in those product markets where competitors have faltered. We therefore examine the following set of hypotheses related to product scope:

H2A: Product scope moderates the relationship between own firm recalls and new product development delay, such that the delay is greater for broad product scope firms compared to focused product scope firms.

H2B: Product scope moderates the relationship between competitor firm recalls and new product development acceleration, such that the acceleration is greater for broad product scope firms compared to focused product scope firms.

FIRM OWNERSHIP

Firm incentives to innovate 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 focus on a single and readily observable factor that potentially affects incentives for new product development within organizations: public versus private ownership.

Public and private organizations differ in their operational strategies and management processes (Trostel and Nichols 1982). Management research on ownership structure is myriad, including examinations of going public on financial outcomes—such as stock price and operating performance (Mikkelson *et al*. 1997)—and on organizational outcomes—such as survival and growth (Fischer and Pollack, 2004). Other research considers differences in new product development and innovation between public and private firms, but with generally mixed findings. Some studies suggest that financial markets (Benner, 2010) and institutional investors (Kochhar and Parthiban, 1996) condition public firm responses to new product development, while other studies argue that external market pressures do not necessarily discourage R&D investment (Hall and Lerner 2010). Additionally, innovation quality—as measured by patent counts and forward patent citations—has been found to be higher for private versus public biotechnology firms (Aggarwal and Hsu 2014); however, no evidence of creativity differences is observed between public and private advertising agencies (Von Nordenflycht 2007).

Any effect of product recalls on new product development likely depends upon underlying financial and organizational resources and incentives, which differ between public and private firms (Wu 2012). First, public firms generally have greater access to financial resources, as compared to private firms. Such resources can more effectively fund R&D efforts, increase financial slack (Greve 2007), and enhance visibility (Pollock and Gulati 2007). Second, public firms arguably have more formal policies, procedures and structures in place, as compared to private firms. Securities and Exchange Commission (SEC) regulatory requirements, investor relations outreach programs, and corporate governance protocols all suggest that more formalized systems and structures are in place that determine, condition and govern new product

development activities. Third, public firms face greater external market pressures and incentives to manage and exceed earnings expectations, as compared to private firms, which are relatively more shielded from such pressures.

Public ownership may therefore amplify the effects of own firm and competitor firm recalls by both reinforcing and strengthening the extant incentives that these firms possess to respond to each distinct recall type. First consider own firm recalls. Public firms arguably face greater public trust concerns after experiencing internal performance failures, as compared to their privately-held brethren. When reputation among the myriad stakeholders is important—as is certainly the case in the large and regulated med-tech industry—then public firms have greater incentives to slow subsequent new product development activities and "get it right" by correcting any and all recall-related problems. The greater external market discipline and more rigid internal formalization that public firms face suggests undertaking any additional new product development activities following own firm product failures is slowed in comparison to private firms.

Next consider competitor firm recalls. The greater external market pressures that public firms face (as compared to private firms) should have the opposite effect following competitor recalls, for at least two reasons. First, external market pressures generally reward efforts by public firms to capitalize on the potentially large and profitable market opportunities that exist. In short, stronger incentives to accelerate new product development exist for public firms in comparison to private firms. Second, greater financial resources are available within public firms, which suggest that such R&D initiatives can be funded. In other words, the requisite resources to accelerate new product development are more readily available for public firms in comparison to private firms. We therefore examine the following set of hypotheses related to ownership structure:

H3A: Public firm ownership moderates the relationship between own firm recalls and new product development delay, such that the delay will be greater for public firms compared to private firms.

H3B: Public firm ownership moderates the relationship between competitor firm recalls and new product development acceleration, such that the acceleration will be greater for public firms compared to private firms.

EMPIRICS

DATA

We download FDA recall data over 2003-2015 and FDA device submission data over 2003-2016—the respective windows for which these data were 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.[8]

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

Recalls – The recall data include unique recall event numbers, severity classifications, dates, and firm identities. We use a digital text-scraping program to identify and collect FDA submission numbers associated with each recall. This novel data connection between submission and recall are not included in the pre-formatted recall data available on the FDA website and allows recalls to be directly linked to individual new product submissions. This linkage is not only important for our primary hypotheses tests, but also for our post-hoc tests where we explore whether and how post-recall new product submission timing is predictive of future recalls on each newly approved product. In all of our regressions, we examine Class I and II recalls as they are the least discretionary and constitute the most significant patient health risks and firm disruptions. For completeness and to demonstrate robustness, we include estimations using Class III recall data.

VARIABLES

Our empirical analysis considers how product recalls affect subsequent new product submission times. All estimations are from the own firm perspective and data elements are reflexive; that is, when Firm B is a competitor of Firm A, Firm A is a competitor of Firm B. We also use novel, dynamic competitor definitions. Our algorithms require that firms have a submission or a recall in the same product type within the most recent five-year window in order to be considered competitors.[9] In other words, the set of competitors vary over products and over time in our analyses.

[8] 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.

[9] 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 years (Wizemann 2010; Nazarian 2009).

Dependent Variables –Research on innovative activity in health care considers 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 "shocks" to examine health care new product development effects (Blume-Kohout and Sood 2013; Krieger *et al*. 2018; and Krieger 2017), we consider own firm recalls as negative shocks and competitor firm recalls as positive shocks. The dependent variable, *510(k) Time,* measures the time between new product submissions in elapsed calendar days.

Independent Variables – The key independent variables are recall counts. Our primary analysis considers recall counts over 24-month windows prior to a new product submission, reflecting the typical med-tech product development timeline (Nazarian 2009). We examine 36-month windows in robustness tests. Because the distributions are left-skewed, recall counts are log transformed. Data are available in 2003, but recall time windows determine the relevant years and data used in empirical analyses. The main analysis thus focuses on the sample years over 2005–2016, inclusive, with earlier years providing historical detail on recalls and product type activity at the firm level. *Own Firm Recalls* tallies own firm recalls; *Competitor Firm Recalls* does the same for competitor firm recalls.

Moderating Variables – Product Scope is a firm-level time-varying measure of the number of products on the market and is included in all estimations. For testing Hypotheses 2A & 2B, we dichotomize this variable at its median to examine firms with focused versus broad product portfolios: *Focused* firms are those with 14 or fewer approved products; *Broad* firms are those with 15 or more approved products. *Public* is a firm-level measure of ownership structure and is also included in all estimations. For testing Hypothesis 3A & 3B, we use this indicator variable to separate publicly-listed versus privately-held firms: of the 444 unique med-tech firms in the sample, roughly 25 percent (114) are publicly-listed, equating to 54 percent (11,926) of the observations in our sample.

Control Variables – Research suggests that new product development and recall propensities can be partially explained by products, by firms, and by 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 controls for product age and own and competitor firm submission counts of all products over five-year windows. *Product Age* is a logged measure of the number of days between the establishment of a product type and the submission date in question. For example, the product age of a 510(k) submission of a cardiac catheter will be the time in days from the first approved cardiac catheter by any firm until the day of the observation by the individual firm in question. We control for product age in this manner to address any concern that recalls could be a function of product viability and not manufacturing firm errors. The submission count controls help control for differences in the frequency of new product submissions across different product classes.

DESCRIPTIVE STATISTICS

Tables 1 and 2 provide descriptive statistics and correlations for the variables used in the estimation. The average elapsed time between submissions is roughly 186 days. Firms experience 1.32 recalls on average in a given product type over a 24-month window, while their competitors experience a total of 65.31 recalls in on average (across all competitors) within a product type across the same time window. The average med-tech firm has roughly 22 unique products, but substantial heterogeneity is present. While roughly one quarter of the firms are publicly-listed, slightly more than half of the observations are from these firm types. All Variance Inflation Factors (VIF) are below the threshold level of ten, helping to alleviate concerns that multi-collinearity bias influences our results.

EMPIRICAL METHODOLOGY

Our empirical methodology accounts for the unique characteristics of the industry setting and our research questions. The data consist of all med-tech firms that are active in new product submissions and experience recalls within at least one product type. Our empirical objective is to examine how recalls by own and competitor firms within a product type—moderated by product scope and ownership structure—impact new product development as measured by the elapsed calendar time between FDA new product submissions for 510(k) products.

We implement survival analysis using Accelerated Failure Time (AFT) models due to their suitability to our setting and enhanced interpretability of the resulting estimates. Other prevalent survival models, such as the Cox Proportional Hazard, estimate the instantaneous hazard rate of

an event occurrence at any point in time. An advantage of AFT models over Cox models is that estimates can be used to examine how independent variable changes influence time to an event. Our use of AFT models is consistent with related innovation research that models time-to-event data (Harhoff and Wagner 2009) and interpretations are similar. Because firms in our data experience multiple submissions and recalls, we employ recurrent-event AFT models with an exponential distribution and clustered standard errors at the firm level (Harhoff and Wagner 2009; Box-Steffensmeier and Jones 2004).[10] The AFT estimation model follows the following generalized equation:

$$Log(t_i) = \beta_0 + \beta X_i + u_i$$

where t_i is the elapsed time between submissions for firm i, β_0 is an intercept term, β is a vector of regression coefficients, X_i is a vector of covariates, and u_i is an error term with an exponential distribution. The number of observations is the sum of all recalls experienced and all submissions observed. Recall counts for own and competitor firms are calculated in relation to each submitted product type only. In other words, if a given row is a cardiac stent product type submission, the own and competitor recall counts are for cardiac stent recalls in the last 24 months. In robustness tests, we consider recalls of any product type for own and competitor firms.

4. EMPIRICAL RESULTS

INTERPRETING COEFFICIENTS

The interpretation of estimated coefficients in AFT models is as follows: a one percent change in a logged recall count is associated with a $(0.01 \times (\exp^{\beta}\text{-}1)$ multiplicative effect on the time to the event of interest (Harhoff and Wagner, 2009; Stock and Watson 2012; Wooldridge 2010). A positive (negative) β coefficient signifies a longer (shorter) time to the event, which in our empirical setting translates to a slower (faster) time to new product submission. As recall counts are highly varied across products and dependent upon category, we consider two meaningful time-to-submission benchmarks: (i) the impact of a one standard deviation recall increase; and (ii) the impact of

[10] We use STREG with the dist(exp) time option in STATA. Results are robust to the other available distribution choices, including Weibull and Lognormal.

a single recall increase. These benchmarks not only show how reasonable variation in recalls influence new product development activity, but also demonstrate how in some cases, a single recall can have a meaningful economic impact on firm behavior.

MAIN RESULTS

Table 3 presents the main AFT model results that test the hypotheses presented above. All models include product, firm, and year fixed effects and product age and submission count controls: Model (1) includes just the control variables. Model (2) incorporates own and competitor firm recalls. Models (3) and (4) segregate Model (2) by product scope while Models (5) and (6) segregate Model (2) by ownership structure. The Model (1) results indicate *Product Age* is positive and marginally significant (β = 0.022; p<0.10). This unsurprising result indicates older products have relatively slower new product submission times. *Product Scope* is found a negative and significant predictor (β = -0.776; p<0.01) of submission time: firms with broader product portfolios appear better able to accelerate new product submissions on average. Finally, the influence of *Public* ownership on new product submission is also negative and significant (β = -1.067; p<0.01). Public firms are similarly better able to accelerate new product development, in comparison to private firms.

The Model (2) results indicates that: (1) *Own Firm Recalls* significantly slow new product submission times (β = 0.270; p<0.001), supporting Hypothesis H1A; and (2) *Competitor Firm Recalls* accelerate new product submission time (β = -0.046; p<0.05), supporting Hypothesis H1B. Examining the influence of *Product Scope* for *Focused* firms in Model (3) and *Broad* firms in Model (4), we observe that *Own Firm Recalls* slow both firm types' new product submissions but *Competitor Firm Recalls* only influence the timing of new product submissions for those firms with broad product portfolios. A similar examination of the influence of ownership structure for *Private* firms in Model (5) and *Public* firms in Model (6) indicate that *Own Firm Recalls* slow new product submissions for both firm categories, while *Competitor Firm Recalls* only influence new product development time for publicly-traded firms. In aggregate, these results fail to support H2A or H3A but strongly support H2B and H3B. In other words, *Own Firm Recalls* have a persistent effect on new product development and in a way that appears independent of firm-level heterogeneity either in product scope or in ownership structure, while *Competitor Firm Recalls* have a context-dependent effect on new product submission timing. In the case of competitor response, meaningful effects are present only for broad and public firms—i.e., those firms that are better

positioned to exploit competitors' failures by leveraging a more diverse set of organizational resources based upon product portfolio or a larger pool of financial resources and those firms that have greater incentives to capitalize on potential market opportunities and competitor misfortunes.

To facilitate interpretation, Table 4 shows the effects of a *one standard deviation increase* and a *one unit increase* in recalls on new product submission times using the Table 3 results. Table 4 indicates that a single own firm recall slows subsequent new product submission times by 43 days on average, and this effect is even stronger for broad product scope firms (51 days) and public firms (48 days). The effect of a single competitor firm recall is smaller in comparison across all rows because this measure is aggregated across all competitors in a product type, meaning that a single recall represents a trivial increase in total recall counts that firms observe among their competitors on average. A one standard deviation increase in competitor firm recalls, however, is more meaningful for interpretation. Such an increase accelerates new product introduction by 11 days in our full sample and by roughly 16 days for broad product portfolio firms and for public firms.

ROBUSTNESS TESTS

We undertake several robustness tests to our main estimation results, which respectively examine potential endogeneity concerns such as reverse causality, measurement selection bias, and omitted variable bias. Appendix Table A-1 provides descriptive statistics for the additional measures used in these robustness tests. We first consider reverse causality. If observed recalls are driven by previous new product development efforts then our results are potentially confounded (Ingram and Baum 1997) with simultaneity bias in our regression models. To address this potential, we implement a propensity score matching (PSM). These models use independent and control variables to predict the propensity of receiving a certain treatment, and then match observations according to equivalent propensities. Once matched, the model examines outcomes of receiving a treatment compared to not receiving a treatment. In our setting, we create a treatment indicator of whether or not the firm experienced a new product submission in the prior 24 months. We then match firms on equivalent propensities using all our control variables as predictors, and compare those firms that experience a treatment to those firms that did not, contingent upon the firms being equally likely to experience the treatment. The outcome measure for this treatment variable is future recall likelihood for that firm measured as an indicator variable. For this analysis, 5374 observations were treated compared to 1289 controls using matching with replacement. The average treatment effect (ATE) was 0.032 with a standard error of 0.412 ($p > 0.05$). The lack of statistical significance

for this treatment effect indicates that—when comparing firms based on equal propensities for new product submission in the prior 24 months—the submission of a new product is not associated with the likelihood of future recalls. This result, in turn, points to a reasonably low risk of simultaneity bias driving our empirical results.

We next consider whether different measurement approaches bias our results. The second robustness test examines recall time windows. Our baseline estimation counts recalls for own and competitor firms over the past 24 months. Recalls over a longer timeframe, however, may better predict future new product submissions. Appendix Table A-2 replicates the Table 3 estimations using 36-month recall windows in place of 24-month windows. The main results are nearly identical in magnitude, sign and significance, indicating that the time window selected is unlikely the sole explanation for our findings. The third robustness test examines recall severity classifications. Our baseline estimation counts severe recalls (i.e., Class I & II), but other less severe recalls (i.e., Class III) might also affect new product submission approaches. Appendix Table A-3 replicates the Table 3 estimations using counts of all recall classes (i.e., I, II & III) in place of severe recall classes. The main variables of interest again maintain their magnitudes, signs and statistical significance using these alternative recall measures. The fourth robustness test considers recall proximity determinations. Our baseline estimation considers only recalls in the same product type as the new product submission. It is possible, however, that recalls outside of the same product type as the new product submission also influence timing. To explore this potential, we create two additional recall measures: *Own Firm (Different) Recalls* and *Competitor Firm (Different) Recalls*, which respectively count the number of own and competitor firm severe class (i.e., I & II) recalls in a 24-month window but in product types different from the new product submission. Appendix Table A-4 replicates the Table 3 estimations with the inclusion of these additional measures.[11] The main variables of interest are again consistent, in terms of magnitudes, signs and statistical significance. Moreover, own firm recalls in product types that differ from the new product submission product type have limited effects (outside of private firms) on submission timing, whereas competitor firm recalls in different product types slow new product submission activity at an aggregate level but this effect dissipates in the subsample estimations.

[11] We note here that *Own Firm Recalls* and *Competitor Firm Recalls* have the additional labeling of (*Same)* in Table A-4 to facilitate interpretation.

We finally consider whether our results are confounded by omitted variable bias. To produce the most representative sample possible, our baseline estimation includes both private and public firms. The inclusion of private firms, however, limits our ability to control for various firm-level factors—e.g., size, research and development (R&D) spending, R&D intensity—given data limitations. Our fifth robustness test examines whether these firm-level factors influence the recall and new product submission relationship, but is conditional on those firms being publicly-listed. Table A-5 presents estimations that include the following firm-level controls from Compustat: *Revenue*, *Employees*, *R&D Spending* and *R&D Intensity*. We take the natural log of first three measures due to skewness. We also use a single firm-level control measure per model due to the high collinearity among these measures. The results around the main variables of interest maintain, however, none of the additional measures achieve statistical significance.

POST-HOC ANALYSIS

Our post-hoc analysis examines the validity of our theorizing and addresses one important alternative explanation to our results. It is possible that submission delays following own firm recalls may indicate recall-related product quality learning and not recall-related distractions. In particular, if a longer time to a new product submission after own firm recalls is associated with higher quality new products once the product is approved by the FDA, then the observed "slowing down" may in fact be beneficial—both for the firm and for public health and safety. However, as we postulate in our hypotheses, submission delay following own firm recalls might instead be indicative of distractions that consume essential organizational resources and subsequently impede the development and submission of new products. In that case, any observed "slowing down" would be detrimental to the firm—given the revenue and profit losses. In a similar vein, submission acceleration following competitor firm recalls might suggest suboptimal "rushing to market" that may increase future product safety risks. Alternatively, if longer submission times post-recall are not associated with higher quality products, then observed accelerated submission responses are rational and strategic approaches.

We examine whether post-recall submission times are predictive of subsequent new product quality as measured by subsequent recalls after product approval by the FDA. To conduct this analysis, we make our dependent variable (*510k Time*) an independent variable and then create a new dependent variable: *Time to Recall* measures the elapsed time (in days) from FDA product

approval (as opposed to product submission) to the first recall occurrence.[12] We then examine whether a longer time to new product submission post-recall influences the time to the first recall. The average time to first recall is 1307 days after FDA product approval for submissions in our sample that actually experience at least one post-approval recall. We only study the time to the *first* Class I or II recall for this analysis—that is, the time when the first serious product quality issue with a device emerges—so each new product submission has only one observation in this empirical model. We implement the same AFT model estimation approach: A positive (negative) and significant coefficient indicates that longer post-recall submission times lead to longer (shorter) times to first recall and, in turn, is suggestive of firm learning and quality improvement.

Table 5 provides the estimation results using the same Table 3 controls (which for parsimony are not presented). Model (1) considers only those new product submissions that experience subsequent recalls; Model (2) considers all new product submissions regardless of whether they experience a recall over the period of observation. As AFT models are able to account for right-censoring in data, both models are valid in this setting. The coefficient estimates are near zero and statistically insignificant in each model. These results indicate that post-recall submission timing is not associated with future recall risks for the newly approved products. Hence, submission delays following own firm recalls do not appear to create substantive learning or quality improvement benefits, and are more likely driven by recall-related distractions. Similarly, submission accelerations following competitor firm recalls do not appear to be associated with reduced product quality therefore and, as such, are much more likely to represent rational approaches to increasing revenue and profit when competitors stumble.[13]

5. CONCLUSION

DISCUSSION

This study examines how product recalls influence subsequent new product development activity in the medical device industry. The theoretical arguments and empirical findings contribute to several literatures and have practical implications for both firms and regulators.

[12] Our data included product approval dates, although we use submission dates in the main analysis.
[13] For clarification purposes, "post-recall submission times" refers to newly submitted 510(k) products that follow a recall at own and competitor firms in similar product areas.

First, we demonstrate that recalls affect new product development. Own firm recalls slow subsequent new product submissions, while competitor firm recalls accelerate subsequent new product submissions. 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 own firms and by competitor firms impact future new product development, but in opposite directions. Our findings also expand upon previous studies that explore factors that influence new product development incentives in health care product markets (Acemoglu and Linn 2004; Dubois *et. al.* 2015; Budish *et. al*. 2015; Carpenter *et al*. 2010; Stern 2017). We find that, at least within med-tech, the often protracted "shocks" induced by product recalls drive meaningful responses by competitor firms.

Second, recalls have meaningful economic effects on med-tech firms. Table 4 estimates the delay or acceleration effects of a standard deviation increase and a one recall increase in recalls. For own firm recalls, a single recall delays new product development by over six weeks (on average, 43 days)—potentially equating to more than $10 million in lost revenue. The magnitude of this effect is even greater for broad product scope firms and public firms, but this phenomenon is present regardless of firm type. The fact that we do not find support for Hypotheses H2A and H3A indicates that recalls slow new product development in ways that are significant and persistent for all firms—a key contribution of our study. The influence of competitor recalls, however, is more context specific. The acceleration of new product development following competitor recalls is primarily explained by broad product scope firms and public firms. This contingency indicates that organizational resources and incentives may explain new product development changes after competitor firm failures. The robustness tests presented in Appendix Table A-4 may help to explain how these firms can accelerate new product development. In particular, by finding a positive and significant effect of *Competitor Firm (Different) Recalls* ($\beta = 0.050$; $p<0.01$) in Model 2 of Table A-4, we find some evidence that recalls in different product types may slow new product submission in the focal product type. Firms may be accelerating new product submission activities to take advantage of market opportunities by repurposing internal resources from other product areas. These results are further bolstered by the fact that the largest responses to competitor failures are observed among broad firms—i.e., those arguably best-positioned to do so—and by public firms—i.e., those arguably with the strongest incentives to take advantage of market opportunities.

Third, not only do we show that there is no association between past submission counts and future recalls in a PSM model, but we also demonstrate in an additional AFT model that post-recall new product submission times are not predictive of the time to the first serious recall on that product after it is approved by the FDA. These results suggests that not only is reverse causality unlikely biasing our results, but also that the new product submission delays for own firms are most likely indicative of recall-related distractions than product quality learning. These results thus suggest that new product development accelerations based on competitor firm failures appear to be rational and strategic, given they come at little to no quality cost.

Our results also have important implications for firms and regulators. For firms, this study suggests a double penalty associated with product failures: recalls not only decelerate own firm new product development activity, but also accelerate competitor firm new product development activity. These results highlight an additional reason why firms should seek to avoid product failures in the first place. The temptation to divert resources from new product development to help resolve product quality problems is no doubt strong, but doing so may simply fix a present problem at the cost of future new product development and subsequent revenue and profit. More concerning perhaps is the fact that product quality issues represent opportunities for competitor firms. A medical device industry executive we spoke with suggested two actions med-tech firms might take in response to our findings. First, creating dedicated product recall recovery teams that retain significant and broad product area expertise, helping to insulate new product development from costly product recall fire-fighting efforts. Second, establishing competitor firm recall surveillance tools, which could integrate market knowledge and take advantage of such opportunities as they emerge. Our findings show that some med-tech firms are already pursuing such strategic responses to recalls—whether highly structured or otherwise—and that any efforts to preempt other firms from exploiting competitor recalls may be beneficial—in particular, by those whose primary competitors are broad in product scope or publicly-listed.

Regulators, such as the FDA, can also draw insights from this study. Our findings highlight the link between new product submissions and recalls. It may benefit regulators to establish formalized coordination and information exchange mechanisms between pre-market product submission approval activities and post-market surveillance compliance activities. In our discussions with senior FDA personnel as a part of this study, we learned that no such coordination currently exists.

Among other opportunities, implementing organizational changes to facilitate pre- and post-market information exchange may help regulators better predict the timing and nature of future regulatory submissions in those products with potential quality concerns.

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 development- and recall-related activities. While such a 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 broad 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 development activities of med-tech firms. Fourth, we examine new product submissions for those devices that receive regulatory approval but do not consider those that are denied approval. The 510(k) submissions that are not approved by FDA are not made public, however, actual rejection rates for these submissions are reportedly quite low. Fifth, though we undertook several steps to address endogeneity, it could still be biasing our results. Methods such as exploiting an exogeneous shock to our data, or instrumental variable analysis, may help to further address endogeneity problems, though identifying valid shocks or instruments in our context is quite challenging and may create another source 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 costs of product failures. In fact, no studies of which we are aware explore the new product development consequences of product recalls. Firms experiencing product recalls therefore face a host of challenges in the form of internal disruptions and opportunistic responses by their most nimble and motivated competitors. Product failure prevention and remediation activities are thus likely to be more valuable for managers than previously thought.

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Table 1: Descriptive Statistics

VARIABLE	DEFINITION	MEAN	ST DEV	MIN	MAX
510(k) Time	Time (in days) Since Own Firm Recall	186.32	416.72	1.00	4611.00
Own Firm Recalls	Count of Own Firm Recalls	1.32	4.42	0.00	54.00
Competitor Firm Recalls	Count of Competitor Firm Recalls	65.31	86.68	0.00	533.00
Product Age	Age (in days) of Product Type	2663.29	1308.05	0.00	5567.00
Product Scope	Number of Unique Product Types of Firm	22.05	23.31	0.00	107.00
Public	Indicator for Public Firm	0.54	0.50	0.00	1.00
Own Firm Submissions	Count of Own Firm Submissions	6.67	17.93	0.00	132.00
Competitor Firm Submissions	Count of Competitor Firm Submissions	132.80	134.15	0.00	638.00
Total 510(k) Clearances	16489				
Total 510(k) Recalls	5752				
Total Unique Products	1089				
Total Unique Firms	444				

Notes: All counts are defined over 24-month window.

Table 2: Correlation Statistics

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
(1) 510(k) Time	1.00							
(2) Own Firm Recalls	-0.07	1.00						
(3) Competitor Firm Recalls	0.00	0.30	1.00					
(4) Product Age	0.08	0.23	0.53	1.00				
(5) Product Scope	-0.32	0.16	0.08	0.11	1.00			
(6) Public	-0.31	0.18	0.13	0.10	0.46	1.00		
(7) Own Firm Submissions	-0.13	0.61	0.43	0.27	0.40	0.27	1.00	
(8) Competitor Firm Submissions	-0.12	0.38	0.77	0.59	0.34	0.26	0.57	1.00

Notes: All counts are defined over 24-month window.

Table 3: Main Results. AFT Model-510(k) Time

Hypothesis		**H1**	**H2**	**H2**	**H3**	**H3**
Model	**(1)**	**(2)**	**(3)**	**(4)**	**(5)**	**(6)**
Firm Type	**All**	**All**	**Focused**	**Broad**	**Private**	**Public**
LN(Product Age)	0.022+	0.029*	0.050**	0.014	0.041*	0.041*
	(0.012)	(0.011)	(0.018)	(0.019)	(0.020)	(0.017)
LN(Product Scope)	-0.776***	-0.787***			-0.758***	-0.603***
	(0.080)	(0.076)			(0.067)	(0.083)
Public	-1.067***	-1.063***	-0.844***	-3.452*		
	(0.290)	(0.292)	(0.099)	(1.515)		
Own Firm Recalls		0.270***	0.185***	0.310***	0.232***	0.297***
		(0.032)	(0.042)	(0.051)	(0.058)	(0.047)
Competitor Firm Recalls		-0.046*	-0.038	-0.066**	0.017	-0.067***
		(0.018)	(0.024)	(0.024)	(0.022)	(0.020)
Constant	5.774***	5.964***	7.346***	5.052**	24.078***	5.485***
	(0.380)	(0.397)	(0.831)	(1.603)	(1.040)	(0.409)
Year Fixed Effects	X	X	X	X	X	X
Product Fixed Effects	X	X	X	X	X	X
Firm Fixed Effects	X	X	X	X	X	X
Submission Count Controls	X	X	X	X	X	X
Observations	22241	22241	10853	11388	10315	11926

+ $p < 0.10$; * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$.

Notes: The dependent variable is the time to FDA submission. All models use 24 month-counts of severe class (1 & 2) recalls for the analysis window. All models include controls for the number of same product class submissions by own and competitor firms. Standard errors (in parentheses) are clustered by firm and are presented below the coefficients. Model 3 examines the lower half of firms with respect to product scope (≤ 14 products); Model 4 examines the upper half of firms with respect to product scope (≥ 15 products); Model 5 examines private firms; Model 6 examines publicly listed firms. Models 5 and 6 use firm fixed effects for firms with twelve or more observations.

Table 4: Hypotheses Results and Interpretation

	Model	Beta	Time in Days One SD of Recalls	Time in Days One Recall
Own Firm Recalls	2	0.270***	193.38	43.75
Competitor Firm Recalls	2	-0.046*	-11.12	-0.13
Focused: Own Firm Recalls	3	0.185***	126.79	28.68
Focused: Competitor Firm Recalls	3	-0.038		
Broad: Own Firm Recalls	4	0.310***	226.74	51.30
Broad: Competitor Firm Recalls	4	-0.066**	-15.79	-0.18
Private: Own Firm Recalls	5	0.232***	162.91	36.86
Private: Competitor Firm Recalls	5	0.017		
Public: Own Firm Recalls	6	0.297***	215.75	48.81
Public: Competitor Firm Recalls	6	-0.067***	-16.03	-0.18

+ $p < 0.10$; * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$

Notes: We describe the determination of economic effects using "Own Firm Recalls" from row 1 above as an example. All interpretations are done in an equivalent manner. The Model column of Table 4 refers to each Model's coefficients from Table 3. We only show interpretations for significant coefficients from Table 3. The mean of Own Firm Recalls = 1.32 and the mean 510(k) time is 186.32 days from Table 1. A one percent change in Own Firm Recalls is 0.0132, which is associated with a (0.01 x ($\exp^{\beta}$-1) percent change in mean days to submission. The coefficient for Own Firm Recalls taken from Model 2 of Table 3 is 0.270: 0.01 x ($\exp^{(0.270)}$-1) = 0.003099645. We multiply this number by the mean number of days to submission to determine the effect of a one percent change in Own Firm Recalls: 186.32 days X 0.003099645 = 0.577525765 days. The standard deviation of Own Firm Recalls is 4.42 from Table 1. Therefore, the effect of a one standard deviation change in Own Firm Recalls is found by scaling the number of recalls in one standard deviation by the number of recalls in a one percent change and multiplying that by the effect of a one percent change on submission time: 4.42 recalls/0.0132 recalls x 0.577525765 days = 193.38 days. The effect of a single own firm recall on submission times is found by dividing the effect of one standard deviation in Own Firm Recalls by the number of those types of recalls in one standard deviation: 193.38 days / 4.42 recalls = 43.75 longer days to submission after one own firm recall.

Table 5: Post-Hoc Results. AFT Model. Time to Recall

Model	(1)	(2)
LN(510K Time)	0.001	-0.011
	(0.012)	(0.021)
Constant	7.849***	7.628***
	(0.279)	(0.237)
Year Fixed Effects	X	X
Firm Fixed Effects	X	X
Observations	2787	19593

+ $p < 0.10$; * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$.

Notes: The dependent variable is the time to a post-submission Class I or II recall. Controls for product age and same product class and different product class submission counts by own and competitor firms are included. Standard errors (in parentheses) are clustered by firm and are presented below the coefficients. Model 1 examines the set of product submissions that experience future recalls, where the number of observations (2787) represents how many occurred. Model 2 examines all submissions (i.e., including those that do not experience future recalls). The number of observations (19593) represents how many occurred, but excludes pre-submission recalls (i.e., recalls related to product submissions that pre-date the sample).

Appendix

Table A-1: Descriptive Statistics for Robustness Tests

VARIABLE	DEFINITION	MEAN	ST DEV	MIN	MAX
Own Firm (36 MON) Recalls	Count of Own Firm Recalls over 36 months	1.76	5.75	0.00	67.00
Competitor Firm (36 MON) Recalls	Count of Competitor Firm Recalls over 36 months	90.86	122.65	0.00	733.00
Own Firm (All Class) Recalls	Count of Own Firm Recalls in All Classes (i.e., I, II, III)	1.35	4.46	0.00	54.00
Competitor Firm (All Class) Recalls	Count of Competitor Firm Recalls in All Classes (i.e., I, II, III)	67.39	87.55	0.00	540.00
Own Firm (Different) Recalls	Count of Own Firm Recalls in Different Product Types	10.10	23.56	0.00	165.00
Competitor Firm (Different) Recalls	Count of Competitor Firm Recalls in Different Product Types	197.07	240.46	0.00	1486.00
Revenues	Amount of Revenue	31100.27	43924.99	-385.97	216626.60
Employees	Number of Employees	88605.05	122319.60	0.00	475000.00
R&D	Amount of R&D Expenses	1452.86	2436.32	0.00	13563.90
R&D Intensity	Revenue / R&D Expenses	0.09	1.24	0.00	91.92

Notes: All counts are defined over 24-month window except for those indicated.

Table A-2: AFT Model-510(k) Time Using 36 Month Recall Windows

Hypothesis		**H1**	**H2**	**H2**	**H3**	**H3**
Model	**(1)**	**(2)**	**(3)**	**(4)**	**(5)**	**(6)**
Firm Type	**All**	**All**	**Focused**	**Broad**	**Private**	**Public**
LN(Product Age)	0.022+	0.032**	0.053**	0.020	0.041*	0.046**
	(0.012)	(0.012)	(0.019)	(0.019)	(0.020)	(0.017)
LN(Product Scope)	-0.776***	-0.834***			-0.758***	-0.645***
	(0.080)	(0.085)			(0.067)	(0.088)
Public	-1.067***	-1.112***	-0.843***	-3.605*		
	(0.290)	(0.333)	(0.109)	(1.564)		
Own Firm (36 MON) Recalls		0.263***	0.185***	0.309***	0.254***	0.287***
		(0.029)	(0.045)	(0.043)	(0.052)	(0.039)
Competitor Firm (36 MON) Recalls		-0.054**	-0.034	-0.076**	0.026	-0.080***
		(0.020)	(0.026)	(0.026)	(0.023)	(0.020)
Constant	5.774***	6.013***	7.220***	5.179**	24.147***	5.561***
	(0.380)	(0.408)	(0.855)	(1.661)	(1.017)	(0.417)
Year Fixed Effects	X	X	X	X	X	X
Product Fixed Effects	X	X	X	X	X	X
Firm Fixed Effects	X	X	X	X	X	X
Submission Count Controls	X	X	X	X	X	X
Observations	22241	22241	10853	11388	10315	11926

+ $p < 0.10$; * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$.

Notes: The dependent variable is the time to FDA submission. All models use 36-month counts of severe class I & II recalls for the analysis window. All models include controls for the number of same product class submissions by own and competitor firms. Standard errors (in parentheses) are clustered by firm and are presented below the coefficients. Model 3 examines the lower half of firms with respect to product scope (≤ 14 products); Model 4 examines the upper half of firms with respect to product scope (≥ 15 products); Model 5 examines private firms; Model 6 examines publicly listed firms. Models 5 and 6 use firm fixed effects for firms with twelve or more observations.

Table A-3: AFT Model-510(k) Time Using All Recall Classes

Hypothesis		**H1**	**H2**	**H2**	**H3**	**H3**
Model	**(1)**	**(2)**	**(3)**	**(4)**	**(5)**	**(6)**
Firm Type	**All**	**All**	**Focused**	**Broad**	**Private**	**Public**
LN(Product Age)	0.022+	0.029*	0.050**	0.014	0.041*	0.041*
	(0.012)	(0.011)	(0.018)	(0.019)	(0.020)	(0.017)
LN(Product Scope)	-0.776***	-0.787***			-0.760***	-0.602***
	(0.080)	(0.076)			(0.067)	(0.083)
Public	-1.067***	-1.060***	-0.842***	-3.446*		
	(0.290)	(0.292)	(0.100)	(1.514)		
Own Firm (All Class) Recalls		0.270***	0.181***	0.311***	0.234***	0.298***
		(0.031)	(0.041)	(0.050)	(0.060)	(0.046)
Competitor Firm (All Class) Recalls		-0.046**	-0.034	-0.065**	0.016	-0.061**
		(0.018)	(0.024)	(0.024)	(0.021)	(0.020)
Constant	5.774***	5.960***	7.355***	5.045**	24.077***	5.481***
	(0.380)	(0.393)	(0.835)	(1.601)	(1.037)	(0.405)
Year Fixed Effects	X	X	X	X	X	X
Product Fixed Effects	X	X	X	X	X	X
Firm Fixed Effects	X	X	X	X	X	X
Submission Count Controls	X	X	X	X	X	X
Observations	22241	22241	10853	11388	10315	11926

+ $p < 0.10$; * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$.

Notes: The dependent variable is the time to FDA submission. All models use 24-month counts of all class (I, II and III) recalls for the analysis window. All models include controls for the number of same product class submissions by own and competitor firms. Standard errors (in parentheses) are clustered by firm and are presented below the coefficients. Model 3 examines the lower half of firms with respect to product scope (≤ 14 products); Model 4 examines the upper half of firms with respect to product scope (≥ 15 products); Model 5 examines private firms; Model 6 examines publicly listed firms. Models 5 and 6 use firm fixed effects for firms with twelve or more observations.

Table A-4: AFT Model-510(k) Time Using Same / Different Recall Types

Hypothesis		**H1**	**H2**	**H2**	**H3**	**H3**
Model	**(1)**	**(2)**	**(3)**	**(4)**	**(5)**	**(6)**
Firm Type	**All**	**All**	**Focused**	**Broad**	**Private**	**Public**
LN(Product Age)	0.029*	0.030**	0.048**	0.017	0.041*	0.042*
	(0.011)	(0.011)	(0.018)	(0.019)	(0.020)	(0.017)
LN(Product Scope)	-0.787***	-0.828***			-0.766***	-0.629***
	(0.076)	(0.080)			(0.063)	(0.086)
Public	-1.063***	-1.078***	-0.813***	-3.457*		
	(0.292)	(0.290)	(0.100)	(1.523)		
Own Firm (Same) Recalls	0.270***	0.266***	0.186***	0.294***	0.225***	0.289***
	(0.032)	(0.032)	(0.043)	(0.051)	(0.060)	(0.048)
Own Firm (Different) Recalls		0.022	-0.051	0.093	0.094**	0.043
		(0.041)	(0.048)	(0.064)	(0.035)	(0.037)
Competitor Firm (Same) Recalls	-0.046*	-0.043*	-0.045+	-0.076**	0.009	-0.066***
	(0.018)	(0.018)	(0.025)	(0.024)	(0.021)	(0.020)
Competitor Firm (Different) Recalls		0.050**	-0.053***	-0.075	-0.016	0.020
		(0.019)	(0.015)	(0.046)	(0.025)	(0.027)
Constant	5.964***	5.945***	7.146***	5.106**	24.199***	5.573***
	(0.397)	(0.376)	(0.848)	(1.576)	(1.044)	(0.409)
Year Fixed Effects	X	X	X	X	X	X
Product Fixed Effects	X	X	X	X	X	X
Firm Fixed Effects	X	X	X	X	X	X
Submission Count Controls	X	X	X	X	X	X
Observations	22241	22241	10853	11388	10315	11926

+ $p < 0.10$; * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$.

Notes: The dependent variable is the time to FDA submission. All models use 24-month counts of severe class (I & II) recalls in same and different product types for the analysis window. All models include controls for the number of same product class submissions by own and competitor firms. Standard errors (in parentheses) are clustered by firm and are presented below the coefficients. Model 1 replicates the Model 2 results in Table 3 for comparison purposes. Model 3 examines the lower half of firms with respect to product scope (≤ 14 products); Model 4 examines the upper half of firms with respect to product scope (≥ 15 products); Model 5 examines private firms; Model 6 examines publicly listed firms. Models 5 and 6 use firm fixed effects for firms with twelve or more observations.

Table A-5: AFT Model-510(k) Time Using Only Public Firms

Hypothesis	**H4**	**H4**	**H4**	**H4**	**H4**	**H4**
Model	**(1)**	**(2)**	**(3)**	**(4)**	**(5)**	**(6)**
Firm Type	**Private**	**Public**	**Public**	**Public**	**Public**	**Public**
LN(Product Age)	0.041*	0.046**	0.040*	0.041*	0.042*	0.040*
	(0.020)	(0.017)	(0.017)	(0.017)	(0.017)	(0.017)
LN(Product Scope)	-0.758***	-0.645***	-0.599***	-0.600***	-0.598***	-0.644***
	(0.067)	(0.088)	(0.082)	(0.083)	(0.083)	(0.088)
Own Firm Recalls	0.254***	0.287***	0.295***	0.296***	0.295***	0.298***
	(0.052)	(0.039)	(0.046)	(0.047)	(0.047)	(0.047)
Competitor Firm Recalls	0.026	-0.080***	-0.068***	-0.067***	-0.068***	-0.057**
	(0.023)	(0.020)	(0.020)	(0.020)	(0.020)	(0.021)
LN(Revenue)			-0.028			
			(0.021)			
LN(Employees)				-0.005		
				(0.015)		
LN(R&D Spending)					-0.028	
					(0.022)	
R&D Intensity						-0.002
						(0.013)
Constant	24.147***	5.561***	5.622***	5.513***	5.548***	5.573***
	(1.017)	(0.417)	(0.432)	(0.423)	(0.419)	(0.435)
Year Fixed Effects	X	X	X	X	X	X
Product Fixed Effects	X	X	X	X	X	X
Firm Fixed Effects	X	X	X	X	X	X
Submission Count Controls	X	X	X	X	X	X
Observations	10315	11926	11916	11926	11926	11599

+ $p < 0.10$; * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$.

Notes: The dependent variable is the time to FDA submission. All models use 24-month counts of severe class (I & II) recalls for the analysis window. All models include controls for the number of same product class submissions by own and competitor firms. Standard errors (in parentheses) are clustered by firm and are presented below the coefficients. Models 1 and 2 replicate Models 5 and 6 from Table 4. Model 3 includes a logged measure of revenue for public firms. Model 4 includes a logged measure of employees for public firms. Model 5 includes a logged measure of R&D spending for public firms. Model 6 includes a measure of R&D intensity for public firms. All models utilize firm fixed effects for those firms with twelve or more observations.