RECALLS, INNOVATION, AND COMPETITOR RESPONSE: EVIDENCE FROM MEDICAL DEVICE FIRMS*

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Abstract

Innovation and new product development are the lifeblood of firms in R&D-intensive industries, yet malfunctioning products can cause immense damage. Product failures thus create managerial challenges and opportunities for focal firms and their competitors. Focal firm failures result in decreases in sales and increases in costs associated with remedial public relations and manufacturing activities. Competitor firm failures, however, can create market opportunities and elicit strategic responses by focal firms. We develop theory and provide empirical evidence of how innovative activity changes in response to recalls in the U.S. medical device industry. Focal firm recalls slow incremental innovation and competitor firm recalls accelerate incremental and major innovation. Recall prevention and remediation efforts are thus more important than previously suggested, due to significant competitor responses.

Keywords: Innovation, Recalls, Product Failures, Medical Devices, FDA, Health Care

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INTRODUCTION

Innovation and new product development are the lifeblood of firms in a wide range of research and development (R&D)-intensive industries, including software, microprocessors, automobiles, and pharmaceuticals. Yet in each of these settings, the impact of faulty, low quality, or dangerous products can be damaging or ruinous. Software bugs can compromise sensitive customer data and cause incalculable losses, while automotive product failures can cause passenger injury and death. Such "first-order effects" of product failures are salient and negatively affect firm performance. Beyond the immediate harm of such product failures, a number of "second-order effects" present serious managerial challenges as well. For instance, product failures are often publicized and heavily scrutinized events, and they may influence subsequent investments in innovation by both directly-affected ("focal") firms as well as their competitors.

An immediate effect of a focal firm product failure is typically a depletion – or complete elimination – of subsequent sales. For example, if a pharmaceutical product is found to be unsafe for patients, its sale and distribution may be halted completely.[1] Further, product failures can be costly to manage from both a public relations and manufacturing perspective. Negative publicity can amplify sales downturns and lead to shareholder losses (Jarrell and Peltzman 1985; Rhee and Haunschild 2006), while manufacturer operations may be severely disrupted if internal resources need to be redirected to correct outstanding product quality problems. These disruptions and resource redirections may also impair innovation efforts at the firm, in particular if the product failure and new innovation activity are in related product areas, or when the product failure is severe.

Competitor firm product failures are also likely to have meaningful implications for focal firms: on the one hand, they may signal overall product category risk and thereby facilitate retreat from a

[1] For example, Vioxx (rofecoxib) is a Merck drug for osteoarthritis that was entirely withdrawn from the worldwide market in 2004 due to heightened risk of cardiovascular disease (Krumholz et al. 2007).

certain area of new product development (Krieger 2017). On the other hand, when the underlying driver of competitors' product failures is firm-specific, they can create market opportunities to either enter a *de novo* product space via new product commercialization or reinforce a competitive position within an existing product space via changes or improvements to existing products (KC *et al.* 2013; Krieger 2017). Such opportunities are likely to be greatest for those focal firms already active in a recall-affected product area, allowing for faster strategic responses. Further, these opportunities are likely to be more attractive for focal firms when competitor firms' product failures are more severe, as such issues can entail lengthy resolution periods and/or indefinite market exits.

In short, focal firm product failures are likely to demand internal remediation efforts and divert energy away from new product development activities, while competitor firm product failures may increase incentives for innovation. We explore these phenomena directly by developing theory and providing empirical evidence of how innovative activity changes in response to the source, proximity, and severity of product recalls in the U.S. medical device industry. By leveraging exhaustive recall and new product submission data from the United States Food and Drug Administration (FDA), we address the following research questions from the perspectives of *both* focal and competitor firms: first, does the source of a recall (i.e., focal firm vs. competitor firm) influence subsequent innovation? Second, does the proximity of a recall (i.e., same product area vs. different product area) influence subsequent innovation? And third, does the severity of a recall (i.e., more severe vs. less severe) influence subsequent innovation?

Medical device firms–also known as medical technology or "med-tech" firms–operate at the frontier of biomedical and technological innovation by developing and marketing devices that enhance and extend human life. It is estimated that med-tech innovations have added approximately five years to life expectancy, cut heart disease fatalities in half, and reduced average hospital stays by more than

50 percent among U.S. patients over 1995-2015.[2] Yet the same devices that can improve and save lives can put patients at risk when product safety is compromised. If medical devices are found to be unsafe, med-tech firms must recall those products from the marketplace until requisite corrections can be made.

Anecdotal evidence suggests that product recalls and subsequent innovative activity are closely linked. For example, Guidant Corporation experienced several patient deaths and related device failures in 2005 that led to recalls of several of its top-selling implantable cardioverter defibrillator (ICD) product lines.[3] Guidant's new product development efforts were side-tracked following this recall, as its next new ICD was not submitted to the FDA for approval until six years later, an unusually long gap in med-tech innovation for such a large firm. However, Guidant's main competitors—Medtronic and St. Jude Medical—ratcheted up their own innovation efforts: both firms submitted new ICDs for regulatory approval in rapid succession following the Guidant recall.[4]

Moreover, both innovative activity and product recall activity in the med-tech setting have increased in recent years, rendering our setting increasingly important: over 2003-2015, the number of FDA regulated devices increased by 11 percent while the number of device recalls increased by nearly 50 percent. Further, the costs of new product development in this industry are considerable: bringing a new device to market is estimated between $31 and $94 million.[5] In such a setting, understanding how product failures impact future innovation efforts is not only crucial for managers and firms, but also has important implications for investors, regulators, health care providers, and patients.

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1 See the Healthcare Institute of New Jersey study at http://hinj.org/value-of-medical-innovation.

3 This product recall affected the Prizm, Renewal and Vitality brands. See http://www.washingtonpost.com/wp-dyn/content/article/2005/06/17/AR2005061700680.html.

4 See https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/.

5 https://www.advamed.org/sites/default/files/resource/30_10_11_10_2010_Study_CAgenda_makowerreportfinal.pdf

The extant strategy and innovation literature is surprisingly silent on whether a relationship between product recalls and innovation exists either in theory or in practice.[6] Some research suggests that firms learn from their own recalls and make quality improvements, which can accelerate or decelerate subsequent innovation (Haunschild and Rhee 2004). Other research suggests that firms observe and learn from their competitors' *pre-market* product development failures, which may also influence subsequent innovation efforts (Krieger, 2017). Our empirical setting differs from these contributions, however, in that we examine the impact of *post-market* product recalls from both focal and competitor firm perspectives. In this respect, our approach is similar to research that examines the determinants of firm performance once technologies are already commercialized (Haunschild and Sullivan 2002; Baum and Dahlin 2007; Kim and Miner 2007), but is distinct in that it considers focal and competitor firm failures as predictors, rather than consequences, of innovation. Further, our data are sufficiently detailed to examine the potential innovation-related effects of the source, proximity, and severity of product recalls—areas that have not been previously studied.

An additional feature of our empirical setting is the ability to differentiate between different types of innovation. New device development occurs in two primary ways: incremental innovation and major innovation. Incremental innovation is characterized by products that are lower-risk, less novel and simpler, and therefore require less development time and fewer resources than major project innovation. For example, a simple catheter would come to market as an incremental innovation. Major innovation is characterized as higher-risk, more novel, complex, and typically entails significant costs and time (Macher 2006). For example, a new implantable cardiovascular device that incorporates previously unused materials would come to market as a major innovation. Because these two types of

[6] Despite limited academic research into firms' responses to rivals' activities, the proliferation of for-profit market intelligence data providers—such as PharmaProjects and Cortellis Competitive Intelligence™ in biotech and pharmaceuticals and Evaluate MedTech™ in medical devices—suggests that health care product firms and their (potential) investors and acquirers have a large appetite for understanding other firms' activities.

innovation are treated very differently by med-tech firms in their new product development activities and handled differently by regulators in the commercialization processes, the effect of product recalls may differ accordingly. For example, it is likely that, given their long development timelines, major innovation activities are less responsive to product failures than incremental innovations. We therefore examine our hypotheses separately in these two distinct innovation categories.

We assemble data on all medical device approvals and recalls from 2003-2015[7] and assign all approvals and recalls to a standardized set of firm names and FDA-designated product areas. Using novel assignment algorithms, we construct detailed firm- and product area-level innovation and recall histories that provide precise definitions of the relevant set of competitors for each med-tech firm, in each product area, over time. Finally, we incorporate these detailed histories into recurrent-event accelerated failure time (AFT) models to determine how recall source, proximity, and severity affect med-tech firms' subsequent incremental and major innovation activities.

Our empirical findings are informative and largely in-line with our hypotheses. With respect to incremental innovation, focal firm recalls *slow* subsequent new product submissions – an effect that is explained by recall proximity (i.e. overlap in the relevant product area) as opposed to recall severity. On the other hand, competitor firm recalls *quicken* the time to incremental innovation – an effect that is explained by recall severity but not recall proximity. With respect to major innovation, focal firm recalls have only a marginal negative influence, consistent with the stickiness and long timelines of major product development efforts. However, competitor recalls *decrease* the time to major innovation – an effect that is explained by existing product overlap in the affected product area *and* by recall severity.

[7] One of the coauthors is a Special Government Employee with the Center for Devices and Radiological Health of the FDA, which allowed us to work closely with the FDA in this study. This ensures that the data are precise, the research questions are relevant, and the empirical analysis and conclusions are important to med-tech firms, regulators, and public policy.

We contribute to several research streams in strategy and innovation, as well as research on product recalls. First, the theoretical lens enhances new product development literature (Brown and Eisenhart 1995) by examining a largely overlooked but critically important determinant of innovative activity: product failures. Second, the empirical approach contributes to product recall research by establishing novel ramifications of product recalls that predict future innovation activity. 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 recalls. While this research arena has identified several effects of recalls, such as firm learning (Haunschild and Rhee 2004), reduced market share (Jarrell and Peltzman 1985), and lost consumer confidence (Rhee and Haunschild 2006), no studies of which we are aware have associated product recalls with subsequent innovation. Third, the empirical methodology builds upon research that explores innovation and competition at a detailed level of analysis. Our comprehensive data and variable definition algorithms allow for the dynamic identification of relevant competitors that vary across firms, products, and over time.

Our results also have implications for regulators and industry practitioners. For regulators, our results demonstrate that within the med-tech industry, prior recalls and subsequent innovative activity are inherently connected. Improved alignment, coordination, and information exchange between regulatory product approval activities and surveillance and compliance activities are likely to provide benefits. For practitioners, we offer evidence that focal firm recalls may crowd out innovation activities. Arguably more surprising and novel, however, are our findings describing how competitor firm recalls alter focal firm innovation activities. Firms experiencing product recalls thus face both *internal* challenges and *external* challenges in that such failures may stimulate competitors' new product development efforts. The prevention of recalls is therefore likely to be more important than previously suggested due to the existence of significant competitor responses.

EMPIRICAL CONTEXT

Medical devices are regulated by the Center for Devices and Radiological Health (CDRH) within the FDA. The CDRH regulates medical devices in two primary ways: as a pre-market gatekeeper and as a post-market regulator. Prior to commercialization, CDRH reviews new product submissions to determine whether 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. Once a product comes to market, CDRH performs ongoing surveillance of approved products to ensure their continued safety and effectiveness. In cases where product safety concerns emerge, federal statutes mandate medical devices that "present a risk of injury, gross deception, or are otherwise defective" be corrected or removed from the market by the manufacturing firm.[8] In its role as pre-market gatekeeper, CDRH assigns medical devices submitted for regulatory approval to product areas based on their intended use, and to incremental or major submission pathways based on their risk and novelty. Product areas represent device categories and are defined by particular product codes. Several thousand product codes categorize medical devices based on description, use, medical specialty, and other device characteristics. Devices within a product code are effective substitutes, as they serve the same function and are reviewed by the same regulators.

Additionally, there are two primary regulatory submission pathways: (1) 510(k) Clearance and (2) Pre-Market Approval (PMA).[9] 510(k) clearances represent incremental innovations: these products are less complex and, by definition, are demonstrably similar to medical devices that have already

[8] While all of the recalls in our data are voluntarily-initiated, FDA maintains the legal authority to mandate recalls. However, it seldom does. Both market corrections and removals are considered as recalls by FDA because they entail modifications to marketed products.

[9] An FDA regulatory pathway category that we purposefully do not examine is for extremely low-risk medical devices. So-called "510(k) exempt" devices represent products such as toothbrushes, Q-tips, and dental floss, among others.

received FDA approval by the same or another med-tech firm.[10] PMAs represent major innovations. Due to their complexity and novelty, devices regulated through this pathway normally require evidence of product safety and effectiveness from clinical trials before the FDA grants approval.[11] We therefore examine 510(k) clearances and PMA approvals as incremental and major innovations, respectively.

In its role as post-market regulator, CDRH is responsible for ensuring that approved devices perform in a safe and effective manner and present no unnecessary risk of patient harm. When medical devices do malfunction, med-tech firms and user facilities, such as hospitals or physicians' offices, are required to report this information to CDRH. Product quality complaints from users are also received by CDRH directly. Medical device malfunctions are categorized in a centralized database for ongoing monitoring of device performance.[12] Product safety is also monitored through a process of manufacturing facility inspections, based upon characteristics of the products manufactured, the facilities themselves, and the prior recall, inspection, and medical device reporting histories, among others (Ball *et al.* 2017; Macher *et al.* 2011). When a pattern of product defects or safety issues arises that is systemic in nature, the med-tech firm must initiate a voluntary recall that is overseen by the FDA. Medical device recalls are classified into three categories, ranging from Class I (most severe) to Class III (least severe). Class I recalls are for what the FDA calls "violative"[13] medical device failures that have a reasonable probability of serious adverse health consequences or death. An example would be a faulty implantable heart valve. Class II recalls occur when the use of a violative medical device may cause

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10 The FDA uses the terminology "substantially equivalent" to describe the sufficient level of similarity required for regulation via the 510(k) pathway.

11 Major innovations can be updated through a process of Supplementary Premarket Approval (SPMA), which represent process improvements to released products. The data and evidence burdens for SPMAs are less than those required for PMAs, but demonstration of safe and effective device performance using rigorous statistical tests by the applicant prior to approval is still required. Because SPMAs are not new product submissions but are approved product improvements, we reserve their examination for robustness tests.

12 The FDA's Manufacturer and User Facility Device Experience ("MAUDE") database is accessible at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.

13 Violative is an FDA term that means an infringement, a transgression, or the act of violating a rule.

medically reversible adverse health consequences, such as a malfunctioning hearing aid. Class III recalls occur when the violative medical device is unlikely to cause adverse health consequences, but should nevertheless be corrected, such as a minor product labeling error.

LITERATURE AND HYPOTHESES

PRODUCT RECALLS

Empirical research on product recalls is largely divided into two categories: (1) studies that examine the effects of recalls; and (2) studies that identify the causes or leading indicators of recalls. The preponderance of research to-date resides in the former category and predominately examines the stock market, market share, and customer loyalty effects of recalls. 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 the firm to rework or replace the 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. Research has also found that past recalls may influence future recalls (Thirumalai and Sinha 2011), especially when the past recalls are initiated voluntarily by the firm (Haunschild and Rhee 2004). A smaller but growing body of empirical research examines recall predictors in various industry settings. For instance, studies find that higher levels of R&D intensity (Thirumalai and Sinha 2011), product and plant variety (Shah *et al.* 2016; Ball *et al.* 2018) and adverse inspection outcomes (Ball *et al.* 2017) are predictive of future recalls.

While the recall literature to date examines both the consequences and causes of recalls, there is a dearth of empirical research that examines any recall and innovation relationship. To our knowledge,

our study is the first to explore the impact of different types of recalls, in different product areas, by focal versus competitor firms, and on future incremental and major innovation efforts.

PRODUCT INNOVATION IN HEALTH CARE

A robust literature on the management of innovation in the health care sector examines the determinants of innovative firm activity. Empirical studies have documented how potential market size positively predicts the amount of 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 context of the FDA regulatory approval process, Carpenter *et al.* (2010) examine FDA review times for new pharmaceutical drug products and Stern (2017) examines these dynamics in the context of new high-risk medical devices. As noted above, however, we are not aware of any empirical studies that use product recalls to predict innovation. In the tradition of other product innovation studies in health care that use unexpected "shocks" to market size to study effects on innovation (Blume-Kohout and Sood 2013; Krieger *et al.* 2018; and Krieger 2017), we consider the incidence of a product recall as a negative shock to the focal firm, and a positive shock to competitor firms in the industry where the recall takes place.

RECALL SOURCE HYPOTHESES

Literature that explores operational disruptions has frequently considered supply-chain problems (Demirel *et al.* 2017; Yang *et al.* 2009) or natural disasters (Kim *et al.* 2010) as the sources, and insurance (Serpa and Krishnan 2016) or buffer-inventory (Dong and Tomlin 2012) as mitigation strategy solutions to protect against such disruptions. Unsurprisingly, these studies find in aggregate that disruptions are harmful to firm performance. A narrower stream of research examines the influence of disruptions on new product development. For example, Sterman *et al.* (1997) finds that when a firm is

heavily focused on quality improvement initiatives, product development speed may suffer. Benner and Tushman (2002) come to similar conclusions.

In the med-tech setting, product recalls represent significant operational disruptions. Beyond managing the negative influence on public relations and the required outreach to affected patients, hospitals, and other user facilities, firms must identify the source of safety problems and fix shortcomings related to the recalled product. Resources are usually reallocated to address the relevant product quality issues and managerial effort must be dedicated to leading and completing 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, everyone works together to recover as quickly as possible. Recall is the preeminent four-letter word in the med-tech industry." We therefore expect that focal firm recalls are likely to divert resources and attention away from new product development immediately following a product recall. This diversion should increase the time to a new product submission.[14] We examine the following hypothesis:

H1A: Focal firm recalls *increase* the time to new product innovation, *ceteris paribus*.

Med-tech firms operate in highly competitive markets and thus are keenly aware of the product approvals and failures of their rivals (Porter and Heppelmann 2014; Wu 2013; Thirumalai and Sinha 2011). This awareness may play a role in subsequent innovation efforts by the focal firm. Specifically, focal firms must decide how to respond to competitor firms' recalls—events that likely represent changes in the competitive landscape. This idea has strong analogs in innovation-based research in pharmaceuticals, a similarly R&D-intensive and regulated health care product setting. Pharmaceutical innovation studies have shown that demand shocks that serve to increase the profitability of a product

[14] While some research indicates firms learn from their own failures (Fung et al., 2018; Rerup, 2009; Madsen and Desai, 2010), these studies do not explore how product failures affect new product innovation efforts. We contend that if learning does occur following focal firm recalls, is it unlikely to manifest in faster innovation, as recall recovery efforts are likely to consume time and resources redirected from ongoing innovation activities.

market may lead to more innovation in that market. Examples of such shocks include exogenous changes in patient populations (Acemoglu and Linn 2004; Dubois *et al.* 2015), changes in regulatory rules (Finkelstein 2004), and additional reimbursement incentives (Blume-Kohut and Sood 2013), among others. At the time of a competitor firm's recall, the focal firm experiences a similar type of positive demand shock, as the competitor is forced to remove one or more defective products from the market. This phenomenon is likely to be particularly strong in the med-tech industry due to the historically high gross- and net-profit margins.[15] If and when competitors face product recalls, therefore, the opportunity to capitalize on such an event is meaningful.

To further support the notion that competitor recalls may increase focal firm innovation efforts, research also indicates that firms are more likely to learn from competitors' failures than from their own failures. Specifically, KC *et al.* (2013) find cardiothoracic surgeons learn more from their fellow surgeons' failures in surgery than from their own mistakes. Desai (2015) and Chan *et al.* (2014) come to similar conclusions. We therefore expect a focal firm to accelerate innovative activity when competitors experience negative shocks.[16] We evaluate the following hypothesis:

H1B: Competitor firm recalls *decrease* the time to new product innovation, *ceteris paribus*.

RECALL PROXIMITY HYPOTHESES

It is unlikely that all focal firm and competitor firm product recalls are considered equal by a focal firm, given significant differences across product areas. As described above, medical devices are assigned by the FDA to distinct product areas using a standardized set of product codes. Devices within the same product code serve the same function and are used in similar ways, making them effective

[15] Med-tech has been documented as one of the highest margin industries globally, with gross-margins of 80-95 percent and net margins of 20-30 percent on average. 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.

[16] It is possible that firms may hesitate to innovate following competitor recalls (Krieger 2017), due to the risks they observe in their rival's missteps. The opportunity costs that exist in the med-tech industry, however, suggest firms are incented to overcome such hesitation given the high profit margins and large potential markets that exist.

substitutes. It is therefore reasonable to assume that product recalls influence innovation efforts differently, depending upon whether the recall and the innovation activity occur in the same product code or in different product codes.

The internal resource demands following a focal firm recall are likely to be affected heterogeneously. One key reason is organizational: med-tech firms are typically organized as separate divisions according to the degree of product or technological overlap. 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.[17] This organizational approach suggests that when a recall occurs in a certain product code, technical expertise to assist in recall resolution is likely to originate from the same division, drawing upon a common set of resources. We further substantiate this claim via a 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 recalled a situation in which a severe and complex pacemaker recall diverted R&D engineers from a new product development project for several months because manufacturing engineering teams needed assistance in identifying the root cause of the product failure. She confirmed that this organizational practice was endemic within the industry, suggesting that resolving product failures most directly impacts business units and resources that are most closely-related.[18]

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17 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.

18 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.

While focal firm recalls within a product code may have a greater negative influence on new product submissions than those experienced in more remote products, we suggest competitor firm recalls may have the opposite effect: when a competitor in a product area issues a recall, it signals its weakness in a product market, creating opportunities for others.[19] A strategic response by the focal firm to a competitor's recall may thus be to accelerate its own product submission process in the affected product area, for at least two reasons. First, focal firms may seek to capitalize on competitors' market problems. Second, focal firms may update or enhance their own products to ensure that they do not encounter similar problems. In either case, competitor firm recalls are likely to lead to a quickening of innovative activity by the focal firm, especially when those failures occur in the same product market as current innovation efforts. We therefore test the following set of additional hypotheses related to recall proximity:

H2A: Focal firm recalls *increase* the time to new product innovation—in particular, when recalls and innovation overlap in the same product market, *ceteris paribus*.

H2B: Competitor firm recalls *decrease* the time to new product innovation—in particular, when recalls and innovation overlap in the same product market, *ceteris paribus*.

RECALL SEVERITY HYPOTHESES

It is also unlikely that all focal firm or competitor firm product failures are treated equally given differences in recall severity. As noted above, the FDA classifies product recalls based on severity, ranging from most (Class I), to moderate (Class II) and to least (Class III) severe. By definition, Class III recalls do not cause health problems or injuries, while Class I and Class II recalls are respectively associated with serious negative or reversible health problems.

[19] This is true to the extent that a recall represents a device-specific rather than device-category-wide safety issue. This condition is likely to be met in our setting, where nearly all recalls occur in product categories in which several devices are already safely marketed.

More severe (Class I or II) focal firm recalls are likely to have a more substantial impact on innovative activity in comparison to less severe (Class III) focal firm recalls, and hence should create greater disruption to subsequent new product innovation activity. This is because more severe recalls are likely to require even greater technical resources to ensure an adequate and swift response, compared to less severe problems. Research demonstrates the criticality of responding appropriately, quickly, and comprehensively to severe recalls, as regulators, physician customers, and investors all pay closer attention when recalls are more severe (Ball *et al.* 2018; Thirumalai and Sinha 2011; Marucheck *et al.* 2011). Popular press articles similarly indicate that severe problems place the greatest demands upon the firm to resolve these issues forthrightly and respond robustly (Burton 2015; Walker 2013; Rockoff 2010). A McKinsey report that documents the cost of quality in the med-tech industry also indicates that when problems are severe, significant resources are required to properly respond, diverting engineering resources from other critical firm functions.[20]

Relative to less severe competitor firm recalls, more severe competitor firm recalls should similarly have a more substantial impact on focal firm innovative activity, as these recalls present the greatest strategic opportunities for firms to benefit from innovation efforts. When facing more severe recalls, competitors are likely to take longer to address and correct problems and, as a corollary, the benefits to a focal firm of entering an affected product market are likely to be greater. That is, recognizing the inherent challenges its competitors face in correcting severe recalls, a focal firm would strive to accelerate its own innovative and commercialization activity, if and where possible. We examine the following set of additional hypotheses related to recall severity:

H3A: Focal firm recalls *increase* the time to new product innovation—in particular, when recalls are more severe, *ceteris paribus*.

H3B: Competitor firm recalls *decrease* the time to new product innovation—in particular, when recalls are more severe, *ceteris paribus*.

[20] https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/capturing-the-value-of-good-quality-in-medical-devices

Finally, we expect that the *combined* effects of recall proximity and severity further strengthen our hypothesized relationships. In particular, we expect to see the strongest impact on innovation when focal firm same-product area recalls are classified as severe, given both proximity and a high degree of disruption. We further expect to see stronger innovation effects as a result of proximate and severe competitor recalls, where opportunities to capture market share are greatest. We therefore examine a final set of hypotheses that speak to *both* proximity and severity:

H4A: Focal firm recalls *increase* the time to new product innovation—in particular, when recalls and innovation overlap in the same product market and recalls are severe, *ceteris paribus*.

H4B: Competitor firm recalls *decrease* the time to new product innovation—in particular, when recalls and innovation overlap in the same product market and recalls are severe, *ceteris paribus*.

EMPIRICAL APPROACH

DATA

We collect data on new product submissions and recalls from FDA medical device databases over 2003-2015. This time period represents the window in which both submission and recall event information are available. Because we test our hypotheses using incremental and major innovation categories separately, we first describe how data on the two types of new product innovations were collected, and then describe recall data. We assign each recall and each new product submission to a standardized firm name based on information included in regulatory filings.[21]

Incremental innovation – We download the complete 510(k) clearance database from the FDA website.[22] Over our study's focal years (2003-2015), there are 16,456 unique 510(k) submissions. The 510(k)

[21] 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. This software is highly flexible, fully parameterized, and effectively deals with foreign names. We undertake additional consistency corrections using a three-person panel of med-tech industry experts.

[22] The Downloadable 510(k) Clearance file (pmn96cur.zip) is available at https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm089428.htm.

database provides detailed information about each product, including a unique 510(k) identification number, the dates of application submission and approval, the submitting firm, and the device's product code.

Major innovation – We download the complete Pre-Market Approval (PMA) database from the FDA website.[23] Over our study's focal years (2003-2015), there are 191 unique PMA submissions. Like the 510(k) database, the PMA database provides detailed information on each device, including a unique PMA identification number, the dates of submission and approval, the applicant firm, and the product code.

Recall Data – We download the complete medical device recall database from the FDA's website.[24] The digitized version of this database includes all medical device recalls over 2003-2015. This database provides detailed information on each recall, including a unique recall event number, the recall classification by severity, the recall date, and the applicant firm associated with the recalled product. We further utilize a digital text-scraping program to identify product information in individual recall reports that is not included in the downloadable data. This product information includes the respective 510(k) or PMA number associated with the product affected by a recall. These data thus allow recalls to be linked directly to specific firms and product codes over time. Consistent with how the FDA categorizes recalls, we treat Class I and II recalls as severe and Class III recalls as not severe.

VARIABLES

The objective of our empirical analysis is to examine how product recalls by focal and competitor med-tech firms, in overlapping and different product areas, and of greater and lesser severity, affect the time to major and incremental innovation activity. All models are estimated from the focal firm

[23] The Downloadable PMA Submission file (pma.zip) is available at https://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/pmaapprovals/default.htm#pma.

[24] Medical Device Recalls Database https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm.

perspective. As in the peer effects literature (Sacerdote 2001 and 2014), data elements are reflexive: that is, when Firm B is the competitor of Firm A, Firm A is the competitor of Firm B. Our empirical setting differs, however, in that we consider dynamic definitions of competitors over time. Specifically, our algorithm requires that for a firm to be counted as a competitor, it must have had either a new product submission or a recall in at least one shared product code within the last five years.[25]

Dependent Variables – The dependent variables measure the time since the last regulatory submission of a new product by a focal firm. For major innovation, this is the time since the focal firm's last PMA submission. For incremental innovation, this is the time since the focal firm's last 510(k) submission. These dependent variables are expressed in elapsed calendar days.

Independent Variables – Table 1 describes the independent variables in detail. We measure the count of recalls at different disaggregation levels in relation to the new product submission: (1) a complete count of all focal firm recalls (F REC) and competitor firm recalls (C REC); (2) recalls that are of the same product code (SPC) and different product code (DPC) relative to a product submission; (3) recalls that are more severe (CL1&2) versus less severe (CL3); and (4) combinations of these features. For example, *F DPC CL3 REC* represents the count of focal firm Class III recalls that occur in a different product code than the submission event analyzed. Our primary analysis uses the count of each category of recalls in the past 24 months prior to the submission event, reflecting the typical development timeline of a med-tech product (Nazarian 2009). For completeness, we also implement a 36-month model in robustness checks. Because these data are skewed, we use the natural log of each of these count measures in our estimations.

Recall data are available in digitized format beginning in 2003. Data availability therefore determines the years and sample sizes used for analyzing innovation behavior following recalls. Because we

[25] We utilize a five-year window because the average product life cycle is roughly three years and the average product development cycle is roughly two years (see Wizemann (2010) and Nazarian (2009)). A five-year window suggests the given firm is not active in a particular product code. Our empirical results are, however, robust to defining active competitors over other windows of time.

use a historical count of product recalls in the most recent 24 months to predict the time to a new product submission, we analyze new product submissions over 2005–2015, inclusive. As a corollary, in robustness tests with models that uses a 36-month lookback period, the sample is limited to the period starting in 2006.

Control Variables – Past research has shown that innovation and recall propensities can be explained in part by firm, product, and time effects (Thirumalai and Sinha 2011; Wowak *et al.* 2014; Shah *et al.* 2017; Ball *et al.* 2017). We therefore include firm, product code and year fixed effects in every model. The incremental innovation analysis includes 243 firm, 1,846 product code, and 10 unique year indicator variables; the major innovation analysis includes 87 firm, 222 product code, and 10 unique year indicator variables.[26] We also control for prior innovation among focal and competitor firms by including counts of each firm's incremental and major new product submissions in the relevant time window (Nerkar and Roberts, 2004).[27]

DESCRIPTIVE STATISTICS

Table 2 provides summary statistics for the variables. The average elapsed time between 510(k) submissions by firms—our measure of incremental innovation—is slightly less than ten months (298 days). Firms with incremental innovations experience slightly less than six focal firm recalls in the past 24 months on average. Competitor 510(k) recall counts are orders of magnitude larger in comparison

[26] Related firm counts for incremental and major innovation are found in Table 3. There are 1,847 product codes in the 510(k) analysis, and 223 product codes in the PMA analysis. All product codes used by the FDA can be found at: https://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/classifyyourdevice/ucm051637.htm. While Table 3 displays 1,318 firms for 510(k), many have too few observations for fixed-effect estimation. We include fixed effects for the top 75 percent of firms by product code count, which represents any firm with more than ten products (thereby representing 244 firms). The remaining small-volume firms are the reference category. Ten-year indicator variables are used because we study innovation from 2005 to 2015 inclusive, or across 11 years.

[27] Submission counts are in relation to the model analyzed; PMA models control for past PMA submissions, and 510(k) models control for past 510(k) submissions. For completeness, these counts are segregated by same and different product codes. While these controls are included in every model, they are not presented in every table.

because they are summed across all competitors. The average elapsed time between PMA submissions—our measure of major innovation—is just under two years (716 days). On average, firms with major innovations experience slightly less than seven focal firm recalls in the past 24 months. Tables A1-A3 in Appendix A provide a detailed breakdown of all recalls by product code and severity and includes their correlations. Table 3 presents the number of recalls, submissions and firms for the 510(k) and PMA analyses, and the total firm-event observations that are included in our regression tables using the empirical methodology described below.

EMPIRICAL METHODOLOGY

Our empirical methodology accounts for the unique characteristics of the industry setting and the research questions. The data consist of all med-tech firms that are active in product submissions and experience product recalls within one or more product codes, although the majority of firms experience multiple submissions and recalls across different product codes over our sample period.

Count-based measures of innovative activity, such as those used in this study, are well-established metrics for quantifying productivity and innovativeness. Scholars in this tradition have used count data in examinations of patenting (Azoulay *et al.* 2015; Li *et al.* 2017), clinical trials (Arora *et al.* 2009; Blume-Kohout and Sood 2013; Chandra *et al.* 2017), and new product approvals (Acemoglu and Linn 2004; Budish *et al.* 2015) to quantify the relationships between product-, firm-, industry- and policy-level factors and subsequent innovation. In many respects, counts of products brought to market and submitted to a regulator for approval represent "clean" measures of successful firm-level innovation, since these efforts are the logical and desired conclusion of the R&D process.[28] In this study, we use

[28] Studies that conversely count patents or patent citations are more focused on early-stage innovative activities in the R&D process (i.e., patents are an input to innovation), and are not necessarily representative of the set of products that ultimately come to market.

a straightforward indicator of innovative activity at the tail-end of the R&D process: the time to submission of a new product to the FDA. By considering new product submissions, we capture med-tech firm behaviors and strategies as they relate to the process of commercializing new products.

Our empirical objective is to examine how product recalls, segregated by source, proximity, and severity, impact incremental and major innovation as measured by the time elapsed between a focal firm's new product submissions to the FDA. We employ survival analysis, in particular AFT models, for the enhanced interpretability of the model estimates. Other commonly used survival models – such as the Cox Proportional Hazard Model – facilitate interpretation of the instantaneous hazard rate of an event occurrence at any point in time. However, an advantage of AFT models is that estimates can be used to examine how changes in the independent variables influence the actual time to an event. In this setting, we are interested in determining how past recalls speed up or slow down innovation activities, making AFT models the most informative. The use of AFT models is also consistent with how other innovation researchers have modeled time-to-event data (Harhoff and Wagner, 2009). In our empirical setting, the AFT model estimates the time to a new product submission for a firm based on factors that change over time. Because the firms in our data experience multiple new product submissions and recalls, we employ a recurrent-event AFT model with an exponential distribution and clustered standard errors at the firm level (Harhoff and Wagner, 2009; Box-Steffensmeier and Jones 2004).[29] The estimation model follows the following generalized equation for AFT models:

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

where t_i is the time between new production 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. In AFT models, a positive (negative) β coefficient signifies an increased (decreased)

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

time to failure, which in our empirical setting translates to a slower (faster) time to new product submission. We also note that in each model, the number of observations (as described in Table 3) is the sum of recalls and submissions observed. In other words, each row of the data is an event – either a recall or a submission – with new product submissions treated as the "failure event" in all models.

EMPIRICAL RESULTS AND DISCUSSION

Interpreting Coefficients

Because our independent variables of interest for each hypothesis are logged counts of recalls in an AFT model, a β coefficient is interpreted as follows: a one percent change in a recall count is associated with a $(0.01 \times (\exp^{\beta}-1)$ multiplicative effect on the time to submission (Harhoff and Wagner, 2009; Stock and Watson, 2012; Wooldridge, 2010). However, because a one percent change in the count of product recalls is highly varied and dependent upon the category and context of recalls, we consider two benchmarks that are likely to be more meaningful for researchers, managers, and policy-makers: first, the effect of a one standard deviation change in recalls on the time to submission; and second, the implied impact of a single recall. These exercises not only show how reasonable levels of variation (e.g., one standard deviation) in our independent variables influence our dependent variables, but also demonstrate how, in certain disaggregated cases, a single product recall can have a significant and deleterious impact on innovation. We present detailed coefficient interpretations in footnote 30 for the first supported hypothesis and replicate the same approach thereafter.

Results

Table 4 presents the AFT model results for incremental innovation (510(k) devices) in models (1)–(4) and major innovation (PMA devices) in models (5)–(8). For each set of results, the first model includes aggregated focal and competitor firm recalls (H1A and H1B); the second model disaggregates recalls by proximity (H2A and H2B); the third model disaggregates recalls by severity (H3A and H3B); and

the fourth model includes recalls disaggregated by *both* proximity and severity (H4A and H4B). All models include product code, firm, and year fixed effects, as well as new product submission counts for the focal firm and competitor firms over the past two years as controls.

We first examine incremental innovation (510(k) submission). Model (1) indicates that focal firm recalls (F REC) significantly increase the time to new product submissions (β=0.13, p=0.000). A one standard deviation increase in F REC is associated with a 148-day delay in a 510(k) submission, and one focal firm recall is associated with a one-week delay in a submission.[30] Competitor-firm recalls (C REC) also have a marginally significant and negative effect on the time to a 510(k) submission (β=-0.06, p=0.045). These results provide strong support for Hypothesis 1A and marginal support for Hypothesis 1B, respectively, as they relate to incremental innovation. Model (2) indicates that product area overlap appears to matter for incremental innovation activity: focal firm recalls are positive and significant (β=0.30, p=0.000) when the product area overlaps (F SPC REC). A one standard deviation increase in F SPC REC is associated with a 578-day delay in a 510(k) submission, and one focal firm recall in the same product code is associated with a 196-day delay. The more proximate the focal firm recall is to the new product submission, the more significant the effect. Competitor firm recalls also have a negative and significant influence on 510(k) submissions (β=-0.05, p=0.012) when the product area overlaps (C SPC REC). A one standard deviation increase in C SPC REC is associated with a 26-day shorter time to submission, and one competitor recall in the same product code is associated with a 0.30-day shorter time to submission. These results provide support for Hypothesis 2A and 2B. Model (3) indicates that the relationship between focal firm recalls and innovation is independent of recall

[30] From Table 2, the mean F REC = 5.74 and the mean 510(k) time is 297.90 days. A one percent change in F REC is .0574, which is associated with a (0.01 x ($\exp^{\beta}$-1) percent change in mean days to submission. The beta coefficient for F REC is 0.13. Hence, 0.01 x ($\exp^{(0.13)}$-1) = 0.00138. We multiply this 0.00138 by the mean number of days to submission to determine the effect of a one percent change in F REC. Therefore, 0.0574 recalls are associated with a 0.41-day delay to submission (297.9 days x 0.00138 = 0.41 days). The standard deviation of F REC is 20.62 from Table 2. We find the effect of a one standard deviation change in F REC 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 the submission delay. This is equivalent to (20.62 recalls/0.0574 recalls) x 0.41 days = 148 days. Finally, to find the effect of just one recall on submission timing, we divide the effect of one standard deviation by the number of recalls in one standard deviation. This is 148 days/20.62 recalls = 7 days per recall.

severity: both F CL1&2 REC (β=0.13, p=0.000) and F CL3 REC (β=0.08, p=0.008 are positive and significant, which fail to support Hypothesis 3A. Competitor firm recalls do appear to be sensitive to recall severity, however, as the relationship between competitor firm recalls and innovation is only significant for more severe recalls (C CL1&2 REC, β=-0.06, p=0.003). A one standard deviation increase in C CL1&2 REC is associated with a 19-day reduction in time to submission, and one severe competitor recall is associated with a 0.12-day reduction. Note that the effects of just one recall for C SPC REC and C CL1&2 REC are small because their means and standard deviations are large (see Table A-3). Interestingly, there is such a difference between competitor firm recalls by severity that the sign of the non-severe Class III competitor recalls becomes positive and significant (C CL3 REC, β=0.09, p=0.000), which indicates further support for Hypothesis 3B, although the sign and the significance of C CL3 REC is unexpected.

Finally, Model (4) disaggregates recalls by severity and proximity and suggests an important difference between how focal firm and competitor firm recalls influence focal firm incremental innovation. Only the SPC – i.e. most proximate – recall measures for the focal firm are statistically significant (F SPC CL1&2 REC, β=0.29, p=0.000 and F SPC CL3 REC, β=0.33, p=0.000) while the DPC focal firm recall measures are not. These results indicate that the relationship between focal firm recalls and incremental innovation is driven by recall proximity and not necessarily by recall severity. The opposite is true, however, when considering competitor firm recalls. Regardless of product area overlap, only the more severe competitor firm recalls significantly decrease the time to submission of incremental innovation by focal firms (C SPC CL1&2 REC, β=-0.06, p=0.003 and C DPC CL1&2 REC, β=-0.08, p=0.008). Though the sign and significance of C DPC CL3 REC is unexpected, this result supports the notion of the contrasting effects of more and less severe competitor recalls on incremental innovation. While neither the focal firm nor competitor firm recall results provide support for Hypotheses 4A or 4A, they do provide some insight into how recalls experienced by firms and their competitors

influence future incremental innovation: one effect is via proximity and another effect is via severity. We explore these results more fully in the discussion section.

We next examine major innovation (PMA submission). In Model (5), we observe that aggregated focal (F REC) and competitor (C REC) recalls have no statistically significant effects on the time to a PMA submission. These results do not support Hypotheses 1A and 1B, as they pertain to major innovation. Model (6) indicates margainal support for Hypotheses 2A (F SPC REC, β=0.49, p=0.091) and strong support for Hypothesis 2B (C SPC REC, β=-0.55, p=0.002), however, in terms of major innovation. A one standard deviation increase in C SPC REC is associated with a 355-day reduction in the time to the next PMA submission, and one competitor recall in the same product code is associated with a 28-day reduction in time to submission. The coefficients for F DPC REC and C DPC REC are not significant. Model (7) provides robust support for Hypotheses 3B but not Hypothesis 3A, indicating that competitor firm recall severity is highly relevant to focal firm major innovation. C CL1&2 REC is a negative and significant predictor (β=-0.45, p=0.012), while C CL3 REC is a positive and significant predictor (β=0.32, p=0.045). A one standard deviation increase in C CL1&2 REC is associated with a 118-day decrease in time to the next PMA submission, while one severe competitor recall is associated with a 10-day decrease. While we did not predict Class III competitor recalls to increase the time to focal firm major innovation, the fact that the signs of the Class I & II and the Class III recalls measures are opposing do lend support to our theorizing that more severe competitor recalls decrease the time to new product innovation more than less severe competitor recalls. Finally, Model (8) provides marginal support for Hypotheses 4A (F SPC CL1&2 REC, β= 0.66, p=0.059) and strong support for Hypothesis 4B (C SPC CL1&2 REC, β=-0.59, p=0.000). A one standard deviation increase in C SPC CL1&2 REC is associated with a 226-day reduction in time to the next PMA submission, and just one severe competitor recall that is in the same product code as the new product submission is associated with a 33-day reduction. This heightened effect of just one recall in this case

is logical, as this is the category of recalls that are proximate and severe, and likely to attract the most attention of competitors. Table 5 provides a summary of the supported, marginally supported, and non-supported hypotheses for incremental and major innovation. It also includes the impact of one standard deviation increase in recalls and one single recall, in either increasing or decreasing the time to submission, for all supported hypotheses. We address all results in detail in the discussion section.

ROBUSTNESS ANALYSES

We next present the results of two robustness checks. First, we demonstrate that the choice of using a 24-month window for counting past recalls does not substantially affect the results. Table 6 provides results using a 36-month window for incremental and major innovation. We observe nearly identical estimates for both incremental and major innovation. The primary difference is that in certain cases where Table 4 provided marginal support for our hypotheses, Table 6 does not. These results indicate that in certain cases, there is a weakening of the relationship between past recalls and future innovation the further back in time recalls are considered.

Second, we demonstrate that our Table 4 findings are not biased by a potential association between past submissions and future recalls. In other words, if past recalls are driven by past innovation efforts, our results would be confounded (Ingram and Baum, 1998). We conduct a reverse causality test using propensity score matching (PSM) model analysis to examine this potential. PSM models use all independent and control variables to predict the propensity for receiving some treatment, and then match observations according to equivalent propensities. Once matched, the model then examines the effect of actually receiving a treatment, compared to not receiving the treatment on an outcome measure. In our setting, we are interested in whether past submissions influence future recalls. We therefore create a treatment indicator variable for whether the med-tech firm experienced a submission in the past 24 months and then match each observation along the propensity to receive this treatment using all other

measures in the analysis (including all firm, product code, and year fixed effects) as predictors of the treatment. After matching, the model estimates how receiving the treatment (in our case, submitting a new product for regulatory approval in the past 24 months) compared to not receiving the treatment (no new product submission in past 24 months) for two comparable observations (which would be expected to otherwise have an equivalent likelihood of receiving the treatment) influences the outcome measure. The outcome measure for this reverse causality test is the likelihood of a recall for the firm-event analyzed. We perform separate analyses for incremental and major innovation. Table 7 indicates that reverse causality does not appear to be driving our results, as the treatment effect is not statistically significant in either case. In other words, after matching observations using factors that predict equal likelihoods of having a new product submission in the past 24 months, *submitting a new product* in the past 24 months does not predict the likelihood of that firm experiencing a recall. These results support the interpretation that recalls are driving subsequent submission behavior; not vice versa.

POST-HOC ANALYSIS

We include two post-hoc analyses in Appendix B. The first analysis investigates alternate measures of innovation. We use "Supplementary PMA" submissions (SPMA), which are used for product or process changes to already approved PMA devices. We find that both competitor and focal firm recalls accelerate SPMA submissions, as we would expect. Please see Table B-1 for these results. We also include an AFT model that explores how the number of competitors may serve as a boundary condition to our results. With regards to incremental innovation, we find that competitor recalls that are proximate and severe reduce the time to a 510(k) submission as the number of competitors in that product code increases. With regards to major innovation, focal firm recalls that are proximate and

severe increase the time to submission, but *only* when there are a larger number of competitors. Further, the accelerating effect of a competitor's severe and proximate recall on focal firm PMA submissions dissipates as the number of competitors increases. Table B-2 includes these results.

DISCUSSION

This study examines how product recalls influence subsequent innovation, and explores how recall source, proximity, and severity shape this relationship. Our results lead to three valuable contributions to the academic literature and two practical implications for med-tech firms and the FDA.

First, we contribute to recall and innovation literature by demonstrating that focal firm recalls increase the time to incremental innovation activity while competitor firm recalls decrease the time to *both* incremental and major innovation activity. 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 uncovering a highly relevant and previously unknown recall ramification: that is, recalls impact future innovation by focal and competitor firms. Further, our findings extend but are distinct from previous innovation studies that explore factors that positively or negatively influence firm innovation incentives (Acemoglu and Linn 2004; Dubois et. al. 2015; Budish et. al. 2015; Carpenter *et al.* 2010; Stern 2017). We find that in the medical device setting, the temporary but often protracted "demand shocks" induced by product recalls can drive responses by competitor firms.

Second, we find that incremental innovation efforts are influenced by focal firm recalls that occur in the same product code and by competitor firm recalls that are severe. Our estimates imply that a single focal firm recall in the same product code can delay subsequent incremental innovation by more than six months; a non-trivial impact on future innovation and revenue. Compared to major innovation projects, incremental innovation is nimbler, lower in cost, and more flexible in timing. It is likely

that such incremental innovation efforts are also more sensitive to focal firm recalls in the same product code, as opposed to more severe recalls elsewhere, because new product development is often specialized and firms are structured by functional expertise. This organizational approach in the med-tech industry has likely led to significant benefits, such as an alignment of goals and a restricted focus on a smaller set of product areas. Our study indicates, however, that there may be a potential downside to this convention. When product failures occur, their resolution taxes functional experts, and subsequently, slows down innovation activities. Further, we also find that incremental innovation efforts are affected more by severe competitor firm recalls as opposed to same product code competitor firm recalls. This finding is both informative and logical when considering the incremental innovation context. The presence of a large number of firms (1,318) across a broad range of product codes (1,847) engaging in incremental innovation indicates a competitive landscape; firms are likely to respond only to those competitor firm recalls that provide the greatest opportunities.[31]

Third, we find that major innovation efforts are only marginally influenced by focal firm recalls but are significantly influenced by competitor firm recalls that are proximate and severe. Compared to incremental innovation, major innovation takes longer, requires dedicated product development teams engaged in expensive clinical trials, and is less nimble and flexible in timing and resource requirements. Our results are consistent with these characteristics: while focal firm recalls do not meaningfully slow down innovation efforts, competitor firm recalls speed them up when recalls are proximate and severe. These results indicate the reluctance that med-tech firms have to retreat on major, long-term product development efforts when product quality problems arise in their current portfolio. However, these efforts can be sped up when the opportunity arises, such as when a competitor is

[31] A firm is also more likely to experience a severe competitor firm recall versus a competitor recall in the same product code In fact, this is what we see in Table A-3 in Appendix A. The average number of total competitor recalls in the same product code (C SPC REC) is 49, while it is 110 for different product codes (C DPC REC). However, the total number of severe recalls is 149 (C CL1&2 REC) while low severe competitor recalls is only 10 (C CL3 REC=10). This means that a firm is much more likely to have a competitor announce a severe recall, than they are to have them announce one in the same product code.

struggling in a narrowly-defined and prominent way. In fact, *just one competitor recall* that is proximate and severe can speed up innovation by one month, estimated to lead to $10MM in additional revenue.[32] These results indicate that there are additional, significant, and (until now) undocumented consequences of recalls in the form of dramatically accelerated rival firm innovation efforts.

Our results also have important implications for firms and, where relevant, their regulators. For firms, this study points to an important relationship between past product failures and future innovation. Recalls not only slow down focal firm innovation efforts, but also simultaneously accelerate competitors' innovation efforts. These results thus highlight additional reasons why firms should seek to avoid product failures in the first place. The temptation to divert resources from innovation activities to help resolve product quality problems is likely strong. However, doing so may simply fix a present problem at the cost of future innovation and subsequent revenue. More concerning perhaps is the fact that product quality issues represent innovation opportunities for rivals. A medical device industry executive stated that there are two actions that he envisioned firms might be able to take in response to our findings. First, it may be beneficial for med-tech firms to create dedicated product recall recovery teams that retain significant and broad product area expertise, helping to insulate new product development engineering and managerial staff from product recall fire-fighting efforts. Second, it may be useful to establish (additional) competitor recall surveillance tools, which could help firms to quickly integrate the learning and market opportunities resulting from recalls and take advantage of opportunities as they emerge. Indeed, we document that rival firms are already pursuing strategic responses to recalls, whether they are doing so in a structured manner or not.

Regulators, such as the FDA, can also extract insights from this study. First, our results point to the importance of the FDA recall classification schema. The severity level associated with a product

[32] https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/the-growth-imperative-for-medical-device-companies

recall appears to have a pivotal and market-wide impact on future innovation efforts. It is thus critical that regulators continue to use great care in assigning recall severity classifications. Further, and perhaps more importantly, it is critical to understand the close link between recall management efforts and new product approval. It may benefit regulators to establish some formalized coordination and information exchange mechanisms between product approval activities and surveillance and compliance activities. In our discussions with senior FDA personnel as a part of this study, we learned that such coordination is limited in practice. Doing so, however, may help regulators better predict the timing and nature of future regulatory submissions in those product codes with quality issues. Knowledge of recent recalls may be separately interesting to regulators so that they ensure that innovator firms are avoiding known challenges with certain types of products.

LIMITATIONS

Certain limitations and caveats related to our empirical setting, variables, and econometric analysis are noteworthy. First, we examine a single industry and its innovation- 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. Second, our primary predictor is recent product recalls, but other dimensions of product failures and other types of negative shocks exist within the med-tech industry. These include non-recall-inducing malfunctions and manufacturing compliance issues. Third, our recall measures are based on source, proximity and severity, and potentially do not capture other relevant recall features that are not necessarily available in our data, such as the degree of media coverage. We nevertheless find that the recall characteristics that we do observe are of substantial importance in predicting the innovation activities of med-tech firms.

CONCLUSION

Product failures such as recalls are challenging for firms, and empirical research has examined both the external market effects and the internal causes or leading indicators of recalls. Despite these contributions, a dearth of research explicitly examines the relationship between product failures and firm innovation. Using over a decade of firm-level FDA data, we addresses this gap by examining the effects of product recalls on subsequent innovation.

Our results are both informative and largely consistent across incremental and major innovation activities. In particular, we provide novel evidence that competitor-firm recalls accelerate incremental and major innovations, shedding new light on firms' strategic responses to their rivals' product failures. Second, proximate and severe recalls appear to lead to more dramatic effects in several contexts, indicating that understanding the nature of a product failure and its relationship to current R&D efforts is crucial for understanding how (and when) recalls impact innovative activity.

Our findings make several contributions to empirical strategy and innovation research. Arguably most importantly, we examine product recalls as a largely overlooked but important determinant of innovative activity by R&D-focused firms. No studies of which we are aware have considered the impact of post-market product failures on subsequent innovation activity by firms and/or their competitors. 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. Firms experiencing product recalls therefore face a host of challenges in the form of both internal disruptions and opportunistic response by competitors. Thus, product failure prevention and remediation activities are likely to be more valuable for managers than previously thought, due to the existence of significant competitor responses.

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Table 1. Independent Variable Descriptions

Source		Proximity		Severity		Proximity and Severity			
		Same Product Code	Different Product Code	More Severe	Less Severe	Same Product Code/More Severe	Same Product Code/Less Severe	Different Product Code/More Severe	Different Product Code/Less Severe
H1A & H1B		H2A & H2B		H3A & H3B		H4A & H4B			
Focal	F REC	F SPC REC	F DPC REC	F CL1&2 REC	F CL3 REC	F SPC CL1&2 REC	F SPC CL3 REC	F DPC CL1&2 REC	F DPC CL3 REC
Competitor	C REC	C SPC REC	C DPC REC	C CL1&2 REC	C CL3 REC	C SPC CL1&2 REC	C SPC CL3 REC	C DPC CL1&2 REC	C DPC CL3 REC

Table 2: Summary Statistics

Focal Firm – 510(k)					Competitor Firm – 510(k)				
VARIABLE	MEAN	ST DEV	MIN	MAX	VARIABLE	MEAN	ST DEV	MIN	MAX
510(k) time	297.90	637.55	1.00	7,256.00					
F REC	5.74	20.62	0.00	198.00	C REC	159.61	254.12	0.00	1,394.00
Focal Firm – PMA					Competitor Firm – PMA				
PMA time	715.59	1,089.78	1.00	7,224.00					
F REC	6.99	8.97	0.00	36.00	C REC	27.57	20.09	0.00	68.00

Table 3. Number of Events

	510(k)	PMA
Recalls	8,676	512
Submissions	16,456	191
Firms	1,318	88[a]
Total firm-event observations	25,132	703

[a] The 88 firms that had PMA submissions are a subset of the 1,318 firms that had 510(k) submissions.

Table 4 – Accelerated Failure Time Models: 510(k) and PMA New Product Submissions

Dependent Variable	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	510(k)				PMA			
F REC	0.13				0.07			
	(0.02)				(0.21)			
C REC	-0.06				-0.42			
	(0.03)				(0.46)			
F SPC REC		0.30				0.49		
		(0.02)				(0.29)		
F DPC REC		0.04				-0.07		
		(0.02)				(0.24)		
C SPC REC		-0.05				-0.55		
		(0.02)				(0.18)		
C DPC REC		0.01				0.20		
		(0.03)				(0.29)		
F CL1&2 REC			0.13				0.23	
			(0.02)				(0.15)	
F CL3 REC			0.08				-0.23	
			(0.03)				(0.27)	
C CL1&2 REC			-0.06				-0.45	
			(0.02)				(0.18)	
C CL3 REC			0.09				0.32	
			(0.02)				(0.16)	
F SPC CL1&2 REC				0.29				0.66
				(0.03)				(0.35)
F DPC CL1&2 REC				0.02				-0.02
				(0.02)				(0.20)
F SPC CL3 REC				0.33				-0.02
				(0.10)				(0.75)
F DPC CL3 REC				0.05				-0.25
				(0.03)				(0.27)
C SPC CL1&2 REC				-0.06				-0.59
				(0.02)				(0.15)
C DPC CL1&2 REC				-0.08				-0.09
				(0.03)				(0.28)
C SPC CL3 REC				0.02				0.31
				(0.02)				(0.28)
C DPC CL3 REC				0.20				0.32
				(0.03)				(0.34)
Observations	25,132	25,132	25,132	25,132	703	703	703	703
Wald Chi^2	52,884	53,570	53,466	53,791	433	497	455	502

All models consider a 24-month time window. Standard errors in parentheses. All models include product code (PC), firm (F) and year (Y) fixed effects as indicated as well as a full set of submission controls. A constant term is included but not shown in all columns.

Table 5. Hypotheses Results and Interpretation

	Model	510(k)	Stdev REC	One REC	PMA	Model	Stdev REC	One REC
H1a	1	S	+148	+7	NS	5		
H1b	1	MS			NS	5		
H2a	2	S	+578	+196	MS	6		
H2b	2	S	-26	-0.30	S	6	-355	-28
H3a	3	NS			NS	7		
H3b	3	S	-19	-0.12	S	7	-118	-10
H4a	4	NS			MS	8		
H4b	4	NS			S	8	-226	-33

S=Support, MS=Marginal Support, NS=No support. Stdev REC is the impact, in days to next submission, of one standard deviation increase in recalls. One REC is same for one recall. "+" indicates more time while "-" indicates less time to submission.

Table 6 – Robustness: Accelerated Failure Time Models: 510(k) and PMA New Product Submissions at 36 Months

Dependent Variable	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
	510(k)				PMA			
F REC	0.13				-0.30			
	(0.03)				(0.46)			
C REC	-0.05				-0.93			
	(0.03)				(0.71)			
F SPC REC		0.29				-0.38		
		(0.02)				(0.24)		
F DPC REC		0.05				-0.13		
		(0.03)				(0.39)		
C SPC REC		-0.07				-0.55		
		(0.02)				(0.22)		
C DPC REC		0.03				-0.17		
		(0.03)				(0.37)		
F CL1&2 REC			0.14				-0.36	
			(0.02)				(0.32)	
F CL3 REC			0.09				0.18	
			(0.04)				(0.25)	
C CL1&2 REC			-0.09				-0.62	
			(0.02)				(0.18)	
C CL3 REC			0.13				0.12	
			(0.02)				(0.23)	
F SPC CL1&2 REC				0.27				-0.35
				(0.02)				(0.28)
F DPC CL1&2 REC				0.03				-0.38
				(0.03)				(0.50)
F SPC CL3 REC				0.36				0.12
				(0.09)				(0.81)
F DPC CL3 REC				0.06				0.21
				(0.05)				(0.19)
C SPC CL1&2 REC				-0.09				-0.68
				(0.02)				(0.19)
C DPC CL1&2 REC				-0.09				-0.33
				(0.03)				(0.35)
C SPC CL3 REC				0.04				0.30
				(0.02)				(0.30)
C DPC CL3 REC				0.24				-0.12
				(0.03)				(0.31)
Observations	23,129	23,129	23,129	23,129	633	633	633	633
Wald Chi^2	47,921	48,733	48,635	48,977	398	449	416	454

All models consider a 36-month time window. Standard errors in parentheses. All models include product code (PC), firm (F) and year (Y) fixed effects as indicated as well as a full set of submission controls. A constant term is included but not shown in all columns. Note that the number of observations decreases in these estimates, as compared to those in Table 4, because we require three years of recall data before analyzing a submission in this model.

Table 7. Robustness Analysis: Propensity Score Matching Model Predicting Recall Likelihood based on Past Submissions

Innovation Category	Treatment group[a]	Control group[b]	Average treatment effect (ATE) on the treated	Standard Error	p-value
PMA	332	128	0.23	0.15	0.14
510k	6,420	2,388	-0.09	0.06	0.13

[a] Firms which had a PMA or 510k submission in the past 2 years respectfully.

[b] Total firm-events analyzed do not equal total firm-events in Table 4 because of the matching process used in PSMATCH2. If outcomes are perfectly predicted, or if matches are not identified, observations are appropriately excluded from the analysis.

Appendix A.
Correlations and Summary Statistics

Table A-1: 510(k) Correlation Statistics

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)	(15)	(16)	(17)	(18)	(19)
(1) F 510(K) TIME	1.00																		
(2) F REC	-0.13	1.00																	
(3) F SPC REC	-0.05	0.56	1.00																
(4) F DPC REC	-0.13	0.99	0.46	1.00															
(5) F CL1&2 REC	-0.13	1.00	0.57	0.99	1.00														
(6) F CL3 REC	-0.11	0.44	0.16	0.45	0.40	1.00													
(7) F SPC CL1&2 REC	-0.05	0.57	1.00	0.46	0.57	0.14	1.00												
(8) F SPC CL3 REC	-0.01	0.07	0.20	0.05	0.06	0.27	0.13	1.00											
(9) F DPC CL1&2 REC	-0.13	0.99	0.45	1.00	0.99	0.46	0.45	0.05	1.00										
(10) F DPC CL3 REC	-0.11	0.45	0.13	0.46	0.40	0.99	0.12	0.11	0.47	1.00									
(11) C REC	-0.15	0.64	0.33	0.64	0.63	0.34	0.33	0.05	0.63	0.35	1.00								
(12) C SPC REC	0.04	0.30	0.27	0.29	0.31	0.09	0.27	0.01	0.29	0.09	0.55	1.00							
(13) C DPC REC	-0.19	0.62	0.28	0.63	0.61	0.36	0.28	0.06	0.62	0.37	0.94	0.23	1.00						
(14) C CL1&2 REC	-0.14	0.64	0.33	0.64	0.63	0.32	0.34	0.05	0.63	0.32	1.00	0.56	0.94	1.00					
(15) C CL3 REC	-0.17	0.40	0.17	0.40	0.38	0.53	0.16	0.12	0.40	0.53	0.60	0.23	0.61	0.56	1.00				
(16) F SPC CL1&2 REC	0.04	0.31	0.27	0.29	0.31	0.08	0.27	0.01	0.29	0.08	0.55	1.00	0.23	0.56	0.20	1.00			
(17) F SPC CL3 REC	-0.01	0.08	0.06	0.07	0.07	0.10	0.06	0.06	0.07	0.10	0.23	0.46	0.08	0.21	0.51	0.41	1.00		
(18) F DPC CL1&2 REC	-0.18	0.62	0.28	0.62	0.61	0.34	0.28	0.05	0.62	0.35	0.94	0.24	1.00	0.94	0.57	0.24	0.07	1.00	
(19) F DPC CL3 REC	-0.19	0.42	0.17	0.43	0.40	0.56	0.16	0.11	0.43	0.56	0.60	0.10	0.66	0.56	0.95	0.09	0.22	0.62	1.00

Table A-2: PMA Correlation Statistics

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)	(15)	(16)	(17)	(18)	(19)
(1) F PMA TIME	1.00																		
(2) F REC	-0.38	1.00																	
(3) F SPC REC	-0.09	0.35	1.00																
(4) F DPC REC	-0.38	0.99	0.24	1.00															
(5) F CL1&2 REC	-0.38	0.99	0.34	0.99	1.00														
(6) F CL3 REC	-0.20	0.52	0.29	0.51	0.41	1.00													
(7) F SPC CL1&2 REC	-0.09	0.35	0.98	0.24	0.34	0.24	1.00												
(8) F SPC CL3 REC	-0.03	0.14	0.46	0.08	0.10	0.34	0.29	1.00											
(9) F DPC CL1&2 REC	-0.39	0.98	0.25	0.99	0.97	0.54	0.25	0.09	1.00										
(10) F DPC CL3 REC	-0.21	0.52	0.22	0.52	0.41	0.98	0.20	0.17	0.55	1.00									
(11) C REC	-0.33	0.50	0.22	0.49	0.49	0.28	0.23	0.06	0.52	0.28	1.00								
(12) C SPC REC	-0.10	0.16	0.13	0.15	0.16	0.11	0.12	0.06	0.18	0.11	0.62	1.00							
(13) C DPC REC	-0.34	0.51	0.18	0.50	0.50	0.27	0.19	0.03	0.51	0.27	0.78	0.00	1.00						
(14) C CL1&2 REC	-0.33	0.51	0.22	0.50	0.51	0.25	0.23	0.05	0.53	0.26	0.99	0.61	0.79	1.00					
(15) C CL3 REC	-0.15	0.14	0.11	0.13	0.10	0.29	0.11	0.08	0.16	0.29	0.51	0.38	0.34	0.39	1.00				
(16) F SPC CL1&2 REC	-0.11	0.17	0.13	0.16	0.16	0.10	0.12	0.06	0.19	0.10	0.62	0.99	0.01	0.62	0.31	1.00			
(17) F SPC CL3 REC	-0.04	0.07	0.08	0.06	0.05	0.14	0.08	0.05	0.08	0.14	0.36	0.62	-0.03	0.27	0.72	0.52	1.00		
(18) F DPC CL1&2 REC	-0.33	0.52	0.18	0.52	0.52	0.24	0.19	0.02	0.53	0.25	0.78	0.00	0.99	0.79	0.25	0.01	-0.05	1.00	

(19) F DPC CL3 REC	-0.18	0.14	0.09	0.13	0.11	0.29	0.08	0.07	0.16	0.29	0.41	0.02	0.51	0.32	0.81	0.00	0.18	0.41	1.00

Table A-3: Summary Statistics

Focal Firm – 510(k) DATA					Competitor Firm – 510(k) DATA				
VARIABLE	MEAN	ST DEV	MIN	MAX	VARIABLE	MEAN	ST DEV	MIN	MAX
510(k) Time	297.90	637.55	1.00	7256.00					
F REC	5.74	20.62	0.00	198.00	C REC	159.61	254.12	0.00	1394.00
F SPC REC	0.53	2.94	0.00	57.00	C SPC REC	49.46	89.67	0.00	661.00
F DPC REC	5.21	19.12	0.00	197.00	C DPC REC	110.15	217.75	0.00	1382.00
F CL1&2 REC	5.45	13.82	0.00	202.00	C CL1&2 REC	149.59	163.97	0.00	1391.00
F CL 3 REC	0.30	1.20	0.00	14.00	C CL 3 REC	10.03	16.09	0.00	108.00
F SPC CL1&2 REC	0.52	2.03	0.00	65.00	C SPC CL1&2 REC	46.63	59.55	0.00	666.00
F SPC CL3 REC	0.02	0.20	0.00	8.00	C SPC CL3 REC	2.83	5.05	0.00	39.00
F DPC CL1&2 REC	4.93	12.78	0.00	201.00	C DPC CL1&2 REC	102.96	139.55	0.00	1374.00
F DPC CL3 REC	0.28	1.16	0.00	14.00	C DPC CL3 REC	7.20	14.20	0.00	106.00
Focal Firm – PMA DATA					Competitor Firm – PMA DATA				
VARIABLE	MEAN	ST DEV	MIN	MAX	VARIABLE	MEAN	ST DEV	MIN	MAX
PMA Time	715.59	1089.78	1.00	7224.00					
F REC	6.99	8.97	0.00	36.00	C REC	27.57	20.09	0.00	68.00
F SPC REC	0.51	1.14	0.00	11.00	C SPC REC	10.61	12.47	0.00	60.00
F DPC REC	6.49	8.64	0.00	36.00	C DPC REC	16.97	15.70	0.00	68.00
F CL1&2 REC	6.47	4.89	0.00	38.00	C CL1&2 REC	25.56	11.67	0.00	71.00
F CL3 REC	0.52	1.25	0.00	6.00	C CL 3 REC	2.01	2.89	0.00	17.00
F SPC CL1&2 REC	0.47	0.68	0.00	13.00	C SPC CL1&2 REC	9.79	6.95	0.00	59.00
F SPC CL3 REC	0.04	0.22	0.00	2.00	C SPC CL3 REC	0.82	1.73	0.00	10.00
F DPC CL1&2 REC	6.00	4.71	0.00	38.00	C DPC CL1&2 REC	15.77	9.22	0.00	71.00
F DPC CL3 REC	0.48	1.19	0.00	6.00	C DPC CL3 REC	1.19	2.03	0.00	16.00

Appendix B.
Post Hoc Analysis. Supplemental PMA submissions

A separate innovation measure that is distinct from incremental (510(k)) and major (PMA) submissions is the "Supplementary PMA" submission (SPMA). SPMAs are used for product or process changes to *already-approved* PMA medical devices. These applications involve significantly reduced data and evidence burdens for regulatory approval because they constitute product improvements and changes rather than new product submissions. Because the focus of our study is new product submissions, we do not include SPMAs in the primary analysis. For completeness, however, we test our model using time to SPMA submission as the dependent variable and using PMA recall counts as the independent variables of interest.

Table B-1 presents the SPMA results. Several interesting conclusions can be drawn from comparing these results in Table B-1 to those in Table 4. First, we note that competitor recalls lead to shorter SPMA submissions times, which are influenced by product area overlap but not severity. Specifically, C REC, C SPC REC, C CL1&2 REC, C CL3 REC, C SPC CL1&2 REC and C SPC CL3 REC are all negative and significant, while none of the C DPC measures are. We also note that focal firm recalls actually *decrease* the time to an SPMA submission, but only for F CL3 REC and F DPC CL3 REC. While the effects are limited to only some focal firm recall categories, they make reasonable sense as SPMA submissions are intended to improve products or fix product problems. It is expected that past PMA recalls would lead to faster SPMA submissions in an effort to fix past problems and – consistent with the Table 4 PMA results – this effect is more prominent for competitor recalls than focal firm recalls. In summary, these findings suggest that firms not only speed up PMA innovation in response to competitor recalls (as seen in Table 4), but also speed up fixes and improvements to already-approved PMA products through SPMA submissions (as seen in Table B-1).

Table B-1. Post-hoc Analysis: Accelerated Failure Time Models: SPMA Submissions

	(1)	(2)	(3)	(4)
Dependent Variable	SPMA			
F REC	-0.02			
	(0.02)			
C REC	-0.19			
	(0.03)			
F SPC REC		-0.01		
		(0.02)		
F DPC REC		0.00		
		(0.02)		
C SPC REC		-0.07		
		(0.02)		
C DPC REC		-0.04		
		(0.03)		
F CL1&2 REC			-0.00	
			(0.01)	
F CL3 REC			-0.04	
			(0.02)	
C CL1&2 REC			-0.05	
			(0.02)	
C CL3 REC			-0.04	
			(0.01)	
F SPC CL1&2 REC				-0.02
				(0.02)
F DPC CL1&2 REC				0.01
				(0.02)
F SPC CL3 REC				0.10
				(0.05)
F DPC CL3 REC				-0.07
				(0.02)
C SPC CL1&2 REC				-0.06
				(0.02)
C DPC CL1&2 REC				-0.03
				(0.03)
C SPC CL3 REC				-0.05
				(0.02)
C DPC CL3 REC				-0.03
				(0.02)
Observations	20,704	20,704	20,704	20,704
Wald Chi^2	26,435	26,411	26,423	26,435

All models consider a 24-month time window. Standard errors in parentheses. All models include product code (PC), firm (F) and year (Y) fixed effects as indicated as well as a full set of submission controls. Controls include SPC and DPC focal and competitor SPMA counts matched to the respective time window. A constant term is included but not shown in all columns. 20,704 observations is comprised of 512 PMA recalls and 20192 SPMA submissions.

Appendix B.
Post Hoc Analysis. Number of Competitors

We include an additional AFT model that examines one possible boundary condition of our primary findings. Columns 4 and 8 of Table 4 – the most comprehensive AFT models for the 510(k) and PMA analyses, respectively – examine how source, proximity, and severity of past recalls influence subsequent submissions. For 510(k) products, severe and localized focal firm recalls increase the time to submission, while competitor firm severe and localized recalls decrease the time to submission. For PMA products, however, only severe and localized competitor firm recalls decrease the time to submission, while localized focal firm recalls appear not to have an influence on the timing of PMA submissions. For this post-hoc analysis, we investigate how the number of competitors in a product code influences these results. For instance, it may be the case that having fewer competitors in a certain market could strengthen these relationships because the withdrawal of one product would represent a relatively larger share of total active firms. To examine this potential boundary condition, we incorporate the number of competitors within the same product code as a moderator in our AFT models. For 510(k) devices (incremental innovation), firms face an average of 23 competitors (i.e. there are an average of 24 products in the same product code), whereas there are an average of just three competitors per product code for PMA devices (major innovation).[33] Table B-2 presents the results of an AFT model that includes this measure (C SPC) as a moderator.

First, we note that C SPC has no main effect in any models in Table 9, indicating that the degree of competition in a product area is not *itself* a statistically significant predictor of innovative activity. Further, the relationship between F SPC CL1&2 REC and 510(k) submissions is not impacted by the number of competitors, as the interaction term is not significant in Model (2) or Model (4). However, the interaction between the count of competitors and the number of proximate and severe recalls is negative and statistically significant in Models (3) and (4), while, the main effect of C SPC CL1&2 REC dissipates in these models, suggesting that the observed main effect of the number of proximate and severe competitor recalls is driven by more crowded product markets. In other words, competitor recalls that are proximate and severe reduce the time to a 510(k) submission as the number of competitors in that product code increases. This is consistent with med-tech firms being particularly eager to rush new products to market in response to recalls in the most competitive product categories.

[33] For 510(k), the number of competitors has a mean of 24, a min of 0, a max of 228, and a standard deviation of 34. For PMA, the number of competitors has a mean of 3, a min of 0, a max of 9, and a standard deviation of 2.

We next move to a similar analysis for PMA submissions. While we did not observe a direct influence of F SPC CL1&2 REC on PMA submissions in Table 4, we now observe a significant interaction effect of this variable with the number of competitors. Focal firm recalls that are proximate and severe increase the time to submission, but *only* when there are a larger number of competitors. This finding suggests that for major innovations firms are particularly cautious about re-entering product markets where they have experienced failures when those markets are more competitive. For major innovation, we also find a significant interaction effect between competitor recalls and the number of competitors. The interaction term is positive and significant, which is opposite in sign to the main effect of C SPC CL1&2 REC on PMA submissions. This finding suggests that the benefits of a PMA submission when a competitor experiences a severe and proximate recall dissipate as the number of competitors increases. Again, the findings here are consistent with firms being particularly cautious in their major innovation activities in markets that are more competitive. But, these findings are in contrast to the findings (Columns 3 and 4 of Table B-2) that firms are, if anything, faster to respond to product failures in more competitive markets when the innovation required is only incremental.

Table B-2. Post-hoc Analysis: Influence of Number of Competitors

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
Dependent Variable	510(k)				PMA			
F SPC CL1&2 REC	0.29	0.36	0.29	0.34	0.66	-0.70	0.75	-0.59
	(0.03)	(0.07)	(0.03)	(0.07)	(0.35)	(0.62)	(0.32)	(0.61)
F DPC CL1&2 REC	0.02	0.10	0.10	0.10	-0.02	-0.03	-0.05	-0.07
	(0.02)	(0.02)	(0.02)	(0.02)	(0.20)	(0.19)	(0.22)	(0.22)
F SPC CL3 REC	0.33	0.37	0.36	0.36	-0.02	-0.16	-0.09	-0.17
	(0.10)	(0.10)	(0.10)	(0.10)	(0.75)	(0.71)	(0.74)	(0.70)
F DPC CL3 REC	0.05	0.08	0.08	0.08	-0.25	-0.29	-0.17	-0.20
	(0.03)	(0.03)	(0.03)	(0.03)	(0.27)	(0.25)	(0.24)	(0.23)
C SPC CL1&2 REC	-0.06	-0.06	0.03	0.02	-0.59	-0.63	-1.02	-1.02
	(0.02)	(0.02)	(0.03)	(0.03)	(0.15)	(0.14)	(0.20)	(0.23)
C DPC CL1&2 REC	-0.08	-0.12	-0.12	-0.12	-0.09	-0.03	0.14	0.19
	(0.03)	(0.03)	(0.03)	(0.03)	(0.28)	(0.33)	(0.32)	(0.35)
C SPC CL3 REC	0.02	0.02	0.02	0.02	0.31	0.35	0.37	0.41
	(0.02)	(0.02)	(0.02)	(0.02)	(0.28)	(0.26)	(0.32)	(0.29)
C DPC CL3 REC	0.20	0.24	0.24	0.24	0.32	0.25	0.33	0.25
	(0.03)	(0.03)	(0.03)	(0.03)	(0.34)	(0.34)	(0.33)	(0.33)
C SPC		-0.05	0.07	0.07		0.01	-0.36	-0.42
		(0.04)	(0.04)	(0.04)		(0.22)	(0.27)	(0.26)
C SPC*F SPC CL1&2 REC		-0.02		-0.01		0.54		0.53
		(0.02)		(0.02)		(0.23)		(0.22)
C SPC*C SPC CL1&2 REC			-0.03	-0.03			0.15	0.15
			(0.01)	(0.01)			(0.06)	(0.06)
Observations	25,132	25,132	25,132	25,132	703	703	703	703
Wald Chi^2	53,791	53,822	53,815	53,823	433	830	829	834

All models consider a 24-month time window. Standard errors in parentheses: $^{+}$ p<0.10, *p<0.05, **p<0.01, ***p<0.001. All models include product code (PC), firm (F) and year (Y) fixed effects as indicated as well as a full set of submission controls. A constant term is included but not shown in all columns. C SPC is the number of competitors in the same product code as the submission analyzed.