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 often result in sales decreases and cost increases 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 product recalls in the U.S. medical device industry. Focal firm recalls slow innovation while competitor firm recalls accelerate innovation. We find that proximity plays a large role in the extent to which recalls impact both focal firms and their competitors: for focal firms, innovation is impacted in a product-specific way, whereas competitor response can be seen among those competitors who are active in both the specifically impacted product as well as adjacent products within the same class. Recall prevention and remediation efforts are thus more important than previously suggested, due to the presence of 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 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 (Wowak *et al.* 2015). Beyond the immediate harm, a number of product failure "second-order effects" present serious managerial challenges as well. For instance, product failures are often publicized and heavily scrutinized events (Jarrell and Peltzman 1985), and they may influence subsequent investments in innovation by both directly-affected focal firms and their indirectly-affected competitors.

An immediate effect of a focal firm product failure is typically a depletion of subsequent sales. For example, if a pharmaceutical product is found unsafe for patient use, its sale and distribution may be reduced or halted completely.[1] Further, product failures can be costly to manage from both public relations and manufacturing perspectives. 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. In this study, we propose that these

[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).

disruptions and resource redirections may also impair innovation efforts at the focal firm: in particular, if the product failure and innovation activity overlap in the same product area or if the product failure is considered severe.

Competitor firm product failures are also likely to have meaningful implications for focal firms. While it is possible that competitor failures may signal risk and thereby facilitate retreat from new product development (Krieger 2017), we contend that this response is unlikely in our context. The extremely high profit margins (in many cases, more than 80 percent gross margin) in medical devices offers a setting in which the risks are often overwhelmed by the potential rewards to innovate, especially when competitors face their own product failures.[2] In such a case, competitors' product failures may 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 may be more likely when competitor product failures occur in product areas in which the focal firm is already active, or when the product failures are severe.

In short, focal firm product failures are likely to demand internal remediation efforts and divert attention 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 United States (U.S.) medical device industry. By leveraging exhaustive recall and new product submission data from the U.S. Food

[2] 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.

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.[3] 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.[4] 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

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

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

efforts: both firms submitted new ICDs for regulatory approval in rapid succession following the Guidant recall.[5]

Moreover, both innovative activity and product recall activity in med-tech 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.[6] 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.

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.[7] 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

[5] See https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/.

[6] https://www.advamed.org/sites/default/files/resource/30_10_11_10_2010_Study_CAgenda_makowerreportfinal.pdf

[7] 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.

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 sufficiently studied.

An additional feature of our empirical setting is the ability to differentiate between different types of innovation. Medical device product development occurs in two primary ways: incremental innovation and major innovation. Incremental innovation is characterized by products that are both less novel and simpler. These present limited patient risks, and require less development time and fewer resources. For example, simple catheters would normally come to market as incremental innovations. Major innovation is characterized by products that are more novel and complex, present more significant patient risks, and typically require substantial costs, resources and time to commercialize (Macher 2006). An implantable cardiovascular device that incorporates previously unused materials would come to market as a major innovation. Because these two types of 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 recalls than incremental innovations. We therefore examine our hypotheses separately using these distinct innovation categories.

We assemble data on all medical device approvals and recalls from 2003-2015[8] and assign all approvals and recalls to a standardized set of firm names and FDA-designated product

[8] 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.

areas. Using novel assignment algorithms, we construct detailed firm- class- and product-level innovation and recall histories that provide precise definitions of the relevant set of competitors for each med-tech firm, in each product, class, and 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 the timing of firms' subsequent incremental and major innovation activities.

Our empirical findings are informative and largely in-line with our hypotheses. With respect to both incremental and innovation, focal firm recalls *slow* subsequent innovation – an effect that is explained primarily by those recalls within the affected product. On the other hand, competitor firm recalls *quicken* the time to incremental innovation – an effect that is seen throughout a class. That is, while focal firm recalls only appear to delay innovation in the affected product, competitors respond to recalls in adjacent products with an active product class. This suggests that competitors are not only responding strategically to recalls, but doing so in a way that is fairly broad when they are already active in R&D within a product class.

We contribute to several research streams in strategy and innovation, as well as research on product recalls. First, the theoretical lens enhances research in new product development (Brown and Eisenhart 1995) by examining a largely overlooked but critically important determinant of innovative activity: product failures and, in particular, product recalls. 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 detailed variable-defining algorithms allow for the dynamic identification of relevant competitors that vary across firms, classes, 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 influence 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.[9] 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, novelty and complexity. Product areas represent device categories and are defined by particular product codes ("products") and regulatory medical specialty areas ("classes"). Same-product devices are effective substitutes, as they serve the same function and are reviewed by the same regulators. Devices within the same class are related by their area of application, which typically maps to business units within manufacturing firms. Figure 1 presents an example of how FDA device classification delineates unique, mutually exclusive device classes and products. Figure 2 presents an example of business unit organization within Medtronic, the world's largest medical device company.

The FDA utilizes two primary regulatory submission pathways: (1) 510(k) Clearance and (2) Pre-Market Approval (PMA).[10] *510(k)s represent incremental innovations*: these products are

[9] 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.

[10] A **510(K)** is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR §807.92(a)(3)) that is not subject to premarket approval (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm). **Premarket approval (PMA)** is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. 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. These products do not undergo any regulatory review process and typically do not represent novel invention or innovation on the part of a manufacturer.

less complex and, by definition, are demonstrably similar to medical devices that have already received FDA approval by the same or another med-tech firm.[11] *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.[12] We therefore examine incremental innovations (510(k) clearances) and major innovations (PMA approvals), 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. 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 recall classifications range from Class I (most severe) to Class II (moderately severe) and 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 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. This study focuses only

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

[12] 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.

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

on Class I and Class II recalls, as these constitute significant risks to patients and significant disruptions to firms.[14]

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.

[14] However, all empirical results presented are robust to the inclusion of Class III recalls (a small share of all 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. In the med-tech setting, management scholars have also studied other determinants of innovation and firm performance (Chatterji 2009, Chatterji and Fabrizio 2016, Wu 2013). As noted above, however, we are not aware of any empirical studies that use product recalls to predict innovation.[15] 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

15 We are aware of just one study in the medical device context that looks at how voluntarily reported adverse events – much less significant negative outcomes than product recalls – may shape subsequent firm innovation activities (Maslach, 2016). However, this study uses data on only one category of medical devices (those that we classify as incremental innovations) and the product "failures" studied are not systematically reported nor, according to regulators, can they be used to establish evidence of product failure (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm).

the focal firm and a positive shock to competitor firms, dependent upon where the recall takes place.

RECALL HYPOTHESES

We first postulate that recall source—as measured by focal firm and competitor firms—influences focal firm innovation, but in opposing directions. We then layer on recall proximity (same vs. different product class and same vs. different product) onto recall source, arguing that our hypothesized relationships strengthen with the degree of overlap between recalled products and firm innovation activities.

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. These studies unsurprisingly 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 suffers. 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.[16] We examine the following hypothesis:

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

Med-tech firms operate in highly competitive markets and are thus keenly aware of the product approvals and failures of their rivals (Porter and Heppelmann 2014; Wu 2013; Thirumalai and Sinha 2011). We suggest that this awareness plays a role in subsequent innovation efforts. 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 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

[16] 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.

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.[17] 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 firm 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.[18] We evaluate the following hypothesis:

H1B: Competitor firm recalls *accelerate* 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, given significant differences across classes and products. As described above, medical devices are assigned by the FDA to distinct product types and product classes (Figure 1) using a standardized set of definitions, which are defined and implemented independently.[19]

Same-product devices serve the same function and are used in similar ways, making them effective substitutes. Devices within the same class are related by their area of application, and,

[17] 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.

[18] 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.

[19] https://www.fda.gov/medical-devices/classify-your-medical-device/device-classification-panels

typically, correspond to a business unit of a firm (see Exhibit 2). Indeed, our detailed review of the top-ten U.S. medical device firms by revenue indicates that each is organized roughly by product class.[20] When a recall occurs for a certain product, technical expertise to assist in recall resolution is likely to originate from workers in the same product and/or product class, drawing upon a common set of resources. This was substantiated via a discussion with a med-tech industry executive, who confirmed that this organizational practice was typical within the industry, suggesting that resolving product failures most directly impacts business units and resources that are most closely-related.[21] Common device classes include cardiovascular devices, radiology devices, and orthopedic devices and it is expected that product recalls will influence innovation differently, depending upon the degree to which a recall is related to a firm's current innovation activities. Relative to products that a firm has in its R&D pipeline, a recall may be a same-product or a different-product recall and may be a same-class or a different-class recall (however, same-product recalls are always, by definition, same-class recalls). Thus, the three possible degrees of proximity from most to least proximate are: (1) same-product, same-class recalls; (3) different-product, same-class recalls; and (3) different-product, different class recalls.

While focal firm recalls within a class and product may have a greater negative influence on new product submissions than those experienced in different classes and/or different products, competitor firm recalls may have the opposite effect: when a competitor issues a recall in a particular product, it signals its weakness in that product market and class, and potentially creates

[20] 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. 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.

[21] Some empirical support for this proposition has also been 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 areas in which recalls occur.

opportunities for others. This is particularly true in well-established products where little uncertainty about the technical viability of the product remains and recalls (which may be issued years or even decades after the establishment of a product type) are device/manufacturer-specific, rather than representative of the underlying viability of a certain product type.[22] A strategic response to competitors' recalls may thus be to accelerate a submission process in the affected product area, for at least two reasons. First, focal firms may seek to capitalize on competitors' market problems.[23] Second, focal firms may update or enhance their own products to highlight differentiation from failed competitors. In both cases, competitor firm recalls would lead to a quickening of innovative activity by the focal firm, especially when those failures occur in the same class and/or 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 *delay* the time to new product innovation—in particular, when recalls and innovation have a greater degree of overlap in the same product market, *ceteris paribus*.

H2B: Competitor firm recalls *accelerate* the time to new product innovation—in particular, when recalls and innovation have a greater degree of overlap in the same product market, *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

[22] This is another feature that distinguishes our setting from Krieger (2018), where a product failure may convey information about the viability of a product type.

[23] This would be expected to be particularly true when there are fewer firms in a given product market and among larger, more nimble multi-product firms, boundary conditions that we test below.

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.[24]

Incremental Innovation – We download the complete 510(k) clearance database from the FDA website.[25] Over our study's focal years (2003-2015), there are 16,456 unique 510(k) submissions. The 510(k) database provides detailed information about each product, including a unique identification number, dates of application submission and approval, submitting firm, and device class and product detail.

Major Innovation – We download the complete Pre-Market Approval (PMA) database from the FDA website.[26] Over our study's focal years (2003-2015), there are 191 unique submissions. Like the 510(k) database, the PMA database provides detailed information on each device, including a unique identification number, dates of submission and approval, applicant firm, and device class and product detail.

Recall Data – We download the complete medical device recall database from the FDA's website.[27] 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 severity classification, the recall date, and the applicant firm associated with

[24] 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.

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

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

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

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 FDA product submission number associated with the product affected by a recall. These data thus allow recalls to be linked directly to specific firms, classes, and products over time.

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 differing severities, affect the time to major and incremental innovation activity. All models are estimated from the focal firm 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 overlapping product within the last five years.[28]

Dependent Variables – The dependent variables measure the time since the last regulatory submission of a new product by a focal firm, with major innovation and incremental innovation measured separately. These dependent variables are expressed in elapsed calendar days.

Independent Variables – Table 1 lists and defines the independent variables in detail. All independent variables are of the form:

$$R_{fcp}$$

[28] 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. Our empirical results are, however, robust to defining active competitors over other windows of time.

where each recall measure, R_{fcp}, is indexed by three exhaustive, mutually exclusive categories:

- firm status, f, where "f" indicates focal or competitor firm
- device class—c, where "c" indicates same or different product class
- product, p, where "p" indicates same or different product code

For example, *R(focal)* measures all recalls experienced by a focal firm, whereas *R(focal, same class, same product)* would include only focal firm recalls that occurred in the same class and same product as a specific new product innovation. 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 the distributions of recall counts are left-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 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 use a 36-month look-back period, the sample starts 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*. 2015; Shah *et al*. 2016; Ball *et al*. 2017). We therefore include firm, product and year fixed effects in our primary models. The incremental innovation analysis includes 243 firm, 1,846 product, 19 class, and ten year indicator variables; the major innovation analysis includes 88 firm,

222 product, 19 class, and ten year indicator variables.[29] We also control for prior innovation activity by focal and competitor firms by including counts of each firm's incremental and major product submissions in the relevant time window (Nerkar and Roberts, 2004).[30]

DESCRIPTIVE STATISTICS

Table 2 provides summary statistics for all recall measures. In the incremental innovation sample, the average elapsed time between submissions by firms is between five and six months (159.7 days). In the incremental innovation sample, firms experienced just over 13 recalls in the past 24 months, on average. Competitor recall counts in this sample (345, on average) are an order of magnitude larger in comparison because they are summed across all competitors. In the major innovation sample, the average elapsed time between submissions is just under two years (641 days). On average in this sample, firms experience slightly more than seven focal firm recalls in the past 24 months, while competitors experience roughly 33 (again here, the larger count reflects the fact that these are summed across all competitors). Table 2 provides summary statistics for all disaggregated recall counts and Tables A1-A2 in the Appendix provide correlation statistics for recall measures by sample.

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

[29] Related firm counts for incremental and major innovation are found in Table 2. There are 1,846 products in the 510(k) analysis, and 222 products in the PMA analysis. All products 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 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. The 88 PMA firms are a subset of the 1,318 510(k) firms.

[30] Submission counts are in relation to the model analyzed (incremental vs. major innovation).

and experience product recalls within one or more products, although the majority of firms experience multiple submissions and recalls across different products over the sample period. Count-based measures of innovative activity, such as those used in this study, are well-established metrics for measuring 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 "cleaner" measures of successful firm-level innovation, since these efforts represent the culmination of the R&D process.[31] In this study, we use 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 efforts and strategies as they relate to the process of commercializing new products.

Our empirical objective is to examine how product recalls, segregated by source and proximity, 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. An advantage of AFT mod-

[31] 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.

els over other survival models, however, is that estimates can be used to examine how independent variable changes influence the actual time to an event. Our use of AFT models is also consistent with how other innovation researchers model 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).[32] 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) 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 2) 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

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

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). Because a one percent change in the count of product recalls is highly varied and dependent upon the category and context of recalls, we instead consider two benchmarks on the time to submission that are likely more meaningful: first, a one standard deviation change in recalls; and second, a single recall. These benchmarks not only show how reasonable levels of variation 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.

Results

Table 3 presents the AFT model results for incremental innovation in models (1)–(3) and major innovation in models (4)–(6). For each set of results, the first model includes aggregated focal and competitor firm recalls (H1A and H1B); the second and third models disaggregate recalls by proximity (H2A and H2B). All models include product, firm, and year fixed effects, as well as new product submission counts by class for the focal firm and competitor firms over the past two years as controls.

We first examine incremental innovation. Model (1) indicates that focal firm recalls, R(focal), significantly increase the time to new product submissions (β=0.179; p=0.000). A one standard deviation increase in R(focal) is associated with a 75.0-day delay in an incremental submission. Competitor-firm recalls, R(competitor), also have a significant and negative effect on the time to an incremental submission (β=-0.245; p=0.000). The results indicate that a one standard deviation in R(competitor) is associated with a 42.4-day acceleration of submission. These

results provide strong support for Hypothesis 1A and Hypothesis 1B, respectively, as they relate to incremental innovation. For major innovation (Model 4), the estimated coefficients are not statistically significant at conventional levels but are of the same magnitude and direction as the results seen for incremental innovation. The small sample size of the major innovation sample makes it difficult to detect effect sizes of these magnitudes.

Models (2) and (3) indicate that recalled product area proximity predicts the speed of subsequent incremental innovation activity: focal firm recalls have a larger positive and highly statistically significant relationship with subsequent submission when the product class overlaps (M2) and even more so when both the product class and the product overlap (M3).

For incremental innovations, a one standard deviation increase in same-class recalls is associated with a 111.5-day delay in an incremental submission, and one focal firm recall in the same product is associated with a 196.9-day delay. In the same models, a one standard deviation increase in same-product competitor recalls is associated with a 12.6-day delay in an incremental submissions.

For major innovations, same-class focal firm recalls do not alone predict subsequent innovation, but same-class, same-product recalls—i.e., the most proximate recalls—a one standard deviation increase in recalls is associated with a 1477-day delay in a major submission, by far the largest effect seen in the data.[33] In this sample, a one standard deviation in competitor recalls in competitor same-class recalls is associated with a 258-day faster time to submission, while a one standard deviation in competitor recalls in the same-class and same-product is associated with a 335-day faster time to submission. These results again suggest that while the effect of an own-

[33] 1477 days are approximately four years. This effect seems quite large, but the standard deviation is roughly four times the mean in this sample, so a one standard deviation increase is quite large. Nevertheless, this value is consistent with the Guidant Corporation recall anecdote included in this paper's introduction.

firm recall is highly localized, competitor response can be seen even when recalls occur in adjacent projects in a class that the competitor operates in. These results provide support for Hypothesis 2A and partial support for Hypothesis 2B.

Table 4 provides a summary of the supported, and non-supported hypotheses for incremental and major innovation. It also includes the impacts of a standard deviation increase in recalls and a one-unit increase in recalls on the time to submission for all supported hypotheses. We address all results in detail in the discussion section.

ROBUSTNESS ANALYSES

We present the results of several robustness tests. First, we demonstrate that the choice of using a 24-month window for counting past recalls does not substantially affect the results. In results not shown, we observe nearly identical estimates for both incremental and major innovation. The primary difference is that in certain cases the results are somewhat less statistically significant. These results indicate that the relationship between past recalls and future innovation weakens the further in time recalls are considered; a relatively intuitive result.

Second, we demonstrate that our results 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 1997). 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 a certain 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 focal

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 as treatment predictors. 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 5 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, and not vice versa.

Third, we show that our main results are robust to controlling for the number of classes in which a firm is active. This accounts for the fact that innovation activity may proceed differently for more focused vs. more broadly-operating firms—even above and beyond the factors already accounted for. Table 6 shows that the key findings are robust to this measure of firm breadth.

POST-HOC ANALYSIS AND MECHANISMS

Table 7 takes the intuition from Table 6 a step further, separating out firms above and below the median count of active product classes. These represent broadly-operating vs. focused firms, respectively. The results indicate that while focal firm recalls are disruptive to both focused and broadly-operating firms, the associated delay in subsequent product submission is greater for

broadly-operating firms. Further, we see that the competitor response is driven almost entirely by broadly-operating firms—i.e. those with the greatest number of active product classes. This likely captures the fact that these are larger firms that are better able to capitalize on market opportunities created by competitor weaknesses in relevant product classes. These results are highly similar when we instead split the samle by the number of products (rather than the number of classes) in which a firm is active (Appendix X).

The next analysis examines another potential mechanism for our results: the number of competitor firms in a product area. Specifically, we investigate whether the number of competitors accentuates or attenuates our main results. Table 8 presents results from models that interact the number of competitors in a given product with the number of recalls that firms and competitors experienced in that product. We find for incremental innovation, and the largest competitor responses are seeing in the markets with fewer competitors, suggesting that competitor response is strongest when the opportunity presented represents a chance to be a key market player.

Future versions of this manuscript will also look for evidence of firm learning. In particular, do firms learn from their own recalls and subsequently commercialize safer products?

DISCUSSION

This study examines how product recalls influence subsequent innovation, and explores how recall source and proximity shape this relationship. Our results suggest 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 slow down incremental innovation activity, while competitor firm recalls accelerate it. With respect to major innovations, we find that more proximate focal and competitor firm recalls impact firm innovation activity in the same ways, however proximity appears to be of particular

importance. Focal firm recalls are most disruptive to subsequent innovation when they are within the same product, however competitor firm recalls appear to create the greatest opportunity for response when they occur in related, but adjacent products in the same product class. These results are bolstered by the fact that the largest responses to competitor failures are seen among multi-class and multi-product firms—i.e. those best positioned to launch a strategic response to a competitor's weakness. 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 but largely understudied recall ramification: that recalls by *both* focal and competitor firms impact future innovation. Further, our findings extend but are distinct from previous innovation studies that explore factors that positively or negatively influence firm innovation incentives in health care product markets (Acemoglu and Linn 2004; Dubois et. al. 2015; Budish et. al. 2015; Carpenter *et al*. 2010; Stern 2017). We find that in the medical device setting, the temporary but often protracted "shocks" induced by product recalls can drive meaningful responses by competitor firms.

Second, we find that incremental innovation efforts are influenced by focal firm recalls that occur in the same product and to a lesser extent those in the same class, and by competitor firm recalls that occur in the same class (both in the same product and adjacent products—these coefficients are not statistically significantly different from one another). Our estimates imply that a single focal firm recall in the same product 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 because new product development is often specialized. This organizational approach in the med-tech industry has likely led to significant benefits, such as a greater alignment of goals and a narrower focus on product areas. Our study indicates, however, that there may be a potential downside to this convention. When product failures occur, their resolution may tax functional experts and slow subsequent innovation activities. We observe that incremental innovation efforts are affected nearly equally by competitor recalls in adjacent products in the same class as well as same-product recalls. This finding is both informative and logical when considering the innovation context. The presence of a large number of firms (1,318) across a broad range of product (1,847) engaging in incremental innovation indicates a competitive landscape. Firms are thus likely to respond only to those competitor shocks that provide the greatest opportunities—indeed, this is what the results that are split firms the numer of conpetitors as well as by firms' general vs. specialized orientation suggest.

Third, we find that major innovation efforts are only influenced by the most proximate focal firm recalls and competitor firm recalls. 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: it is only when a firm is already engaging in R&D activities in a specific product that it can respond strategically to a competitor's failure. In fact, *a single competitor recall* that is proximate and severe can speed up innovation by one month; a window of time estimated to result in roughly $10 million in lost revenue.[34] These results thus indicate that there are additional, significant, and largely undocumented consequences of recalls that emerge in the form of accelerated rival firm innovation efforts.

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

Our results also have important implications for firms and regulators. For firms, this study points to an important "double-whammy" relationship between past product failures and future innovation: recalls not only slow down focal firm innovation, but also accelerate competitors' innovation. 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 and profits.

More concerning perhaps is the fact that product quality issues represent 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. It is critical to understand the close link between recall management efforts and new product approval. It may benefit regulators to establish formalized coordination and information exchange mechanisms between product approval activities and surveillance and compliance activities. In our discus-

sions with senior FDA personnel as a part of this study, we learned that such coordination is limited if not non-existent. Implementing this change may help regulators better predict the timing and nature of future regulatory submissions in those products with quality issues.

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. Many R&D-intensive industries are subject to product failures and recalls, which suggests that our findings likely have broader applicability. Second, our primary predictor is 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 and proximity and potentially do not capture other relevant recall features that are not 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 forward-looking 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 address 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, more proximate 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 innovation.

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 their closest and most nimble 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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Figure 1. Device Classes and Products (Proximity)

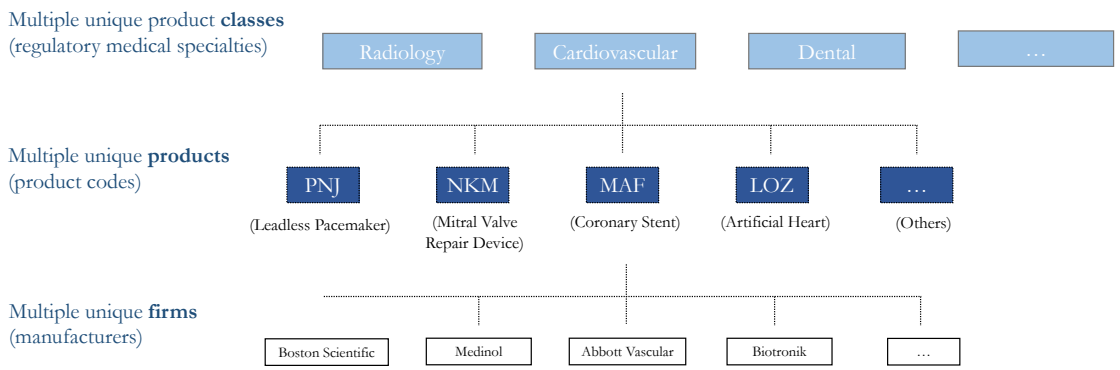

Figure 2: Business unit organization within Medtronic

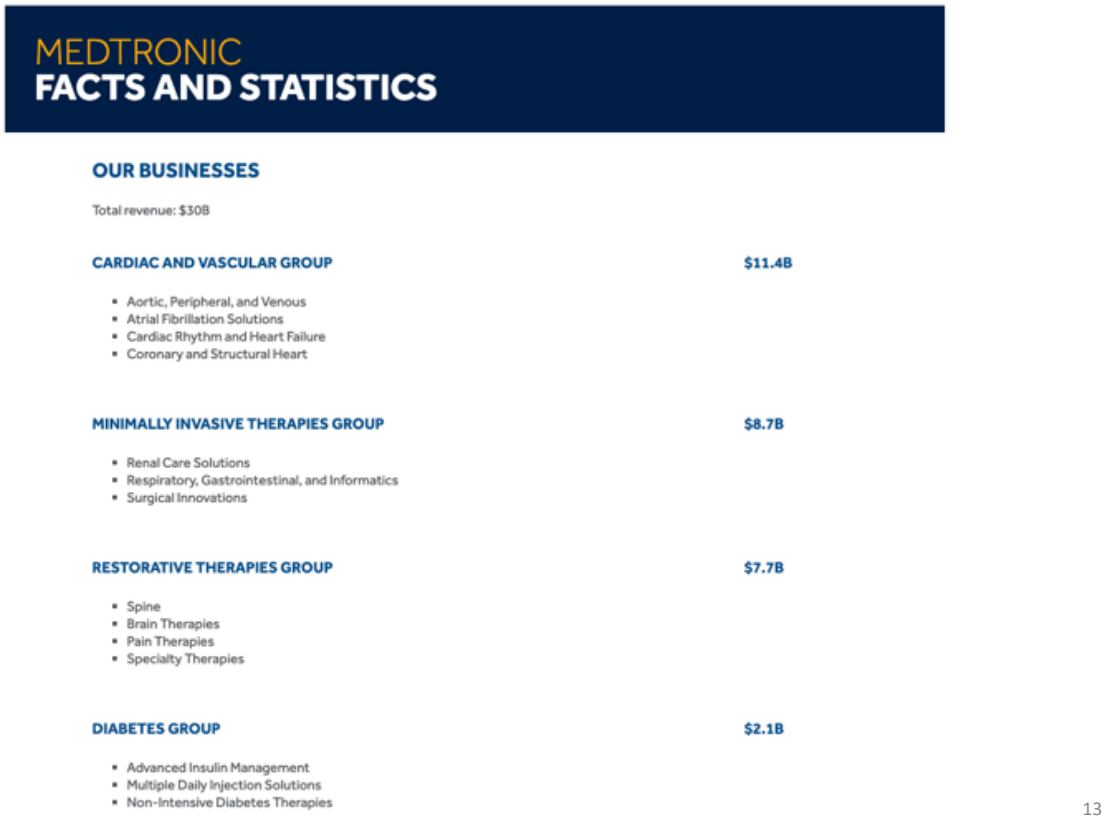

Table 1. Independent Variable Descriptions

Detailed explanations of recall measures

Focal Firm	Recall Measure
R(focal)	Recalls experienced by **focal firm**
R(focal, same class)	...within the same product class
R(focal, different class)	...within a different product class
R(focal, same class, same product)	...within the same product class and the same product
R(focal, same class, different product)	...within the same product class and a different product
R(focal, different class, different product)	...within a different product class and a different product

Competitor Firm	Recall Measure
R(competitor)	Recalls experienced by **competitor firm**
R(competitor, same class)	...within the same product class
R(competitor, different class)	...within a different product class
R(competitor, same class, same product)	...within the same product class and the same product
R(competitor, same class, different product)	...within the same product class and a different product
R(competitor, different class, different product)	...within a different product class and a different product

Table 2: Summary Statistics

VARIABLE	MEAN	ST DEV	MIN	MAX
Incremental Innovation				
Submission time	159.70	443.57	1.00	7023.00
R(focal)	13.36	32.43	0.00	237.00
R(competitor)	345.23	421.54	0.00	2165.00
R(focal, same class)	7.05	20.85	0.00	181.00
R(focal, different class)	6.31	18.13	0.00	229.00
R(competitor, same class)	155.49	190.93	0.00	903.00
R(competitor, different class)	189.74	285.70	0.00	1499.00
R(focal, same class, same product)	1.25	4.99	0.00	72.00
R(focal, same class, different product)	5.80	18.13	0.00	179.00
R(focal, different class, different product)	6.31	18.13	0.00	229.00
R(competitor, same class, same product)	71.34	110.73	0.00	720.00
R(competitor, same class, different product)	84.15	128.15	0.00	871.00
R(competitor, different class, different product)	189.74	285.70	0.00	1499.00
Major Innovation				
Submission time	641.02	1031.88	1.00	7224.00
R(focal)	7.05	8.52	0.00	36.00
R(competitor)	32.85	23.63	0.00	122.00
R(focal, same class)	3.18	4.12	0.00	18.00
R(focal, different class)	3.87	6.03	0.00	36.00
R(competitor, same class)	21.13	17.72	0.00	65.00
R(competitor, different class)	11.72	13.56	0.00	67.00
R(focal, same class, same product)	0.51	1.09	0.00	11.00
R(focal, same class, different product)	2.67	3.88	0.00	18.00
R(focal, different class, different product)	3.87	6.03	0.00	36.00
R(competitor, same class, same product)	10.30	11.56	0.00	56.00
R(competitor, same class, different product)	10.83	12.32	0.00	64.00
R(competitor, different class, different product)	11.72	13.56	0.00	67.00

Table 3. AFT Models: Incremental and Major Submissions (24 Months)

	Time to Incremental Innovation						Time to Major Innovation					
	M1		M2		M3		M4		M5		M6	
R(focal)	0.179***	(0.024)					0.100	(0.239)				
R(competitor)	-0.245***	(0.036)					-0.440	(0.572)				
R(focal, same class)			0.212***	(0.035)					0.264	(0.225)		
R(focal, different class)			0.094**	(0.034)					-0.395	(0.282)		
R(competitor, same class)			-0.045	(0.036)					-0.654**	(0.231)		
R(competitor, different class)			-0.063*	(0.032)					-0.336	(0.234)		
R(focal, same class, same product)					0.268***	(0.038)					0.731*	(0.320)
R(focal, same class, different product)					0.149***	(0.035)					0.037	(0.233)
R(focal, different class, different product)					0.077*	(0.035)					-0.296	(0.291)
R(competitor, same class, same product)					-0.052***	(0.014)					-0.627***	(0.158)
R(competitor, same class, different product)					-0.065***	(0.014)					-0.111	(0.152)
R(competitor, different class, different product)					-0.050	(0.032)					-0.518+	(0.282)
Control variables												
Focal firm, same class count	-0.756***	(0.046)	-0.778***	(0.047)	-0.756***	(0.047)	-0.981*	(0.381)	-1.088**	(0.345)	-1.016**	(0.366)
Focal firm, different class count	-0.518***	(0.033)	-0.530***	(0.032)	-0.520***	(0.032)	-1.299***	(0.264)	-1.420***	(0.233)	-1.250***	(0.211)
Competitor firm, same class count	0.075**	(0.029)	-0.034	(0.043)	0.039	(0.028)	-0.229	(0.336)	-0.010	(0.288)	0.016	(0.213)
Competitor firm, different class count	0.019	(0.012)	0.028	(0.028)	0.021	(0.028)	-0.037	(0.316)	-0.035	(0.291)	-0.081	(0.316)
Product fixed effects	X		X		X		X		X		X	
Firm fixed effects	X		X		X		X		X		X	
Year fixed effects	X		X		X		X		X		X	
Constant	7.358***	(0.682)	7.289***	(0.667)	6.976***	(0.615)	10.680***	(2.125)	12.034***	(1.639)	10.907***	(1.674)
Observations	23524		23524		23524		703		703		703	
Adjusted R-squared												

+ p<0.10, * p<0.05, ** p<0.01, *** p<0.001

Table 4 – Hypotheses Results and Interpretation

	Days to Submission Analysis			
	Incremental		Major	
	One Std Dev Recalls	One Recall	One Std Dev Recalls	One Recall
R(focal)	75.99	2.34	NS	NS
R(competitor)	-42.37	-0.10	NS	NS
R(focal, same class)	111.54	5.35	NS	NS
R(focal, different class)	45.23	2.49	NS	NS
R(competitor, same class)	NS	NS	-258.05	-14.56
R(competitor, different class)	-14.68	-0.05	NS	NS
R(focal, same class, same product)	196.88	39.42	1476.68	1351.42
R(focal, same class, different product)	80.13	4.42	NS	NS
R(focal, different class, different product)	36.73	2.03	NS	NS
R(competitor, same class, same product)	-12.56	-0.11	-335.13	-28.98
R(competitor, same class, different product)	-15.31	-0.12	NS	NS
R(competitor, different class, different product)	NS	NS	NS	NS

Table 5. 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 2 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.

Table 6. Robustness in AFT Models: Incremental and Major Submissions (24 Months), with product class activity controls

	Time to Incremental Innovation						Time to Major Innovation					
	M1		M2		M3		M4		M5		M6	
R(focal)	0.157***	(0.025)					0.044	(0.231)				
R(competitor)	-0.260***	(0.036)					-0.356	(0.584)				
R(focal, same class)			0.213***	(0.032)					0.168	(0.238)		
R(focal, different class)			0.060+	(0.034)					-0.361	(0.288)		
R(competitor, same class)			-0.052	(0.035)					-0.585*	(0.239)		
R(competitor, different class)			-0.069*	(0.031)					-0.343	(0.233)		
R(focal, same class, same product)					0.271***	(0.038)					0.710*	(0.329)
R(focal, same class, different product)					0.150***	(0.033)					-0.027	(0.237)
R(focal, different class, different product)					0.041	(0.035)					-0.281	(0.299)
R(competitor, same class, same product)					-0.052***	(0.014)					-0.589***	(0.176)
R(competitor, same class, different product)					-0.067***	(0.014)					-0.100	(0.159)
R(competitor, different class, different product)					-0.057+	(0.032)					-0.500+	(0.282)
Control variables												
Focal firm, same class count	-0.763***	(0.046)	-0.788***	(0.047)	-0.765***	(0.047)	-1.110**	(0.417)	-1.165**	(0.374)	-1.063**	(0.399)
Focal firm, different class count	-0.604***	(0.037)	-0.596***	(0.037)	-0.588***	(0.038)	-1.258***	(0.282)	-1.390***	(0.252)	-1.238***	(0.225)
Competitor firm, same class count	0.083**	(0.030)	-0.027	(0.043)	0.040	(0.028)	-0.171	(0.354)	0.006	(0.298)	0.026	(0.225)
Competitor firm, different class count	0.015	(0.012)	0.026	(0.028)	0.019	(0.028)	-0.013	(0.308)	0.004	(0.293)	-0.052	(0.322)
Active classes (firm)	0.053***	(0.013)	0.048***	(0.014)	0.050***	(0.014)	-0.353**	(0.133)	-0.265+	(0.154)	-0.157	(0.179)
Product fixed effects	X		X		X		X		X		X	
Firm fixed effects	X		X		X		X		X		X	
Year fixed effects	X		X		X		X		X		X	
Constant	7.323***	(0.650)	7.229***	(0.633)	6.927***	(0.586)	12.132***	(1.905)	13.138***	(1.423)	11.584***	(1.452)
Observations	23524		23524		23524		703		703		703	
Adjusted R-squared												

+ p<0.10, * p<0.05, ** p<0.01, *** p<0.001

Table 7 – Robustness in AFT Models: Incremental and Major Submissions (24 Months), Broad vs. Focused Firms

	Time to Incremental Innovation		Tim to Major Innovation		Time to Incremental Innvation		Time to Major Innovation	
	Focused Firms		Focused Firms		Broadly-operating Firms		Broadly-operating Firms	
	M1		M2		M3		M4	
R(focal, same class, same product)	0.175***	(0.035)	0.910	(0.676)	0.308***	(0.052)	0.144	(0.545)
R(focal, same class, different product)	0.138**	(0.051)	0.378	(0.398)	0.058	(0.036)	-0.224	(0.390)
R(focal, different class, different product)	0.026	(0.060)	0.385	(0.423)	0.067*	(0.033)	0.074	(0.414)
R(competitor, same class, same product)	-0.046+	(0.025)	-0.334	(0.311)	-0.054**	(0.020)	-0.588***	(0.076)
R(competitor, same class, different product)	-0.010	(0.013)	0.064	(0.214)	-0.019	(0.015)	-0.470	(0.524)
R(competitor, different class, different product)	-0.016	(0.030)	-0.064	(0.179)	-0.107	(0.087)	-1.158*	(0.565)
Control variables								
Focal firm, same class count	-1.118***	(0.032)	-1.836***	(0.389)	-0.457***	(0.039)	0.215	(0.529)
Focal firm, different class count	-0.647***	(0.040)	-0.845**	(0.299)	-0.612***	(0.055)	-0.869*	(0.366)
Competitor firm, same class count	0.045	(0.033)	-0.064	(0.368)	0.056	(0.053)	0.165	(0.436)
Competitor firm, different class count	0.025	(0.025)	-0.487+	(0.273)	-0.014	(0.089)	-0.558	(0.594)
Product fixed effects	X		X		X		X	
Firm fixed effects	X		X		X		X	
Year fixed effects	X		X		X		X	
Constant	7.041***	(0.175)	24.533***	(2.318)	7.402***	(1.378)	11.652***	(2.460)
Observations	10503		400		13021		303	
Adjusted R-squared								

+ p<0.10, * p<0.05, ** p<0.01, *** p<0.001

Table 8 – Mechanisms: Incremental and Major Submissions (24 Months) and Competition
(to be inserted)

Appendix A.
Correlations and Summary Statistics

Table A-1: Incremental Innovation Sample Correlation Statistics

	Submission time	R(focal)	R(competitor)	R(focal, same class)	R(focal, different class)	R(competitor, same class)	R(competitor, different class)	R(focal, same class, same product)	R(focal, same class, different product)	R(focal, different class, different product)	R(competitor, same class, same product)	R(competitor, same class, different product)	R(competitor, different class, different product)
Submission time	1.00												
R(focal)	-0.11	1.00											
R(competitor)	-0.15	0.60	1.00										
R(focal, same class)	-0.09	0.86	0.47	1.00									
R(focal, different class)	-0.10	0.80	0.53	0.38	1.00								
R(competitor, same class)	-0.06	0.54	0.82	0.55	0.33	1.00							
R(competitor, different class)	-0.17	0.53	0.93	0.33	0.56	0.55	1.00						
R(focal, same class, same product)	-0.04	0.54	0.29	0.63	0.24	0.38	0.17	1.00					
R(focal, same class, different product)	-0.09	0.84	0.46	0.98	0.37	0.53	0.33	0.45	1.00				
R(focal, different class, different product)	-0.10	0.80	0.53	0.38	1.00	0.33	0.56	0.24	0.37	1.00			
R(competitor, same class, same product)	0.04	0.40	0.49	0.46	0.18	0.76	0.21	0.35	0.44	0.18	1.00		
R(competitor, same class, different product)	-0.12	0.46	0.80	0.42	0.34	0.83	0.63	0.26	0.41	0.34	0.27	1.00	
R(competitor, different class, different product)	-0.17	0.53	0.93	0.33	0.56	0.55	1.00	0.17	0.33	0.56	0.21	0.63	1.00

Table A-2: Major Innovation Sample Correlation Statistics

	Submission time	R(focal)	R(competitor)	R(focal, same class)	R(focal, different class)	R(competitor, same class)	R(competitor, different class)	R(focal, same class, same product)	R(focal, same class, different product)	R(focal, different class, different product)	R(competitor, same class, same product)	R(competitor, same class, different product)	R(competitor, different class, different product)
Submission time	1.00												
R(focal)	-0.36	1.00											
R(competitor)	-0.34	0.56	1.00										
R(focal, same class)	-0.29	0.76	0.54	1.00									
R(focal, different class)	-0.31	0.90	0.43	0.39	1.00								
R(competitor, same class)	-0.19	0.36	0.82	0.51	0.15	1.00							
R(competitor, different class)	-0.33	0.51	0.67	0.27	0.54	0.13	1.00						
R(focal, same class, same product)	-0.07	0.32	0.18	0.34	0.22	0.10	0.18	1.00					
R(focal, same class, different product)	-0.28	0.71	0.52	0.96	0.35	0.52	0.23	0.08	1.00				
R(focal, different class, different product)	-0.31	0.90	0.43	0.39	1.00	0.15	0.54	0.22	0.35	1.00			
R(competitor, same class, same product)	-0.09	0.14	0.46	0.27	0.02	0.72	-0.14	0.11	0.25	0.02	1.00		
R(competitor, same class, different product)	-0.19	0.38	0.75	0.49	0.20	0.76	0.32	0.04	0.51	0.20	0.10	1.00	
R(competitor, different class, different product)	-0.33	0.51	0.67	0.27	0.54	0.13	1.00	0.18	0.23	0.54	-0.14	0.32	1.00