FAILURES AND INNOVATION:

EVIDENCE FROM MEDICAL DEVICE RECALLS*

MAY 2018

George P. Ball
Assistant Professor
Kelley School of Business
Indiana University
gpball@indiana.edu

Jeffrey T. Macher
Professor
McDonough School of Business
Georgetown University
jeffrey.macher@georgetown.edu

Ariel D. Stern
Assistant Professor
Harvard Business School
Harvard University
astern@hbs.edu

Abstract Medical technology firms seek to operate at the frontiers of innovation and new product development. When functioning properly, innovative medical devices can prolong and improve lives; when malfunctioning, these same devices can harm patients, lead to regulatory product recalls, and disrupt manufacturer operations. Medical device firms' innovation efforts are therefore likely affected by product failures. Using 13 years of firm-level FDA data, this paper examines the effects of product recalls on new product approvals. Product recalls vary by source (firm or rival), proximity (product area) and severity (classification); new product approvals vary based on technological sophistication and novelty. Recurrent-event hazard estimation models are used to examine how failures affect major and minor innovation. The empirical results are informative: first, own-firm recalls decrease and rival-firm recalls increase the rate of innovative activity; second, same product area recalls slow innovative activity more than different product area recalls; and third, more severe recalls decelerate innovative activity more than less severe recalls. The results suggest that product failures influence innovation, but these relationships are highly nuanced. The strategic and public policy implications that result are highlighted and discussed.

* The authors thank participants at the Industry Studies Association (ISA) Conference and Society of Institutional and Organizational Economics (SIOE) Conference. We are grateful to Melissa Ouellet for excellent research assistance. Any errors or omissions are our own.

1. INTRODUCTION

Medical device firms–also known as medical technology or "med-tech" firms–operate at the frontier of technological innovation by developing and marketing products that enhance and extend human life. It is estimated that med-tech innovations added approximately five years to life expectancy, cut heart disease fatalities in half, and reduced patient average hospital stays by more than 50 percent among United States (US) patients over 1995-2015.[1] Yet the same devices that can improve and even save lives can also put patients at risk when product safety is compromised. If medical devices are found to be unsafe (for any number of reasons), med-tech firms are required by law to recall those products from the marketplace and correct them.

Because med-tech product recalls are highly-publicized and heavily-scrutinized events, they likely influence subsequent innovation of not only directly-affected firms, but also their unaffected competitors. A focal firm that experiences a product recall might have incentives to innovate in the near-term—e.g., undertaking product modifications and implementing process changes—such that the recalled medical device operates as intended or a *de novo* medical device can be commercialized to take its place. Alternatively, the focal firm may shy away from innovative activities in the short-term to address and correct the root cause of the recall. Competitor firms not directly affected by the product recall might have increased incentives to innovate, given the window of opportunity presented. Alternatively, these rival firms may shy away from innovation—especially in the same product area—if the recall presents substantial risks or uncertainties. In short, recalls create innovation pressures for directly-affected focal firms and simultaneously alter the innovation payoffs for indirectly-affected competitor firms. We explore these phenomena directly by developing theory and providing empirical evidence of how innovative activity—i.e., major and minor product approvals—changes in response to the source, proximity and severity of failures—i.e., product recalls—using the med-tech industry as our empirical setting and public and proprietary data collected from the Food and Drug Administration (FDA).

Anecdotal evidence suggests that product failures and innovative activity are not only important, but also interrelated: Guidant Corporation in 2005 experienced several patient deaths and related de-

[1] See the Healthcare Institute of New Jersey study here.

vice failures that led the med-tech firm to recall many of its top-selling implantable cardioverter defibrillator product lines.[2] Guidant's new product development efforts appear to have been side-tracked following this recall, as its next major innovation in this product space was not submitted to the FDA until six years later; an unusually long gap in med-tech innovation and especially for a large and dominant firm. The main competitors of Guidant—Medtronic and St. Jude Medical—ratcheted up their own innovation efforts, however, as both firms submitted major new medical devices for regulatory approval in this product space and in rapid succession following the Guidant recall.

Furthermore, med-tech industry innovation and failures have both increased in recent years: Over 2000-2015, our FDA data indicate medical device approvals increased by XX percent, while recalls reportedly nearly doubled.[3] In such a challenging and uncertain industry, understanding how product failures such as recalls impact future innovation efforts is of significant value not only to managers and firms, but also to investors, regulators, healthcare institutions, and patients. In addition to delayed patient access, a one-month delay in product approval for major med-tech innovations is purported to cost nearly $1MM in additional product development expenses and to translate into nearly $10MM in lost revenue.[4]

Unpacking the mechanisms by which recalls affect subsequent innovation is nevertheless challenging. First consider recalls that directly affect a *focal* med-tech firm: On the one hand, own-firm recalls may dull subsequent innovation, mainly because internal resources must be redirected to correct these product quality problems. On the other hand, own-firm recalls may stimulate subsequent innovation, especially if product or process corrections can be made or new product introductions can be commercialized to compensate for the lost revenue incurred. Next consider recalls that directly affect a *competitor* med-tech firm but leave the focal firm unaffected: On the one hand, competitor-firm recalls might encourage the focal firm to take a wait-and-see approach, to better understand the potential costs and regulatory risks in that product space, and thereby slow subsequent innovation. On the other hand, competitor-firm recalls might stimulate innovative activity within the focal firm, such that it can more quickly enter the product space, and thereby gain market share (KC et al., 2013; Krieger, 2017). For both focal and competitor firms, therefore, the sign of the relationship between failures and innovation is not entirely self-evident.

---

2 This product recall affected the Prizm, Renewal and Vitality brands. See an Associated Press report here.

3 See a *Wall Street Journal* article here.

4 See a Stanford University study here and a McKinsey Consulting study here.

The extant strategy and innovation research is, somewhat surprisingly, largely silent on whether either scenario exists in theory or in practice. Some innovation-related 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 influence subsequent innovation efforts (Krieger, 2017). Our empirical setting differs from these contributions, however, as 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 considers the determinants of firm performance once technologies are already commercialized (Haunschild and Sullivan, 2002; Baum and Dahlin, 2007; Kim and Miner, 2007), but remains distinct in that we consider own- and competitor-firm failures as predictors of innovation rather than sources of learning around ongoing operational risks.

Despite the limited academic research, the proliferation of for-profit market intelligence data providers—e.g., PharmaProjects and Cortellis Competitive Intelligence™ in biotech and pharmaceuticals and Evaluate MedTech™ in medical devices—suggests a large appetite for understanding these issues in healthcare markets. With this in mind, we seek to answer the following research questions: first, does the source (i.e., own-firm versus competitor-firm) of recalls influence subsequent innovation? Second, does the proximity (i.e., same product area versus different product areas) of recalls influence subsequent innovation? And third, does the severity (i.e., high versus low FDA classification) of recalls influence subsequent innovation?

We take the following steps to examine these research questions empirically: First, we assemble public and proprietary FDA data on all medical device approvals that came to market over 1996-2015 and all product recalls that occur over 2003-2015.[5] Second, we assign all medical devices approvals and recalls to a standardized set of firm names and product markets. Third, we construct detailed firm- and product market-level innovation and recall histories, which provides a precise definition of the relevant set of competitors for each med-tech firm in each product market and over time. Fourth, we incorporate these detailed histories into a recurrent-event accelerated failure time hazard model to

[5] One of the coauthors is a Special Government Employee (SGE) with the Center for Devices and Radiological Health (CDRH) of the FDA. Direct access to proprietary data is provided under confidentiality agreements. Several proprietary recall and submission data fields provide insight into med-tech firms' innovation efforts in a regulatory context. Working closely with the FDA helps to ensure that the data are precise, the research questions are relevant, and the empirical analysis and conclusions are important to both med-tech firms and public policy.

determine how recall source, proximity, and severity affect med-tech firms' subsequent major and minor innovation.

The empirical findings are informative. First, own-firm recalls *decrease* that rate of major innovation activity, but only for recalls and innovation with product market overlap and recalls that classify as high severity. Own-firm recalls also *decelerate* minor innovation efforts, but the effect is broader and persists across different product markets and recall severities. Second, competitor-firm recalls *increase* the rate of major innovation activity, but again only for recalls and innovation that overlap in product market and recalls that classify as high severity. Prior competitor-firm recalls *accelerate* subsequent minor innovations across related and unrelated product spaces, but only when such recalls classify as high severity.

The empirical results contribute to several strategy and innovation research streams. First, our theoretical lens contributes to the new product development literature (several cites here), by examining a largely overlooked but important determinant of innovative activity: product failures. These negative shocks significantly impact firms' subsequent innovation, but the effects are contingent on initiator, product area and severity. Second, the empirical approach adds to product recall research by offering a novel ramification that we translate into future innovation activity. While this research arena has identified several effects of recalls—e.g., increased firm learning (Haunschild and Rhee, 2004), reduced market share (Jarrell and Peltzman, 1985), and lost consumer confidence (Rhee and Haunschild, 2006)—no examinations of which we are aware have associated past failures with future innovation. Third, the empirical methodology contributes to research that explores innovation and competition at a fine-grained level of analysis that changes within and across focal and competitor firms, product markets, and time.

The empirical results also offer implications to regulators and industry practitioners. To regulators, our results demonstrate that within the med-tech industry prior product recalls and subsequently innovative activity are inherently connected. Improved alignment, coordination and information exchange between product approval activities and surveillance and compliance activities by the regulator might provide some benefits. For instance, the underlying quality of new product submissions prior to approval is often difficult to determine *ex-ante* by regulators. The use of recall data might prove informative in these determinations, however, and potentially reduce the rate or incidence of future product failures from these submissions. Given the rather sizeable effects that recall severity has on subsequent innovation efforts, our results also suggest that regulators strive for a reliable, fair and accurate classification system. To industry practitioners, it is perhaps not surprising that own-firm

recalls are problematic for focal firms, given the subsequent disruption to status-quo operations and (temporary) reshuffling of internal resources. But arguably more surprising is how competitor-firm recalls alter innovation for focal firms. In particular, the empirical results clearly document that med-tech firms accelerate innovative efforts precisely in those product markets where their competitors face more—and more severe—recalls. Firms facing product recalls therefore not only face internal challenges in responding to negative shocks, but also face external challenges in incenting the innovative efforts of their rivals. These effects appear most problematic, moreover, within a two- to three-year recall window.

This rest of this paper is organized as follows: Section 2 describes the empirical setting by reviewing the regulatory role of the FDA in both pre-market approval and post-market surveillance. Section 3 provides a literature review of relevant new product innovation, product failure and recall research, and then derives testable hypotheses from this review. Section 4 describes the public and proprietary FDA data assembled, defines the variables constructed for estimation, provides descriptive statistics, and details the empirical approach. Section 5 presents and discusses the empirical baseline and robustness results, addresses potential limitations, and highlights the relevant strategy and policy implications. Section 6 offers concluding comments.

2. EMPIRICAL CONTEXT

The Food and Drug Administration (FDA) is a U.S. government agency that regulates the medical device industry in two primary ways: pre-market gatekeeper and post-market regulator. The FDA first reviews new product submissions to determine whether these devices are safe and effective. Federal statutes make it illegal to market and sell a medical device in the U.S. without first receiving clearance or approval. The FDA then regulates approved products on an ongoing basis to ensure their continued safety and effectiveness. Federal statutes mandate medical devices that "present a risk of injury, gross deception, or are otherwise defective" be corrected or removed from the market.[6]

In its role as pre-market gatekeeper, the FDA assigns medical devices submitted for regulatory approval to product areas based on use and to submission pathways based principally on risk and novelty. Product areas represent generic device types and are defined by particular product codes. Several thousand product codes categorize medical devices, based on the description, use, medical

[6] While all of the recalls in our data are voluntarily-initiated, FDA maintains the legal authority to mandate recalls. It seldom does, however.

specialty, medical review, and other device characteristics. There are three primary submission pathways: (1) Pre-Market Approval (PMA); (2) 510(k) Clearance; and (3) Supplementary Premarket Approval (SPMA).[7] PMA approvals represent major innovations. These pathways require evidence of product safety and effectiveness from clinical trials, due to their complexity and novelty, before approval is granted. 510(k) clearances conversely represent minor innovations. These products are demonstrably similar to medical devices that have already received FDA approval by the same or another med-tech firm.[8] SPMA approvals are distinct from PMAs and 510(k)s as this regulatory approval pathway is not used for new product innovation necessarily, but instead for product or process changes to already approved PMA devices.[9] We therefore examine PMA approvals and 510(k) clearances as respective major and minor innovations, and consider SPMA approvals in a post-hoc manner.

In its role as post-market regulator, the FDA is responsible for ensuring that approved and marketed med-tech products perform in a safe and effective manner and present no unnecessary risk of user (patient) harm. When medical devices do malfunction, med-tech firms and user facilities (e.g., hospitals, physicians' offices, etc.) are required to report this information to the FDA. Product quality complaints are also received by FDA directly from users. These medical device malfunctions are reported and categorized in a centralized database for ongoing monitoring of device performance. 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, Siemsen & Shah, 2018; Macher & Nickerson, 2017). When a pattern of product defects 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 by FDA into three severity categories, ranging from Class I (most severe) to Class III (least severe). Class I recalls are for violative medical device failures that have a reasonable probability of serious adverse health consequences or death. An illustrative example might be a faulty implantable heart valve. Class II recalls are for failures in which the use of or exposure to a violative medical device may cause medically reversible adverse health consequences, such as a malfunctioning hospital bed brake. Class

---

7 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.

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

9 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. SPMAs thus fall somewhere in between major (i.e., PMAs) and minor (i.e., 510(k)s) along an innovation continuum.

III recalls are for situations where the violative medical device is unlikely to cause adverse health consequences, such as a minor labeling error.

3. LITERATURE AND HYPOTHESES

We first review related theoretical and empirical research that examines product recalls and new product innovation—both within and outside the medical device industry. Wen then develop a set of empirically testable hypotheses based on this literature review.

PRODUCT RECALLS

Empirical research on product recalls can be 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 resides in the former category, however, and predominately examines the stock market, market share and customer loyalty effects of recalls. 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. This same relationship is documented by Davidson and Worrell (1992) in a separate study of the automotive industry; by Cheah et al. (2007) in the pharmaceutical industry; and by Chen et al. (2009) in the consumer products industry. Thirumalai and Sinha (2011) alternatively find no stock market effect following recalls in the medical device industry, as investors appear to "bake" future recall expectations into pre-recall share prices. Archer and Wesolowski (1996) similarly determine that product recalls in the automotive industry do not significantly impact customer loyalty. Other empirical research suggests a firm learning component exists around recalls: Haunschild and Rhee (2004) use decades of automotive recall data and find that voluntary recalls lead to fewer future recalls, in comparison to mandatory recalls, and attribute this effect to firm volition. Rhee and Haunschild (2006) examine the impact of organizational reputation on post-recall market share, and find that firms with high-quality reputations suffer more severe market share penalties following a recall than firms with low-quality reputations.

A relatively fewer but growing number of empirical studies examine recall predictors. Thirumalai and Sinha (2011) find that med-tech firms with a higher level of R&D intensity experience a higher number of recalls. Hora et al. (2011) investigate predictors of the time-to-recall in the toy industry and

find, among other things, that design defects are associated with a longer time-to-recall than manufacturing defects. Shah et al. (2016) use a seven-year panel of North American automotive plant and recall data, and find product variety, plant variety and plant overtime are significant predictors of future manufacturing-related recalls. Mukherjee and Sinha (2017) investigate judgement bias by medtech firms in recall decisions and establish a relationship between user feedback and firm recall decisions: user feedback on high-severity product failures leads firms to over-react in other recall decisions (i.e., to recall when not appropriate); user feedback on low-severity failures leads firms to under-react in other recall decisions (i.e., to not recall when appropriate). Ball et al. (2017) study how FDA plant inspections and inspector characteristics influence how predictive FDA inspection outcome scores are of future medical device recalls, and find that the more times an investigator visits the same plant the less predictive their inspection scores are of future recalls.

While the extant literature examines both the extent and causes of recalls, there is a dearth of empirical research that explores the recall and innovation relationship. Thirumalai and Sinha (2011) is the only study of which we are aware, and differs from our study in two principle dimensions: (1) innovative activity is used to predict subsequent recalls; and (2) innovation is operationalized as firm-level R&D intensity (R&D expenses to sales ratio) using Compustat data. In recognition of the tremendous effort involved in responding to product recalls and their very public nature, we instead explore this relationship in the opposite direction and use more disaggregated innovation measures. In particular, we examine how future major and minor innovation efforts are affected by recalls that differ by source (firm or competitor), proximity (same or different product area) and severity classification (low or high). To the best of our knowledge, an exploration of the impact of different types of recalls, in different product areas, and by focal and rival firms has not been considered in the strategy and innovation literatures.

PRODUCT INNOVATION IN HEALTH CARE

A robust literature on the management of innovation in the healthcare sector examines the determinants of innovative firm activity. Empirical studies document how potential market size predicts the amount of innovation in pharmaceutical markets (see, e.g., Acemoglu and Linn, 2004 and DuBois et. al., 2015), or how time-to-market shapes R&D activities and new drug commercializations (Budish, et. al., 2015). In the context of the FDA regulatory approval process, Carpenter et al. (2010) examine time-to-market for new pharmaceutical drug products and Stern (2017) examines these dynamics in

the context of new high-risk medical devices. As noted above, however, no study of which we are aware directly links product recalls to innovation measures.

Count-based measures of innovative activity are well-established metrics for quantifying productivity and innovativeness. Scholars in this tradition have used count data in studies of patenting (Azoulay, et al., 2017; Li et al., 2017), clinical trials (Arora et al., 2009; Blume-Kohout and Sood, 2013), and new products submissions (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, studies using counts of products brought to market and/or submitted to a regulatory body are arguably the cleanest measure of completed firm-level innovation, since these efforts represent the logical and desired conclusion of the R&D process. Studies that conversely count patents or patent citations are arguably more focused on innovative activities earlier 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. In this study, we use the most straightforward measure of innovative activity at the completion of the R&D process: the final submission of a new product to the FDA. By considering new product submissions, we capture med-tech firm behavior and strategies vis-à-vis the process of commercializing new products.

HYPOTHESES

Product recalls represent significant operational disruptions for med-tech firms. Beyond managing the negative influence on public relations and outreach to patients, hospitals and other user facilities, firms must fix shortcomings related to the recalled product(s). Internal resources must be reallocated to address the relevant product quality issues, and managerial effort must be put forth to lead and complete the requisite product/process changes. As one former med-tech industry executive suggests, "[r]ecalls 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 own-firm recalls divert resources and managerial attention away from new product development and toward recalled product corrections and updates. One likely effect of disruptions to operations and diversions to resources is a slowdown in innovative efforts around product submissions. Some research does suggest, however, that product failures represent a more important source of firm learning than product successes. Madsen and Desai (2010) in particular study the orbital launch vehicle industry and find firms learn more effectively from failures than successes:

in particular, knowledge from failures depreciates more slowly than knowledge from successes. While this argument has merit, it does not consider the timeframe with which learning from product failure translates into innovative activity, and subsequently, new product launches. The net effect of own-firm product failures and the subsequent disruptions to managerial and operational activities should therefore be exhibited in a near-term deceleration of innovation related to new product submissions, and thereby, approvals. We examine the following hypothesis:

H1a: More own-firm recalls *decrease* the rate own-firm new product approvals, *ceteris paribus*

Med-tech firms are keenly aware of the product approvals and the product failures of their competitors. We suggest that this awareness plays a major role in subsequent innovation efforts. For instance, when rival firms experience product recalls, focal firms face decisions on whether and how to respond. One possible response is to decelerate or even retreat from innovative activity if competitors experience product failures. If the recalled product(s) present inherent (patient) risk, the focal firm might decide to pause and review its product commercialization plans. Especially if significant product or technological overlap exists between the firm and its recalled rival or if limited recall information is available, slowing innovation might represent the best near-term risk mitigation approach. Boyd et al. (2008) suggest firms delay response to better and more comprehensively understand particular environmental conditions and situations: moving too quickly and waiting too long have negative performance consequences.

Another possible response is to accelerate innovative activity if competitors experience product failures. In other words, firms may proceed with abandon and adjust new product development and commercialization plans dynamically after competitor recalls. Such an approach might allow the firm to enter the market more quickly and subsequently capitalize on the problems of competitors. There is some theoretical support for this approach rooted in the competitive dynamics literature: Ferrier, Smith, Grimm (1999) theorize that moving faster is superior to moving slower when responding to the actions of competitors, and empirically support this argument in Smith et al. (1989). KC et al. (2013) provide further empirical evidence that firms learn more from others' failures than their own failures, as managers are potentially more objective in problem formulation and solution search.

Dutton and Jackson (1987) theorize that firms view the actions of competitors in distinct categories: (1) opportunities and (2) threats. Firm are in general more likely to respond to opportunities and less likely to respond to threats. Applied to our empirical setting, firms may speed up or slow down

market submissions in response to competitors' recalls, depending upon the perceived level of control: more preventable failures (e.g., manufacturing equipment problems) represent opportunities and should accelerate innovation; less preventable failures (e.g., adverse reactions to implantable medical devices) represent threats and should decelerate innovation. We suggest that the former approach dominates in most cases; especially if the reason for the product recall is driven by design or manufacturing activities idiosyncratic to individual med-tech firms as opposed to the overall riskiness of a given product type. Our data show that XX% of recalls have reason codes that suggest within-firm drivers of product recalls (e.g. manufacturing flaws or faulty components) rather than within-product-type drivers of recalls. The net effect of operational disruptions to rival firms due to product failures should therefore be exhibited in an acceleration of innovative activity around new product submissions, and thereby approvals, by the focal firm. We examine the following hypothesis:

H2a: More competitor-firm recalls *increase* the rate of own-firm new product approvals, *ceteris paribus*

It is unlikely that own- and competitor-firm product failures are treated equally, given differences across product areas. As mentioned, medical devices are assigned by the FDA to particular standardized product codes. Devices within a product code serve the same function and are used in similar ways, making them effective substitutes. It is therefore reasonable to assume that product failures influence innovation differently, depending upon whether they occur in the same or different product market.

Given the "localization" of failures to product areas, the internal resources of focal firms are therefore likely affected heterogeneously. One principle reason is organizational: Med-tech firms typically organize as separate divisions (i.e., strategic business units), whereby a given division has some product similarity or technological overlap. A former med-tech industry executive described the cardiac device division of his firm as being organized into discrete teams, with each team focused on a specific product—e.g., pacemakers, stents, and cardiac catheters. Because technical and clinical personnel engaged in development and commercialization activities are typically specialized within a given product area, it is expected that product recalls draw most intently upon the most "relevant" resources. For example, a pacemaker recall would most likely lead to a diversion of internal resources with pacemaker expertise and experience, but would have less of an effect on teams working in other product areas or other divisions of the med-tech firm.

Some empirical support for this proposition is found in the banking industry. Kim and Miner (2007) find organizations can vicariously learn 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. We therefore suggest that the net effect of operational disruptions for the focal firm from failures should be exhibited most profoundly when those recalls occur in the same product market as current innovative activity, in comparison to recalls that occur in different product markets as current innovative activity.

We expect the focal firm to respond strategically through accelerated innovative efforts when rival firms experience product recalls. The "proceed with abandon" approach suggests that focal firms can learn from the failures of their rivals: in short, recognizing the mistakes made and taking corrective actions if and where appropriate. But focal firm responses to rival firm failures are likely to be heterogeneous across the population of product areas. If rival firms failures are in those product areas where the focal firm has current innovative efforts, more rapid new product commercialization approaches may occur in order to displace the affected products and gain market share.

As medical device approvals and recalls are part of the public record, med-tech firms know with certainty the set of products—and thereby, the set of competitors—that they face within and across product areas.[10] Rival firm recalls are therefore likely to lead to an acceleration of innovative activity by the focal firm especially when the rival firm failure occurs in the same product market as current innovation efforts. Given these product market moderating conditions, we examine the following set of hypotheses:

H1b: More own-firm recalls *decrease* the rate of own-firm new product approvals especially when recalls and approvals overlap in the same product market, *ceteris paribus*

H2b: More competitor-firm recalls *increase* the rate of own-firm new product approvals especially when recalls and approvals overlap in the same product market, *ceteris paribus*

It is also unlikely that all own-firm or competitor-firm product failures are treated equally by the focal firm, given differences in severity. As discussed above, the FDA classifies product recalls based

[10] For example, the NIU product code is used for all drug-eluting superficial femoral artery stents. While there may be some product variation within this product code, it is clear that all medical devices in this product code are used in the same *location* (i.e., the superficial femoral artery), for the same *purpose* (i.e., keeping the artery open), and with the same *features* (i.e., coated with a drug to prevent re-clotting). Section 4 presents a detailed description of the approach that we use to define direct product market competitors.

on their severity, ranging from most (Class I) to moderate (Class II) and least (Class III). Class III recalls, by definition, do not cause health problems or injuries, while Class I and Class II recalls are respectably associated with either serious negative or reversible health problems.

More severe own-firm recalls would likely have a more substantial impact on innovative activity, in comparison to less severe own-firm recalls, as they create greater disruption to internal activities. More severe recalls are also more likely to rely upon technical resources, which are often commandeered from their normal innovation activities. Med-tech firms that experience recalls in which patients have some chance of experiencing serious health problems or death are more likely to engage in "all hands on decks" activities to implement correct approaches and solutions as quickly as possible, in comparison to less severe product failures. A McKinsey report that documents the cost of quality in the med-tech industry indicates, moreover, that when problems are severe, significant resources are usually required to properly respond; diluting engineering resources from other critical firm functions (Fuhr, et al., 2013). The R&D resources of the med-tech focal firm are therefore likely to be diverted for the foreseeable future to engage in problem solution search and corrective action, and especially those internal resources where product failures and innovative activity experiences product market overlap.

At the same time, more severe competitor-firm recalls also have to a substantial impact on focal-firm innovative activity, in comparison to less severe competitor-firm recalls, as they arguably offer the greatest opportunities. In particular, if focal firms can learn from the failures of rival firms and implement their own corrective solutions, substantial benefits can accrue. The focal firm may recognize the inherent challenges its proximate product area competitors face in correcting severe recalls, and respond by accelerating innovative and commercialization activity, if and where possible. Given these severity classification moderating conditions, we examine the following set of hypotheses:

H1b: More own-firm recalls *decrease* the rate of own-firm new product approvals especially when recalls and approvals overlap in the same product market and recalls are severe, *ceteris paribus*

H2b: More competitor-firm recalls *increase* the rate of own-firm new product approvals especially when recalls and approvals overlap in the same product market and recalls are severe, *ceteris paribus*

4. EMPIRICAL APPROACH

This section first describes the data collected from the public and proprietary Food and Drug Administration (FDA) databases. It then defines the variables constructed from the data collected, and provides summary and correlation statistics for a subset of these variables. It finally lays out the methodology used in the empirical estimation.

DATA

We collect data on medical device approvals and recalls from several public and proprietary FDA databases over 2003-2015, which represent the years over which submission and recall event information are available and comparable. Since the empirical analyses are at the firm level, the assignment of approvals and recalls to med-tech firm identities is critical. Fortunately, the focal firm associated with each product approval or product recall is included as a text-based variable. Firm names are cleaned and matched using *MatchIT*, a software package that uses multiple methodologies to search for duplicates and grade and score text match quality. This software is highly flexible, fully parameterized, and effectively deals with foreign names. We undertake additional consistency corrections by cross-checking the FDA database names with a Compustat list of all publicly-traded med-tech firms. The approval and recall data are merged based on cleaned firm name matches, and then sorted by event date (and product code). We provide overviews of the 510(k) clearance, PMA approval, product code, and product recall FDA databases.

510(k) Clearances – We download the complete 510(k) clearance (i.e., approvals) database from the FDA website.[11] The digitized version is available over 1996-2016 and yields 70,128 unique observations.[12] Over our sample estimation window (2003-2015), there are 40,535 unique 510(k) clearances. Most 510(k) clearance devices are classified as traditional (n=30,393), followed by special (n=8,612), abbreviated (n=1,528), and dual track (n=2). The 510(k) clearance database provides detailed information, including the unique 510(k) number; the dates of submission and clearance; the submitting firm; the product code (see below); and the regulatory advisory committee that reviewed the clearance.

[11] We downloaded the 510(k) Clearance file (pmn96cur.zip) from this FDA website.

[12] This excludes XX *de novo* devices approved over this period.

PMA Approvals – We download the complete Pre-market Approval (PMA) database from the FDA website.[13] The digitized version provides 33,959 unique observations over 1976-2017: 1,143 original PMA applications and 32,816 supplementary PMA applications (i.e., SPMAs).[14] Over our sample estimation window (2003-2015), there are 20,648 unique PMA events: 401 original PMA applications and 20,247 SPMA applications. We further cross-check the original PMA dataset to ensure that all applications in the Releasable PMA Database are present.[15] The PMA database similarly provides detailed information, including a unique PMA number; the dates of submission and approval; the submitting firm; the product code (see below); and the regulatory advisory committee that reviewed the submission. We examine original PMA approvals in the baseline estimation, as these are considered major innovations. SPMA approvals are important but more follow-on innovations, and accordingly, are relegated to the robustness analysis.

Product Code Data – FDA assigns a specific three-letter code to each approved medical device according to site of use and purpose. FDA maintains a proprietary product code database that includes detailed information on regulatory classification; market submission; creation date (e.g., used to determine age); regulatory medical specialty (i.e., an aggregate product area); and respective indicators of whether the device is implantable, life sustaining, or poses significant risk. We match this product code data to the 510(k) clearance and PMA approval data using the three-letter code. These data mainly serve as controls in our empirical estimation and are described in further detail below.

Recall Data – We download the complete medical device recall data from the FDA website.[16] The digitized version includes medical device recalls over 2003-2015. This database provides detailed information, including a unique recall event number; the recall classification; the recall posting and (if relevant) clearance dates; and the applicant firm associated with the recalled product. We further utilize a digital text-scraping program to identify text in individual recall reports that provide product information not included in the downloadable data. This information includes the respective 510(k) or

[13] We downloaded the PMA Submission file (pma.zip) from this FDA website.

[14] We dropped 10 original PMAs and 3 PMA supplements that did not include device product codes. These devices do not affect our analyses, as they are outside the focal date range of our study.

[15] The original PMA database is available at this FDA website. We manually exported and merged these data with our constructed PMA data to confirm that no submissions are missing.

[16] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm

PMA number—which uniquely identifies a medical device, its manufacturer, and the marketing approval date—associated with a recall; the reason for the recall; and the quantity of devices recalled. These data allow recalls to be linked directly to either 510(k) clearance or PMA submission data.

Several issues that relate to the final data assembled for the empirical analyses are noteworthy: First, we undertake separate empirical analyses for 510(k)s and PMAs, given the notable differences in products, product failures, and innovation between these submission pathways. To be included in a respective sample, however, a med-tech firm must have at least one 510(k) clearance or PMA approval. This constraint ensures that only those med-tech firms with innovation histories are considered, but simultaneously captures all firms that operate across the med-tech innovation spectrum (i.e., from minor to major). Second, separate empirical analysis require that two datasets suitable for estimation be constructed. We merge the FDA 510(k) clearance or PMA approval data with the recall data at the firm and product code levels and then sort by calendar date. These respective merged datasets thus provide event-level histories of product failures and minor and major innovative activity by med-tech firms over long time horizons. Third, the data construction presents certain (and mainly correctable) challenges. Applicant names in the approval data match to owner names in the product recall data with a trivial number of exceptions.[17] A single recall event can lead to multiple product recalls (i.e., a single recall event can affect multiple approved products), so we expand all recall events to firm-level recalls that are unique at the firm, date, and product level. Finally, recalls occur for a subset of approved 510(k) and PMA medical devices, and therefore affect only a subset of firms in the data. Our empirical analysis, however, examines how recalls affect major and minor innovation. Some observations in the respective datasets are therefore dropped from the event history estimation: i.e., those med-tech firms that undertake innovative activity but experience no product failures.

VARIABLES

Our empirical objective is examine how product recalls by focal and rival med-tech firms, in particular product areas, and of different severity classifications affect major and minor innovation. We proceed by constructing dependent and independent variables derived from the two datasets above. To ease explication, we first provide a general overview of the variable construction process prior to particular variable definitions. Variables are created in multiple dimensions: (1) for focal and rival firms, (2) in

[17] In 92 instances, we are unable to match a recall to a firm in the market submission data. These instances represent a small share (0.45%) of total recall events.

identical and different product codes, (3) for different recall classifications, and (4) across distinct time horizons. Firms are matched using the recorded approval and recall firm names. Product code designations define whether own- or competitor-firm events occur in identical or different product areas. Recall classifications define whether own- or competitor-firm recalls are considered most (i.e., class I or II) or least (i.e., class III) severe. The exact calendar dates that market approvals and recall events occur are recorded. Elapsed calendar times are calculated from specific calendar dates (e.g., the time since the last own- or competitor-firm event relative to some other own- or competitor-firm event), and range from a single day to several years. A four-year window, however, is used as an upper-bound to create relevant own- and competitor-firm event counts. In other words, product approvals and recalls must occur within a four-year window to be in the relevant set of own- and competitor-firm events. Separate yearly event counts (between one and five years), however, are created to examine robustness.

Dependent Variables – The dependent variables measure the time since last market approval for focal firms. Two dependent variables are from the PMA database: (1) time since last original PMA approval (*OF PMA TIME*) represents a measure of major innovation; and (2) time since last supplementary PMA approval (*OF SPMA TIME*) represents a measure of moderate innovation. One dependent variable is from the 510(k) database: time since last 510(k) clearance (*OF 510(k) TIME*) represents a measure of minor innovation. These dependent variables are expressed in elapsed calendar days.

Independent Variables – The independent variables measure focal and rival firm events as counts—i.e., the number of 510(k) clearances, PMA approvals or recall issuances over specific time windows. The main independent variables of interest are recall counts by focal and rival firms. *OF REC* represents the number of own-firm recalls that occur across all product codes. These own-firm recall counts are further disaggregated by product code: *OF SPC REC* represents the number of focal firm recalls that occur in the same product code as current market approval activity; *OF DPC REC* represents number of focal firm recalls that occur in all different product codes as current market approval activity.[18] The own-firm SPC and DPC recall counts are further disaggregated by FDA severity classification: i.e., *OF SPC CL*i *REC* (where i ranges 1…3) represent respective counts of focal firm Class I, II and III recalls in the same product code as current market approval activity, and *OF DPC CL*i *REC* represent respective counts of these focal firm recall classifications in all different product codes.

[18] We use the acronyms: SPC for same product codes; and DPC for different product codes.

The competitor-firm recall count variables are constructed in a similar fashion. Competitors represent those rival firms that compete directly against a focal firm in at least one overlapping product area and within a four-year window. But competitor-firm recalls are dependent upon where they occur: (1) in the same product code as the focal firm's current innovative activity (e.g., a rival firm recall and a focal firm submission are in identical product codes); or (2) in a different but overlapping product codes as the focal firm (e.g., a rival firm recall and a focal firm approval are in different product codes but the rival firm recall has product code overlap with other innovative activity by the focal firm). *CF REC* represents the number of rival firm recalls that overlap in product code with the focal firm. Competitor-firm recall counts are similarly first disaggregated by product code: *CF SPC REC* represents the number of rival firm recalls that occur in the same product code as current market approval activity by the focal firm; *CF DPC REC* represents number of rival firm recalls that occur in all different but overlapping product codes as current market approval activity by the focal firm. The competitor-firm product code recall counts are similarly further disaggregated by FDA severity classification: *CF SPC CLi REC* (where *i* ranges I...III) represent respective counts of rival firm recall classifications in the same product code as current market activity activity by the focal firm, and *CF DPC CLi REC* (where *i* ranges 1…3) represent respective counts of rival firm recall classifications in different but overlapping product codes as current market approval activity by the focal firm. We aggregate Class I and Class II recall counts in the empirical estimation, given their similarities to each other but substantive differences with Class III recalls. Recall variables are constructed over n-year windows, where n ranges from one to four inclusive.

Control Variables – Several other variables at different levels are constructed and used principally as controls in the empirical estimations. At the product code level, the (logged) age of the medical device (*MD AGE*) is controlled for by determining the number of years since the medical device was first introduced.[19] Age helps capture any potential differences in "new to the market" (i.e., novel products) versus "newly launched" (i.e., recently introduced) medical devices. Particular medical device characteristics are controlled for using a series of indicator variables: Implantable devices (*MD IMP FLG)* replace a missing biological structure, support a damaged biological structure, or enhance an existing biological structure (e.g., pins, rods, screws, plates); life-sustaining devices (*MD LS FLG*) are considered essential to the restoration or continuation of a bodily function important to the continuation of

[19] CDRH commenced medical device creation date tracking in 1990, with reliable dates to 1988. Medical devices created prior to 1988 are, however, coded with a 1990 creation date meaning *MD Age* is bounded artificially.

human life; and significant risk devices (*MD SR FLG*) are considered of substantial importance in diagnosing, curing, mitigating and treating disease. In some estimations, regulatory medical specialty (RMS) or product code (PC) fixed effects are used. RMS codes are equivalent to broad product categories, and the FDA assigns all product codes into one of 19 distinct RMS categories.[20] Each RMS indicator variable takes the value one if the medical device is that particular RMS classification, and is zero otherwise. As mentioned, PCs are narrowly-defined product categories and number in the thousands. Each PC indicator variable takes the value one if the medical device is that particular PC classification, and is zero otherwise.

At the firm level, we control for the approval activity of both focal and rival firms in different time windows. Counts of the number of own-firm and competitor-firm 510(k) clearances and PMA approvals in the same product code and in different product codes as current own-firm innovation activity are constructed. The own- and competitor-firm clearance and approval count variables are similarly constructed over n-year windows, where n ranges from one to four inclusive. These measures help to control for the scale of focal and rival firm product market activity. Counts of the total number of product codes (*PC SCOPE*) or total number of RMS codes (*RMS SCOPE*) that the focal firm is engaged in over rolling four-year windows are also constructed. These measures help control for the scope of focal firm product market activity. Firm fixed effects are implemented in the PMA estimations.

Finally, we control for changes over time in all estimations using year fixed effects.

DESCRIPTIVE STATISTICS

Table 1 provides summary statistics for the 510(k) clearance and recall data. The average time between 510(k) clearances is less than one year (i.e., 290 days). For these products, average own-firm SPC recalls range from 0.31 to 0.97 over the respective year windows, while average own-firm DPC recalls range from 2.80 to 10.37. Average competitor-firm 510(k) recalls are generally two to three times larger the number of own-firm 510(k) recalls. Class II represent the predominant recall classification type. The average number of own-firm 510(k) clearances in different product codes is substantially larger than the average number in the same product code, which suggests med-tech firms operate

[20] The RMS categories are anesthesiology; cardiovascular; clinical chemistry; clinical toxicology; dental; ear, nose and throat; gastroenterology-urology; general and plastic surgery; general hospital; hematology; immunology; microbiology; neurology; obstetrics and gynecology; ophthalmic; orthopedic; pathology; physical medicine; and radiology.

across a wide product range. Finally, the average number of competitor-firm 510(k) clearances is orders of magnitude larger than own-firm 510(k) clearances, suggesting substantial competition exists in these product markets on average.

Table 2 provides summary statistics for the PMA approval and recall data. The average time between PMA approvals is just under two years (i.e., 720 days). Average own-firm SPC PMA recalls range from 0.26 over one year to 1.16 over five years, while average own-firm DPC PMA recalls range from 3.29 in one year to 14.95 over the year windows. Average competitor-firm PMA recalls—for both same and different product codes—are generally orders of magnitude larger than the number of own-firm recalls across the respective year measures. Class II again represent the predominant recall severity classification. Finally, own- and competitor-firm PMA approvals demonstrate the following general trends: (1) more own- and competitor-firm PMA approvals occur in different product codes than in the same product code; and (2) more competitor-firm PMA approvals occur than own-firm PMA submissions, in the same or in different product codes.

Tables 3 and 4 respectively provide pair-wise correlations for the 510(k) data and the PMA data. Given the large number of variables, a baseline using two-year (24 MON) counts is presented. Table 3 indicates 510(k) clearance times are generally negatively correlated with own-firm recalls: in both same and different product codes. Correlations between 510(k) clearance times and competitor-firm recalls, however, are more nuanced: positive correlations in the same product code but negative correlations in different product codes. Clearance times are not surprisingly negatively correlated with clearance number for 510(k) devices. Finally, Table 3 indicates: (1) positive correlations between own-firm recalls of all types; and (2) positive correlations between own-firm and competitor-firm recalls of all types.

Table 4 indicates PMA submission times are negatively correlated with both own-firm and competitor-firm recalls, regardless of product code category or recall classification. PMA submission times are also negatively correlated with the number of PMA submissions for both focal and rival firms. Table 4 finally indicates: (1) positive correlations between own-firm recalls of all types; and (2) generally positive correlations between own-firm and competitor-firm recalls of all types, except for those of Class I severity.

EMPIRICAL METHODOLOGY

The empirical methodology accounts for the unique characteristics of the empirical setting. The data consist of med-tech firms that receive product approvals and experience product failures over different time windows. To be included in one of the final data samples, a med-tech firm must have respectively incurred a 510(k) clearance or a PMA approval. To be included in the estimation, a med-tech firm must have incurred a product recall. The data indicate, however, that the majority of med-tech firms in each sample experience multiple approvals and multiple recalls. Our empirical objective is to examine how the time between major and minor innovations by med-tech firms is affected by product failures from focal and rival firms, in the same or different product areas, and of different severities—over different time windows. Event history analysis is therefore utilized because such estimation approaches are designed to properly measure time between events via a hazard rate. In our empirical setting, the survival models estimate the hazard of a 510(k) clearance or a PMA approval for med-tech firms based on factors (e.g., focal and rival firm recalls) that change over time.

Within the general class of survival estimation techniques, Cox proportional hazard (CPH) models are most commonly implemented because they do not require specification of the underlying distributional form of the hazard thus making them more flexible and less prone to misspecification (Box-Steffensmeier and Jones 2004). As the med-tech firms in our samples undergo multiple approvals and recalls, we require a more specialized CPH model that can accommodate recurrent events. Two groups of recurrent-event models with different distributional assumptions exist: Shared-frailty models estimate the parametric distribution that accounts for unobserved heterogeneity of multiple events, but are conditional upon the chosen distribution; Variance-corrected models do not impose any distributional assumptions, but are still able to correct for the shared variance of multiple events. We therefore utilize variance-corrected models as our estimation approach, given their greater distributional flexibility.

Three variance-corrected models are most common: Anderson-Gill, Marginal and Conditional Gap Time (Box-Steffensmeier and Jones 2004). The Anderson-Gill and Marginal models both cluster on firms to better control for heterogeneity, but analyze the hazard of an event based on the initial time when a firm enters the data and not on the intermittent time between events. The Conditional Gap Time (CGT) model also clusters on firms to control for heterogeneity, but instead analyzes the hazard of an event based on event types (e.g., approvals and recalls) and allows for time resets based upon specific events. We therefore utilize the CGT model because it better fits our data and research

questions: in particular, the determination of the hazard of one type of an event (e.g., a market approval) following the most recent occurrence of another event (e.g., a product recall). Coefficients are interpreted multiplicatively after exponentiation using the following equation:

$$h(t, X) = h_0(t) \cdot e^{\Sigma \beta X}$$

where $h(t, X)$ represents the hazard of a future event at time *t* conditional on a set of independent and control variables (*X*); $h_0(t)$ represents the baseline hazard rate; and $e^{\Sigma \beta X}$ represent the exponentiated variables. As in all event history models, positive (negative) coefficients signify that hazard—i.e., the risk of a 510(k) clearance or PMA approval by a med-tech firm—is increasing (decreasing).

5. EMPIRICAL RESULTS

This section presents the baseline and robustness estimation results. It then addresses any potential limitations associated with the empirical setting, the data collected, or the estimation methodology. It concludes with a discussion of the main results and the strategy and policy implications that obtain.

BASELINE ANALYSIS

A two-year count window is used for the baseline estimation; all other time windows are relegated to the robustness estimation. Table 5 presents the baseline 510(k) results in Models (1)–(3) and the baseline PMA results in Models (4)–(6). For each set of results: (1) the first model include aggregated own- and competitor-firm recalls; (2) the second model replaces aggregated recalls with disaggregated SPC and DPC recalls; and (3) the third model disaggregates SPC and DPC recalls further by severity classification. Class I and II recall counts are aggregated; Class III recall counts are separate. All models include year and product code fixed effects; PMA models also include firm fixed effects. Standard errors are adjusted for clustering (by med-tech firm).

We first discuss the 510(k) results. Model (1) indicates own-firm recalls decrease the hazard of 510(k) approvals ($p < 0.01$), while competitor-firm recalls increase the hazard of 510(k) approvals ($p < 0.001$). These results provide strong support for Hypothesis 1a and Hypothesis 2a, respectively. Model (2) indicates own-firm SPC and DPC recalls decrease the hazard of 510(k) innovative activity ($p < 0.001$). The own-firm SPC recall coefficient, moreover, is larger in magnitude than the own-firm DPC recall coefficient. These results provide strong support for Hypothesis 1b. Competitor-firm SPC

and DPC recalls increase the hazard of 510(k) innovative activity ($p < 0.001$). Competitor-firm SPC recall coefficients are smaller in magnitude than competitor-firm DPC recall coefficients. These results provide only partial support for Hypothesis 2b. Model (3) indicates own-firm SPC and DPC recalls disaggregated by severity classification each decrease the hazard of 510(k) approvals ($p < 0.001$). Own-firm SPC recall coefficients are again larger in magnitude, in comparison to the own-firm DPC recall coefficients. SPC Class I and II recalls have slightly larger effects on 510(k) innovative activity than SPC Class III recalls. These results provide support for Hypothesis 1c. Competitor-firm SPC and DPC Class I & II recalls increase the hazard of innovative activity ($p < 0.001$); by contrast, competitor-firm DPC Class III recalls have an opposite effect. Competitor-firm SPC recalls are again smaller in magnitude than their equivalent DPC recalls. These results support Hypothesis 2c.

We next discuss the PMA results. Model (4) indicates own- and competitor-firm recalls do not achieve statistical significance regarding the hazard of PMA approvals. These results fail to support Hypotheses 1a and 2a. Model (2) provides two sets of results: first, own-firm SPC recalls decrease the hazard of innovative activity ($p < 0.05$), while own-firm DPC recalls fail to reach statistical significance; and second, competitor-firm SPC and DPC recalls both increase the hazard of PMA approvals ($p < 0.001$), but the DPC recall effect is larger in magnitude than the SPC recall effect. These results support for Hypothesis 1b but do not support Hypothesis 2b. The Model (3) results indicate own-firm SPC recalls in more severe classifications decrease the hazard of PMA innovative activity ($p < 0.05$); all other own-firm recalls fail to reach statistical significance. These results support Hypothesis 1c. The Model (3) results also indicate competitor-firm SPC recalls in more severe classifications increase the hazard of innovative activity ($p < 0.01$); all other competitor-firm recalls fail to reach statistical significance. These results provide support for Hypothesis 2c.

ROBUSTNESS ANALYSIS

We examine the robustness of the empirical results to various time windows, methodological distributional assumptions, control variable inclusions and dependent variables. Table 6 presents empirical results using alternative three- and four-year time windows. The 510(k) results are not robust to (unreported) one-year time windows, but are robust to three- and four-year time windows in terms of magnitudes, direction and statistical significance. Recall coefficient magnitudes generally decrease in longer time windows. The PMA results are similar to the 510(k) results: i.e., limited robustness using (ureported) one-year time windows and general robustness using three- and four-year time windows.

While direction of the coefficients remains, degradations in magnitude and statistical significance obtain in longer time windows. The Table 5 and 6 results overall suggest that the effects of product recalls on both major and minor innovative activity for med-tech firms appear to be concentrated within a two- to three-year window.

The variance-corrected CPH models, and in particular, the Conditional Gap Time (CGT) model that we employ offers distributional flexibility in the estimation approach. We examine other distributional assumptions around the estimation methodology to determine empirical robustness using the weibul, gompertz, of logistic distributions. We can confirm that the results are robust to these alternative distribution assumptions.

The baseline analysis uses own-firm market approval counts as control variables. Depending upon the estimation, these count variables are matched to respective recall measures and time windows. Unreported regression results indicate the following: (1) own-firm SPC and DPC 510(k) clearances decrease the hazard of minor innovation activity; and (2) own-firm SPC PMA approvals decrease the hazard of major innovation activity, while own-firm DPC PMA approvals increase the hazard. The inclusion or exclusion of these own-firm approval count measures, however, do not affect the main variables of interest.

Finally, the baseline analysis uses time between 510(k) clearances and between PMA approvals as dependent variables, which respectively represent minor and major innovative activity by med-tech firms. A separate innovation measure that falls between 510(k) clearances and PMA submissions is Supplementary PMA submissions. SPMAs are for significant product or process changes to already approved PMA medical devices, but with reduced data and evidence burdens required for regulatory approval. Table 7 provides the SPMA results, using a two-year window as a baseline but also providing three- and four-year windows for robustness. Model (1) reports own-firm aggregate recalls decrease the hazard ($p < 0.01$) and competitor-firm aggregate recalls increase the hazard ($p < 0.01$) of SPMA approvals. Model (2) indicates own-firm recalls in different product codes decrease the hazard ($p < 0.05$) of SPMA innovative activity, but other recalls fail to achieve statistical significance. Model (3) indicates own-firm DPC class I and II recalls decrease the hazard ($p < 0.01$), own-firm DPC class III recalls increase the hazard ($p < 0.01$), and competitor firm SPC class III recalls increase the hazard ($p < 0.05$) of SPMA approvals. These results, moreover, generally disappear over longer time windows. Prior recalls therefore appear to affect med-tech firms' major and minor innovative activities to greater extents than innovative activities located somewhere in the middle.

LIMITATIONS

Certain limitations and caveats related to our empirical setting, variables and econometric analysis are noteworthy. First, we examine a single and somewhat idiosyncratic industry, as well as a narrow set of innovation- and recall-related activities. While such focus potentially limits the generalizability of our findings and implications, it simultaneously offers greater precision in our measures and estimation.

Second, our failure measure is based on product recalls. Other dimensions of failures exist within the med-tech industry, however, including malfunctions (at a product level) or manufacturing compliance (at a firm level). Our recall measures are based on source, proximity and severity, and potentially do not capture other important public health features (i.e., size or effect concerns) that relate to recalls. We nevertheless suggest the recall characteristics (i.e., number and severity) that we do measure are of substantial importance to med-tech firms.

Third, our performance measures examine the respective times between 510(k) clearances and between PMA approvals for med-tech firms. These outcomes are determined based upon the universe of medical devices that achieve regulatory approval from FDA after submission and review. We do not observe those medical devices that were submitted and reviewed, but failed to gain approval. Our results therefore capture the set of innovative activities within med-tech firms that achieves market commercialization success, but we nevertheless recognize it likely builds upon the set of innovative activities that do not.

Fourth, our event history approach is useful in that it effectively handles time resets based upon specific and recurrent events. In our approach, we examine whether past recalls affect current innovation efforts. Some concerns might exist as to whether reverse causality is present: in particular, the potential that prior market submission approvals lead to recalls (Thirumalai & Sinha, 2011). We directly test for this potential in unreported hazard model estimations, but find no statistically significant effects of past approvals on the hazard of recalls. We further recognize that other estimation approaches (e.g., sample selection models) might be more usefully employed, but simultaneously require different estimation approaches given event history estimation approach limitations.

DISCUSSION

The baseline results are largely supportive of the proposed hypotheses. Three results are, moreover, generally consistent across the 510(k) clearance and PMA approval activities of med-tech firms. First, own-firm recalls decrease the hazard of these respective minor and major innovative activities, while competitor-firm recalls increase the hazard of these activities. Second, recalls that occur in the same

product code as current innovative activity have larger effects than recalls that occur in different product codes as current innovative activity (except in the competitor-firm 510(k) results). Third, more severe recalls have larger effects than less severe recalls.

For minor med-tech innovation, the results indicate that own-firm recalls overall, by product area disaggregation, and by product area and severity disaggregation operate largely as hypothesized. But the results indicate that competitor-firm recalls have slightly different effects. Competitor-firm recalls in the same product area and in different but overlapping product areas both increase the hazard of 510(k) submissions, but different product areas matter more than same product areas. These results appear to be driven by recall severity: more severe recalls by competitors in product areas that overlap with the focal med-tech firm but are outside of its current innovative activity facilitate the hazard of 510(k) approval, while less severe recalls have the opposite effect. This result might obtain because recall severity (i.e., classification) matters more than recall proximity (i.e., area for minor med-tech innovation. These results remain, moreover, over successively longer time windows.

For major med-tech innovation, the results indicate that both own-firm and competitor-firm recalls by product area disaggregation and by product area and severity disaggregation operate largely as hypothesized. The PMA results do not indicate, however, that all recalls matter: aggregated recalls have limited explanatory power; same product area recalls matter more than different product area recalls; and more severe recalls matter more than less severe recalls. It appears that major innovative activity within med-tech firms is only impacted by those recalls directly related and considered severe.

To provide a more complete understanding of how failures affect med-tech major innovation, we generate Kaplan-Meier survival probability charts based on recall source, proximity and severity. Figure 1 shows the survival probability of PMA submissions based on different own-firm class 1 and 2 recall counts over a 30-day window: (1) none; (2) one; (3) two or (4) three or more. The zero own-firm recall condition represents the baseline, and demonstrates the risk of PMA approval (expressed as 100% – survival probability) increases with the time since the last PMA approval. In comparison, more own-firm severe recalls have a markedly smaller effect on the risk of PMA approval. In short, med-tech firms facing more internal severe product recalls are much slower to innovate than those med-tech firms facing no severe recalls. Figure 2 shows the same survival probability of PMA submissions but based on different competitor-firm class 1 and 2 recall counts. The zero recall condition again represents the baseline, and demonstrates the risk of PMA approval increases with the time since the last PMA approval. However, more severe competitor-firm recalls have a markedly larger effect

on the risk of PMA approval than own-firm recalls. In some competitor-firm recall count classifications that are greater than zero, the risk of PMA approval exceeds its counterpart with zero competitor-firm severe recalls. In short, med-tech firms that witness their competitors facing more severe product recalls are faster to innovate than those med-tech firms whose competitors face no severe recalls.

6. CONCLUSION

Failures such as product recalls are not surprisingly challenging for firms. Empirical research accordingly examines both the external market effects of product recalls and the internal causes or leading indicators of recalls. The former research stream includes examinations of how stock market, market share and customer loyalty outcomes are affected from recalls, while the latter research stream considers how internal and external factors determine or contribute toward recalls. Despite these contributions, a relative dearth of empirical research specifically examines recalls and innovation.

Using 13 years of firm-level FDA data, this paper seeks to contribute to that gap by examining the effects of failures via product recalls on innovation via new product approvals using the medical device industry as the empirical setting. Product recalls are defined in multiple dimensions, including source (firm or rivals), proximity (same or different product areas) and severity (low or high severity classifications). New product approvals vary from minor to major innovative efforts, based on technological sophistication and novelty.

The empirical results are both informative and largely consistent across minor and major innovation activity: First, own-firm recalls decrease the hazard of minor and major innovative activities, while competitor-firm recalls increase the hazard of these activities. Second, recalls that occur in the same product code as current innovative activity have larger effects than recalls that occur in different product codes as current innovative activity especially for major innovation. Third, more severe recalls have larger effects than less severe recalls.

Several contributions based on these empirical findings are made to empirical strategy and innovation research. Arguably most important, we examine a largely overlooked but important determinant of innovative activity in product failures. These negative shocks significantly impact firms' subsequent innovation, but the effects are contingent on initiator, product area and severity. No examinations of which we are aware have associated past failures with future innovation. The empirical setting and

methodology allows us to examine both minor and major innovation at a fine-grained level of analysis within and across focal and competitor firms, product markets, and time.

Implications are also offered to regulators and industry practitioners. Our results suggest that failures and innovation are connected within the med-tech industry, and regulators might benefit from greater coordination and information exchange between product approval activities and surveillance and compliance activities. Our results also suggest that own-firm recalls are a double-edged sword for firms: on the one hand, these recalls create internal challenges in disruptions to operations; on the other hand, these recalls create external challenges in incenting the innovative efforts of rivals.

REFERENCES

Acemoglu, D. and Linn, J., 2004. Market size in innovation: theory and evidence from the pharmaceutical industry. *The Quarterly Journal of Economics*, *119*(3), pp.1049-1090.

Baum, J.A. and Dahlin, K.B., 2007. Aspiration performance and railroads' patterns of learning from train wrecks and crashes. *Organization Science*, *18*(3), pp.368-385.

Bromiley, P & Marcus, A. (1989). The deterrent to dubious corporate behavior: Profitability, probability and safety recalls. *Strategic Management Journal, 10*(3), 233-250.

Budish, E., Roin, B.N. and Williams, H., 2015. Do firms underinvest in long-term research? Evidence from cancer clinical trials. *The American economic review*, *105*(7), pp.2044-2085.

Carpenter, D.P., Moffitt, S.I., Moore, C.D., Rynbrandt, R.T., Ting, M.M., Yohai, I., Zucker, E.J., 2010. Early entrant protection in approval regulation: theory and evidence from FDA drug review. *J. Law Econ. Org.* 26 (3), 515–545.

Cheah, E. T., Chan, W. L., & Chieng, C. L. L. (2007). The corporate social responsibility of pharmaceutical product recalls: An empirical examination of US and UK markets. *Journal of Business Ethics, 76*(4), 427-449.

Chen, Y., Ganesan, S., & Liu, Y. (2009). Does a firm's product-recall strategy affect its financial value? An examination of strategic alternatives during product-harm crises. *Journal of Marketing, 73*(6), 214-226.

Davidson, W. N., & Worrell, D. L. (1992). Research notes and communications: The effect of product recall announcements on shareholder wealth. *Strategic Management Journal, 13*(6), 467-473.

Dubois, P., De Mouzon, O., Scott-Morton, F. and Seabright, P., 2015. Market size and pharmaceutical innovation. *The RAND Journal of Economics*, *46*(4), pp.844-871.

Fuhr, George, Pai https://www.mckinsey.com/~/media/McKinsey/dotcom/client_service/Public%20Sector/Regulatory%20excellence/The_business_case_for_medical_device_quality.ashx

Haunschild, P.R. and Sullivan, B.N., 2002. Learning from complexity: Effects of prior accidents and incidents on airlines' learning. Administrative science quarterly, 47(4), pp.609-643.

Hora, M., Bapuji, H., & Roth, A. V. (2011). Safety hazard and time to recall: The role of recall strategy, product defect type, and supply chain player in the US toy industry. *Journal of Operations Management, 29*(7), 766-777.

Jarrell, G., & Peltzman, S. (1985). The impact of product recalls on the wealth of sellers. *The Journal of Political Economy, 93*(3), 512-536.

Krieger, J. (2017). Trials and Terminations: Learning from Competitors' R&D Failures. *MIT Sloan School of Management Working Paper,* (March 20, 2017).

Mukherjee, U. K., & Sinha, K. K. (2017). Product Recall Decisions in Medical Device Supply Chains: A Big Data Analytic Approach to Evaluating Judgment Bias. Forthcoming, *Production and Operations Management.*

Nanda, R. and Rhodes-Kropf, M., 2016. Financing risk and innovation. *Management Science*, *63*(4), pp.901-918.

Rhee, M., & Haunschild, P. R. (2006). The liability of good reputation: A study of product recalls in the US automobile industry. *Organization Science*, *17*(1), 101-117.

Shah, R., Ball, G. P., & Netessine, S. (2016). Plant operations and product recalls in the automotive industry: An empirical investigation. Forthcoming, *Management Science.*

Stern, A.D., 2017. Innovation under regulatory uncertainty: Evidence from medical technology. *Journal of Public Economics*, *145*, pp.181-200.

Thirumalai, S., & Sinha, K. K. (2011). Product recalls in the medical device industry: An empirical exploration of the sources and financial consequences. *Management Science, 57*(2), 376-392.

Figure 1: PMA Approval Risk with Own-Firm Class 1 & 2 Recalls

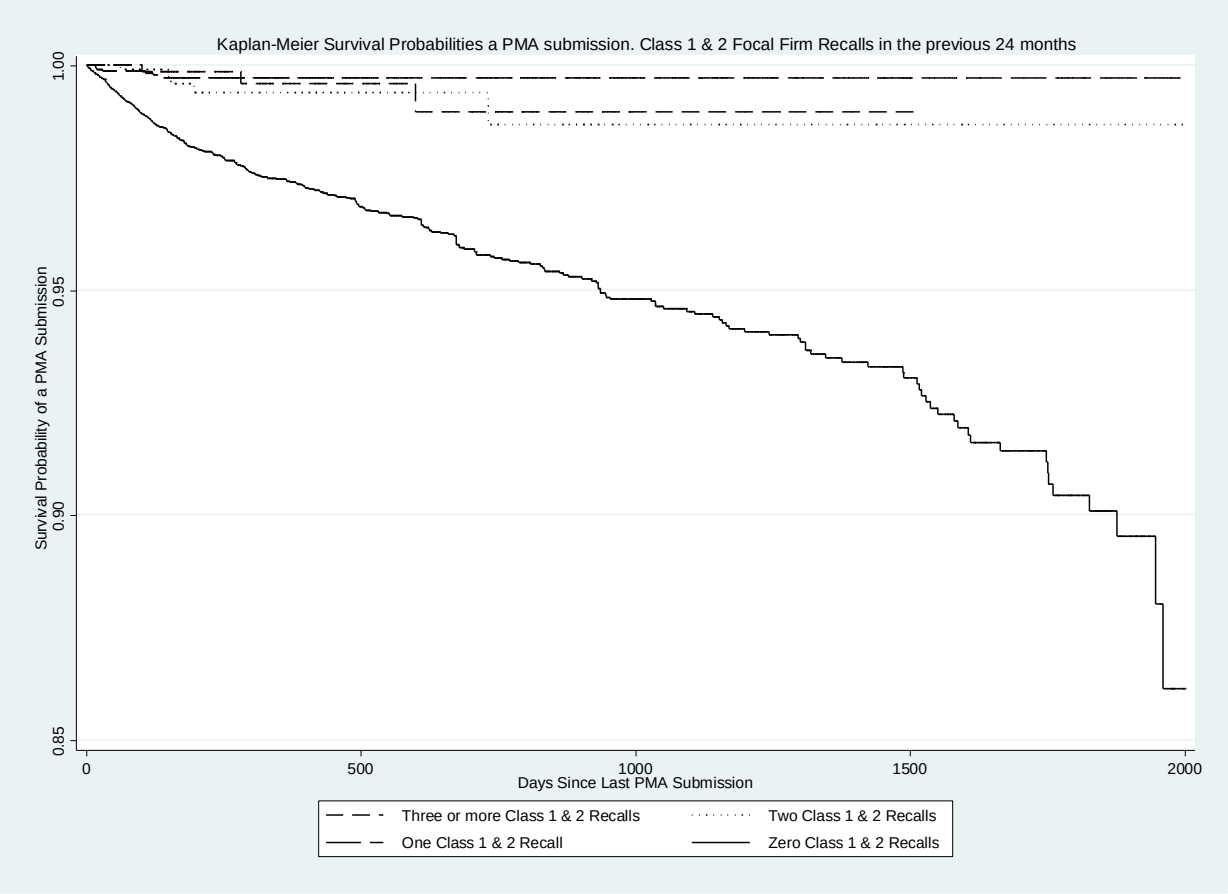

Figure 2: PMA Approval Risk with Rival-Firm Class 1 & 2 Recalls

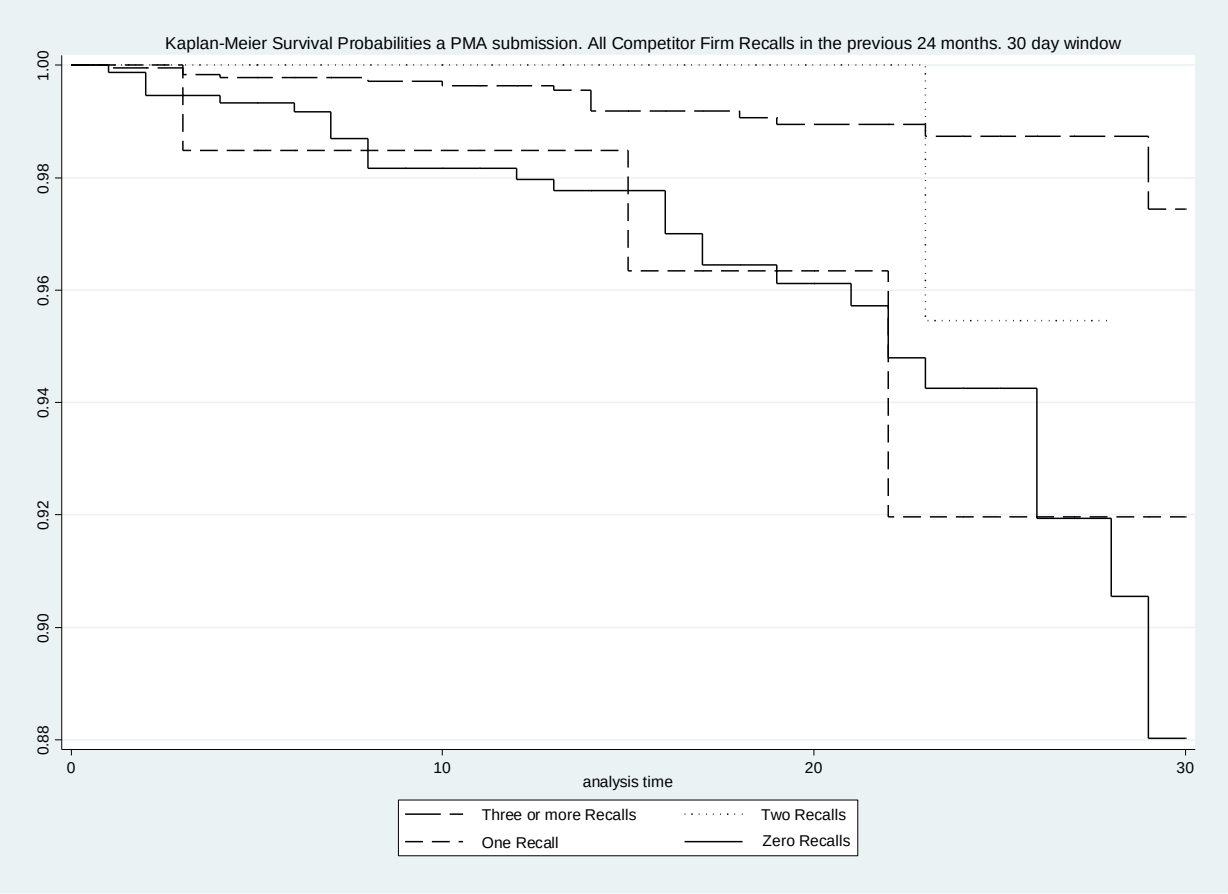

Table 1: 510(k) Summary Statistics

VARIABLE	MEAN	ST DEV	MIN	MAX	VARIABLE	MEAN	ST DEV	MIN	MAX
OF 510(K) TIME	297.90	637.55	1.00	7256.00					
OF REC - 12M	3.11	11.38	0.00	133.00	CF REC - 12M	84.12	131.61	0.00	749.00
OF REC - 24M	5.74	20.62	0.00	198.00	CF REC - 24M	159.61	254.12	0.00	1394.00
OF REC - 36M	7.95	28.43	0.00	263.00	CF REC - 36M	224.82	365.14	0.00	2043.00
OF REC - 48M	10.68	38.32	0.00	377.00	CF REC - 48M	279.49	463.12	0.00	2640.00
OF SPC REC - 12M	0.31	1.81	0.00	41.00	CF SPC REC - 12M	26.13	46.78	0.00	348.00
OF SPC REC - 24M	0.53	2.94	0.00	57.00	CF SPC REC - 24M	49.46	89.67	0.00	661.00
OF SPC REC - 36M	0.72	3.88	0.00	71.00	CF SPC REC - 36M	69.41	127.89	0.00	915.00
OF SPC REC - 48M	0.86	4.66	0.00	86.00	CF SPC REC - 48M	85.92	160.58	0.00	1173.00
OF DPC REC - 12M	2.80	10.50	0.00	126.00	CF DPC EC - 12M	57.99	113.07	0.00	738.00
OF DPC REC - 24M	5.21	19.12	0.00	197.00	CF DPC REC - 24M	110.15	217.75	0.00	1382.00
OF DPC REC - 36M	7.24	26.41	0.00	263.00	CF DPC REC - 36M	155.40	312.19	0.00	2007.00
OF DPC REC - 48M	9.82	35.42	0.00	325.00	CF DPC REC - 48M	193.57	395.44	0.00	2591.00
OF SPC CL1 REC - 12M	0.01	0.16	0.00	7.00	CF SPC CL1 REC - 12M	1.03	2.41	0.00	26.00
OF SPC CL1 REC - 24M	0.02	0.23	0.00	8.00	CF SPC CL1 REC - 24M	1.96	4.29	0.00	40.00
OF SPC CL1 REC - 36M	0.02	0.26	0.00	11.00	CF SPC CL1 REC - 36M	2.73	5.89	0.00	47.00
OF SPC CL1 REC - 48M	0.02	0.28	0.00	11.00	CF SPC CL1 REC - 48M	3.30	7.16	0.00	57.00
OF SPC CL2 REC - 12M	0.29	1.76	0.00	41.00	CF SPC CL2 REC - 12M	23.67	43.96	0.00	327.00
OF SPC CL2 REC - 24M	0.50	2.86	0.00	57.00	CF SPC CL2 REC - 24M	44.67	84.11	0.00	626.00
OF SPC CL2 REC - 36M	0.67	3.78	0.00	71.00	CF SPC CL2 REC - 36M	62.52	119.78	0.00	869.00
OF SPC CL2 REC - 48M	0.81	4.56	0.00	86.00	CF SPC CL2 REC - 48M	77.20	150.25	0.00	1110.00
OF SPC CL3 REC - 12M	0.01	0.15	0.00	7.00	CF SPC CL3 REC - 12M	1.44	2.80	0.00	22.00
OF SPC CL3 REC - 24M	0.02	0.20	0.00	8.00	CF SPC CL3 REC - 24M	2.83	5.05	0.00	39.00
OF SPC CL3 REC - 36M	0.02	0.24	0.00	8.00	CF SPC CL3 REC - 36M	4.17	7.18	0.00	48.00
OF SPC CL3 REC - 48M	0.03	0.26	0.00	8.00	CF SPC CL3 REC - 48M	5.42	9.10	0.00	66.00
OF DPC CL1 REC - 12M	0.09	0.55	0.00	8.00	CF DPC CL1 REC - 12M	2.90	6.86	0.00	55.00
OF DPC CL1 REC - 24M	0.18	0.91	0.00	10.00	CF DPC CL1 REC - 24M	5.52	12.85	0.00	100.00
OF DPC CL1 REC - 36M	0.25	1.16	0.00	15.00	CF DPC CL1 REC - 36M	7.71	18.03	0.00	133.00
OF DPC CL1 REC - 48M	0.31	1.44	0.00	15.00	CF DPC CL1 REC - 48M	9.38	22.17	0.00	157.00
OF DPC CL2 REC - 12M	2.56	9.97	0.00	123.00	CF DPC CL2 REC - 12M	51.38	102.42	0.00	681.00
OF DPC CL2 REC - 24M	4.75	18.05	0.00	191.00	CF DPC CL2 REC - 24M	97.44	196.93	0.00	1274.00
OF DPC CL2 REC - 36M	6.58	24.90	0.00	251.00	CF DPC CL2 REC - 36M	137.12	281.75	0.00	1843.00
OF DPC CL2 REC - 48M	8.94	33.56	0.00	310.00	CF DPC CL2 REC - 48M	170.42	356.33	0.00	2389.00
OF DPC CL3 REC - 12M	0.14	0.69	0.00	10.00	CF DPC CL3 REC - 12M	3.71	7.49	0.00	62.00
OF DPC CL3 REC - 24M	0.28	1.16	0.00	14.00	CF DPC CL3 REC - 24M	7.20	14.20	0.00	106.00
OF DPC CL3 REC - 36M	0.41	1.60	0.00	19.00	CF DPC CL3 REC - 36M	10.58	20.64	0.00	139.00
OF DPC CL3 REC - 48M	0.56	2.01	0.00	21.00	CF DPC CL3 REC - 48M	13.77	26.63	0.00	167.00
OF 510(K) CLR - 12M	9.45	17.81	0.00	137.00	CF 510(K) CLR - 12M	364.38	395.71	0.00	1996.00
OF 510(K) CLR - 24M	18.14	34.19	0.00	237.00	CF 510(K) CLR - 24M	725.07	796.36	0.00	3860.00
OF 510(K) CLR - 36M	26.31	50.18	0.00	310.00	CF 510(K) CLR - 36M	1077.71	1198.87	0.00	5721.00
OF 510(K) CLR - 48M	36.39	67.67	0.00	392.00	CF 510(K) CLR - 48M	1418.72	1598.61	0.00	7468.00
OF SPC 510(K) CLR - 12M	0.80	2.12	0.00	53.00	CF SPC 510(K) CLR - 12M	104.98	105.43	0.00	549.00
OF SPC 510(K) CLR - 24M	1.44	3.25	0.00	58.00	CF SPC 510(K) CLR - 24M	208.40	210.78	0.00	1009.00
OF SPC 510(K) CLR - 36M	1.97	4.27	0.00	66.00	CF SPC 510(K) CLR - 36M	308.69	316.14	0.00	1514.00
OF SPC 510(K) CLR - 48M	2.43	5.16	0.00	87.00	CF SPC 510(K) CLR - 48M	405.00	420.04	0.00	1980.00
OF DPC 510(K) CLR - 12M	8.65	17.23	0.00	133.00	CF DPC 510(K) CLR - 12M	259.40	376.35	0.00	1986.00
OF DPC 510(K) CLR - 24M	16.70	33.20	0.00	236.00	CF DPC 510(K) CLR - 24M	516.68	755.89	0.00	3818.00
OF DPC 510(K) CLR - 36M	24.34	48.77	0.00	310.00	CF DPC 510(K) CLR - 36M	769.01	1135.27	0.00	5644.00
OF DPC 510(K) CLR - 48M	33.97	65.53	0.00	378.00	CF DPC 510(K) CLR - 48M	1013.71	1510.19	0.00	7403.00

Table 2: PMA Summary Statistics

VARIABLE	MEAN	ST DEV	MIN	MAX	VARIABLE	MEAN	ST DEV	MIN	MAX
OF PMA TIME	715.59	1089.78	1.00	7224.00					
OF REC - 12M	3.55	4.96	0.00	21.00	CF REC - 12M	13.66	10.64	0.00	43.00
OF REC - 24M	6.99	8.97	0.00	36.00	CF REC - 24M	27.57	20.09	0.00	68.00
OF REC - 36M	10.27	12.59	0.00	48.00	CF REC - 36M	40.83	29.48	0.00	92.00
OF REC - 48M	14.22	16.44	0.00	60.00	CF REC - 48M	53.03	38.50	0.00	119.00
OF SPC REC - 12M	0.26	0.70	0.00	8.00	CF SPC REC - 12M	5.30	6.62	0.00	37.00
OF SPC REC - 24M	0.51	1.14	0.00	11.00	CF SPC REC - 24M	10.61	12.47	0.00	60.00
OF SPC REC - 36M	0.74	1.49	0.00	13.00	CF SPC REC - 36M	15.59	17.89	0.00	80.00
OF SPC REC - 48M	0.96	1.81	0.00	15.00	CF SPC REC - 48M	20.26	22.98	0.00	100.00
OF DPC REC - 12M	3.29	4.78	0.00	21.00	CF DPC REC - 12M	8.36	8.19	0.00	43.00
OF DPC REC - 24M	6.49	8.64	0.00	36.00	CF DPC REC - 24M	16.97	15.70	0.00	68.00
OF DPC REC - 36M	9.53	12.09	0.00	48.00	CF DPC REC - 36M	25.24	23.21	0.00	92.00
OF DPC REC - 48M	13.26	15.61	0.00	49.00	CF DPC REC - 48M	32.78	30.26	0.00	119.00
OF SPC CL1 REC - 12M	0.03	0.24	0.00	5.00	CF SPC CL1 REC - 12M	0.74	1.48	0.00	9.00
OF SPC CL1 REC - 24M	0.06	0.38	0.00	6.00	CF SPC CL1 REC - 24M	1.43	2.46	0.00	12.00
OF SPC CL1 REC - 36M	0.09	0.48	0.00	6.00	CF SPC CL1 REC - 36M	2.06	3.37	0.00	18.00
OF SPC CL1 REC - 48M	0.12	0.59	0.00	7.00	CF SPC CL1 REC - 48M	2.64	4.12	0.00	18.00
OF SPC CL2 REC - 12M	0.21	0.56	0.00	5.00	CF SPC CL2 REC - 12M	4.19	5.08	0.00	27.00
OF SPC CL2 REC - 24M	0.41	0.89	0.00	7.00	CF SPC CL2 REC - 24M	8.36	9.52	0.00	47.00
OF SPC CL2 REC - 36M	0.59	1.15	0.00	8.00	CF SPC CL2 REC - 36M	12.26	13.61	0.00	64.00
OF SPC CL2 REC - 48M	0.76	1.37	0.00	10.00	CF SPC CL2 REC - 48M	15.82	17.42	0.00	78.00
OF SPC CL3 REC - 12M	0.02	0.14	0.00	2.00	CF SPC CL3 REC - 12M	0.37	1.04	0.00	9.00
OF SPC CL3 REC - 24M	0.04	0.22	0.00	2.00	CF SPC CL3 REC - 24M	0.82	1.73	0.00	10.00
OF SPC CL3 REC - 36M	0.06	0.28	0.00	2.00	CF SPC CL3 REC - 36M	1.28	2.39	0.00	14.00
OF SPC CL3 REC - 48M	0.09	0.34	0.00	2.00	CF SPC CL3 REC - 48M	1.80	3.06	0.00	17.00
OF DPC CL1 REC - 12M	0.60	1.32	0.00	6.00	CF DPC CL1 REC - 12M	0.95	1.58	0.00	11.00
OF DPC CL1 REC - 24M	1.15	2.14	0.00	10.00	CF DPC CL1 REC - 24M	1.85	2.55	0.00	15.00
OF DPC CL1 REC - 36M	1.63	2.90	0.00	13.00	CF DPC CL1 REC - 36M	2.70	3.51	0.00	20.00
OF DPC CL1 REC - 48M	2.18	3.61	0.00	14.00	CF DPC CL1 REC - 48M	3.43	4.25	0.00	21.00
OF DPC CL2 REC - 12M	2.48	3.53	0.00	17.00	CF DPC CL2 REC - 12M	6.87	6.67	0.00	33.00
OF DPC CL2 REC - 24M	4.85	6.31	0.00	28.00	CF DPC CL2 REC - 24M	13.92	12.79	0.00	56.00
OF DPC CL2 REC - 36M	7.11	8.72	0.00	35.00	CF DPC CL2 REC - 36M	20.64	18.85	0.00	75.00
OF DPC CL2 REC - 48M	9.89	11.22	0.00	36.00	CF DPC CL2 REC - 48M	26.73	24.52	0.00	97.00
OF DPC CL3 REC - 12M	0.21	0.70	0.00	6.00	CF DPC CL3 REC - 12M	0.54	1.19	0.00	11.00
OF DPC CL3 REC - 24M	0.48	1.19	0.00	6.00	CF DPC CL3 REC - 24M	1.19	2.03	0.00	16.00
OF DPC CL3 REC - 36M	0.79	1.66	0.00	8.00	CF DPC CL3 REC - 36M	1.89	2.84	0.00	20.00
OF DPC CL3 REC - 48M	1.19	2.14	0.00	9.00	CF DPC CL3 REC - 48M	2.62	3.59	0.00	21.00
OF PMA APP - 12M	1.42	1.69	0.00	8.00	CF PMA APP - 12M	7.94	5.57	0.00	29.00
OF PMA APP - 24M	2.90	2.92	0.00	12.00	CF PMA APP - 24M	16.13	10.10	0.00	49.00
OF PMA APP - 36M	4.35	4.05	0.00	17.00	CF PMA APP - 36M	24.53	14.69	0.00	71.00
OF PMA APP - 48M	6.22	5.39	0.00	23.00	CF PMA APP - 48M	33.00	19.28	0.00	89.00
OF SPC PMA APP - 12M	0.07	0.31	0.00	6.00	CF SPC PMA APP - 12M	2.33	2.60	0.00	16.00
OF SPC PMA APP - 24M	0.17	0.50	0.00	7.00	CF SPC PMA APP - 24M	4.75	4.74	0.00	26.00
OF SPC PMA APP - 36M	0.29	0.65	0.00	8.00	CF SPC PMA APP - 36M	7.19	6.76	0.00	36.00
OF SPC PMA APP - 48M	0.39	0.76	0.00	8.00	CF SPC PMA APP - 48M	9.63	8.79	0.00	47.00
OF DPC PMA APP - 12M	1.36	1.66	0.00	8.00	CF DPC PMA APP - 12M	5.61	4.97	0.00	28.00
OF DPC PMA APP - 24M	2.72	2.86	0.00	12.00	CF DPC PMA APP - 24M	11.37	9.11	0.00	49.00
OF DPC PMA APP - 36M	4.06	3.99	0.00	17.00	CF DPC PMA APP - 36M	17.34	13.32	0.00	70.00
OF DPC PMA APP - 48M	5.82	5.22	0.00	21.00	CF DPC PMA APP - 48M	23.37	17.57	0.00	88.00

Table 3: 510(k) Correlation Statistics (using 24 MON counts)

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)	(15)	(16)	(17)	(18)	(19)	(20)	(21)
(1) OF 510(K) TIME	1.00																				
(2) OF REC	-0.13	1.00																			
(3) OF SPC REC	-0.05	0.56	1.00																		
(4) OF DPC REC	-0.13	0.99	0.45	1.00																	
(5) OF SPC CL1/2 REC	-0.05	0.56	1.00	0.45	1.00																
(6) OF SPC CL3 REC	-0.01	0.07	0.19	0.04	0.13	1.00															
(7) OF DPC CL1/2 REC	-0.13	0.99	0.45	1.00	0.46	0.03	1.00														
(8) OF DPC CL3 REC	-0.11	0.44	0.12	0.45	0.11	0.11	0.40	1.00													
(9) CF REC	-0.15	0.64	0.33	0.64	0.33	0.04	0.63	0.33	1.00												
(10) CF SPC REC	0.04	0.32	0.28	0.30	0.28	0.01	0.30	0.08	0.54	1.00											
(11) CF DPC REC	-0.19	0.61	0.27	0.62	0.27	0.05	0.61	0.35	0.94	0.24	1.00										
(12) CF SPC CL1/2 REC	0.04	0.32	0.29	0.30	0.29	0.01	0.31	0.08	0.54	1.00	0.24	1.00									
(13) CF SPC CL3 REC	-0.01	0.07	0.06	0.07	0.06	0.06	0.06	0.09	0.21	0.44	0.07	0.39	1.00								
(14) CF DPC CL1/2 REC	-0.18	0.61	0.27	0.61	0.27	0.04	0.61	0.33	0.94	0.24	1.00	0.24	0.06	1.00							
(15) CF DPC CL3 REC	-0.19	0.41	0.15	0.41	0.15	0.10	0.39	0.55	0.58	0.08	0.64	0.07	0.22	0.59	1.00						
(16) OF 510(K) APP	-0.26	0.43	0.15	0.44	0.15	0.04	0.43	0.41	0.40	0.04	0.45	0.04	0.07	0.43	0.57	1.00					
(17) OF SPC 510(K) APP	-0.18	0.16	0.13	0.15	0.13	0.02	0.15	0.09	0.11	0.10	0.09	0.10	0.10	0.09	0.13	0.31	1.00				
(18) OF DPC 510(K) APP	-0.25	0.43	0.14	0.44	0.14	0.04	0.42	0.41	0.40	0.03	0.45	0.03	0.06	0.43	0.57	1.00	0.22	1.00			
(19) CF 510(K) APP	-0.29	0.43	0.17	0.44	0.17	0.07	0.43	0.43	0.61	0.17	0.64	0.16	0.21	0.62	0.68	0.83	0.21	0.83	1.00		
(20) CF SPC 510(K) APP	-0.06	0.04	0.03	0.03	0.03	0.01	0.03	0.02	0.15	0.49	-0.02	0.47	0.56	-0.02	0.01	0.08	0.19	0.07	0.28	1.00	
(21) CF DPC 510(K) APP	-0.29	0.44	0.17	0.45	0.17	0.07	0.44	0.44	0.59	0.04	0.67	0.04	0.07	0.65	0.71	0.84	0.17	0.85	0.97	0.02	1.00

Table 4: PMA Correlation Statistics (using 24 MON counts)

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)	(15)	(16)	(17)	(18)	(19)	(20)	(21)
(1) OF PMA TIME	1.00																				
(2) OF REC	-0.38	1.00																			
(3) OF SPC REC	-0.09	0.35	1.00																		
(4) OF DPC REC	-0.38	0.99	0.23	1.00																	
(5) OF SPC CL1/2 REC	-0.09	0.35	0.98	0.23	1.00																
(6) OF SPC CL3 REC	-0.03	0.14	0.46	0.08	0.29	1.00															
(7) OF DPC CL1/2 REC	-0.38	0.98	0.21	0.99	0.22	0.06	1.00														
(8) OF DPC CL3 REC	-0.21	0.52	0.21	0.51	0.19	0.17	0.40	1.00													
(9) CF REC	-0.33	0.48	0.21	0.47	0.21	0.06	0.46	0.27	1.00												
(10) CF SPC REC	-0.10	0.14	0.12	0.13	0.11	0.06	0.13	0.10	0.61	1.00											
(11) CF DPC REC	-0.34	0.49	0.17	0.49	0.18	0.02	0.48	0.26	0.77	-0.04	1.00										
(12) CF SPC CL1/2 REC	-0.11	0.15	0.11	0.14	0.11	0.06	0.13	0.08	0.61	0.99	-0.03	1.00									
(13) CF SPC CL3 REC	-0.04	0.05	0.08	0.04	0.07	0.05	0.03	0.13	0.35	0.61	-0.05	0.51	1.00								
(14) CF DPC CL1/2 REC	-0.33	0.50	0.17	0.50	0.18	0.02	0.50	0.24	0.76	-0.04	0.99	-0.03	-0.08	1.00							
(15) CF DPC CL3 REC	-0.18	0.12	0.08	0.12	0.07	0.07	0.08	0.28	0.40	0.00	0.50	-0.02	0.17	0.39	1.00						
(16) OF PMA APP	-0.55	0.48	0.14	0.48	0.14	0.04	0.47	0.31	0.19	-0.04	0.27	-0.04	-0.05	0.27	0.16	1.00					
(17) OF SPC PMA APP	-0.16	-0.07	-0.03	-0.07	-0.04	0.05	-0.07	-0.01	-0.10	-0.06	-0.08	-0.06	-0.07	-0.09	-0.01	0.18	1.00				
(18) OF DPC PMA APP	-0.53	0.50	0.15	0.50	0.15	0.03	0.49	0.31	0.21	-0.03	0.29	-0.03	-0.04	0.29	0.17	0.98	0.00	1.00			
(19) CF PMA APP	-0.52	0.31	0.12	0.31	0.13	0.03	0.30	0.16	0.43	0.19	0.39	0.18	0.22	0.36	0.40	0.50	0.01	0.50	1.00		
(20) CF SPC PMA APP	-0.14	-0.09	-0.01	-0.09	-0.01	0.01	-0.09	-0.04	0.11	0.47	-0.24	0.46	0.34	-0.25	-0.02	0.00	0.12	-0.02	0.41	1.00	
(21) CF DPC PMA APP	-0.49	0.39	0.14	0.38	0.15	0.02	0.38	0.20	0.41	-0.04	0.55	-0.05	0.06	0.52	0.45	0.55	-0.05	0.57	0.88	-0.07	1.00

Table 5 – Baseline Analysis: Hazard of 510(k) and PMA

	(1)	(2)	(3)	(4)	(5)	(6)
Dependent Variable	510(k)	510(k)	510(k)	PMA	PMA	PMA
Time Window	24 Mon.	24 Mon.	24 Mon.	24 Mon.	24 Mon.	24 Mon.
OF REC	-0.14***			0.05		
	(0.02)			(0.13)		
CF REC	0.23***			0.17		
	(0.02)			(0.17)		
OF SPC REC		-0.35***			-0.86*	
		(0.02)			(0.42)	
OF DPC REC		-0.10***			0.19	
		(0.01)			(0.16)	
CF SPC REC		0.04***			0.31**	
		(0.01)			(0.09)	
CF DPC REC		0.21***			0.07	
		(0.01)			(0.15)	
OF SPC CL1&2 REC			-0.35***			-1.01*
			(0.03)			(0.47)
OF DPC CL1&2 REC			-0.07***			0.07
			(0.01)			(0.15)
OF SPC CL3 REC			-0.32***			0.46
			(0.08)			(0.80)
OF DPC CL3 REC			-0.07*			0.35
			(0.03)			(0.38)
CF SPC CL1&2 REC			0.05***			0.37**
			(0.01)			(0.14)
CF DPC CL1&2 REC			0.33***			0.05
			(0.02)			(0.21)
CF SPC CL3 REC			-0.01			-0.53+
			(0.02)			(0.30)
CF DPC CL3 REC			-0.19***			-0.05
			(0.02)			(0.29)
Fixed Effects	PC Y	PC Y	PC Y	PC F Y	PC F Y	PC F Y
Submission Controls	X	X	X	X	X	X
Observations	41898	41898	41898	25185	25185	25185
Wald Chi^2	92513.15	94015.87	94255.82	2200.06	2746.78	4888.67

Standard errors in parentheses: $^{+}$ p<0.10, *p<0.05, **p<0.01, ***p<0.001. Estimations include product code (PC), med-tech firm (F) and year (Y) fixed effects as indicated. Submission controls include SPC and DPC focal and competitor PMA counts matched to the respective time window. A constant term is included but not shown in all columns.

Table 6 – Robustness Analysis: Hazard of 510(k) and PMA

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
Dependent Variable	510(k)	510(k)	510(k)	510(k)	510(k)	510(k)	PMA	PMA	PMA	PMA	PMA	PMA
Time Window	36 Mon.	36 Mon.	36 Mon.	48 Mon.	48 Mon.	48 Mon.	36 Mon.	36 Mon.	36 Mon.	48 Mon.	48 Mon.	48 Mon.
OF REC	-0.13***			-0.15***			0.15			0.11		
	(0.02)			(0.01)			(0.18)			(0.19)		
CF REC	0.21***			0.17***			0.16			0.07		
	(0.02)			(0.02)			(0.13)			(0.16)		
OF SPC REC		-0.33***			-0.28***			-0.67*			-0.64+	
		(0.02)			(0.02)			(0.34)			(0.33)	
OF DPC REC		-0.09***			-0.09***			0.30			0.28	
		(0.01)			(0.02)			(0.20)			(0.22)	
CF SPC REC		0.04***			0.03***			0.24**			0.14	
		(0.01)			(0.01)			(0.09)			(0.09)	
CF DPC REC		0.18***			0.15***			0.04			-0.02	
		(0.01)			(0.01)			(0.12)			(0.15)	
OF SPC CL1&2 REC			-0.33***			-0.29***			-0.87*			-0.82**
			(0.03)			(0.03)			(0.36)			(0.30)
OF DPC CL1&2 REC			-0.05***			-0.06***			0.25			0.18
			(0.02)			(0.02)			(0.19)			(0.21)
OF SPC CL3 REC			-0.29***			-0.19**			0.41			0.18
			(0.07)			(0.06)			(0.72)			(0.71)
OF DPC CL3 REC			-0.06+			-0.06+			0.16			0.21
			(0.03)			(0.03)			(0.30)			(0.33)
CF SPC CL1&2 REC			0.06***			0.04***			0.31*			0.29+
			(0.01)			(0.01)			(0.16)			(0.17)
CF DPC CL1&2 REC			0.32***			0.25***			-0.07			-0.18
			(0.02)			(0.02)			(0.19)			(0.21)
CF SPC CL3 REC			-0.03			-0.02			-0.36			-0.51+
			(0.02)			(0.02)			(0.31)			(0.31)
CF DPC CL3 REC			-0.20***			-0.15***			0.15			0.29
			(0.02)			(0.02)			(0.30)			(0.27)
Fixed Effects	PC Y	PC Y	PC Y	PC Y	PC Y	PC Y	PC F Y	PC F Y	PC F Y	PC F Y	PC F Y	PC F Y
Controls	X	X	X	X	X	X	X	X	X	X	X	X
Observations	41898	41898	41898	41898	41898	41898	25185	25185	25185	25185	25185	25185
Wald Chi^2	91301.04	92778.60	93033.21	93022.76	94099.19	94246.86	2371.19	3276.32	4232.36	2593.58	3487.17	4956.47

Standard errors in parentheses: $^{+}$ p<0.10, *p<0.05, **p<0.01, ***p<0.001. Estimations include product code (PC), med-tech firm (F) and year (Y) fixed effects as indicated. Controls include SPC and DPC focal and competitor PMA counts matched to the respective time window. A constant term is included but not shown in all columns.

Table 7 – Robustness Analysis: Hazard of SPMA

	(1)	(2)	(3)	(4)	(5)
Dependent Variable	SPMA	SPMA	SPMA	SPMA	SPMA
Time Window	24 Mon.	24 Mon.	24 Mon.	36 Mon.	48 Mon.
OF REC	-0.05**				
	(0.02)				
CF REC	0.06*				
	(0.03)				
OF SPC REC		-0.01			
		(0.02)			
OF DPC REC		-0.06*			
		(0.02)			
CF SPC REC		0.01			
		(0.03)			
CF DPC REC		0.01			
		(0.03)			
OF SPC CL1&2 REC			0.00	-0.02	0.03
			(0.02)	(0.01)	(0.02)
OF DPC CL1&2 REC			-0.07**	-0.06*	-0.07+
			(0.02)	(0.03)	(0.04)
OF SPC CL3 REC			-0.10+	-0.01	-0.04
			(0.05)	(0.05)	(0.04)
OF DPC CL3 REC			0.06**	0.05	0.00
			(0.02)	(0.03)	(0.03)
CF SPC CL1&2 REC			0.01	0.01	-0.00
			(0.03)	(0.03)	(0.03)
CF DPC CL1&2 REC			0.00	0.01	0.01
			(0.03)	(0.03)	(0.03)
CF SPC CL3 REC			0.05*	0.03	-0.01
			(0.02)	(0.02)	(0.02)
CF DPC CL3 REC			0.03	0.03	0.01
			(0.04)	(0.03)	(0.03)
Fixed Effects	PC F Y	PC F Y	PC F Y	PC F Y	PC F Y
Controls	X	X	X	X	X
Observations	25185	25185	25185	25185	25185
Wald Chi^2	5900.88	7447.81	15699.43	12321.30	35345.84

Standard errors in parentheses: $^{+}$ p<0.10, *p<0.05, **p<0.01, ***p<0.001. Estimations include product code (PC), med-tech firm (F) and year (Y) fixed effects as indicated. 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.