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LEARNING FROM INTERORGANIZATIONAL PRODUCT FAILURE EXPERIENCE IN THE MEDICAL DEVICE INDUSTRY

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Abstract

Much research examines the *causes* of product failures such as the Ford Pinto gas tank design. Research also examines the *consequences* of product failures such as new product introductions resulting from the need to improve failed products. However, little is known about how the causes and consequences of product failures *interact* across different firms, and generate inter-organizational learning, within the same industry. Specifically, limited research has examined if a firm learns to reduce *its own* annual rate of product failures (e.g., experiences fewer product-related adverse events) by attending to the product failures and new product introductions *of its competitors*. In addition, we also do not know (1) how delayed reporting of product failure influences inter-organizational learning, and (2) how the introduction of new products by one company impacts another firm's effort to learn from this competitor's product failures.

To address these gaps, this dissertation develops and tests relationships between (1) inter-organizational learning from product failures, (2) product failure reporting delays, and (3) new product introductions. Regression analysis of 98,576 manufacturing firm-year observations from the medical device industry over a ten-year period (1998 to 2008) supports the proposed model. Specifically, the analysis supported two insights:

(1) As expected, a competitor's reporting delays can inhibit learning from others' failures by increasing the chance of making poor inferences about the failure. Unexpectedly, however, delays can also improve inter-organizational learning because in reports that have taken longer to file, a clearer understanding of the failure's cause-effect relationships is developed.

(2) As expected, a competitor's new product introductions positively impact inter-organizational learning by transferring knowledge of product design between firms. Unexpectedly, a competitor's new product introductions can also negatively impact inter-organizational learning from product failure by distracting the observing firm's attention away from the competitor's failures.

The thesis contributes to the inter-organizational learning literature by: (1) modelling learning from others' product failures, (2) highlighting the effects of reporting delays, and (3) showing how others' new product introductions can distract. This thesis shows that learning from others' product failures and new product introductions has significant benefits because it prevents serious injury and death among device users.

Keywords: inter-organizational learning, product failure rates, product failure experience, reporting delays, distractions, new product introductions, medical devices.

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"My death will not be for nothing."
~ Scott Jerome-Parks after receiving a fatal radiation overdose caused from a medical linear accelerator malfunction (Bogdanich 2010).

1. Introduction

Sooner or later products fail, either with expected or more unexpected consequences. Whether or not organizations learn from product failure experience is a complicated story. The purpose of this thesis is to explore interorganizational learning by a firm in response to their competitors' product failure experiences, resulting in an observed annual reduction in organization's product failure rates, and to tease out conditions under which learning does or does not exist. I challenge three common assumptions: (1) learning from competitor product failure experience is inconsequential to product failure rates, (2) delays in the reporting of competitor product failure experience has negligible learning effects compared to the product failure experience itself, and (3) learning from competitor failure experience in existing products is independent from learning from a competitor's new product technologies.

I chose to examine product failure in medical device companies. In the medical device industry, product failure is defined in terms of adverse events, which the Safe Medical Devices Act of 1990 defines as product-caused serious injury or death. Ideally, new medical devices allow patients to recover faster and live longer lives. A New York Times article offers an example (Bogdanich 2010). A linear accelerator is a state-of-the-art treatment for cancer. Computer controlled gates, called multileaf collimators, in the linear accelerator control a beam of radiation directed at cancerous tissue. The cancer destroying radiation is more narrowly focused than previous radiation treatments that

destroy both healthy and cancerous tissue. However, the product does not always work as expected. People get hurt or die from medical device failure. The article describes a slow and painful death caused by a linear accelerator failure (Bogdanich 2010). Scott Jerome-Parks was undergoing treatment for tongue cancer in 2007, which doctors believed he developed from exposure to carcinogenic dust while volunteering with search-and-rescue at the September 2001 World Trade Center attack. Mr. Jerome-Parks was overexposed to radiation when the gates were left open because of a software bug and he subsequently developed radiation poisoning. The story documented unbearable pain, burns, and continuous nausea. After which, he lost his eyesight, hearing, and eventually the ability to eat. The patient died 10 months after his treatment.

Learning from Product Failure Experience

Unfortunately, manufacturers are often faced with the difficult choice between providing advanced technology without fully understanding the potential for product failure and preventing patients from accessing life-saving devices. It is sometimes unclear how learning from product failure manifests itself because of the trade-off between product development and product reliability. In many cases, organizations gain a deeper understanding of existing devices and organizational processes - while allowing patients to continuously use the devices. Bill George, the former CEO of Medtronic - one of the largest medical device companies in the world, emphasizes one such instance of learning from product failure. In his book, "*Authentic Leadership*", he recalls one instance where Medtronic product failure diminished as Medtronic gained product failure experience.

Bill George (2003: Pg. 85) writes how a single failure of a balloon catheter caused a systematic change in the way that Medtronic dealt with its quality control procedures.

> *"I vividly recall an angioplasty case where the doctor was using a Medtronic balloon catheter to open up clogged arteries. The product literally fell apart in the doctor's hands as he was threading it through the patient's arteries. He was so angry that he took the catheter, covered with blood, and threw it at me. I ducked as it went sailing across the room! ...*
>
> *It was evident from these field visits that Medtronic's customers had real questions about the company's problems and the quality of our products. At the time Medtronic was using the popular Crosby quality program with its emphasis on internal training, testimonial talks from top management, and the concept of internal customers. All of this was making Medtronic more internally oriented and less focused on its customers... **We decided to abandon the Crosby program and create our own quality initiative.**"*

The balloon catheter example illustrates that Medtronic followed a familiar learning from failure path where failure decreases with cumulative experience (Kim and Miner 2007). The learning from product failure phenomenon is a close variant of the learning curve (Argote and Epple 1990; Dutton and Thomas 1984; Yelle 1979), in which the hypothesis is that the unit cost of a product decreases at a decreasing rate as organizations gain additional production experience.

The highlighted section illustrates the catheter failure led to significant changes in how Medtronic dealt with product failures in the future in the balloon catheter situation. The abandonment of the Crosby program is a familiar scenario to scholars of learning (Levinthal and March 1993) and failure (Hollnagel 2004; Reason 1997; Vaughan 1999; Weick and Roberts 1993) in which organizations make significant changes to avoid failed behaviours. Organizations can learn to detect latent failures by being heedful (Reason

1997, 2000; Weick and Roberts 1993; Weick et al. 1999) or mindful (Levinthal and Rerup 2006) of their own actions. In fact, studies by Sitkin (1992) and McGrath (1999) deduce that organizations should strive to have failures (in a controlled manner) to obtain valuable lessons and adapt to a changing environment. Learning from own failure effects have been seen in a variety of contexts, such as chemical processing (Carroll 1998), museums (Christianson et al. 2009), passenger buses (Hollnagel 2004), and pharmaceutical manufacturing (Rerup 2009).

Difficulties in Learning from Product Failure Experience

Learning from product failure experience is not always as clear as in the balloon catheter example. The introduction of Medtronic's Xytron pulse generator in 1976 is an example where product failure experience caused higher product failure rates (Jeffrey 2001). At that time, Medtronic used a mercury-zinc battery to power its pacemakers, which had to be shielded from bodily fluids to avoid shorting out the pacemaker. However, it was found that tightly sealed pacemakers with mercury-zinc batteries had the potential to explode because the batteries emitted hydrogen gas. The Xytron pulse generator was a breakthrough innovation because it was the first implantable pacemaker that was enclosed with a stainless steel housing coated with epoxy. The epoxy was porous so it vented the hydrogen gas. Medtronic believed they had a superior product for they sold 100,000 Xytron pulse generators. The Xytron solved one problem, but it caused another. The epoxy also allowed fluids to contact the stainless steel housing. Unintended welding problems on the stainless steel housing allowed fluids to short-out the pacemaker once it

was implanted. Medtronic's product failure rates shot up. Medtronic quickly discovered the problem and recalled 50,000 Xytron pulse generators (Jeffrey 2001).

Past research indicates that the Xytron pulse generator example is not an isolated case of product failure experience that led to higher product failure rates. The literature shows that difficulties in learning are the result of two organizational limitations. First, difficulties can occur when past experiences are not fully understood. Perrow (1984) argues that organizations do not learn from accidents such as the 1979 Three-Mile Island nuclear reactor explosion and the 1984 Bhopal gas leak because the causes of failure are often too complex to understand. Similarly, difficulties in learning may occur because of organizational forgetting (de Holan and Phillips 2004) or employee turnover (Carley and Harrald 1997). For example, Carley and Harrald (1997) find that a lack of feedback from the firing of organizational actors after a failure or the promotion of actors with little failure experience may cause failures to be repeated. A case study of Cuban resorts by de Holan and Nelson (2004) discovers that organizations forget how to get better with additional experience because of turnover in critical managers, supporting this view.

Second, difficulties in learning may be caused by the inability to predict future actions using past experience. Unintended consequences from the inability to predict the future may result from production process tampering (Deming 1982) and superstitions (Denrell 2008). Deming (1982) indicates that tampering to correct defective products may induce variance in the production process. Product failure is more likely with variable production processes. Learning scholars show that difficulties in learning may

be due to superstitions that occur when organizations blindly imitate or avoid an outcome without fully understanding why it occurred (Denrell 2008).

Nevertheless, difficulties in learning from product failure experience are often short-lived for intraorganizational learning. In the Xytron pulse generator case, Medtronic recalled the product once it received feedback on the poor product performance and physicians developed a healthy skepticism of the reliability of Medtronic products. The Xytron pulse generator mistake is also galvanized in Medtronic's folklore (Bakken 1999). Medtronic now performs a series of pre-market failure tests on all of its products to prevent similar product failures. Quick product performance feedback, distinguishable product failure causes, and memories of past failures maybe luxuries only available when learning from an organization's own product failures.

Learning from Interorganizational Product Failure Experience

I focus learning to reduce product failure rates from interorganizational product failure experience. The difficulties of learning from others' experience are well recognized by organizational learning theorists. Organizational learning scholars suggest knowledge transfer problems can occur – indicating that organizations are more likely to have poor attempts to reduce product failure rates by observing a competitor's experience with product failures. For example, organizations have less feedback on their actions when learning from others. As well, learning traps (Ahuja and Lampert 2001; Levinthal and March 1993; Levitt and March 1988) may occur, which is when learning from local and

clearly understood outcomes drive out learning from distant, more uncertain, but larger pay-off outcomes.

The limited interorganizational learning from failure literature shows that a competitor's failure experience does affect an organization's own rate of failure. Chuang and Baum (2003) show that Long-Term Care Facilities decrease their use of a naming strategy with failures of others' naming strategies. Baum and Dahlin (2007) found that American freight railroads were able to reduce their own accident costs by analyzing the accident and operating experiences of other railroads. Madsen (2009) found similar evidence in American coal mining disasters.

However, results on learning from others' experience are often confusing and unclear. For example, studies that focus on the impact of the transfer of learning between WWII Liberty shipyards on unit cost reductions are contradictory. On the one hand, Argote and Epple (1990) find evidence that interorganizational experience leads to learning. They find a positive and significant relationship between recent cumulative production experience and the number of ships built. This suggests that the unit cost of production decreases with interorganizational experience because shipyards are able to build more ships with available resources. On the other hand, Argote and Epple (1990) show that interorganizational experience is a learning detriment. Their results indicate a negative and significant relationship between interorganizational experience and the number of ships built. These findings indicate that interorganizational experience increases the unit cost of production. In a subsequent study, Darr, Epple, and Argote (1995) provide evidence that interorganizational cumulative experience decreases the unit

cost of producing a pizza for commonly owned franchises, but not across different franchises. The specific reasons for the mixed results are unclear, while they show that parlours owned by the same franchisee use knowledge transfer mechanisms more extensively.

A revisit of the Liberty shipyard data by Thornton and Thompson (2001) reveals the difficulties of interorganizational learning studies. Their results consistently support Argote and Epple's (1990) findings that cumulative interorganizational production experience actually increase the unit cost of production. Thornton and Thompson (2001) further apply second-order effects and nonparametric cubic splines to tease out the inconsistent interorganizational effects. The subsequent explorations yield only slightly more supportive results of interorganizational learning.

Studies that use interorganizational experience to predict outcomes other than unit cost reductions are not immune to the inconsistent results. Baum and Ingram (1998) show no support that interorganizational experience decreases the organizational mortality rate of Manhattan hotels, while they find a significant relationship between the stock of experience at the time of founding decreases the organizational mortality rate of Manhattan hotels. Salomon and Martin (2008) discover that the effects of interorganizational experience are insignificant when other experience variables are added in their study of time-to-build manufacturing establishments. Levin (2000) show that cumulative experience across (a) platform, (b) division, (c) company, and (d) industry had no effect on consumer reports of automobile reliability. The mixed findings are replicated by Haunschild and Sullivan (2002) and Kim and Miner (2007) who both

show a non-significant effect of industry experience on airline accident and bank failure rates – indicating that cumulative interorganizational experience has no impact on the risk of failure.

Perhaps the reason why these confusing and unclear results go unnoticed is because the theory behind learning from others is intuitive - interorganizational experience leads to organizational improvement - and the empirical evidence against it is ambiguous. But, one assumption that this research makes is that the processes of learning are constant over time. For example, studies investigating the transfer of knowledge across Liberty shipyards (Argote and Epple 1990; Thompson 2001) minimize the possibility that learning processes change by investigating a context that has: (1) very little product innovation - the same ships are repeatedly built, (2) a lack of between yard competition - the shipyards were government sanctioned for the war-effort, and (3) a long history of the craft of shipbuilding. These factors provide a natural experiment where the processes of learning were fairly controlled (Argote et al. 1990), suggesting that the experience acquired between ships and across time may have actually varied very little.

Inquiries of intraorganizational learning show that learning is transitory and situational (Cook and Brown 1999; Elsbach et al. 2005; Garud and Rappa 1994; Tyre and Hippel 1997), contrary to the assumption of stability in learning. Cook and Brown (1999) highlight that the mere possession of experience does not always lead to learning. Their philosophical study shows that the effects of experience on organizational outcomes really depend upon how organizational members attend to experience at the moment they acquire it. For example, Tyre and von Hippel (1997) show that attention to

failure alters how past failures are understood inside a manufacturing plant. They explain that engineers believed product flaws were caused by the inability of a user to operate the product correctly. It was only after the engineers noticed a loose screw that the engineers realized that it was a product flaw, suggesting that attention is particularly important to learning from product failure.

In the medical device industry, awareness to others' product failure experience is central to interorganizational learning. Interorganizational learning – defined as product modifications by a firm in response to adverse events caused by their competitors' products, resulting in an observed annual reduction in organization's product failure rates – is ensured because of industry guidances and regulations. The Center for Devices and Radiological Health (CDRH) of the US Food and Drug Administration (FDA) guidances are non-binding documents that give guidance on good practise in the industry, such as the norms and standard operating procedures in the design, production, manufacturing, and testing of products.

Interorganizational learning from the adverse events caused by competitors' products is largely ensured by industry regulations and guidances, for two reasons. First, firms are legally required to make product modifications that improve product failure rates, once manufacturers are made aware of potential flaws that compromise safety. Regulations mandate that manufacturers "protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective (FDA 2009)." These regulations ensure constant evaluation and modification of a firm's own existing product design and quality control in manufacturing.

Second, guidances ensure that manufacturers monitor and compare the safety of their own products against the safety of their competitors' devices. When manufacturers modify devices that could "significantly affect the safety and effectiveness (Alpert 1997)" of a device, they are required to compare the changes to an already approved and marketed device and notify the CDRH about the modifications. The comparison can be based on their own device, a more recent device, or another firm's substantially equivalent device. In the case of comparison to a competitor's product, manufacturers have to justify both the comparison and that the product changes do not alter the performance of the originally intended use (Alpert 1997). The mandated evaluation and comparison to the safety of a competitor's devices, ensures interorganizational learning in the industry.

While the medical device guidances and regulations explicitly decree that manufacturers monitor, compare, and modify their own devices on the basis of the risk of adverse events of their competitors' products; the guidances and regulations allow manufacturers flexibility in the interpretation of what constitutes awareness of significant increases in safety concerns. The CDRH made the guidances flexible on purpose because it would be too difficult for manufacturers to pay attention all device types and monitor a constant evolution of devices to assess the risks of potential adverse events on the basis of a competitor's products (Alpert 1997). Indeed, there may be many different ways to weigh the safety of a device against a competitor's products, such as predicting a firm's own adverse events based on a death caused by a competitor's product flaw or based on media attention to a competitor's product.

I focus on the number of reported adverse events by competitors in this study, and investigate whether medical device firms reduce their annual product failure rates in response to increases in the number of reported adverse events by their competitors. I narrow on the number of reported adverse events by a competitor to highlight the role of attention to public reports of adverse events on interorganizational learning.

In this study, the primary lesson obtained by observing others' reported adverse events is that product modification may be required due to safety concerns. In general, firms generally do not modify medical devices, unless manufacturers become aware of safety concerns. This thesis investigates the impact of three salient phenomena (product failure, the reporting of product failure, new product introductions) on learning to reduce product failure rates. The nature of product failure, the reporting of product failure, and new product introductions are central to the structure of medical device organizations, the regulatory agencies in charge of industry oversight, and medical device users (healthcare facilities, patients, physicians, etc.). Consequently, the story of interorganizational learning from product failure in the medical device industry rests at the intersection of the reporting of failures in existing devices and the development of new devices.

Interorganizational Product Failure Experience in the Medical Device Industry

Product Failure

Product failures occur frequently and have a small, localized impact relative to impactful failures, such as industry-wide disasters or catastrophes. Product failures include a wide range of events – including product-caused deaths and product malfunctions. I uncover two medical device examples that were reported to the Center for Devices and Radiological Health (CDRH) of the US Food and Drug Administration (FDA) in 2009. In the first, a memory overwrite malfunction in a blood glucose monitoring system caused diagnosis problems. In the second, an unusual bend in a cardiac catheter meant that a procedure failed and a new catheter had to be reinserted, without injury. Product failures are different from near-failures (Kim and Miner 2007) or near-accidents (Sagan 1993) because they occur frequently and can be taken for granted, in the sense that most organizations recognize that they occur but few pay particular attention to them.

Product failures are different from near-misses (Heinrich 1990; Muermann and Oktem 2002) because they have local negative consequences, such as a serious injury caused by a product. A medical device example that was reported to the CDRH illustrates the difference. The example occurred in 2009 when a surgeon was performing a single-incision laparoscopic surgery (SILS) cholecystectomy. The SILS technique is a common procedure for removing the gallbladder. In this instance, the clamp used was too long for the procedure, causing the surgeon to make an accidental incision, and the patient to bleed excessively. Because of the bleeding, the surgeon had to abort the

laparoscopic procedure in favour of the riskier and more painful open surgery. The example illustrates that the clamp failure caused a localized injury to the patient. Although the causes can be minor, product failures occur frequently because it is difficult to predict all possible contingencies (e.g., produce universal clamps that fit all people).

The SILS clamp example illustrates two points about medical device failure. First, medical device users often compensate with workarounds for product failures. Prior work on medical errors explains why product failure workarounds persist, rather than product flaw corrections by the manufacturer (Edmondson 2003, 2004). Edmondson (2003) tells of an error made by a registered nurse (RN) assisting in a cardiac bypass. A RN drops a vein graft on the floor and the surgeon responds by quickly making another incision – without saying a word. Similarly, users often have to quickly move on when a medical device failure occurs. Device users are less concerned with providing detailed feedback to manufacturers than maintaining patient wellbeing while navigating of product failure.

Second, product failure often has socio-technical causes. Product failure is similar in this way to the complexity identified in accident research (Hollnagel 2004; Perrow 1984). Normal accident theory (Perrow 1984) identifies the complexity by showing that one type of failure, organizational accidents, have catastrophic potential when multiple failures occur simultaneously. As well, normal accident theory puts forth that organizational accidents occur because actors often do not understand that a failure in one part of an organization may cause a failure in another. Indeed, the theory holds that failures are inevitable because actors do not have a full understanding of what can

fail, why, and to what extent. In normal accident theory, the only way to prevent organizational accidents, such as disasters, is to learn how to buffer, contain, and absorb the complex set of interactions when failures occur. Perhaps the SILS clamp failure is the result of flawed product design or the surgeon's decision to use that type of clamp in the first place, but neither can be the conclusive root-cause of the product failure.

Maybe the elusiveness of the causes and user inattention to product failure are the reasons why learning from interorganizational product failure experience has not been researched in the medical device industry. However, students of the attention-based view (Ocasio 1997; Rerup 2009) put forth another reason: attending to product failure may be difficult. This view argues that organizations limit their attention to some product failures and not others because organizations cannot attend to all decisions (Kim and Miner 2007). Once critical issues have been resolved, organizations focus on other issues (Greve 2008).

The primary explanation why organizations may overlook product failures is because actors limit their attention to reduce the information available for decision-making (Simon 1945). Research asserts that it is difficult to pay attention to product failure because organizational actors cannot easily identify lessons or categorize practices from vast amounts of information (Vendelo and Rerup 2009). While some organizations may attend to a few product failures (Rerup 2009; Weick 1995), most organizations do not have the resources to closely process many of these failures.

A supplementary explanation of why it is difficult to pay attention to product failures of other firms is that some organizations try to offer self-serving information and

distort negative information (Staw et al. 1983). Together, these explanations suggest that organizations may have difficulty learning from others' product failures.

Anecdotal evidence of the reaction of Medtronic to the June 2006 Boston Scientific (Guidant) recall of pacemaker and implantable cardioverter defibrillators (ICDs) illustrates that some medical firms reduce their own failure rates by learning from others' product failure experience. Implantable cardioverter defibrillators (ICDs) are small devices that are implanted in a cavity near a patient's heart. The ICD shocks a patient's heart if it detects an irregular heartbeat. Boston Scientific recalled 49,800 ICDs because a faulty capacitor could cause a deadly electrical shock. The day after the recall, Medtronic stated that they did not use the same capacitor in their ICDs. Medtronic could have stopped there, and blamed the electrical shocks on poor manufacturing practices. However, after further inspection, Medtronic voluntarily recalled its ICDs in October 2007. The recall drew attention to a high occurrence of everyday failures in ICDs. One recent study finds that 3% of patients receive inappropriate electrical shocks, due to ICD failure (Nielsen et al. 2008). Medtronic was able to deduce that the product failure was not caused from poor manufacturing practices, but rather the lack of patient feedback about device problems. Medtronic learned to reduce its own product failure rates from Boston Scientific's ICD failures by introducing an ICD remote monitoring system, which monitors patient and device indicators. Medtronic introduced the Lead Integrity Alert (LIA) system which gives 76% of patients an audible warning three days in advance of inappropriate shocks (Burri and Senouf 2009).

Evidence from Boston Scientific's ICD failures also indicates that product failures may induce competitors to set up knowledge transfer mechanisms to reduce their own product failure rates. In 2004, Boston Scientific had a problem with its leads on the ICD. A lead is the wire that connects an ICD to the heart tissue. Boston Scientific's leads were not adequately connecting with the heart – causing some patients to be without the electrical shocks they needed to stay alive. In September 2004, ICD manufacturers and physicians set up a National ICD Registry to track and share ICD information about patients in response to the negative publicity (DeJohn 2007). The registry is maintained by the the American College of Cardiology and the Heart Rhythm Society (Meier 2009). The ability to freely share ICD performance information between the 1,450 participating hospitals (DeJohn 2007) and competitors allows organizations to track and compare the causes of others' product failure. The interorganizational learning value of the registry is demonstrated when analysis of the registry by a cardiologist led to recall of Medtronic's Sprint Fidelis leads for ICDs in 2007 (Meier 2009).

In general, theoretical perspectives suggest that learning from competitor's product failure experience is sometimes difficult. The attention-based view indicates that some product failures of competitors will be easier to attend to depending on the information available at the time. Learning from failure research shows that product failure causes are not always apparent, even if organizations have detailed reports of others' product failures. Thus, my first research question is:

Do firms reduce their own product failure rates by attending to a competitor's product failure experience?

Competitor Product Failure Reporting

The reporting process of product failure may be as important as the actual reports in explaining interorganizational learning in the medical device industry. Three notable changes that impacted the reporting of adverse events were the introduction of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Thacker 2003), leadership succession in the CDRH, and the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). Implemented on April 14, 2003, HIPAA changed the privacy protection of health information (1) allowing the FDA to have freer access to monitor medical devices adverse events and their side-effects and, (2) forcing the FDA to adopt national standards for electronic healthcare transactions to keep up with information demands. A second change was that Daniel Schultz took over directorship of the CDRH in 2004 and continued the role until 2009 from David Feigal who was the director of the CDRH from 1999 to 2004. Daniel Schultz was instrumental in the monitoring and enforcement of adverse event reporting. One of his primary objectives was to have a "robust and effective program to quickly detect and analyze problems that arise with devices after they are marketed (CDRH 2009a)." Finally, MDUFMA is one of the most significant medical device-specific changes since the enactment of the Medical Device Legislation Amendments of 1976 (MDLA). MDUFMA was enacted on October 22, 2002, speeding up the time to market of medical devices to allow patient access to cutting-edge devices, but possibly allowing an increase in adverse events because of less rigorous pre-market testing.

Studies in a number of industries support the view that failure reporting systems may explain the effects of interorganizational product failure experience. One study found that idiosyncratic safety violations in nuclear power plants can go undetected by government safety inspectors (Feinstein 1989). However, Feinstein (1989) did find that further inspections diminish the likelihood of undetected safety violations. Another study establishes that government monitoring of pharmaceutical manufacturers may be highly variable, depending on the training of individual inspectors (Macher et al. 2008). In several studies on airline accident reporting and pharmacy drug dispensing errors, Tamuz and colleagues (2001a, b; 2004) show that the reporting process and the regulatory environment are central to understand learning from failure.

Reporting delays are indicative of the medical device product failure reporting process. A reporting delay represents a temporal gap between the occurrence of a product failure and the detection of the event by the focal firm. The FDA mandates that manufacturers and users of medical devices report adverse events within 30 days of learning that the event occurred. However, this standard is not always met. An audit of reporting between 2003 and 2008 by the Inspector General of the US Department of Health and Human Services finds that 11% of adverse events reported by manufacturers are after the 30 day window. I find that 5% of reports are delayed by more than 174 days in analysis of CDRH data (CDRH 2009b). Reporting delays and the FDA's slow response to improving the adverse event reporting system are also well-documented in industry trade journals (Dickinson 2009b) and the popular press (Meier 2005). For example, Boston Scientific received the attention of the *New York Times* because it

withheld knowledge of pacemaker defects from physicians and the CDRH for three years (Meier 2005).

Experimental analysis affirms that learning difficulties may occur with delays between an action and its outcome at the intraorganizational level (Sterman 1989). Simulations by Denrell et al. (2004), Fang and Levinthal (2009), and Rahmandad (2008) show that delays can decrease learning. Q-learning simulations by Rahmandad (2008; Rahmandad et al. 2009) suggest that learning complexity grows exponentially as delays lengthen, and that learning may be suboptimal because projects with long lead times are initially undervalued. A case study by Repenning and Sterman (2002) showed that quality improvement projects were prematurely abandoned because of delays in outcomes. In a subsequent paper, Rahmandad et al. (2009) proposes that learning is hampered if perceived delays do not match actual delays.

Interorganizational learning research is silent about the effect of reporting delays on learning. On one hand, competitors that spend time processing product failure reports may present a clear picture of the causes of product failure. Learning from failure research demonstrates that paying close attention and articulating the root-causes of failure may reveal how devices really work and may uncover unrelated problems (Carroll 1998). Competitor reporting delays may improve interorganizational learning in cases were investigators find novel insights. On the other hand, scholars of delays (Denrell et al. 2004; Rahmandad 2008) and of the attention-based view (Ocasio 1997; Rerup 2009) would argue that the additional complexity of reporting delays would cause firms to neglect or discount reports of product failure. Given these two bodies of literature, it is

not clear what kind of an impact, if any, a competitor's reporting delays will have on learning from interorganizational product failure experience. Therefore, my second research question is:

How do others' reporting delays influence the impact of others' product failure experience on a firm's product failure rates?

Competitor New Product Introductions

Innovation is a common response to product failure in the medical device industry. Organizations innovate to solve or overcome a particular problem. Anecdotal evidence illustrates that firms reduce their own product failures by learning from others' new product introductions. Magnetic Resonance Imaging (MRI) uses powerful electromagnets to polarize water molecules in soft tissue and then present information as pictures on a computer screen (Wood 2001). The technology was a major breakthrough in medical imaging because it allowed doctors and researchers to see how soft tissue behaves inside the human body, without invasive surgery.

The major problem with early MRI technology was that the powerful electromagnets created stray magnetic fields that interfered with sensitive hospital equipment and posed dangers for patients standing between MRI equipment and missile-like projectiles of ferrous materials. In the early 1980s, engineers overcame this problem by placing MRI machines in rooms installed with passive iron plates to absorb stray magnetic fields. However, an iron-plated room was not ideal because the magnetic field within the room was still strong, creating the same problems but confined to a smaller area. Iron-plating also added significant installation costs and limited where the machines could be physically located in hospitals. The iron plates eventually became polarized themselves, defeating the purpose of the containment area. Oxford Instruments, now Siemens, was the first company to overcome this problem (Wood 2001) by counteracting the magnetic field with coils wrapped around the core of the machine, in

the opposite direction. Within a short period, almost all MRI manufacturers had introduced their own version of Oxford Instrument's active shield technology.

Research on product innovation within firms sustains the view that firms may a competitor's new product introductions may affect learning from product failures. Work on absorptive capacity, which is the ability to acquire, assimilate, transform, and exploit knowledge (Cohen and Levinthal 1990) suggests organizations that have a history of product innovation may be more likely to share product failure reports and collaborate to solve product failures. A hospital study of medical device implementation by Edmondson et al. (2004) further supports the view that a competitor's new product introductions impacts learning from failure. Their study suggests that the codified product design specifications in a competitor's new product introduction reports may increase the transfer of design knowledge across organizations, without learners being close to a competitor's product designers. Levin's (2000) study illustrates why firms may want to learn others' design knowledge. Levin (2000) shows that organizations improve automobile quality at an accelerated rate the first time an automobile is introduced because manufacturers have a chance to introduce the very latest product designs and manufacturing processes.

A small amount of literature on interorganizational learning from new product introductions shows that a competitor's new product introductions can be a source of interorganizational experience. Srinivasan and Haunschild (2007) show how high technology digital camera companies obtained better resolution, or pixels per area, by learning from other high technology companies, rather than low technology companies.

Powell and his colleagues investigated several geographic and network characteristics that affect innovation activities, using patents in new biotechnology organizations (Owen-Smith and Powell 2004; Powell et al. 1996). Overall, this work suggests that competitors pay attention to others' new product introductions.

However, simple and clear solutions to product failures like Oxford Instrument's active shield technology are the exception. The difficulties of highlighting the impact of new product introductions may be the reason why Dutton and Thomas (1984) conclude that the impact of product design changes on learning from experience is mixed and not fully understood. One of two problems arise. First, a competitor's new product introductions may lead to postponement of existing product development. Formal models show that some firms may postpone improvements until better technologies are available (Balcer and Lippman 1981). When their competitors are innovating, firms may exploit existing products with higher product failure rates than explore new products with design improvements (March 1991).

The second problem is that a new product introduction is distracting for a firm that learns from a competitor's failure in an existing product. Distractions from product failure experience occur when organizations pay attention to seemingly more salient events rather than the product failure itself; and commonly occur when new products are introduced simultaneously as failure occurs in existing products, creating confusing and conflicting outcomes. Evidence of others' new product introductions often confounds their product failures, which makes the causal relationships difficult to disentangle. Simulation studies highlight this problem. Rivkin's (2001) study finds a firm's ability to

understand a competitor's new product introductions may depend on the specific product features of a referent other. Another simulation study shows that firms may learn irrelevant or misleading information from some new product introductions (Gavetti et al. 2005).

The notion that a technology is a distraction is somewhat pedestrian. In-car cell-phone use is an analogous example at the individual level. A number of legal jurisdictions are prohibiting the use of cell-phones because the devices are distracting for drivers (Richtel 2010). The reason is that individuals prioritize attention resources to cell-phone use rather than driving. The belief is that drivers are more likely to get in accidents because they are focusing on the cell-phone conversation rather than focusing on driving.

Evidence highlights similar attention challenges at the organizational level. Haleblian and Finkelstein (1999) show that large, publically traded firms make better mergers and acquisitions if they discriminate past experience. Adler and Clark (1991) find that cumulative engineering activity on product design changes increases total productivity in some departments of an electronic equipment manufacturing company. However, they also discover that engineering activity in other departments of the same company on design changes decreases productivity. Adler and Clark (1991) reveal that the productive engineers paid attention to productivity concerns, but the less productive engineers paid attention to reliability concerns in follow-up fieldwork. Their research implies that attention to different forms of experience can have negative effects (and positive effects) on learning.

I make a unique contribution to the existing research because I argue that a competitor's new product introductions may act as a distraction for organizations in the medical device industry. From 1978 to 2008, there were 62,924 class I and II medical devices, defined as devices that are relatively benign and similar to existing but not the same device, introduced to the US market and recorded by the FDA. This averages out to six devices every day. On average, medical device firms introduce a device every 140 days. Two-thirds of the revenue for a medical device firm comes from devices launched within the last two years (Young 2008). Firms may prioritize whether to learn from product failures in existing devices or learn from product innovations in new devices that arise every year.

Here lies a contradiction that research has yet to answer about a competitor's new product introductions. Product innovation research suggests that product failures rates are likely to decrease when a competitor introduces a new product. I create a counterargument using organizational attention and learning scholarship. While the effects of a competitor's new product introductions on learning from existing failure is unclear, a competitor's new product introductions may be distracting and inhibit the ability to learn from a competitor's product failure experience. Therefore, I ask:

How does the juxtaposition of others' product failures with their new product development reports influence an organization's ability to learn from others' product failures?

Why would competitor product failure, reporting delays, and new product introductions make it difficult to learn from product failure? The most likely reason is because learning from others' product failure requires some organizational attention. I focus on interorganizational learning to reduce failure because organizations deliberately seek to prevent their own failures by learning from others (Haunschild and Sullivan 2002; Kim and Miner 2007). Interorganizational learning reduces an organization's failures by selective exploration of the product failures of a referent other. My research questions relate to how organizations learn from the delayed and distracting information of other organizations at a specific point in time.

Answering these three research questions will contribute to the literature on interorganizational learning of product failure and interorganizational learning with delays and distractions. Chapter Two reviews the literature on the organizational learning and interorganizational learning. Chapter Three theorizes how organizations learn from others' product failures. Chapter Four discusses the medical device industry and describes how the theory will be tested. Chapter Five outlines the results. Chapter Six summarizes the contributions of this study.

2. Literature Review

Organizational learning research assumes that organizations change in response to past outcomes and that these changes drive and constrain future outcomes. The view assumes that even though boundedly rational actors have poor memories, biases, and limited attentional abilities (Simon 1957), the organization as an aggregate unit nullifies the limitations of individual members. Yet, the same organizational processes that help nullify individual limitations and guide improvements, can sometimes hinder future outcomes.

Learning from Failure

Organizations learn (but not always) from their own experience. Learning curve research (Yelle 1979), for example, illustrates that organizations learn to be efficient by accumulating experience. The research assumes that accumulating experience allows some firms to become efficient by engaging in trial and error learning through observing the outcomes of different actions and reinforcing those actions that lead to successful outcomes. Typically, this scholarship focuses on reducing costs per unit in manufacturing environments. Asher (1956) and Wright (1936), for example, show how costs per unit production in the airline industry decline with cumulative experience. Wright (1936) and Asher (1956) both use learning curves to describe the rate of aircraft production. They find that the unit of labour input per unit decreases with experience. Scholars (Argote and Epple 1990; Rapping 1965; Thompson 2001) similarly find that the unit of labour input decreases with experience with WIII Liberty shipbuilding. More

contemporary work that does not focus on unit costs demonstrates the occurrence of experiential learning from reinforcing successes. Pisano, Bohmer, and Edmondson (2001) show that as hospitals gain experience with minimally invasive cardiac surgery, procedure times decline at different rates. Other scholars have found that costs per unit decrease with experience, e.g. in pizza parlours (Darr et al. 1995) and postal services (Wiersma 2007).

But success is only one part of the story. Firms may also learn because of experience with failure. Past research has shown that experience with failure in the past leads to reductions in future failures (Baum and Dahlin 2007; Kim and Miner 2007; Madsen 2009). Some scholars recognize that viewing experience in terms of failures may be a fruitful approach to understanding learning (McGrath 1999; Sitkin 1992). Starbuck and Milliken (1988) argue that the Challenger shuttle disaster occurred partly because the actors concerned had been exposed to too many successes and not enough failures. Sitkin (1992) argues that failures are a prerequisite to effective learning because failures simulate experimentation-like processes in the organization. Focusing only on successful outcomes can have three effects. First, concentrating on successes leads to complacency because successful outcomes indicate that current actions are satisfactory and corrective actions are not needed. Second, paying attention to only successes increases risk aversion because the risk of blame may increase for those actors who have acted and failed. Third, focusing on successes can restrict search and increase homogeneity because only positive outcomes are investigated or rewarded. McGrath (1999) further argues that organizations can better manage uncertain environments by

having a portfolio of systematic controlled failures and the systems in place to learn from the failures. Allowing failures to occur may be a way of overcoming systematic biases in decision-making. For example, organizations that fail early and often may encourage entrepreneurial risk-taking, create more far-reaching activities, and better manage the costs of failure (McGrath 1999; McGrath and MacMillan 2000).

Failures may be a valuable form of experience for three reasons. First, inattention to failure can have damaging consequences because of sample selection biases. Sample selection biases exist because successful outcomes tend to persist and failed outcomes tend to disappear in repeated sampling (Denrell 2003). Denrell (2003) asserts that risky but successful outcomes persist and risky but failed outcomes extinguish because successful outcomes are repeatedly reinforced. Over time, failed actions are systematically absent from a sample. Denrell (2003) simulates how the under-sampling of failures leads to a situation where organizations prefer to take chances on new, unreliable and even lucky practices rather than revert to well-rehearsed, reliable, and more optimal practices.

Second, failure is valuable for learning because controlled failures expose weaknesses in an organization that would otherwise lead to more disastrous outcomes. This second reason relates to normal accident theory (Perrow 1984), which suggests that one type of failure, organizational accidents, have catastrophic potential when multiple failures occur simultaneously. As well, normal accident theory puts forth that organizational accidents occur because actors often do not understand that a failure in one part of an organization may cause a failure in another. Indeed, the theory holds that

failures are inevitable because actors do not have a full understanding of what can fail, why, and to what extent. In normal accident theory, the only way to prevent organizational accidents, such as disasters, is to learn how to buffer, contain, and absorb the complex set of interactions when failures occur.

The third reason is that the occurrence of failure breeds mindfulness of future failures and improves ability to better resolve failures when they do occur as evident in the experience of the high reliability organization (Reason 1997, 2000; Weick and Roberts 1993; Weick et al. 1999). The high reliability organization literature assumes that failures incubate over time, in the sense that organizations can recognize the signs of failure before it occurs. High reliability organizations are able to avoid failure because they are heedful or mindful (Levinthal and Rerup 2006) of the signs of failure and make appropriate changes before failures occur. Weick and Roberts (1993) maintain that continuous attending to failures can pre-empt accidents on the flight decks of aircraft carriers. Weick's (1993) study of the Mann Gulch fire disaster, demonstrates that recognizing the causes of failure before they occur can reduce the severity of failures. Taken together, the work by normal accident theory and high reliability organization scholars suggests that costly mistakes can be contained or avoided altogether if organizations try to infer what failures could happen.

Interorganizational Failure Experience

A number of reasons suggest that it may be difficult to learn from others' failure experience. First, some of the failures of others are difficult to notice. For example, Kim and Miner (2007) found evidence that banks learnt less from the failures of non-local and

different banking sector organizations, than from local and closely related firms. Firms may overlook failures that are difficult to understand. Haunschild and Sullivan (2002) found that airlines learned more from simple accidents than from complex ones. Less frequent failures may also be difficult to pay attention to. Haunschild and Miner's (1997) work on investment banks shows that organizations may ignore the infrequent outcomes of their competitors because infrequent outcomes are less salient. This work suggests that timing and the structure of failures are important factors that can prevent organizations from noticing the failures of others.

Moreover, several factors may impact a firm's ability to detect, understand, and develop practices that avoid the actions that cause others' failures. Organizational experience, for example, may play a role in interorganizational learning from failure. The argument is similar to that used to explain learning curve effects (Yelle 1979) and learning spillovers (Thornton and Thompson 2001). Organizations become more efficient at noticing and avoiding others' failures as the activity is repeated (Baum and Ingram 1998; Ingram and Baum 1997), and they can use others' failures as a substitute for their own experiences (Baum and Dahlin 2007; Chuang and Baum 2003). Baum and Dahlin (2007) showed that the accident and operating experiences of other firms can reduce a railroad's accident costs. Ingram and Baum (1997) found that US hotel chains could reduce their failure rate by using the experiences of other organizations.

Additional research emphasizes that others' failures may be difficult to recognize if organizations have little slack. Studies by West (2000) and Edmondson (2004) have found that busy nursing staff sometimes overlook errors because they do not have enough

time to be vigilant to all failures. These two studies reveal that interorganizational learning may be especially difficult in hospitals, and similar high-demand or fast-paced contexts. Overall, these studies on the internal processes of learning suggest that not all organizations are going to learn from others' failure experience to the same degree (possibly not at all or in negative ways), even when failure information is accessible and when attending to others' failures may avoid future failure.

Interorganizational Learning from Failure

Some failures make interorganizational learning easier than others. In order to comprehend failures, organizations try to find the detailed story of events that led to a failure by looking for more interpretations, more experiences, and more ways to evaluate the failure (March 1994). For example, Beck and Plowman (2009) theorize that utilizing the insights of middle-managers is an effective way to obtain a rich understanding of a failure. March and his colleagues (1991) further highlight that organizations can learn from failures by creating a history of hypothetical failures, and comparing rare failures with known near-failures. Nevertheless, pooling across diverse contexts and creating hypothetical situations may be particularly prone to the effects of distracting or delayed data. A study by Christianson et al. (2009) suggests that distracting and incomplete information is particularly problematic in pooling information from failures. They find that failure triggers organizations to reorganize using single-point in time audits of strengths and weaknesses. Pooling may lead to inaccurate or incomplete representations of what failures could occur and poor memories of what failures actually occurred.

Organizations can learn from others' impactful failures, such as disasters. Impactful failures are outcomes that are significantly worse than expected, for instance those that incur high costs or human casualties. Starbuck's (2009) theoretical article argues that learning directly and immediately from impactful failures is difficult. He lists several reasons: (1) actors view these failures as idiosyncratic, (2) actors misunderstand that these failures develop over long periods, and (3) actors underestimate the likelihood of future failures. However, impactful failures like the Mann Gulch disaster are salient (Weick 1993) and create occasions for learning and analysis long after they occur. Weick (1993), for example, used archival records from the original investigation to reanalyze the events that led to the death of 13 men in the 1949 Mann Gulch disaster. The Challenger space shuttle disaster is another impactful failure. NASA uses Vaughan's (1996) study of the Challenger disaster to prevent future failures. The subsequent Columbia space shuttle disaster illustrates that it can be difficult for intraorganizational learning from impactful failures (Farjoun and Starbuck 2005). However, the repeated use of the Challenger disaster as an example in learning studies (Beck and Plowman 2009; Farjoun and Starbuck 2005; Starbuck 2009; Starbuck and Milliken 1988; Vaughan 1996) and disaster investigations suggests that impactful failures often have a long history and can be used for future interorganizational learning.

The impactful failures of others may also present a rich opportunity to understand the inner workings of a rival. Impactful failures are usually accompanied by a vast amount of detailed information from multiple perspectives (Farjoun and Starbuck 2005; Vaughan 1996). That is because impactful failures are often investigated by third party

regulators (Madsen and Desai 2010). For example, Madsen (2009) notes that the Mine Safety and Health Administration (MSHA) investigates mining disasters to prevent future disasters from occurring. The inner workings of an organization are often made public when third party investigations are combined with the complex relationships that led to an impactful failure (Perrow 1984; Reason 1997; Weick et al. 1999). As well, others' impactful failures are often used as a template of what not to do. Carroll (1998; 2002), for example, describes how root cause analysis reports of some impactful events (e.g., Three Mile Island) are often shared with outside actors to illustrate the many problems that led up to the disaster.

3. Theory and Hypotheses

Product Failure

I follow prior studies that demonstrate failures are often predictors of future failures. Madsen (2009) shows that minor accidents reduce the likelihood of mine disasters and Tamuz et al. (2004) find that routines that encourage hospital pharmacy staff to notice errors reduce medication mistakes. Hayward (2002) demonstrates that small acquisition losses increase the next acquisition because small losses highlight problems in previous actions without directly blaming individuals. Although researchers have yet to analyze product failures, the existing work on minor failures and near-failures suggests that organizations do notice and change actions based on product failures. Organizations can also take lessons from others. Kim and Miner (2007), for instance, found that banks are less likely to fail when they learn from the near-failures of other banks. Their findings support the view that others' product failures contain vast and rich information to inform organizational actions.

In the medical device industry, a competitor's product failure experience may actually interact between multiple organizations, leading to possible increases in a firm's product failure rate. My own qualitative analysis of CDRH data reveals an example of how product failure is connected between medical device manufacturers. Firm 2645 and Firm 271 manufacture wound closures. Firm 2645 is a manufacturer of surgical staplers. Surgical staplers were one of the main alternatives in wound closures for doctors in 1998. In 2000, Firm 2645 experienced a wide-spread device failure. The surgical stapler was

allegedly misfiring and did not properly close wounds. Firm 2645 was later tried of the wrongful death of a woman that underwent surgery with the allegedly defective device. The device misfired and caused the woman's stomach contents to leak. The defender was ordered to pay $5 million dollars to the family of the victim[1]. There is currently a class-action lawsuit against Firm 2645.

Firm 2645 may have learned from the surgical stapler adverse events. A 10% increase in the cumulative product failure experience of Firm 2645 caused a 30% decrease in the rate of its own product failure. However, Firm 2645's product failure experience may have increased its competitor's product failure rate. In 2001, Firm 271 introduced a revolutionary device in the minimally-evasive surgery sector that was an effective electrosurgerical alternative to surgical staples. The electrosurgical device cauterized wounds after surgery was performed. Firm 2645's product failure caused an increase in the demand for Firm 271's electrosurgerical device – causing an increase in Firm 271's product failure rate while doctors learned how to effectively use the device.

The wound closure story demonstrates an important point: a story of interorganizational learning from medical device failure is incomplete without emphasizing the competitions' new technologies. Theoretically, this is not a new idea. Studies on the demand-side that show that physician's may choose a new technology over an existing technology are well known (Burt 1987; Coleman et al. 1957; Conley and Udry 2010; Strang and Tuma 1993; van den Bulte and Lilien 2001). Coleman et al. (1957) studies the adoption process of a medical innovation by 107 physicians over 17

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[1] This is a study of the US medical device industry. All references to currency are US dollars and all references to legal jurisdictions, legislation, governments, agencies, and so forth refer to the US context.

months. The study shows that physicians who are scientifically oriented (attending conferences, reading journals, etc.), have close advisors and colleagues who have already adopted the drug, and are central to the medical community are most likely to choose to begin prescribing a new pharmaceutical, tetracycline. Various follow-up articles using the same data medical innovation refine understanding the interaction effects of the social contagion effect. For example, Burt (1987) suggests that social network effects in the medical community are more important for social contagion than with interactions with colleagues who have already adopted. Strang and Tuma (1993) show that Burt's (1987) conclusion that interaction with colleagues is not important for social contagion may be due to model misspecification of neglecting heterogeneity in the industry. Nevertheless, interorganizational experience interaction is a distinct concept from the literature on social contagion in individual social learning – making the reasons for physician social contagion not necessary in my study.

Interorganizational experience interaction is distinct from individual-level social contagion for three grounds. First, interorganizational experience interaction focuses on organizational processes (the supply-side), given that social contagion exists in the product market. Physician social influence is one of many factors that effects interorganizational experience interactions. One could think of a broad range of competitor interactions beyond cumulative industry production that can alter the role of interorganizational experience. For example, product pricing between competitors, expectations of product innovation, and scientific publications demonstrating the usefulness of one device over another all can affect the concatenating role of the demand

by medical device users. Second, interorganizational product failure experience begins after physician adoption of medical devices. It is very likely that medical device companies can use the lack of physician adoption of devices as a signal of how to improve device quality. However, the necessary condition for learning from interorganizational product failure experience is that at least some physicians adopt the devices and report to the other physicians and the manufacturer on product reliability and usability. Indeed, medical device companies often benchmark products and ask physicians what they like and dislike about their products relative to the competition. Third, physician social contagion may be more of a function of organizational experience and interorganizational experience than vice versa. van den Bulte and Lilien's (2001) analysis of the Coleman et al. data is an example of the influence of organization experience on physician social contagion. Their study finds that social contagion effects became insignificant when they control for marketing efforts by the tetracycline manufacturers. The article also highlights the importance of the interaction with a competitor's product (chloramphenicol). Physicians began to extensively use tetracycline because the doctors learned that it was a superior product in terms of price per drug efficacy and because it was a generational product in a family of existing drugs. van den Bulte and Lilien (2001) reinforce the importance of organizational learning of how to introduce the medical products and how to improve upon medical product reliability (ie. the reduction of side-effects from previous product generations), while emphasizing the importance of contextual effects of organizations in explaining social contagion of medical innovation.

The wound closure example shows that competitor product failure experience may cause a firm's product failure rates to increase because of the nature of interactions between competitors. Possibly some of the interorganizational experience interactions are not important to interorganizational learning. Yet, the fact that product failure rates increased for Firm 271 suggests that the way some interorganizational experience interacts does has a significant impact on interorganizational learning in the medical device industry. I try to uncover the importance of two ways competitors interact when drawing from a competitor's product failure experience in the medical device industry by emphasizing the product failure reporting delays and the competitions' new products.

Learning to Reduce the Rate of Product Failure

This thesis focuses on learning to reduce a firm's own product failure rates from interorganizational product failure experience. I center on the year-to-year rate of product failure (relative to past failures) on two accounts. First, I want to capture that a firm modified its product due to awareness about safety concerns, which is the primary lesson that is obtained by observing others' reported adverse events. I capture such product modifications at the firm-level by looking at how the current number of adverse events compares against the past number of adverse events per firm. In general, firms generally do not modify medical devices, unless manufacturers become aware of safety concerns. Most modifications require regulatory approval (Alpert 1997), but guidances due allow for manufacturers to make minor changes in product design, as long as the minor changes do not affect the safety and effectiveness of devices. Manufacturers have to be careful not to modify medical devices if there is little reason too because (i) changes in product design and labelling from what the device was originally intended put users at risk of adverse events, and (ii) the CDRH can revoke a manufacturer's privileges to sell devices and prosecute if manufacturers violate regulations. Additionally, manufacturers are careful to ensure that modifications from safety concerns, actually do improve product safety because of potential liability concerns.

Second, research on attention-based supports the idea that learning is better captured by looking at the number of adverse events relative to past adverse events (Ocasio 1997; Rerup 2009). The view suggests that paying attention to emerging issues and filtering noise in failures is particularly important to preventing large failures before

they occur. Medical device firms focus on year-to-year failure rates because they can focus on relevant product failures that differ from what is expected - rather than attending to all medical device adverse events.

The CDRH guidances and industry regulations allow three types of product modifications that manufacturers can perform to improve reduce product failure rates, upon awareness that product improvement is required. The first option is to remove a device from the market, either through a recall, planned obsolescence, or other procedure. The second option that a manufacturer may perform is to make technical alterations to their product design, these include technology or performance specifications changes and materials changes. The third option is to inform, teach, and educate medical device users not to perform specific tasks that may result in an increase of the risk of experiencing adverse events. This option is often done through changes to labelling and documentation.

Table 1 presents a statement of each hypothesis and the variables of interest in my thesis. The first three hypotheses build theory on the effects of a competitor's reporting delays on interorganizational product failure experience. In Hypothesis 1, I extend previous theory on interorganizational learning and argue that product failure rates decrease with interorganizational product failure experience. Hypotheses 2 and 3 moulds literature on intraorganizational learning with delays, error reporting, and interorganizational learning to suggest that reporting delays have counterintuitive effects on learning from others' product failures. Hypothesis 2 argues that a competitor's reporting delays decrease the rate of product failure because of reporting clarity comes

with time. Conversely, Hypothesis 3 makes the case that a competitor's reporting delays of product failure reduces the ability of organizations to pay attention to and generate insights from a competitor's product failure experience.

Hypotheses 4 and 5 focus on distractions to interorganizational learning from product failure. I claim that a competitor's new product introductions decrease the rate of product failure because of gains in knowledge about product design and increases in knowledge transfer from the reports of new product introductions. However, I demonstrate paradoxical effects of a competitor's new product introductions on interorganizational product failure experience in Hypothesis 5. I use sequential attention and superstitious learning arguments to suggest that a competitor's new product introductions may distract an organization from learning from the failures in a competitor's existing products.

Table 1
Hypotheses and Variables of Interest

Statement of Hypothesis	Dependent Variable (DV) Independent Variable (IV) Moderator Variable (MV)
1. Increases in a competitor's product failure experience will lead to decreases a firm's future rate of product failure.	**DV:** Rate of product failure ($R_{i,t}$) **IV:** Average increase in competitor product failure experience ($E_{j,t-1}$)
2. A firm's product failure rates will decrease if a competitor takes longer to report product failures to the CDRH.	**DV:** Rate of product failure ($R_{i,t}$) **IV:** Average increase in competitor product failure reporting delay ($D_{j,t-1}$)
3. Reporting delays will moderate the effectiveness of interorganizational learning from others' product failures, such that an organization learning from others will be less likely to reduce its own rate of failures when reporting delays are longer and more likely to do so when reporting delays are shorter.	**DV:** Rate of product failure ($R_{i,t}$) **IV:** Average increase in competitor product failure experience ($E_{j,t-1}$) **MV:** Average increase in competitor product failure reporting delay ($D_{j,t-1}$)
4. A firm's product failure rates will decrease with increases in competitor's new product introductions.	**DV:** Rate of product failure ($R_{i,t}$) **IV:** Number of new product introductions by an average competitor ($NP_{j,t-1}$)
5. Distractions from the simultaneous occurrence of a competitor's new product introductions and failure reports will moderate the effectiveness of interorganizational learning from others' product failure experience. That is, an organization learning from others' product failures will be less likely to reduce its own incidence of failure with more reports of others' new product introductions and more likely to do so with fewer reports of others' new product introductions.	**DV:** Rate of product failure ($R_{i,t}$) **IV:** Average increase in competitor product failure experience ($E_{j,t-1}$) **MV:** Number of new product introductions by an average competitor ($NP_{j,t-1}$)

Learning from Interorganizational Product Failure Experience

Learning from others' product failures can be beneficial (see Appendix A.1 for an overview). There are three, mutually complementary, yet distinct benefits to learning from the product failures of others: 1) cost reduction, 2) reputation management, and 3) organizational renewal. First, learning from product failures can reduce the future costs of failures. Baum and Dahlin (2007) showed that a competitor's accident experience decreases the costs of future accidents. Second, coping with product failures teaches organizations how to manage their reputation – specifically, by helping them anticipate and prevent reputation losses of future product defects. Rhee and Haunschild (2006) showed that firms with good reputations could charge higher prices and incur lower costs. However, these firms suffer high penalties when their products fail. Rhee and Haunschild's (2006) work supports the view that making incremental and frequent adjustments to organizational actions, via product failures, may prevent large reputation losses when more impactful failures occur. Third, product failures can sustain organizational renewal, by promoting mindful attention to reliability. Rerup (2009) found that focusing on frequent but subtle clues helped a pharmaceutical manufacturer avoid potentially harmful failures. His study supports the view that product failures may help organizations continuously attend to high reliability.

There are several underlying arguments why these three mechanisms are more effective when learning from others' product failures. First, organizations which learn from others may be less prone to inertia and less defensive of the status quo, because others' failures are easier to accept and process than their own. There is evidence to

support this argument. Lant and Mezias (1992) find that organizations may be buffered from the effects of their own failure, especially if they have little past experience with failure. Nystrom and Starbuck (1984) argue that firms continuously and fruitlessly change actions if they experience many of their own failures. Although some organizations do recognize their own product failures, their threat-rigidity response may prevent them from processing the information (Audia and Greve 2006; Milliken and Lant 1991; Ocasio 1995; Staw et al. 1981). Organizations learning from others' product failures are free from this problem. Second, organizations which learn from others are less prone to the biases that blind them to failure. These firms may be more easily able to see the causal associations between others' failures and managerial actions (Staw et al. 1983). Third, organizations may devise more innovative responses to others' product failures because these incidents are very heterogeneous, facilitating the growth of organizational response repertoires (Haunschild and Sullivan 2002; Sitkin 1992). However, while it may be easy to learn from others' product failures, identifying the relevant failures is rife with difficulties.

Two factors emphasize why increases in a competitor's product failure experience have such a strong learning effect in the medical device industry. First, organizations with extensive product failure experience attract the attention of regulators and third party analysts. The FDA, for example, can revoke selling privileges or recall unsafe medical devices (CDRH 2009b). The FDA is likely to intervene if a device imposes a greater than average risk to consumers, although there is likely to be some variation in the timing of FDA intervention (Feinstein 1989; Macher et al. 2008). These third-party

interventions can help transfer knowledge and may help motivate exceptionally unreactive medical device firms. One airline industry study found that knowledge transfer through regulatory efforts is a particularly strong motivation for organization learning (Tamuz 2001b). Second, firms and technologies with a history of product failure may not receive external research and development funding to develop future devices. Funding penalties for unreliable devices motivate firms to change actions quickly.

Hypothesis 1. Increases in a competitor's product failure experience will lead to decreases in a firm's future rate of product failure.

Competitor Reporting Delays

A reporting delay represents a temporal gap that separates the occurrence of a product failure and the detection of the event by the focal firm. There may be a counterintuitive trade-off between (1) the time it takes for a competitor to process a product failure and (2) the firm's accuracy in attending to a competitor's delayed product failure (Appendix A.1 presents a brief synopsis of reasons). Learning curve studies indicate that organizations that spend more time training their employees and devote extra resources can be better at what they do (Yelle 1979). Similarly, I argue competitors that spend more time processing product failures by unravelling the causes of product failure and perfecting written reports of product failure can present clear lessons to third-party product failure systems. However, there is an interorganizational sacrifice of this intraorganizational attention. Learning from others' product failures experience will be less effective when failure reports are delayed. I tackle arguments about the duration of a competitor's product failure processing and attentional accuracy to a competitor's product failure experience in sequence.

Recent intraorganizational studies identify two reasons why a competitor's reporting delays increase an organization's ability to learn. One reason is that delays can be used to pay closer attention and identify product failure causes. Hayward (2002) shows that moderate amounts of time between acquisitions reveals meaningful acquisition results while allowing the ability to vividly remember acquisition efforts. Indeed, Carroll (2002) found that safety reports that took a long time to investigate showed considerable clarity and depth.

Reporting delays allow time to coordinate attention within organizations. For instance, different actors may only witness fragments of events and it takes time to coordinate this information (Rerup 2009; Vendelo and Rerup 2009). For example, a report submitted to the CDRH by a German medical devices company in 2008, written by a biomedical engineer, indicated that a patient died because an alarm on a patient monitoring system was "silenced by users". If ignoring the alarm could lead to death, why did it have a shut-off function in the first place? The example illustrates that reporting delays may occur if it takes a long time to properly investigate a failure. That is, it could be incredibly time-consuming and difficult for the biomedical engineer to coordinate, analyze, and write up data collected from all the people involved in the failure, including the engineers who designed it and family of the unfortunate patient who used it. Formalizing experiences requires time to retrospectively make sense of adverse events (Weick 1995). One report submitted to the CDRH by a heart valve manufacturer in 2009 indicated that "the cause of [the death of the patient] could not be determined" and that there may be an update of the cause in the future. This example illustrates that sometimes it takes longer than 10 days to understand the causal mechanisms of a failure.

Another reason is that reporting delays afford greater understanding of cause and effects. Reporting delays sometimes provide emotional distance or time to corroborate information to interpret product failures that were misleading at the time. A simulation by Denrell and others (2004) emphasizes that organizations that piece together sources of delayed information slowly may develop a clear overall picture. At the individual level, actors feel negative emotions, such as fear, guilt, and shame, when they report failures

because they may be concerned about the economic and reputation costs of the failure (Zhao and Olivera 2006). Because of these negative emotions, reporting delays may allow more 'cool-headed' actors to report product failures in a less emotional way. Research on the psychological safety of error reporting (Edmondson et al. 2001) supports the view that elapsed time may direct attention of product failure reports away from user blame to deeper reflection of failure causes.

Research on interorganizational learning from failure highlights at least one cause why a competitor's reporting delays may lead to decreases in product failure rates. Madsen and Desai (2010) theorize that an organization's failures are often made public by regulators. Because many product failures will inevitably be known by product users, delays allow time for competitors to manage reputations by wider publicizing product failures as learning opportunities, rather than as fatal flaws in product design (Rhee and Haunschild 2006). Rhee and Haunschild (2006) provide evidence that supports this view by showing that high reputation organizations receive a disproportionately larger amount of media coverage of product recalls than low reputation organizations.

Counter intuitively, a competitor's reporting delays are likely to decrease the rate of product failure of a firm in the medical device industry, for two factors. The first factor is that reporting delays assist in discussion between a competitor and the user facility where the product failed. Healthcare professionals may wait until the end of their shift, or later, to report adverse events. A theoretical study on medical device safety reporting by Maisel (2005) argues that physicians may not even report because of the significant physician liabilities involved in public reporting of patient data. Practically,

delays allow time for competitors to assemble and get input from the healthcare professionals who report the adverse event.

A second factor is that reporting delays attract attention. More impactful product failures may require larger financial costs and legal concerns that need to be sorted out before firms report adverse events to the FDA. For example, Boston Scientific publically stated that it was balancing its risks when it delayed reporting defibrillator defects from physicians and the CDRH for three years (Meier 2005). The manufacturer argued that the risks of alarming patients and recalling the pacemaker outweighed the risks of allowing the pacemaker to run its natural 6-7 year lifespan. Their choice seems warranted considering medical studies that show that 100 infections and 1 death occurs for every 6000 ICD replacements (Gould and Krahn 2006) and 9.1% of replacements have some complications (Gould et al. 2008). However, Boston Scientific tactic of delaying product failure reports backfired. Boston Scientific's pacemakers came under intense scrutiny by the media and the FDA – intimately revealing their product and process design practices.

The Boston Scientific example emphasizes that report delays can signal product failure importance. The signaling argument relies on two assumptions. The first assumption is that firms strategically delay failure reports (within reporting requirements). This is not a far-reaching assumption considering that regulations in the medical device industry are designed to deflate the financial and reputational incentives to delay and hide negative product performance. TMJ Implants, a manufacturer of temporomandibular joint prostheses, offers an example (Dickinson 2010). TMJ Implants

and its CEO, Robert W. Christensen, was forced to pay $340,000 for 17 counts (the law allows a maximum penalty of $16,500 per offense) of not reporting product failure to the FDA on time. Christensen indicated that he will have to liquidate TMJ Implants to pay the civil penalties. Yet, Boston Scientific's penalty of delaying reports of defibrillator failure in 2005 overshadows the penalties paid by TMJ Implants. Boston Scientific paid $296 million to the US Department of Justice and $16.75 million to the Attorney General for its intentional delaying of product failure reports.

The high profile cases of TMJ Implants and Boston Scientific are the exemption. The FDA may not have the resources to monitor all product failure reports. The US Department of Health and Human Services Inspector General details that FDA analysts only had time to read one third of the product failure reports within 30 days and less than one half within 60 days of receiving a report in an investigation of the medical device adverse event reporting system between 2003 and 2007 issued by (Levinson 2009). The FDA also does not have resources to penalize all late reporters. The FDA deals with delays by informally calling late reporters to reduce demands on the regulatory system. In addition, the process of penalizing firms that strategically delay product failure reports is expensive and long. For example, penalizing TMJ Implants required a panel of 12 judges and multiple court battles.

The second assumption is that a firm has knowledge or can predict of a competitor's reporting delay, but it is not difficult to imagine in the medical device industry. Competition in the medical device industry is largely based on innovations so predicting product reliability is a necessary function of organizations and regulators. As

well, medical device organizations have to demonstrate adherence to quality tolerance levels prior to FDA approval.

Hypothesis 2: A firm's product failure rates will decrease if a competitor takes longer to report product failures to the CDRH.

Recent intraorganizational studies identify two reasons why delays decrease the ability to learn from others. First, reporting delays decrease the speed at which firm's are aware of others' product failure. Reporting delays create confusion by making it hard to understand the action that caused an outcome, or by confounding the evaluation of outcomes. For example, some simulations model a series of intraorganizational actions with outcomes that, over time, are revealed to be failures or successes (Denrell et al. 2004). They show that organizations are better able to associate temporally close action-outcomes pairs and that delays increase the risk of spurious causal associations. Organizations require quick processing of product failure to generate an accurate and reliable inference of the product changes that may have led to product failure.

Reporting delays in others' product failures may introduce two possible attentional inaccuracies. The first inaccuracy arises because organizations make simple causal associations about the failures and solutions of other firms. Terlaak and Gong (2008) highlight this practice by arguing that most organizations infer solutions by observing how others abandon and retain actions. Organizations are more likely to make poor inferences of others' delayed product failures because observation from a distance makes simple causal associations more likely. Organizations have an increased chance of wrongly associating a delayed outcome (from a past action) with a current action,

because simple causal associations tend to be based on limited understanding of underlying mechanisms. The second inaccuracy arises because organizations pay attention to salient social referents. Delays confuse the choice of social referents because they make failing competitors appear to be failure-free, and other competitors failure-prone, even though they have successfully navigated a bout of product failures in the past.

Other problems of simple association arise in regulatory reporting systems of competitors' product failures because it is difficult to distinguish whether a single action, or multitude of actions, caused the failure. An abundance of product failures in a regulatory reporting system allows organizations to make simple associations between many actions, even if the action is unrelated to the product failure report. The situation gets worse when delays are combined with an abundance of product failures because both current and past actions appear to have simultaneously caused a failure. Similarly, delays plus diverse product failures in regulatory reporting systems add to the confusion because it can then appear that a failure has heterogeneous, and possibly incongruent, past and current causes.

One reason why delays in failure reports are particularly problematic for organizations trying to learn from others is that organizational attention is selective (Ocasio 1997). Attention is selectively biased by underlying scanning and interpretation routines, which typically favour recent and salient outcomes (Kim and Miner 2007). Evidence corroborates that organizations are more attentive to more easily observable outcomes (Denrell 2003; Denrell and March 2001), more immediate outcomes (Levinthal

and March 1993), and stronger signals of outcomes (Weick 2005). These organizational attention effects are interdependent with a systematic over-representation of recent or self-confirming indicators (Nisbett and Ross 1980) at the individual level. Delays reduce the saliency of outcomes. Theory substantiates that delays reduce the ability to discern differentiating characteristics, because organizational memory has coarse encoding schemes (March et al. 1991; Walsh and Ungson 1991). Some organizations can redirect their attention and improve the way they process delayed outcomes by fine-tuning their attention processes and underpinning routines (Levinthal and Rerup 2006; Weick et al. 1999); however, reconsidering past product failures is attention intensive.

The second reason why reporting delays decrease ability to learn from others is because the complexity of learning from temporal separation of actions and outcomes cause missed opportunities to learn. Rahmandad (2008) emphasizes that longer delays exponentially increase the complexity of learning in simulations. Repenning and Sterman's (2002) conducted a case study that linked delays with the premature abandonment of quality improvement projects. They find that learning complexity from delays might discourage learning attempts. They also find that organizations abandon high return, long-term projects because delays create obscure and ambiguous outcomes that can be easily misinterpreted. Instead, firms revert to actions with clear and unambiguous outcomes, such as low return but quick projects, because they do not notice their efforts immediately. Reporting delays increase the chance of missed opportunities to learn because plausible explanations of causation can transform in changing organizational contexts. Learning curve studies suggest that informal communication

patterns (Darr et al. 1995; Pisano et al. 2001), staff turnover (Wiersma 2007) and imperfect memories (Bailey 1989; Benkard 2000; Thompson 2007) may alter the learning curve. A micro-explanation by Sterman (1989) confirms that delays may lead to lost opportunities. He shows that individuals have difficulty processing delayed information because they do not account for the complex interactions that can occur between an action and its delayed outcome. Further, he finds that when individuals notice delays, they tend to overcorrect; for example, by overshooting operating capacity when there is no response to earlier operating increases. The work suggests that organizations are likely to decrease the ability to learn from others because organizations perceive a competitor's recent actions as causes of delayed product failure.

The literature on organizational routines uncovers a complementary mechanism that explains why a competitor's reporting delays may cause missed opportunities to learn from others' failure. The literature on absorptive capacity shows that the ability to evaluate and use others' product failures is a function of prior experience (Cohen and Levinthal 1990). The capability to recognize the value of these product failures and understand the intermediate technologies to use product failures effectively is based on accumulating knowledge of past failures. This effect is supported by the fact that a competitor's reporting delays increase the cost of information processing because delays increase the demand for a sharp memory (Bailey 1989) and the ability to pool past and present information (Levinthal and March 1993). Feldman and March (1981) also argue that more costly processing increases the need for more information, yet rapidly diminishes the marginal returns of new information. As well, the costs of the investments

needed to acquire and interpret a competitor's product failures quickly outpace the value that may be extracted. Taken together, this creates a vicious cycle that progressively makes it more costly and less attractive to learn from a competitor's delayed product failures.

Reporting delays to the FDA are likely to decrease the ability to learn from interorganizational product failure experience in the medical device industry, for two reasons. First, when reports about product failures are delayed, corrective regulatory action (if warranted) is also delayed, which allows recalcitrant firms to sustain revenue streams from unreliable devices. Observers may infer that they, too, can continue to produce unreliable devices without immediate sanctions. Second, reporting delays make it more difficult for the FDA to prevent product failure. Specifically, delays increase the complexity of analyzing their product failure reporting systems, slow the dissemination of solutions, and delay regulatory change.

Accounts in industry trade journals (Dickinson 2009b) and government documents (Crosse 2009) uphold these arguments. In March 2009, Dickinson (2009b) reported that it took the FDA 47 days to recall Baxter Healthcare's intravenous infusion pumps which could fail and lead to serious injury or death. At the same time, the FDA recalled Nellcor's tracheostomy tubes four months after it knew that the device could cause serious injury or death. Although these two events are likely unconnected, it does suggest that delays *may* weaken industry regulatory efforts and provide an incentive for firms to be recalcitrant, both of which reduce the impetus for interorganizational learning to reduce product failures. A Government Accountability Office document confirms that

the addition of reporting delays may lead to some product failure reports being overlooked (Crosse 2009) because the volume of reports exceeds the capacity of the FDA to consistently review all reports they receive.

Hypothesis 3: Reporting delays will moderate the effectiveness of interorganizational learning from others' product failures, such that an organization learning from others will be less likely to reduce its own rate of failures when reporting delays are longer and more likely to do so when reporting delays are shorter.

Competitor New Product Introductions as Distractions

Distractions hinder learning from others' product failures (See Appendix A.1 for a summary of arguments). Distractions encompass a broad range of events that hinder organizational focus. Perhaps the most common type of distraction from product failure experience in existing devices in the medical device industry is the simultaneous introduction of new devices. Several situations may arise in which new product reports are not a distraction or are only a weak distraction; for instance, when competitors simply do not imitate the developments of others. As well, organizations likely use a number of indicators to measure the performance of competitors (Audia and Brion 2007). However, a new product introduction may result in significant distraction because organizations often use exploration, innovation, and development as heuristics or 'first-glance' indicators of success (Feldman and March 1981). It may be the case that new product introductions do not indicate true product development. For example, organizations may contract out product design. In these situations, organizations need to pay more attention to analyzing the new product introduction, which may come at the cost of understanding the causes of product failure.

Literature has yet to explicitly study the effect of a competitor's new product introductions on a focal firm's product failure rates; however, I argue that competitor's new product introductions will likely improve a focal firm's product reliability for two reasons. Studies on product innovation support the first reason that competitors quickly replicate more reliable innovations in an industry (Podolny and Stuart 1995; von Hippel 1988). von Hippel (1988) shows that competitors replicate product innovations because

of a firm's economic incentives to improve products in the scientific instrument industry. Podolny and Stuart (1995) demonstrates that competitors build upon existing innovations to carve out new semiconductor product niches. The product innovation literature highlight that it is likely that a competitor's new product introductions will lead to product improvements by a focal firm. A competitor's new product introductions may decrease product failure rates, even though the particular improvement is specific to the underpinning characteristics of the organization.

A second reason why product failure rates should decrease with other's new product introductions is that the reporting process of others' new product introductions offer a mechanism to transfer knowledge of a competitor's product design. In some cases, organizations can rely on reliable, credible, and easily accessible third party information. Third party information may be particularly important when competitors are difficult to identify, such as in emerging technological fields, or when information on these competitors is difficult to obtain. Well-known, legitimate, and trusted third parties are a substitute for first-hand information (Greve 2003) and a gateway to common comparison features, such as sales or product reliability.

Of course, rumours often circulate in advance of a formal product launch; however, there are several reasons why I expect that formal announcements will be an important mechanism to transfer product design knowledge. First, the relevant audiences (analysts, customers, doctors) rely on formal announcements to calibrate their expectation of specific firms, and of their rivals. Second, formal announcements carry detailed product information, which informs both the R&D development of rivals' alternative

products and their competitive responses. Third, the launch channels attention, such that firms that launch new products will attract greater attention.

Learning curve literature suggests that the mechanism of knowledge transfer is important for interorganizational learning. For example, Darr et al. (1995) posit that regular communication between pizza stores may account for why common owner franchisees exhibit higher declines in pizza costs from of interorganizational learning than different owner franchisees. This work shows that the increased potential for knowledge transfer from reports of new product introductions may be an effective way to allow organizations to decrease product failure rates, over and above the impact of product innovation.

A competitor's new product introductions will likely decrease product failures in the medical device industry, for two reasons. First, the FDA's pre-market approval process and product review boards are processes that encourage firms to learn from product failure. FDA procedures prevent market-approval of devices that are less effective and less reliable than devices that are currently on the market. Second, new product introductions encourage users (ie. doctors) to learn state-of-the-art techniques. Edmondson, Bohmer, and Pisano (2001) provide an account of an implementation of minimally evasive surgery in a surgery team in hospitals. Their study shows that successful new medical device introductions encouraged users to practice, communicate, and reflect collectively – thereby leading doctors to update knowledge of how to use medical devices and reduce the rate of adverse events caused by user error.

Hypothesis 4: A firm's product failure rates will decrease with increases in competitor's new product introductions.

I explain that a competitor's new products introductions may cause distractions in learning from interorganizational product failure experience. Distractions (i.e., simultaneous introduction of new products) inhibit learning from interorganizational product failure experience for two reasons.

First, distractions may decrease the ability to learn from others' product failures. The literature on sequential attention hints to one reason why distractions hinder interorganizational learning. The literature suggests that firms may sequentially attend to others' new product introductions and product failures in order to treat one as a constraint for interpreting the other (Greve 2008). Several papers suggest that organizations sequentially inform and shift their attention from product failures to new product introductions (Audia and Brion 2007; Greve 2003). Audia and Brion (2007) show that organizations often resolve conflicting outcomes in a self-serving manner, indicating that organizations can miss out on valuable information because of their own attentional distractions. Such self-serving biases are said to help organizations prioritize tasks. For example, both Greve (1998) and Baum et al. (2005) suggest that organizations neglect some information or process conflicting information slower, when information about others is inconsistent. Greve (1998) puts forth the "fire alarm" rule, which argues that organizations pay attention to correcting failures when successes and failures are inconsistent. In doing so, interorganizational product failure experience has less impact on reducing the rate of product failure.

Second, distractions inhibit the ability to learn from others' product failure experience or others' new product introductions because the consequences of a product

failure are harder to tease apart and often induce superstitious learning. One reason why distractions from failure reports tend to be problematic is that learning from a competitor's product failures with distractions may lead to superstitious behaviours. Superstitious learning occurs when actions that are causally unrelated to actual success or failure are reinforced (Denrell 2008; Lave and March 1975; March and Olsen 1976). Conceptual arguments emphasize that superstitious learning occurs because organizations are continuously learning, but indiscriminate about what they learn. For example, Lave and March (1975) note that organizations search for an action to explain a failure, even if they themselves did not cause the failure. Levitt and March (1988) propose that superstitious learning is more likely when experience is compelling, in the sense that it seems plausible, even though actual causes are difficult to understand. Research on superstitions in interorganizational learning is sparse, but research on intraorganizational learning may provide insight on how interorganizational superstitious behaviours form.

A number of simulations point to why distractions during learning from others' product failures may become superstitious. One reason is that simultaneous new product introduction and product failure makes it difficult to distinguish which action caused the outcome. Supporting evidence from Levinthal and March (1981) and Lounamaa and March (1987) points out that larger distractions to a competitor's failures may cause indiscriminant learners to adapt correct and incorrect lessons[2]. It takes effort to

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[2] Evolutionary game theory may provide additional insight. Simulations of the repeated prisoners' dilemma game (Bereby-Meyer and Roth 2006) show that learning to cooperate diminishes when payoffs are difficult to discriminate, because such outcomes make it difficult for actors to understand if defection is an error or an intended choice. In an ultimatum game simulation, Gale et al. (1995) demonstrated that difficult to discriminate payoffs lead players to reject money, even if it is rational to accept it, because

distinguish between actions that cause success and/or failure. Another reason why distractions may lead to superstitious learning is because of errors in comparing actions that lead to success and/or failure. Organizations use the lessons obtained from success and failure as starting points for future learning; hence, subtle imperfections (e.g., focusing on irrelevant features and ignoring salient ones) can lead to learning incorrect lessons (Gavetti et al. 2005). Incorrect comparisons provide poor guidance and may lead to a build-up of many inappropriate and costly organizational changes over time. Research at the individual level suggests that comparisons are highly sensitive to errors (Gilovich 1981). Mezias and Starbuck's (2008) theoretical work on organization decisions with complex data – may help articulate why organizations act even with distractions. Their work implies that the potential downfall of distractions is not immediately identified because it accumulates slowly and its costs are not immediately apparent.

Superstitious interorganizational learning from others' product failures is likely to occur. On the one hand, superstitions are more likely because there are numerous direct and indirect outcomes that cause others' product failures. It is very difficult to both pay attention to product failures and distinguish between what caused an existing product failure and what led to a new product introduction; hence, organizations are likely to incorrectly mix causal associations. Supporting evidence corroborates that the ability to discriminate experience is important to learning. Haleblian and Finkelstein (1999) reveal

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actors could not distinguish a good offer from a bad offer. Gale et al.'s (1995) study also argues that learning is highly sensitive to potential distractions - as little as 0.01 of a percent of noise in payoffs reinforces outcomes imperfectly.

that the ability to discriminate, and to generalize experience gained in previous acquisitions to current acquisitions, can result in a successful acquisition. de Holan and Phillips (2004) shows that the ability to discriminate the experiences of others that are useful and forget the experiences of others that are less useful is important for interorganizational learning. In their case study of forgetting in Cuban resorts, they show that a competitor's experience is first acquired and then implemented. It is only after managers at the resorts realized that the others' experience was inappropriate that they were able to forget the poor experiences that they acquired.

On the other hand, the literature on institutional theory points out that superstitions are more likely when there is impetus to learn from others. Institutional theories propose that organizations try to gain legitimacy and enhance survival by imitating the actions of other organizations that seem more legitimate (Meyer and Rowan 1977). Zbaracki's (1998) case study shows that organizational actors adopt Total Quality Management (TQM) practices because they do not want to miss out on an opportunity taken up by a competitor, even if they do not fully understand the opportunity. This is further supported by Haunschild and Miner (1997), who found evidence that organizations adopt behaviours they perceive as more legitimate, and avoid behaviours they perceive as less legitimate, based on the frequency, features, and outcomes of others' actions; even if they do not understand why others' actions succeed or fail. Overall, these studies support the view that distractions inhibit learning by either confusing outcomes or encouraging superstitious learning.

The interorganizational learning inhibiting effects of distractions will be more likely in the medical device industry, for two reasons. First, the technological complexity of many devices may allow some self-serving firms (Audia and Brion 2007) to disassociate from others' product failures and associate with others' new products, because consumers find it difficult to tell devices apart. Second, firms have inherent incentives to make quick temporary changes to keep devices marketable, which encourage shallow learning. Two-thirds of revenue comes from devices launched within the last two years (Young 2008), encouraging medical device firms to make quick fixes. Medical device firms may choose to opt out of major design changes and mask deeper device flaws by mimicking a rival's new product developments.

Hypothesis 5. Distractions from the simultaneous occurrence of a competitor's new product introductions and failure reports will moderate the effectiveness of interorganizational learning from others' product failure experience. That is, an organization learning from others' product failures will be less likely to reduce its own incidence of failure with more reports of others' new product introductions and more likely to do so with fewer reports of others' new product introductions.

4. Data and Methods

The Medical Device Industry

Organizations in the medical device industry routinely face, and possibly learn from product failure. The industry is comprised of manufacturers and distributors of products intended for diagnosing, treating, or preventing ailments in humans or animals (CDRH 2009b). The medical device industry is an apt context for studying learning from product failure, on three grounds. First, medical devices are part of everyday life. For example, most of us will use gauze, sanitary wipes, Band-Aids, tweezers, splints, compresses, and needles at some point in our lives. Medical devices are also important for healthcare professionals. Venture into any doctor's office, hospital, pharmacy, or veterinarian's office and you will see a vast array of devices: ultrasound equipment, x-ray machines, latex gloves, glucose meters, screws, fasteners, cutting tools, and so on. Estimates indicate that over 100 million surgical procedures requiring the use of medical devices are performed in the United States each year (Stalcup 2009). Secondly, medical device firms have a significant positive impact on life expectancy and the economy. Consequently, it is important to understand how firms learn to reduce medical device failures because advancements in medical devices have added as much as three years to the average life in the past twenty years alone (MEDTAP 2004). One study suggests that these three extra years amount to cumulative productivity gains of $1.92 trillion, or 30% of US GDP (Murphy and Topel 2006). Finally, organizations in this industry have access to public information about others' product failures and new product introductions. I focus on the public reports because "when experience is visible and salient, *interpretable*

(or at least inferable) based on available information, and generalizable across organizations, decision makers can gain access to experience created by other organizations (Baum and Dahlin 2007: Pg. 370, emphasis added)."

Prior investigations have identified several interesting aspects of intraorganizational learning in the medical device industry. Barley (1986) first looked at the social structure of CT scanner implementation in the 1980s, and subsequent studies have identified the complex social structure that unfolds when practitioners use and manage medical devices (Barley 1990, 1996; Black et al. 2004). Edmondson and her colleagues studied learning and adaptation of a medical device in hospitals (Edmondson 2003; Edmondson et al. 2001; Edmondson et al. 2004; Pisano et al. 2001). Specifically, they studied a technology for minimally invasive cardiac surgery that allows surgeons to access the heart through small incisions, instead of the conventional procedure of splitting the breastbone. They found that the outcomes of learning are often unique, even in very similar settings. Recently, Chatterji and his coauthors discussed how physician–industry innovation collaboration encourages the transfer of tacit knowledge from physicians to firms (Chatterji and Fabrizio 2007; Chatterji et al. 2008). They discovered that this knowledge transfer resulted in more useable medical devices for physicians.

Interorganizational learning in the medical device industry has yet to be studied. One unique aspect of this industry is that information about others' product failures is widely available because the industry is required to publicly disclose medical device adverse events. These regulations are enforced by the United States Food and Drug Administration (FDA). These public reports describe product failures in detail and may

point to underlying problems and solutions. But, as discussed above, the solutions to product failure are not always clear.

Prior studies have identified some of the barriers to interorganizational learning, such as communication difficulties, high fixed cost of revealing information, and credibility issues. In the medical device industry, the availability of third party reports mitigates some of these common hurdles. Formal models by Akerlof (1970) and Shapiro (1982) claim that communication difficulties (i.e., asymmetric information) decrease the volume and quality of devices sold on the market. As well, formal models by Salop and Stiglitz (1977) suggest that the high fixed costs of revealing information reduce competitive pressure because consumers may be unwilling to search for the extra information needed to make an informed decision. Together, these findings establish that mandatory reporting of adverse events creates competitive incentives for organizations to reduce failures by making it difficult to hide poor quality devices. Additionally, a central, industry-wide archive of problems and future developments reduces interorganizational search costs by reducing the influence of intermediate factors. Instead of directly acquiring information, organizations can rely on the information acquired by the FDA because this agency is a credible source that regularly monitors and audits the quality of its information (Macher et al. 2008). For example, many medical device firms (even new ventures) have dedicated regulatory affairs specialists who submit adverse event reports. Taken together, mandatory reporting and public posting facilitates interorganizational learning.

An additional emphasis to reduce product failures is through tighter pre-market approval. The 1976 Medical Device Legislation Amendments Bill aims to prevent failures by requiring that all devices go through a pre-market approval process. This process is expensive. In 2008, applicants had to pay $185,000 to have their devices reviewed by the FDA. The review process is also time-consuming. It may take up to 335 days for approval (Tillman 2008) and up to four years to bring a device to market (Dixon et al. 2006). To improve the probability of approval, most medical device developers sort out as many problems as possible by trialling prototypes and conducting clinical tests.

Evidence on the efficacy of the pre-market approval activity is mixed. Studies show that the faulty devices can get pre-market approval. Dhruva et al. (2009) show that the FDA granted market approval for cardiovascular devices is prone to bias, even in their most rigorous review process. They show that approval was granted based on questionable clinical studies. They find that the FDA based approval on clinical studies where only 27% used randomized trials, 14% were blinded, 65% were based on a single study, and only 52% of the studies compared results to control groups. Clinical studies that lack any one of these characteristics calls into question the efficacy and safety of devices.

The FDA pre-market approval process is rigorous enough to at least prevent some failure. Studies argue that the pre-market approval process identifies and corrects many potential failures, before devices go to market. For example, Maisel (2006) argues for tougher pre-market approval testing for ICDs, such as simulations and bench testing for

faulty batteries. The pre-approval process will select out exceptionally faulty devices, even though some grey-area devices will likely get approval.

Interorganizational learning from product failure is an important second (arguably first) line defence to prevent failure, especially if the efficacy of the pre-market approval process is debatable. Despite problem-solving from regulatory pre-market approval, product failures are inevitable because devices need to be put into practice to resolve unforeseen problems (Edmondson et al. 2004; Yelle 1979). Bench testing and simulations cannot replicate every clinical condition, no matter the extensiveness of the testing procedures. Such inventible failures provide opportunities for organizational learning and may be the only way to reduce failures without depriving patients of potentially life-saving devices.

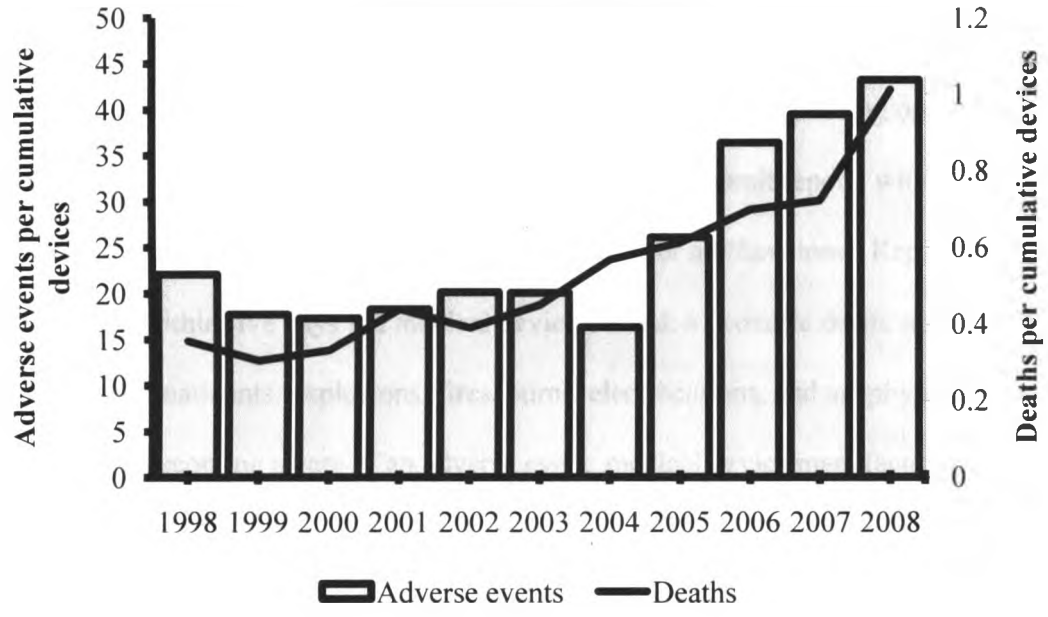
The Puzzle of Organizational Learning in the Medical Device Industry

Paradoxically, the medical device industry shows a high and persistent incidence of medical device failures, despite the fact that the industry has both the information and motivation to learn from failure. Figure 1 depicts a learning curve that I developed using CDRH data of adverse events and deaths, which is the number of annual adverse events and deaths that occur per cumulative device category in the US medical device industry. The Safe Medical Devices Act of 1990 defines medical device adverse events as product malfunctions or suspected product-caused events leading to death or serious injury. A serious injury is either 1) life threatening, 2) results in permanent impairment of a body function, or 3) necessitates medical intervention to treat the adverse event. The data

show that from 1998 to 2008, additional experience with medical devices increases, rather than decreases, adverse events and deaths.

My own statistics suggest that the likelihood of adverse events and deaths increases as more devices are manufactured. Analysis of FDA data (CDRH 2009b) shows that 265 adverse events occur every day. About one in 300 people entering a US hospital will experience a serious injury or death caused by a medical device (CDRH 2009b). But this figure may be significantly under-estimated. One hospital-level study puts the number at 1 in 150 and, in some procedures, as high as 1 in 4 (coronary artery bypass surgery) (Samore et al. 2004). Another study suggests that 2% of the implanted cardioverter defibrillators (ICDs) were replaced because of malfunctions between 1990 and 2002 (Maisel et al. 2006). For every device registered in the US, there were 0.69 deaths per device every year between 1998 and 2008. One plausible reason for these alarming statistics, despite the abundance of credible reports about failures in the industry, is that reporting delays and distractions are hindering interorganizational learning.

FIGURE 1
Industry learning curve for manufacturers: Adverse events and deaths per cumulative devices introduced to market



The Medical Device Adverse Event Reporting Process

Figure 2 depicts the adverse event reporting process. The solid lines indicate mandated reporting and the dotted lines represent voluntary or informal reporting relationships. Reporting adverse events to the CDRH involves a device user facility, the CDRH, and the medical device manufacturer. Device user facilities are usually the first to be aware of an adverse event. A device user facility usually notifies the medical device manufacturer and the CDRH that a product failure has occurred. User facilities are required to the CDRH within 10 days, but most of the time this does not occur (Maisel 2005). The exception to the rule of device user facilities being the first point of contact is when the device manufacturer has a representative on site. For example, a Medtronic

representative is in the operating room providing technical support to surgeons for 70 percent of all Medtronic implants (George 2003).

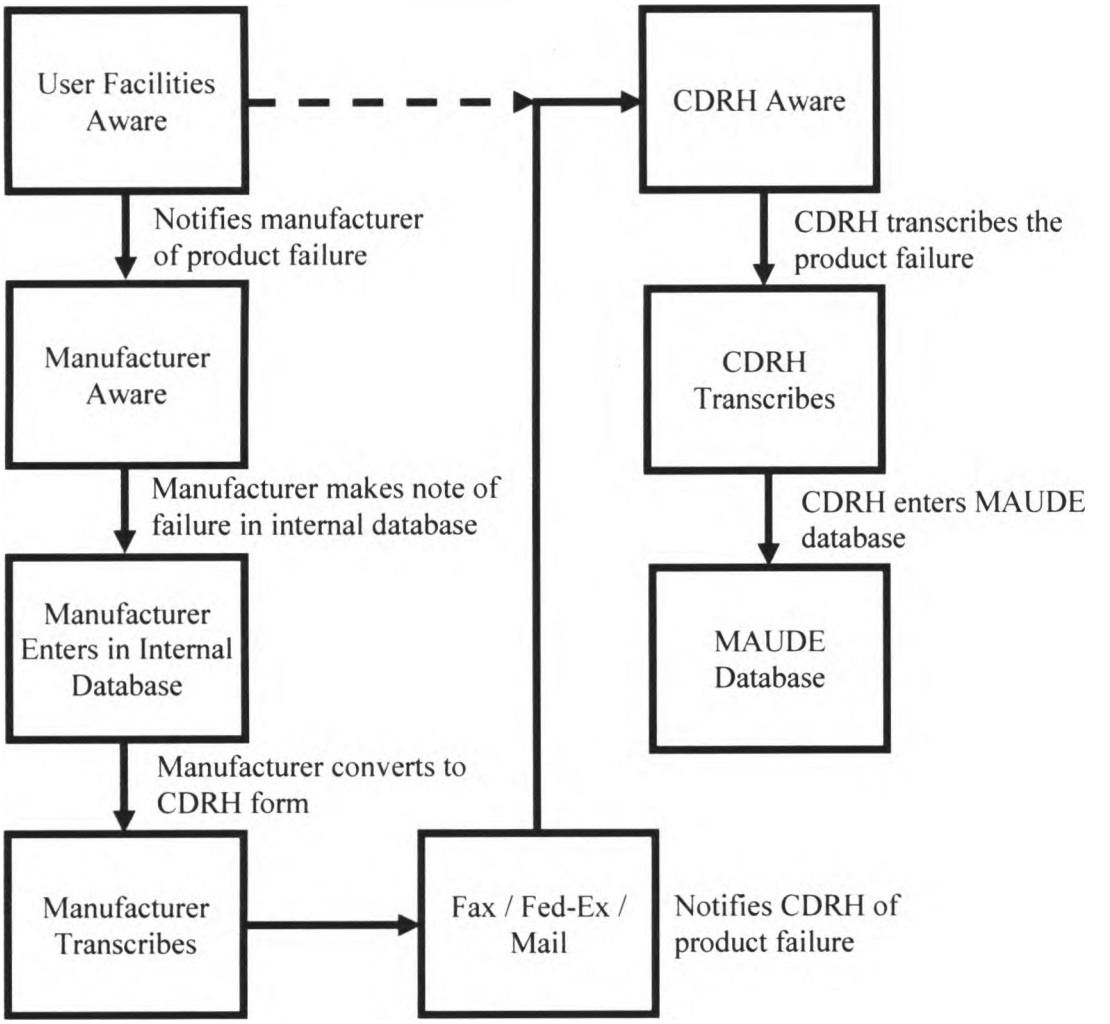
Medical device manufacturers are mandated to report within 30 days of becoming aware of the event. However, the 30 day requirement is shorter depending on the severity of the event. The FDA requires manufacturers to submit reports within 20 days of knowing about product caused death, serious injury, or malfunctions. Reports are to be submitted within five days if a medical device caused: a pediatric death, multiple deaths, exsaguinatioants, explosions, fires, burns, electrocutions, and anaphylaxis.

Upon becoming aware of an adverse event, medical device manufacturers first make note of adverse events in their own internal electronic databases. Regulatory affair specialists use the information from internal to complete and mail an adverse event report to the CDRH. Appendix A.3 shows a typical adverse event report. An exception occurs for foreign manufacturers. Foreign manufacturers relay adverse event reports through US Agents, who report adverse events to the CDRH on behalf of the manufacturer. At the CDRH, the adverse event reports are manually transcribed in a large room full of people into the CDRH electronic adverse event database (MAUDE database) for analysis (Lloyd 2009).

It is natural to ask why the CDRH medical device adverse event reporting process is prone to redundancy of transcribing between manual reports and multiple electronic databases. The answer lies in the costs of implementing an electronic CDRH submission process. In August 2009, the FDA announced a proposal to implement an electronic submission system. However, a new electronic submission process is estimated to cost

between $58-80 million, whereas the current data entry costs are $1.25 million (Lloyd 2009). The low operating costs allow the current system to persist, especially given the budget constraints of the FDA.

FIGURE 2
Medical Device Adverse Event Reporting Process



Alternative Explanations

Learning from the product failure experience of others is not the only way to reduce the rate of product failure. Organizations can learn from the regulatory pre-market approval process or from mergers and acquisitions; individuals can learn about failures; or organizations can simply avoid situations that make failures more evident. I combine several sources of data to control for, and rule out, possible (but less effective) explanations of how medical device firms learn (or fail to learn) from their industry peers.

Most learning from failure studies do not have the luxury of explicitly testing for alternative explanations. Nor can they control for the unique importance of contextual factors in studies that use one or two cases (Carley and Harrald 1997; Farjoun and Starbuck 2005; Rerup 2009; Weick and Roberts 1993). Research using multiple cases of failure (Edmondson 2003, 2004) mitigated this constraint by comparing and contrasting contextual factors, but the work is difficult to generalize statically. I use a purposeful sampling methodology within the medical device industry that offers a representative, and thus externally valid, examination of competitor reporting delays and new product introductions on learning from others' product failures. Table 2 lists the many alternative explanations that are ruled out by my study design.

TABLE 2
Implicit controls to alternative explanations by purposeful sampling

Alternative Explanation	Implicit Control
Regulatory learning and intervention	Recalls remove devices with impactful failures, not all product failures
	Pre-market approval encourages manufacturers to develop reliable devices
	Adverse event tracking keeps FDA informed, but unable to deal with all failures
	User experience, sector diversity, geographic diversity, and device turnover affords constant change and heterogeneity, but makes regulatory learning difficult
Learning through other mechanisms, like mergers and acquisitions	Most mergers and acquisitions occur prior to devices coming onto the market
	Mergers and acquisitions are a strategic response to interorganizational learning
Individual level affecting organizational capacities to learn	Individual-level effects, such as turnover and job demands, are moderate
Firms selecting out of the US market	The large and open US market is attractive and encourages firms to reduce failures

There are several reasons why learning from others' adverse events stands out from other learning mechanisms for medical device firms. First, FDA reports make it easy for firms to access information on others' failures. This creates incentives to learn because it is difficult to hide unreliable devices. Second, certain structural features of the industry reduce the search costs of drawing from others' failures and solutions (i.e., scientific openness, technological clusters). Third, the industry has inherent incentives to attend to others' new product introductions and product failures (Ghemawat and Spence 1985; Lieberman and Montgomery 1988).

Regulatory Learning

One alternative explanation for interorganizational learning is reducing failure through mandated FDA processes. The FDA has long recognized that medical device adverse events are a chronic problem, possibly because there were serious shortcomings in early regulatory statutes. In the US, food and drugs were originally controlled by the US Post Office under the 1872 Postal Fraud Statutes. The Post Office's role was to protect against dangerous foreign goods. The FDA was created by the 1906 Pure Food and Drug Act after Upton Sinclair's novel, "The Jungle," caused public outrage about the lack of regulation in the food industry (Swann 1998). However, these statutes contained no direct regulation and fraudulent medical devices were still common. Wilhelm Reich sold the Orgone Accumulator and Cloudbuster, for example, to improve human health by ethereal orgone energy.

Faulty medical devices remained a problem, despite the introduction of the 1938 Food Drug and Cosmetics Act, which allowed the FDA to seize or criminally prosecute persons who misbranded or adulterated devices. For example, after 16 deaths were linked to a intrauterine device, the Federal Register issued a report detailing that medical devices had contributed to 10,000 serious injuries and 750 deaths from 1959 to 1969 (Monsein 1997). This report laid the groundwork for the 1976 Medical Device Legislation Amendments (MDLA) Bill (Geddes 1998). This amendment gave the FDA authority to approve devices pre-market, register manufacturers, develop good manufacturing practices, and ban devices.

Since the MDLA, the FDA has introduced several extra regulatory tools to reduce the occurrence of medical device adverse events. First, medical device manufacturers cannot sell medical devices within the US until a panel of experts has reviewed and approved the device. Firms have to submit detailed information to obtain regulatory approval, including engineering drawings, proposed labelling, manufacturing and sterilization processes, software validation, and clinical data. As well, firms selling devices in the US must register with the FDA every year. This applies to domestic manufacturers and agents or distributors of foreign manufacturers. The FDA approves medical devices through one of two processes. The first, called Pre-Market Notification 510(K), is faster because the applicant product is similar to (but not the same as) an existing device, imposes minimal risk of harm (Class I Devices), or is assured to not cause harm (Class II Devices). Class I devices are relatively benign or non-evasive, such as gauze or gloves. A bone anchor is a Class II device. 3,192 (97%) of the regulatory submissions occur through the 510(k) process (Crosse 2009; Tillman 2008) and the FDA accepts 2,725 substantially new Class I and II devices each year (CDRH 2009c). The second process, called Pre-Market Notification (PMA), involves rigorous review because the device is significantly different from existing devices or is "life-supporting or sustaining" (Class III). Only 10% of medical devices are Class III devices; for example, coronary stents and neurostimulators. In 2008, the FDA received 31 (3%) original PMA submissions (Crosse 2009; Tillman 2008). These two regulatory processes help reduce product failures by selecting out dangerous devices before they reach the market.

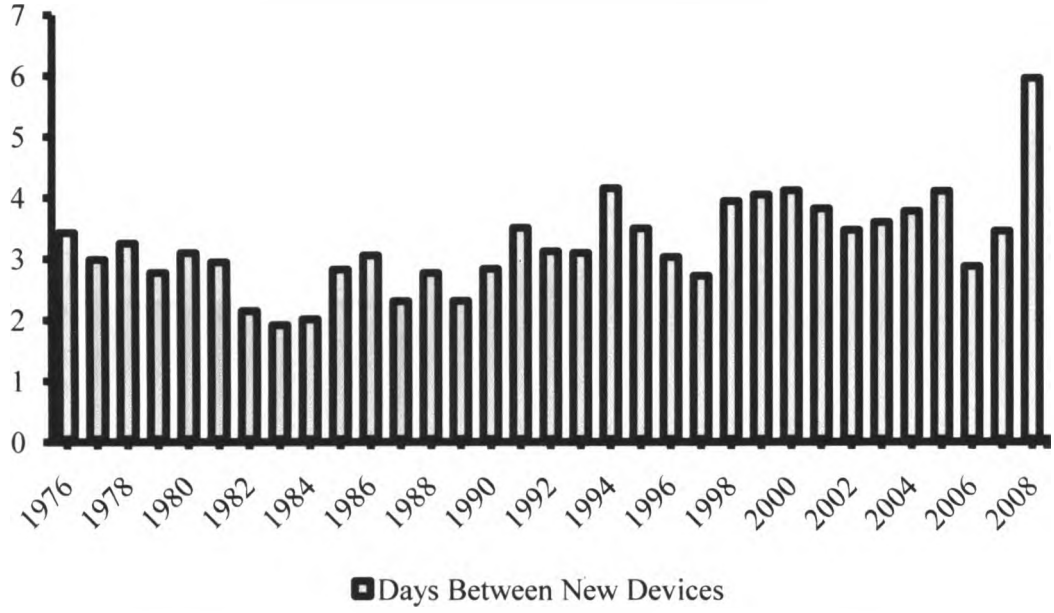
Second, the FDA may recall unsafe devices. A recall removes defective devices from the market and the FDA recalls about 1,000 devices a year. Recalls are usually voluntary actions by the manufacturer; however, the FDA may issue a recall if adverse events are particularly salient (Thirumalai and Sinha Working Paper). In 2007, the FDA began imposing civil penalties on firms found guilty of "misbranding"; that is, providing misleading and faulty information (Young 2008).

Third, the 1984 Medical Device Reporting Regulation allows the FDA to track medical device adverse events. This regulation was established in response to a Congressional subcommittee investigation that established that tracking might have prevented the four deaths that were caused by the Puritan-Bennet Corp. anesthesia machine. However, medical device failure continued. For instance, mechanical failure of the Bjork-Shiley convexo-concave heart valve led to the death of 422 patients (Maisel 2005). Additionally, post-market surveillance was often criticized for being ineffective. For example, General Accounting Office studies conducted in 1986 and 1989 concluded that only 1% of adverse events occurring in hospitals were reported to the Center for Devices and Radiological Health (CDRH). In 1990, the US government passed the Safe Medical Devices Act (SMDA), which mandated that facilities using devices must report adverse events to the FDA and the manufacturer. In 1995, Congress amended the SMDA to make it mandatory to report all adverse events, from 1997 onwards. Even so, Samore et al. (2004) suggest that 27% to 98% of adverse events are still going unreported. These FDA reports form the baseline data for my study.

It is still unclear whether the FDA approval, recall, and reporting processes are effectively reducing medical device adverse events. A Government Accountability Office report discusses that the FDA has insufficient resources and failed to effectively monitor medical device adverse events (Stalcup 2009). The report outlines a several problems: (i) numerous independent and redundant databases, (ii) slow response to postmarket safety issues, (iii) lack of regulatory staff, and (iv) unclear and ineffective decision processes for medical device oversight. Some failures are inevitable, no matter how much planning is done, and how many pre-market hurdles are overcome.

User Experience. The learning literature reveals several tacit factors that make failure an imperative, regardless of regulatory intervention. Edmondson et al. (2004) studied how medical practitioners learn surgical procedures. They found that some aspects of learning require a tacit understanding of the medical device, and that surgeons do make errors in the process of learning. Their evidence points out that a device needs to be put into practice before one can observe all possible combination of failures. The FDA regulatory process encourages organizations to learn from impactful failures or potential failures before going to market. However, there is pressure to be the first to introduce a new device (Lieberman and Montgomery 1988) – and the pace of innovation is fast in the medical device industry. Figure 3 shows a plot that I fashioned from CDRH data. Figure 3 indicates that a new type of medical device category is introduced every 3.2 days in the US, on average (CDRH 2009c). This has many firms rushing to launch as soon as regulatory approval is granted.

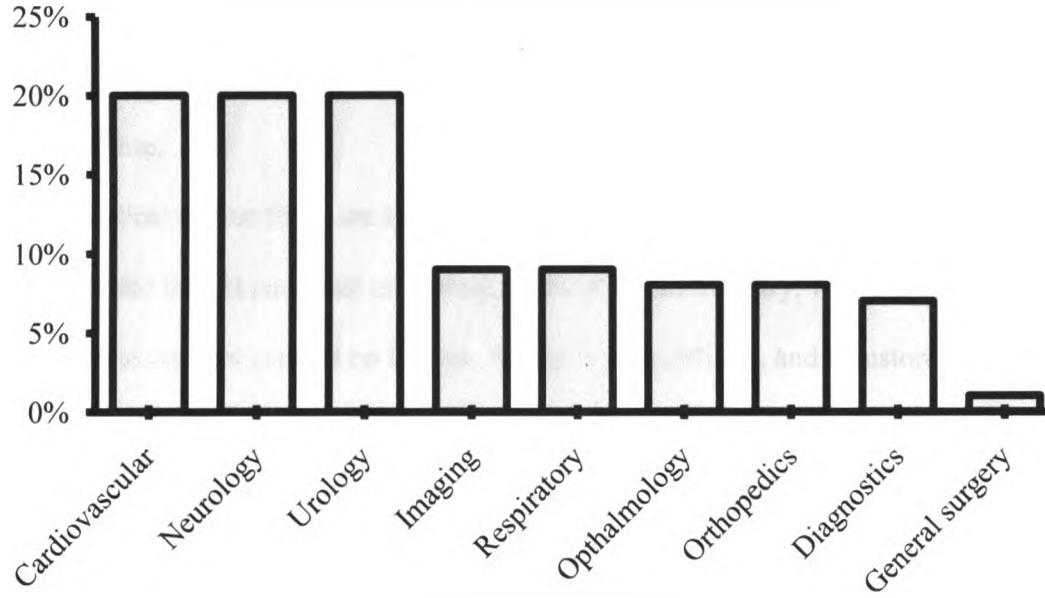
FIGURE 3
Days between new devices categories



Sector Diversity. A second factor contributing to the high incidence of adverse events in the medical device industry is the diverse uses of these devices. Medical devices have numerous applications and there are many competitors in each market segment. Thus, there are multiple templates for conflict and opportunities for errors. The most competitive segments are protective sunglasses, optical frames, and toothbrushes, with 2,060, 1,580, and 876 manufacturers, respectively. However, 25% of devices have fewer than two manufacturers. As shown in Figure 4, the breakdown of medical devices as a percentage of global revenue (Scott 2007) is balanced across several segments. Cardiovascular (Electrocardiograms, defibrillators, heart stents, etc.), neurological (spinal cord stimulators, deep brain stimulators, etc.), and urological (catheters, urethral stents, etc.) uses account for 60% of the market, but there is a heterogeneous distribution

between industry sectors. This diversity makes regulatory control difficult because it increases the knowledge demands on regulators. But it also creates opportunities to learn from a diverse set of others' failures.

FIGURE 4
Global market share of medical device segments



Geographic Diversity. Medical device firms are also ***geographically diverse***. Medical device manufacturing occurs around the world, but is concentrated in Southeast Asia and North America. I highlight the geographical diversity using Figure 5 which I produce from CDRH data. Firms from 84 countries sell devices into the US. Over 20% of the 7,608 device manufacturing establishments registered with the FDA are located in China (14.5%), Denmark (7%), and Taiwan (3.8%). So far, medical device firms have figured prominently in developed countries, but analysts expect that these firms will play more significant roles in developing countries as their increasing wealth is spent on medical

care. For example, the growth rate of the industry in the Asia-Pacific region is 5.9%. The region accounts for 18.8% of global market value, compared to the US medical device industry which accounts for 4.3%. A recent Government Accountability Office report highlights that the geographic diversity of medical device manufacturing is a high-risk issue for US safety (Stalcup 2009). The report states that it would take up to 27 years for the FDA to visit each foreign manufacturing establishment, at its current inspection rate.

Medical device firms are also diverse within regional boundaries. For example, the US has the largest and most prominent medical device industry, with major technological clusters centred on Boston, Silicon Valley, Miami, and Houston. The five US states with the largest share of medical device firms are California, Florida, and Massachusetts, Texas, and New York. I create Table 3 from CDRH data to emphasize the regional nature of medical device firms. Table 3 shows the distribution of medical device firms in the US (CDRH 2009c). The shade of blue indicates the number of firms selling medical devices to the US. Medical device firms are widespread, not only around the world, but also within regional boundaries. Given this context, one of the only feasible ways to reduce failures is to learn from similar competitors.

FIGURE 5
Geographical origins of medical devices

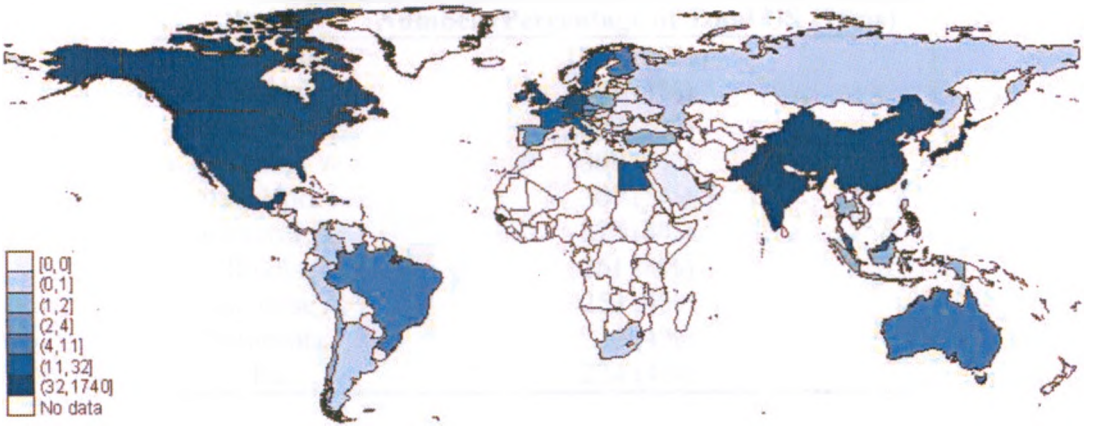


FIGURE 6
Medical device establishments in the United States in 2008

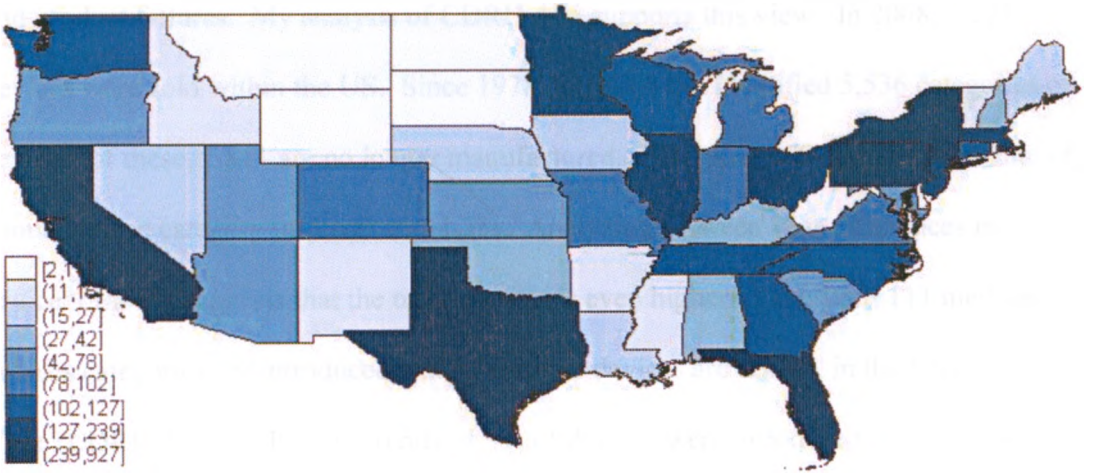
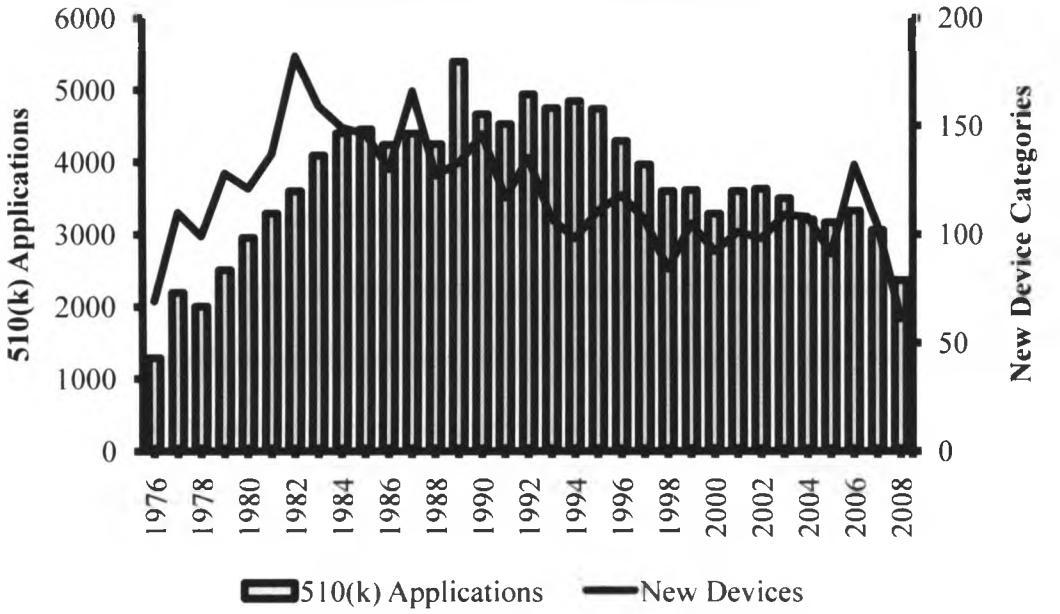


TABLE 3
Top ten US states with medical device firms in 2008

State	Number (Percentage of Total US Firms)
California	1234 (20%)
Florida	398 (7%)
Massachusetts	309 (5%)
Texas	309 (5%)
New York	307 (5%)
Pennsylvania	272 (4%)
Illinois	261 (4%)
New Jersey	253 (4%)
Minnesota	236 (4%)
Ohio	224 (4%)

Device Turnover. Constant device turnover ensures a constant supply of new problems and product failures. My analysis of CDRH data supports this view. In 2008, 2,725 devices were sold within the US. Since 1978, the FDA has identified 5,536 categories of devices; of these, 2,811 are no longer manufactured. Between 1978 and 2008, the rate of annual device category turnover was 1.7%. Analyzing between year differences in device turnover suggests that the turnover rate is even higher. Each year, 111 medical devices categories are introduced and 94 medical devices are retired, in the US market alone (CDRH 2009c). Put differently, 4.9% of devices were introduced and 5.1% were discontinued, each year between 1978 and 2008. Moreover, the competition to introduce new devices is intense (albeit marginally declining since 1994). Figure 7, which I create from CDRH data, shows that the annual rate of Class I and Class II new device categories, and the rate of applications approved to sell a device in the US, are still high.

FIGURE 7
New medical devices categories (510k)



This ***rapid turnover*** means devices are very ***heterogeneous,*** affording many opportunities for failure. For example, Yelle's (1979) argues that interruptions or discontinuities in the learning curve occur because new device introductions and model changes increase failures. I ask how the greater incidence of failure motivates effective interorganizational learning.

Taken together, these four factors (user experience, sector diversity, geographic diversity, and device turnover) pose a paradox. Abundant adverse events offer heterogeneous, revolving opportunities to learn, yet they may also make learning more difficult and regulatory efforts to manage failure more challenging. This is likely true to some degree; however, FDA regulation requires that firms contribute to a common, easily accessible archive of failure. This archive may necessarily neglect information that is

tacit (Edmondson et al. 2004) or localized (Almeida and Kogut 1999; Jaffe et al. 2000; Jaffe et al. 1993); however, there are well established benefits to codifying information. Databases create timely and relevant knowledge spillovers, which may be of benefit interested firms.

Overall, user experience, sector diversity, geographic diversity, and device turnover suggest that there is a large supply of potential product failures and possible solutions in the medical device industry. However, it is unclear whether, and how effectively, firms learn from others' product failures.

There are several more subtle reasons why firms fail to learn from others' product failures. They may wait and see which failures are particularly problematic (causing recalls), or postpone improvements until better technologies are available (Balcer and Lippman 1981). However, the pressure to innovate is high in the industry. A firm's reputation is made on first mover advantages that prove technological proficiency (Lieberman and Montgomery 1988). Additionally, governments encourage faster medical device innovation because the welfare benefits are significant (Murphy and Topel 2006, 2007). The following anecdote shows how acute the incentive is to innovate. In 2008, ReGen Biologics allegedly influenced US Congress members to weaken the regulatory review process so the firm could get its knee repair device to market more quickly (Dickinson 2009b).

Learning through Mergers and Acquisitions

A second rationale for not learning from others' product failure is that some firms have better learning opportunities. For example, some firms may rely on other

interorganizational learning mechanisms, such as mergers and acquisitions. Haleblian and Finkelstein (1999) provide evidence that organizations can learn from mergers and acquisitions, with an event study of acquisition experience in large publicly traded firms. Similarly, Beckman and Haunschild (2002) show that organizations learn through network heterogeneity in acquisition attempts. Descriptive statistics demonstrate that there are significant numbers of mergers and acquisitions occurring in the global medical device industry. In the first nine months of 2008, there were 347 reported mergers and acquisitions, with a total transaction value of over USD38 billion (Burkhardt and Tardio 2008). Nine of these transactions were each valued at over USD1 billion and 149 were valued at less than USD1 billion each (the remaining were undisclosed) (Burkhardt and Tardio 2008). The descriptive statistics also illustrate that these transactions are geographically diverse. 40% of the transactions involved European firms and 11% involved Asian firms.

Mergers and acquisitions are common in the medical device industry, but they may not be as important for reducing failures as in other settings (Beckman and Haunschild 2002; Haleblian and Finkelstein 1999). Mergers and acquisitions are a primary exit strategy for firms that develop medical devices, but less common among firms that market and distribute devices. Appendix A.2 shows that the typical sequence in the medical device industry is for large firms to acquire smaller firms once devices have either been proven or obtained regulatory approval. For example, firms that distribute devices tend to be large and publicly traded; and only 5% of the mergers and acquisitions that occurred in 2008 involved publicly traded firms (Young 2008). This

suggests that mergers and acquisitions may have a strong effect on learning to reduce failures for firms with devices in the proof of concept or development stage, rather than on firms learning from product failures.

Individual-Level Learning

A third alternative explanation is that learning happens at the individual level. Employee turnover (Baron and Hannan 2001; March 1991) and contract employees (Barley and Kunda 2004) bring new insights into a firm and help challenge and refresh old information (Almeida and Kogut 1999). Turnover is an important source of skills; however, it is difficult to get the best employees because other firms hoard prized competitive assets (Felin and Hesterly 2007; Zucker et al. 1998). Moreover, crossing firm boundaries does not necessarily improve skills (Dokko et al. 2009). Most medical device firms are suspicious of contract employees, fearing patent infringement and device failure (Scott 2007). Contract employees are used in manufacturing, but most opportunities to learn from failures arise in device development.

Failure to learn may also be attributed to individuals. Job demands and fatigue may uniformly reduce the cognitive ability of actors and, subsequently, impair the firm's overall ability to gather and process information (Perlow 1999). Nevertheless, the average work week of medical device employees is 50 hours (Nighswonger 1999), which is relatively moderate compared to professionals in similar industries (engineering, law, etc.) (Perlow 1999). Arguments concerning the skill and engagement of employees fall beyond the scope of this thesis; however, the large sample and controls help control for firm-level differences, which may stem from individual-level learning. Heterogeneous

organizational structures and processes will likely introduce additional variance into the observed relationships, making the tests more conservative.

Selection Bias

A fourth explanation is a selection bias away from firms that choose not to enter the US market (the empirical context of my investigation), either because they wish to enter other markets or avoid regulations. However, there is no reason to expect that the market entry decision would reduce pressures to monitor and learn from others' failures. Rather, one expects the opposite. The US accounts for 40.4% of the global medical device industry and the US portion of the industry is forecasted to grow from USD93.9 billion in 2007 to USD114 billion in 2012 (Datamonitor 2008a). Failing in the US market has negative consequences in terms of reputation and regulatory imposts; however, the sheer size of the US market is a strong incentive for firms to take these risks. Thus, firms may be more motivated to learn from the failures of others in the US market where innovation is fast-paced, there is more regulatory scrutiny, and higher penalties for failure. Second, 41.7% of device manufacturing establishments are located in the US. Yet, irrespective of their location, firms targeting the US market are subject to the same FDA approval processes.

Sample

I sample medical device firms that target the US market, and thus have to meet mandatory FDA reporting. This choice ensures homogeneity in regulatory expectations, while still capturing 40.4% of the demand and 41.7% of medical device manufacturing establishments worldwide. Figure 8 depicts the value of the US industry from 2004 to 2008. For baseline comparisons, Figure 8 also includes the pharmaceutical industry. Although the market value of the pharmaceutical industry is larger than the medical device industry, growth in the medical device industry is outpacing that of pharmaceuticals (Datamonitor 2008a, b).

I limit the sample to Class I and II devices. Class I and II devices are the majority of the medical devices in the US (> 90%) (Crosse 2009; Tillman 2008). I excluded Class III devices because the FDA has stricter pre-market approval processes, more rigorously monitors, and intervenes more often for Class III devices[3]. Increases in Class III device reliability are more likely a function of improvements in regulatory action than interorganizational learning.

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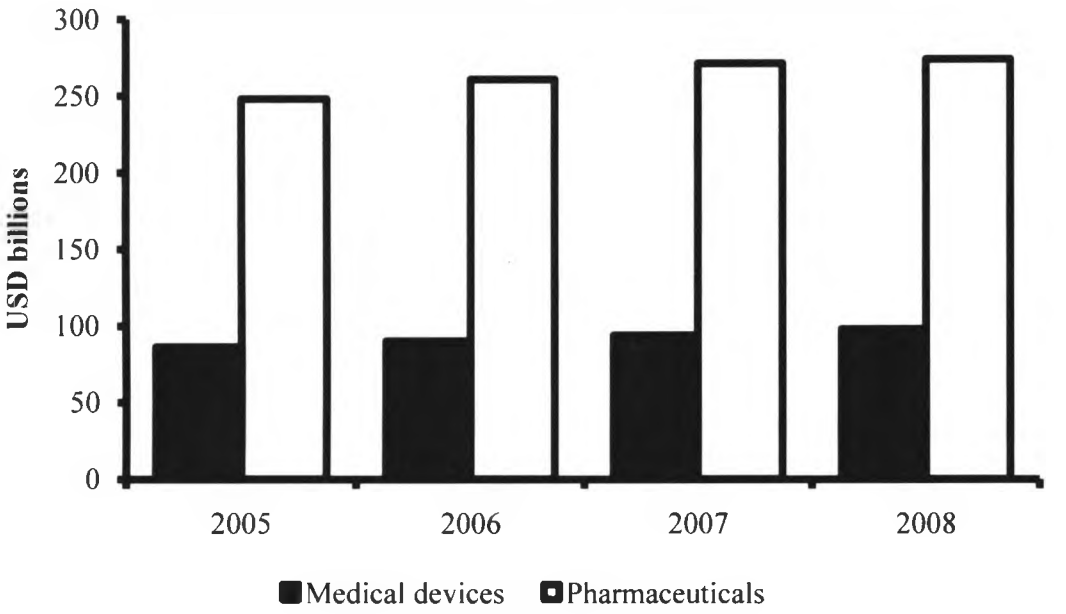
[3] A Government Accountability Office report indicates that the FDA inappropriately reviews some Class III devices in the less strict 510(k) premarket notification process and misclassified the devices as Class I and II devices. However, this should not affect my results as the proportion of these inappropriately reviewed and misclassified devices is small (1.7% or 228 between 2003 and 2007) (Crosse 2009).

FIGURE 8
Value of US medical device and pharmaceutical industries



Data

The US Food and Drug Administration (FDA) mandates that all manufacturers, hospitals, and users of medical devices report medical device adverse events to the Center for Devices and Radiological Health (CDRH). The Safe Medical Devices Act of 1990 defines medical device adverse events as product malfunctions or suspected product-caused events leading to death or serious injury. Since 1984, the FDA's Center for Devices and Radiological Health (CDRH) has recorded medical device adverse events in its Medical Device Reporting database. Medical device firms are required to report every single adverse event, regardless of the cause (user error, poor maintenance, etc) or whether a similar event was reported previously. In 1993, the CDRH began collecting voluntary information about medical device adverse events and in 1996 it began

collecting mandatory information, storing the data in its Manufacturer and User Facility Device Experience Database. Reports have been collected from user facilities since 1991, distributors since 1993, and manufacturers since 1996. The reports contain a variety of information, ranging from descriptive narratives of the events leading up to the adverse event, to technical characteristics of the device and event in question. The FDA regularly updates these databases and mandates that firms that sell medical devices in the US submit annual product information. Information is collected about the patients, devices, manufacturers, and hospitals involved in the adverse event. In 2006, the CDRH databases were made publicly available on the Internet (Meier 2006).

Matching Algorithm

I combine multiple FDA databases using a 'brute-force' algorithm that match firm, device, and dates[4]. I used unique identifiers when available. For example, each adverse event record has a corresponding patient record with a unique identifier. If the data did not have unique identifiers, I combine datasets using the 'brute-force' algorithm. I start by capitalizing all letters and removing punctuation and common words from each name field (device name, firm name, and establishment name). For example, I remove text containing spaces, "*", and "-". I also removed words like "inc.", "company", and "enterprise."

Because many people enter data into the FDA database, there is considerable variability in names and identifying information. To account for this, I designed the

[4] I pursued other avenues of matching, such as fuzzy logic, but the 'brute force' method was by far the most accurate.

algorithm to search every name field for matches. The algorithm checked to see if there was a match after I removed each word from each name field. If there were matches, the algorithm would only search the remaining records. After the algorithm was run, I checked for words that could match remaining records. I kept adding words to the list until I matched all possible records. Given the magnitude of data, it is difficult to assess the accuracy of this matching process; however, from a random sample of 100 matched records, only three were inaccurately matched.

Matching Process

I began by matching a product's registration date in the FDA's Pre-Market Notification [510(k)] database with the Registry Database. The 510(k) database contains information on the intention to develop and sell medical devices in the US. The FDA introduced the database in 1978 to address chronic quality problems in the medical device industry. Next, I combined the resulting database with databases containing firm, device, and adverse event information. In addition, I restricted the sample from January 1997 to December 2008 so that I only obtained mandatory reported documents to ensure reasonable reporting quality.

The sample size of firms with adverse events and new product introductions were relatively large. I first investigated the sample size of the population and subsample of the firms with adverse events. The final database had 1,072,196 records of firms which reported adverse events or no events. Table 4 lists the sample size of the population and matched samples. I analyzed 9,893 active parent firms with their 11,017 manufacturing plants. There were 654 (6.61 %) parent firms with at least one adverse event and 134,605

adverse events. After aggregating to the parent-firm level, I had a total sample of 128,254 firm-year observations and a subset of 2,695 firm-year observations of firms with adverse events. 8,442 firm-year observations had at least one adverse event from 1997 to 2008. I avoid problems of selection bias (Denrell 2003) because the sample includes firms with and without adverse events.

Second, I examined the subsample size of the firms with new product introductions and the sample of firms with both new product introductions and adverse events. The database had records of 8,825 new product introductions for Class I and II devices. 115 of these new product introductions were distinctly new, in which no other firm had previously introduced the device. There were 609 parent firms (6.16%) with at least one new product introduction and 1,422 firm-year observations with at least one new product introduction. The sample had 170 firms and 610 firm-year observations with at least one new product introduction and at least one adverse event with an existing product.

Third, I restrict the sample to firms with more than 50 adverse events throughout the ten year period from 1997 to 2008. Theoretically, this makes it a more rigorous test of making product modifications in response to awareness of others' product failure experience. The sample is less likely to include product modifications in response to out noise from one-off reports and misinterpretations of product failure.. I include observations for years when firms have no adverse events by imputing zero. The end result is a balanced panel sample with 127 firms with 1,397 firm year observations. Nevertheless, restricting the sample to firms with more than 50 adverse events may

induce sample selection bias. For example, firms with fewer products will appear to fail less often. I ensure that sample selection is not a problem by performing post-hoc analysis on (a) firms that fail more than once and (b) all firms in my sample.

Finally, seasonality exists in my sample. There is a 20.1% difference between new device introductions in high months (March and July) and low months (January and June). Seasonality may exist because hospital capital budgets tend to require more rigorous approval processes than operating budgets. Requests for devices from hospital capital budgets occur at the end of the fiscal year, while requests for devices from operating budgets are ongoing. This encourages medical device firms to discount technologically complex devices, but put high margins on spare parts and service. For example, the capital cost of the da Vinci robotic surgeon system by Intuitive Surgical is $1-1.7 million, but the combined servicing costs of EndoWrist attachment and training costs of the system is USD 100,000-150,000 per year. 46% of Intuitive Surgical's revenue ($276 million) comes from servicing and instruments (Anonymous 2008). As well, capital budgeting timelines likely encourage firms to rush device development programs and strategically time device introductions to align with hospital budgets. I annualized the data to smooth these seasonality effects.

Seasonality may affect learning from medical device failure. Healthcare facilities may sometimes purchase new devices before they have personal and training to use them. Administrators first purchase devices at year end on capital budgets patterns in an effort to keep up with state-of-the-art technology. This budgeting pattern may cause an inability to learn from product failure because training and hiring of qualified people

occur once the device is purchased and operating requirements are understood. A *New York Times* article suggests this pattern is true (Bogdanich 2010). Bogdanich (2010) suggests that hospitals purchased linear accelerators before they had operating standards and qualified personnel. Administrators purchased the linear accelerators on the basis of the popularity of treatment. Theoretical work lends support to this seasonality of learning effect. In a study of adoption of TQM in manufacturing, Zbaracki (1998) confirms that organizations often adopt technologies prior to when they are fully understood because of their popularity.

TABLE 4
Size of population and subsamples for Class I and II medical devices from 1997 to 2008

	Database				
Sample	**Firm-product Registry**	**510(k) Device Approval**	**MAUDE Adverse Events**	**Matched Database (Firm-year obs.)**	
Parent firms*	9,893			9,893	
Manufacturing establishments	11,017			11,017	
Medical devices	2,733			2,733	(128,254)
Firms with approved new medical device+		22,009		609	(1,422)
New medical device approvals+		122,016		8,825	(1,044)
Distinct new medical device approvals+		3,879		115	(102)
Adverse event reports			1,092,759	134,605	(2,500)
Firms with adverse events+			36,218	654	(8,442)
Firms with new product introductions				609	(1,422)
Firms with adverse events and new product introductions				170	(610)
Firms with greater than 50 adverse events				127	(1,397)

*Only active firms on December 2008 were included in the sample. Inactive firms are not publically available through the FDA.
+510(k) data includes new product introductions dating back to 1978. The total number of firms is overrepresented in the 510(k) and MAUDE databases. The number is overrepresented because names with incorrect spelling (ie. ABC vs. ABC Inc.) are recorded as distinct firms. The matched database corrects for overrepresentation with the matching algorithm.

Level of Analysis

The level of analysis will be the parent firm, rather than the manufacturing establishment or product, for three reasons. First, tests are more robust with measures at the parent firm-level, because information on parent firms is more readily available than information on their manufacturing establishments. It is important to note that the database contains multi-divisional firms. I classify the parent firm to be the strategic business unit rather than the corporate parent. For example, I classify Ethicon and Depuy as separate firms, rather than as subsidiaries of Johnson and Johnson because Ethicon and Depuy are well-known and viewed as independent in the industry.

Second, I aggregate to smooth idiosyncrasies in manufacturing technologies at the product and manufacturing establishment levels. Medical devices undergo constant product innovation – suggesting that learning occurs at the organizational level rather than the product level. Argote and Epple (1990) argue that interorganizational learning may be variable because of organizational forgetting and impediments to transfer of knowledge. Frequent turnover of devices may significantly increase organizational forgetting and impede knowledge transfer every-time a new device cannibalizes an older one if a significant amount of learning is at the device level.

Third, delays and distractions are less likely to be characteristic of short-term and localized actions. Rather, I highlight systematic delays and distractions by aggregating to the parent firm-level.

Measures and Model Specification

Interorganizational Learning

I model interorganizational learning from product failure as a reduction in the rate of year-to-year medical device adverse events with additional adverse event experience gained by competitors in the previous year. The model of learning is given by

$$R_{i,t} = \beta_0 + \beta_1 \cdot E_{i,t-1} + \gamma'_{i,t}\pi + \epsilon_{i,t} \quad (1)$$

In my case of learning from product failures, i denotes each firm. The product failure experience and the rate of failure are summed across all of a firm's devices. I define $E_{i,t-1}$ as the product failure experience in the previous period, R_{it} is the product failure rate per firm, and $\gamma'_{i,t}\pi$ as a vector of controls that impacts learning that firm i experiences in year t. The error distribution of the rate of failures is denoted $\epsilon_{i,t}$. The exponent, β_1, suggests that learning occurs at an exponential rate.

Product Failure Rates

I model product failure rates as the year-to-year adverse event rate (See Table 5 for a summary of the operationalization of key variables). I used the FDA definition of adverse events (product-caused serious injuries or deaths) and included events reported to the FDA from 1998 to 2008. I define $R_{i,t}$ as the product failure rate for firm i in year t, shown in Equation 2.

$$R_{i,t} = \frac{\ln AE_{i,t} - \ln AE_{i,t-1}}{\ln AE_{i,t-1}} = \frac{\ln AE_{i,t}}{\ln AE_{i,t-1}} - 1 \quad (2)$$

where $\ln AE_{i,t}$ is the natural logarithm of the number of adverse events for firm i in year t.

Table 5
Operationalization of Variables

Hypothesis	Variable	Operationalization
	Product failure rate ($R_{i,t}$)	Year-to-year adverse event rate.
1.	Interorganizational product failure experience ($E_{j,t-1}$)	Mean of adverse events for all other competitors gained in period *t-1*.
2. & 3.	Competitor reporting delays ($D_{j,t-1}$)	The mean of the logged number of days it took for a competitor to report an adverse event to the FDA for all other competitors in period *t-1*.
4. & 5.	Competitor reporting delays ($NP_{j,t-1}$)	The mean of the logged number of new product introductions for all other competitors in year *t-1*.

Logarithm of adverse events. I incorporate the natural logarithm of the number of adverse events ($\ln AE_{i,t}$) in product failure rates to linearize the data. There are two theoretical reasons to take the log before calculating the rate. First, I explicitly incorporate the *Power Law* into my model. The *Power Law* states that the log of the probability of an event occurring positively correlates with the log of the impact of the event. More simply, impactful failures are often rare. The *Power Law* corresponds with theoretical discussions of failure. For example, normal accident theory suggests that some devices will have rare and impactful failures (Perrow 1984). In addition, rare and impactful product failures will tend to interact – causing positive feedback between in number of product failures. In the healthcare arena, larger medical failures attract the attention of physicians and patients because of media attention. In turn, physicians and patients with no current adverse events start paying attention to their device. Patients sometimes discover medical device adverse events when patients pay attention to their

device. A positive feedback loop developments in which impactful product failures cause more impactful failures.

The *Power Law* is also demonstrated in production functions of learning. Jones (2005) uses a micro-economic derivation of the standard form of the production function to show that the growth of ideas that make up organizational experience follows *Power Laws*. Learning actually follows a *Power Law*. The paper highlights that a *Power Law* relationship would appear as a more standard learning curve in more stable and predictable industries. I incorporate the *Power Law* in my model by taking logarithms of adverse events prior to calculating product failure rates.

Second, the rate of logged adverse events is comparable across organizations. Product failures follow a similar pattern across organizations, even though they may seem different for each firm. Figure 9 through 11 illustrates this point. The three figures highlight the five least reliable firms in general and plastic surgery sector. The three Figures have different vertical axis. The number of adverse events per year is on the vertical axis of Figure 9. The natural log of adverse events is on the vertical axis of Figure 10. The rate of change in log of adverse events is on the vertical axis of Figure 11. The figures include Firm 2645. Firm 2645 manufacturers the allegedly faulty surgical stapler (introduced in the theory section). The surgical stapler problem in 2000 is attributable to over 2500 reportable adverse events including 10 deaths. Firm 2645 had a comparable pattern of product failure as Firm 914 in 2000, even though Figure 9 does not suggest it. Firm 914 had only about 1000 product failures. The pattern is observable in Figure 10. Without taking the log, Firm 2645 cannot be compared to other firms

because it biases estimates away from the mean. The logarithm smoothes Firm 2645's adverse event count and focuses on the magnitude of product failure without losing available information. The magnitude of product failure reports is difficult to compare without the logarithmic scale because it makes smaller incidents of product failure comparable to larger, industry wide failures. Using a logarithmic scale for product failure makes it comparable across organizations and across time. I compare on magnitude rather than the absolute number of product failures.

FIGURE 9

Adverse events per firm of the top five least reliable firms in general and plastic surgery

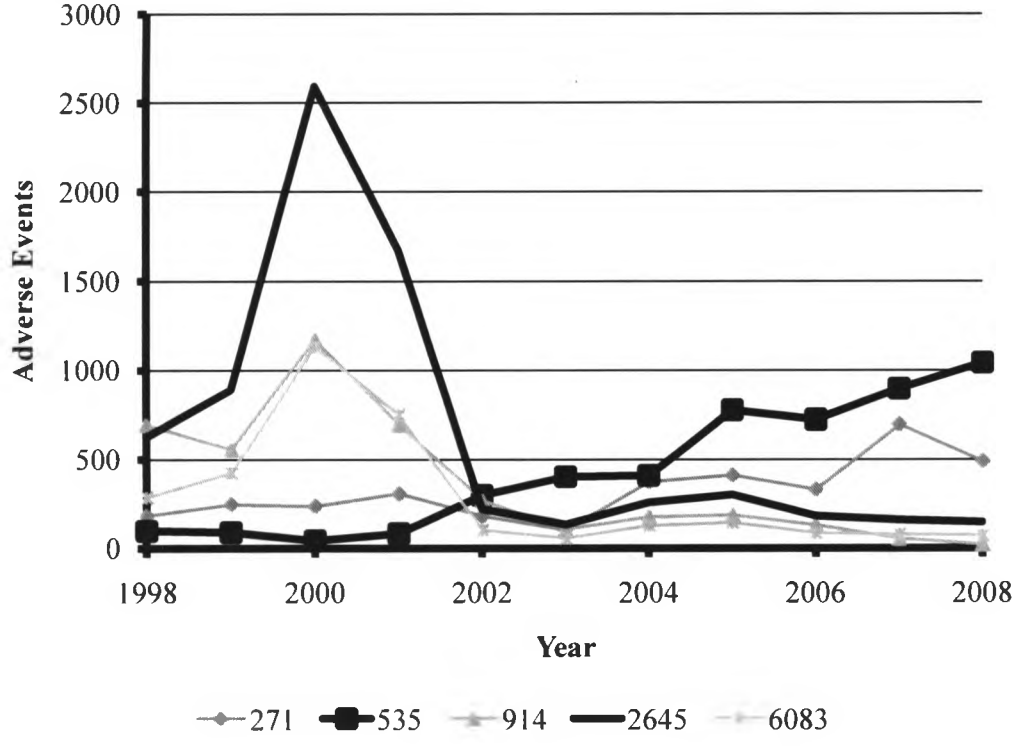


FIGURE 10
The natural log of adverse events per firm of the top five least reliable firms in general and plastic surgery

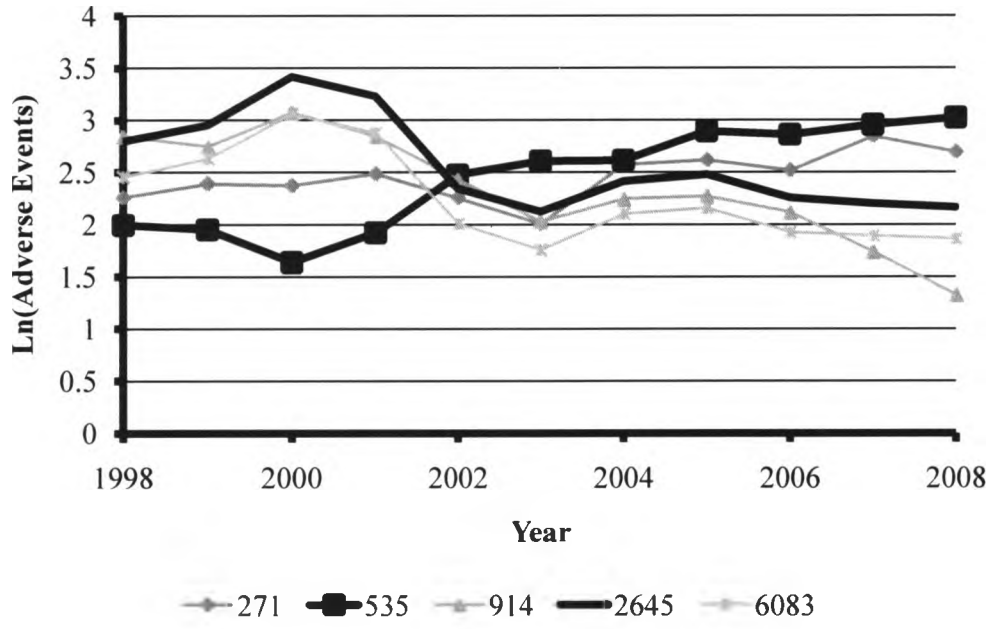
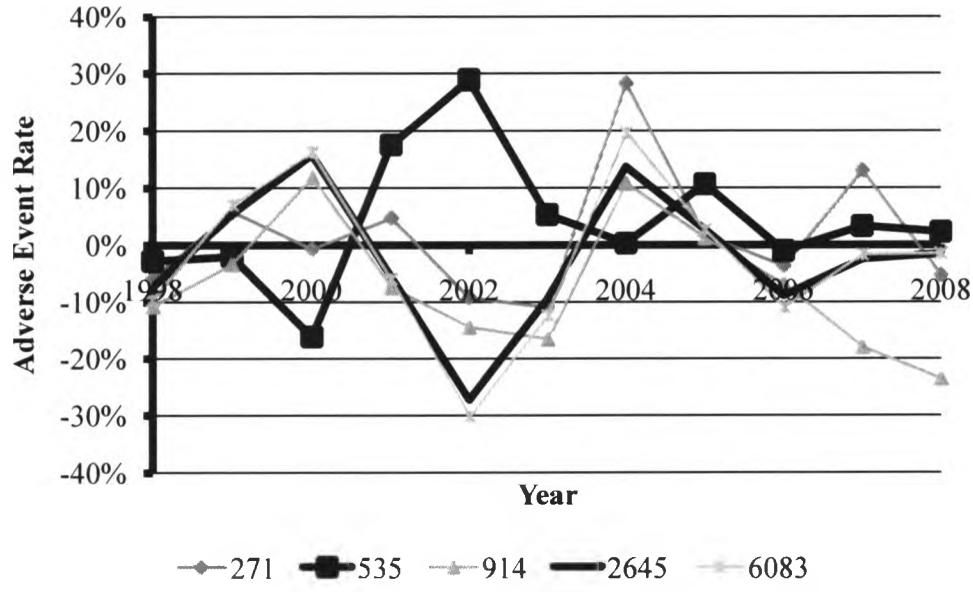


FIGURE 11
The rate of change in adverse events per firm of the top five least reliable firms in general and plastic surgery



Adverse Event Rate. I use the rate of change in adverse events as a proxy for product failure rates. This is called a 'numerator-only' method used by the CDRH in tracking reported adverse events (Gross 2007). Numerator-only methods suggest that the changes in the number of adverse events are tracked, and they are not scaled by the total number of devices (ie. denominator). It would be impractical to gather cost and productivity data on the medical devices that are used in an estimated 100 million surgical procedures in the United States each year (Stalcup 2009).

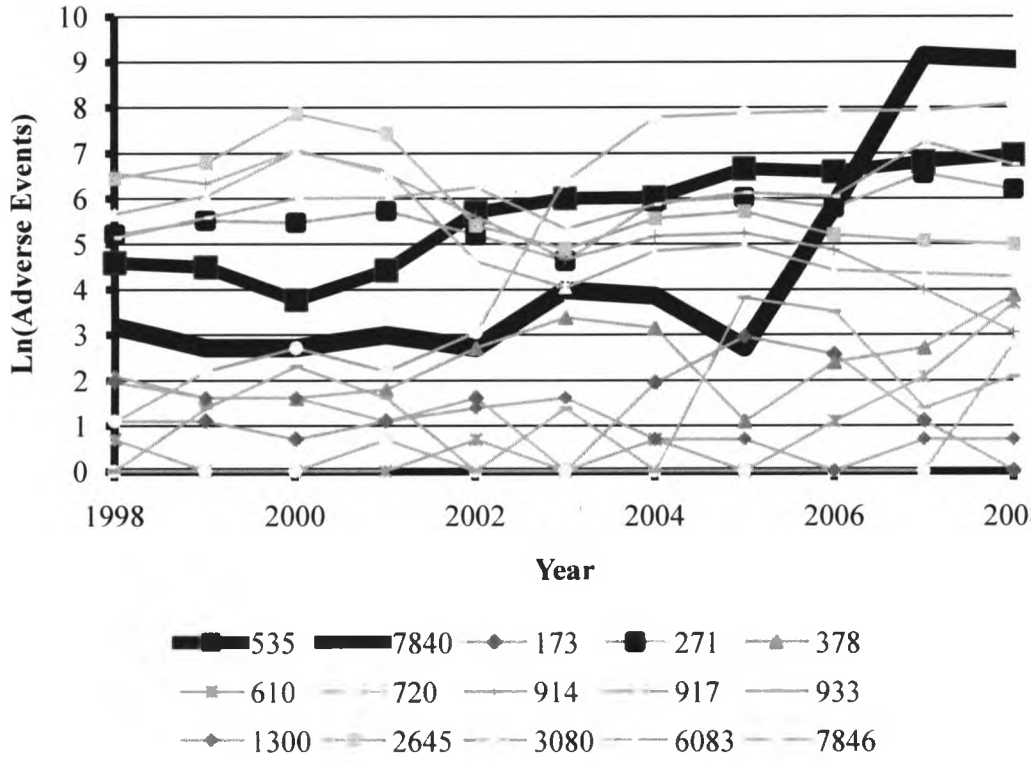
I emphasize the heterogeneity of product failures across organizations. The rate of change in adverse events is also distinct measure from intraorganizational learning from failure studies that use the number of failures divided by the number of devices produced in year *t* (Yelle 1979), the count of failure (Haunschild and Sullivan 2002; Madsen 2009), qualitative measures of product reliability (Levin 2000) or hazard rate to a failure (Kim et al. ; Kim and Miner 2007) as a dependent variable. See Appendix A.4 for a summary. Figure 12 shows that the logged number of adverse events for the five most unreliable firms in each of the three most unreliable medical device sectors (Gastroenterology/Urology, General and Plastic Surgery, and Radiology). Figure 12 depicts that adverse events per firm is heterogeneous. Some rates trend upward, some structurally change upward, and few are similar.

Firm 7840 is a striking example of the difficulties of comparing product failure. The firm specializes in radiological devices. Firm 7840 is depicted as the dashed, black line in Figure 12. The logged number of product failure for firm 7840 trends upward with significant variability until 2005. In 2005, firm 7840 introduced a new X-ray

technology used in angiography. Angiography is used to highlight the insides of a patient's blood vessels or organs. The X-ray technology takes images of a radioactive dye that was injected into the patient.

Firm 7840 is a good example of the difficulties of comparing product failure across firms because the device introduced in 2005 experienced an unusually high rate of software malfunctions. A qualitative report that I gleaned from the CDRH data offers an extreme example of the malfunction. The report discusses that "the system has a known lock-up issue and has been addressed under current recall notifications" and "death of pt [patient] during coronary angio due to failure of xray equipment and need to restart frequently. Caused significant delay and repeated engagement of coronary artery."

FIGURE 12
Natural logarithm of adverse events per year for the five most unreliable firms in Gastroenterology/Urology, five most unreliable firms in General and Plastic Surgery, and five most unreliable firms in Radiology



Product failure rates make product failure comparable across organizations. It is arguable from Firm 7840's report that the problem is not comparable to other medical device organizations. The problem may be unique to coronary angiography, imaging technology, and regulatory attention. However, it is possible to compare product failure by looking at year-to-year rates of change in adverse events. The heterogeneous failure rates in Figure 9 seem more after the transformation in Figure 11. The change in adverse events is comparable because of two reasons. First, it implicitly controls for a large

portion of firm-specific heterogeneity. The measure captures only differences from previous failure rates. This focuses on how firm's rate of failure changes through time so one firm with systematically more product failures can be compared with another firm with less product failures. As well, conditioning on past adverse events takes the variability of a competitor's failure reporting practices into consideration by comparing with the failures that the competitor had in the past. Second, it controls for some of the dynamics and growth in the medical device industry. Adverse events that are growing at an exponential rate will be captured in the intercept – capturing the growing number of adverse events from new product development, changing portfolio of devices, and exponential demand for medical devices. Two examples illustrate this capture of product failure change. The x-ray technology by Firm 7840 offers the first example. The product failure rate decreases in 2008 because the FDA intervened in 2007. The company signed a consent decree of permanent injunction to prohibit the manufacturing and distribution of the X-ray technology until the company met the FDA's current good manufacturing practise (CGMP) requirements. CGMP are FDA issued protocols of acceptable manufacturing and quality control standards in the industry. The FDA found that firm 7840 did not establish procedures to test device design and did not have procedures to monitor continuous improvement. In addition, the firm issued voluntary recalls of the faulty products. Product failure rates capture this change. The product failure rate is negative in 2008 because the number of product failures is less than in 2007.

Firm 535 (the black, solid line with square marker) in Figure 9-11 is an example of capturing growth. Firm 535, an orthopaedic device manufacturer, appears to failing at

a progressively higher rate in Figure 9. However, the product failure rate is decreasing once exponential growth is accounted for in Figure 11 – indicating that product failure is likely to do with an increased number of users from market demand.

Independent Variables

Product Failure Experience

I measure experience in terms of past adverse events. Modeling learning in this way is not entirely unconventional - past research has modeled experience in terms of failures (Baum and Dahlin 2007; Kim and Miner 2007; Madsen and Desai 2010). Measuring experience in terms of product failure is arguably better than other ways for two reasons. First, organizations tend to remember failures more than they do successes (Carroll et al. 2002). Second, it better reflects the way that scholars believe how learning in organizations actually occurs. Learning scholars believe that the reinforcement process of learning focuses on the extinction of acts that lead to failures rather than the propagation acts that lead to successes (Cyert and March 1963; Sutton and Barto 1998; Thorndike 1898).

I define $E_{i,t-1}$ as the number of adverse events in year *t-1* for medical device firm *i*. I normalize the number of adverse events by the total number of adverse events that a firm experienced since it registered its first device with the FDA[5].

I calculate the experience gained in year *t-1* as a percentage of total adverse event experience to isolate contemporaneous effects of moderating variables on experience. This allows me to observe how a moderator in year *t-1* impacts the effect of adverse event experience gained in year *t-1* on product failure rates in year t.

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[5] This is a similar specification to Lapre et al. (2000). However, my specification is different because I allow the linear combination of management factors to change year-to-year. Additionally, I focus attention on gains in experience.

I proxy product failure experience using adverse events in the past year because recent information is valued in the medical device industry. In general, medical device firms have learning curves that are steep because many medical devices are relatively new (an average device is five years old). The rapid pace of product development in the industry rule out the experience effects of failures far in the past because (1) users quickly develop workarounds to known product flaws (Edmondson et al. 2004) and (2) the rapid pace of product development in the industry antiquates information about past failures. Further, the CDRH often identifies and removes devices with systematic problems before significant failure experience accumulates. Even so, it is unclear whether experience gained far in the past is relevant to recent reduction in failure rates. Several studies on organizational forgetting show that experience decays quickly with time (Argote et al. 1990; Benkard 2000; Thompson 2007), supporting the view that recent product failure experience has greater importance in the medical device industry..

Interorganizational Product Failure Experience

I assume that aggregate values of all other competitor's experience impacts the organizational rate of change in adverse events[6]. I define $E_{j,t-1}$ as the mean of adverse events for all other competitors gained in period *t-1*.

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[6] Little research focuses on how intraorganizational and interorganizational learning interact. A learning from failure process in which intraorganizational and interorganizational learning are interdependent is $R_{i,t} = f(E_{i,t}|\cdot) + f(E_{j,t}|\cdot) + f(E_{i,t}, E_{j,t}|\cdot) + \epsilon_{i,t}$. For simplicity, I assume that the two processes are independent.

Measuring interorganizational product failure experience as the average increase in the number of adverse events of all competitors can have endogeneity problems in an industry where the reported adverse events are growing each year (See Figure 1). I reduce endogeneity problems in two ways.

First, I only aggregate a competitor's product failure experience if it increased in the previous year. Reports of medical device failure can persist long after competitors correct product design flaws. The reason for the persistence is because physicians decide that the risks of device downtime and treatment (ie. infection) while upgrading a medical device outweigh the risks of product failure. Some physicians wait until the planned product retirement to replace the device, but if these products fail before the retirement date the failures are still reported to the FDA. I aggregate only increases in product failure by a competitor to avoid capturing the trickle of product failure reports from known issues. I also do not aggregate experience when firms have one year gains of more than 50% product failure experience and more than 300 reports of product failure[7]. This is to avoid capturing one-shot products that quickly fail once the product goes on the market.

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[7] I focus the sample on reactions to the average competitor, so I exclude catastrophic failures (50 % gains and 300 reports). There is a theoretical and an empirical reason. Theoretically, medical device firms may or may not react to catastrophic events. While attention to catastrophic adverse events may be high, theory suggests that organizational actors have difficulty in attending to, interpreting, and reacting to catastrophic failures (Lampel and Shapira 2001; Perrow 1984). I focus on adverse events that are more likely to predicted by attention problems, rather than include catastrophic adverse events which may have confounding mechanisms.

Empirically, the mean of others' adverse events is skewed towards these catastrophic events. The empirical results would not reflect the adverse events of competitors if the adverse events are included. Instead, the empirical results are likely due to singular catastrophic events by a single competitor if these events are included. Nevertheless, I tested my hypotheses with an unrestricted sample, which includes firms with gains over 50% and more than 300 reports. The hypotheses are supported with the unrestricted results.

Second, I condition interorganizational product failure experience on the volume of adverse event reports in the industry. The acceptable amount of reported adverse events is likely growing for various reasons, such as; regulatory pressure to report adverse events, and an increasing usage of medical devices. Consequently, it becomes difficult to observe any interorganizational learning effects with increases in the number of reported adverse events because the greater volume of reports reduces the saliency of any single report. I first use ordinary least squares regression for each firm using average competitor's adverse event experience as a dependent variable and an intercept and the total number of adverse events recorded by the FDA in the industry as predictors. I use the predicted values (excluding the intercept) as the measure of interorganizational product failure experience.

The rate of product failure experience per year should decrease at a decreasing rate with interorganizational product failure experience. The key assumption with this approach is that the organizations pay attention to the industry average product failure experience. There is evidence in past interorganizational learning studies that organizations do respond to the average competitor (Baum and Ingram 1998; Irwin and Klenow 1994). For example, Irwin and Klenow (1994) find that the unit cost of semiconductors decrease with others' cumulative experience and Baum and Ingram (1998) show that the Manhattan hotel survival increases with others' cumulative experience. Nevertheless, I explore this assumption further in the results section by analyzing firm-sector-year observations by restricting social referents to firms within $E_{j,k,t-1}$ and between $E_{j,-k,t-1}$ medical device sectors.

The effect of interorganizational learning from failure is identified by a negative correlation between the reduction of product failure and interorganizational product failure experience. However, the effect may be overstated without explicitly ruling out improvements in manufacturing protocols and standard operating procedures in the medical device industry. Edwards Lifesciences manufactures transcatheter valves for coronary valve replacement provide an example (Conroy 2009). The artificial heart valves are manufactured by hand sewing material and take on average 6 to 8 hours to sew. Employees gain gradual knowledge of the stitching quality and avoid poor stitching practices that could cause an adverse event over time. While I did not have data on the labour-hours in manufacturing per device, total expenditures or the number of devices manufactured per firm, I address different the effects of improvements in experience in manufacturing *post-hoc* by analyzing the learning rates in different medical device sectors.

Competitor Product Failure Reporting Delays

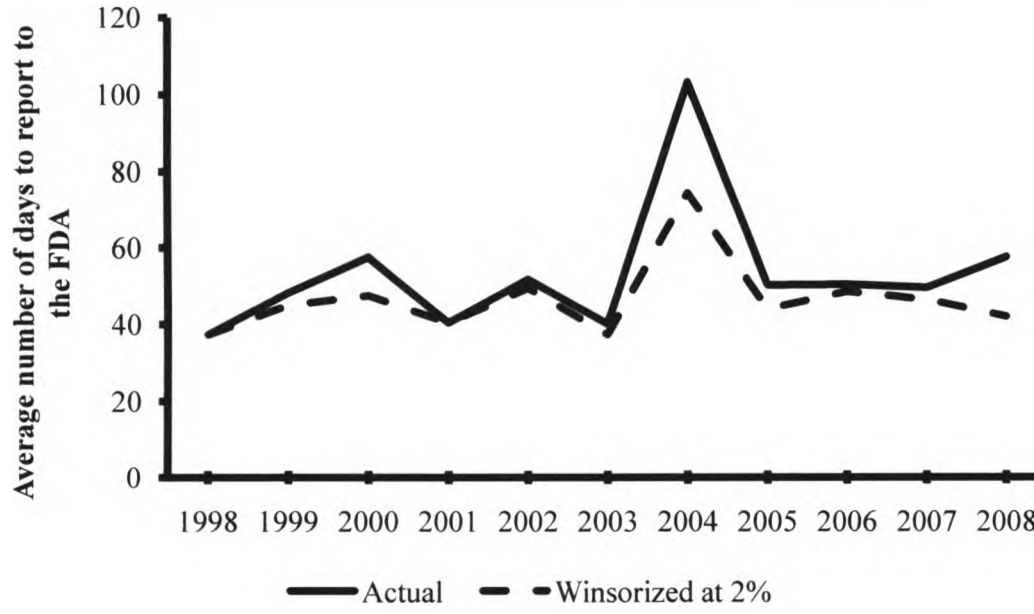
I suggest that the negative effect of the average competitor's reporting delays has a decreasing influence with the length of report delays. I measure delays as the number of days between the firm finding out about an adverse event (date of occurrence) and then reporting it to the FDA (date of reporting). FDA regulations require firms to submit both dates for each adverse event.

I use these formally notified dates, for several reasons. First, formal modes are generally slower than informal modes of communication. On one hand, some actors may be aware of others' adverse events before the events are formally reported to the FDA — word travels quickly through the medical community. On the other hand, informal indicators are noisy, possibly less credible, and may take time to work their way through organizations. Second, firms often have heuristics for attending to formal adverse event reports, for selecting relevant events, and incorporating these formal events into their decision-making processes. It is possible that anticipating a formal report may give isolated actors time to grapple with its implications and sort through responses, but these benefits will likely be random, due to the idiosyncrasies in events and organizations.

Formally, I define competitor reporting delays as the mean of the logged number of days it took for a competitor to report an adverse event to the FDA for all other competitors in period t-1. I subtract the time fixed-effect of delays for a competitor to center the variable, and thereby reduce the chance of multicollinearity. There is also a theoretical reason. Removing the time fixed effect helps rule out competitor- specific reporting heterogeneity – such as reporting pressures from the FDA.

Figure 13 plots the average delay length – the average number of days to a firm took to report an adverse event to the FDA. Figure 13 demonstrates that using my measure of delays is appropriate. First, Figure 13 shows that the delay length is stationary and the winsorized values suggests that this particularly stationary when outliers are removed from the sample. This demonstrates that using mean values is appropriate. Second, the significant effects of outliers also suggests that removing the time fixed-effect of delays is suitable, otherwise competitor delays estimates may be biased from firms with long report times.

FIGURE 13
Average number of days to report to a medical device adverse event to the FDA for firms with more than 50 adverse events between 1998 and 2008



Systematic reporting delays are not the focus of this study because organizations easily detect and account for the systematic reporting of their competitors. I focus on

inter-temporal changes in reporting delays in three ways. First, I remove between competitor heterogeneity by subtracting the time fixed-effect of competitors' delays.

Second, I aggregate only firms that increase reporting delays. I also sum firms with reporting delays longer than the CDRH mandated acceptable limit of 10 days to ensure that the firms have incentive to pay attention to report times. 10 days is maximum limit for user facilities and the limit for manufacturers is 30 days. By looking at reporting times over 10 days ensures I only capture reporting delays by manufacturers. Additionally, informal discussions with manufacturers in the industry indicate that the internal reporting requirement for these manufacturers is 10 days. Reports submitted beyond the 10 day limit may be considered delayed by manufacturers. I avoid double-counting and overlap of reporting delays between years by aggregating reporting delays that are less than 365 days.

Third, I make competitor reporting delays conditional on the average annual industry reporting time. The procedure is identical to one used on interorganizational product failure experience. I use the residual values from ordinary least squares regressions for each firm in which the dependent variable is competitor product failure reporting times and the predictor is average annual industry reporting time. The new measure of competitor reporting delay is orthogonal to industry average reporting time.

I model the impact of delays as a moderation of the change in the average competitor's accident experience, as shown in Equation 3.

$$f(E_{j,t-1} | \cdot) = \beta_0 + \beta_1 \ln E_{j,t-1} + \beta \quad \ln D_{j,t-1} + \beta_3 \ln(D_{j,t-1}) \cdot \ln(E_{j,t-1}) \qquad (3)$$

where $E_{j,t-1}$ is interorganizational product failure experience and $D_{j,t-1}$ is the competitor reporting delay. I assume a multiplicative form of interactions in learning. One sees the multiplicative interaction clearly if they take the log of Equation 3. The equation becomes $R_{it} = \beta_0 E_{j,t-1}^{\beta_1} D_{j,t-1}^{\beta_2} \exp\left(\ln E_{j,t-1} \cdot \ln D_{j,t-1}\right)^{\beta_3} \exp(\gamma'_{i,t}\pi + f(E_{i,t}|\cdot) + \epsilon_{i,t}))$.

In line with my theory, an average competitor's reporting delays should decrease a firm's rate of change in adverse events at a decreasing rate. That is, the failure reducing impact of an average competitor taking the time to understand their own failures and provide clear reports before reporting to the FDA has diminishing returns. As well, β_3 is an estimate of the interorganizational learning difficulties caused by a competitor delaying a failure report.

The case where competitors do not delay (ie. $D_{j,t-1} = 0$) illustrates that Equation 3 reduces to a more familiar learning form. Assume that firms only learn from competitors and not from themselves in both cases. Equation 3 reduces to the more common form of the learning equation: $R_{it} = \beta_0 E_{j,t-1}^{\beta_1+\beta_3}$, where $\beta_1 + \beta_3$ is the learning curve exponent.

It is not clear if a multiplicative form of interaction is the most appropriate. Studies on intraorganizational delays reveal similar multiplicative exponential effects on intraorganizational learning (Denrell et al. 2004; Rahmandad 2008). These studies show that learning becomes exponentially more difficult with delays. In addition, laboratory studies on organization forgetting suggest that experience gained from failure reports would decay at an exponential rate (Bailey 1989). The multiplicative forms seems most

appropriate in tests (not presented) I of an additive form of interaction (ie. $\beta_3 \ln(D_{j,t-1} + E_{j,t-1})$) of delays in the medical device industry.

I measure a competitor's product failure report delay from the previous year impact on the rate of future product failure. Firms can look up and analyze a competitor's product failures from many years past because failure reports are kept in a centralized database. The assumption implicit in Equation 3 is that report delays from years other than the previous year do not impact product failure experience and are uncorrelated with report delays from the previous year. If the assumption is false, Equation 3 will be biased and the impact of report delays from the previous period will be inflated. I control for this by removing the time-fixed effect of a competitor's report delays, which removes consistent year-to-year reporting patterns. In addition, there should not be significant bias because reporting delays are typically less than one year (See Figure 13) and I calculate product failure reduction and product failure experience in one-year intervals. Nevertheless, I present the effects of different lags for reporting delays in the results section.

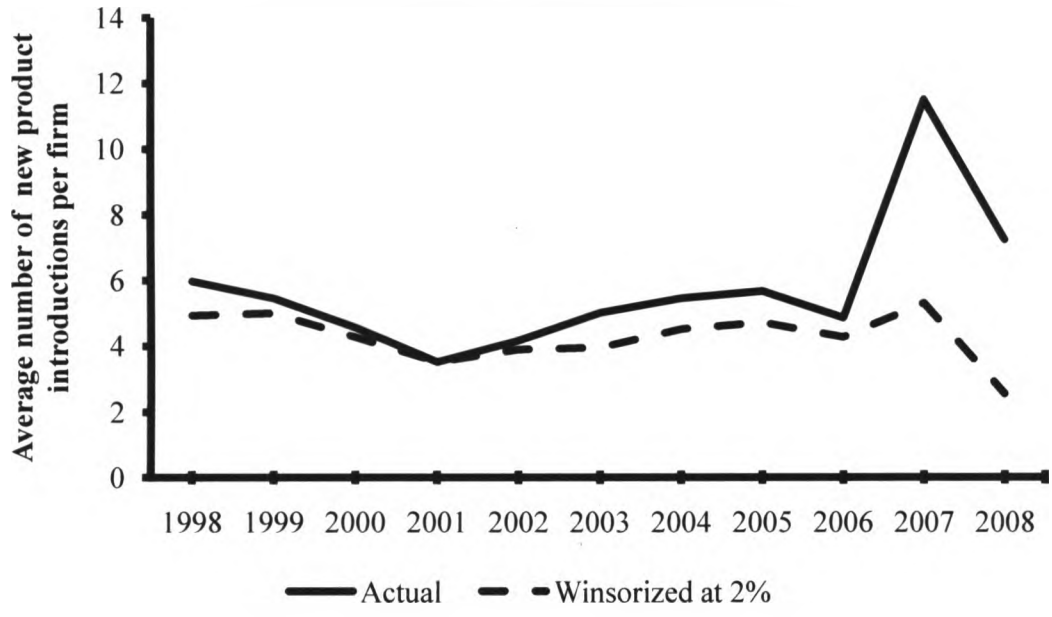
Competitor New Product Introductions

I model that a competitor's new product introductions are distractions to interorganizational learning from failure in existing products. I argue that these distractions have a negative effect on interorganizational learning from failure, but larger distractions have a decreasing influence. I measure distractions as the number of competitor's new product introductions registered with the FDA within the last 365 days

for firm *j* preceding a competitor's adverse event in an existing product. The FDA's Pre-Market Notification [510(k)] database contains all applications to introduce a new product or significantly modify an existing one. I will proxy distractions with others' new product introductions because these are salient, warrant ongoing screening, and have a robust association with success in the industry (AdvaMed 2004). As well, product introductions have been shown to trigger vicarious learning among competitors (Srinivasan et al. 2007).

Formally, I define the average competitor's distractions ($NP_{j,t-1}$) in period t-1 as logged number of new product introductions for all other competitors in year *t-1*. I aggregate firms that have greater than 10 new product introductions to rule out one-shot new product introductions. I subtract the time fixed-effect of new product introductions for a competitor for similar empirical and theoretical reasons as delays. Removing the time fixed-effect reduces multicollinearity with interactions and removes systematic patterns in a competitor's new product development cycle. Figure 14 suggests that removing the time fixed-effect is valid – firms typically have a systematic amount of innovation each year.

FIGURE 14
Average number of new product introductions for medical device firms with more than 50 adverse events between 1998 and 2008



It is arguable that viewing a competitor's new product introductions as a distraction depends upon the state of overall innovation during each year in the industry. A competitor's new product introductions may not be as comparably distracting in years when new product introductions are common. Consequently, the learning impact of others' new product introductions on product failure rates may fluctuate with the total amount of new product introductions in the industry. For example, Donna-Bea Tillman, the CDRH Office of Device Evaluation Director announced that the FDA will slow down the 510(k) premarket review process to more closely examine new product introductions applications in September 2009 (Dickinson 2009a). The approval of a device during vigilant regulatory screen may be a sign of an effective device. Similarly, the slow approval of a device may be a sign of an innovative device. I address the problem of

changing significance of new product introductions by making competitor new product introductions orthogonal to the state of overall innovation in the industry. I regress the average competitor's new product introductions ($\widehat{NP_{j,t}}$) with the total number of 510(k) applications received by the FDA. I use the predicted values from an ordinary least squares regression for each firm as the new measure of competitor new product introductions.

I model distractions following previous work on delays in interorganizational learning from others' product failure experience, as shown in Equation 4.

$$f(E_{j,t-1}|\cdot) = \beta_0 + \beta_1 \ln E_{j,t-1} + \beta \quad \ln NP_{j,t-1} + \beta_3 \ln(NP_{j,t-1}) \cdot \ln(E_{j,t-1}) \qquad (4)$$

where $E_{j,t-1}$ is the percent of accident experience gained and $NP_{j,t-1}$ is the number of new product introductions for the average competitor in year *t-1*. An average competitor's new product development should decrease a firm's rate of adverse events at a decreasing rate, which is consistent with my theory. The interaction term reflects the difficulties of paying attention to a competitor's existing product failure and new product introduction.

I model that a distraction to product failure should occur in the same period as product failure experience. While I test if distractions can occur in different years than the product failure experience in the results section, the present analysis assumes distractions occur in the same period as a product failure. I also partially rule out its effects by removing systematic new production introductions with within-competitor time-fixed effects. In practise, violations of this assumption is likely not substantial because the novelty of a competitor's new product introduction quickly decreases.

Controls

Death. Organizations are more likely to respond to medical device adverse events that caused deaths. I control for year-to-year differences in the death count for a firm ($\Delta DEATH_{i,t}$) and the average competitor ($\Delta DEATH_{j,t}$). I use year-to-year differences to remove systematic effects of the context of product use – some settings (ie. the operating room) are prone to have reportable deaths. I expect medical device firms to have a significant decrease in adverse event rates and product failure report times when a death occurred because of FDA and user pressure.

Product failure complexity. Organizations may have greater difficulty understanding complex adverse events. To control for complexity, I measure adverse event entropy based on the intra-industry sector of the adverse event. The entropy measure will be $-\sum_{i=1}^{n}\sum_{r=1}^{m} p_{i,r} ln(p_{i,r})$, where p is the proportion of adverse events that occurred in medical sectors, designated r, for firm i. Past studies have suggested that complexity encourages deep understanding of underlying causes, when learning vicariously (Haunschild and Sullivan 2002). I expect that firms are more likely to heed complex failures because organizational members view complex failures are caused by systematic problems.

I define $\Delta COMPLEXITY_{i,t}$ as the year-to-year first order difference in product failure complexity. Looking at year-to-year change in complexity is theoretically sound because it reflects the changing nature of complexity. Organizations have less ability to

unpack product failures with increasing complexity and less likely to attend to a competitor's product failure reports.

Delays. I control for a firm's own product failure report delays. I measure report delays as the logged number of days a firm took to report a failure to the FDA in period t ($D_{i,t}$). I expect longer report delays to decrease the rate of product failure because firms that take the time to process failures likely have a better understanding of their causes.

New product introductions. The effect of interorganizational learning from failure may be overstated without controlling for an organization's own new product introductions. Organizations with better product designs and innovative design teams may be able to preempt product design problems before they occur (Adler and Clark 1991). Thus, decreases in the rate of product failure due to new product development may actually decrease the need to refer to competitor's product failures. New product introductions will cause a spurious negative effect between the average competitor's product failure experience and product failure rates. I address this problem by including a count measure of an organization's new product introductions within 365 days preceding the start of year *t* ($NPI_{i,t}$).

Firm complexity. Firm complexity will be modeled as intra-industry diversification based on the medical sector of manufacturing establishments (Li and Greenwood 2004). I will use an entropy measure using the proportion of products in the country or medical sector for firm *i*. I define this variable as $\Delta DIVERSE_{i,t}$. Complexity should increase annual adverse event rates because of information diffusion and coordination problems – increasing the impact of a competitors' delays and distractions.

Competition. I proxy competition as the mean of the parent firm's number of competitors in each product type. Measuring competition this way, rather than by the more common approach of matching SIC codes, will rule out assigning firms to the incorrect industry. Annual adverse event rates should decrease with competition because it increases inter-firm learning by providing templates and incentives for information exchange across firms (Greve 2003).

Interorganizational product failure interaction. The interaction of product failure between firms will likely cause underestimation of the effect of interorganizational product failure on the rate of product failure. Previous research on shows that medical device failure may interact (Coleman et al. 1957). Product failure interaction between firms may occur with awareness of the specific causes of product failure for two reasons. First, regulators may inform manufacturers and users of faulty components. The awareness causes waves of failures between firms as users are suddenly able to identify product failures or reclassify human errors as product failure. Second, the failure of subcomponents may cause failure in multiple devices. I capture product failure interaction using an indicator variable for increases in product failure with increases in interorganizational product failure experience. Formally, I define interaction as $INTERACT = I(\Delta R_{i,t} > 0 \; AND \; \Delta E_{j,t-1} > 0)$.

Studies on social learning propose similar interaction effects (Burt 1987; Conley and Udry 2010; Strang and Tuma 1993; van den Bulte and Lilien 2001). They argue that social learning is difficult to estimate because of this interrelatedness of observed outcomes. The studies control for interrelatedness by using a number of fine-grained

controls of how individual *i* relates to individual *j* and how individual *j* relates to individual *i*. However, it is easy to determine farming neighbours (Conley and Udry 2010) and physician colleagues (Coleman et al. 1957) at the individual level. Conley and Udry (2010) and Coleman et al. (1957) simply asked the individuals who their neighbours and colleagues were. The task of determining how determining how product failure interacts is considerably more difficult at the interorganizational level. The level (ie. physician or organization), type (ie. technology alliances vs. device substitutes), and pattern of how fine-grained network data is related between organizations is unclear for interorganizational learning from product failure.

I calculate product failure interaction using an indicator variable of interorganizational product failure experience rather than more refined measures, such as public reports of faulty subcomponents. I recognize that the interaction measure also captures incidents where organizations improperly learn from others and increase adverse events rates unintentionally. However, FDA oversight and recall procedures prevent systematic learning to fail from others' product failures in the medical device industry.

Learning organizations. I control for learning organizations using an indicator variable ($LEARN$) for decreases in interorganizational product failure experience that correlate with decreases in the product failure rate ($I(\Delta R_{i,t} < 0 \; AND \; \Delta E_{j,t-1} < 0)$). This specification captures firms that always learn to reduce product failure rates, even when others' experience less product failure then in the past. I expect learning organizations to be negatively correlated with product failure rates because they are able to extract knowledge from fewer product failures.

Regulatory controls. Regulatory effects are prominent issues in the medical device industry. I model regulatory complexity as the number of independent FDA regulations a parent firm deals with on an annual basis, which will be extracted from the FDA's regulatory database. I define $\Delta REGULATION_{i,t}$ as the year-to-year difference in the number of regulations. Annual adverse event rates should decrease with additional regulations because of the punitive consequences of non-compliance. As well, under-reporting of adverse events should decrease with regulation because of increased monitoring activities by regulators.

Firm demographics. I control for firm size using the log of the number of products a firm manufactures. I include firm size for both the firm ($\Delta PRODUCT_{i,t}$) and the average competitor ($\Delta PRODUCT_{j,t}$). This is a proxy for firm size because I assume that larger firms produce more products than smaller firms. I take the first order year difference because the odds of failure increase proportionally as the firm organically grows its products and processes.

Enrst and Young (2008) estimates that 301 (4.9%) medical devices firms are publicly traded in the US. I also include an indicator variable for publicly owned firms by matching parent firms to the COMPUSTAT and CRSP databases ($PUBLIC_{i,t}$). Public firms comprise of 26% of my sample. While this is higher than Enrst and Young's estimate, my sample contains more firms manufacturing and distributing medical devices than design firms, which typically are more likely to be publically owned. Public firms should have high annual adverse event rates and place greater emphasis on learning from

product failure because public companies face stringent reporting requirements and intense screening by different stakeholders, such as shareholders and analysts.

Year-fixed effects, time trends, and MDUFMA. I include a time trend and structural change variable for MDUFMA, rather than including year-fixed effects. Figure 15 presents the mean rate of change of adverse events for firms between 1998 and 2008. The figure illustrates a time trend and a structural change caused from regulatory changes after 2004. To test whether I can exclude year-fixed effects, I run four models. Table 6 presents four models of the ordinary least squares regression results of the rate of change in adverse events on year indicator variables. In model 1, I regress the rate of change on year indicator variables. In model 2, I regress winsorized rate of change at the 2% level ($W(R_{it})$) on year indicator variables – to remove the effects of outliers. I varied the amount of winsorizing. Winsorizing at the 1% or 3% level makes little difference to the results. In model 3 and 4, I include a time trend.

FIGURE 15
Product failure rates for medical device firms with more than 50 adverse events between 1998 and 2008

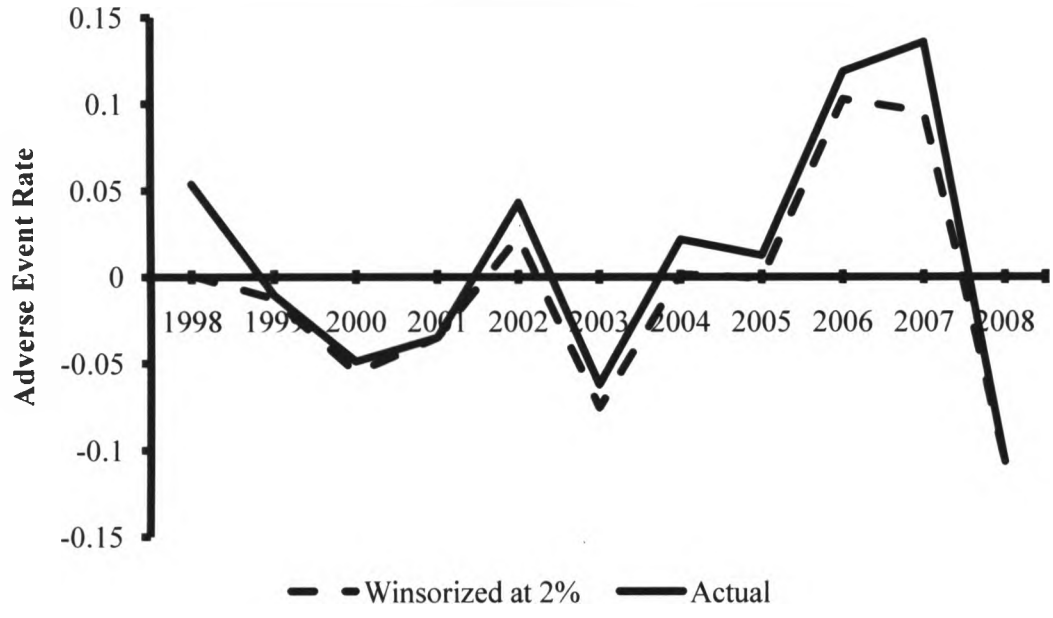


TABLE 6
Regression results for year indicators and time trend

	(1)	(2)	(3)	(4)
	R_{it}	$W(R_{it})$	R_{it}	$W(R_{it})$
1999	-0.04	0.008	-0.02	0.02
	(0.09)	(0.07)	(0.08)	(0.07)
2000	-0.10	-0.06	-0.06	-0.03
	(0.09)	(0.07)	(0.08)	(0.06)
2001	-0.08	-0.03	-0.02	0.01
	(0.09)	(0.06)	(0.07)	(0.05)
2002	-0.01	0.03	0.07	0.09
	(0.09)	(0.07)	(0.07)	(0.06)
2003	-0.13	-0.09	-0.03	-0.02
	(0.10)	(0.07)	(0.07)	(0.06)
2004	-0.04	0.00	0.09	0.08*
	(0.09)	(0.07)	(0.06)	(0.05)
2005	-0.03	0.01	0.12*	0.12*
	(0.09)	(0.07)	(0.07)	(0.06)
2006	0.02	0.06	0.19***	0.18***
	(0.08)	(0.06)	(0.05)	(0.04)
2007	0.04	0.06	0.23***	0.19***
	(0.09)	(0.06)	(0.07)	(0.05)
2008	-0.20**	-0.15**	0.00	0.00
	(0.09)	(0.07)	(0.00)	(0.00)
t			-0.02**	-0.02**
			(0.01)	(0.01)
Constant	0.05	0.01	40.8**	29.3**
	(0.07)	(0.05)	(17.00)	(13.00)
Observations	1092	1092	1092	1092
F-stat	2.81	3.11		
R-squared	0.02	0.02	0.02	0.02
RMSE	0.49	0.42	0.49	0.42

* Baseline is 1998

I control for HIPAA, leadership change in the FDA, and MDUFMA using a single indicator variable for adverse events occurring between 2004 and 2008. I refer to their combined regulatory effect as MDUFMA because MDUFMA is regulation that is directly solely to the medical device industry since it is difficult to disentangle the effects

of MDUFMA from the effects of HIPAA and leadership succession. Model 3 and 4 in Table 6 indicates that the MDUFMA caused a significant structural change after 2004. The models indicate that the rate of change in adverse events increased significantly each year since the implementation of MDUFMA in 2004.

I tested to see if firms with particularly high adverse event rate were affecting this rate of change to rule out the possibility that the structural change is from changes in regulations rather than from abnormally high failure rates. I included indicator variables for two firms that accounted for 3.0% of the 1,092,759 reports of adverse events in my sample. Firm 7846 experienced a high rate of failure with drug eluding stents. In 2003, the FDA expedited the premarket approval process for Firm 7846's breakthrough drug-eluding coronary stents. A conventional bare-metal stent is a scaffold for diseased arteries in the heart. The breakthrough innovation was inclusion of drugs that inhibit cell proliferation that could lead to stent blockages. By the end of 2004, drug-eluding stents were preferred over bare-metal stents in almost 80% of the percutaneous coronary interventions in the United States (Maisel 2007). However, product failure rates of drug-eluding stents dramatically increased after 2004 and attracted considerable media attention. In my analysis of the CDRH data, the rates of drug eluding stents failure reports increased by 2,846% from 2003 to 2004. The stent was thought to cause thrombosis, or clotting of the artery, that could possibly lead to death. Maisel (2007) indicates that the potential reasons for the higher risk of thrombosis are unclear because of the lack of long-term clinical data.

Learning about stent-caused thrombosis may have led to systematic changes in drug eluding stent and other medical device improvements. Learning may have occurred through sharing of information between manufacturers. Learning across the industry may have broadly occurred because of the media attention on drug-eluding stents. Political and consumer advocacy put pressure on regulators and manufacturers to improve the drug-eluding stents. In December 2006, the FDA set up a panel to asset the safety of drug-eluding stents because of the confusion and the inexperience with drug-eluding stents from manufacturers and physicians and the FDA. Physicians, patients, regulators, and competing manufacturers convened to exchange information about the product failures during the panel.

Product failure from the introduction of a new x-ray system product failure experience of Firm 7840 may have been the reason for the systematic increase in product failure rates. I discussed the malfunctioning X-ray earlier. To reiterate, the product failure was significant. The product failure rate for Firm 7840 increased by 2,265% from 2006 to 2007 and accounted for 65% of the firm's failures. The X-ray system was malfunctioning because software issues. These malfunctions account for a 99.9% of Firm 7840's 9,321 adverse events reported in 2007.

In both cases, the structural increase could have been from media attention, additional regulatory scrutiny, and increased information exchange of the causes of product failure. The added attention may cause all other firms to step up product failure reporting, but this does not seem to be the case. The indicator variable for these two firms is insignificant - the coefficient is 0.072 (P-value < 0.34). This indicates that the

product failures that accounted for the largest number of product failure reports were not causing structural increases in product failure after 2004.

I also looked at the sensitivity of the start date by using an indicator variable for adverse events between 2003 and 2008 and using an indicator variable for adverse events between 2005 and 2008. MDUFMA starting in 2003 is insignificant and MDUFMA starting in 2005 is more significant. The coefficient for MDUFMA between 2005 and 2008 is 0.058 (P-value < 0.03) and between 2003 and 2008 is 0.035 (P-value < 0.18). The insignificance of years prior to 2004 and greater significance of years after 2004 for MDUFMA and significance of the indicator variables for adverse events between 2004 and 2008 (the coefficient is 0.053, P-value < 0.05) indicate that I capture the structural change in the data. The start date of 2004 also suggests that both MDUFMA and HIPAA are likely causes of the structural change because both regulatory changes were enacted just prior to 2004.

Analyses

I analyze the model using a within groups, fixed effect estimator regression. Because I am interested in effects over time, I use fixed effect estimator to obtain efficient estimates of the time-varying component of variables. My model has firm-specific heteroskadasticity using Huber-White sandwich variances. I lag independent variables by one year to prevent issues with simultaneity. Because of the one year lags, I omit 127 firm-year observations for 1998.

I explore the model using quantile regression. Quantile regression is well suited to investigate product failure because product failure is often a complex event. Failure often interacts and impactful failures can be extreme outliers in a distribution. I explicitly incorporate and analyze these outliers in quantile regression, rather than discard the outliers as one would in ordinary least squares regression. Quantile regression is a semi-parametric technique – meaning that it is insensitive to the distribution of product failure rates. This approach (i) maps the relationship between predictors and criterion across the whole distribution of adverse events, (ii) does not assume a distribution, (iii) is insensitive to outliers, and (iv) minimizes deviations from a cut-point (τ) (Koenker 2005). For example, the coefficients of a quantile regression of $\tau = 0.9$ indicate how the independent variables affect the most unreliable firms, or firms falling in the 90^{th} percentile of adverse events. This helps eschew problems of statistical averages, such as focusing on commonalities and avoiding the rich and vivid information at the extremes of distributions. I use simultaneous quantile regression to estimate the model.

5. Results

Summary Statistics

Table 7 presents the summary statistics for the overall sample. The moments (mean, standard deviation, skewness, kurtosis) variables in the overall sample appear to be normally distributed. However, the Bera-Jarque (1980) Test of normality indicates that all of the variables are non-normal. The test looks at whether the skewness and kurtosis are jointly not normal. The Bera-Jarque Test statistic ranges from 14 to 5.9 X 10^6. Additionally, the Bera-Jarque Test statistic for the variables of interest ranges from 0.28 to 1,948 between each year. The data are normal within firms because the Test statistic ranges from 0.34 to 4.73 within firms and most are not significant. The non-normality is caused by the variables being inflated with zeros and a few outliers. The data appears to be normally distributed with winsorized data and the zeros are removed. This suggests that a fixed effect estimator is suitable. Nevertheless, the section on robustness and sensitivity analyses explores the impact of non-normality by winsorizing outliers and performing quantile regression, which does not rely on assumptions of normality.

The summary statistics highlight an important finding. The adverse event rates and product failure experience both have a mean of zero. This highlights that adverse event rates do not improve (or get worse) year-to-year. In addition, it shows that medical devices fail in a predictable manner across firms once accounting for firm fixed effects. Product failure is because of organization idiosyncrasies.

TABLE 7
Overall summary statistics

		Mean	S.D.	Skewness	Kurtosis[+]
Change in adverse events	$R_{i,t}$	0	0.5	2.131	15.46***
Product failure experience	$E_{i,t}$	0	0.84	0.665	4.98***
Competitor product failure experience	$E_{j,t}$	0	0.22	0.829	2.33***
Competitor delay	$D_{j,t}$	0.05	0.18	0.15	2.6***
Competitor new product introductions	$NPI_{j,t}$	-0.03	0.08	-0.563	4.08***
Change in deaths	$\Delta DEATH_{i,t}$	0.02	0.5	0.281	14***
Change in competitor deaths	$\Delta DEATH_{j,t}$	0.02	0.05	-0.162	2.2***
Change in diversification	$\Delta DIVERSE_{i,t}$	0.02	0.39	1.15	16.79***
Change in failure complexity	$\Delta COMPLEXITY_{i,t}$	0.05	0.84	0.51	9.65***
Change in number of products	$\Delta PRODUCT_{i,t}$	0	0.02	15.511	321.11***
Change in number of competitor products	$\Delta PRODUCT_{j,t}$	0	0	-0.094	2.33***
Change in number of regulations	$\Delta REGULATION_{i,t}$	0	0.03	8.08	241.71***
Change in number of competitors	$\Delta COMPETITOR_{i,t}$	0.0	0.18	-0.86	17.5***
Delay	$D_{i,t}$	0.05	1.55	0.298	3.29***
New product introductions	$NPI_{i,t}$	-0.03	0.62	1.185	10.9***
Public firm	$PUBLIC_{i,t}$	0.26	0.44	1.07	2.14***
MDUFMA structural change	MDUFMA	0.45	0.5	0.183	1.03***
Time trend	T	2003	3.16	0	1.78***
Interorganizational product failure interaction	$INTERACT_{i,t}$	0.28	0.45	0.20	2.00***
Learning organization	$LEARN_{i,t}$	0.14	0.12	2.11	5.48***
US Hospital Stays	$STAYS_t$	0.27	0.28	1.89	5.74***
US Hospital stays with procedures	$OPERATIONS_t$	0.07	0.05	0.26	2.26***
US Healthcare expenditures	$HEALTH_t$	0.11	0.35	2.83	9.04***

N = 1397 firm-year observations.
[+]Significance of the Bera-Jarque (1980) test for normality.

Multicollinearity

I check for multicollinearity problems using variance inflation factors (VIFs). Table 8 presents the variance inflation factors for the independent variables, lagged one year. Multicollinearity is not a problem because the VIFs are well below the common rule of thumb of VIFs less than 10 (Paetzold 1992). I calculate VIFs excluding controls for the year trend (t), interorganizational product failure interaction ($INTERACT_{i,t}$), and learning

organization ($LEARN_{i,t}$) because I expect these to be collinear with variables that change over time. The mean VIF is 3.18 and the maximum VIF is 8.96. In addition, the low overall sample VIFs indicates that multicollinearity is not an issue within each panel.

TABLE 8
Variance inflation factors

		VIF
Competitor product failure experience	$E_{j,t-1}$	8.96
Change in competitor deaths	$\Delta DEATH_{j,t-1}$	5.80
Change in number of competitor products	$\Delta PRODUCT_{j,t-1}$	4.58
Competitor delay	$D_{j,t-1}$	3.52
MDUFMA structural change	MDUFMA	3.12
Change in number of products	$\Delta PRODUCT_{i,t-1}$	1.76
Competitor new product introductions	$NPI_{j,t-1}$	1.73
Change in number of regulations	$\Delta REGULATION_{i,t-1}$	1.71
Change in diversification	$\Delta DIVERSE_{i,t-1}$	1.51
Product failure rate	$R_{i,t-1}$	1.33
Product failure experience	$E_{i,t-1}$	1.28
Delay	$D_{i,t-1}$	1.20
New product introductions	$NPI_{i,t-1}$	1.13
Change in failure complexity	$\Delta COMPLEXITY_{i,t}$	1.12
Public firm	$PUBLIC_{i,t-1}$	1.11
Change in number of competitors	$\Delta COMPETITOR_{i,t}$	1.07
Change in deaths	$\Delta DEATH_{i,t-1}$	1.06
	Mean VIF	3.18

*N.B. N = 1270 firm-year observations.

Correlation Table

Table 9 presents descriptive statistics and correlations derived from the variance-covariance matrix of model 2 in the main results. The correlation table highlights high correlation (>0.4) between several relationships. High correlation values may be due to multicollinearity. However, multicollinearity is unlikely in this instance because the variance inflation factors presented in Table 8 indicate that multicollinearity is low.

The high correlation values highlight three important results about product failure experience in the medical device industry (See Appendix A.5 for a summary of the findings). The three results echo the theme of my thesis – product failure experience, new product introductions, and failure reporting processes are critical to interorganizational learning to reduce product failure rates. First, new product introductions correlate positively with product failure experience. The correlation between a competitor's new product introductions ($NPI_{j,t-1}$) and their product failure experience ($E_{j,t-1}$) is 0.61. Similarly, the correlation between a firm's new product introductions ($NPI_{i,t-1}$) and their product failure experience ($E_{i,t-1}$) is 0.04. The positive correlation has two possible explanations: (1) product innovation increases product failure experience, or (2) firms report adverse events in existing products when they introduce a new product.

Second, reporting delays correlate negatively with interorganizational product failure experience. The correlation between interorganizational reporting delays ($D_{i,t-1}$) and interorganizational product failure experience ($E_{j,t-1}$) is -0.71. The negative correlation implies that competitors have less reporting delays with larger gains in product failure experience. Two possible reasons may explain why a competitor's reporting delays decrease with interorganizational product failure experience. The first reason is that organizations learn better product failure reporting practises and operating procedures with additional failure experience. The correlations of -0.51 between total adverse events (TE_i) and reporting delays and -0.45 between a competitor's new product introductions ($NPI_{j,t-1}$) and reporting delays ($D_{j,t-1}$) support this argument. These two correlations show that product innovation and a large number of product failures decrease

reporting delays. The second reason is that additional product failure experience may attract the attention of regulators and additional stakeholders. The negative correlation value of -0.18 between being a public firm and reporting delays supports the latter argument. The negative correlation between reporting delays and public firms suggest that external stakeholders monitor and value efficient product failure reporting practises.

Third, MDUFMA correlates negatively with interorganizational product failure experience, but is only a small correlation. The correlation between MDUFMA and interorganizational failure experience is -0.14. The negative correlation implies that MDUFMA regulatory changes decreased the number of product failures in the industry. However, MDUFMA may have been detrimental to product failure in the medical device industry. The correlation between an average competitor's new product introductions and MDUFMA is -0.50 – indicating that product development dropped significantly after the introduction of MDUFMA. Additional regulations may decrease the number of devices on the market. The correlation between regulations ($\Delta REGULATION_{i,t-1}$) and number of devices ($\Delta PRODUCT_{i,t-1}$) is -0.89. While the tougher regulatory environment may improve the product reliability of existing devices, the high negative correlation between product failure experience and new product introductions suggests that it may have inadvertently decreased the product reliability of future medical devices by raising the hurdle of pre-market approval.

The low correlation between regulation and interorganizational product failure experience may be due to reactions to death in the industry. The correlation between death ($\Delta DEATH_{i,t-1}$) and interorganizational product failure experience is -0.89. The high negative correlation indicates that death sharply decreases product failure in

competitors. Perhaps, there are two reasons. One reason is because of actions by competitors. The positive correlation between death and competitor's reporting delays ($D_{j,t-1}$) is 0.69. The correlation illustrates a wake-up call for competitors. Competitor's process failure reports slower, leading to richer and clearer failure reports for other competitors. Another reason is because of regulatory oversight. The correlation between death and regulations is 0.15 and the correlation between death and a competitor's new product introductions ($NPI_{j,t-1}$) is -0.46. These two correlations suggest that death causes the CDRH to quickly increase regulations and be cautious with new device approval in order to decrease product failure amongst competitors.

TABLE 9
Descriptive Statistics and Correlations

	Mean	S.D.	1	2	3	4	5	6	7	8	9	10	11	12	13
1 $E_{i,t-1}$	0.00	0.84													
2 $E_{j,t-1}$	0.00	0.22	0.23												
3 $D_{j,t-1}$	0.05	0.18	0.00	-0.71											
4 $NPI_{j,t-1}$	-0.03	0.08	0.22	0.61	-0.45										
5 $R_{i,t-1}$	0.00	0.50	-0.05	0.29	-0.47	-0.14									
6 $D_{i,t-1}$	0.05	1.55	-0.01	-0.23	0.12	-0.27	-0.12								
7 $NPI_{i,t-1}$	-0.03	0.62	0.04	-0.06	-0.03	-0.27	0.32	0.23							
8 $PUBLIC_{i,t-1}$	0.26	0.44	-0.23	-0.15	0.21	0.03	-0.31	-0.18	-0.12						
9 $\Delta COMPETITOR_{i,t-1}$	0.00	0.18	0.01	-0.07	0.16	-0.13	0.00	-0.03	0.36	-0.04					
10 $\Delta DEATH_{j,t-1}$	0.02	0.05	-0.25	-0.16	0.05	-0.17	-0.07	0.04	-0.13	0.06	-0.08				
11 $\Delta DEATH_{i,t-1}$	0.02	0.50	-0.12	-0.85	0.69	-0.46	-0.32	0.22	0.02	0.06	0.06	0.09			
12 $\Delta DIVERSE_{i,t-1}$	0.02	0.39	-0.55	-0.25	0.15	-0.13	-0.39	-0.03	-0.22	0.31	0.08	0.13	0.16		
13 $\Delta COMPLEXITY_{i,t-1}$	0.05	0.84	-0.12	0.31	-0.07	0.20	0.01	0.02	-0.11	-0.07	-0.01	0.02	-0.21	-0.09	
14 $\Delta PRODUCT_{i,t-1}$	0.00	0.02	0.16	0.20	-0.16	-0.04	0.18	0.05	0.11	-0.09	0.21	0.01	-0.16	-0.23	-0.20
15 $\Delta PRODUCT_{j,t-1}$	0.00	0.00	0.26	0.40	0.10	0.27	-0.13	-0.11	-0.10	0.00	0.03	-0.07	-0.10	-0.21	0.30
16 $\Delta REGULATION_{i,t-1}$	0.00	0.03	-0.11	-0.22	0.16	0.02	-0.16	-0.05	-0.15	0.08	-0.30	0.07	0.15	0.08	0.11
17 t	2003	3.16	0.05	-0.03	0.06	0.33	-0.27	-0.03	-0.10	0.22	-0.03	-0.10	0.26	0.01	0.05
18 MDUFMA	0.45	0.50	-0.10	-0.14	0.27	-0.50	0.09	0.03	0.11	-0.06	0.15	0.09	-0.11	0.07	-0.02
19 $LEARN_{i,t}$	0.14	0.12	0.18	0.29	0.05	0.38	-0.03	-0.18	0.05	0.15	0.15	-0.19	-0.16	-0.05	0.13
20 $INTERACT_{i,t}$	0.28	0.45	-0.18	-0.35	0.22	-0.36	-0.01	0.01	0.13	0.09	-0.05	0.14	0.21	0.12	-0.08
21 Constant			-0.05	0.03	-0.07	-0.33	0.27	0.03	0.10	-0.22	0.03	0.10	-0.26	-0.01	-0.05

TABLE 9 – Continued
Descriptive Statistics and Correlations

	14	15	16	17	18	19	20
15 $\Delta PRODUCT_{j,t}$	0.15						
16 $\Delta REGULATION_{i,t-1}$	-0.89	-0.15					
17 t	-0.10	0.50	0.03				
18 MDUFMA	0.06	-0.21	-0.01	-0.83			
19 $LEARN_{i,t}$	-0.15	0.24	0.18	0.08	-0.11		
20 $INTERACT_{i,t}$	0.05	-0.31	-0.04	-0.27	0.23	-0.23	
21 Constant	0.10	-0.50	-0.03	-1.00	0.83	-0.09	0.27

N=1,270 firm-year observations; Correlations from the variance-covariance matrix of model 2.

Control Results

Model 1 in Table 10 presents the control variables. Most of the significant coefficients have the predicted sign. Appendix A.5 presents a summary of the control results. Delaying product failure reporting to external organizations does not affect their own product failure rate. The coefficient for a firm's own reporting delays is zero and not significant. This complements research on patient safety reporting systems in intraorganizational learning from failure (Tamuz et al. 2004). Tamuz et al. (2004) find that processes to enhance reporting and learning from medication errors within hospital pharmacies decreases the flow of error reports to and reliance on hospital level learning. This suggests that a product failure reporting delay to external reporting systems does not affect intraorganizational learning because organizations have internal product failure databases with richer and more recent data.

A firm's own new medical device introductions do not affect its rate of product failure. The coefficient for a firm's own new product introductions is non-significant. The result suggests that organizations do not gain additional product knowledge after announcing a new product introduction.

Death has mixed results. Death caused by a competitor's product triggers a decrease in the incidence of adverse events for medical device firms. The coefficient for product-caused death among others has the expected negative and significant effect. The coefficient of -0.31 indicates that a product-caused death by an average competitor decreases the product failure rate by 0.31 X (ln(1 death+1) / 127 firms) = 0.017%.

Product failure rate would decrease by 0.31 X ln(1+1) = 21% if the death rate of all competitors systematically increased by 1 additional death.

Although, a death caused from a firm's own products does not have a significant impact on reducing the rate of adverse events. There are both empirical and theoretical explanations for this result. Empirically, product-caused death for a firm is infrequent. The infrequency of death may cause insignificant coefficients for a medical device firm because the vector becomes zero-inflated. However, death among competitors can be significant because the vector has aggregate values of product-caused death of all other firms. I have no means to rule out the effects of power, but expanding the sample to include firms that experienced more than one adverse event and all medical device firms did not change this result in subsequent sensitivity analyses (see robustness and sensitivity analysis).

There are three theoretical reasons for the non-significance of a firm's own death. First, learning from a competitor's product-caused death may be lead to a greater impact because distance affords less immediate and more thoughtful responses. Failure research supports this argument which suggests that airlines are more likely to blame individuals rather than systematic organizational causes for more localized, homogenous airline accidents (Haunschild and Sullivan 2002). Second, own adverse event rates may be truncated because the FDA selects out medical devices that cause death. However, the legacies of medical devices that cause death serve as key examples to learn from others' product failures. Third, medical device firms may preemptively correct death-causing problems before reporting a product-caused death. While medical device firms may

correct problems to prevent reputation-loses or FDA legal action prior to reporting their own product-caused deaths, problem-solving in anticipation of a death caused by a competitor's product is difficult.

Product failure complexity does not decrease the product failure rate. The coefficient failure complexity is negative and not significant. This result does not support Haunschild and Sullivan (2002). They find that failure heterogeneity decreases failure because organizations are more likely to view heterogeneous failures as systematic problems. A possible explanation for the difference with Haunschild and Sullivan's (2002) results is the difficulties to coordination actions within organizations in response to product failure. Theoretical models by Blume and Franco (2007) show that increasing complexity leads to organizations having greater difficulties learning from failure because of breakdowns in coordination. The coefficient for intra-industry diversification is positive and not significant (but is highly significant is subsequent models) which supports the view that difficulties in coordination may reduce the ability to learn from product failure. These results point to a more complete story for intraorganizational learning from failure: firms are able to recognize failures as systematic flaws when failures occur across the organization, but the ability to coordinate resources in response to failure diminishes with greater organizational complexity.

Regulations do not have a significant impact on reducing the rate of adverse events. The coefficient for change in number of regulations and the coefficient for MDUFMA are insignificant. There are two plausible explanations. The first explanation is that adverse event reporting captures the ability of CDRH to monitor but not enforce

product failure. This view is supported by a U.S. Government Accountability Office report that suggests the CDRH does not have enough resources to effectively enforce dangerous medical devices (Crosse 2009). The second explanation is that tougher restrictions may reduce current medical device adverse events but may actually increase adverse events in future products because of restricted product innovation. The latter explanation holds up in model 2. MDUFMA becomes significant once introducing covariates for new product introductions.

The two controls for specific interorganizational learning processes are significant. Organizational learning does matter. The coefficient (LEARN) for organizations that reduce product failure rates even when interorganizational product failure experience decreases is negative and strongly significant (p-value < 0.001). Product failure does interact between organizations in the medical device industry. The coefficient (INTERACT) for product failure interaction is positive and strongly significant (p-value < 0.001). Combined, these results show that it is not always clear whether what conclusions can be drawn from aggregate measures of interorganizational experience. Some interorganizational experience always decreases (even when experience decreases) product failure rates and some interorganizational experience increases product failure rates.

TABLE 10
Regression results of product failure rates for medical device firms from 1998 to 2008

	(1)	(2)	(3)	(4)	(5)
	$R_{i,t}$	$R_{i,t}$	$R_{i,t}$	$R_{i,t}$	$R_{i,t}$
$R_{i,t-1}$	-0.01	0.01	0.02	0.02	0.02
	(0.03)	(0.03)	(0.03)	(0.03)	(0.03)
$D_{i,t-1}$	0.00	0.00	0.00	0.00	0.00
	(0.00)	(0.00)	(0.00)	(0.00)	(0.00)
$NPI_{i,t-1}$	0.00	0.00	0.00	0.00+	0.00+
	(0.00)	(0.00)	(0.00)	(0.00)	(0.00)
$PUBLIC_{i,t-1}$	0.04+	0.03	0.03	0.01	0.02
	(0.02)	(0.02)	(0.02)	(0.02)	(0.02)
$\Delta COMPETITOR_{i,t-1}$	-0.03	0.03	0.03	0.02	0.02
	(0.06)	(0.06)	(0.06)	(0.06)	(0.06)
$\Delta DEATH_{i,t-1}$	-0.02	0.01	0.02	0.02	0.02
	(0.02)	(0.02)	(0.02)	(0.02)	(0.02)
$\Delta DEATH_{i,t-1}$	-0.31***	0.46***	0.53***	0.36***	0.42***
	(0.06)	(0.10)	(0.10)	(0.10)	(0.10)
$\Delta DIVERSE_{i,t-1}$	0.01	0.12***	0.11***	0.11***	0.11***
	(0.03)	(0.03)	(0.03)	(0.03)	(0.03)
$\Delta COMPLEXITY_{i,t-1}$	-0.03	-0.02	-0.02	-0.02	-0.02
	(0.02)	(0.02)	(0.02)	(0.02)	(0.02)
$\Delta PRODUCT_{i,t-1}$	0.84	0.35	0.18	0.11	0.09
	(0.98)	(0.90)	(0.85)	(0.90)	(0.87)
$\Delta PRODUCT_{i,t-1}$	-34.07*	-169.7***	-232.9***	-199.9***	-223.6***
	(15.87)	(18.32)	(20.39)	(18.73)	(21.38)
$\Delta REGULATION_{i,t-1}$	-0.45	-0.36	-0.32	-0.21	-0.23
	(0.33)	(0.35)	(0.34)	(0.33)	(0.33)
T	-0.03*	-0.04***	-0.07***	-0.07***	-0.08***
	(0.01)	(0.01)	(0.01)	(0.01)	(0.01)
MDUFMA	0.09	0.12+	0.27***	0.22***	0.27***
	(0.06)	(0.06)	(0.07)	(0.06)	(0.07)
$LEARN_{i,t}$	-0.31***	-0.37***	-0.41***	-0.42***	-0.42***
	(0.03)	(0.03)	(0.03)	(0.03)	(0.03)
$INTERACT_{i,t}$	0.43***	0.52***	0.52***	0.52***	0.52***
	(0.04)	(0.04)	(0.04)	(0.04)	(0.04)
$E_{i,t-1}$		-0.21***	-0.21***	-0.20***	-0.20***
		(0.03)	(0.03)	(0.03)	(0.03)

$E_{j,t-1}$		-4.41***	-4.53***	-4.74***	-4.71***
		(0.48)	(0.48)	(0.49)	(0.49)
$D_{j,t-1}$		1.79***	1.23**	1.62***	1.38***
		(0.40)	(0.39)	(0.39)	(0.39)
$NPI_{j,t-1}$		-2.49***	-3.65***	-1.79***	-2.56***
		(0.39)	(0.48)	(0.39)	(0.58)
$E_{j,t-1}$ X $D_{j,t-1}$			27.38***		13.78+
			(5.41)		(7.32)
$E_{j,t-1}$ X $NPI_{j,t-1}$				21.14***	15.45***
				(3.30)	(4.42)
Constant	53.11*	85.69***	139.99***	146.72***	157.61***
	(21.90)	(22.06)	(24.25)	(21.43)	(23.11)
Observations	1270	1270	1270	1270	1270
R-squared	0.22	0.32	0.34	0.34	0.35
F-stat	16.28	20.32	19.39	20.15	18.97
Log-Likelihood	-718.6	-625.9	-611.6	-607.6	-605.3
LR Test (2 X LR)$^{+}$		185.4***	28.6***	36.6***	12.6***

+ The unrestricted log-likelihood is from model 1, model 2, and model 3 for model 2, models 3-4, and model 5, respectively.

Primary Results

Model 2 of Table 10 reports the estimates of Equation 2 using a log-linear form of product failure experience, reporting delays, and new product introductions. Model 2 is highly significant (p-value < 0.001) using the likelihood ratio test, where the unrestricted log-likelihood is model 1. The theorized relationships are all highly significant (p-value < 0.001) – indicating that the relationships are log-linear (See Appendix A.5 for a summary of the main results). The coefficient for product failure experience and competitor's product failure experience are negative and highly significant (p-value < 0.001). The coefficient for others' new product introductions is negative and highly

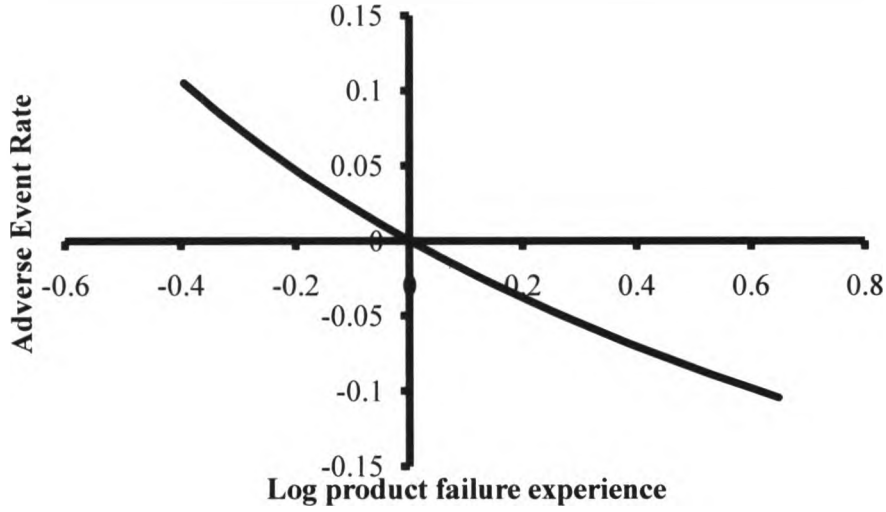
significant (p-value < 0.001), but the coefficient for others' reporting delays is positive and highly significant (p-value < 0.001). Model 5 explains 35 % of the variance in product failure rates and the hypothesized relationships explain 13 % of the variance in product failure rates. I explain hypothesis 1, 2, and 4 in the primary results, hypothesis 3 and 5 in the interaction results.

Intraorganizational Learning

The intraorganizational learning estimates support theory. Figure 16 depicts the product failure experience curve for the rate of change in adverse events for medical device firms. The horizontal axis has product failure experience and the vertical axis has the rate of adverse events. The data in the graph are centered. Product failure experience is concave and downward sloping because the coefficient for product failure experience is negative. Figure 16 demonstrates diminishing returns to product failure experience. Small gains in product failure experience reduce the product failure rate to a larger degree than large gains in product failure experience. At the sample average, the coefficients suggest that a ten percent increase in product failure experience in the past year equates to a 2.1% decrease in the rate of product failure in the following year[8]. These results combined suggest that the rate of adverse events decreases at a decreasing rate with product failure experience.

[8] The value is equal to - 0.21 X Log(10%+1).

FIGURE 16
The effect of product failure experience on the rate of adverse events



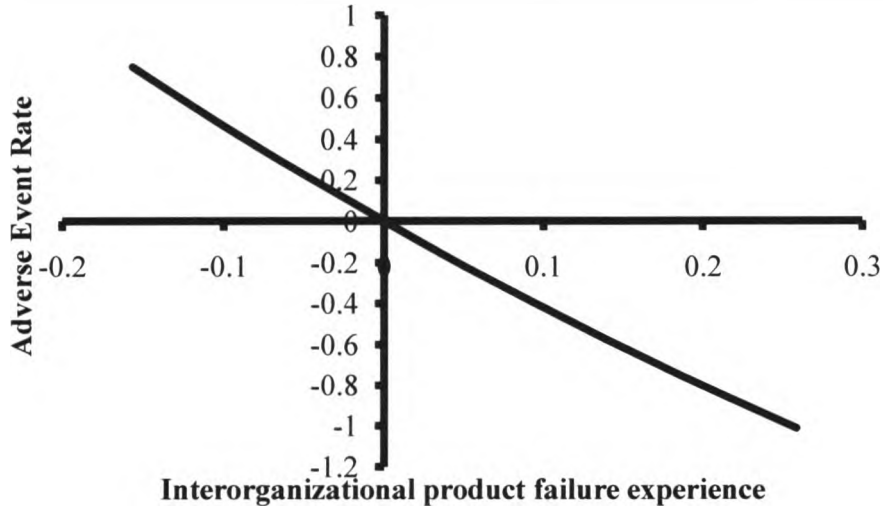
Interorganizational Learning

My first hypothesis is supported. Figure 17 shows that the rate of adverse events decreases with interorganizational product failure experience. The horizontal axis is interorganizational product failure experience and the vertical axis is the rate of adverse events. The data in the graph are centered. The coefficient for interorganizational product failure experience is negative and significant at the P-value < 0.001 level. The effects are similar to product failure experience. There are diminishing returns to interorganizational product failure experience; such that small amounts of others experience has a larger impact than large amounts.

The effect size for interorganizational product failure experience is different than product failure experience. At the sample average, a 10% gain in interorganizational

product failure experience equals a 42% decrease in the product failure rate[9]. However, this value is an estimate of systematic changes to interorganizational experience. A major product failure would have to happen or all firms would have to gain 10 % of their failures in one period. The effect of interorganizational product failure experience by a single competitor is more modest. A 10% gain in product failure experience by a competitor equals a 0.33% decrease in the product failure rate. This means that firms learn from both product failure experience and interorganizational product failure experience, but a firm's own product failure experience is 6.4 times more effective than learning from a competitor's product failure experience.

FIGURE 17
The effect of interorganizational product failure experience on the rate of adverse events



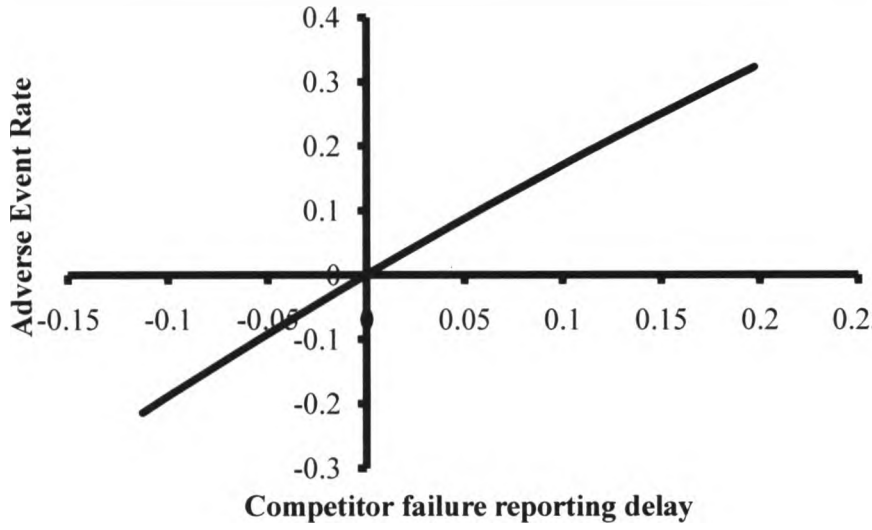
[9] The systematic value is equal to – 4.41 X Log(10%+1) and the individual effect is equal to – 4.41 X Log(10%+1) / 127 firms.

Competitor Reporting Delays

Figure 18 shows that the results do not support hypothesis two. The horizontal axis is competitor reporting delays and the vertical axis is the rate of adverse events. The data in the graph are centered. A competitor's reporting delays increase the rate of adverse events for medical device manufacturers at a diminishing rate. The coefficient for a competitor's delays is positive and significant at the P-value < 0.001 level. At the sample mean, the coefficient of 1.79 on the average competitor's reporting delay ($D_{j,t-1}$) indicate that if one competitor delays by one more day than normal that the product failure rate increases by 0.98 %[10]. Product failure rates would increase by 124 % if the product failure reports of all competitors were systematically delayed by one day. This means that a competitor's reporting delays does not decrease the rate of product failure.

[10] The individual delay effect is equal to -2.49 X Log(1 new product introduction +1) / 127 firms and systematic new product introductions effect is equal to -2.49 X Log(1 new product introduction +1).

FIGURE 18
The effect of competitor reporting delays on the rate of adverse events



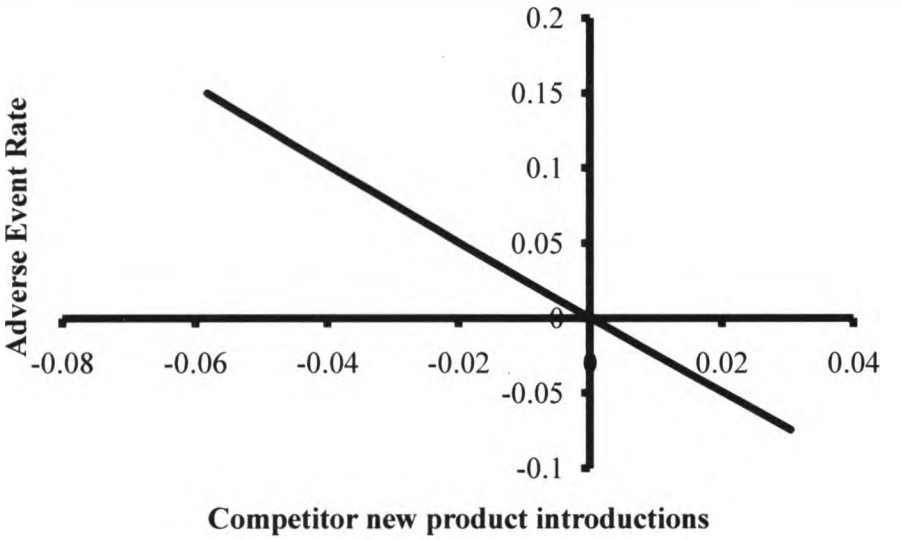
Competitor New Product Introductions

Hypothesis four is supported. Figure 19 demonstrates that additional new product introductions by the competitors significantly lower the rate of adverse events at an increasing rate. The horizontal axis is competitor new product introductions and the vertical axis is the rate of adverse events. The coefficient for a competitor's new product introductions is negative and significant at the P-value < 0.001 level. At the sample average, the rate of adverse events decreases by 1.3% if a single average competitor introduces one new product in the previous year[11]. The rate of adverse events will decrease by 173% if all 126 competitors each introduce one new product. This means

[11] The individual new product introduction effect is equal to 1.79 X Log(1 day +1) / 127 firms and systematic delay effect is equal to 1.79 X Log(1 day +1).

that medical device firms are less likely to have product failures if competitors introduce new products.

FIGURE 19
The effect of competitor new product introductions on the rate of adverse events



Interaction Results

Competitor Reporting Delays and Interorganizational Product Failure Experience

Model 3 of Table 10 presents the results for competitor reporting delays interacted with interorganizational product failure experience. Hypothesis three is supported. The interaction coefficient is positive and significant at a P-value < 0.001. The interaction effect indicates that the rate of product failure increases with longer competitor reporting delays. This means that a competitor's reporting delays decreases the effect of interorganizational experience on product failure rates.

Equation 5 presents the interaction effect as a first order derivative of the rate of adverse events with respect to log of interorganizational product failure experience.

$$\frac{\partial R_{i,t}}{\partial \ln E_{j,t-1}} = -4.53 + 27.38 \ln D_{j,t-1} \quad (5)$$

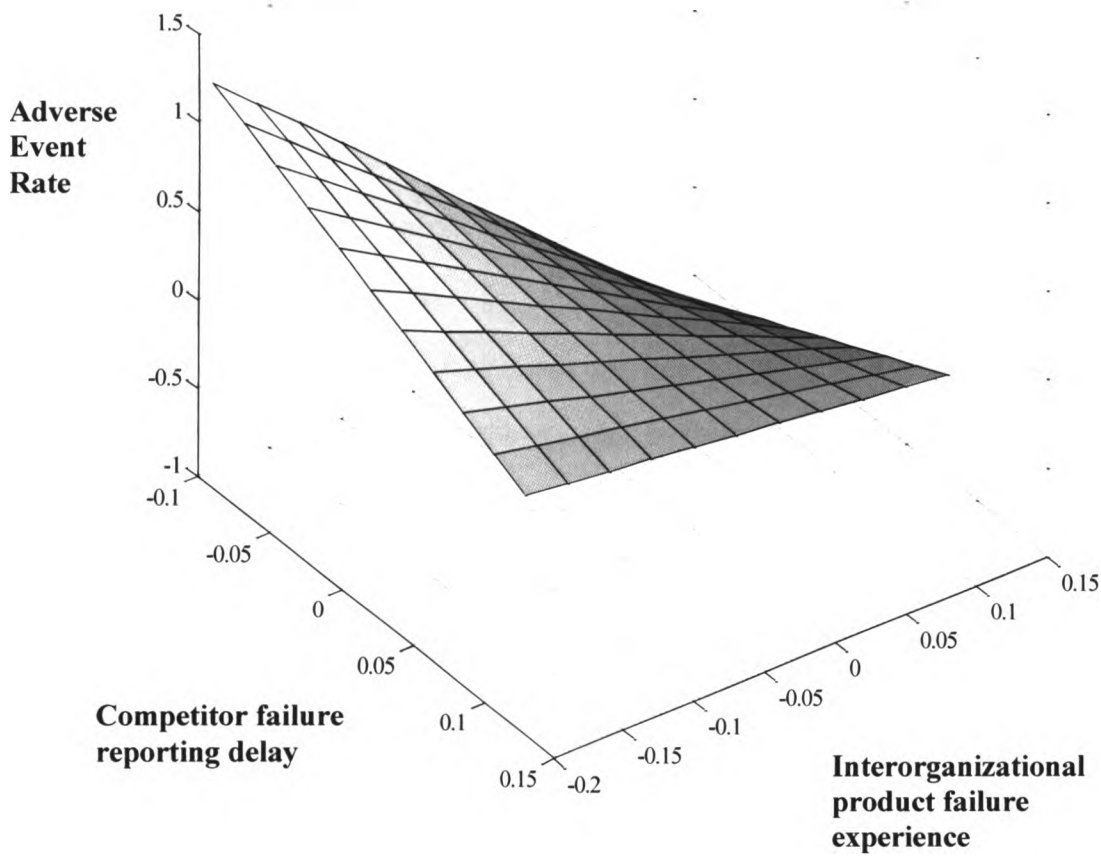
The first order derivative supports my arguments. Equation 5 indicates that the effect of competitor product failure experience on the rate of adverse events decreases with reporting delays of a competitor's product failure. The derivative indicates that interorganizational product failure experience decreases the rate of product failure with no reporting delays. However, a competitor's reporting delays erases the effect of a competitor's product failure experience. The point at which interorganizational product failure experience has no impact on the rate of adverse events is found by equating Equation 9 to zero. Interorganizational product failure experience has no impact when reports are systematically delayed 0.17 days past the average report time. This is within one standard deviation of report delays in this sample. A single competitor that takes more than 22 days to report a product failure will drive up the rate of adverse events for all other firms.

Figure 20 graphically illustrates support for hypothesis four. Figure 20 is a graph of the interaction effect of the log of competitor reporting delays on the relationship between the log of competitor product failure experience and the rate of adverse events. I retain the log transformation to more clearly illustrate the interaction effect. The horizontal axis is competitor report delays, the depth axis is competitor product failure experience, and the vertical axis is the rate of adverse events. Competitor product failure experience decreases the rate of adverse events with short reporting delays. Competitor

product failure experience has no effect on the rate of adverse events with long reporting delays. Consistent with my hypothesis the rate of adverse events is lowest with short reporting delays and large gains in competitor product failure experience.

Figure 20 illustrates a surprising result. Inspection of Figure 20 supports hypothesis two, while hypothesis two is not supported with a linear relationship. The rate of product failure is highest with short reporting delays and small gains in interorganizational product failure experience. At short reporting delays, the effects are pronounced: the rate is higher for small gains than large gains in interorganizational product failure. At long reporting delays, the effects are moderate but the product failure rates are lower. This indicates that a competitor's reporting delays increases the interorganizational learning. I explore this result further in the post-hoc analysis.

FIGURE 20
The impact of competitor reporting delays and interorganizational product failure experience on the rate of adverse events



Do reporting delays matter? I look at the impact on the product failure for a single competitor delaying one day. I present four measures: adverse event rate, number

of additional adverse events, number of additional patient days in hospitals caused by the adverse events, and the healthcare costs of these patient days. I assume a 10 % gain in product failure experience evaluated at the sample mean, an adverse event causes a 6-day patient hospital stay (Baker et al. 2004), and one day hospital stay costs USD 7,000 (ADRQ 2009). My summary statistics indicate that the average adverse event rate per firm is 27.9 adverse events / year. Canadian data indicates that patients that experienced an adverse event spent an average of 6 additional days in the hospital (Baker et al. 2004). Data gathered on US hospital stays (NCHS 2009) and US health expenditures (ADRQ 2009) suggests one additional day in the hospital per patient costs $7,000, assuming the average hospital stay is one day.

Reporting delays do matter. A one day reporting delay by a competitor leads to an annual increase in 1.5 serious injuries or deaths for all other competitors in the US and these events cost the US healthcare system USD $8.1 million in patient hospital costs alone. This value underestimates the actual costs because it neglects the costs of medical complications, patient litigation, and FDA regulatory costs. These are stylized facts, but the results are economically significant, even if they are a fraction of these values. Patient stay costs dwarf the costs of the regular maintenance of the MAUDE database (Lloyd 2009). This means that speeding up the reporting and diffusion of medical device adverse events has significant financial and patient benefits.

Additionally, there may be competitive incentives to delay reporting. There are no financial or product failure costs to delaying one's own product failure reports. However, a firm that delays reporting product failure by one day increases a competitor's

rate of product failure. This suggests that there are competitive incentives to delay the learning of others.

Competitor New Product Introductions and Interorganizational Product Failure Experience

Model 5 of Table 10 adds the interaction between competitor product failure experience and competitor new product introductions. Equation 6 is the first order derivative of the rate of adverse events with respect to product failure experience of an average competitor.

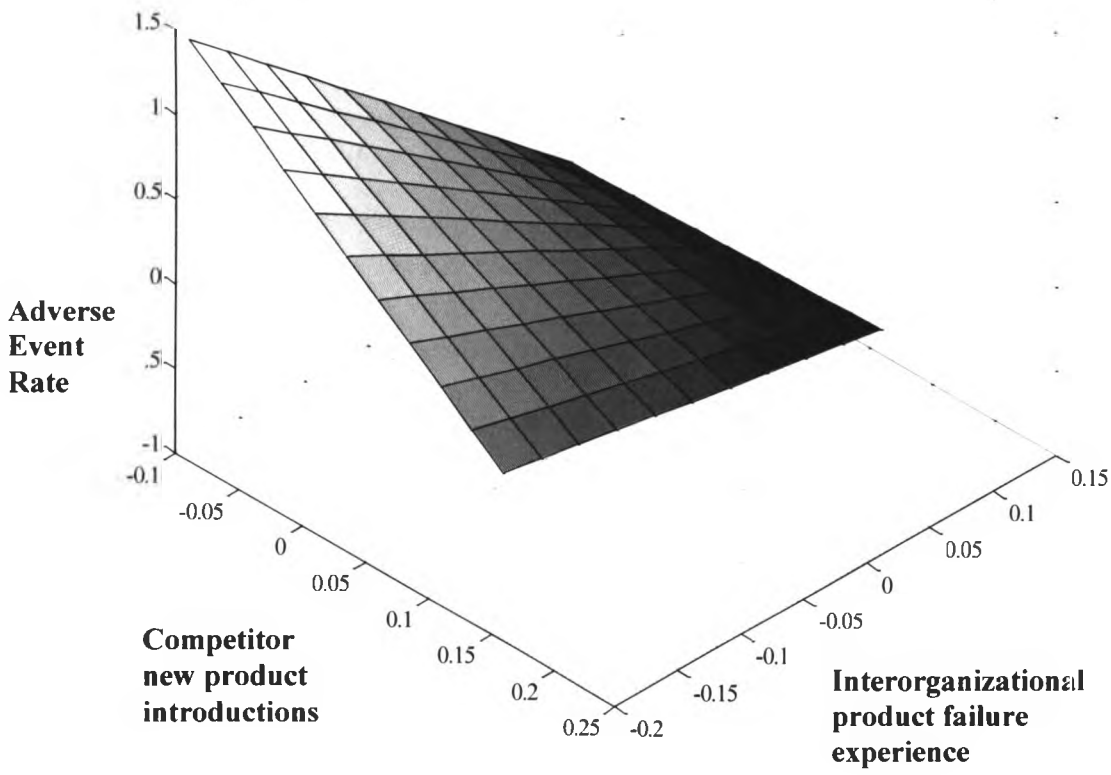
$$\frac{\partial R_{i,t}}{\partial E_{j,t-1}} = -4.74 + 21.14NPI_{j,t-1} \quad (6)$$

Equation 6 supports hypothesis five – the negative correlation between competitor product failure experience and the rate of adverse events decreases with a competitor's new product introductions. Interorganizational product failure experience has no net effect when there is a systematic increase of 0.22 competitor's new product introductions. However, 0.22 is beyond the bounds of the sample. This bound illustrates that a competitor's new product introductions may serve as an imperfect distraction. The new product introductions have a negative impact on interorganizational learning from product failure, but they never completely counteract the effect of interorganizational learning from product failure experience.

Figure 21 illustrates the supporting evidence. Figure 21 shows the interaction effect of competitor new product introductions on the relationship between interorganizational product failure experience and the rate of adverse events. The horizontal axis is competitor new product introductions, the depth axis is interorganizational product failure experience, and the height axis is the rate of adverse events. Competitor product failure experience decreases adverse events at a faster rate with few new product introductions than with many new product introductions. The highest rate of adverse events occurs when competitors have few new product introductions and a large gain in product failure experience. While the lowest rate of adverse events occurs when competitors have few new product introductions and small gains in product failure experience.

The supported results show that a competitor's new product introductions have a double effect. That rate of adverse events decreases with competitor's new product introductions – highlighting gains in technological advances. However, the effect of interorganizational learning from product failure experience decreases with a competitor's new product introductions – indicating that a competitor's new product introductions are distractions to understanding failures in existing products.

FIGURE 21
The impact of competitor new product introductions and interorganizational product failure experience on the rate of adverse events



Do distractions matter? Table 11 presents the impact of competitor's introducing new products on interorganizational learning. I look at the impact on the product failure for a firm in two scenarios: a systematic ten percent increase in the annual rate of new product introductions and a single competitor introducing one new product introduction. I present four measures: percent increase in the adverse event rate caused from the

distraction, number of additional adverse events, number of additional patient days in hospitals caused by the adverse events, and the healthcare costs of these patient days.

TABLE 11

The impact of the competition's new product introductions for a medical device firm and the US Healthcare system

Scenario	**Adverse event rate / firm**	**Additional adverse events / firm**	**Adverse event caused hospital days / firm**	**Healthcare costs due to hospital stays**
A 10% increase in new product introductions	+ 19.2%	+ 5.36	+ 32.1	+ $28.6 million
One competitor introduces 1 new product	+ 1.1%	+ 0.31	+ 1.84	+ $1.64 million

Distractions are substantive. In general, new product introductions decrease the rate of product failure. However, the distraction effect from a single new product introduction costs the US healthcare system $12,900 per firm per year in patient stay costs alone. This means that reducing the distraction effect of technology can save lives and money in the medical device industry.

Post-hoc Analysis for Competitor Reporting Delays

Size of Interorganizational Product Failure Experience

The first derivative of the rate of adverse events with respect to competitor reporting delays indicates that the rate of adverse events decreases with reporting delays at below average amounts of competitor product failure experience[12]. The derivative indicates that reporting delays decrease the rate of adverse events with increases in competitor product failure experience that are four percent below the industry average. Intraorganizational theory on small losses supports the view that the size of failure experience alters learning (Hayward 2002; Madsen and Desai 2010; McGrath 1999; Sitkin 1992). Sitkin (1992) argues that it is easier to learn from small losses than large losses because people are likely to take responsibility for small losses and uncover the reasons for the losses. Small losses are easier to accept, allowing organizations to acquire information about what works and does not work. This implies that medical device firms can learn more from small amounts of product failure experience than from large amounts of product failure experience.

Recent evidence of learning from small losses contradicts Sitkin (1992). Madsen and Desai (2010) illustrates intraorganizational learning from small losses is difficult in their study of the orbital launch vehicle industry. Madsen and Desai (2010) find that organizations learn more from large failures because small failures can be redefined as

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[12] The first derivative is given by $\frac{\partial R_{i,t}}{\partial D_{j,t-1}} = 1.23 + 27.38E_{j,t-1}$. Interorganizational product failure experience ($E_{j,t-1}$) can be negative in my results because I centre the variable.

successes through organization self enhancement processes. They also argue that large failures are difficult to ignore because of pressure by external stakeholders.

This post-hoc test is in the spirit of research on small losses. I suggest that interorganizational learning is likely to be different for small gains than large gains in product failure experience. Learning from interorganizational product failure experience is likely to support Sitkin's (1992) propositions, rather than Madsen and Desai's (2010) findings. Interorganizational learning is not susceptible to the same self enhancement processes as intraorganizational learning because organizations are not directly involved in the failure experience (Kim and Miner 2007). Specifically, competitors provide reporting clarity and depth the longer they take to report failures for both small and large gains in product failure experience. As a consequence, organizations are able to reduce their product failure rates more from interorganizational product failure experience when there are competitor reporting delays. However, time is valuable for large gains in product failure experience. Firms need earlier notification of large gains in competitor's product failure experience in order to make appropriate changes to product design and to anticipate user and media reaction.

I regress on two samples to investigate whether the effects of a competitor's reporting delays varies with the size of gains in interorganizational product failure experience. The two samples are restricted to either low and high values of interorganizational product failure experience. High values are greater than the overall mean plus one standard deviation of interorganizational product failure experience. Low

values are less than the overall mean minus one standard deviation. Both regressions include controls.

Table 12 present the results of the subsample analysis (See Appendix A.5 for a summary of the post-hoc results). Model 1 contains the results for small gains in interorganizational product failure experience and model 2 contains the results for large gains in interorganizational product failure experience. The results of the post-hoc test partially support hypothesis two. Hypothesis two is supported when there are small gains in interorganizational product failure experience. The significant negative coefficient for competitor's reporting delays in model 1 indicate that the competitor reporting delays decrease the rate of adverse events when there are small gains in competitor product failure experience. The significant positive coefficient on the interaction term in model 1 indicate that competitor reporting delays partially moderate small gains in competitor product failure experience.

TABLE 12
Ordinary least squares regression results for medical device firms with low and high values of interorganizational product failure experience

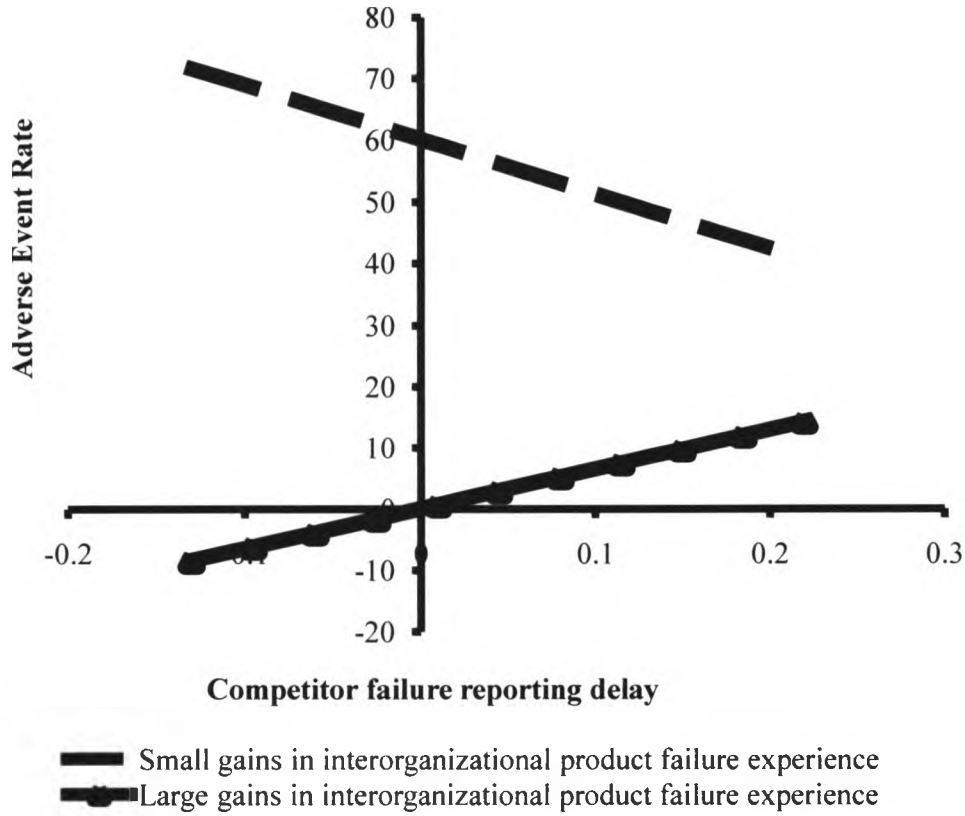
	(1)	(2)
	Small	**Large**
	$R_{i,t}$	$R_{i,t}$
$E_{i,t-1}$	-2.71**	-0.21**
	(0.91)	(0.08)
$E_{j,t-1}$	-353.50**	0.13
	(112.65)	(10.48)
$D_{j,t-1}$	-19.67*	0.05
	(8.16)	(2.76)
$NPI_{j,t-1}$	-3.72	15.87
	(3.20)	(10.50)
$E_{j,t-1}$ X $D_{j,t-1}$	402.35**	282.14***
	(137.35)	(71.76)
Constant	-2,801.80**	482.26
	(991.97)	(495.26)
Controls	Included	Included
Observations	254	362
R-squared	0.47	0.413

+ Low values are minus one standard deviation and high values are plus one standard deviation from the overall mean, respectively.

Hypothesis two is supported with small gains, but not supported with large gains in interorganizational product failure experience. The significant positive coefficient on the interaction in model 2 shows that the rate of adverse events will increase with a competitor's reporting delays when there are large gains in competitor product failure experience. The insignificance of the lower order variables indicates that competitor reporting delays fully moderate interorganizational product failure experience with large gains in interorganizational product failure experience.

Figure 22 displays the interaction results. The figure shows that large losses are valuable for learning. Large gains in interorganizational product failure experience reduce the rate of adverse events more than small gains. Supporting my post-hoc theorizing, reporting delays decrease the product failure rate when firms have small gains in interorganizational product failure experience. However, time matters for large gains in interorganizational product failure experience. The rate of adverse events with competitor reporting delays when firms have large gains in interorganizational product failure experience.

FIGURE 22
The effect of interorganizational product failure size on the relationship between competitor reporting delays and the rate of adverse events



The findings from the main results and the post-hoc test show that reporting delays vary with the size of competitor product failure experience. This supports the small losses hypothesis (Hayward 2002; McGrath 1999; Sitkin 1992). On average, the main results indicate that a competitor's reporting delays increase the rate of product failure directly and indirectly through moderation of interorganizational product failure experience. However, the subsample analysis shows a counteracting picture of a competitor's reporting delays. Reporting delays can benefit learning with small gains in interorganizational experience. Competitor reporting delays decreases the rate of product failure with small gains in a competitor's product failure experience, even though reporting delays decrease the effects of interorganizational product failure experience. This result suggests that reporting delays likely lead to reporting clarity and depth. Yet, reporting delays only hinders interorganizational learning with large gains in interorganizational experience. There are no observable positive learning effects of reporting delays when a competitor has major gains product failure experience. This pattern suggests that the value of immediate notification of product failure overrides clear and concise failure reports when a competitor experiences a major product failure.

Post-hoc Analysis for Competitor New Product Introductions

Organizational Innovativeness

Organizational focus varies in the medical device industry. Typically, organizational actors can be distracted by a number of external stimuli in the medical device industry. Firms may be distracted by regulators, as in the case of firm 7840 and its malfunctioning X-ray technology in 2005. The primary objective of firm 7840 is the design and manufacture of medical devices. The CDRH forced firm 7840 to devote attention and other resources away from this objective. Instead, firm 7840 had to focus on standard operating procedures in order to meet the FDA's current good manufacturing practise (CGMP) requirements. While most medical device firms are preoccupied with the actions of the CDRH, distractions from regulatory intervention is relatively rare. Firms are more likely to be distracted by a competitor's new product introductions.

Most medical device firms keep tabs on a competitor's technologies, but not all do. The reasons why managers choose not to pay attention to a competitors' new product introductions are wide ranging. For firm 7840, the CGMP is an issue that takes priority over a competitor's new product introductions, as well as design and manufacturing. Previous studies show different attention effects. Adler and Clark (1991) reason that the reason why engineering departments had variance in productivity estimates is because some departments focus on productivity and others focus on product reliability. Other research shows that some managers are simply ambivalent to strategic issues (Plambeck and Weber 2009).

Non-innovative firms are likely to be distracted from a competitor's new product introductions for two reasons. First, innovative medical device firms have up to date expectations of a competitors' new product introductions and are less likely to be surprised by a competitor's new product introductions. The most innovative medical device firms follow their competitors' new product introductions closely. They routinely attend device and user conferences. Some have similar suppliers. Innovative firms get updates on their competitors' new products and future products from physicians. In general, innovative firms are less likely to suddenly refocus in response to a competitor's new product introductions and allocate resources to play product development 'catch-up.'

Second, innovative medical device firms may not react to a competitor's new product introductions. Innovative medical device firms cannot allocate much more resources to 'catch-up' in product design because they already have a significant amount of resources devoted to product design. Innovative medical devices may choose to forgo product updates in response to a competitor's new product introductions. Medtronic did (George 2003). In 1994, Guidant (it is now Boston Scientific) introduced new dual chamber defibrillator. Medtronic was not expecting the defibrillator advancement. Bill George, the CEO at the time, wrote that Medtronic quickly disregarded the new technology as "large and clunky," instead of reacting to the Guidant's new product introduction. Medtronic opted to focus on a new design that prevented unnecessary shocks because it was already in the product development pipeline, rather than introduce a reactionary dual chamber defibrillator in response to Guidant's new product offering.

Theoretical models on technology adoption support the notion that innovative competitors forgo product design changes in response competitor new product introductions (Balcer and Lippman 1981; Jovanovic and Nyarko 1996). Theory can be extrapolated from Balcer and Lippman's (1981) model that shows actors will delay adopting a technology in expectations of improvements. Similarly, medical device firms are likely to delay reactions if firms are expecting a future new product launch. Jovanovic and Nyarko (1996) show that agents forgo learning about new technology because they excel at older generations of technology – suggesting that an innovative firm may fully develop its current product portfolio before they make changes in response to a competitor's new product introductions. This result is likely to be amplified in medical device development because devices take up to four years to bring a device to market (Dixon et al. 2006).

I regress on two samples to investigate whether innovative firms are less likely to be distracted from a competitor's new product introductions than less innovative firms. The two samples are restricted to either low and high amounts of innovativeness. High values are greater than the overall mean plus one standard deviation of own new product introductions ($NPI_{i,t-1}$). Low values are less than the overall mean minus one standard deviation. Both regressions include controls.

Table 13 present the results of the subsample analysis. Model 1 contains the results for not innovative firms with few new product introductions and model 2 contains the results for innovative firms with many new product introductions. The post-hoc test strongly supports the distraction hypothesis (Hypothesis 5). The negative coefficient on

competitor's new product introductions is significant at the p-value < 0.1 in model 1 and the negative coefficient on the competitor's new product introductions is significant at the p-value < 0.05 in model 2. These two findings suggest that not innovative and innovative medical device firms pay attention to a competitor's new product introductions. However, the interaction coefficient for a competitor's new product introductions and interorganizational product failure experience is significant at the p-value < 0.01 level for not innovative firms, but is not significant for innovative firms. This comparison suggests that not innovative firms are distracted by a competitor's new product introductions and innovative firms are not distracted by a competitor's new product introductions.

TABLE 13
Regression results for medical device firms with low and high values of new product introductions

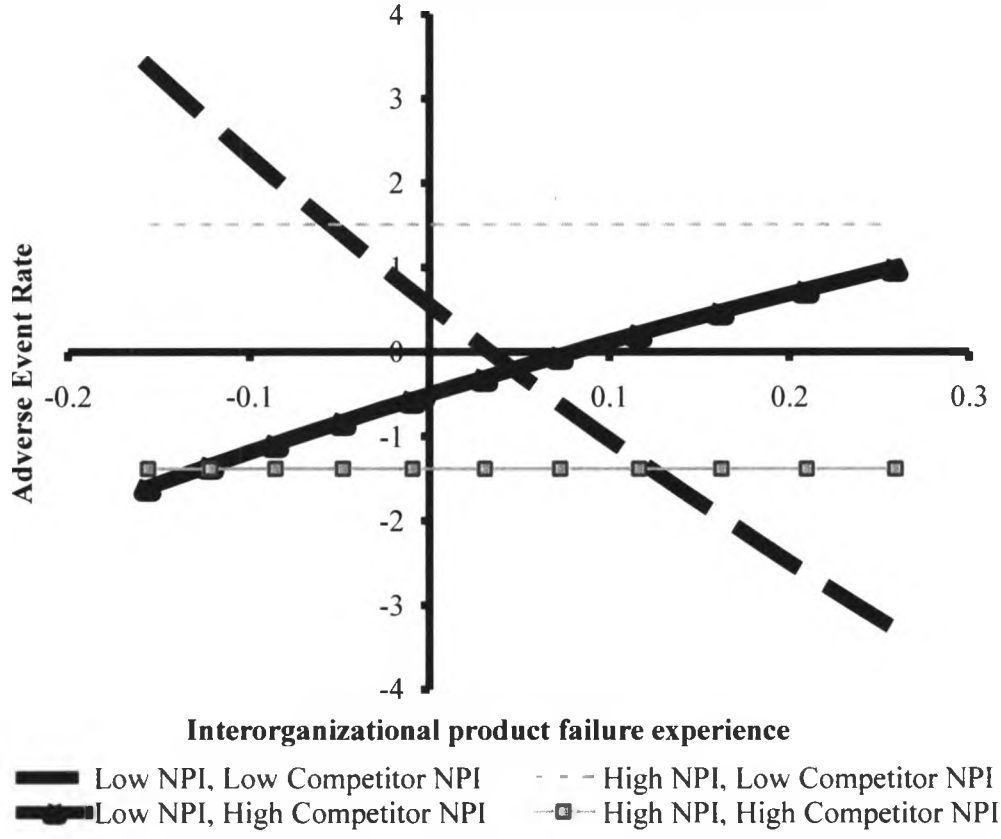
	(1)	(2)
	Low	**High**
	$R_{i,t}$	$R_{i,t}$
$E_{i,t-1}$	-0.21***	-0.27***
	0.04	0.05
$E_{j,t-1}$	-4.63***	-0.54
	0.84	1.28
$D_{j,t-1}$	0.87	-2.80*
	0.64	1.04
$NPI_{j,t-1}$	-0.84+	-2.31*
	0.46	0.95
$E_{j,t-1}$ X $NPI_{j,t-1}$	18.54**	12.93
	5.6	11.35
Constant	101.79**	247.63*
	30.1	93.56
Controls	Included	Included
Observations	319	172
R-squared	0.39	0.464

+ Low values are minus one standard deviation and high values are plus one standard deviation from the overall mean, respectively.

Perhaps Figure 23 provides more intuitive support for my post-hoc theorizing and distraction hypothesis (Hypothesis 5). The horizontal axis is interorganizational product failure experience and the vertical axis is the product failure rate. Not innovative firms get distracted by a competitor's new product introductions. The black lines represent firms with low amounts of new product introductions. The dashed black line represents low distractions and the solid black line represents many distractions. Figure 23 shows the product failure rate for not innovative firms decrease at a decreasing rate with

interorganizational product failure experience. This indicates that product failure rates for not innovative firms with few competitive distractions decrease with interorganizational product failure experience.. The figure also highlights that the product failure rate for not innovative firms increases with interorganizational product failure experience when a competitor introduces a new product.

FIGURE 23
The effect of a firm's new product introductions on the relationship between competitor new product introductions and the rate of adverse events



Innovative firms are not distracted by a competitor's new product introductions. The grey lines represent firms with high amounts of new product introductions. The dashed line represents low competitor new product introductions and the solid line represents high competitor new product introductions. Figure 23 depicts that innovative firms only benefit from a competitor's new product introductions for two reasons. First, interorganizational product failure experience insignificantly effects the product failure rate for innovative firms. This emphasizes others' product failure experience does not alter product design decisions for innovative firms. Second, innovative firms benefit from the direct effect of innovative competitors, while a competitor's new product introductions have no effect on product failure rate. This suggests that there is no distraction effect for innovative firms - supporting my post-hoc analysis and Hypothesis 5.

The combined findings from the post-hoc test and the main results illustrate that characteristics from both the firm and its competition determines whether competitive actions are distracting. This supports propositions that organizational attention alters the value of interorganizational product failure experience. The main results show that a competitor's new product introductions decrease the rate of product failure directly and increase the rate indirectly through the moderation of interorganizational product failure experience. However, the post-hoc analysis shows a richer view of a competitor's new product introductions. The product failure rate for an innovative firm always decreases with additional new product introductions by a competitor. In contrast, a competitor's new product introduction increases the product failure rates of a not innovative firm. The

results suggest that competitor's new product introductions likely leads to added knowledge transfer and technological progress for medical device firms. They also indicate that innovative medical firms benefit jointly from (1) better updating of the technological landscape and (2) the ability to forgo reacting to a competitor's new product introductions.

Quantile Regression

Table 14 presents the simultaneous quantile regression results for medical device firms. I highlight how the effects of competitor reporting delays and new product introductions changes across the distribution of product failure rates. The quantile results correspond to learning effects at the 10%, 30%, 50%, 70%, and 90% quantile of product failure rates. Low quantiles (<50%) of the product failure rate distribution are decreasing rates of product failure. High quantiles (> 50%) are increasing rates of product failure. I include only significant controls from the main results to improve statistical power. I bootstrap the standard errors using 100 subsamples.

In general, the control results do not change across the distribution. Although, the effects of MDUFMA is positive and significant for product failure rates less than the 70% quantile and becomes non-significant at the 90% quantile. Table 14 presents the coefficient for MDUFMA, while the coefficients for the non-changing controls are not shown for brevity. This shows that MDUFMA regulation increased product failure rates for the firms with decreasing product failure rates. MDUFMA had no impact on the firms with increasing product failure rates.

Table 14 presents evidence of learning from product failure experience. The coefficient for product failure experience is more negative for firms with increases in product failures rates than firms with decreases in product failure experience ($E_{i,t-1}$). This result indicates that medical device firms use more product failure experience when product failure rates increase. The coefficient for interorganizational product failure experience is most negative when product failure rates are decreasing ($\tau = 10\%$) and increasing ($\tau = 90\%$). This result indicates interorganizational learning because medical device firms use interorganizational product failure experience when product failure rates change.

The direct effects of competitor reporting delays and new product introductions are generally the same as the main effects across the distribution of product failure rates. Indeed, they may provide stronger support. Competitor reporting delays increase product failure rates faster when product failure rates are decreasing. Competitor new product introductions decrease product failure rates faster when product failure rates are decreasing.

The competitor reporting delay interaction effects support the hypotheses. Figure 24 depicts the effects of competitor reporting delays on interorganizational product failure experience. The figure includes coefficients for the 10%, 50%, and 70% quantile of product failure rates. The horizontal axis is interorganizational product failure experience and the vertical axis is the rate of product failure. The dashed lines depict the relationship between interorganizational product failure experience and product failure rates when competitor reporting delays are low (-1 standard deviation from mean). The

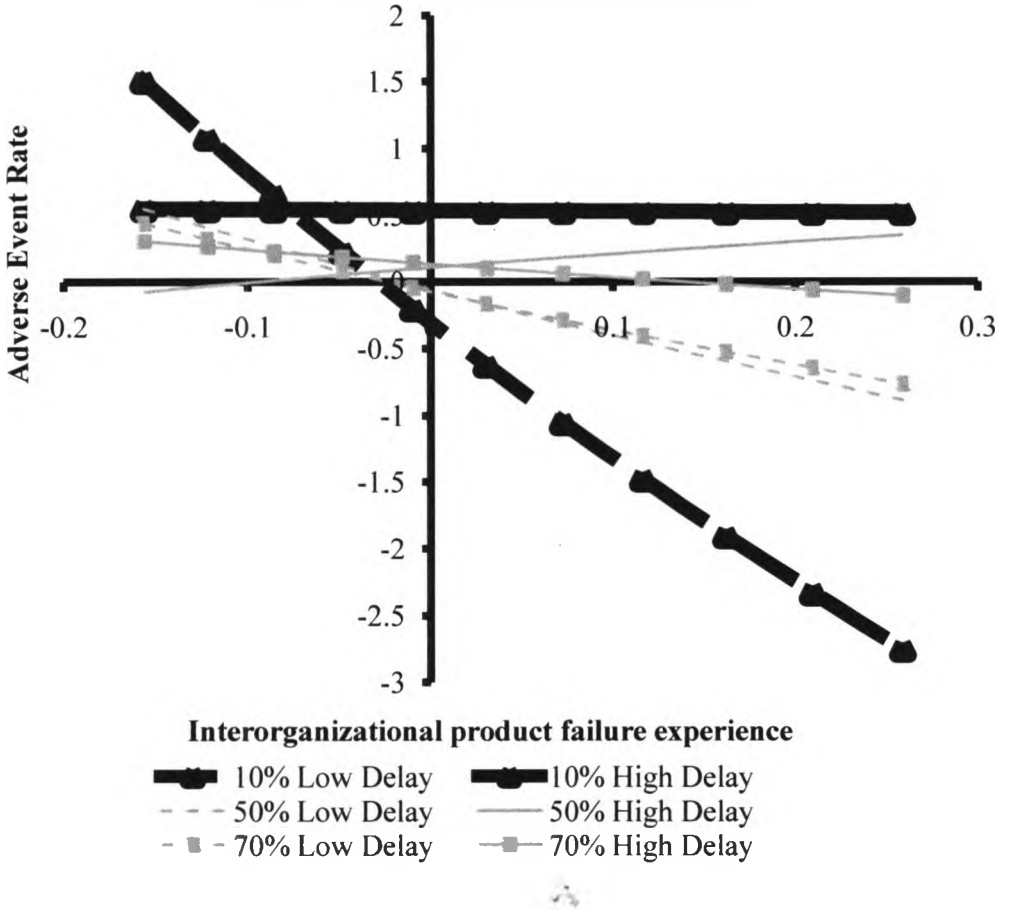
solid lines depict the relationship when competitor reporting delays are high (+1 standard deviation from mean). The bold lines show the relationship for the 10 % lowest product failure rates.

The bold lines highlight a strong competitor reporting delay effect. Interorganizational product failure experience effects product failure rates the most when product failure rates are decreasing ($\tau = 10\%$) and competitor's do not delay reporting product failure. However, interorganizational product failure experience has almost no effect when product failure rates are decreasing and competitor's delay reporting product failure. The grey lines indicate that the moderation effect of competitor reporting delays is replicated across the distribution of product failure rates, but the effects are not as pronounced.

TABLE 14
Simultaneous quantile regression results for medical device firms

	(1)	(2)	(3)	(4)	(5)
	10%	**30%**	**50%**	**70%**	**90%**
	$\mathbf{R_{i,t}}$	$\mathbf{R_{i,t}}$	$\mathbf{R_{i,t}}$	$\mathbf{R_{i,t}}$	$\mathbf{R_{i,t}}$
$E_{i,t-1}$	-0.06***	-0.07***	-0.10***	-0.13***	-0.22***
	(0.02)	(0.02)	(0.01)	(0.02)	(0.04)
$E_{j,t-1}$	-6.84***	-2.25***	-1.91***	-2.30***	-5.16***
	(0.37)	(0.36)	(0.23)	(0.33)	(1.10)
$D_{j,t-1}$	2.34***	0.64**	0.46**	0.57**	1.12
	(0.28)	(0.29)	(0.19)	(0.21)	(0.75)
$NPI_{j,t-1}$	-3.74***	-1.22**	-1.56***	-1.08**	-1.74*
	(0.43)	(0.39)	(0.29)	(0.34)	(0.77)
$E_{j,t-1}$ X $D_{j,t-1}$	29.41***	15.20***	12.95***	5.57+	-3.19
	(5.80)	(4.58)	(3.63)	(3.44)	(15.13)
$E_{j,t-1}$ X $NPI_{j,t-1}$	12.28***	9.43**	0.64	4.92+	22.87**
	(3.21)	(3.28)	(2.16)	(2.77)	(8.70)
MDUFMA	0.22***	0.25***	0.12***	0.05*	0.20
	(0.06)	(0.06)	(0.03)	(0.02)	(0.13)
Controls	Included	Included	Included	Included	Included
Constant	176.18***	128.45***	80.22***	62.32***	149.33***
	(19.27)	(23.94)	13.31	13.85	41.58
Observations	100	50	80	40	305
R-squared	0.64	0.79	0.373	0.69	0.36

FIGURE 24
The effect of competitor reporting delays on the rate of adverse events at the 10%, 50%, and 70% quantile of product failure rates



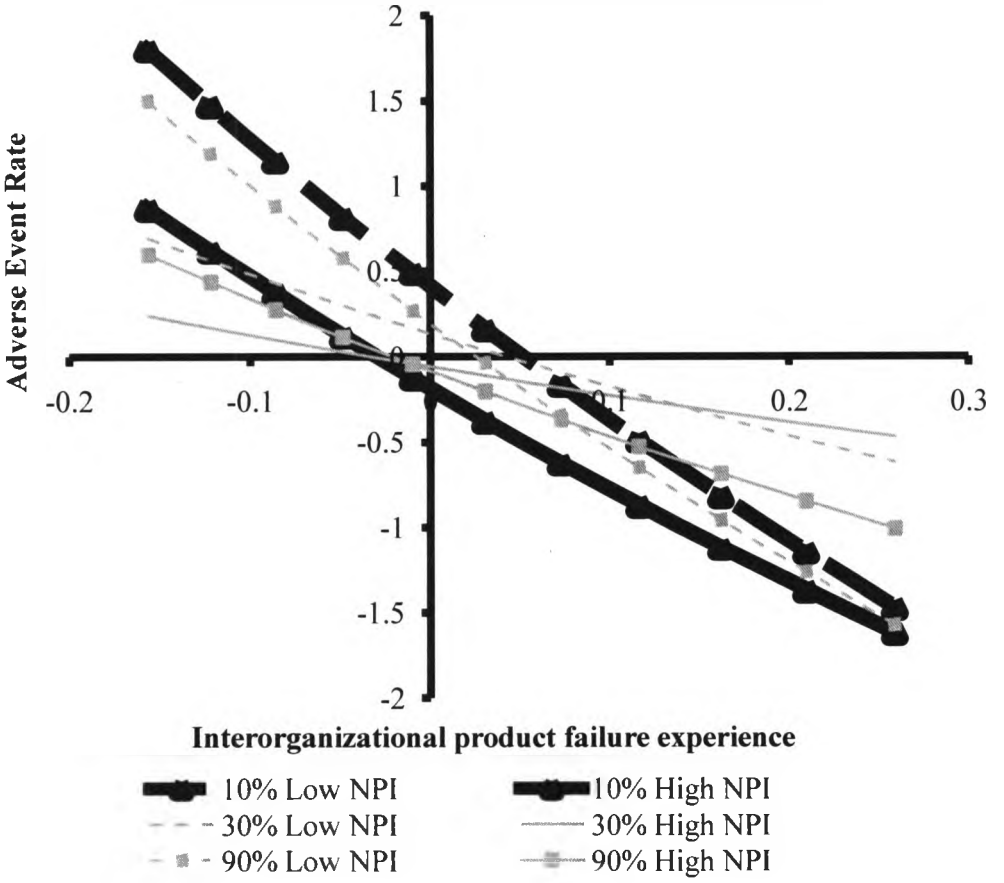
Additionally, the competitor new product introduction interaction effects support the hypotheses. Figure 25 depicts the effects of competitor new product introductions on interorganizational product failure experience. The figure includes coefficients for the 10%, 30%, and 70% quantile of product failure rates. The horizontal axis is interorganizational product failure experience and the vertical axis is the rate of product failure. The dashed lines depict the relationship between interorganizational product failure experience and product failure rates when competitor new product introductions

are low (-1 standard deviation from mean). The solid lines depict the relationship when competitor new product introductions are high (+1 standard deviation from mean). The bold lines show the relationship for the 10 % lowest product failure rates.

The bold lines show a distraction effect. The rate of product failure is lower with competitor new product introductions. However, the effect of interorganizational product failure experience on product failure rates becomes less pronounced when competitors have large gains interorganizational product failure experience and many new product introductions. The grey lines indicate that the moderation effect of competitor reporting delays is replicated across the distribution of product failure rates. The distraction effects are more pronounced when product failure rates are increasing ($\tau = 0.9$).

In general, the quantile regression results provide strong evidence of interorganizational learning. Interorganizational product failure experience has the least effect on product failure rates when rates are moderate. There are two important findings. First, competitor reporting delays affects those that are interorganizational learning (negative rate of product failure) the most. Second, distractions are most severe for organizations that need competitor information the most. Those with very low and very high rates of product failure are most affected by competitive distractions. Indeed, competitor delays and the distraction effect of a competitor's technology almost disappear for firms with moderate changes in product failure rates.

FIGURE 25
The effect of competitor new product introductions on the rate of adverse events at the 10%, 30%, and 90% quantile of product failure rates



Robustness and Sensitivity Analysis

Incidental Controls

In addition to FDA regulations, firms with geographically dispersed facilities deal with regional laws and regulations. In Table 15, I include controls for locational effects with indicator variables for each country that represent more than 5% of the products manufactured. The dominant location of a firm is chosen using the mode of the number of products manufactured in a country. I add an indicator variable for those firms operating prior to 1997 to control for survival effects (LEFT).

I control for age variables in Table 15. I control for firm using the log of the number of products a firm manufactures and the log of elapsed time since registering with the FDA (FIRM AGE). I also control for product demographics. I measure the age of each product category as the log of elapsed days since FDA registration for the product category (PRODUCT AGE). I will also control for sector idiosyncrasies with indicator variables for each sector that accounts for more than 5% of products manufactured. Annual adverse event rates should differ across sectors and decrease with product age because of learning curve effects.

Table 15 shows that the results do not change with the inclusion of incidental controls. Product failure rates behave similarly as the main results. The incidental controls provide additional insight specifically to medical device failure rates. Manufacturers from China, Germany, and the United States have significantly lower product failure rates. Devices in general and plastic surgery and ophthalmic have higher

product failure rates than average, whereas devices in general hospital have lower product failure rates than average.

TABLE 15
Regression results with incidental controls

	(1)
	$R_{i,t}$
$E_{i,t-1}$	-0.21***
	(0.03)
$E_{j,t-1}$	-4.61***
	(0.47)
$D_{j,t-1}$	1.35***
	(0.38)
$NPI_{j,t-1}$	-2.51***
	(0.58)
$E_{j,t-1}$ X $D_{j,t-1}$	14.58*
	(7.34)
$E_{j,t-1}$ X $NPI_{j,t-1}$	14.62**
	(4.41)
Left	-0.10
	(0.06)
Dental	-0.01
	(0.05)
General and Plastic Surgery	0.10**
	(0.03)
General Hospital	-0.05+
	(0.03)
Ophthalmic	0.12**
	(0.04)
Physical Medicine	0.04
	(0.03)
United States	-0.09***
	(0.03)
China	-0.12***
	(0.03)
Germany	-0.09+

	(0.05)
Firm Age	0.00*
	(0.00)
Product Age	-0.00**
	(0.00)
Constant	142.89***
	(22.28)
Controls	Included
Observations	1270
R-squared	0.36

Outliers

Table 16 presents results with winsorized product failure experience and change in adverse events at the 2% level. Controls are not presented in Table 16, but I ran the models with controls. The models in Table 16 lend further support for my hypotheses – even correcting for outliers. Winsorizing the data removes the biasing impact of outliers on ordinary least squares regression estimates. The same patterns that I observed in Table 10 are seen in Table 16. The models and coefficients are significant at the p-value < 0.001 level. This means that the interorganizational learning processes are the same when firms learn from exceptionally rare and impactful failures.

TABLE 16
Regression results for medical device firms with the rate of adverse events and independent variables winsorized at 2%

	(1)	(2)	(3)	(4)
	$R_{i,t}$	$R_{i,t}$	$R_{i,t}$	$R_{i,t}$
$E_{i,t-1}$	-0.18***	-0.18***	-0.17***	-0.18***
	(0.03)	(0.02)	(0.03)	(0.02)
$E_{j,t-1}$	-4.14***	-4.26***	-4.44***	-4.42***
	(0.38)	(0.38)	(0.39)	(0.39)
$D_{j,t-1}$	1.66***	1.11***	1.49***	1.24***
	(0.33)	(0.31)	(0.32)	(0.30)
$NPI_{j,t-1}$	-2.14***	-3.28***	-1.49***	-2.32***
	(0.30)	(0.42)	(0.30)	(0.52)
$E_{j,t-1}$ X $D_{j,t-1}$		26.98***		14.90*
		(4.84)		(6.53)
$E_{j,t-1}$ X $NPI_{j,t-1}$			19.82***	13.69***
			(2.78)	(3.72)
Constant	79.46***	132.83***	136.78***	148.50***
	(18.44)	(20.58)	(18.65)	(19.97)
Controls	Included	Included	Included	Included
Observations	1270	1270	1270	1270
R-squared	0.37	0.39	0.39	0.39
F-stat	24.32	23.09	24.46	23.03
Log-Likelihood	-398.1	-378.4	-375.2	-371.3
LR-Test		39.4***	45.8***	14.2***

+ The unrestricted log-likelihood is from model 1 and model 2 for models 2-3 and model 4, respectively.

Sample Selection Bias

Do my results generalize to all medical device firms registered with the FDA? I widen the sample in two ways. First, I broaden my sample to include medical device firms that have failed at least once. The sample includes 11,009 firm-year observations. I impute the failure rate as 0 in years when a firm does not fail. Table 17 shows that the results are

similar to the primary results. Product failure experience has a negative coefficient and significant. This indicates learning effects. Interorganizational product failure experience has a negative coefficient, but is insignificant. The main effect for others' new product introductions is negative, but insignificant. The interaction between others' reporting delays and interorganizational product failure experience is still positive and significant at the p-value < 0.001 level. The interaction with others' new product introductions is positive, but not significant.

However, there are a few differences. One difference is that interorganizational product failure experience, others' new product introductions, and the interaction effect with new product introductions are not significant. This may be caused from zero inflation of product failure rates. Nevertheless, it suggests that most firms learn from their own failures for solutions, rather than others' product failures and new products. Another difference is that the main effect of others' reporting delays is negative and significant at the p-value < 0.001 level. This indicates that others' reporting delays decrease product failures for firms that fail at least once. Combined with the primary estimates, this yields an interesting result. The clarity from a competitor's product failure reporting delays reduces product failure for a population of firms seeking to improve product reliability, but firms that fail more often require speed over reporting clarity.

TABLE 17
Regression results for medical device firms that fail at least once product failure

	(1)	(2)	(3)	(4)	(5)
	$R_{i,t}$	$R_{i,t}$	$R_{i,t}$	$R_{i,t}$	$R_{i,t}$
$E_{i,t-1}$		-0.23***	-0.22***	-0.23***	-0.22***
		(0.02)	(0.02)	(0.03)	(0.02)
$E_{j,t-1}$		-0.01	-0.01	-0.01	-0.01
		(0.01)	(0.01)	(0.01)	(0.01)
$D_{j,t-1}$		-0.14***	-0.14***	-0.14***	-0.14***
		(0.01)	(0.01)	(0.01)	(0.01)
$NPI_{j,t-1}$		-1.51	-1.49	-1.48	-1.45
		(1.16)	(1.16)	(1.15)	(1.15)
$E_{i,t-1}$ X $D_{j,t-1}$			0.08***		0.08***
			(0.02)		(0.02)
$E_{j,t-1}$ X $NPI_{j,t-1}$				2.61	3.57
				(2.72)	(2.85)
Constant	12.50*	31.92***	31.74***	31.86***	31.64***
	(5.13)	(5.39)	(5.38)	(5.40)	(5.39)
Controls	Included	Included	Included	Included	Included
Observations	11009	11009	11009	11009	11009
R-squared	0.09	0.134	0.14	0.134	0.14
F-stat	14.97	18.55	17.9	17.91	17.38
Log-Likelihood	-2235	-1941	-1923	-1941	-1922
LR Test		588***	36***	0	38***

+ The unrestricted log-likelihood is from model 1, model 2, and model 3 for models 2, 3-4, and model 5, respectively.

Second, I expand the sample to include all firms in the medical device industry. Table 18 shows that the estimates support the primary results. The sample includes 98,576 firm-year observations. I impute 0 for product failure rates in years with no failures. The coefficients for the main effects and interaction effects in model 5 are the same as the primary results. Model 5 and the coefficients are significant to the P-value < 0.001 level.

The model explains 42.2 % of the variance in product failure rates and the hypothesized relationships explain 11.1 % of the variance in product failure rates.

Model 5 combined with models 2-4 in Table 19 suggest the importance of product failure, reporting delays, and new product introductions. While model 5 includes all of the hypothesized relationships and has identical estimates as the primary findings, models 2-4 have different estimates than the primary results. This shows that one has to understand the immediate results of three intertwining phenomena (product failure, the reporting of product failure, new product introductions) to uncover how interorganizational product failure experience affects product failure rates in the medical device industry.

TABLE 19
Regression results for all medical device firms

	(1)	(2)	(3)	(4)	(5)
	$R_{i,t}$	$R_{i,t}$	$R_{i,t}$	$R_{i,t}$	$R_{i,t}$
$E_{i,t-1}$		-0.47***	-0.47***	-0.47***	-0.47***
		(0.03)	(0.03)	(0.03)	(0.03)
$E_{j,t-1}$		0.94+	1.36*	-4.53**	-10.06***
		(0.54)	(0.55)	(1.40)	(2.51)
$D_{j,t-1}$		-2.92***	-1.09+	2.57+	13.55***
		(0.36)	(0.65)	(1.33)	(3.64)
$NPI_{j,t-1}$		6.76***	-7.09+	-6.61+	-56.08***
		(1.28)	(3.94)	(3.52)	(13.93)
$E_{j,t-1}$ X $D_{j,t-1}$			2,790.5***		6,739.97***
			(702.74)		(1,482.11)
$E_{j,t-1}$ X $NPI_{j,t-1}$				6,577.2***	14,454.6***
				(1,431.45)	(3,045.65)
Controls	Included	Included	Included	Included	Included
Constant	3.13***	-7.35***	6.13	11.98*	67.68***
	(0.49)	(1.44	(4.10)	(4.78)	(16.58)

Observations	98576	98576	98576	98576	98576
R-squared	0.31	0.42	0.421	0.421	0.422
F-stat	88.39	87.49	85.49	86.41	86.11
Log-Likelihood	100614	109277	109294	109298	109364
LR Test		17326***	34***	42***	140***

+ The unrestricted log-likelihood is from model 1, model 2, and model 4 for models 3-4, model 5, and model 6, respectively.

Medical Device Sector

This section examines whether the effects of interorganizational product failure experience differs between medical device sectors. The 19 sectors are narrowly defined, such as anaesthesiology devices, clinical toxicology devices, and neurology devices by scientific experts in the Office of Device Evaluation. The devices in each sector are often technological substitutes. For example, Philips Medical, Mallinckrodt, Spacelabs Healthcare, Siemens, and General Electric view each other as competitors in radiological devices, but they each have slightly different underlying technologies and product designs. I perform this robustness test for two reasons. The test shows that organizational learning from gains in product failure experience is heterogeneous across sectors is the first reason. Variance across sectors shows that at least some of the improvements can be attributed to product design and manufacturing changes, rather than industry-wide changes like regulation. The specific reasons for heterogeneity between each sector are beyond the scope of this thesis.

Analyzing across sectors implicitly shows the effects of medical device production quantity is the second reason. Figure 4 shows that production quantity for medical devices varies across sectors. However, the heterogeneity of production quantity

is difficult to capture because the CDRH does not maintain data on the number of devices manufactured. I use the coefficient heterogeneity to illustrate the effects of production quantity.

Other proxies for production quantity have been used in past research, but they are inferior in the medical device industry. Some specific devices have production quantity numbers available directly from the manufacturer. For example, Boston Scientific, St. Jude, and Medtronic produce device performance and reliability brochures that contain production quantity numbers for pacemakers and ICDs. Detailed analysis of specific devices is beyond the scope of this thesis and does not capture organizational learning effects. Revenues can proxy production quantity, but medical device prices are likely more correlated with device demand because of their life-saving nature.

Table 20 and 21 presents the coefficients for the ten medical device sectors that have more than 30 firm-year observations. I sort the models based on the number of observations for each sector. The sectors are based on the 19 sector classifications that the CDRH uses to evaluate devices. The sector that a firm belongs to is the maximum number of devices registered within a sector. I exclude sectors with less than 30 firm-year observations because there is not enough statistical power to estimate the model. The sectors are general and plastic surgery, general hospital, orthopaedic, physical medicine, anaesthesiology, dental, gastroenterology/urology, clinical chemistry, ear/nose/throat, and radiology.

This robustness test uses two forms of interorganizational product failure experience, following Thornton and Thompson (2001). The models in Table 20 use

interorganizational product failure experience that is summed across all sectors. The models in Table 21 use interorganizational product failure experience that is restricted to within sectors. Table 22 presents summary statistics for three models. I include the coefficients from the main results for convenience in model 1. Model 2 and 3 in Table 22 contain estimates of the mean between and within sector ordinary least squares regression coefficients. Model 2 highlights across sector interorganizational learning and contains the mean for each coefficient in Table 20. Model 3 emphasizes within sector interorganizational learning and contains the mean for each coefficient in Table 21. The numbers in the brackets are the standard deviation of each coefficient. I test the significance of the mean and standard deviation using a two-tailed T-test.

Across Sector Learning. The coefficients in Table 20 highlight significant intraorganizational learning for 5 of the 10 medical device sectors. The standard deviations of the coefficients in Table 22 are significant at the p-value < 0.01 level. The standard deviations indicate that the coefficients differ significantly between medical device sectors. In general, gains in product failure experience are more significant in larger medical device sectors. The significant of large sectors (ie. general and plastic surgery) and insignificance of small sectors (ie. radiology) suggests that organizations learn more from product failure experience when production quantity increases.

Interorganizational learning across sectors is evident. The interorganizational product failure experience coefficient is -4.87 in model 2 of Table 22 and is significant at the p-value < 0.001. The significance of this coefficient highlights across sector interorganizational learning from medical device failure. Across sector

interorganizational learning is significant in 8 of the 10 medical device sectors if one includes significant interaction terms.

Table 22 shows that product failure rates increase with across sector competitor reporting delays in general, but the effect varies across sectors. Across sector competitor reporting delays significantly increase the product failure rates in general hospital and anaesthesiology. However, across sector competitor reporting delays significantly (p-value < 0.1) decreases the product failure rates in clinical chemistry. The moderation effect of across sector competitor reporting delays on interorganizational product failure experience is significant in general hospital and clinical chemistry.

The effects of across sector competitor reporting delays are summarized in two points. First, the significance of the direct competitor reporting delay effects suggests that organizations benefit from across sector competitor reporting delays when the incidence of product failure is low within sectors. Organizations do not benefit from across sector competitor reporting delays when the incidence of product failure is high. Second, the significant positive moderation effects show that interorganizational learning from product failure is more difficult with competitor reporting delays.

Table 22 shows that across sector competitor's new product introductions decreases product failure at the p-value < 0.001 level. The table also indicates that there is significant variance across sectors. The two largest sectors, general and plastic surgery and general hospital, significantly benefit directly from across sector competitor new product introductions. Radiology, general and plastic surgery, and physical medicine have distraction effects from across sector new product introductions. Across sector

competitor new product introductions led to a decrease in product failure rates for clinical chemistry.

The effect of across sector competitor new product introductions reflects my overall argument. In general, product failure rates decrease with new product introductions by competitors in other sectors. However, a competitor's new product introductions moderate interorganizational product failure experience across sectors for medical device firms in sectors with a large incidence of product failures. The across sector competitor new product introduction effect provides evidence of across sector distractions.

TABLE 20
Regression results for medical device firms across sectors

	(1)	(2)	(3)	(4)	(5)
	General and Plastic Surgery	**General Hospital**	**Orthopaedic**	**Physical Medicine**	**Anaesthe-siology**
	$R_{i,t}$	$R_{i,t}$	$R_{i,t}$	$R_{i,t}$	$R_{i,t}$
$E_{i,t-1}$	-0.33***	0.02	-0.29**	-0.1	-0.38*
	(0.07)	(0.06)	(0.07)	(0.08)	(0.16)
$E_{j,t-1}$	-5.12***	-5.47***	-2.46+	-3.5	-8.23*
	(1.23)	(0.77)	(1.15)	(2.02)	(2.60)
$D_{j,t-1}$	1.56	2.86***	-0.2	1.43	5.70*
	(0.99)	(0.53)	(0.86)	(1.09)	(2.49)
$NPI_{j,t-1}$	-2.16+	-4.25***	-2.35	-1.52	-4.44
	(1.15)	(0.98)	(1.61)	(2.02)	(4.33)
$E_{j,t-1}$ X $D_{j,t-1}$	2.39	49.96***	7.09	-23.84	-15.04
	(17.83)	(11.82)	(17.78)	(20.83)	(45.3)
$E_{j,t-1}$ X $NPI_{j,t-1}$	28.95**	2.37	5.69	27.42+	18.80
	(10.46)	(6.32)	(11.22)	(13.56)	(20.65)
Constant	131.57**	129.42*	160.62**	245.66**	208.62
	(40.88)	(46.75)	(50.66)	(60.71)	(136.74)
Controls	Included	Included	Included	Included	Included
Observations	305	228	150	130	100
R-squared	0.36	0.53	0.51	0.476	0.64

TABLE 20 – Continued
Regression results for medical device firms across sectors

	(6) Dental	(7) Gastro-enterology/ Urology	(8) Clinical Chemistry	(9) Ear, Nose, Throat	(10) Radiology
	$R_{i,t}$	$R_{i,t}$	$R_{i,t}$	$R_{i,t}$	$R_{i,t}$
$E_{i,t-1}$	-0.13+	-0.19	-0.29+	-0.05	0.18
	(0.06)	(0.12)	(0.13)	(0.09)	(0.24)
$E_{j,t-1}$	-6.45*	-2.24	-4.25+	-2.30	-8.69
	(2.24)	(1.62)	(1.66)	(1.73)	(4.59)
$D_{j,t-1}$	2.28	0.07	-1.95+	-2.25	4.85
	(1.38)	(2.25)	(0.87)	(3.48)	(4.32)
$NPI_{j,t-1}$	-3.55	-0.68	-4.95	1.69	-5.78
	(3.80)	(3.62)	(2.62)	(3.40)	(5.22)
$E_{j,t-1}$ X $D_{j,t-1}$	16.51	32.82	78.98*	-17.42	32.57
	(37.69)	(40.63)	(28.17)	(46.86)	(54.55)
$E_{i,t-1}$ X $NPI_{i,t-1}$	15.69	-16.21	-47.14+	41.67	80.77*
	(30.33)	(28.87)	(21.07)	(78.98)	(15.48)
Constant	-11.11	41.34	18.25	276.94	868.92
	(146.20)	(145.58)	(194.12)	(328.04)	(657.34)
Controls	Included	Included	Included	Included	Included
Observations	80	60	50	40	30
R-squared	0.373	0.636	0.79	0.69	0.86

Within Sector Learning. Intraorganizational learning has a greater impact on reducing product failure rates within sectors than between medical device sectors. The coefficient for product failure experience is significant in 6 of 10 medical device sectors and the within sector mean-estimate is more negative than across sector. Gains in product failure experience are more significant in larger medical device sectors, like the across sector

results. Indeed, the trend indicates that organizations learn more from product failure experience when production quantity increases.

Interorganizational learning within sectors is significant, but the effect is less than interorganizational learning between sectors. 5 out of the 10 estimates for interorganizational product failure experience in Table 21 are significant and Table 22 shows that the mean estimate is -1.41, which is less than learning across sectors or across the industry. These results indicate that medical device firms are likely to learn from their own product failure experience if a failure occurs within their industry sector and more likely to learn from others' product failure experience if a failure occurs outside of their sector. The pattern of interorganizational learning from product failure highlights interorganizational product failure experience has a larger effect if failures are unpredictable. Firms can pay attention to and anticipate their nearest competitor's product failures better than product failures of competitor's in another sector. In being able to better predict their competitors; interorganizational product failure experience has less effect on reducing product failure rates.

The lack of significance for competitor's reporting delays, and new product introductions, and interactions for within sector interorganizational learning supports the view the attention-based view of interorganizational learning. There is variation in the effect of competitors' reporting delays and new product introductions on interorganizational learning from product failure experience. For example, the coefficient for competitor's new product introductions in general and plastic surgery is negative and significant – showing that a competitor's innovations leads to a decrease in

product failure rates in surgical procedures. As well, reporting delays have a positive effect on product failure rates in general hospital and orthopaedics. However, medical device firms often reduce product failure rates using the knowledge gained from within sector interorganizational product failure experience and competitor new product introductions. Medical device firms in general hospital and anaesthesiology offer an example. The coefficients for the new product introduction interaction term is positive (but not significant) for across sector learning in both cases. This suggests that a competitor's new product introduction may be a distraction across sectors, or at the very least have no effect on product failure rates. The same coefficients are negative and significant at the p-value < 0.05 level for within sector learning. The negative coefficient implies that competitor's that introduce new products within-sector increase the effect of interorganizational product failure experience on learning to reduce product failure rates. The contrasting within sector and between sector results suggests that firms are not distracted and can only benefit from the new product introductions if they can expect and pay attention to competitor new product introductions.

TABLE 21
Regression results for medical device firms within sectors

	(1)	(2)	(3)	(4)	(5)
	General and Plastic Surgery	**General Hospital**	**Orthopaedic**	**Physical Medicine**	**Anaesthe-siology**
	$R_{i,t}$	$R_{i,t}$	$R_{i,t}$	$R_{i,t}$	$R_{i,t}$
$E_{i,t-1}$	-0.40***	0.04	-0.27*	-0.03	-0.49*
	(0.08)	(0.07)	(0.09)	(0.08)	(0.18)
$E_{j,t-1}$	-2.45***	-4.66***	0.67	-1.25	-1.94***
	(0.50)	(1.11)	(0.43)	(0.86)	(0.40)
$D_{j,t-1}$	0.05	1.23*	-0.58	-0.06	0.67
	(0.40)	(0.46)	(0.40)	(0.55)	(0.47)
$NPI_{j,t-1}$	-3.26**	1.27	-0.80*	-0.92	1.55
	(0.97)	(0.88)	(0.36)	(5.56)	(1.03)
$E_{j,t-1}$ X $D_{j,t-1}$	0.15	5.37***	3.06**	-4.12	2.45
	(2.52)	(0.94)	(0.98)	(3.76)	(2.23)
$E_{i,t-1}$ X $NPI_{i,t-1}$	5.07	-16.69*	0.80	19.8	-12.23*
	(4.58)	(6.25)	(1.72)	(14.79)	(4.95)
Constant	202.55***	-574.61**	315.06**	23.74	30.59
	(42.49)	(159.81)	(104.67)	(83.75)	(130.39)
Controls	Included	Included	Included	Included	Included
Observations	305	228	150	130	100
R-squared	0.36	0.45	0.48	0.34	0.63

TABLE 21 - Continued
Regression results for medical device firms within sectors

	(6)	(7)	(8)	(9)	(10)
	Dental	**Gastro-enterology/ Urology**	**Clinical Chemistry**	**Ear, Nose, Throat**	**Radiology**
	$R_{i,t}$	$R_{i,t}$	$R_{i,t}$	$R_{i,t}$	$R_{i,t}$
$E_{i,t-1}$	-0.33*	-0.33+	-0.37*	-0.15	-1.28
	(0.12)	(0.16)	(0.09)	(0.14)	(1.21)
$E_{j,t-1}$	-1.36*	-0.78	-0.14	0.24	-2.41
	(0.40)	(0.46)	(0.15)	(0.25)	(2.56)
$D_{j,t-1}$	0.02	-0.06	0.37	0.21	1.27
	(0.22)	(0.15)	(0.33)	(0.17)	(1.39)
$NPI_{j,t-1}$	-0.75	-0.02	-0.25	-0.48	1.18
	(0.68)	(0.16)	(0.31)	(0.40)	(3.93)
$E_{j,t-1}$ X $D_{j,t-1}$	1.04	0.14	0.77	1.04	-0.78
	(1.86)	(0.45)	(0.86)	(1.15)	(0.93)
$E_{i,t-1}$ X $NPI_{i,t-1}$	3.15	1.00	-0.87	0.56	1.25
	(3.95)	(0.66)	(0.60)	(0.99)	(0.87)
Constant	129.26	34.59	-169.88	-71.62	131.33
	(191.07)	(73.10)	(155.13)	(167.54)	(264.28)
Controls	Included	Included	Included	Included	Included
Observations	80	60	50	40	30
R-squared	0.32	0.55	0.67	0.70	0.79

TABLE 22
Regression results for medical device firms across sectors and within sectors

	(1) Across industry	(2) Mean-estimate Across sector	(3) Mean-estimate Within sector
	$R_{i,t}$	$R_{i,t}$	$R_{i,t}$
$E_{i,t-1}$	-0.20***	-0.16***	-0.36***
	(0.03)	(0.18)**	(0.36)*
$E_{j,t-1}$	-4.71***	-4.87***	-1.41**
	0.49)	(2.37)**	(1.56)***
$D_{j,t-1}$	1.38***	1.44+	0.31+
	(0.39)	(2.63)**	(0.59)***
$NPI_{j,t-1}$	-2.56***	-2.80***	-0.25
	(0.58)	(2.25)**	(1.41)*
$E_{j,t-1}$ X $D_{j,t-1}$	13.78+	16.40++	0.914
	(7.32)	(32.67)**	(2.50)***
$E_{i,t-1}$ X $NPI_{i,t-1}$	15.45***	15.80++	0.184
	(4.42)	(34.12)	(9.77)**
Constant	157.61***	207.02**	5.10
	(23.11)	(251.45)**	(245.14)***
Controls	Included	Included	Included

***, **, *,+, and ++ represent p-value < 0.001, 0.01, 0.05, 0.1, and 0.15 on a two-tailed T-test.
The numbers in brackets for Model 2 and 3 represent standard deviations of the coefficients. The significance of the standard deviation indicates significance of the mean of the estimated standard error.

Competitors with Both Product Failure Experience and New Product Introductions

Until now, I assume increases in new product introductions across all competitors cause distractions. In this section, I investigate whether a new product introduction by the same firm that has a product failure is a distraction. This is arguably a more rigorous test of distractions than the main results. Organizations should be able to process

interorganizational product failure experience more effectively from a single competitor because of reductions in information. More effective processing of a single competitor's experience implies that organizations should be able to parse out the effects from new product introductions.

The literature on intraorganizational learning from failure and recovery experience provides another reason why restricting interorganizational product failure experience to competitors that have both product failures and new product introductions is a more robust test (Kim et al. 2009). Kim and colleagues (2009) find that banks with both near-failure and recovery experience have a lower probability of organizational failure in the future. One would expect similar findings by extrapolating their findings to interorganizational learning in the medical device industry. The cause for a new medical device is likely to be linked to the cause of an existing product failure if it comes from the same competitor at the same time. In the absence of a distraction effect of a competitor's new technology, Kim et al.'s (2009) work suggests that the interaction coefficient between interorganizational product failure and a new product introduction is from the same competitor should be negative.

Table 23 presents interorganizational product failure experience ($E_{j,t-1}$) results for competitors that have both product failures and new product introductions. The interaction coefficient for interorganizational product failure experience and a competitor's new product introductions is positive and significant at the p-value < 0.001. The positive coefficient indicates that a competitor's new product introduction reduces the effect of interorganizational product failure experience on product failure rates. The

positive interaction coefficient suggests that medical device firms are distracted by a competitor's new product introductions – even if the failure in existing products and new product comes from the same competitor.

TABLE 23
Regression results for medical device firms with both product failure experience and new products

	(1)	(2)	(3)	(4)	(5)
	$R_{i,t}$	$R_{i,t}$	$R_{i,t}$	$R_{i,t}$	$R_{i,t}$
$E_{i,t-1}$	-0.21***	-0.21***	-0.20***	-0.20***	-0.21***
	(0.03)	(0.03)	(0.03)	(0.03)	(0.03)
$E_{j,t-1}$	-4.41***	-4.53***	-4.74***	-4.71***	-4.89***
	0.48)	(0.48)	(0.49)	(0.49)	(0.50)
$D_{j,t-1}$	1.79***	1.23**	1.62***	1.38***	1.47***
	(0.40)	(0.39)	(0.39)	(0.39)	(0.39)
$NPI_{j,t-1}$	-2.49***	-3.65***	-1.79***	-2.56***	-3.24***
	(0.39)	(0.48)	(0.39)	(0.58)	(0.73)
$E_{j,t-1}$ X $D_{j,t-1}$		27.38***		13.78+	13.96+
		(5.41)		(7.32)	(7.19)
$E_{j,t-1}$ X $NPI_{j,t-1}$			21.14***	15.45***	22.34**
			(3.30)	(4.42)	(7.92)
Controls	Included	Included	Included	Included	Included
Constant	85.69***	139.99***	146.72***	157.61***	134.09***
	(22.06)	(24.25)	(21.43)	(23.11)	(33.54)
Observations	1270	1270	1270	1270	1270
R-squared	0.324	0.34	0.34	0.346	0.347

+ The unrestricted log-likelihood is from model 1, model 2, and model 4 for models 3-4, model 5, and model 6, respectively.

Regression Lags

Are immediate effects of competitor reporting delays different than the effects far in the past? I test the period of the learning effect with additional lags in gains of experience.

Table 24 shows the results for two lags of interorganizational product failure experience, two lags of competitor reporting delays, and two lags of interactions. I only include two lags to ensure statistical power. I compare lags of product failure experience coefficients in model 2. I reject the null hypothesis that gains in experience two years prior is the same as gains in experience one year prior at the p-value < 0.001 level. I reject the null hypothesis that gains in interorganizational product failure experience two years prior is the same as gains in experience one year prior at the p-value < 0.06 level. There is evidence that recent interorganizational product failure experience reduces product failure rates more than past experience. Additionally, there is no evidence that recent delays have any different impact than older reporting delays. However, the interaction effect from one year prior is significantly less the past year at the p-value $<$ 0.02 level. This indicates that the moderation effect of competitor reporting delays on interorganizational product failure experience is less with more time. Overall, the post-hoc test indicates that time benefits interorganizational learning when a competitor has reporting delays.

TABLE 24
Regression results for different lags

	(1)	(2)	(3)	(4)	(5)	(6)
		$R_{i,t}$	$R_{i,t}$	$R_{i,t}$	$R_{i,t}$	$R_{i,t}$
$E_{i,t-1}$	-0.21***	-0.19***	-0.21***	-0.20***	-0.20***	-0.20***
	(0.03)	(0.04)	(0.03)	(0.05)	(0.05)	(0.05)
$E_{i,t-2}$		0.00		0.00	0.00	0.00
		(0.03)		(0.03)	(0.03)	(0.03)
$E_{j,t-1}$	-4.52***	-5.07***	-4.60**	-6.83+	-5.11	-5.12
	(0.46)	(1.44)	(1.75)	(3.80)	(3.86)	(3.88)
$E_{j,t-2}$		0.67		0.98	0.52	0.37
		(0.78)		(1.41)	(1.41)	(1.48)
$D_{j,t-1}$	1.21**	1.26	1.97	3.22*	1.85	1.90
	(0.39)	(0.79)	(1.38)	(1.52)	(1.84)	(1.85)
$D_{j,t-2}$			-0.34	-0.98+	-1.15*	-1.03+
			(0.46)	(0.51)	(0.49)	(0.56)
$E_{j,t-1}$ X $D_{j,t-1}$	26.70***				27.25+	24.68
	(5.29)				(13.88)	(16.11)
$E_{j,t-2}$ X $D_{j,t-2}$						-5.27
						(9.74)
Controls		Included	Included	Included	Included	Included
Constant	143.96***	99.75*	82.88**	94.85	108.63	115.44
	(24.13)	(50.09)	(27.45)	(110.95)	(108.48)	(111.37)
Observations	1270	1143	1270	1143	1143	1143
R-squared	0.34	0.336	0.322	0.34	0.34	0.342

Do organizations obtain interorganizational product failure experience from different periods with competitor reporting delays? I test this by comparing cross-year interactions for competitor reporting delays and interorganizational product failure experience. I present the results in Table 25. The results indicate that competitor reporting delays in the prior period does not change interorganizational product failure experience in more recent periods. However, interorganizational product failure experience in prior periods reduces product failure rates significantly if competitor delays

occur in more recent periods. The result shows that medical device firms use past interorganizational product failure experience if their competitors delay reporting more recent product failures.

TABLE 25
Regression results for cross-time interaction effects

	(1)
	$R_{i,t}$
$E_{i,t-1}$ X $D_{i,t-2}$	-1.62
	21.57
$E_{i,t-2}$ X $D_{i,t-1}$	-25.36*
	12.07

Time does not change the effect of new product introductions. I use the same tests on new product introductions as reporting delays. Table 26 presents the lag coefficients for competitor new product introductions and Table 27 presents the cross-time interactions.

None of the tests are significant. There is no evidence that recent new product introductions have any different impact than older new product introductions (p-value < 0.89). There is no evidence that the moderation effects of competitor new product introductions changes through time (p-value < 0.89). The interaction coefficient for interorganizational product failure experience and competitor new product introductions from prior years is not significantly different from the past year (p-value < 0.89). Finally, there are no significant cross-time effects of competitor new product introductions.

TABLE 26
Regression results for new product introductions period of effect

		(1)	(2)	(3)	(4)	(5)
		$R_{i,t}$	$R_{i,t}$	$R_{i,t}$	$R_{i,t}$	$R_{i,t}$
$E_{i,t-1}$	-0.20***	-0.19***	-0.21***	-0.20***	-0.20***	-0.20***
	(0.03)	(0.04)	(0.03)	(0.05)	(0.05)	(0.05)
$E_{i,t-2}$		0.00		0.00	0.00	0.00
		(0.03)		(0.03)	(0.03)	(0.03)
$E_{j,t-1}$	-4.73***	-5.07***	-4.60**	-6.83+	-7.33+	-6.89
	(0.47)	(1.44)	(1.75)	(3.80)	(4.32)	(4.23)
$E_{j,t-2}$		0.67		0.98	1.08	2.24
		(0.78)		(1.41)	(1.52)	(1.53)
$NPI_{i,t-1}$	-1.79***	0.54	-3.15***	-0.44	0.22	-0.87
	(0.38)	(0.72)	(0.68)	(2.04)	(3.26)	(3.14)
$NPI_{i,t-2}$			0.26	-0.95	-1.07	-1.44
			(1.11)	(1.57)	(1.60)	(1.66)
$E_{j,t-1}$ X $NPI_{i,t-1}$	21.28***				-5.75	-27.47
	(3.34)				(26.00)	(33.66)
$E_{j,t-2}$ X $NPI_{j,t-2}$						-31.44
						(19.87)
Controls		Included	Included	Included	Included	Included
Constant	150.04***	99.75*	82.88**	94.85	89.09	-37.17
	(21.03)	(50.09)	(27.45)	110.95)	(118.03)	(126.07)
Observations	1270	1143	1270	1143	1143	1143
R-squared	0.34	0.336	0.322	0.34	0.339	0.34

TABLE 27
Ordinary least squares regression results for cross-time interaction effects of new product introductions

	(1)
	$R_{i,t}$
$E_{j,t-1}$ X $NPI_{j,t-2}$	32.57
	(33.19)
$E_{j,t-2}$ X $NPI_{j,t-1}$	-29.75
	(25.91)

6. Discussion and Implications

I find supportive evidence for my propositions. First, firms reduce their own product failure by attending to a competitor's product failure experience. Second, competitor reporting delays reduce the impact of others' product failure experience on a firm's product failure rates, but competitor reporting delays directly reduce product failure rates for small gains in others' product failure experience. Third, competitor new product introductions reduce an organization's ability to learn from others' product failure experience, but competitor new product introductions directly reduce product failure rates. The underlying theme of these questions is to partially explain how interorganizational learning from existing product failure experience occurs for medical device firms. New regulations, new technologies, and differing product portfolios suggest that the value of product failure experience may equally depend on the process of reporting product failure, and the contextual events that simultaneously occur as a competitor's product fails (Elsbach et al. 2005). In answering these three research questions, I expect to make three contributions to the literature on interorganizational learning by: (1) highlighting learning from others' product failure experience, (2) emphasizing the importance of regulatory information, and (3) showing the learning effects of reporting delays and distractions (see Appendix A.6 for an overview).

Interorganizational Learning from Product Failure Experience

Theoretical contribution. I add to the theoretical understanding of interorganizational learning from failure by showing how firms learn to reduce product failure rates from interorganizational product failure experience in the medical device industry. Few

studies have looked at interorganizational learning from product failure, even though product failure is wide-ranging across many contexts and may be a natural by-product of technological development. This is surprising considering that many studies show intraorganizational learning to reduce product failure, such as how production experience leads to automobile quality (Haunschild and Rhee 2004; Levin 2000), waste reduction in manufacturing plants (Lapre et al. 2000), and customer complaints in airline service (Lapre and Tsikriktsis 2006). There are two reasons why it is important to understand learning from others' product failures. First, learning to reduce product failure is central to the medical device industry. Second, learning from others' product failures can help with organization renewal at relatively little cost.

This thesis emphasizes learning from interorganizational product failure experience in the medical device industry. I show how organizations learn to reduce product failures rates at the moment they gain interorganizational product failure experience. I place theoretical focus on the moment that organizations gain experience rather than looking at long histories, following intraorganizational learning work on the importance of context (Cook and Brown 1999; Elsbach et al. 2005; Garud and Rappa 1994). In the medical device industry, it is not the history of interorganizational experience that is important but what happens when experience is acquired.

I emphasize that the impact of learning from others' experience depends on the context and what happens when organizations gain interorganizational product failure experience. I demonstrate that interorganizational learning from product failure experience requires simultaneously accounting for competitor's new product

introductions and the process of product failure reporting at the moment an organization acquires experience. The effect of interorganizational product failure experience on product failure rates is very different depending on the existing stock of product failure reports to draw upon, a competitor's product portfolio, and the speed at which competitors report failure.

Organizational attention is the primary reason why competitor new product introductions and competitor reporting delays affect interorganizational learning from product failure in the medical device industry. I argue that organizational attention to the experience is vital to explaining interorganizational learning. Medical device firms have to prioritize the experience they pay attention too. The attentional aspect of learning is evident for most medical device firms that carefully balance experience gained from product failure, product development, and regulatory interactions.

Regulatory and policy contribution. I add to a contextual understanding of medical device failure by focusing on interorganizational learning. Work on medical device failure has been done at the product level (Maisel 2005, 2007; Maisel et al. 2006). These clinical studies are an important component in reducing product failure by highlighting potential problems in medical devices (Maisel et al. 2006). Additionally, the detailed descriptive information on protocols-of-use steer physicians towards the correct use of these devices (Gould et al. 2008; Gould and Krahn 2006).

A considerable amount of work focuses on regulatory intervention. Maisel (2005) highlights the need for regulations with reporting clarity and physician education on the reliability of medical devices. Maisel (2007) shows that FDA efforts were a crucial

component in evaluating, distributing, and allowing for the exchange of information about the causes of product failure in a commentary on the actions of the FDA during drug-eluding stent failure. Maisel (2006) argues that the FDA should encourage better bench testing and device evaluation prior to market introduction. Dhruva et al. (2009) highlights that the medical device approval process needs to be improved because the current process relies on potentially biased studies. In general, the work finds that the best mechanisms for reducing medical device failure is through tougher regulatory intervention, more attentive medical staff, and increasing hospital safety procedures.

My work suggests that interorganizational learning is an important and neglected way to mitigate medical device failure and contributes to these product failure studies in two ways. This is the first study that treats medical device adverse events at the manufacturing firm level. My study suggests that a considerable amount of learning how to reduce product failure occurs after regulatory approval. Combining these results indicates that organizational and interorganizational learning processes are important additions in the toolkit of medical failure prevention. It also highlights that medical device firms should be responsible for designing safe devices – providing additional context behind the February 2008 US Supreme Court ruling in *Riegel vs. Medtronic (Scalia et al. 2008)*. The legal decision puts safety responsibility on the FDA approval process and pre-empts consumers from suing device manufacturers over faulty devices.

This thesis challenges the role of expanding CDRH into more rigorous pre-market testing. A more comprehensive pre-market approval will potentially slow the dissemination of life-saving devices. Device flaws and potential uses for devices are not

easy to identify, *ex ante*. I identify that a large number of device flaws and potential uses can only be found and corrected after the device has been put into use. I also find that manufacturers are good at learning from their failures and the failures of others. My work highlights the important responsibility of the CDRH to carefully disseminate product failure information.

Managerial contribution. Managers in the medical device industry should be able to gather two lessons from my analysis of interorganizational learning from product failure experience. First, my work implies that the managers are not fully appreciating the value of a competitor's product failure experience. I find that a firm's own product failure experience is 6.4 times more effective than interorganizational product failure experience at reducing product failure rates. Interorganizational learning may be inherently difficult and difficulties may be due to any number of factors; such as (1) a strong focus on a firm's own research and development because of the long length of product development and large development costs, (2) a focus on obtaining regulatory approval and compliance, and (3) the complex nature of medical device failure. However, learning from interorganizational product failure experience is necessary in the industry. Firms can not only reduce their product failure rate by avoiding the actions that cause others' failures, but also reduce costs, manage their reputation, and uncover new ways to renew their organization.

I discover that learning from interorganizational product failure is significant in the medical device industry. Interorganizational learning is even significant across industry sectors. The significance implies managers can learn from a competitor's

product failure experience. Firms may be able to increase product reliability by devoting more resources to competitive surveillance. It also indicates that medical device firms have a responsibility in reducing the product failure rates of others. Ideally, responsible medical device firms should facilitate reciprocity of product failure information. Although, irresponsible and deviant firms can inevitably take advantage of the fact that their actions can and do increase a competitor's product failure rates.

The Regulatory Process of Product Failure Reporting

This thesis is the first time that interorganizational learning research explicitly involves interactions with third-party regulators. Past research demonstrates that failure reporting systems are important to learning from failure (Tamuz 2001b; Tamuz et al. 2004). Until now, studies of interorganizational learning from failure have not yet acknowledged that the source and nature of failure information is as important as the failure itself. For example, Kim and Miner (2007) and Kim et al. (2009) obtain data to predict bank near-failures from the Federal Deposit Insurance Corporation (FDIC) and the Federal Reserve, organizations that have been known to be secretive about the causes of bank failure. Haunschild and Sullivan (2002) gather data on airline accidents from the US National Transportation Safety Board (NTSB), but Tamuz (2001b) demonstrates that the aviation safety monitoring systems are prone to reporting biases by design.

Theoretical contribution. Explicitly modeling interorganizational interactions with third-party regulators is an important theoretical contribution (see Appendix A.6 for an overview). My thesis builds upon work by Sullivan (2010) that shows regulators interact and respond to organization actions that cause failure. Sullivan's (2010) study only

demonstrates one side of the regulator-organization learning dyad. It demonstrates that the US Federal Aviation Administration (FAA) generates more rules when airlines have more accidents. The study implies that regulators pay more attention to and are more urgent when organization's experience problems. My study demonstrates the other side. I focus on how organizations learn from regulator information. Reporting time, clarity, and completeness of a competitor's product failure reports are functions of the regulator's and the competitor's actions. I show that the information regulators provide (or do not provide) is important to how interorganizational product experience is used in the medical device industry.

Regulatory and policy contribution. My thesis raises an important policy point for regulators. The regulatory system and process of reporting impacts product failure reduction. This logic builds on Feinstein (1989) and Macher et al. (2008) that both show variability in the efforts to encourage reporting by regulators. Specifically, the medical device industry has significant variability in efforts to reduce product failure rates when others' fail. I find that more recent interorganizational product failure reports have a greater impact on the reduction of product failure rates than past reports, even though the adverse event reports are kept in a public, centralized, and stable database. Regulators should not only be encouraged to develop faster, more transparent, and easier to use failure reporting systems, but also collaborate in the investigation of more complex product failures.

Competitor Reporting Delays and New Product Introductions

Competitor Reporting Delays

Theoretical contribution. I contribute to theory by investigating separate gaps in two bodies of literature (refer to Appendix A.6). First, research on interorganizational learning generally assumes that outcomes quickly follow actions. For example, Haunschild and Sullivan (2002) assumed that airlines simultaneously learned from others' accidents. Moreover, most simulations assume synchronous behaviour and simultaneous timing of actions. Levinthal and March (1981) model immediate organizational learning in response to attainment discrepancy between an organization's performance and a competitor's performance. Lant and Mezias (1992) show how organizations immediately adapt to changes in their environment. Delays are common in organization settings, yet so far organizational scholars have not systematically investigated how delays may affect interorganizational learning.

Second, the simulation studies that specifically address delays between an action and outcome focus on intraorganizational processes (Denrell et al. 2004; Fang and Levinthal 2009; Rahmandad 2008). Simulations by Denrell et al. (2004), Fang and Levinthal (2009), and Rahmandad (2008; 2009) suggest that delays can decrease learning because the complexity of learning grows exponentially with the length of a delay. A case study by Repenning and Sterman (2002) shows that delays may discourage attempts to learn. Combining the findings suggests that learning with delays is, overall, more difficult in the interorganizational setting of arms-length learning.

I combine literature on the effects of delays on learning with studies of interorganizational learning from failure to uncover when organizations may and may not learn from others' product failures. Two factors suggest this is an important contribution. The first factor is that reporting delays emphasize the shortfalls of selective attention (Ocasio 1997) and organizational memory in interorganizational learning. Specifically, delays in outcomes may lead some organizations to learn from more proximate information than from the performance of others. The second factor is that delays bring attention to the complexities of learning and the costs of processing delayed information, particularly in contexts where such complexities and costs are important.

I find that a competitor's reporting delays can reduce product failure rates. However, I show that the positive learning benefits from reporting delays depend on the magnitude of the interorganizational product failure experience. A competitor's reporting delays reduces product failure rates with small gains in interorganizational product failure experience because the additional time allows competitors to provide clear and richer product failure reports. Time is important with large gains in interorganizational product failure experience. A competitor's reporting delays will only increase product failure rates with large gains in interorganizational product failure experience in a post-hoc analysis.

The differing reporting delay effect of small gains versus large gains in interorganizational product failure experience is a significant contribution to research on small losses (Hayward 2002; Madsen and Desai 2010; Sitkin 1992; Starbuck and Milliken 1988). The central argument is that learning from small losses is more effective

because managers find small losses easier to accept, and small losses provide constant feedback on actions because they are more frequent. I contribute to this argument in two ways. First, this thesis generalizes theory on intraorganizational learning from small losses to the interorganizational domain. I demonstrate that learning from small gains in interorganizational product failure experience is perhaps a simpler picture than demonstrating it with intraorganizational learning. Organizations learning from others' product failures are unlikely to ignore and redefine others' failures because of self-enhancement processes (Madsen and Desai 2010). Indeed, firms may be more likely to inflate others' small losses because it makes their own product design look better. Second, the moderating role of reporting delays underscores the lack of discussion about the failure reporting process in the debate over small and large losses. I emphasize counteracting forces between the magnitude of failure and the actual reporting of failure. Failures require time to investigate, but large losses that are reported slowly have a detrimental effect on product failure rates.

I show that a competitor's reporting delays can inhibit the effects of interorganizational product failure experience. Understanding reporting delays helps clarify previous mixed results in interorganizational learning research. I provide evidence that delays in the failure reporting process can significantly decrease the effect of interorganizational product failure experience on product failure rates. Competitors that delay reporting when they have extensive product failure experience to report can even increase a firm's product failure rates. The detrimental effects of reporting delays occur even with a formal knowledge transfer mechanism – the MAUDE database. The

results suggest that reporting delays are likely to have a larger impact in contexts with no formal knowledge transfer systems, where the costs of communication are higher.

The effects of report delays add to error and failure reporting research. Some studies suggest that immediate and clear failure reporting is important for organizational learning. For example, Zhao and Olivera (2006) suggest that rapid error detection and reporting is a necessary function for organization learning. Carroll and colleagues (2002) also so that organizations show process failures more slowly to fruitfully glean all possible lessons from failure. I show that both quick failure reporting and slow processing of failures have their downsides and unintended consequences. Fast feedback reduces clarity, but slow processing reduces experience. Interorganizational product failure experience has less of an impact on reducing product failure rates when a competitor takes to report a product failure.

Regulatory and policy contribution. This thesis identifies three practical implications for regulators about the unintended consequences of reporting delays. First, my thesis suggests that failure reporting databases with transparent data are necessary to reduce product failure rates in an industry. The interorganizational learning effects from a competitor's product failure experience are significant. Second, regulators should carefully think through industry failure reporting processes, as they must balance the need for rapid diffusion of product failure reports with the need for clear and reliable reports. In particular, regulators may want to develop emergency procedures for large gains in product failure experience to help speed up failure reporting. Third, regulators should weigh the costs of persecuting a single tardy competitor versus tackling systemic

issues that delay or make product failure reports less transparent. I find that some reporting delays can decrease product failure rates, but I also find that firms have large competitive incentives to delay failure reports. Firms can delay product failure reports in order to raise the product failure rates of their competitors at no cost to themselves.

Managerial contribution. The effects of reporting delays of product failure demonstrated in this thesis raises important practitioner questions. When should a firm learn from others' product failures? Should managers wait until all of their competitors' product failure experience is clear and complete or should they learn quickly from a competitor's product failures and move on? These questions depend upon the urgency of product failure information that managers wish to seek. In the medical device industry, it is best to avoid frequent evaluation and reaction to small gains in interorganizational product failure experience. I discovered that managers are better off waiting if their competitors have small gains and better off not waiting if their competitors have large gains in product failure experience. I also find firms that failed previously and are seeking immediate solutions are better off learning from their own product failure experience.

Competitor New Product Introductions

The medical device industry may be one of many contexts where interorganizational learning from product failure co-mingles with interorganizational learning from new product introductions. Research does not address this phenomenon in either the new product introduction literature or learning from failure literature. Kim and Miner (2007), for example, show that the near-failures of banks help prevent other banks from failing.

Haunschild and Sullivan (2002) suggest that others' complex failures decrease the likelihood of failure in the future. Furthermore, interorganizational learning from new product introductions literature is scant, most of the new product development research focuses on intraorganizational processes. Even still, the few interorganizational learning from new product introductions articles that are available only look at how firms learn from others' new product introductions. For example, Srinivasan and Haunschild (2007) demonstrate that interorganizational learning from new product introductions is possible in the digital camera industry. These studies collectively show that learning from others' product failures is likely, but do not address whether learning is possible and what happens when there are reports of others' existing product failures and future product innovations.

Theoretical contribution. A reduction in an organization's product failure rates when a competitor introduces a new product is an important finding for interorganizational learning (refer to Appendix A.6). The finding highlights interorganizational learning of product design and product modifications. Most learning studies find the impact of product design on the intraorganizational learning has mixed results (Adler and Clark 1991; Dutton and Thomas 1984; Levin 2000). This is a unique contribution because most interorganizational learning studies emphasize interorganizational learning of operation and manufacturing techniques (Argote and Epple 1990; Yelle 1979). In previous manufacturing settings, a competitor's technologies are relatively fixed and manufacturing technologies improve. For example, Hatch and Mowery (1998) stress the combined intraorganizational learning effect of new process introductions and cumulative

production in decreasing the defect density of semiconductor manufacturing. My finding highlights that firms learn from others in settings where product technologies improve and organizations have to repeatedly learn about a competitor's new technologies.

Evidence that product failure rates decrease with a competitor's new product introductions also contributes to organizational learning from failure literature. I make interorganizational learning inferences from intraorganizational learning from failure literature that illustrates that firms attend to differing sources of information to reduce the risk of failure (Christianson et al. 2009; Kim et al. 2009). Christianson et al. (2009) find that a railroad museum made positive changes after it collapsed. They suggest the positive changes are in response to audits of what the museum did well and what it did poorly. Kim et al. (2009) find that banks have a better chance of survival if they combine success and recovery experience. I extend these findings and suggest that organizations reduce their own product failure rates because reports of other's successes (new product introductions) are information sources about failures. A competitor's new product introductions attract attention, provide knowledge transfer mechanisms, and highlight product design flaws in existing devices.

Counter intuitively, learning from others' new innovations and learning from others' existing products interact in the medical device industry. I find that interorganizational product failure experience and others' new product introductions reduce product failure rates when they are independent of each other. However, I reveal that the learning effect of interorganizational product failure experience on product

failure rates is weaker when others' introduce new products. I label this effect a distraction.

The interdependent effect of interorganizational product failure experience and new product introductions contributes to learning research by stressing the importance of organizational attention. I add to organization learning research which suggests that organizations do not focus on one goal (Cyert and March 1963; Ethiraj and Levinthal 2009; Ocasio 1997; Simon 1945). My research demonstrates that organizational attention is a scarce resource. I show that interorganizational product failure experience has less effect because of organizational attention to a competitor's new product introductions.

The interdependent effect additionally contributes to the attention-based view of organizational learning. Recent empirical intraorganizational work demonstrates organizational attention focuses resources within organizations (Ocasio 1997; Weick and Sutcliffe 2006). Sullivan (2010) shows that airline regulators are likely to compete for the attention of the organization, providing greater urgency to rule making in some areas rather than others. Sullivan (2010) shows that organizations allocate resources faster when organizations find new problems while simultaneously working through old problems. Rerup (2009) shows that a drug manufacturer learned how to devote attention to both manufacturing and regulatory concerns, illustrating that attention can channel resources to one issue over another.

A gap exists in the literature on the attention-based view that highlights the problems and benefits of being unfocused. In this thesis, I emphasize the former and suggest that organizational distractions can occur. I contribute to attention-based view

literature by emphasizing the effects of distractions in interorganizational learning, building on work on intraorganizational learning (Rerup 2009; Sullivan 2010). In particular, I emphasize two distraction mechanisms. First, medical device firms that pay less attention to a competitor's existing product failures when competitors introduce a new product are likely to postpone product improvements to match competitors. Second, firms are likely to learn superstitiously when both interorganizational product failure experience and competitor new product introductions occur simultaneously.

I contribute additional evidence of distractions. Non-innovative medical device firms are distracted, but innovative firms are not distracted by a competitor's new product introductions. I suggest that the innovation effect is because not innovative firms do not regularly update expectations of a competitor's technologies and are more reactive to a competitor's technologies. Distractions occur even if the failing device and new device comes from the same competitor. This suggests a competitor's new product introductions are distracting because: (1) they provide greater knowledge about how to improve product design than reports of product failure, or (2) medical device firms do not have resources to attend to even narrow details about competitors.

Regulatory and policy contribution. A holistic view of competitor's new technologies and existing product failures has important public policy implications. This is the first study to incorporate product failure and product innovation in the medical device industry. This thesis suggests studies that focus solely on medical device failure present an incomplete picture of the medical device industry. The usual conclusions of these studies are: (1) stricter regulatory enforcement and surveillance reduces product failures,

and (2) better training in hospitals reduces product failures. I add two more conclusions: (3) technological progress reduces product failures, and (4) indirect technological progress through interorganizational learning reduces product failures. Barriers to either new product development or interorganizational learning will inevitably lead to increased rates of product failure.

Public policy analysts should be careful not to impede new product development and interorganizational learning in efforts to curtail existing product failure. Public policy should strive to increase the number of competitors and increase knowledge transfer between organizations because learning between organizations is an important way to improve medical device reliability. For example, longer and more comprehensive pre-market approval processes and post-market safety enforcement may result in long-term increases of product failure rates because of technological and interorganizational learning barriers, although sanctions may result immediate reductions in product failure rates.

Stricter regulatory approval processes may increase the distraction effect of a competitor's new technology. The value of a competitor's new product introduction increases if regulatory approval is more difficult to obtain. Organizations are more likely to pay attention to a competitor's new product introductions if that competitor devotes a considerable amount of resources and time to getting the product approved. Consequentially, tighter regulatory approval processes encourage firms to discount reports of existing interorganizational product failure experience in favor of reports of a competitor's new product introductions.

This thesis highlights that a key role for the CDRH is to focus on disseminating product information that is clear and easy to compare. Allowing competitors and users to compare product information easily reduces distraction effects and reporting ambiguity effects. A possible project for the CDRH is to develop comparison tables of products within similar product classes and similar uses. The tables can contain both information on known product issues and new innovations.

Managerial contribution. Managers may want to take note of attentional distractions. Managers that wish to improve their products should focus on a competitors' product failure experience and their new product introductions. However, they should provide additional attention to existing product failures because they have a bias towards new product introductions. I discover that managers in failing organizations can inhibit competitors from learning from their product failures. Managers can inhibit interorganizational learning by timing the introduction of a new product to when they report product failures.

Limitations

My findings are subject to several important assumptions. First, I assume that formal reports sent to the FDA represent widespread information diffusion across firms. On a related note, I assume medical device manufacturers pay attention to their competitor's reports of adverse events to the FDA. Because information sensing and gathering functions depend upon resource constraints and the effective utilization of resources, certain firms, such as start-ups or small businesses, may not be aware of the information available within institutions or networks. Future research can put this assumption to

further test by exploring how institutions and networks affect the exchange of adverse event information between firms. Additional research may want to investigate the individual level effects of regulatory specialists in the medical device industry.

A second assumption is that others' new production introductions are unrelated to their current product failures. I mitigate this problem by ruling out multicollinearity problems and investigating only competitors that have both gains in product failure experience and reports of new product introductions at the same time. However, organizations may introduce next generation (revolutionary) products in response to problems in their (evolutionary) existing products. Product level learning and organization learning may also interact. One way organizations learn is by selecting better products and abolishing poor products from a portfolio of medical devices. Future research could mitigate these problems by exploring whether and when new product introductions are responses to failures – that is, firms may innovate around their failures. Another fruitful avenue of research is to explore how product portfolio selection affects organizational learning.

Third, I assume that interorganizational learning is unidirectional in two ways. First, I neglect to model the dyadic relationship between firms. I only observe how firms learn from a competitor's product failure experience, but firms release product failure reports in anticipation that competitors will learn from these reports. Second, I theorize that competitor's reporting delays are partially strategic, but I neglect to account for managers correcting for a competitors' strategic actions. This opens opportunities to connect with game theoretic models about information in learning research.

Fourth, I am the first to model the learning concatenation effects at the interorganizational level. This idea borrows from contagion in individual-level social learning (Burt 1987; Coleman et al. 1957; Conley and Udry 2010; Strang and Tuma 1993). However, my article differs by not specifically highlighting both the network effects of learning and the substitution effects of technology. My data is not sufficiently fine-grained enough to directly observe how each competitor learns from each other. In addition, I also lump medical device substitution effects with controls for interrelated product failure. Refining the concatenation of learning measure is a fruitful avenue for future research. I implore future research to disaggregate learning to fail effects from the interrelatedness of product failure.

Fifth, I argue that the interorganizational learning is very likely given correlations in medical device adverse events. I take the view that correlations in adverse event reports are the artefacts and signatures of underlying cognitive and behavioural learning processes between organizations. In-depth exploration of the underlying mechanisms of how reporting delays affects interorganizational learning should be undertaken in future research.

Finally, I make assumptions about medical device failures. I assume that medical device cost is not important for product failure. However, there are some medical devices where price is clearly important. For example, a magnetic resonance imaging machine is costly and purchasing one of these machines can be an important capital budget decision for hospitals. It would be interesting to investigate if hospitals make do with faulty devices because of product cost and whether this impacts interorganizational

learning from product failure in the medical device industry. I assume that adverse events are socio-technical events, that product design and human error cannot be meaningfully separated. Future research may want to disentangle these processes and determine their separate effects on interorganizational learning.

Future Research

Interorganizational Learning

Research on interorganizational learning is far from complete. Future studies may want to tease out elements of interorganizational experience that lead to differences in learning. Research may also want to unlock the contextual conditions and the type of organizational experience that is required to improve learning due to interorganizational experience. Future research can apply some of the solutions to the challenges of interorganizational product failure experience in the medical device industry to product failure in other dynamic settings.

Reporting Delays

My thesis illustrates caution in drawing conclusions based on product failure experience reported to third-party reporting systems - reporting delays can nearly cancel out interorganizational product failure experience. Future learning research based on secondary data should emphasize the reporting system in which secondary data is gathered.

Studies may want to look at the interorganizational effects of other failure reporting practices. For example, articles may want to highlight how interorganizational learning is affected by reporting clarity, the length of reports, or reporting omissions. Another possible study may look at underreporting of product failure reports at the organizational level.

An investigation of intentional failure report delaying may shed light on unethical organizational behavior (Sullivan et al. 2007). Sullivan et al. (2007) find presence of the effects of unethical behavior in US publically listed firms. They show that firms limit network contact with unethical organizations. Similarly, a possible study is to investigate whether reporting delays affect an organization's choice of competitors they can learn from.

Distractions

The theory I develop in this thesis suggests that interorganizational learning from product failure requires focus. However, distractions may be necessary in some cases. At a theoretical level, Levitt and March (1988) argue that organizations may get stuck in competency traps if their focus is limited to solutions that are close to the problem. Jovanovic and Nyarko (1996) confirm that competency traps can exist using a single agent Bayesian learning model. In the model, they demonstrate that learners may fail to choose better technologies because they perfect what they know how to do and the costs of learning a new technology are high. At a practical level, the literature on disruptive innovation (Christensen 1997) indicates that an organization's technologies can be over-run by a competitor who makes unreliable but cost effective devices because managers fail to pay attention to these inferior technologies. Combined, these all point out that circumstances where distractions may be helpful to learning.

I implore future research to explore distractions. I leave a number of possible routes unexplored. There may be an optimal level of distraction on a scale of distracted-ness, rather than the discrete choice (ie. distracted / not distracted) as I conceived it.

Distractions may persist for a long time in some cases, and may be particularly likely in matrix-type organizations that try to balance multiple goals. The persistent organizational distraction may be an opposing learning deficiency to competency traps, in which the scattered rather than the focused are trapped in suboptimal search. Researchers may want to explore how managers integrate contrasting information about competitors..

Possible avenues to explore distractions are at different levels in the organization and comparison studies of where distractions may occur but do not. Distractions may be widespread in the everyday life of organizations. Anecdotal evidence shows that distractions are relevant in activities other than interorganizational learning to reduce product failure. Earl Bakken, the founder of Medtronic, alludes that product failure distracts innovation. He reflects on the market reaction after the Xytron pacemaker failure and the difficulties Medtronic had in promoting new product introductions in the following excerpt from his autobiography. He writes (Bakken 1999: Pg. 52),

> *"But you learn from your setbacks and failures — more from them, in fact, than from your successes. We brought on a large number of additional materials scientists to make sure the Xytron problem didn't happen again; and, in spite of the loss of confidence and customers, we forged ahead with new products.* ***In fact, the Xytron issue unfortunately overshadowed some of the important advances our scientists and engineers were pushing through during the period.*** *Among these were the Xyrel system, our first rate-programmable, lithium-powered, implantable pacemaker, introduced in 1977; the Spectrax SX, a multiprogrammable pacemaker that gave physicians the ability to adjust its function in response to a patient's changing requirements without additional surgery, implanted for the first time the following year; and the Byrel system, the first A-V sequential pacemaker, introduced in 1979."*

The quote suggests that product failure is a distraction for product innovation. The highlighted section illuminates that competitors and users were more concerned with the poor reliability of Medtronic past failures than Medtronic's new product introductions.

Future research should address the larger question of the usefulness of distractions as a tool for marketing. My results, and Earl Bakken's experience, show an interesting twist to interorganizational learning. Organizations that experience unreliable products may not get rewarded for product development, but product development may be a competitive ruse for unreliable products. Consumer psychology may explore how timing of products may move attention from existing product failure to product innovation. On a related note, organizations may use distractions to blur product categorization in the market (Porac et al. 1995). Organizations may promote state-of-the-art components and downplay unreliable components in a device if their competitors do not innovate.

Conclusion

The linear accelerator-caused death of Scott Jerome-Parks matters. This thesis demonstrates that learning from a competitor's product failure experience is an important way to reduce serious injury and death due to medical device unreliability. I find that firms learn to reduce product failure rates from their own product failure experience 6.4 times faster than from others' product failure experience. However, immediate access to a competitor's product failure reports can significantly reduce the rate of product failure if they do not have their own product failure experience to draw upon. As a consequence, I illustrate a peculiar industry dynamic. Firms have incentives to learn from a competitor's product failure experience and it may be a key way to increase organizational performance. Contrastingly, competitors have incentives to delay reporting their own product failure to maintain a competitive distance in medical device reliability.

I validate the theory that a competitor's delays in reporting product failure plays a role in manufacturing and product design in the medical device industry. The effect of a competitor's reporting delays on product failure rates are not obvious. In general, a competitor's reporting delays increases product failure rates. I find that product failure rates increase by 0.7% and US healthcare costs due to hospital stays by $1.5 million if one competitor delays reporting product failure by one day. Additionally, reporting delays significantly decrease the effect of interorganizational product failure experience on product failure rates. However, reporting delays decrease product failure rates when there are small gains in interorganizational product failure experience, but increase

product failure rates with large gains in interorganizational product failure experience. The differing reporting delay effects between small gains and large gains highlights counteracting competitive dynamics. Firms should learn from a competitor's slowly reported product failures because (1) the delay suggests that investigators took the time to understand the failure and (2) the delay signals either strategic concealment or impactful product failures. However, the interorganizational learning effects of immediate notification outweigh the reporting clarity and strategic signalling effects for large gains in interorganizational product failure experience. By illustrating that reporting delays matter, I stress that the process of reporting experience is just as important as experience itself in organizational learning.

I show that interorganizational learning to reduce product failure rates from a competitor's existing product failure experience depends on learning from a competitor's new product introductions in the medical device industry. I show that new product introductions have both advantageous and disadvantageous effects on the rate of product failure. Firms immediately reduce product failure rates when competitors' introduce new products because of knowledge transfer and organizational attention to new product introduction reports. Counter intuitively, a competitor's new product introductions sometimes act as distractions to learning from their product failure reports. I uncover that when medical device firms are learning from a competitors' existing product failure experience, they increase their rate of product failure by 1.1 % when a single competitor introduces a new product to the market. Additionally, I find that innovative firms are less likely to be distracted because these organizations already pay close attention to their

competitor's new product introductions. In demonstrating the distraction effect, I highlight the need to account for organizational attention in interorganizational learning research.

These results may generalize to other industries where product failure, product development, and product failure reporting systems are common. For example, the software development and the pharmaceutical industries may learn from a competitor's product failure experience by investigating government reports of failed drug trials[13] or electronic discussion-boards of a competitor's product flaws. The importance of a competitor's product failure experience varies with the rate of industry product innovation and accessibility of product failure reports.

Finally, I move organization learning theory one step closer to understanding how organizations learn from others' product failures. By focusing on product failure, product failure reporting, and new product introductions in the medical device industry, I highlight that failure reporting and product innovationare essential to understanding how organizations learn from failures in others' existing products.

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[13] The US government maintains a publically available database of clinical trials at http://clinicaltrials.gov/.

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Appendix

Appendix A.1

Advantages and disadvantages of learning from others' product failures

	Advantage	**Disadvantage**
Learning from interorganizational product failure experience	H1 Mechanism: decrease product failure rates 1. Increase knowledge transfer mechanisms 2. Cost reduction 3. Reputation management 4. Organizational renewal 5. Less inertia and less threat-rigidity 6. Less prone to attentional biases	1. Inability to attend to interorganizational product failure experience 2. User workarounds 3. Socio-technical causes 4. Competitor's distort negative information 5. Product failures interact
Competitor reporting delays	H2 Mechanism: decrease product failure rates 1. Reporting clarity takes time 2. Competitor can spend more attention to failure 3. Competitor has time to coordinate attention to failure 4. Competitor has deep learning of product failure 5. Long reporting delays attract attention and regulatory action 6. Long reporting delays signals significant competitor product failure	H3 Mechanism: moderates the effect of interorganizational product failure experience on product failure rates 1. Decreases product failure processing speed 2. Poor choice of social referent 3. Poor inferences 4. Difficult to distinguish which competitor actions caused failure in third-party reporting system 5. Selective attention to recent reports 6. Increases complexity of learning 7. Increases need for more information 8. Weakens regulatory efforts
Competitor's new	H4 Mechanism: decrease	H5 Mechanism: moderates the

product introductions	product failure rates	effect of interorganizational product failure experience on product failure rates
	1. Builds absorptive capacity for sharing reports and solving product failures 2. Reports transfer codified knowledge of product design 3. Attracts attention 4. Improves existing devices 5. FDA's pre-market approval encourages product reliability	1. Distraction 2. May cause postponement of own device improvements 3. Sequential attention to more salient competitor outcome 4. Superstitious learning (confusion of outcomes, increased risk of mixing causal associations) 5. Self-serving firms disassociate from competitors with product failure and associate with competitors with new product introductions 6. Incentives for shallow learning

Appendix A.2

Stages of medical device development

There are three stages of medical device development (Ohashi 2006). The first stage is proof of concept which usually involves university research and culminates with substantial patenting of the technology. For example, 26,158 medical device patents were registered at the US Patent and Trademark Office (USPTO) from 1990 through 1996 (Chatterji et al. 2008). The proof of concept stage is usually funded by angel capital, governments, or sometimes corporate research labs. This stage is characterized by limited funding (< $2 million), a long lead time (> 5 years), and significant risk that the device will not be marketable. However, there may be relatively large funding behind the basic science and technology of the device. Usually, early-stage firms have one or two devices in the proof of concept stage.

Stage two is the stage in which devices are further developed, clinically tested, and granted regulatory approval. This stage is often funded by venture capital (early to late stage), corporate venture capital, and large firms. Funding for this stage is a magnitude larger (< $50 million) than stage one, but the time spent in this stage is shorter (> 14 months). In 2007, the average venture capital (VC) deal size was $14.6 million, a 64% increase on 2004 (Young 2008). As well, 302 medical devices firms received VC funding in the first 9 months of 2008 (Burkhardt and Tardio 2008). The total value of US VC funding in 2007 was $3.7 billion (Young 2008).

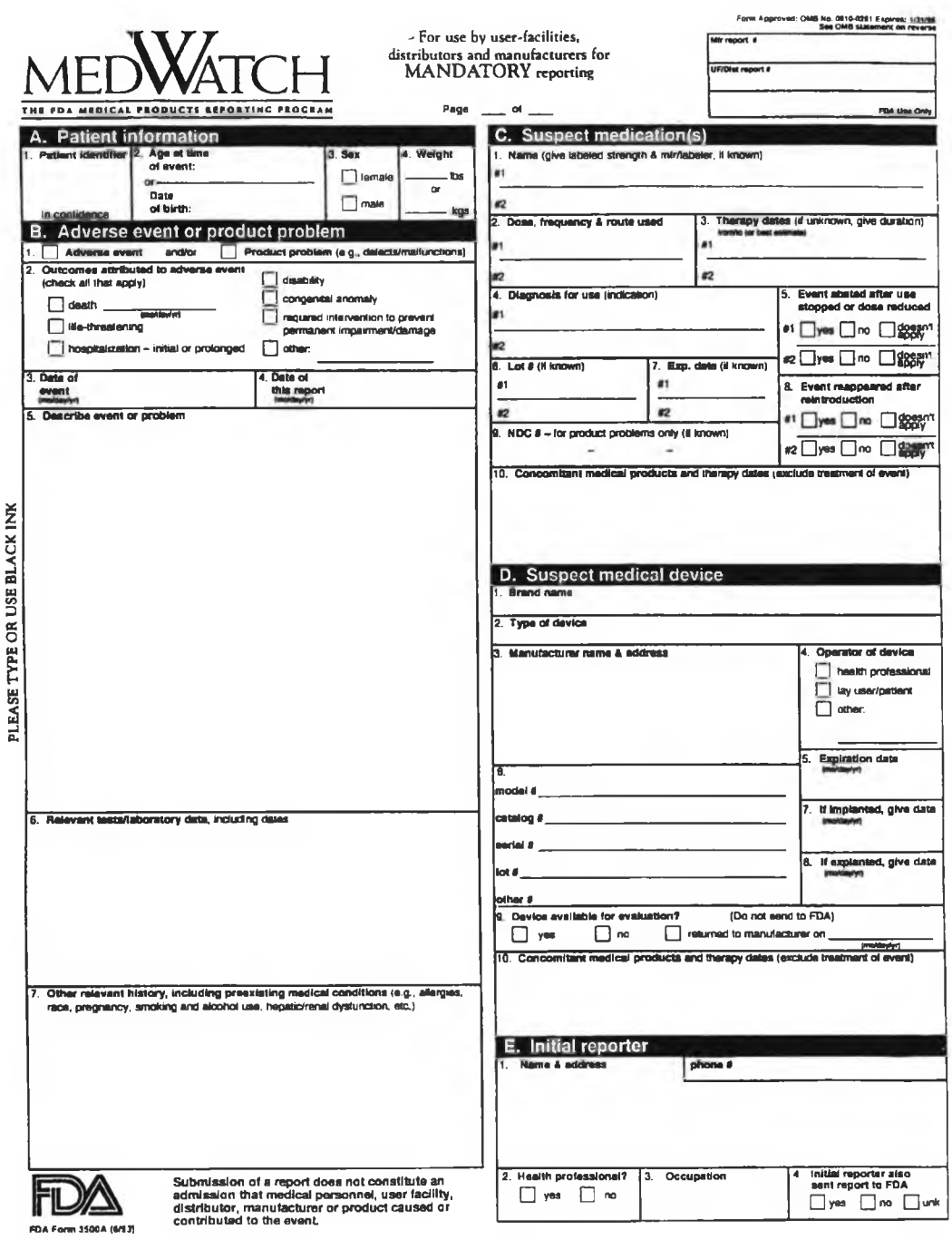
The third and final stage is marketing and distribution. Around the time of regulatory approval, a medical device firm or the rights to a device are often acquired

through a merger and acquisition process (Ohashi 2006). Public firms use equity markets to raise capital for such acquisitions. In 2007, about $1.5 billion was raised in public equity offerings of medical device firms and $4.9 billion in convertible debt financing (Young 2008). Firms may seek an initial public offering (IPO) through a capital market exchange, especially if they possess a platform device. However, IPOs are rare. In 2006 and 2007, there were only 13 IPOs (Young 2008). The 13 IPOs in 2007 were valued at $1.1 billion, although this is highly skewed towards two firms TomoTherapy $201m; Accuracy $187m). Funding for this stage is significantly larger than stage two (< $1 billion) and the time spent is considerably shorter, depending on market demand and device manufacturing.

FIGURE 26
Stages of medical device firms

Appendix A.3

Adverse event report



MEDWATCH
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

- For use by user-facilities, distributors and manufacturers for MANDATORY reporting

Page ___ of ___

Form Approved: OMB No. 0910-0291 Expires: 1/31/98
See OMB statement on reverse

Mfr report #

UF/Dist report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. Patient information

1. Patient identifier — in confidence
2. Age at time of event: — or — Date of birth:
3. Sex: ☐ female ☐ male
4. Weight: ____ lbs or ____ kgs

B. Adverse event or product problem

1. ☐ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
   - ☐ death ____ (mo/day/yr)
   - ☐ life-threatening
   - ☐ hospitalization – initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☐ other: ____
3. Date of event (mo/day/yr)
4. Date of this report (mo/day/yr)
5. Describe event or problem
6. Relevant tests/laboratory data, including dates
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1 ____ #2 ____
2. Dose, frequency & route used
   #1 ____ #2 ____
3. Therapy dates (if unknown, give duration) (mo/day/yr or best estimate)
   #1 ____ #2 ____
4. Diagnosis for use (indication)
   #1 ____ #2 ____
5. Event abated after use stopped or dose reduced
   #1 ☐ yes ☐ no ☐ doesn't apply
   #2 ☐ yes ☐ no ☐ doesn't apply
6. Lot # (if known)
   #1 ____ #2 ____
7. Exp. date (if known)
   #1 ____ #2 ____
8. Event reappeared after reintroduction
   #1 ☐ yes ☐ no ☐ doesn't apply
   #2 ☐ yes ☐ no ☐ doesn't apply
9. NDC # – for product problems only (if known)
   – –
10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address
4. Operator of device
   - ☐ health professional
   - ☐ lay user/patient
   - ☐ other: ____
5. Expiration date (mo/day/yr)
6. model # ____ catalog # ____ serial # ____ lot # ____ other # ____
7. If implanted, give date (mo/day/yr)
8. If explanted, give date (mo/day/yr)
9. Device available for evaluation? (Do not send to FDA)
   ☐ yes ☐ no ☐ returned to manufacturer on ____ (mo/day/yr)
10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Initial reporter

1. Name & address
   phone #
2. Health professional? ☐ yes ☐ no
3. Occupation
4. Initial reporter also sent report to FDA ☐ yes ☐ no ☐ unk

FDA

FDA Form 3500A (6/93)

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Medication and Device Experience Report
(continued)

Refer to guidelines for specific instructions

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service • Food and Drug Administration

Page ___ of ___

FDA Use Only

F. For use by user facility/distributor–devices only

1. Check one ☐ user facility ☐ distributor
2. UF/Dist report number
3. User facility or distributor name/address
4. Contact person
5. Phone Number
6. Date user facility or distributor became aware of event (mo/da/yr)
7. Type of report ☐ initial ☐ follow-up # ___
8. Date of this report (mo/da/yr)
9. Approximate age of device
10. Event problem codes (refer to coding manual) patient code ___ – ___ – ___ device code ___ – ___ – ___
11. Report sent to FDA? ☐ yes ___ (mo/da/yr) ☐ no
12. Location where event occurred ☐ hospital ☐ home ☐ nursing home ☐ outpatient treatment facility ☐ outpatient diagnostic facility ☐ ambulatory surgical facility ☐ other: ___ (specify)
13. Report sent to manufacturer? ☐ yes ___ (mo/da/yr) ☐ no
14. Manufacturer name/address

G. All manufacturers

1. Contact office – name/address (& mfrng site for devices)
2. Phone number
3. Report source (check all that apply) ☐ foreign ☐ study ☐ literature ☐ consumer ☐ health professional ☐ user facility ☐ company representative ☐ distributor ☐ other: ___
4. Date received by manufacturer (mo/da/yr)
5. (A) NDA # ___ IND # ___ PLA # ___ pre-1938 ☐ yes OTC product ☐ yes
6. If IND, protocol #
7. Type of report (check all that apply) ☐ 5-day ☐ 15-day ☐ 10-day ☐ periodic ☐ initial ☐ follow-up # ___
8. Adverse event term(s)
9. Mfr. report number

H. Device manufacturers only

1. Type of reportable event ☐ death ☐ serious injury ☐ malfunction (see guidelines) ☐ other: ___
2. If follow-up, what type? ☐ correction ☐ additional information ☐ response to FDA request ☐ device evaluation
3. Device evaluated by mfr? ☐ not returned to mfr. ☐ yes ☐ evaluation summary attached ☐ no (attach page to explain why not) or provide code: ___
4. Device manufacture date (mo/yr)
5. Labeled for single use? ☐ yes ☐ no
6. Evaluation codes (refer to coding manual) method ___ – ___ – ___ – ___ results ___ – ___ – ___ – ___ conclusions ___ – ___ – ___ – ___
7. If remedial action initiated, check type ☐ recall ☐ repair ☐ replace ☐ relabeling ☐ other: ___ ☐ notification ☐ inspection ☐ patient monitoring ☐ modification/adjustment
8. Usage of device ☐ initial use of device ☐ reuse ☐ unknown
9. If action reported to FDA under 21 USC 360(f), list correction/removal reporting number:
10. ☐ Additional manufacturer narrative and/or 11. ☐ Corrected data

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Appendix A.4

Learning approaches

		Difference with present context	
Study	**Past specification**	**Past**	**Present**
Product-level learning in manufacturing			
Airframe production studies (Asher 1956; Benkard 2000; Wright 1936) Liberty shipbuilding production studies (Argote et al. 1990; Thompson 2001)	Dependent variable: Unit cost Independent variable: Cumulative experience	Manufacturing process improvement Stable environment - Few product changes - Single product - Few competitors - Long industry history Rate of failures tends to zero with experience	New product development and process improvement Dynamic environment - Many device changes - Portfolio of devices per firm - Many competitors - Short industry history Rate of failures may be constant
Learning from failure: Analyzing failure rates			
1.Baum and Dahlin (2007) 2.Haunschild and Sullivan (2002) 3.Rhee and Haunschild (2004) 4.Madsen (2009)	Dependent variable: Organizational failure rates: (Accident costs / operating miles; # of accidents / 100,000 departures; # of accidents; probability of failure) Independent variable: Cumulative accident experience	1.Railway equipment accident reports 2.Airline accident and incident reports 3.Reports of product recalls of US automakers 4.Coal-mining accident reports 5.Reports of failed rocket launches	Process of reporting reports and regulatory involvement Underreporting (secretive competitors)

5. Madsen and Desai (2010)		Stable environment - Few product changes - Single product - Few competitors - Long industry history Failures as counts	Dynamic environment - Many device changes - Portfolio of devices per firm - Many competitors - Short industry history Failure as change
Learning from failure: Analyzing likelihood to fail			
Kim and Miner (2007) Kim et al. (2009)	Dependent variable: Hazard rate of bank failure Independent variable: Cumulative experience	Failure of FDIC-insured commercial banks is impactful	Product failures numerous and localized impact
Interorganizational learning			
Ingram and Baum (1997); Ingram and Baum (1998)	Dependent variable: Hazard rate of hotel failure Independent variable: Cumulative operating experience	Failure of hotel chain impactful	Product failures numerous and localized impact
Irwin and Klenow (1994)	Dependent variable: Price Independent variable: Cumulative output	Industry-level and DRAM chips are commodities driven by process improvements (Moore's Law)	New product development and process improvement Heterogeneous products

Appendix A.5

Summary of Findings

Statement of Hypothesis	Support	Post-hoc Findings
1. Increases in a competitor's product failure experience will lead to decreases a firm's future rate of product failure.	Support	Medical device firms use more product failure experience when product failure rates increase. Across sector interorganizational learning is significant in 8 medical device sectors, however there is significant variance across sectors. Within sector interorganizational product failure experience is significant, but has less effect than across sector interorganizational product failure experience. Recent interorganizational product failure experience reduces product failure rates more than past experience.
2. A firm's product failure rates will decrease if a competitor takes longer to report product failures.	Partial support	Hypothesis two is supported with small gains, but not supported with large gains in interorganizational product failure experience. Organizations benefit from across sector competitor reporting delays when the incidence of product failure is low within their own sector. A competitor's reporting delays as little effect on interorganizational learning within sectors, however it does increase product failure rates in general hospital and orthopaedic.
3. Reporting delays will moderate the effectiveness of interorganizational learning	Support	Reporting delays partially moderate small gains, but fully moderate large gains in interorganizational product

from others' product failures, such that an organization learning from others will be less likely to reduce its own rate of failures when reporting delays are longer and more likely to do so when reporting delays are shorter.		failure experience. Firms with the 10 % lowest product failure rates (negative product failure rates) are most affected by reporting delays. Medical device firms use past interorganizational product failure experience if competitors delay reporting more recent failures.
4. A firm's product failure rates will decrease with increases in competitor's new product introductions.	Support	The two largest sectors, general and plastic surgery and general hospital, significantly benefit from across sector competitor new product introductions.
5. Distractions from the simultaneous occurrence of a competitor's new product introductions and failure reports will moderate the effectiveness of interorganizational learning from others' product failure experience. That is, an organization learning from others' product failures will be less likely to reduce its own incidence of failure with more reports of others' new product introductions and more likely to do so with fewer reports of others' new product introductions.	Support	Not innovative firms are, but innovative firms are not distracted by a competitor's new product introductions. Firms with the 10 % highest and 10 % lowest product failure rates are most affected by distractions. Distractions occur even if existing products and new products comes from the same competitor. A competitor's new product introductions are distracting across sectors for medical device firms in sectors with a large incidence of product failures, but a competitor's new product introduction within sectors are not distracting and only benefit medical device reliability.
Controls / additional findings		
CDRH-related		
MDUFMA significantly increased product failure reporting. Overall increase in product failure rates not due to two most unreliable devices - drug-		

eluding coronary stents or X-ray angiography.
MDUFMA correlate negatively with competitor's new product introductions.
Regulations do not have a significant impact on reducing the rate of adverse events on average.
MDUFMA increased product failure rates for the firms with decreasing product failure rates. MDUFMA had no impact on the firms with increasing product failure rates.
Firm-related
A firm's own new medical device introductions do not affect its rate of product failure.
Product failure complexity does not decrease the product failure rate.
There is significant variance in intraorganizational learning between sectors, but medical device firms use their own gains in product failure experience more so in larger medical device sectors than in small sectors.
Recent product failure experience reduces product failure rates faster than past experience.
Devices in general and plastic surgery and ophthalmic have higher product failure rates than average, whereas devices in general hospital have lower product failure rates than average.
Manufacturers from China, Germany, and the United States have significantly lower product failure rates.
Competitor-related
Product failure experience and new product introductions are highly positively correlated.
Reporting delays correlate negatively with interorganizational product failure experience.
Death caused by a competitor's product triggers a decrease in the incidence of adverse events for medical device firms.

* Results stay the same with the exclusion of outliers, lack of distributional assumptions, and sample selection bias.
** Results are generalizable to all medical device firms registered with the CDRH (98,576 firm-year observations).

Appendix A.6

Summary of Contributions

Focus	Theoretical Contribution	Regulatory and Policy Contribution	Managerial Contribution
Inter-organizational learning from product failure experience	*Contribution:* First study to show interorganizational learning from others' product failure experience.	*Existing assumption:* Only considers reducing medical device failure through tougher regulatory intervention, more attentive medical staff, and increasing hospital safety procedures. *Contribution:* Show that interorganizational learning at the manufacturing firm is an important and neglected way to mitigate medical device adverse events.	*Contribution:* Show that managers should learn from a competitor's product failures.
Regulatory process of product failure reporting	*Existing assumption:* Considers the failure reporting process negligible relative to failure itself. *Contribution:* Provide evidence that learning from interorganizational product failure experience depends on the regulatory reporting process (ie. competitor reporting delays to CDRH).		

Competitor reporting delays	*Existing assumption:* Interorganizational learning studies assume that outcomes quickly follow actions. Simulation studies that specifically address delays focus on intraorganizational processes. *Contribution:* Combine competitor reporting delays with interorganizational learning. Bridge interorganizational learning and intraorganizational delays literature with learning from small losses studies. Illustrate a timing trade-off between intraorganizational learning from product failure and interorganizational learning from product failure.	*Contribution:* Show that regulators should balance the need for rapid diffusion of product failure reports with need for accurate reports. Underscore that regulators should develop emergency investigation and report dissemination procedures for large gains in product failure experience.	*Contribution:* Discover that managers are better off to learn from large gains in interorganizational product failure experience and to wait if their competitors only have small gains in product failure experience. Show that managers should learn from their firms own product failures if the organization has its own product failure experience, rather learn from competitor's product failure experience.
Competitor new product introductions	*Existing assumption:* Interorganizational learning from failure is treated independently from learning from competitor new product introductions and mostly emphasizes learning of manufacturing techniques. The impact of product design on learning has mixed results. *Contribution:* Show supportive learning effects of interorganizational learning of competitor's product design when own products perform badly.	*Existing assumption:* Main focus is on reducing current medical device adverse events. *Contribution:* Provide evidence that impediments to new product introductions and interorganizational learning in efforts to curtail existing medical device adverse events may increase	*Contribution:* Argue that managers should provide extra attention to a competitor's product failure experience because they have a bias towards competitor's new product introductions.

	Demonstrate that learning from a competitor's new product introductions is a distraction to learning from interorganizational product failure experience. Emphasize organizational attention to different experience. Discover that distractions are more likely for not innovative firms because they do not regularly update expectations of a competitor's technologies and are more reactive to a competitor's technologies.	future medical device adverse events. Explain that stricter regulatory approval processes may increase the distraction effect of a competitor new product introduction.