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ABSTRACT

Liability laws designed to compensate for harms caused by defective products may also affect innovation. We examine this issue by exploiting a major quasi-exogenous increase in liability risk faced by US suppliers of polymers used to manufacture medical implants. Difference-in-differences analyses show that this surge in suppliers' liability risk had a large and negative impact on downstream innovation in medical implants, but it had no significant effect on upstream polymer patenting. Our findings suggest that liability risk can percolate throughout a vertical chain and may have a significant chilling effect on downstream innovation.

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1 Introduction

The relationship between risk, uncertainty and investments is fundamental to understanding economic growth (inter alia, see Bernanke, 1983; Bloom, 2009; Fernandez-Villaverde et al. 2015). A major source of risk faced by firms arises from product liability laws that are designed to protect customers from defective or dangerous products (Jarrell and Peltzman, 1985; Hay and Spier, 2005). In 2016, product liability cases accounted for roughly 70 percent of the personal injury civil cases filed in US district courts. These cases often make the headlines because of their large damage awards. For example, General Motors recently paid about $2.5 billion in penalties and settlements in cases involving faulty ignition switches linked to 124 deaths and 275 injuries. Recently, advances in fields such as artificial intelligence and sophisticated robotics (e.g., driverless cars, robot-assisted surgeries, and robot caregivers for the elderly and disabled) have rekindled lively policy debates over whether existing liability systems constrain technological progress and present an opportunity to redesign liability rules.[1]

In an influential book examining more than 100 industries across major trading nations, Porter (1990) recommends "a systematic overhaul of the U.S. product liability system," arguing that in the U.S., "product liability is so extreme and uncertain as to retard innovation." This idea that liability is high and has a negative effect on firms' willingness to develop new technologies is common in the legal literature (e.g., Huber, 1989; Parchomovsky and Stein, 2008; Priest, 2011); has shaped high-profile legal cases (e.g., the 2007 Riegel v. Medtronic Supreme Court case); and often underlies the arguments by proponents of tort reforms.[2]

Despite its intuitive appeal, this widely-adopted negative view does not seem to find support in the scarce empirical evidence linking liability risk and innovation. If anything, the two large-sample empirical studies examining this issue—Viscusi and Moore (1993) and Galasso and Luo (2017)—show that, on average, higher liability risk induces higher R&D spending and more patenting. Theoretical frameworks in both studies show that the impact of liability risk on innovation depends on the characteristics of

[1] Indeed, in February 2017, the European Parliament adopted—by a large majority—a resolution containing recommendations for EU-wide legislation to regulate "sophisticated robots, bots, androids and other manifestations of artificial intelligence" and to establish legislative instruments related to the liability for their actions (European Parliament, 2017).

[2] For example, in August 2017, the American Tort Reform Association (ATRA) filed an amicus brief in the Massachusetts case of Rafferty vs. Merck, arguing that excessive liability risk "would substantially disrupt innovators' ability to invest in further innovation and their incentive to innovate."

the technologies and the economic environment. In particular, while liability risk may chill innovation due to higher costs, it may also incentivize the development of risk-mitigating technologies and safer product designs that reduce the likelihood of injuries.

While the theoretical ambiguity and the general lack of empirical support suggest that wholesale scaling back of the liability system may not be the appropriate policy, a natural question arises: *Are there conditions under which the product liability system is likely to generate unintended, negative effects on innovation?* Identification and examination of such conditions can offer useful information to policy makers. This paper provides new insights in this direction by characterizing and empirically analyzing an environment in which an increase in liability risk had a substantial negative effect on innovation. Specifically, exploiting a quasi-exogenous surge in liability risk that affected medical implants in the early 1990s, we show that when large, common suppliers face high uncertainty about liability, the result may be a large decline in downstream innovation.

Implants are medical devices placed inside or on the surface of the body, such as replacement joints, intraocular lenses, fixation devices, and heart valves. The implantable device market is large and innovative and accounts for roughly 25 percent of total medical device sales (Lind, 2017), 20 percent of medical device patenting, and about 60 percent of Food and Drug Administration (FDA) Class III device applications.[3] Medical implants are manufactured using biomaterials that are direct or modified applications of common materials such as metals, polymers and ceramics. These raw materials are often produced by large companies that supply to a wide range of sectors in the economy. During the 1970s and 1980s, large firms, such as DuPont and Dow Chemicals, were the dominant suppliers of polymers and silicone used in many implants, including prostheses, body tissues, pacemakers, and heart valves (Aronoff, 1995). The standard policy for these large companies was to not withhold materials from the medical sector and to warn device producers that suppliers were not responsible for testing and determining the safety of implants (Feder, 1994; Kerouac, 2001).

In the late 1980s, a series of unexpected and widespread problems arose with temporomandibular joint (TMJ) jaw implants and silicone breast implants. Vitek, the leading producer of TMJ implants

[3] Class-III devices are devices used to support or sustain human life; devices of substantial importance in preventing impairment of human health; or devices that present a potential, unreasonable risk of illness or injury.

at the time, filed for bankruptcy in 1990, thus inducing a large number of TMJ implant recipients to file lawsuits against DuPont, which was the 'deep-pocket' polymer supplier of Vitek. During the same time period, a leading manufacturer of silicone breast implants also filed for bankruptcy, and silicone suppliers were named as defendants in numerous lawsuits (Feder, 1994). We present a variety of evidence based on industry accounts, congressional hearings, field interviews, courts dockets and media mentions, documenting how Vitek's bankruptcy in 1990 and the subsequent TMJ and breast implant litigations dramatically raised liability concerns for all material suppliers (not just DuPont) selling to all implant manufacturers (not just the two types of devices directly involved in these litigations). The focus of our analysis will be the impact that this surge in upstream suppliers' liability risk had on medical implant innovation overall.

To illustrate the key mechanism at work, we propose a simple model in which innovation can take place at both the upstream and the downstream stages of a vertical chain. In our model, an upstream supplier sells a homogeneous and necessary input to multiple downstream markets. We show that when serving one of the markets generates a high liability risk for the upstream supplier, it may choose to withdraw from (i.e., foreclose) the risky downstream market. This would have a strong negative impact on downstream firms' profits and innovation incentives in the foreclosed market. At the same time, when the foreclosed market accounts for only a small fraction of upstream revenues, the upstream supplier's innovation incentives are only marginally affected.

Our empirical analysis focuses on the impact of this surge in liability risk on implant technologies, using non-implant technologies as the control. Our main sample includes the universe of granted medical device patents applied for at the United States Patent and Trademark Office (USPTO) between 1985 and 1995. We develop a textual analysis algorithm to identify patents related to implant technologies, exploiting the written description of the invention. We then use the detailed USPTO classification system to identify a set of implant subclasses—i.e., technological subclasses containing a large fraction of implant patents.

We present estimates from a series of difference-in-differences regressions that compare patenting in implant subclasses (treatment group) against patenting in other medical device subclasses (control group) before and after the increase in upstream liability triggered by Vitek's 1990 bankruptcy. Im-

portantly, we exclude patenting related to TMJ and breast implants and focus on the impact on other implant technologies.

Our main finding is that medical implant patenting decreased by 36 percent relative to patenting in other medical device technologies after 1990. We show that this decline was not driven by differential patenting trends in implant and non-implant subclasses before 1990. Dynamically, the decline started immediately in 1990 and grew larger over time. The increasing magnitude is compatible with implant innovators steadily reducing their patent applications, as an increasing number of polymer and silicone suppliers withdrew from the market.

To control for confounding factors—such as demand and technology trends differently affecting implant and non-implant innovation—and to isolate alternative mechanisms such as a greater concern about lawsuits among implant producers themselves and a potential decline in the demand for implant devices, given the failures of TMJ and breast implants, we subject the data to a variety of additional tests. In particular, we present triple-differences regressions that use patents by foreign firms as the benchmark. Industry reports suggest that foreign implant producers were less affected by the supply disruption than US firms were because they had greater access to foreign polymer suppliers; at the same time, both should be subject to similar shocks to demand, direct liability concerns, and other trends unrelated to our natural experiment. The triple-differences estimates show that, in line with our baseline result, implant patenting by US firms experienced a significant decline, even relative to foreign firms.

We examine the extent to which our finding is driven by firms that could reallocate R&D resources from implant to non-implant technologies. Our estimates suggest that even if such within-firm substitution took place, its influence was likely to be small, implying an overall decline in medical device innovation. We also show that the decline in implant patenting appears to be across the board: the estimated effect is negative and significant across firms of different sizes and patents of different values. Furthermore, we confirm the significant decline in implant technologies, relative to non-implant technologies, after 1990, using FDA device approval data as an alternative measure of innovation. This suggests that the relative decline in implant innovation takes place both at the early invention stage and at the commercialization stage.

Having documented a large and significant decline in implant innovation, we then explore what

happened to innovation by upstream suppliers of polymers used in medical implants. We find no evidence of a negative impact on upstream innovation, even for DuPont. This is consistent with our theoretical model and confirms that the innovation incentives of these large firms were driven by the aggregate demand from multiple downstream markets.

Our results show that an unexpected increase in the liability risk faced by upstream suppliers could have a substantial negative impact on downstream innovation. A back-of-the-envelope calculation, based on estimates by Grennan and Swanson (2017), suggests that the total welfare loss was at least $4.1 billion per year. To restore the supply incentive of material producers, Congress passed the Biomaterials Access Assurance Act (BAAA) in 1998. This Act exempted material suppliers from liability risk as long as they were not engaged in the design and production of the implants. A precise estimate of the policy's impact on the industry is outside the scope of this paper, but we provide an illustrative analysis indicating that, relative to non-implant technologies, implant patenting recovered gradually four to five years after the BAAA. This finding suggests that federal exemption regulation could be a useful policy instrument when state product liability laws are insufficient to insulate important players in the value chain from high uncertainty about liability. Moreover, we do not observe an overshoot of implant patenting in the longer run, suggesting that the decline observed in the early 1990s does not capture simply a delayed investment.

Taken together, our findings show that liability risk can percolate throughout an industry's vertical chain and may have a significant chilling effect on downstream innovation. The channel we document is rather general: large suppliers of general-purpose inputs interacting with many downstream industries may restrict their supply to segments in which liability risk and uncertainty are the highest. In particular, they may do so if (i) the extent of harms and their probabilities are difficult to predict; and (ii) many downstream innovators are small and are likely to resort to bankruptcy when liability claims exceed the value of the firm. Nascent domains such as artificial intelligence and robotics, for which start-up innovation can be critical, are natural settings in which these concerns may emerge. More broadly, our paper provides new evidence for how the tort system may affect innovation incentives and suggests that these policies should be designed with such dynamic effects in mind (Finkelstein, 2004).

The paper is organized as follows. Section 2 reviews the literature. Section 3 provides background

information on the US medical implant industry and the 1990 shift in liability risk faced by upstream material suppliers. Section 4 presents a motivating theoretical framework, and Section 5 describes the data and our empirical approach. Section 6 presents the empirical results linking liability risk to innovation in medical devices. Section 7 studies the upstream effect of liability risk on innovation in polymers. Section 8 discusses welfare and policy implications, and Section 9 concludes.

2 Related literature

We are aware of only two empirical studies in economics and management linking liability and innovation: Viscusi and Moore (1993) and Galasso and Luo (2017).[4,5] In their pioneering work, Viscusi and Moore (1993) examine the relationship between product liability insurance costs for manufacturers and their R&D investments. Theoretically, higher liability decreases R&D because of higher costs, but it also encourages innovation that increases product safety. Using a cross-sectional dataset covering large US firms in the 1980s, Viscusi and Moore (1993) document a strong positive correlation between liability insurance expenditures and firms' R&D intensity, suggesting that, on average, product liability promotes rather than discourages innovation. Galasso and Luo (2017) explore this relationship through a demand channel: how changes in physicians' liability exposure affect their demand for new technologies and, hence, firms' innovation incentives. Theoretically, they also derive off-setting effects: higher liability chills demand for new technologies associated with greater risk but increases demand for risk-mitigating technologies that reduce injuries. Their empirical results support the idea that the positive effect of liability on innovation tends to dominate. Specifically, they show that, on average, states passing tort reforms that decrease physicians' exposure to medical malpractice liability experience a significant decrease in medical-device patenting. Our paper contributes to this line of research by providing new,

[4] In two collections of surveys and case studies, Huber and Litan (1991) and Hunziker and Jones (1994) bring together experts from a variety of sectors of the economy. These essays suggest that the impacts of liability can be context-specific and that systematic empirical evidence is scarce.

[5] The number of theoretical papers on the relationship between liability and innovation is also small. The key question is how different liability regimes (e.g., negligence versus strict liability) affect the rate and direction of innovation. Daughety and Reinganum (1995) study how firms' R&D investment can influence product safety and pricing decisions when product safety is unobservable to consumers, and how different liability regimes affect these choices. Baumann and Heine (2013) argue that punitive damages may be used to offset the competitive pressure that forces innovators to introduce innovations too early, thereby raising buyers' risk of harm. Dari-Mattiacci and Franzoni (2014) study how the adoption incentives of old versus new technologies depend on the due-care standard (for example, whether the standard is uniform across technologies or favors the new technology).

causal estimates of a large chilling effect of liability on innovation and by identifying a novel mechanism—upstream liability percolating through the value chain.

Our paper also contributes to the broader economic literature on product liability, a key question of which is how alternative liability rules affect the incentives to take precautions and to conduct potentially harmful activities (see Shavell (2007) for a survey). Many empirical studies related to this question focus on the link between legal liabilities and medical practice (e.g., Kessler and McClellan, 1996; Currie and MacLeod, 2008; Frakes, 2013; Avraham and Schanzenbach, 2015; and Frakes and Jena, 2016). These studies tend to focus on the liability cost faced by a single party, though two exceptions are Hay and Spier (2005) and Helland et al. (2018), which explicitly consider the allocation of liability cost across a vertical chain.[6] Hay and Spier (2005) study, theoretically, the optimal allocation of tort liabilities between manufacturers and consumers, when consumers are insolvent and their use of a product may cause harms to third parties. They show that even though manufacturer-residual liability can be optimal under certain conditions, a consumer-only liability regime may be preferable when consumers are heterogeneous or possess private information. Helland et al. (2018) argue that when upstream producers' choices, such as pricing, need to be uniform across jurisdictions, imposing higher liability on upstream producers in a small jurisdiction will actually increase the sales of a potentially harmful product. They test this hypothesis by linking physicians' prescription behaviors to state tort reforms shifting liability towards drug companies. Our paper differs from Helland et al. (2018) in its focus on vertical foreclosure and the effect of liability shift on upstream and downstream innovation investments.

Our paper also adds to the literature on the spillover effects of shocks through industry linkages. Barrot and Sauvagnat (2016) and Boehm et al. (2018) are two recent papers that examine the effects of exogenous negative shocks—natural disasters—to suppliers. Both papers find economically large negative spillover effects on their downstream customers, as well as negative horizontal spillover to other suppliers that are not directly affected by the disasters due to strong complementarity of intermediary inputs.[7] At a more aggregate level, a growing number of papers (e.g., Long and Plosser, 1983; and Ace-

[6] There are studies about liability costs involving multiple parties but without explicitly considering a vertical relationship. See, e.g., Currie and MacLeod (2008) for an empirical analysis of joint and several liability.

[7] Our results can also be interpreted as evidence for horizontal spillover: Vitek's bankruptcy negatively affects all other

moglu et al. 2012) explain aggregate fluctuations and business cycles using micro-level shocks through production networks and sectorial linkages.

Finally, our paper is related to studies examining how public policies focusing on achieving social goals other than innovation affect the rate and direction of innovation.[8] In the health sector, Finkelstein (2004), exploiting three policy changes designed to increase the usage of pre-existing vaccines, finds that these policies are associated with a 2.5-fold increase in clinical trials for new vaccines. Acemoglu et al. (2006) find that the introduction of Medicare is not associated with an increase in drug consumption among the elderly; and, consistent with this, they find no evidence of an increase in the approval of new drugs targeting diseases that affect the elderly. Studying the energy and environment sector, Jaffe and Palmer (1997) conclude that environmental compliance standards increase R&D spending at the firm level, but does not necessarily induce inventive output in the form of successful patent applications.

3 Medical implants and their liability risk

The FDA defines medical implants as devices or tissues that are placed inside or on the surface of the body. Typically, implants are prosthetics (i.e., replacements of body parts) but may also deliver medication, monitor body functions, or provide support to organs and tissues. Silicone breast implants, hip replacement joints and artificial heart valves are all examples of implantable medical devices. Implants are produced using synthetic biomaterials that replace or restore function to body tissue (Davis, 2003). Biomaterials are direct or modified applications of common materials (such as metals, polymers, ceramics, and their composites) that can sustain continuous or intermittent contact with body fluids. These common materials are often produced by large companies that supply a wide range of industrial sectors.

TMJ implants are intended to replace (entirely or in part) the temporomandibular joint (jaw). In the 1980s, Vitek was the leading producer of TMJ implants in the US. Its product obtained FDA approval in 1983 after expert panels reviewed a series of scientific reports and clinical trial results. Oral surgeons across the US liked Vitek's product, which quickly became the state-of-the-art device in the field (Schmucki, 1999). Several years later—unexpectedly and despite the initial positive response—

implant producers because of the resulting surge in the liability risk faced by large common suppliers.

[8] Recent studies that examine the effect of policies directly targeted at innovation include Moser and Voena (2012) and Sampat and Williams (2018).

surgeons started to notice widespread problems with Vitek's implants, including fragmentation, bone resorption and delamination. In January 1990, the FDA issued a letter to Vitek advising them to warn surgeons against implanting further devices. In June 1990, Vitek filed for bankruptcy under a deluge of lawsuits.

After Vitek's bankruptcy, implant recipients started to file a large number of lawsuits against DuPont, the polymer supplier for Vitek's implants and a large firm with a 'deep pocket.' A total of 651 lawsuits were filed, involving 1,605 implant recipients and their spouses (Schmucki, 1999). Eventually, DuPont won all suits that went on trial, but the process took ten years and cost the company over $40 million (House of Representatives, 1997). This was a large sum compared to the revenue that DuPont obtained from TMJ implants (a few thousand dollars in total, as each device Vitek produces contained only five cents' worth of DuPont's raw material). Contemporaneously with the TMJ litigation, problems also surfaced with silicone breast implants, with numerous recipients reporting joint soreness and body pain allegedly related to leakages (Czuba, 2016). Again due to widespread litigation, one of the leading implant manufacturers, Dow Corning, filed for bankruptcy in May 1995. Silicone suppliers, including Dow Corning's parent companies—Dow Chemicals and Corning—and other suppliers such as General Electric and Union Carbide, became targets of litigation by implant recipients (Feder, 1994).[9]

The TMJ and breast implant litigations had a tremendous impact on the entire medical implant industry because raw materials producers, including those directly involved in these cases, supplied materials to medical device manufacturers for all sorts of implants, from sutures and fracture fixation devices to pacemakers and heart valves. For 30 years, the common supply policy had been to not withhold materials from the medical sector, even though, for many large firms, the revenue from this sector was negligible in comparison to their revenues from other applications (e.g., automotive, electrical or textile markets). According to Aronoff (1995), the implant market value for polymers accounted for only 0.005% of the total revenues from other industries. A common practice, followed by DuPont since the 1950s, was to state that the materials were not made for medical applications and that medical

[9] At the time of these events, both TMJ and breast implants were classified as Class-II devices, without a stringent requirement of demonstration of safety and effectiveness. In response to emergent safety concerns, the FDA reclassified TMJ devices into Class III—the highest risk category—in 1993 and called for submission of Premarket Approval Applications (PMAs) from all manufacturers of these devices in 1998. For breast implants, the reclassification took place in 1988 and the call for submission of PMAs occurred in 1991.

implant manufacturers would have to rely upon their own independent medical judgment. The old supply policy relied on common law protections for component and raw-material suppliers.[10] DuPont often went a step further and included citations to the relevant scientific literature on types of adverse reactions from finished implants (Schmucki, 1999).

The TMJ and breast implant litigations implied that these industry practices were not sufficient to protect suppliers from disproportionately high liability risk relative to their expected revenue. Following these events, many material producers dramatically changed their policy for supplying permanent implant producers (Service, 1994).[11] DuPont issued a new supply policy (see Appendix 1) by which it refused to sell materials to manufacturers of permanently implantable medical devices and restricted the supply to temporary implants, whereas its old policy remained unchanged for non-implant devices. A number of other major suppliers also exited the market, and, notably, Dow Chemicals and Dow Corning ceased supplying materials to permanent implant producers in 1992.

A comprehensive report commissioned by the Health Industry Manufacturers Association (HIMA) examined the status of the biomaterial market in the early 1990s (Aronoff, 1995). A survey conducted in the study showed that about 60 percent of surveyed suppliers were unwilling to supply medical implants producers and identified the fear of product liability suits as their primary reason. Respondents were explicit about not wanting to find themselves in the same situation as DuPont. Many of the remaining suppliers required purchasers to execute strong indemnification agreements. They also required proof, in advance of sales, that buyers had enough insurance coverage and other assets to honor those agreements (Baker, 1995).

This supply shift had a significant impact on the availability of biomaterials to medical implant manufacturers. The May 20, 1994 hearing of the US Senate Subcommittee on Regulation and Government Information provides a number of testimonies making this point. For example, James Benson,

[10] In particular, the 'component parts' and 'sophisticated purchaser' doctrines stipulate that the suppliers are not liable unless the component or material per se is defective, or the process of integrating them has caused the adverse effect (Kerouac, 2001). The basic rationales are that if the supplier sells a product that has widespread use in many industries, it would have no specialized knowledge of how the buyer will use the product and could not foresee and remedy the potential hazards. Similarly, if the buyer substantially alters the material, the material supplier will not be held liable to the ultimate consumer.

[11] Permanent implants are commonly defined in the industry as devices that stay inside a human body for longer than 30 days.

Senior VP of the Health Industry Manufacturers Association, explained how "*in many cases, there are no alternative suppliers for these materials.*" Other testimonies emphasized that even when alternative existed, the costs required to identify suitable replacements were extremely large. Other statements made in the hearings explained how device companies were responding to these shortages by stockpiling resources that were still available or by signing more onerous contracts with the few suppliers willing to serve the market. Testifiers claimed that these reactions have affected firms' innovation investments by diverting resources away from the development of new products toward finding and securing materials required for current product lines (Aronoff, 1995).

4 Theoretical framework

In this section, we describe a simple model to capture some of the basic features of our empirical setting. The framework illustrates the key channel through which a surge in liability risk faced by an upstream supplier may affect innovation investments in our empirical context. We discuss many of the details that we abstract away in Section 4.2.

An upstream (polymer) producer may develop a new product that can be used by manufacturers in downstream market A (medical implants), as well by many other industries (collectively denoted as a residual large market B). Both the upstream firm and the downstream firms in market A can invest in innovation. For simplicity, we assume that no innovation occurs in market B. In the absence of innovation, the upstream firm sells a 'standard' product in a competitive market and obtains zero profits. Innovation requires a fixed development cost, I^U. If successful, the upstream firm can now sell a new (high-quality) product as a monopolist in both market A and market B. The marginal cost of production for the new product is equal to zero.

Market A is comprised of a continuum of downstream users of mass one. Buying one unit of the upstream input, each user can obtain gross surplus v after sustaining a fixed development cost, I^D. We assume that v is uniformly distributed over the interval $\left[I^D, 1 + I^D\right]$. This implies that when the input is sold at price p, only users for which $v - p - I^D \geq 0$ buy the good, and that the downstream demand

for market A is equal to

$$D^A(p) = 1 - F(p + I^D) = 1 - p.$$

Similarly, we denote the demand curve for market B by $D^B(p) = \theta(1-p)$, where $\theta > 1$. We can think of market B as the collection of θ downstream markets, each with demand $1-p$. The assumption that $\theta > 1$ implies that market B captures a larger share of the upstream firm's business. The upstream firm can charge different prices for different markets. In Section 4.2, we discuss this assumption and examine alternative specifications in which the upstream firm is restricted to serving both markets at the same price.

Profit maximization by the upstream firm yields $p_A = p_B = 1/2$, which is intuitive because both markets have the same price elasticity (Section 4.2 discusses this assumption). Thus, the total profit of the upstream firm is

$$\Pi^0 = \frac{1+\theta}{4}.$$

We now introduce a product liability risk that the upstream firm faces when serving market A. Specifically, we assume that each unit sold in market A generates an expected loss of l for the upstream firm. The simplest way to interpret l is that it captures the expected value of damages that the firm has to pay; i.e., $l = E(d)$, where d is a random variable accounting for both the likelihood of being found liable and the adjudicated amount. At the same time, l may also include additional costs sustained by the upstream supplier, such as litigation costs and the opportunity cost of time and resources, as well as losses due to risk aversion (the variance of d) and uncertainty aversion (inability to specify a unique probability distribution for d), as modeled in Maccheroni et al. (2013). We are agnostic about the exact nature of l, as Vitek's bankruptcy and the subsequent events increased both risk and uncertainty.

Incorporating the liability risk, the upstream firm's objective function in market A becomes $\max_{p_A}(p_A - l)(1-p_A)$, and that for market B does not change.[12] First consider the case in which the liability risk is moderate ($l < 1$) such that it is still profitable to serve market A. The profit-maximizing price in

[12] Theoretically, it is possible that the downstream demand in market A changes when liability changes. For example, because victims of failed implants receive liability payments when they win or settle their lawsuits, consumers' (and, hence, downstream firms') willingness to pay could increase when the upstream firm is held liable for more damages. For simplicity, we assume that demand is invariant. This assumption is not unreasonable in settings like ours because (i) the buyers do not foresee the shock; and (ii) the increased costs for the upstream firm are captured mostly by class-action attorneys or are lost in the form of opportunity costs of time and resources.

market A is $p_A = (1 + l)/2$, and the upstream firm's profits become

$$\Pi(l) = \Pi^0 - \Delta(l),$$

where $\Delta(l) = l(2-l)/4$, the profit difference between the scenarios with and without liability, is increasing in l.

However, if the liability risk is high (i.e., when $l > 1$), no increase in the input price would be large enough to make market A profitable for the upstream firm.[13] The upstream firm is then better off foreclosing market A and focusing only on market B. In this case, the upstream firm's profit will be

$$\pi^B = \frac{\theta}{4}.$$

4.1 Liability risk and innovation incentives

To examine the impact of liability risk on innovation investments, we begin with an analysis of downstream innovation incentives. Because we abstract away from the liability risk directly faced by firms in market A, these firms are affected only through the input price. When the input is sold at price p_A, the total development cost sustained by downstream firms is

$$R^D = I^D \int_{p_A + I^D}^{1+I^D} dx = I^D(1 - p_A),$$

which decreases in p_A. As the liability risk increases, downstream innovation decreases because the input price, $p_A = (1 + l)/2$, increases in l. Thus, fewer firms are actively innovating in the downstream market. Moreover, when $l > 1$, $R^D = 0$ because the upstream firm forecloses market A.

Consider, now, the innovation incentives for the upstream firm. In the absence of product liability risk, innovation investment takes place if

$$\Pi(0) - I^U \geq 0;$$

that is, if $\theta > 4I^U - 1$. In the presence of product liability risk, l, innovation occurs if

$$\max\left\{\Pi(0) - \Delta(l), \pi^B\right\} - I^U \geq 0.$$

[13] The case of a large shift in liability risk ($l > 1$) maps well to our empirical setting because the expected costs faced by the upstream suppliers—including losses due to risk and uncertainty aversion, their opportunity costs of time and resources, plus the possibility of damage awards to compensate for the pain and suffering of implant patients—may well exceed the market value of the focal input (that is, the gross margin of the implant producers after excluding all other costs).

This implies that as long as the profits from market B are large enough (i.e., $\pi^B \geq I^U$ or, equivalently, $\theta > 4I^U$), there will be no change in the upstream innovation activity.

4.2 Implications and discussion

In spite of its simplicity, our model delivers a number of insights into the impact of liability risk on innovation incentives.

First, the theoretical framework shows that, while liability risk related to supplying a specific downstream market may affect upstream innovation incentives, its effect is likely to be limited when the downstream market is substantially smaller than the other markets served by the upstream firm. Empirically, this implies that, in our setting, we should expect a very small change in polymer (upstream) innovation activity, despite the large shifts in liability risk perceived by upstream suppliers in the medical implant (downstream) market.

Second, our model illustrates the rationale behind DuPont's decision to foreclose the medical implant market, which we documented in Section 3. The upstream firm may be able to compensate for the increase in liability risk by charging a higher input price, but if the increase is too large, the supplier is better off focusing on market B and foreclosing the riskier market A completely. Our model, thus, identifies a novel factor—liability risk—that may induce market foreclosure (see Rey and Tirole (2007) for a review of the other mechanisms considered in the literature).

Third, we show that the impact of liability risk may percolate throughout an industry's vertical chain. Even if the direct costs of litigation are incurred only by the upstream firm, the drop in innovation investment could take place in the downstream market.

We intentionally make the above model as simple as possible to illustrate the potential mechanism and effects. The setup abstracts away from a number of details that require discussion. First, we assume that the shift in liability affects only the upstream firm, not the downstream firms operating in market A. This simplifying assumption makes the point that liability risk can percolate throughout the vertical chain starker. A direct increase in downstream liability is likely to reduce the downstream innovation incentives even more.[14]

[14] Vitek's bankruptcy may, indeed, increase the (perceived) liability risk faced by downstream firms directly. We aim to isolate this channel in our empirical analysis.

In our model, when liability risk is sufficiently high, the mechanism through which the upstream supplier protects itself is to foreclose the risky downstream market. In principle, there exist other contractual remedies that could be used to mitigate liability risks. For example, the upstream supplier may demand a stronger indemnification contract from the downstream firms or require larger product-liability insurance coverage. As mentioned in Section 3, suppliers who chose to remain in the market made these arrangements. Introducing these contractual solutions does not change the comparative statics of our model because they reduce downstream firms' margins, which, in turn, discourage innovation. There are a number of potential explanations of why many suppliers in our empirical context did not choose these contractual solutions. The transaction costs of writing complex contracts with many downstream buyers were probably very high relative to the profit margins obtained before the surge in liability risk. Furthermore, parties had to agree on the riskiness of the transaction in order to specify the new contractual terms. This was probably challenging, as uncertainty increased substantially after Vitek's bankruptcy.

In the model, we do not consider the possibility that 'deep-pocket' firms may attract more lawsuits, which may be another important reason that large firms such as DuPont chose to withdraw from the market. The law and economics literature has discussed a number of reasons that large firms are more likely to be targets of litigation (Spier and Sykes, 1995; Spier, 2007). Intuitively, when the plaintiffs have a small probability of winning, they find it profitable only to file claims against defendants able to pay large damage awards. Cohen et al. (2016) provide empirical support for this idea in the context of patent litigation. We can model this effect explicitly by assuming that the risk of litigation increases with the size of the upstream firm's other market B, and this would lead to a higher likelihood of vertical foreclosure with a larger B.

We also assume that the upstream firm can charge different prices in different markets. Interviews with industry practitioners suggest that price discrimination was not common in our context. This is because downstream firms can potentially access the homogeneous inputs in secondary markets, because distribution is often through large wholesalers, and because transaction costs of writing different contracts with a large number of customers are generally high. If we, instead, restrict the input price to be the same across different markets in the model, the incentive to foreclose market A will be even

stronger. This is because a higher uniform price, as a result of the liability risk in market A, will also negatively affect the upstream firm's profitability in its larger market B.

Finally, the basic implications are robust to a number of ways to relax the demand specifications. An interesting extension is to assume that : (i) consumers in the larger market B are less price-elastic than consumers in market A (e.g., $D^B(p) = \theta - p$ and $\theta > 1$); and (ii) the upstream cannot price discriminate. In this extension, even without liability concerns, vertical foreclosure may happen if market B is sufficiently large ($\theta > \bar{\theta} = 1 + \sqrt{2}$). This is a standard result in the theory of multi-market price discrimination: differences in demand elasticities may induce a monopolist to serve only selected markets if it is forced to charge the same uniform price (Robinson, 1933; Tirole, 1988). Adding liability to this setting induces foreclosure even before market B hits threshold $\bar{\theta}$.[15]

5 Data and methods

Our main source of data is the patent record database from the United States Patents and Trademark Office (USPTO). Each patent is classified by the USPTO using the US patent classification (USPC) system, a detailed scheme of classes and subclasses. Classes typically demarcate broad technological boundaries, whereas subclasses delineate technical features within the scope of a class. A class/subclass pair uniquely identifies a subclass within a class (for example, within class 623 "Prosthesis," one can find subclass 623/5.12 "Corneal ring" and subclass 623/10 "Ear or nose prosthesis"). Henceforth, for simplicity, we refer to these class/subclass pairs as subclasses.

The USPTO provides a comprehensive list of the subclasses related to medical devices.[16] Moreover, each patent record indicates the primary subclass to which the patent is assigned. Exploiting this information, we retrieved a total of 227,866 medical device patents that were eventually granted and for which the application date was between 1975 and 2015. These patents span 2,699 unique subclasses.

To categorize subclasses into treatment and control groups, we first identify technologies that are

[15] It is straightforward to show that our results are robust to simply relaxing the assumption that markets A and B have the same price elasticity without introducing uniform pricing because the two markets are independent of each other. Similarly, assuming that pricing is uniform but that market A is more price-elastic than market B, we will also have a case in which liability concerns would be the only reason for vertical foreclosure because the upstream supplier will always supply market A in the absence of liability concerns.

[16] Details are described in www.uspto.gov/web/offices/ac/ido/oeip/taf/meddev.htm.

related to medical implants at the patent level. We use a two-step textual analysis procedure to determine whether a patent is an implant patent. First, from the FDA's product classification database, we retrieve a comprehensive list of device names, each corresponding to a unique product code that identifies a generic category of a device. For each device name, the data provide an "implant flag," indicating whether the FDA considers it a medical implant. In total, the data comprise 6,044 unique device names in 19 medical specialties. Of these, 568 device names in 14 specialties are flagged as implanted devices. From these 568 implanted device names, we construct a dictionary of keywords capturing the underlying device types. Examples of such keywords are: "stent," "knee," "hip," and "catheter."

Second, we develop an algorithm to scan the text of the titles, abstracts, and the first claims for each of the 227,866 medical device patents between 1975 and 2015. We classify a patent as an implant patent if it contains at least one of the keywords in the abovementioned dictionary, together with one of the following terms: "implant," "implanted," "implantable," "implantation," "prosthetic," "prosthesis," and "graft."

On average, about 20 percent of the patents in each subclass are identified as implant patents, but the variance is substantial. In roughly 65 percent of the subclasses, the fraction of implant patents is below 0.1, and in 19 percent, it is above 0.5. We define a subclass as an *implant subclass* if at least 80 percent of the patents belonging to this class are implant patents.[17] This corresponds to the top decile of the distribution of the shares of implant patents across subclasses. Examples of implant subclasses include: 623-2.21 "Cylindrical pins for heart valves" (83 percent implant patents); 623/19.14 "Implantable humeral bone" (97 percent implant patents); and 623/14.11 "Artificial vocal cords" (100 percent implant patents). Examples of subclasses with a minimal fraction of implant patents include: 128/201.21 "Respiratory devices using liquefied oxygen" (0 percent); 602/22 "Orthopedic bandages for fingers" (0 percent); and 606/36 "Surgical instruments for depilation" (3 percent).[18]

[17] We use this threshold approach to take advantage of the extensive expertise at the USPTO. As mentioned above, patents are classified together, based on their technological similarity. Therefore, a patent that is not identified as an implant by our algorithm, but is in a subclass consisting mostly of implant patents, are likely to be either implant patents whose patent texts are not explicitly written as such or inventions that are related to implant technologies and, hence, are potentially affected by our shock.

[18] As additional supporting evidence for our textual analysis, consider the primary patent class 623, titled "Prosthesis (i.e., artificial body members), parts thereof, or aids and accessories therefor," which includes about 18,500 patents classified in 376 subclasses. About six percent of the patents in this class belong to subclasses that include only implant patents. Roughly 60 percent of the patents belong to subclasses in which the fraction of implant patents is greater than

The main sample for our empirical analysis is a panel tracking patenting activities in each of the medical device subclasses for the period 1985-1995. Because of granting delays, we date the patents using their application year rather than their grant year. The 11-year window 1985-1995 has been chosen to capture a symmetric window around 1990, the year in which Vitek went bankrupt. We end our sample in 1995 because of major industry lobbying efforts around that time, which eventually led to the passage of the BAAA in 1998. In Section 8.2, we extend the sample to 2010 for an analysis of the likely effects of the policy response and the longer-run outcomes. To address one of the endogeneity concerns discussed in the next section, we drop three patent subclasses related to TMJ and breast implants from our analysis. The 11-year window includes 46,645 patents, with which we construct the panel dataset of our main sample. The total number of subclasses in our main dataset is 2,696, and the number of observations is 29,656.

Table 1 provides summary statistics of the main sample. On average, there are 1.57 patent applications per year in each of the medical device subclasses in our sample. Figure 1 plots the average number of patent applications in implant and non-implant subclasses during our sample period. The figure shows that patenting in non-implant subclasses grew faster than patenting in implant subclasses. Moreover, the two groups of subclasses started to diverge around 1990. While this figure provides a first look at our main result, we now turn to regression analysis to control for other factors that might also contribute to the differential growth rates between the two groups.

Our analysis also exploits additional information about these patents, including assignee identifiers, country of origin, and the number of citations received. Moreover, we use the FDA device application data as an alternative measure of innovation. We describe these data in Section 6. Finally, we examine whether the increase in liability risk faced directly by upstream suppliers affects upstream innovation in materials. The data used to conduct this analysis are described in Section 7.

5.1 Econometric model

Our analysis exploits the unexpected surge in litigation against material suppliers involved in TMJ and breast implants to identify how changes in the liability risk upstream suppliers face affect the innovation

0.8, and about 95 percent of the patents belong to subclasses in which the fraction of implant patents is above 0.5.

incentives of downstream firms. Following Moser and Voena (2012), our empirical strategy compares changes in innovative activity between 1985 and 1995 across medical device patent subclasses that were affected differentially by the increased liability risk. The dependent variable is the number of patents per USPTO subclass and year:

$$Patents_{c,t} = \alpha + \beta Implant_c \times After1990_t + \delta_t + f_c + \varepsilon_{c,t}, \quad (1)$$

where $Implant_c$ equals 1 if subclass c is an implant subclass; $After1990_t$ equals 1 for every year after (and including) 1990; and δ_t and f_c are year and subclass fixed effects. The coefficient β of the interaction term between $Implant_c$ and $After1990_t$ is the standard difference-in-differences estimator. We cluster the standard errors at the subclass level for all regressions.

The variable $After1990_t$ captures the post-period in which material suppliers faced high uncertainty about liability following Vitek's bankruptcy in 1990. Numerous industry and academic studies that describe the state of the medical implant industry during our study period stress that the industry did not foresee the massive litigation against DuPont and other material suppliers. We confirmed this in an interview with Ross Schmucki, senior counsel of DuPont at the time, who stated: "*This sort of mass tort product liability litigation against a raw material supplier was unprecedented and unexpected by the medical device industry and by material suppliers such as DuPont.*" To further examine the timing of the liability shift, we also manually collected litigation and media-mention data. Panel (a) of Appendix Figure A1 plots the timing of TMJ lawsuits involving DuPont as one of the defendants, collected from Bloomberg Law.[19] Only one case per year was recorded in 1987 and 1988, and 17 cases were filed in 1989. Starting in 1990, litigation increased dramatically, from 55 to 135 cases per year by 1994. Panel (b) of Figure A1 plots the timing of news articles referring to DuPont's implant litigation, retrieved through keyword searches in the Factiva (Dow Jones) database. This figure shows that the media coverage of implant-related litigation events involving DuPont increased substantially in 1991

[19] We searched the database using two keywords in the full text: DuPont (and other variations of the company's name) and Vitek. We included lawsuits in the following categories: personal Injury/health care/pharmaceutical personal injury/product Liability; personal injury/product liability; personal property/product liability; and contract/product liability. The initial search returned about 650 cases, which is consistent with the number in Schmucki (1999). Removing "spin-off" cases that originated from a different case, there are 485 unique lawsuits. In 44% of these lawsuits, DuPont was named as one of the defendants, while Vitek was not (because Vitek had filed for bankruptcy). In the remaining 56%, both DuPont and Vitek were named among the defendants.

and persisted throughout the following years. The litigation and media-mention data provide additional support for our choice of the treatment timing. Furthermore, the wide media coverage supports the idea that information on DuPont's legal battle spread across all industry participants, affecting all participants' perception about liability risk.

It is important to note that, together with the increase in liability exposure for upstream suppliers, Vitek's bankruptcy may have also generated (i) a decline in implants' demand driven by consumers' concerns about potential failures; and (ii) an increase in liability litigation risk for downstream implant producers themselves. Both of these additional effects could also generate a decline in downstream innovation, but through mechanisms different from those in our theoretical framework. Moreover, additional confounding factors such as demand trends or technology shocks differently affecting implant and non-implant innovation may also lead to correlation between $After1990_t$ and the error term, $\varepsilon_{c,t}$.

To address both types of concerns, we first exclude the three patent subclasses related to TMJ and silicone breast implants from all of our regressions. Industry accounts and congressional documents suggest that implant failures and the corresponding litigation triggering the surge in liability concerns were concentrated in these two fields. The exclusion of these fields makes our approach similar to a reduced-form regression, in which the variation in TMJ and breast implant litigation is used as an instrument for the increase in liability risk for other types of implants.

Furthermore, we perform triple-differences regressions using foreign patents of each patent subclass as the benchmark. The rationale behind this exercise is that industry reports suggest that foreign implant producers were less affected by liabilities than US firms because they had greater access to foreign polymer suppliers; at the same time, it is reasonable to assume that both foreign and U.S. firms experienced similar shocks to demand, direct liability concerns, and other trends unrelated to our natural experiment. In Section 8.3, we discuss in greater detail a collective set of evidence that helps us isolate the upstream-foreclosure mechanism explored in our theoretical framework.

Another complication in our setting is that the control group might be 'contaminated' in certain ways, which could affect the interpretation of our estimated effect. This may happen for a number of reasons. First, medical device firms patenting in both implant and non-implant subclasses may respond to the liability shift in implant technologies by reallocating their resources from implant to non-implant

technologies. Such a substitution effect would generate an increase in patenting in the control group, indicating a change in the direction of R&D rather than a reduction in innovation overall. In the analysis, we explicitly examine the extent to which such a substitution effect, if it exists, might affect the magnitude of the estimated effect on implant technologies. We also exploit an alternative control group, drug patents, in which substitution is less likely to take place.

Second, because of the threshold approach that we use to define the treatment and control groups, the control subclasses also include implant patents. In principle, this will cause attenuation bias and lead to an underestimation of the impact of the increase in liability. For robustness, we vary the threshold separating the two groups. In one specification, we use a control group that includes only subclasses with a very low proportion of implant patents (below 2%).

Finally, our analysis may also be subject to measurement error because our algorithm could misclassify implant patents. To address this issue, we employed a team of graduate students with degrees in kinesiology and biochemistry to manually classify a random sub-sample of 520 patents. The algorithm classifies 19 percent of these patents as implants, whereas the manual classification resulted in 23 percent, though the difference between the two proportions is not statistically significant (p-value = 0.11). This exercise suggests that, if anything, our algorithm might undercount the number of implant patents; and our control subclasses are likely to contain more implant patents than we currently measure. This, again, suggests that our estimate may be conservative.

6 Baseline results

Table 2 presents the first set of estimates quantifying the relationship between the increase in the liability risk after 1990 and the patenting activities in implant devices. Column 1 presents the difference-in-differences estimate based on equation (1). The result shows that in the years after 1990, implant subclasses experienced a reduction of roughly 0.56 patents per year, on average, relative to non-implant subclasses; and the estimate is statistically significant at the one-percent level. Assuming the same difference between implant and non-implant subclasses before and after 1990, the 'hypothetical' average number of patents for implant subclasses would have been 1.54 per year after 1990. This implies that

the average decline in implant patenting after 1990 is 36 percent.[20]

Columns 2 and 3 show that the effect is robust to varying the cut-off used to define the implant subclasses. The estimated effect of the increase in liability risk is slightly weaker when we employ a more lenient cut-off (column 2). The coefficient is similar to that of our baseline if we employ a more stringent cut-off (column 3). Column 4 shows that the result is robust to dropping patent subclasses for which the fraction of implant patents is between 0.02 (median of the subclass distribution) and 0.8. This regression exploits a more demanding control group (with a fraction of implant patents below 0.02), which is more likely to be totally unaffected by the liability change. Overall, these regressions suggest that how we define treated and untreated subclasses does not substantially affect our baseline result.[21]

In Table A1 in the Appendix, we confirm our findings using a number of alternative econometric models. First, to account for the heterogeneity in the size of different subclasses, we show that results are slightly stronger when we use a weighted regression, with each observation weighted by the (logarithm of) total patenting in the subclass during the pre-sample period of 1972-1982. Second, the results are robust to using the logarithm of the number of patents in the subclass as the dependent variable. This specification mitigates concerns related to the skewed nature of the distribution of patenting.[22] Third, Table A1 shows that our results are also robust to using the count of patents weighted by the citations received from other patents as the dependent variable. As we discuss in greater detail in Section 6.6 on heterogeneous effects, citations are a common measure of patent value in the economics of innovation literature (Pakes and Griliches, 1980).

Finally, in Table A1, we also confirm our results with two Poisson models. First, we use the fixed-effects Poisson estimator of Hausman et al. (1984), which isolates the within-subclass variation in patenting and drops subclasses in which there is no patenting for our entire sample period. Second, we use the Poisson 'mean scaling' estimator of Blundell et al. (1999). To implement this method, we

[20] The average number of patents for non-implant subclasses after 1990 is 2.06, and the pre-1990 difference between implant and non-implant subclasses is -0.52 patents per year.

[21] The sample means for treated and untreated subclasses are slightly different, depending on the specified cutoffs. In column 4 (excluding the mixed subclasses), the estimated coefficient amounts to a reduction of 31 percent, which is similar to the 36-percent reduction estimated in column 1.

[22] We add one to the number of patents to be able to include subclass-year observations with no patenting. We also include a dummy control variable for observations in which the subclass has zero patents in the year (this correction has essentially no impact on our estimates).

calculate the mean of the dependent variable in the 1972-1982 pre-sample data and use it directly in the estimation to control for the initial condition. In both models, we find a large negative decline in implant patenting after 1990.

Overall, the results in this section show a statistically and economically significant decline in medical implant patenting after 1990, relative to non-implant patenting. This is consistent with the idea that the increase in the liability risk driven by high-profile implant litigations triggered by Vitek's bankruptcy had a large chilling effect on downstream innovations. In the following, we subject this basic result to a number of additional tests.

6.1 Pre-treatment trend and time-specific treatment effects

A key assumption required for the difference-in-differences approach is that the treatment subclasses have trends similar to those of the control subclasses in the absence of the treatment. To provide support for this assumption, we extend our baseline model to estimate the year-specific differences between the treatment and control subclasses, β_t. Specifically, we estimate:

$$Patents_{c,t} = \alpha + \beta_t Implant_c \times Year_t + \delta_t + f_c + \varepsilon_{c,t}, \tag{2}$$

where 1989 is the baseline year.

Panel A of Figure 2 provides a graphical illustration of the estimated coefficients and their 95-percent confidence intervals. Before the liability shift, the estimated differences between the implant and non-implant subclasses are small; they bounce around zero and are statistically insignificant. The results, which show that the decline in implant patenting did not start until 1990, support the common-trends assumption.

The relative decline in implant patenting became statistically significant in 1990. The size of the negative effect became larger and statistically more significant over time. By 1995, the average yearly decrease relative to non-implant subclasses was close to 0.9 patents, four times as large as the effect in 1990. Overall, this pattern is compatible with implant innovators gradually reducing their patent applications as an increasing number of polymer and silicone suppliers withdrew from the market.

6.2 Substitution toward non-implant patents

We have shown that patenting in implant subclasses (treatment group) declined relative to patenting in non-implant subclasses (control group) after 1990. An important caveat of our baseline analysis is that patenting in non-implant subclasses may also have been affected by the shift in liability risk. For example, a negative shock affecting implant subclasses may have induced some medical device firms to reduce their research efforts for both implant and non-implant technologies. In this case, our difference-in-differences analysis would underestimate the negative impact of liability risk on medical implant innovation. Alternatively, some medical device firms that patented in implant and non-implant subclasses may have responded to an increase in liability risk by shifting their research efforts from implant to non-implant technologies. This substitution effect deserves more attention in our context, because it may generate an increase in patenting in the control group that would lead us to overestimate the negative effect of liability risk on the treated technology classes. In other words, the observed decline in implant patenting may not indicate an overall decline in innovation.

In this section, we conduct a number of exercises to examine the extent to which the effect of liability risk spills over to the control group. First, we identify the patentees that patented in both implant and non-implant subclasses during our sample period. We find that about seven percent of the assignees in our sample patented in both treatment and control technology classes and that these assignees account for roughly 30 percent of the sample patents.

In column 1 of Table 3, we estimate the impact of the increase in liability risk in a sample that excludes patenting by assignees active in both the implant and non-implant subclasses. We find that, in this sample, implant subclasses experience a reduction of 0.46 patents a year, on average, relative to non-implant subclasses. The estimated coefficient is slightly smaller and not statistically different from the one estimated in the full sample, which suggests that within-firm substitution between implant and non-implant patenting is likely to be small and that there is a significant decline in overall innovation.[23]

As a second empirical exercise, we contrast patenting in implant patent subclasses with patenting

[23] The magnitude of the difference between the two coefficients provides an upper bound to the impact of the shift in patenting from implant to non-implant technologies by firms operating in both technology areas. Our estimates suggest that such substitution may account for, at most, 17 percent of the total effect estimated in the full sample.

in subclasses that include only pharmaceutical drug innovations and not medical device innovations.[24] The technological distance between implant and drug classes mitigates the concern that liability risk may spill over from the treated to the control subclasses. At the same time, this alternative control group is likely to respond to macro-shocks affecting the entire health sector. Appendix Figure A2 plots the average number of patents, based on the raw data and by application year, in implant and drug subclasses during our sample period. The figure shows that patenting in drug subclasses grew faster than patenting in implant subclasses later in the sample period and that the divergence started a couple of years after 1990. Column 2 of Table 3 estimates equation (1), exploiting this alternative control group. To address the concern that trends in patenting in drug subclasses may differ from those in implant subclasses, in column 3, we match each implant subclass with one of the drug subclasses, minimizing differences in patenting pre-trends. Specifically, for each implant subclass, c, we identify the nearest neighbor drug subclass with the smallest distance from class c in terms of patenting in each year from 1985 to 1989. The estimates in columns 2 and 3 are similar to our baseline results. This finding, based on an alternative control group in which contamination concerns are less severe, provides additional support for the idea that the substitution effect is not the primary driver of our main result.

6.3 Patents by foreign firms and triple-differences

In this section, we examine the impact of the increase in liability risk, distinguishing between patents by US and foreign firms. The purpose of this analysis is to address two empirical issues. First, as in Moser and Voena (2012), we employ patents by foreign firms to account for potential confounding factors that may influence the overall propensity to patent, such as technological or demand shocks affecting an entire technology field. Second, we use differences between foreign and US firms to isolate the mechanism described in our theoretical framework; that is, the negative impact on downstream innovation is caused mainly by upstream foreclosure rather than by an increase in the liability risk perceived by downstream implant producers themselves or by a reduction in demand for implants due to an increased concern over potential failures.

[24] Specifically, we exploit USPTO patent classes 424 and 514, both titled "Drug, bio-affecting and body treating compositions." The number of firms operating in both the treated and control fields is smaller than in our main sample (only 1 percent of the assignees).

In a detailed report illustrating the state of the medical implant industry, Aronoff (1995) explains that non-US implant producers were not as affected by DuPont's withdrawal as their competitors in the United States. The reason is that litigations against suppliers were US-based, and foreign firms had easier access to non-US material suppliers, such as Rhône-Poulenc in Europe. At the same time, the liability risk downstream firms faced was similar for foreign and US firms, as both were subject to the US product-liability laws when selling devices in the US market, but foreign suppliers considered sales to foreign producers less risky than sales to US implant producers (Aronoff, 1995).[25] Similarly, we expect US and foreign implant producers to be subject to the same general decline in demand due to concerns about potential failures.

We base our identification of US versus foreign medical device innovators mainly on the country of patent assignees reported by the USPTO. Unfortunately, this requires us to drop 30 percent of the patents in our sample because they are unassigned; and for patents with assignee information, 72 percent belong to a US assignee and 28 to a foreign one. As an alternative, we show that results are similar when we classify patents using the information on the country of the first inventor, which is available for all patents.[26]

Our first set of regressions is the baseline difference-in-differences analysis with patents by US firms in a subclass-year as the dependent variable. Patents by foreign firms serve as an additional explanatory variable that controls for unobservable factors affecting the overall innovation activity in each subclass (such as common technology or demand shocks and litigation's direct impact on implant producers' liability risk). Column 1 of Table 4 reports the results using the assignees' country of origin to define US versus foreign patents. Consistent with our baseline result, we see that, relative to non-implant technologies, US implant patenting experienced a large and significant decline after 1990. In column 2 of Table 4, we show that this result is robust to using the inventor's country of origin to categorize

[25] This is likely due to the increase in complexity and legal costs involved, from the perspective of US litigants, in suing a foreign supplier as opposed to a US supplier. This is because international supply contracts involve performance obligations that engage the substantive laws of multiple jurisdictions, not only raising complex conflict of laws issues, but also potentially engaging courts of different jurisdictions.

[26] Almost all patents by US inventors that have assignee information (97 percent) are assigned to a US entity. About 85 percent of patents by foreign inventors that have assignee information are assigned to a foreign entity. Moreover, about six percent of the patents are assigned to a non-profit organization, such as a government entity, a hospital, or a university or research institute. The results are similar if we exclude non-profit organizations from the analysis.

the patents. We also reestimate the time-specific treatment effects (equation 2) using only patents by US assignees as the dependent variable. The results, illustrated in panel B of Figure 2, appear to be sharper than those in panel A of Figure 2, which uses all patents. The estimated differences between implant and non-implant subclasses before the liability regime shift are all very small. They are not only statistically indistinguishable from the default year of 1989 but also indistinguishable from each other. The decline in implant patenting started in 1990 but became statistically significant only in 1991. The magnitude of the decline increased steadily until the end of the sample period.

The second set of regressions goes a step further and uses a triple-differences approach. Specifically, for each subclass-year, we generate two observations, one for patents with US assignees and the other with foreign assignees. Therefore, the total number of observations is twice as many as that in column 1 of Table 4. Column 3 reports the triple-differences results based on the assignees' country of origin. The coefficient of the triple-interaction term (-0.344) is the differential effect of the increase in liability risk on implant patenting by US versus foreign firms. Specifically, after isolating the change experienced by foreign innovators, this estimate captures the decrease in implant patenting by US firms. Column 4 of Table 4 replicates column 3, using the inventor's country of origin to categorize the patents, and the results are similar.[27]

To confirm that the increase in liability risk had a substantially lower impact on foreign inventors, we also examine datasets of medical device patents granted by UK, French and German patent offices to non-US applicants. Difference-in-differences regressions comparing implant and non-implant technology subclasses show small and statistically insignificant effects. As an example, our baseline regression (equation 1), using the sample of UK data, gives a coefficient of 0.022 with a standard error of 0.034. This pattern is confirmed in Appendix Figure A3, which plots the year-specific coefficients estimated from equation (2) using the UK sample. These findings support the idea that the increase in liability risk affected mainly American patentees' innovation incentives.[28]

[27] We also run the triple-differences regressions including primary class-specific linear trends. Meer and West (2016) show that research designs incorporating time trends are prone to erroneously estimated null effects of policies when the effects are expected to unfold dynamically. Despite the potential downward bias, we find that the triple-difference estimates are robust and stable.

[28] The analysis is conducted exploiting a textual algorithm similar to that described in Section 5 to identify implant technologies and classify subclasses (based on the EPO system) into the control and treated groups according to the relative fraction of implant patents. It is important to note that the UK, French and German patent data have a number

Overall, these estimates show that implant patenting by US firms significantly decreased after 1990 relative to foreign firms. This finding supports the idea that access to upstream suppliers was an important driver of downstream patenting, and that upstream foreclosure was a key mechanism through which liability risk affected innovation in our context (we discuss this mechanism in greater detail later in Section 8.3).

6.4 Additional robustness tests

Table 5 presents a variety of additional robustness tests to confirm our main finding. First, column 1 uses a continuum version of the model, in which the treatment variable is equal to zero before 1990 and to the fraction of implant patents of the subclass after 1990. Recall that the fraction of implant patents of a subclass is calculated using the data from 1975-2015 and, hence, is constant over time. The estimate confirms our baseline finding and shows that doubling the mean value of the fraction of implant devices in the subclass, from 0.2 to 0.4, reduces patenting in implant classes by about 0.12 patents per year after 1990.

For about five percent of the subclasses in our sample, we observe no patenting during the entire sample period of 1985-95. In column 2, we show that our result is robust to dropping these subclasses. In column 3, following Moser and Voena (2012), we show that our results are robust in an unbalanced panel that includes only subclasses-years for which we observe at least one patent in year t or in the years before t. This approach, which excludes subclasses with no patenting before year t, gives an estimate very similar to that in column 2.

Finally, in column 4, we reestimate our baseline, dropping two prominent patent subclasses: pacemakers and heart valves. These subclasses include complex technologies that experienced very large growth in the 1990s and were associated with the most adverse events. Our estimates show that our results are robust (if anything, the effect is stronger) in this subsample.

Betrand et al. (2004) show that in the presence of serial correlation in the dependent variable, standard errors in difference-in-differences models may be underestimated, even with clustering. Following

of important limitations, restricting our ability to conduct further analysis. First, we have the title for each of the patents in the sample, but the abstracts are available for only 70 percent of the patents, and we do not have the claims data. Second, for a substantial fraction of the German and French patents, the textual fields are not in English and cannot be read by our algorithm.

their suggestion, we confirmed the results of our baseline regressions with a block-bootstrapping estimation that maintains the autocorrelation structure within subclasses. The standard errors are essentially identical to those estimated with our baseline clustering procedure, indicating that serial correlation is not of significant concern in our setting (the results are not reported).

The USPTO subclass system follows a hierarchical nested structure in which subclasses are grouped into subclasses at higher indent levels. Our main analysis uses the most disaggregated level of classification and takes each subclass as a unique group without explicitly considering the hierarchical structure. The benefit of this approach is that it avoids imposing an arbitrary level of aggregation, given that indent levels across technical fields are not necessarily consistent (for example, indent level 2 in Prosthesis may not have the same level of technological detail as indent level 2 in Surgery). In appendix Table A2, we show that our baseline analysis is robust to using more-aggregate technology classifications. Specifically, building on the USPTO hierarchical structure, we rerun our analysis using 1,862 subclasses (aggregating associated 'children' subclasses, if applicable, up to indent level 3), 1,178 subclasses (up to indent level 2), and 459 subclasses (up to indent level 1). In all of these cases, we find a strong negative decline in implant relative to non-implant technologies.

6.5 Confirming the impact of liability on innovation with non-patent data

To this point, we have used patents as our measure of innovation. To examine whether our finding of a negative impact of liability risk on innovation holds with non-patent measures of innovation, we use the medical-device application data from the U.S. Food and Drug Administration (FDA). The FDA has the primary authority to approve medical devices sold in the US. The regulatory requirement for approval differs in stringency levels, depending on the nature of the products.

We focus on devices that the FDA designates as class III. These are defined as devices used to support or sustain human life, devices of substantial importance in preventing impairment of human health, or devices that present a potential, unreasonable risk of illness or injury. The FDA classifies each device with a specific product code, which identifies the generic category of the device. After excluding TMJ and breast implants, we have 304 unique product codes for class III devices between 1985 and 1995. For each product code, the FDA data also provide an "implant" flag indicating implant devices. About 37

percent of the 304 class III product codes for the sample period were for implant devices.

Column 1 of Table 6 reports our baseline regression result using this alternative data set. The unit of observation is the number of FDA applications in each product code-year. The estimate confirms (at the 0.1 level) a decline in implant-device commercialization after 1990, relative to non-implant devices. In column 2, we match each FDA implant code with a non-implant code, minimizing the differences in pre-trends. This matched control group generates a larger coefficient, which is now statistically significant at the 0.05 level. In column 3, we drop two outlier product codes that have the largest number of applications per year (pulse-generators and electrode components of pacemakers). Dropping these outliers reduces the magnitude of the coefficient but confirms the negative impact of liability risk on innovation. At the same time, removing these outliers reduces the residual variance of our dependent variable and helps sharpen the statistical precision of our estimate. Assuming the same difference between implant and non-implant product codes after 1990, the estimated effect of -0.141 in column 3 implies a 50-percent reduction in implant innovation.[29]

The FDA Medical Device Reporting Program (MDR) database provides reports on suspected device-associated deaths, serious injuries and malfunctions. Exploiting this information, we created a new variable, *MDR reports*, equal to the number of reports in year t for the device category. On average, there are 47.8 reports per year in a product code, but the distribution is quite skewed. The median number of reports in a year is zero and the 75th percentile is three. Column 4 shows that our results are robust to including this control variable that captures differences in liability risk across product codes. This finding provides additional support for the idea that implant innovation not only responded to the liability risk faced by downstream manufacturers, but it was also affected by the risk faced by upstream suppliers that led to market foreclosure.

Overall, this analysis using product-based measures of innovation confirms our earlier conclusion from regressions based on patent data. It suggests that the relative decline in implant innovation took place in the early invention and the commercialization stages. The strength of the FDA data lies in the fact that they are more closely linked to the final products than the patent data are. Furthermore, the

[29] Recall that our estimated reduction in implant patenting is 36 percent. A coefficient of -0.094, rather than -0.14, would be equivalent to a 36-percent drop in FDA applications in our preferred specification (column 3 of Table 6). We cannot reject that the estimated -0.14 is different from -0.094 ($p = 0.32$).

expenditure required to complete the FDA approval process can be substantial, which implies that the FDA data may provide a reasonable window on technologies of higher value. That said, these data are also subject to a number of limitations. First, the FDA often reclassifies devices over time. For example, both TMJ implants and breast implants were reclassified from class II to class III during our sample period. Such reclassification leads to new class-III device applications, which are, in fact, about existing rather than new devices. Second, relative to patenting, device applications take significantly longer to materialize, and there is evidence of strategic delays in the introduction of medical devices in the U.S. market relative to the European markets (Grennan and Town, 2015). Both of these issues may generate substantial measurement errors for new innovative activities and their timing. Finally, in Section 7, we will also examine the effect of liability risk on upstream innovation (polymers). Patenting data allow us to generate an innovation metric that is consistent across upstream and downstream technologies. This would not be possible with FDA data because they capture only downstream medical devices.

6.6 Heterogeneous effects

The preceding analysis shows that, on average, the liability risk affected patenting activity during our study period. In this section, we explore whether the impact of liability risk is heterogeneous and dependent on characteristics of innovators and technologies.

We first test whether liability risks are more important for small patentees than for large ones. For each assignee in our sample, we construct a patent portfolio equal to the number of medical device patents between 1985 and 1995.[30] Because of the skewness in the distribution of patent portfolios, we allocate patentees into three groups. The first group (small patentees) includes patents assigned to assignees whose total number of patents ranges from one to four: this group covers 50.5% of the patents. The second group (medium patentees) includes assignees whose total number of patents ranges from five to 40, which covers 24.2% of our sample patenting. The third group (large patentees) includes all assignees whose total patent counts exceeds 40, which covers the remaining 25.2% of the patents. In addition, we further examine the effect on patenting by the largest assignees in our sample, creating two additional groups: the 'Top 16 assignees' group covers roughly 10% of the patents, and 'Top six

[30] We impute a portfolio of 1 to unassigned patents.

assignees' group covers roughly 5% of the patents.

Panel A of Table 7 estimates our baseline regression across these five groups of patentees. The coefficients are negative and statistically significant across all groups. Taking into consideration the average level of patenting across different groups, the effect ranges from -17.9 to -37.9 percent, all economically large. It is worthwhile noting that the effect is smaller for the six largest assignees than for the rest of the sample.[31] This seems consistent with industry accounts, which suggest that the largest firms had the financial resources to provide contractual and insurance remedies to the remaining polymer suppliers, and they could have had easier access than smaller firms had to polymer suppliers outside the U.S. Moreover, the largest firms might have had the resources and incentives to patent new devices using alternative materials, creating a potential offsetting positive effect.

Next, we explore whether liability risk had differential impact across patents of different quality. The welfare interpretation of the average decline in innovation would differ greatly according to whether or not it affected high-quality patents or marginal patents with limited impact. To unbundle the heterogeneous effects of the increase in liability risk across different quality levels, we exploit information on the citations received by each patent. The economics of innovation literature has often employed the number of citations that a patent receives as an indirect measure of patent value (Pakes and Griliches, 1980). Since citation counts are inherently truncated, and levels differ across technology areas, we filter citations by removing application-year and (two-digit) technology class effects. We then identify the (filtered) citation quintile to which each patent belongs. Panel B of Table 7 reports our baseline regressions using these quality-quintile subsamples.

The coefficients are also negative and statistically significant across all five quality quintiles. The magnitude of the effect appears to be the smallest for the intermediate-quality range. With a more restrictive input supply (and, hence, higher development and production costs), it is not surprising that R&D activities that are more likely to result in the lowest-value patents are terminated. Multiple factors may explain why we also observe a larger decline in patents of the highest values. For one, with risk-averse innovators and ex-ante uncertainty in the value of innovation, a higher development cost may

[31] We have confirmed the robustness of these results using alternative approaches to define firm size: (i) using patents from all fields (not just medical devices); and (ii) constructing portfolios using only a pre-shock window of 1970-89. Across the various definitions, the impacts are industry-wide; and the effect size tends to be smaller for the largest firms.

discourage the exploration of risky projects. This, in turn, may lead to a reduction in breakthrough innovations. This idea is consistent with the management literature on slack resources and innovation originated by Cyert and March (1963), as well as with studies on the welfare implications of lowering entry costs when quality is ex-ante unpredictable (Aguiar and Waldfogel, 2018). Furthermore, the findings in Galasso and Luo (2017) suggest that patents of intermediate quality are more likely to include technologies developed to mitigate liability risk. This may also help explain the smaller decline that we observe for these patents if input supply is relatively less restrictive for implants with lower liability risk profiles.

Overall, these results indicate that increased in liability risk faced by implant innovators in 1990 had a broad impact: its effects spanned the entire medical device industry, as well as technologies' quality distribution.[32]

7 Upstream effect: liability risk and material innovation

We have documented a negative impact of the increase in liability risk on medical implant patenting. In this section, we examine the effect of this increase on 'upstream' innovation related to the polymers used as material inputs for inventing and manufacturing medical implants. Because the change in litigation risk around 1990 affected mainly the upstream suppliers, one might expect such a change to also have affected innovation incentives behind these basic technologies.

To explore this issue, we use an approach similar to the one we employed in the analysis of implant innovation in Section 6. We start with the sample of 229,446 chemical patents applied for during the period 1975-2015 and belonging to the NBER patent subcategories of resins and organic compounds. These patents span 8,988 unique USPTO subclasses. To identify the patents related to generic polymers employed in medical implants, we exploit the information provided in the transcription of the August 1, 1995 congressional hearing on the FDA Regulation of Medical Devices, in which various subcommittees discussed the impact of breast and TMJ implant litigation on the medical device industry. Among the

[32] We also examined whether the surge in liability risk had differential impacts across patents with different levels of originality (using the measure developed by Hall, Jaffe, and Trajtenberg, 2001). Also in this case, we found that patenting decreased across the entire originality distribution. This is consistent with industry accounts emphasizing the difficulty of identifying input replacements (Aronoff, 1995).

documents submitted for the record is a comprehensive list of the generic polymers used in medical implants and affected by the vertical foreclosure. These polymers include urethane, polyurethane, silicone and polyvinylchloride. We identify all the patents that refer to one of these materials in the patent's title, abstract, or first claim, and we label them as "affected-polymer patents." We then classify each of the 8,988 USPTO subclasses as an affected-polymer vs a control subclass, depending on whether at least 80 percent of the patents are identified as polymer patents involved in medical implants.

Table 8 examines the relationship between the increase in liability risk and polymer patenting. Column 1 shows a positive and statistically insignificant coefficient, suggesting that patenting in affected-polymer subclasses did not decline relative to control chemical subclasses after the Vitek bankruptcy. To remove the impact of differential pre-trends between affected-polymer and control subclasses, in column 2, we contrast patenting in affected-polymer subclasses with patenting in a matched control group of chemical sub-classes chosen to minimize pre-trend differences. The coefficient becomes smaller and remains statistically insignificant, confirming the finding of no effect on upstream innovation. Figure A4 illustrates the coefficient of a regression run on this sample, including separate dummies for each year before and after the change in liability risk (normalizing the coefficient for 1989 to zero). All coefficients are statistically insignificant and of small magnitudes, further corroborating our finding of no effect.

In columns 3 and 4 of Table 8, we examine whether the increase in liability risk affected DuPont's patenting in affected polymers relative to its patenting in other chemical subclasses. DuPont was the main target for the TMJ implant litigation, and one may expect its innovation strategy to have been affected. We find no evidence of a decline in DuPont's patenting in affected-polymer subclasses relative to other subclasses. As a robustness check, in appendix Table A3, we repeat the analysis with a less stringent definition of polymer subclass, moving the threshold of affected-polymer patents from 80 percent to 65 percent. We still find no evidence of a negative impact on upstream innovation.

Overall, our finding of no impact on upstream innovation is consistent with our model and suggests that suppliers' innovation incentives were driven by the aggregate demand from multiple downstream markets.

8 Discussion and policy implications

Our main empirical finding is that the increase in liability risk triggered by Vitek's 1990 bankruptcy is associated with a substantial reduction in implant innovation. The reduction appears to have occurred across firms of all sizes and technologies of all values, and it took place both at the invention and the commercialization stage. This section complements our analysis by (i) discussing the welfare implications of our findings; (ii) examining the response to a federal policy implemented to address the shortage of biomaterials; (iii) providing additional support for the idea that restricted access to upstream suppliers was an important driver of the decline in downstream innovation; and (iv) discussing the external validity of our results.

8.1 Welfare impact: a back-of-the-envelope calculation

In this section, we discuss a back-of-the-envelope calculation of the likely impact on welfare due to the increase in liability risk. Details of this exercise are presented in Appendix 2.

A recent study by Grennan and Swanson (2017) provides estimates of the increase in total surplus, including both consumer surplus (physician, patient, and hospital combined) and producer gross profit, when physicians have access to an additional medical device. Their estimates include four prominent implant device categories for which we can obtain data on the number of procedures from the 1992 annual summary of the National Hospital Discharge Survey: pacemakers, cardiac catheters, knee prostheses, and hip prostheses. Given the estimated surplus per procedure and the volume data, we obtain the yearly surplus that would have been generated by an additional new product for each of the four implant categories.

We then combine these estimates with our estimated effect of liability risk on FDA applications for medical implants.[33] Our preferred model (column 3 of Table 6) implies an average reduction of 0.14 FDA device applications per year per product code. Multiplying this average reduction by the total number of implant product codes yields an estimated reduction of 15.96 implant devices per year. Assuming that the drop is distributed across the implant categories in proportion to their respective levels of

[33] We use the estimated effect based on the FDA data rather than on the patent data because a device might be associated with multiple patents.

applications before the increase in liability risk, we obtain estimates for the yearly reduction in the number of applications for each of the four implant categories. Multiplying these estimated reductions by the corresponding surplus generated by a new implant yields the loss in yearly surplus due to the increase in liability risk. The sum of the reductions in total surplus for all four categories—pacemakers, cardiac catheters, knee prostheses and hip prostheses—equals $20.3B per year.

The above estimate is an upper bound because it assumes that each new device would have been available to all the physicians if it had been developed. Grennan and Swanson (2017) show that, for these four device categories, a typical product is in the consideration set for 56 to 91 percent of the hospitals. Adjusting for the penetration rate in each of the device categories, we obtain an estimated decline in total surplus equal to $11.9B per year. If we use the lowest penetration rate documented by Grennan and Swanson (2017) across all Class-III devices for all four categories, which is 20 percent, the decline in total surplus is $4.1B.

Grennan and Swanson (2017) also estimate how total surplus would be divided between consumer surplus and producer's gross profit. Building on these estimates, for the scenario in which device-specific penetration rates are used, the increase in liability risk generated a total loss in consumer welfare of $10.6B per-year and a loss in producers' gross profit of $1.2B per-year.[34]

These calculations are only illustrative and should not be over-interpreted. Because Grennan and Swanson (2017) estimate the welfare loss using prices negotiated between hospitals and medical device vendors, they do not explicitly consider patient and social welfare related to product malfunctions and tort litigation. Furthermore, by focusing on the drop in FDA applications, our computations do not consider potential welfare gains generated by the development of safer and risk-mitigating devices. Finally, Grennan and Swanson (2017) exploit data from 2009 to 2015, which is later than our sample period. On the one hand, new devices may have generated greater welfare in more-recent periods if technological progress accelerated over time. On the other hand, it is possible that the marginal gain from one additional device has declined over time as the total number of options available to physicians

[34] For reference, one industry estimate suggests that the total sales of implant devices was $43B in 2011 (Lind, 2017). Assuming that the share of revenues corresponds to the share of FDA application counts and that the average gross margin is 60 percent, an estimate of $1.2B loss in producer profit for these four product categories would suggest that the increased liability risk resulted in about 5.3 percent of revenue loss.

has increased. Nonetheless, these simple estimates suggest that the decline in innovation documented by our regressions had a non-trivial impact on consumer surplus and industry profits.

8.2 Policy remedy: the 1998 Biomaterials Access Assurance Act

To restore the supply incentive of raw-material producers, the U.S. Congress passed the Biomaterial Access Assurance Act (BAAA) in August 1998. BAAA came about after a number of failed attempts to address the potential shortage of biomaterial supplies through federal product-liability reforms.[35] The main goal of the BAAA was to "*safeguard the availability of a wide variety of lifesaving and life-enhancing medical devices*" (U.S.C. §1601(15)). The Act provides liability exemption for the suppliers of bulk components and raw materials for implants, as long as they do not engage in the design, testing, and production of the implants. It is important to note that the BAAA is not a blanket legislation giving liability exemption to deep-pocketed defendants; instead, it protects *suppliers not sufficiently involved in downstream production.*[36] BAAA is one of few federal liability reforms, an area of legislation typically reserved for the states (Kerouac, 2001).[37]

Potential material-supplier plaintiffs may invoke the Act to request early dismissal from the court, avoiding the costly and lengthy litigation process. According to Czuba (2016), during the 18 years (at the time his article was published) since BAAA's passage, it has been tested five times. The same article quotes Frederick Stearns of Keller and Heckman LLP: "*...in each case the Biomaterials Act was invoked and each was resolved in favor of the materials supplier. I see no reason to expect a different outcome in similar cases in the future.*"

Figure 3 plots the average patenting in implant and non-implant subclasses by US firms (based on the assignee's country of origin) between 1985 and 2010. The raw data suggest that implant patenting started to recover shortly after 1998 (i.e., the growth rate for implant patents appeared greater than

[35] Bipartisan legislation was filibustered in September 1992 and again in June 1994. In March 1996, both the House and the Senate passed the Common Sense Product Liability and Legal Reform Act, which President Clinton vetoed on May 2, 1996 (House of Representatives, 1997).

[36] The rationale of the BAAA is similar to that underlying common-law protection for suppliers: imposing liability on raw-material suppliers would require them to retain expertise in a large variety of areas in order to determine the possible risks associated with each potential use. In contrast, finished-product manufacturers know what they intend to do and, therefore, are in a better position to guarantee that the material is suitable for their particular applications.

[37] Examples of such federal policies include the General Aviation Revitalization Act of 1994, which exempts makers of small aircraft from liability for planes after 18 years; and the National Childhood Vaccine Injury Act of 1986, which limits liability for drug companies and creates a no-fault compensation system for those injured by vaccines.

that for non-implant patents) and that four or five years later, it was restored to a level comparable to that of non-implant patents (i.e., the relative difference between implant and non-implant patents became the same as that before 1990).

We extended our baseline difference-in-differences regression results to include both shifts in the liability risk: the first increased the liability risk faced by upstream suppliers following Vitek's bankruptcy in 1990; and the second reduced the risk to a low level, following the passage of the BAAA in 1998. This regression uses only patents assigned to US firms. The (unreported) results show that, relative to the default years (before 1990), implant patenting decreased significantly between 1990 and 1998 (confirming our main result), and it recovered after the BAAA (the coefficient is slightly positive and not statistically different from the default years before 1990). The coefficients of the two interaction terms are statistically different from each other at the ten-percent level (p-value = 0.086).

Although these empirical patterns are only suggestive, they are consistent with the federal exemption law helping to restore the pace of implant innovation. As discussed previously, common law does provide protection for component and material suppliers, and these provisions were in place throughout our entire sample period. Our finding is consistent with the idea that additional ex-ante regulation can encourage innovation investment by mitigating the uncertainty over the litigation process (Kaplow, 1992; Galasso and Schankerman, 2010).

Finally, it is important to note that, in addition to seeking a change in the law, the industry also took other measures to address the shortage of material suppliers. Medical device firms reallocated resources to identifying alternative supply sources or substitute materials, and they also provided stronger indemnification contracts and liability insurance to ensure suppliers of minimal liability risk and faster monetary recovery for suppliers. These measures might also have contributed to the recovery of implant patenting. Regardless of the exact reasons for the recovery, we do not observe an overshoot of implant patenting in the longer run. This implies that the decline in the intervening years was a real loss rather than a delay in investment.

8.3 Access to upstream inputs or downstream liability risk?

Our interpretation of the empirical findings has been guided by a theoretical model in which liability risk induces an upstream supplier to foreclose a risky downstream market. Even though our model does not consider the direct impact that liability risk may have on downstream firms, in our empirical context, it is reasonable to expect that failures in TMJ and silicone breast implants may have led to an overall increase in the liability risk perceived by implant producers or to a drop in demand for implants by patients in discretionary medical procedures. Both of these downstream channels may have generated a decline in innovation activity. To empirically disentangle the upstream and downstream effects of liability risk on innovation is challenging and requires structural modeling assumptions on the R&D responses along the vertical structure. This leads to the concern that our estimates may be driven predominantly by the litigation risk or by the decline in demand faced by downstream firms and not by vertical foreclosure. In this subsection, to address this concern, we discuss a body of evidence supporting the idea that market foreclosure driven by upstream suppliers' concern over liability risk was the key mechanism behind the decline in innovation.

First, all industry reports and congressional hearings describing the status of the medical implant industry after Vitek's bankruptcy reflect concerns over vertical foreclosure and upstream liability risk rather than over downstream litigation or decline in demand. The downstream medical device manufacturer themselves appeared more concerned by the lack of suppliers than by other potential downstream channels. For example, in her 1994 Congressional testimony, Eleanor Gackstatter, President and COO of Meadox Medicals, asked "*When supplies are vanishing, how can we choose to provide R&D supplies for future innovative products when the surgeon needs our products to save a life today?*" In the same congressional hearing, Paul Citron, VP for Science and Technology at Medtronic, testified that a "*remedy must be found which will provide the protection necessary to assure that suppliers will continue to provide materials to manufacturers. Unless such a remedy is put in place, we will experience inexorable declines in medical device innovation.*"

Second, it is important to note that our empirical analysis does not rely on changes in patenting in TMJ and silicone breast implants subclasses. These were the fields in which most implant failures and

downstream litigation were concentrated, and they are dropped from our analysis. In column 4 of Table 5, we go a step further and confirm our results, dropping two additional prominent patent subclasses—pacemakers and heart valves—which were also associated with the highest numbers of adverse events. Moreover, in Section 6.5 we showed that our results are robust to including a control variable that captures differences in liability risk across FDA product codes. Overall, these findings support the idea that the decline in implant innovation was not driven by the downstream fields in which liability risk was the greatest.

Third, the triple-differences results presented in Section 6.3 showed that higher liability risk significantly reduced patenting by US firms relative to foreign innovators, which were less affected by vertical foreclosure. This differential effect provides additional support for the mechanism described in our theoretical model.

Finally, as we discussed in Section 8.2, implant patenting did recover following the implementation of the BAAA, which reduced upstream suppliers' liability risk. We also conducted a triple-differences regression analysis to estimate the differential response of foreign and US innovation after the BAAA. The (unreported) estimates suggest a stronger policy response for US innovators and show that implant patenting by US producers reached a level comparable to that before 1990 once the BAAA was implemented. This is consistent with our theoretical model and points to the importance of vertical foreclosure driven by upstream liability risk.

8.4 External validity

Our analysis helps to identify situations in which liability risk may negatively affect innovation incentives and percolate throughout a vertical chain. In particular, this appears to be the case when (i) the extent of harms and their probabilities are difficult to predict, and, therefore, it is hard for downstream producers to be fully insured and for the parties to write complete contracts regarding the allocation of liability; (ii) downstream innovators are small and are likely to resort to bankruptcy when liability claims exceed firm values; and (iii) some of the critical inputs are supplied by large multi-market firms with deep pockets and the ability to foreclose a risky downstream segment.

The first two conditions are likely to hold in economically important and technologically vibrant

industries that are associated with high inherent risks, such as healthcare, transportation, and energy. The last condition is rather common given the prevalent use of mass-produced general-purpose inputs, including basic materials and components such as chips, engines, and batteries (Helpman, 1998). Moreover, such liability concerns may go beyond suppliers and apply also to other critical players in the value chain (e.g., a large distributor). Finally, even if large suppliers can be replaced by smaller and more-specialized firms, or even by the downstream players through vertical integration, innovation may still suffer when scale and experience from other domains are important for efficiency.

One might argue that a special feature of the medical device industry is FDA regulation. Many risky industries tend to be regulated, and regulations can play an important role in mitigating uncertainty over liability risk. In this respect, the pharmaceutical and commercial aviation industries—which are characterized by a combination of extremely stringent ex-ante standard setting, testing, and federal preemption (of state laws)—may be settings in which the role of the channel we have described in this paper is more limited. Our results are more likely to be relevant in industries in which regulation is less stringent or new technologies are at any early stage, given that regulation often takes years to develop.[38] The medical device industry during our sample period is an example of such environments because product liability laws and the court system tend to play a substantial role in governing liability events in an ex-post fashion, even in the presence of FDA regulation.

9 Conclusions

In this paper, we examine the relationship between product liability and innovation, taking advantage of a quasi-exogenous surge in the liability risk that affected the medical implant industry in the early 1990s. Our empirical analysis illustrates a decline in medical implant patenting relative to patenting of other

[38] For example, as mentioned in Section 3, TMJ and breast implants were classified as Class-II devices at the time of the litigations. They were reclassified as Class-III (and, hence, subject to a stricter approval process and, potentially, federal preemption under the Medical Device Amendments of 1976) only a few years after Vitek's bankruptcy. Even for Class-III devices, the exact scope of federal preemption remained unclear for a long time. In Medtronic Inc. v. Lohr (1996), the Supreme Court denied preemption for a number of claims related to a Class-III device marketed under 510(k), and legal uncertainty about federal preemption persisted until Riegel v. Medtronic, Inc. (2008). Consistent with this lack of clarity, historical documents and our interviews with industry insiders also suggest that polymer suppliers at the time were concerned about potential liability risk related to devices such as pacemakers and heart valves, which were classified as Class-III at the time. In transportation, it also took the National Highway Traffic Safety Administration, a federal agency, over a decade to establish the standards for conventional vehicles. The current regulatory status for autonomous vehicles is still at the state level and is highly heterogeneous in terms of scope and clarity.

medical devices, on the order of 36 percent. We show that the decline in innovation was concentrated among downstream implant innovators, even if the liability litigation targeted mainly upstream suppliers of polymers. Our findings, together with rich historical accounts and interviews, indicate that this surge in upstream liability risk led to vertical foreclosure, which, in turn, negatively affected downstream innovation. Consistent with this mechanism, the decline in implant patenting appears to be industry-wide, involving firms of various sizes and patents of different values.

An implication of our analysis is that product liabilities may have a substantial impact on innovation when they affect suppliers of general purpose inputs and technologies. Large 'deep-pocket' upstream firms serving many downstream sectors may prefer to foreclose market segments in which liability risk is the greatest, rather than facing the risk of litigation. Our analysis of the BAAA is only illustrative and does not allow us to make causal inferences. Nonetheless, the patenting patterns that we document suggest that policy remedies that reduce uncertainty and protect input suppliers from excessive liability risk can be critical for cultivating (or, at least, not disrupting) R&D investments. This insight may be particularly valuable for regulators evaluating the role of a country's liability systems in its competitiveness, especially in emerging fields such as artificial intelligence and sophisticated robotics and their various applications (Agrawal, Gans and Goldfarb, 2018).[39]

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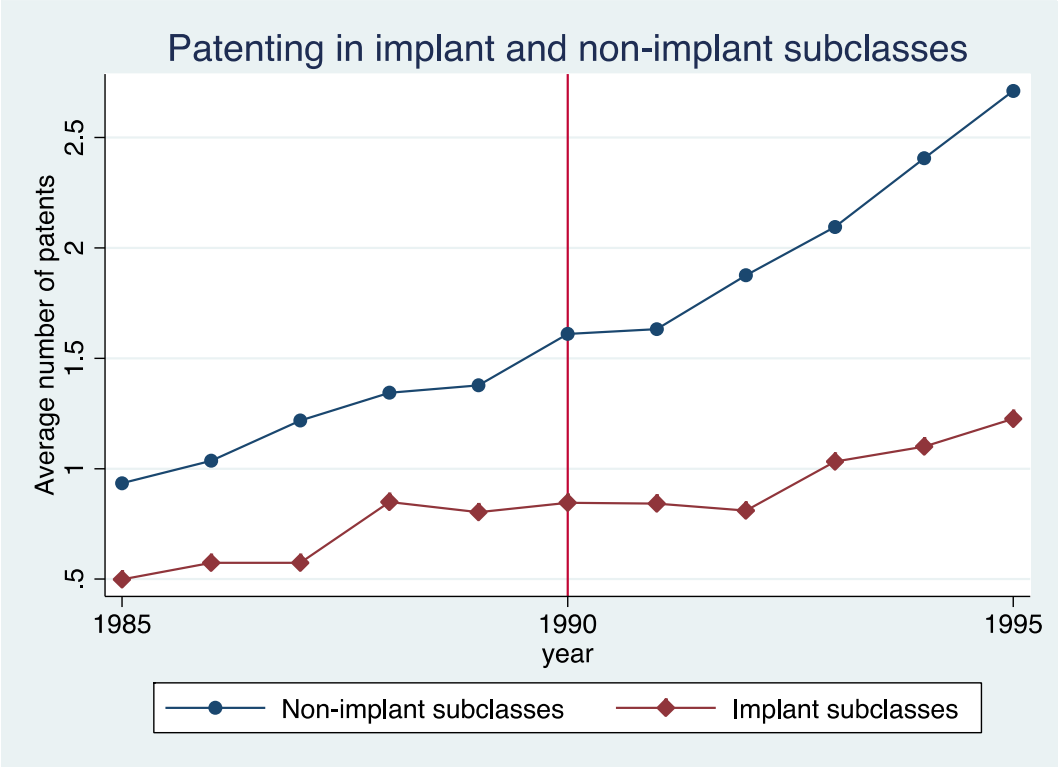
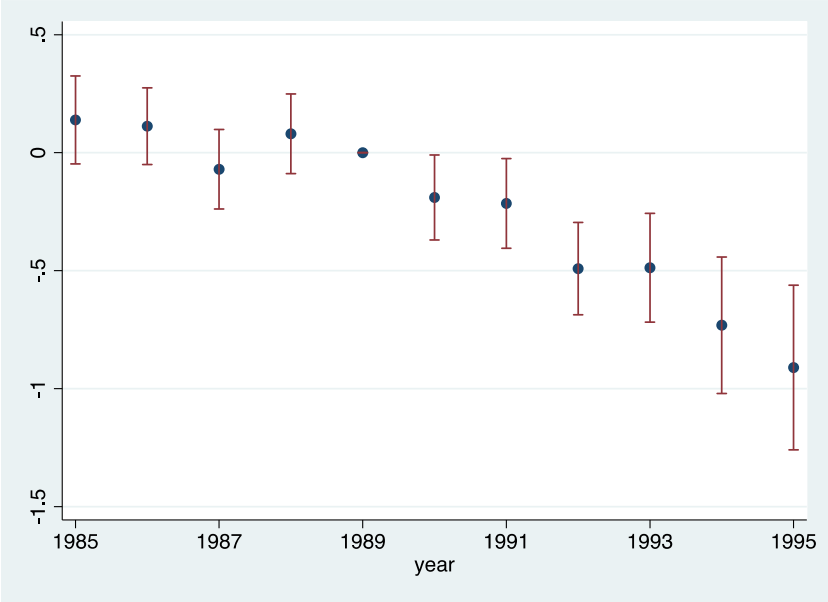
Figure 1. Patenting over time



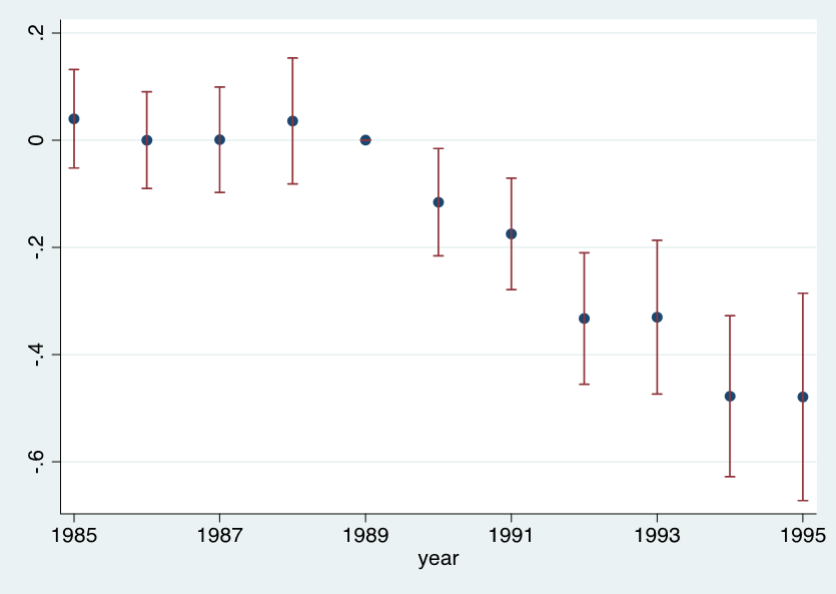
Average number of patents over all implant and non-implant subclasses by application year. Implant subclasses (the treatment group) are subclasses for which at least 80 percent of all the patents between 1975 and 2015 are implant patents; non-implant subclasses are the remaining subclasses.

Figure 2. Estimated annual treatment effects

a. Total patenting

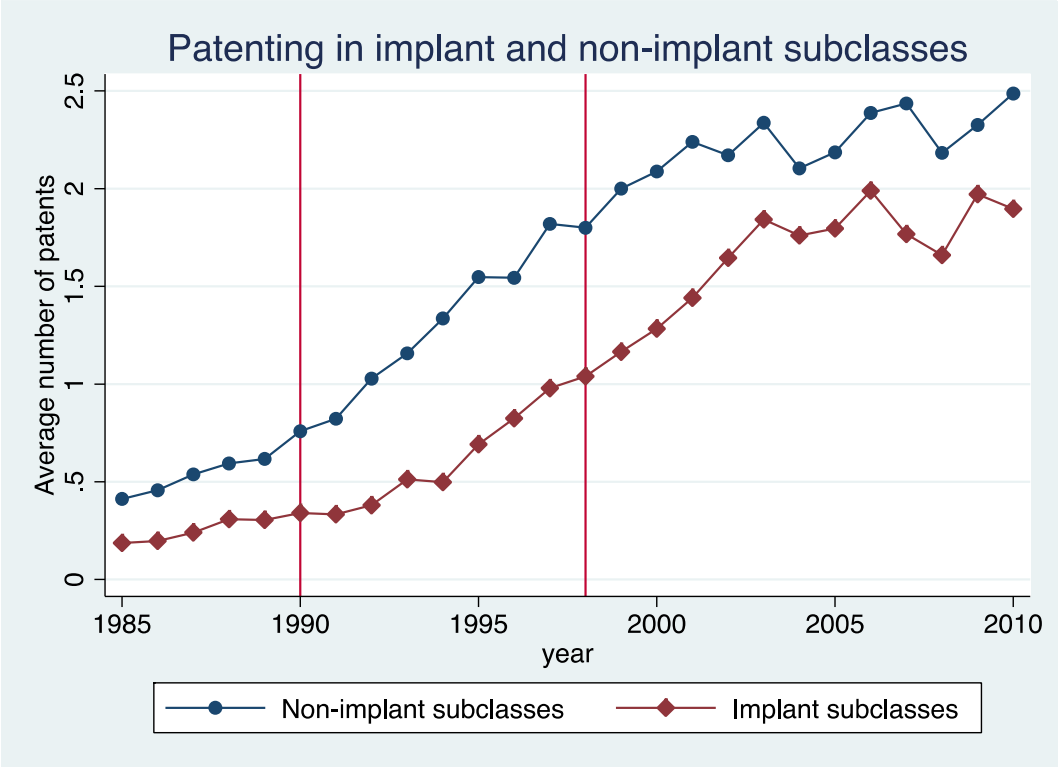


b. Patenting by US firms



Both regressions correspond to equation (2) in the paper, controlling for subclass and year fixed effects. (a) uses all medical device patents in 1985-1995; (b) uses patents by US assignees in 1985-1995. The figures plot the coefficients (and 95% confidence intervals) of the interaction terms between year dummies and the implant class dummy, which equals one if at least 80 percent of all the patents in the subclass are implant patents.

Figure 3. Patenting by US firms over time, extended to 2010



Average number of patents over all implant and non-implant subclasses by application year. Implant subclasses (the treatment group) are subclasses for which at least 80 percent of all the patents between 1975 and 2015 are implant patents; non-implant subclasses are the remaining subclasses.

Table 1. Summary statistics

	Obs.	Mean	Std. Dev.	Min	Max
Patents	29656	1.570	3.340	0	102
Year	29656	1990	3.160	1985	1995
Implant	29656	0.103	0.304	0	1

Patents = the number of patent applications in a subclass-year. Implant = 1 if at least 80 percent of all the patents in a subclass are implant patents.

Table 2. Liability risk and implant innovation

	(1)	(2)	(3)	(4)
Dependent variable	Patents	Patents	Patents	Patents
Implant x After 1990	-0.557***	-0.350***	-0.558***	-0.302***
	(0.084)	(0.097)	(0.105)	(0.085)
Year effects	YES	YES	YES	YES
Subclass effects	YES	YES	YES	YES
Drop mixed subclasses	NO	NO	NO	YES
Cut-off for implant subclass	0.8	0.5	0.9	0.8
Observations	29656	29656	29656	17820

OLS regressions with robust standard errors clustered at the subclass level. * significant at 10 percent, ** significant at 5 percent and *** significant at 1 percent. Patents = the number of patent applications in a subclass-year. Implant = 1 if the fraction of implant patents in a subclass exceeds the specified cut-off. Column 4 drops patent subclasses with the fraction of implants between 0.02 and 0.8.

Table 3. Testing for substitution effects

	(1)	(2)	(3)
Dependent variable	Patents	Patents	Patents
Implant x After 1990	-0.464***	-0.827***	-0.644***
	(0.052)	(0.105)	(0.140)
Year effects	YES	YES	YES
Subclass effects	YES	YES	YES
Observations	29656	22033	6138
Sample	drop assignees that patent in both implant and non-implant subclasses	implant and drug subclasses	implant and matched drug subclasses

OLS regression with robust standard errors clustered at the subclass level. * significant at 10 percent, ** significant at 5 percent and *** significant at 1 percent. Patents = the number of patent applications in a subclass-year. Implant = 1 if at least 80 percent of all the patents in a subclass are implant patents.

Table 4: Patents by foreign firms and triple differences

	(1)	(2)	(3)	(4)
Dependent variable	Patents by US firms	Patents by US firms	Patents	Patents
Implant x After 1990	-0.334***	-0.393***	-0.106***	-0.068***
	(0.046)	(0.056)	(0.031)	(0.026)
Implant x After 1990 X US firms			-0.344***	-0.305***
			(0.060)	(0.051)
Patents by foreign firms	0.716***	0.812***		
	(0.086)	(0.099)		
US firms			0.454***	0.261***
			(0.024)	(0.017)
After 1990 X US firms			0.567***	0.485***
			(0.038)	(0.031)
Implant X US firms			-0.331***	-0.199***
			(0.047)	(0.037)
Year effects	YES	YES	YES	YES
Subclass effects	YES	YES	YES	YES
Country status defined by	assignees	inventors	assignees	inventors
Observations	29656	29656	59312	59312

OLS regression with robust standard errors clustered at the subclass level. * significant at 10 percent, ** significant at 5 percent and *** significant at 1 percent. The dependent variables in columns (1) and (2) are the number of patent applications by US firms in a subclass-year, with the former based on the country of origin of the patent's assignee and the latter on the country of the patent's first inventor. Correspondingly, these two columns control for the number of patent applications by foreign firms based on the country of origin of the assignee and the inventor, respectively. In columns (3) and (4), the sample includes two observations, one for US firms and the other for foreign firms, for each subclass-year. US firms = 1 if the observation relates to patenting by US firms. Implant = 1 if at least 80 percent of all the patents in a subclass are implant patents.

Table 5. Robustness of baseline regression

	(1)	(2)	(3)	(4)
Dependent variable	Patents	Patents	Patents	Patents
Implant fraction X After 1990	-0.610***			
	(0.091)			
Implant class x After 1990		-0.586***	-0.635***	-1.011***
		(0.090)	(0.095)	(0.184)
Year effects	YES	YES	YES	YES
Subclass effects	YES	YES	YES	YES
Drop observations	NO	Subclasses with no patents	Subclasses with no patents and years before first patent	Pacemakers and heart valves
Observations	29656	27753	26749	14706

OLS regressions with robust standard errors clustered at the subclass level. * significant at 10 percent, ** significant at 5 percent and *** significant at 1 percent. Patents = the number of patent applications in a subclass-year. Implant = 1 if the fraction of implant patents in the subclass exceeds 0.8. Column 2 drops subclasses with no patenting during our sample period. Column 3 exploits an unbalanced panel in which a subclass enters the sample in the first year of positive patenting. Column 4 drops subclasses involving pacemakers and heart valves.

Table 6. Liability risk and FDA applications

	(1)	(2)	(3)	(4)
Dependent variable	Applications	Applications	Applications	Applications
Implant x After 1990	-0.394*	-0.469**	-0.142***	-0.144***
	(0.236)	(0.236)	(0.048)	(0.048)
MDR reports				0.012***
				(0.003)
Year effects	YES	YES	YES	YES
Product code effects	YES	YES	YES	YES
Matched Control	NO	YES	YES	YES
Drop outliers	NO	NO	YES	YES
Observations	3344	2486	2464	2464

OLS regressions with robust standard errors clustered at the subclass level. * significant at 10 percent, ** significant at 5 percent and *** significant at 1 percent. Applications = the number of FDA applications in a product code-year. Implant = 1 if the FDA identifies the product code as an implant. MDR reports = the number of device-associated reports of deaths, serious injuries, and malfuctions. Column 2 exploits a matched control group that minimizes pre-trend differences. Column 3 drops two outlier product codes.

Table 7. Heterogeneous effects

	(1)	(2)	(3)	(4)	(5)
Panel A. Firm size					
Dependent variable	Patents	Patents	Patents	Patents	Patents
Firm size	Small	Medium	Large	Top 16	Top 6
Percent of patents	50%	25%	25%	10%	5%
Implant x After 1990	-0.170***	-0.113***	-0.150***	-0.046***	-0.015**
	(0.039)	(0.021)	(0.027)	(0.010)	(0.006)
Sample mean	0.795	0.382	0.396	0.166	0.084
Observations	29656	29656	29656	29656	29656
Panel B. Citation quintiles					
Dependent variable	Patents	Patents	Patents	Patents	Patents
Quntile	Q1 (lowest)	Q2	Q3	Q4	Q5 (highest)
Implant x After 1990	-0.099***	-0.095***	-0.050***	-0.035*	-0.075***
	(0.022)	(0.015)	(0.019)	(0.020)	(0.026)
Sample mean	0.314	0.314	0.314	0.314	0.314
Observations	29656	29656	29656	29656	29656

OLS regressions with robust standard errors clustered at the subclass level. * significant at 10 percent, ** significant at 5 percent and *** significant at 1 percent. Patents = the number of patent applications in a subclass-year. Implant = 1 if the fraction of implant patents in the subclass exceeds 0.8. In (a), small patentees if portfolio has less than five patents; medium if portfolio has five to 40; and large if portfolio size is above 40. Top 16 includes the largest 16 assignees in the sample, and Top 6 includes the six largest assignees. In (b), each column includes only patents of a specific citation quartile (filtered by application year and technology class).

Table 8. Impact on polymer patenting

	(1)	(2)	(3)	(4)
Dependent variable	Patents	Patents	DuPont's patents	DuPont's patents
Affected-polymer class x After 1990	0.204	0.092	-0.002	-0.025
	(0.151)	(0.207)	(0.022)	(0.026)
Year effects	YES	YES	YES	YES
Subclass effects	YES	YES	YES	YES
Matched control	NO	YES	NO	YES
Observations	98868	3124	98868	3124

OLS regressions with robust standard errors clustered at the subclass level. * significant at 10 percent, ** significant at 5 percent and *** significant at 1 percent. Patents = the number of patent applications in a subclass-year. Affected-polymer class = 1 if the fraction of affected-polymer patents exceeds 0.8. The sample for column (1) includes all subclasses related to resins and organic compounds; and column (2) exploits a matched control group that minimizes pre-trend differences. Columns (3) and (4) are similar to the first two columns, using only DuPont's patents in resins and organic compounds.

When does product liability risk chill innovation? Evidence from medical implants

APPENDIX

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Hong Luo
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1 Appendix 1: DuPont's revised supply policy

Below, we report the January 15, 1993 letter that DuPont sent to its customers describing the change in its supply policy regarding implant manufacturers. The source of this letter is the May 20, 1994 hearing before the Subcommittee on Regulation and Government Information of the Committee on Governmental Affairs of the US Senate.

Dear (Customer's Name):

This communication affects only those customers who use DuPont materials in implantable medical devices.

Recently DuPont has determined that unpredictable and excessive costs of doing business with manufacturers of implantable medical devices no longer justifies unrestricted sale of standard raw materials to such manufacturers at customary prices. Our new Policy and Caution Statement regarding these sales are attached. Under DuPont's new Policy there is a very strong presumption against sales to customers making permanent implants.

Therefore, as of January 15, 1993, DuPont will begin to phase out sale of materials to customers using our materials in medical articles intended for permanent implantation in the human body or in permanent contact with internal body fluids or tissues. We intend to complete this phase out as soon as possible, but no later than January 31, 1994.

To allow our customers time to locate alternate suppliers of materials, or alternate materials, during this phase out period we will honor our existing customer/supplier relationships. Also, effective immediately Du Pont will restrict sales of materials to companies who use those materials in medical articles intended for brief or temporary implantation in the human body or in contact with internal body fluids or tissues. DuPont will not supply the material to customers making temporary implants, unless the material comes directly from DuPont under a contract which expressly acknowledges the contemplated use and contains specific business risk management requirements.

Permission to refer to material Master Files will be withdrawn, and given only to direct customers who are purchasing material from DuPont under contract. We intend to complete transition to this type of supplier/customer relationship as soon as possible, but no later than January 31, 1994.

Unless expressly agreed by contract, do not make reference to the Du Pont name or any DuPont trademark in association with any implantable medical device. Do not use a DuPont trademark as the descriptive name of an implantable medical device. A copy of DuPont's Policy and Caution are attached. We sincerely regret any inconvenience this may cause you. If you have any questions, please contact me at (xxx-xxx-xxxx).

Sincerely.

Appendix 2: Back-of-the-envelope welfare calculation

This Appendix explains in greater detail the welfare calculation conducted in Section 8.1. The calculation follows four steps.

In step 1, we obtain the total surplus that would have been generated from having one new device. This number is the product of the total number of procedures involving each of the four device types used in the analysis—which are obtained from the 1992 annual summary of the National Hospital Discharge Survey—and the increase in total surplus per procedure when physicians have access to a new medical device, estimated by Grennan and Swanson (2017). Note that the increase in total surplus is the sum of the increase in consumer surplus (physician, patient, and hospital combined) and producer gross profit (price minus marginal cost). For example, for hip replacement, the total estimated increase in surplus is \$7,233 + \$932 = \$8,165 per procedure. The number of procedures in 1992 for hip replacement (ICD-9 code 81.51 in Table 22) was 127K. Thus, the increase in total surplus is \$1.03B per year for hip replacement. This number for knee replacements, pacemakers, and cardiac catheterization are, respectively, \$3.9B, \$2.6B, and \$4.2B.

In step 2, we derive the reduction in the total number of devices per year based on our estimates. Our preferred model (column 3 of Table 6) implies an average reduction of 0.14 FDA device applications per year for implant product codes relative to non-implant codes. Multiplying this average effect by the number of product codes involving medical implants (107 codes), we obtain an estimated reduction of 15.96 implant devices per year.

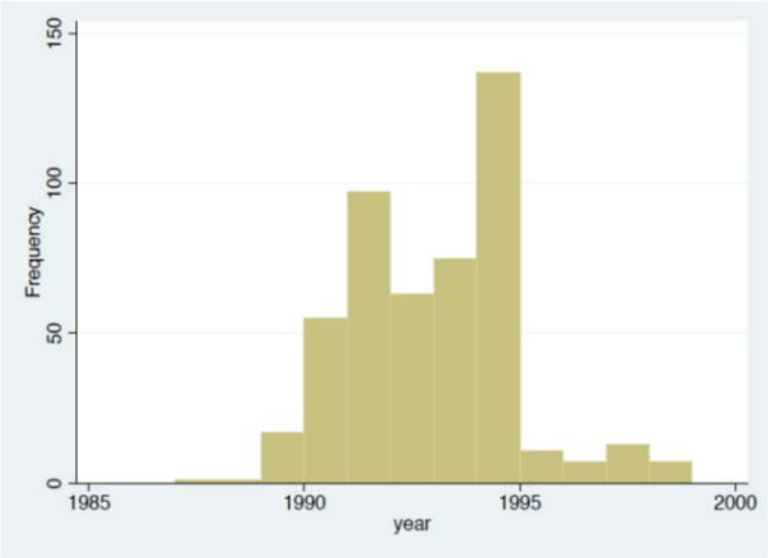
In step 3, we obtain the drop in the number of new devices associated with the four specific implant types. Assuming that the drop in applications is distributed across categories in proportion to the level of applications before the increase in liability risk (that is, between 1985-1989), the yearly reductions in the number of applications are, respectively, 4.2, 0.1, 0.4, and 3.4 for hip implants, knee implants, pacemakers, and catheters.

In step 4, multiplying the above numbers of yearly reductions in applications by the increase in total surplus per new device per year yields the estimated reduction in total surplus due to the increase in liability risk. The welfare loss for these four device types, in total, is \$20.3B. Grennan and Swanson (2017) show that for these four device categories, a typical product is in the consideration set of 56 percent to 91 percent of hospitals. Taking these penetration rates into account, the decline in the total surplus for these four implant categories combined is \$11.9B per year.

Note that Grennan and Swanson (2017) provide estimates of the splits of the total surplus between consumers surplus and producer gross profit for each device category. Repeating the above four steps using each of the two components in Step 1 would provide us with an estimate of the loss in consumer surplus and the loss in producer gross profits separately.

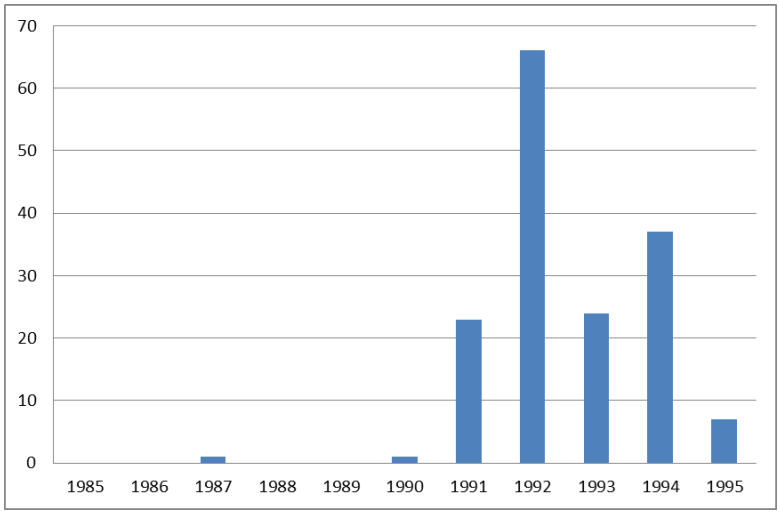
Figure A1. TMJ Lawsuits involving DuPont and medical implants media mentions

a. Number of TMJ lawsuits with DuPont among the defendants



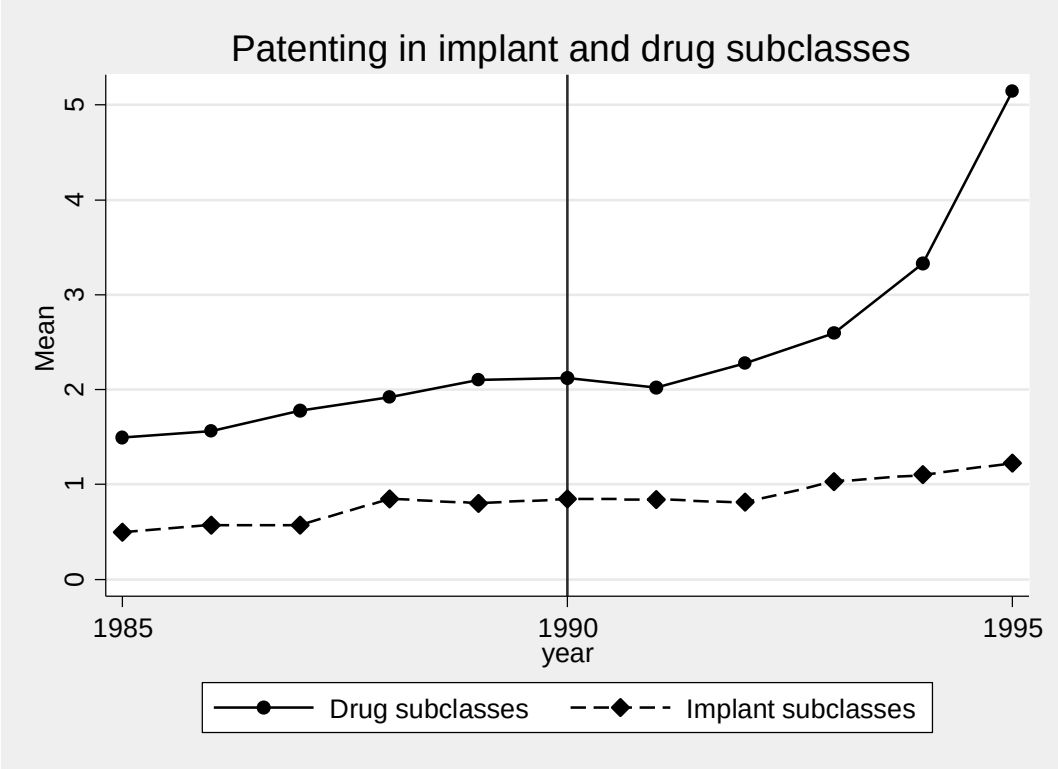
Source: Bloomberg Law

b. Media mentions of medical implants



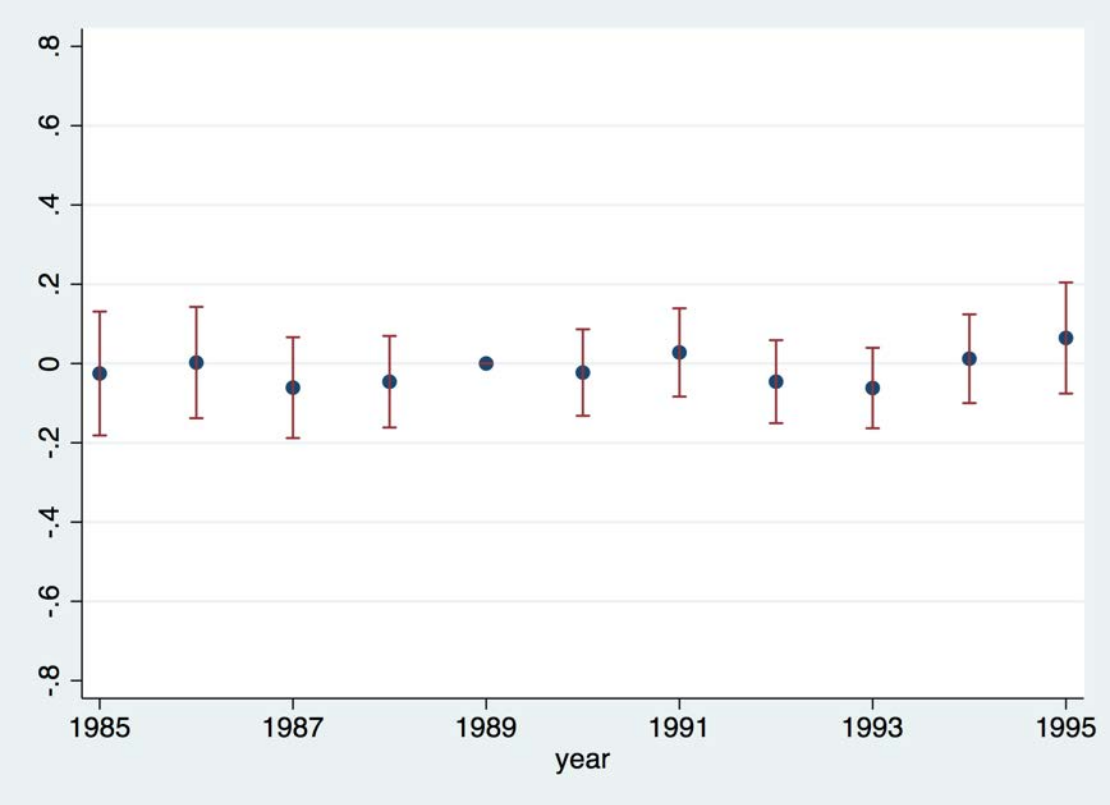
Source: Factiva (Dow Jones), textual searchers use keywords 'implant,' 'DuPont,' 'jaw,' and 'breast.'

Figure A2. Patenting over time in implant and drug subclasses



Average number of patents over all implant and drugs subclasses (an alternative control group) by application year. Implant subclasses are medical device subclasses for which their fraction of implant patents is greater than 80 percent. Drug subclasses belong to USPTO classes 424 and 514, both titled “drugs, bio-affecting and body treating compositions.”

Figure A3. Estimated annual treatment effects using patents published by the UK patent office



This regression uses medical device patents published by the UK patent office and applied for between 1985 and 1995. The regression corresponds to equation (2) in the paper, controlling for subclass and year fixed effects. The figure plots the coefficients (and 95% confidence intervals) of the interaction terms between year dummies and the implant class dummy. We use the classification system used in Europe during our sample period and define class A61 ("Medical or Veterinary Science, Hygiene") as medical device patents. We use a less demanding textual algorithm than we use for US patents–that is, searching only for keywords of 'implant, graft, prosthesis, or prosthetic' without combining that with the device name keywords–to identify implant patents because our data for UK, Germany and France contain fewer textual variables. Similar to our baseline analysis, the cut-off threshold for defining an implant class is chosen so that the treated implant subclasses contain roughly the top tenth percentile of the distribution of the fraction of implant patents.

Figure A4. Estimated year effects on upstream innovation

The regression is similar to equation (2) in the paper, using patents related to resin and organic compounds in 1985-1995 and controlling for subclass and year fixed effects. The figure plots the coefficients (and 95% confidence intervals) of the interaction terms between year dummies and the affected-polymer class dummy, which equals one if at least 80 percent of all the patents in the subclass are affected-polymer patents. The sample used in this regression includes all affected-polymer subclasses (i.e., the treatment group) and control subclasses (i.e., the fraction of affected-polymer patents is less than 80 percent) that are matched to minimize the difference in the pre-trend (1985-1989) from the treated group.

Table A1. Alternative econometric models

	(1)	(2)	(3)	(4)	(5)
Dependent variable	Patents	log(patents+1)	Citations	Patents	Patents
Model	Weighted OLS	OLS	OLS	Poisson	Poisson - Mean scaling estimator
Implant x After 1990	-0.729***	-0.078***	-30.896***	-0.161**	-0.313***
	(0.151)	(0.012)	(10.303)	(0.073)	(0.046)
Year effects	YES	YES	YES	YES	YES
Subclass effects	YES	YES	YES	YES	NO
Observations	29656	29656	29656	27753	29656

Robust standard errors clustered at the subclass level. * significant at 10 percent, ** significant at 5 percent and *** significant at 1 percent. Patents = the number of patent applications in a subclass-year. Implant = 1 if the fraction of implant patents in a subclass exceeds 0.8. In column 1, weights are equal to the logarithm of the pre-sample patenting (period 72-82). Column 2 includes a dummy for subclasses-years with no patenting. Column 5 includes the log of pre-sample patenting as control.

Table A2. Aggregation of patent subclasses

	(1)	(2)	(3)
Dependent variable	Patents	Patents	Patents
Aggregated subclasses	1862	1178	459
Implant x After 1990	-0.667***	-1.279***	-3.369***
	(0.17)	(0.39)	(1.24)
Year effects	YES	YES	YES
Subclass effects	YES	YES	YES
Observations	20482	12958	5049

Robust standard errors clustered at the subclass level. * significant at 10 percent, ** significant at 5 percent and *** significant at 1 percent. Patents = the number of patent applications in an (aggregated) subclass-year. Implant =1 if the fraction of implant patents in an aggregated subclass exceeds 0.8.

Table A3. Additional robustness of upstream effect

	(1)	(2)	(3)	(4)
Dependent variable	Patents	Patents	DuPont's patents	DuPont's patents
Affected-polymer class x After 1990	0.056		-0.004	
	(0.161)		(0.023)	
Affected-polymer class x After 1992		0.104		-0.035
		(0.243)		(0.027)
Year effects	YES	YES	YES	YES
Subclass effects	YES	YES	YES	YES
Matched control	NO	YES	NO	YES
Cut-off for polymer class	0.65	0.08	0.65	0.08
Observations	10120	3124	10120	3124

OLS regressions with robust standard errors clustered at the subclass level. * significant at 10 percent, ** significant at 5 percent and *** significant at 1 percent. Patents = the number of patent applications in a subclass-year. Affected-polymer class = 1 if the fraction of affected-polymer patents exceeds 0.8. The sample for columns (1) and (2) includes all subclasses related to resins and organic compounds; and the sample for columns (3) and (4) includes only DuPont's patents. Columns (2) and (4) exploit a matched control group that minimizes pre-trend differences.