When Does Product Liability Risk Chill Innovation? Evidence From Medical Implants

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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.

Keywords: product liability, innovation, tort, medical devices, vertical foreclosure
JEL Codes: O31, O32, O34, K13.

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

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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 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

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¹Indeed, 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).

²For 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.”
there conditions under which the product liability system is likely to generate unintended, negative effects on innovation? Identification and examination of such conditions may offer useful information for more targeted policy interventions. 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. 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 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. Importantly, 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.

We subject our data to a variety of tests to 1) control for potential confounding factors, such as demand and technology trends that affect implant and non-implant innovation differently; and 2) 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.

Triple-differences regressions—which control for common technology or demand trends taking place in the same technological areas—show that implant patenting by US firms experienced a large and statistically significant decline relative to patenting by foreign firms in the same technology classes. Industry reports describing the events suggest that these heterogeneous effects were likely driven by differences in access to foreign material suppliers, thus supporting the predictions of our theoretical framework.

Using FDA device approval data as an alternative measure of innovation, we confirm the significant decline in implant innovation. The FDA data also help us to consider alternative mechanisms. First, taking advantage of data on adverse events that form the basis for lawsuits, we show that not only is the large decline in implant innovation robust to controlling for the extent of adverse events associated with a given product type, but that it also holds for product types for which there should be little concern about downstream liability. Second, we show that data on FDA approval time do not suggest a significant change in regulatory concerns over implant safety in general.

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 sub-stitution 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.

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. 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 and if the inputs themselves are not dangerous or defective. 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 welfare implication of the foregone innovations is a complex matter, as we need to contrast potential welfare costs from fewer new devices against potential social gains from fewer product failures and greater safety. Such an analysis is beyond the scope of our paper. Nonetheless, we leverage our results and estimates from Grennan and Swanson (2018) to assess the magnitude of potential welfare costs associated with the lost devices. Such cost is estimated to be at least $4.1 billion per year.

The mechanism we document in this paper can be 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
c polymers. Section 8 discusses welfare and policy implications and alternative mechanisms, 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

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\(^4\) 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).
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, 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. 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

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6There 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.
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.\footnote{Our results can also be interpreted as evidence for horizontal spillover: Vitek’s bankruptcy negatively affects all other implant producers because of the resulting surge in the liability risk faced by large common suppliers.} At a more aggregate level, a growing number of papers (e.g., Long and Plosser, 1983; and Acemoglu 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.\footnote{Recent studies that examine the effect of policies directly targeted at innovation include Moser and Voena (2012) and Sampat and Williams (2018).} 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.

\section{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
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—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 across over 40 different states (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 significantly affected raw material producers assessment of their liability when supplying to implant manufacturers. As a result, many suppliers changed their

\(^9\)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.
supply policies. 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 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. 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 may not be sufficient
to protect suppliers from disproportionately high liability risk relative to their expected revenue. Follow-
ing these events, many material producers dramatically changed their policy for supplying permanent
implant producers (Service, 1994). 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. This
affected a wide range of implants using polymeric materials, from sutures and fracture fixation devices
to pacemakers and heart valves. A number of other major suppliers also exited the market, and,
notably, Dow Chemicals and Dow Corning ceased supplying materials to permanent-implant producers

Prompted by DuPont’s withdrawal, the Health Industry Manufacturers Association (HIMA) com-
misioned a comprehensive report examining the status of the biomaterial market (Aronoff, 1995). A

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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.

12 Documents submitted to the 1995 congressional hearing include a list of potentially affected implants, covering close
to 100 different types of permanent and temporary implants using polymeric materials.
survey conducted for 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 was, perhaps, the greatest for polymer and silicone materials, but anecdotal evidence suggests that the liability concerns reached beyond polymeric materials; according to Citron (1994), for example, a certain well-established manufacturer of integrated circuits refused to supply its chips for implanted devices. The May 20, 1994 hearing of the US Senate Subcommittee on Regulation and Government Information heard testimony regarding the availability of biomaterials. For example, James Benson, Senior VP of HIMA, explained that “in many cases, there are no alternative suppliers for these materials.” Other testimonies emphasized that even when alternatives existed, the costs required to identify suitable replacements and to qualify them could be extremely high. 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.13 Testifiers also claimed that these reactions affected firms’ innovation investments by diverting resources away from the development of new products toward finding and securing materials required for existing 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

13Even with some suppliers stepping in, some suggest that the overall quality standard of the portfolio of implantable materials may have declined as suppliers shifted from “large, sophisticated chemical companies with well established quality procedures” to “smaller, undercapitalized, and less sophisticated supply sources.” (Citron, 1994).
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 \([I^D, 1 + I^D]\). 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 \( \theta \) 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. 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 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. 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 $p_A$,

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14Theoretically, 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.

15The 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).
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

\[ \max \{ \Pi(0) - \Delta(l), \pi^B \} - I^U \geq 0. \]

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. Empirically, this implies that an analysis of the firms directly targeted by litigation may find no impact, thus missing significant effects taking place elsewhere in the value chain.

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.\footnote{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. Finally, according to Citron (1994), even with contractual remedies, suppliers may still be joined in the lawsuits and “must put up with the expense of discovery procedures and the great inconvenience it entails, as well as adverse publicity.”

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 $\bar{\theta}$.\footnote{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.}

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.\footnote{Details are described in www.uspto.gov/web/offices/ac/ido/oeip/taf/meddev.htm.} 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 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.”

We then calculate the fraction of implant patents at the subclass level. 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. This corresponds to the top decile of the distribution of the shares of implant patents across subclasses. We conduct our analysis at the subclass level, instead of at the patent level, mainly to take advantage of the extensive expertise at the USPTO. As mentioned above, patents are classified by the USPTO 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, is likely to be either an implant patent whose texts are not explicitly written as such or an invention that is related to implant technologies and, hence, is potentially affected by our shock.

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). Three subclasses are associated with jaw and breast implants involved in the litigations, and their fractions of implant patents are, respectively, 85, 87, and 93 percent. 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).

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 suppliers’ liability concerns probably changed around that time. This is partly because major industry lobbying efforts resulted in two congressional hearings around then, which eventually led to the passage of the BAAA in 1998, and partly because DuPont won critical lawsuits that essentially stopped new lawsuits in 1995 (Schmucki, 1999; and see panel A of Appendix Figure A1, which we will explain in the next section). In Section 8.2, we extend the sample to 2010 for an analysis of the longer-run outcomes. To address one of the endogeneity concerns discussed in the next section, we drop the three patent subclasses related to jaw 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 to implant producers face in general affect the innovation 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:

\[ \text{Patents}_{c,t} = \alpha + \beta \text{Implant}_c \times \text{After1990}_t + \delta_t + f_c + \varepsilon_{c,t}, \]  

where Implant\(_c\) equals 1 if subclass \(c\) is an implant subclass; After1990\(_t\) equals 1 for every year after (and including) 1990; and \(\delta_t\) and \(f_c\) are year and subclass fixed effects. The coefficient \(\beta\) 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 to implant producers 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.\(^{20}\) 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 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

\(^{20}\) 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.
participants’ perception about liability risk.

It is important to note two types of concerns. The first is about identification: there may be concurrent confounding factors that affect implant and non-implant innovation differently, leading to correlation between $After_{1990_t}$ and the error term, $\varepsilon_{c,t}$. For example, there may have been technological breakthroughs in non-implant technologies that drove up the growth of the control group after 1990. It is also possible that the stagnation of implant innovation took place because implant products began to fail more generally in the early 90s, leading to disruption or a decline in demand. The second type of concerns are related to the interpretation of the identified effect. In addition to 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 implant failures in general (Jarrell and Peltzman, 1985); (ii) an increase in the liability risk that downstream implant producers perceived for themselves; and (iii) a more stringent regulatory oversight for other implants (Dranove and Olsen, 1994). All of these additional effects could also have generated a decline in downstream innovation, but through mechanisms different from the upstream-supply channel proposed in our theoretical framework.

In the paper, we rely on a collective set of evidence to address both types of concerns. First, we 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.

Second, industry reports suggest that foreign implant producers had easier access to foreign polymer suppliers than their US counterparts had. Building on this observation, we perform triple-differences regressions using foreign patents of each subclass as a benchmark. These regressions help to control for confounding trends, for either the supply or the demand side, that are common to US and foreign patentees in the same patent subclass, and they provide additional support for the upstream-supply mechanism. Third, we use adverse events data to directly control for potential liability concerns that downstream producers face themselves. In Section 8.3, we discuss in greater detail additional 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. We also compare drug patents to our main control group of non-implant medical devices to further address potential identification concerns, as they both display a growth trend present in the medical sector during this sample period.

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.\textsuperscript{21}

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.\textsuperscript{22}

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.\textsuperscript{23} Third,  

\textsuperscript{21}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.  
\textsuperscript{22}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.  
\textsuperscript{23}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).
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 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, $\beta_t$. Specifically, we estimate:

$$
Patents_{c,t} = \alpha + \beta_t \text{Implant}_c \times Year_t + \delta_t + f_c + \epsilon_{c,t},
$$

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 was small but 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.\textsuperscript{24}

As a second empirical exercise, we contrast patenting in implant patent subclasses with patenting in subclasses that include only pharmaceutical drug innovations and not medical device innovations.\textsuperscript{25} 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. Column 2 of Table 3 estimates equation (1), using 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 before 1990. 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.

The last column of Table 3 compares the two control groups—non-implant medical device subclasses and the (matched) drug subclasses used in column 3. The difference-in-differences coefficient of this placebo analysis is small and statistically insignificant. This result suggests that non-implant devices grew similarly to other areas of the medical sector, which is consistent with the idea that the estimated effect in our baseline regression is driven by a slowdown in implant technologies.

\textsuperscript{24}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.

\textsuperscript{25}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).
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. This analysis further mitigates identification concerns about potential confounding factors differentially affecting implant versus non-implant innovation—as discussed previously, there may be technological breakthroughs for non-implant technologies, or implant products may have begun to experience failures more generally in the early 90s. Patenting by foreign firms helps to control for trends taking place in a given technology area that are common to US and foreign patentees.

There are a number of reasons to expect foreign firms to be less affected by the TMJ and breast implant litigations and the resulting disruption to the industry’s supply chain. Even though foreign producers selling products in the US generally face the same product liability rules as domestic producers, US plaintiffs face complexities and additional legal costs (such as matters of personal jurisdiction, conflicts of laws, and greater difficulties in enforcing judgment) that make foreign producers less concerned about liability risk (Sisum and Timoney, 2011; Klerman, 2012).

Moreover, Aronoff (1995) (the HIMA-commissioned industry report) specifically pointed out that “foreign medical implant manufacturers will have an easier time obtaining replacement materials from foreign suppliers, as sales to these manufacturers are apparently not considered as risky as sales to their United States counterparts.” An important driver of this asymmetry may be the high legal costs and complexities that US plaintiffs face in holding upstream suppliers liable for product failures when both parties of the supply contracts are foreign entities. Apart from legal reasons, there may be other transactions costs that make it easier for foreign suppliers to supply to foreign implant producers than to supply US implant producers, including trust and reputation developed over past business relationships that are especially important under heightened uncertainty. Our theoretical model suggests that these differences in material access should generate a heterogeneous effect on innovation of US firms relative to foreign firms.

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.\textsuperscript{20}

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 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

\textsuperscript{20}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.
4 of Table 4 replicates column 3, using the inventor’s country of origin to categorize the patents, and
the results are similar. Appendix Figure A2 presents the triple-interaction coefficients in a year-specific
version of column 4 of Table 4. This figure illustrates a pattern that is qualitatively consistent with
that in Figure 2 (panel B), with the estimated differential effects on implant patenting experienced by
US firms being only slightly smaller. This is consistent with the idea that our liability shock had a
substantially lower impact on foreign firms that commercialize in the US.27

To further examine the effect of our liability shock on foreign inventors, we also examine datasets
of medical device patents granted by UK, French and German patent offices to non-US applicants.
Different from foreign patentees of US patents, these foreign firms pool together firms that do and do
not commercialize in the U.S. 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

Overall, these estimates show that implant patenting by US firms significantly decreased after 1990
relative to foreign firms. This finding helps to isolate potential confounding factors that differentially
affect implant and control technologies. As discussed above, the finding supports our proposed upstream-
supply mechanism to the extent that differences between US and foreign patenting reflects producers’
differential access to materials, (we continue to provide evidence for assessing alternative mechanisms
in Section 6.5 and collectively discuss the body of evidence in Section 8.3).

27We confirmed the triple-differences results, in unreported regressions, using the logarithm of the number of patents
as the dependent variable. 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.

28The 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
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.
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. We also estimated the coefficient of the interaction term between the fraction of implant patents and year fixed effects to obtain a flexibly estimated pattern over time in the dependent variable, as suggested by Finkelstein (2007). We obtain a figure similar to Panel A of Figure 2—the size of the negative effect becomes larger and statistically more significant over time.

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 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 using FDA 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 the levels of FDA applications before 1990. 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 deaths, injuries and malfunctions that are associated with a specific FDA product code. Because the presence of adverse events provides the basis for lawsuits, this information helps to control for the extent of liability risk faced by downstream producers themselves. We created a new variable, Adverse events reports, equal to the total number of reports in year $t$ for the product code. Column 4 shows that our results are robust to including this control variable. Column 5 includes only product codes that are associated with zero adverse event reports throughout 1985-1995. For producers of these products, jaw and breast implant litigations presumably had little impact on their own perceived liability risk, given that these products were never associated with any adverse events. The estimated coefficient is statistically significant, and the economic magnitude remains large relative to the low baseline level of applications for these products.30 The finding of a large and significant negative effect on implant innovation, even when for products with minimum concerns over direct liability risk, provides further evidence that the upstream supply channel is an important driver of the relative decline in implant innovation.

Finally, we find that the amount of time taken by the FDA to approve a device does not change differentially for implant versus non-implant product codes after 1990 relative to before.31 This result

29Recall 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).

30Assuming the same difference between implant and non-implant product codes in this subsample after 1990, the estimated effect in column 5 implies a reduction of about 60 percent in implant innovation.

31In particular, we run an application-level regression using devices applied between 1985 and 1995. The dependent variable is the logarithm of the number of months taken by the FDA to approve a device, and we control for year and
is inconsistent with the alternative explanation that the drop in innovation is driven by a significant change in regulatory scrutiny of medical implants.

Overall, our analysis using product-based measures of innovation confirms the 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 and that the adverse-events data linkable to product codes help to control for downstream direct liability risk. Furthermore, the 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. 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). This 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.\footnote{We impute a portfolio of 1 to unassigned patents.} 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.

\footnote{The interaction term between a dummy indicating implant product codes and a dummy indicating application years after 1990 yields a coefficient of -0.11 (p-value is 0.458).}
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 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 even though the effect is industry-wide, it is smaller for the six largest assignees than for the rest of the sample. 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 in the U.S. They also could have had easier access to polymer suppliers outside the U.S. than smaller firms had because these large firms are unlikely to be insolvent and more likely to honor their contractual obligations.

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

33 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.
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 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.\textsuperscript{34}

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

\textsuperscript{34}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).
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 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. Appendix 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, which suggests that suppliers’ innovation incentives were driven by the aggregate demand from multiple downstream markets. It also demonstrates that the impact of liability may not show up for those directly targeted by litigation but elsewhere in the value chain.

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 stages. This section complements our analysis by (i) discussing the welfare implications of our findings; (ii) examining the longer-run outcomes after a federal policy was 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 implications

In this section, we discuss how one might think about the decline in implant innovation documented in our empirical analysis from the welfare perspective.

In a simple market setup in which firms face no risk of insolvency or other frictions, the allocation of liability risk across the vertical chain should have no impact on total welfare. The intuition is that shifts in liabilities will trigger price adjustments that preserve firms’ profits and, hence, production and innovation incentives (Daughety and Reinganum, 2013). As we depart from the benchmark case and, in particular, consider scenarios involving downstream insolvency, the allocation of liability begins to matter. In cases with no other frictions and homogeneous downstream firms (in terms of safety and solvency levels), imposing liability on upstream suppliers may be beneficial. This is because, by charging higher input prices or imposing more stringent contracts, suppliers can reduce the number of harmful products developed. When there are significant downstream firm heterogeneity, asymmetric
information, and contractual frictions, however, downstream-only liability can be a preferable policy (Hay and Spier, 2005).

Asymmetric information and contractual frictions are likely to be important features in contexts like ours, where large upstream firms supply general-purpose inputs to a wide range of downstream markets. This is because upstream suppliers are unlikely to have the specialized knowledge required to understand the features of all the applications using their inputs. Furthermore, downstream firms may possess private information about how they will process these inputs and about the safety levels of the final products. As discussed in Section 4.2, such information asymmetry combined with other transactions costs may prevent differential pricing or contractual remedies that can pass the upstream liability costs to downstream firms in a way that is specific to the safety levels of the final products.

In such environments, upstream suppliers may change their supply policies uniformly when faced with an increased liability risk, ranging from a higher input price to more stringent contractual requirements, which will result in a higher cost to all downstream firms indiscriminately. Moreover, in cases where the total profits from supplying a given risky market are sufficiently small relative to other revenue sources (as in the case of implants), large firms may resort to vertical foreclosure. These supply responses generate inefficiencies because they raise costs for firms that can internalize the liability costs themselves, including firms that are unlikely to be insolvent and whose products are reasonably safe. As Hay and Spier (2005) show theoretically, the argument in favor of leaving liability exclusively to downstream firms is stronger when there are sufficiently many solvent downstream firms in the population, not when the population is dominated by insolvent firms. The evidence we present in Section 6.6 shows that the decline in innovation is present for firms of all sizes and patents of all values. This provides additional support to the idea that both marginal and infra-marginal innovations are likely to be impacted.

A full welfare analysis, thus, requires contrasting two forces: (i) the surplus lost from fewer new devices; against (ii) the social gains due to fewer product failures and greater safety.\textsuperscript{35} Such an analysis is beyond the scope of our paper. Nonetheless, we can leverage our estimates to assess the first force—the magnitude of potential welfare costs associated with the decline in implant innovation.

\textsuperscript{35}Both Viscusi and Moore (1993) and Galasso and Luo (2017) suggest that a higher liability risk may incentivize the development of safer products; and Galasso and Luo (2019) directly measure and estimate the development of risk-mitigating technologies for CT scanners following accidents that increased the awareness of medical radiation risk.
To do this, we exploit the results of a recent study conducted by Grennan and Swanson (2018). They estimate the increase in total surplus per procedure, including both consumer surplus (physician, patient, and hospital combined) and producer gross profit, when physicians have access to an additional medical device. These estimates are derived from a bargaining model between hospitals and medical device vendors. It is important to note that their model does not explicitly consider patient and social costs related to product malfunctions and tort litigation. That said, because physicians and hospitals face liabilities themselves and disputes due to product failures may also be costly to them, these estimates implicitly incorporate social costs due to product failures to a certain extent.

Details of this exercise are presented in Appendix 2. Briefly, we focus on four prominent implant device categories for which we can also 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. Apart from the estimated surplus per procedure and the volume data, other inputs of the calculation include our preferred estimate of the average reduction of 0.14 FDA device applications per year per product code (column 3 of Table 6) and the penetration rate of a typical device in each of the four device types into the consideration set of the hospitals (56 to 91 percent from Grennan and Swanson, 2017). The decline in total surplus due to the increase in liability risk is estimated to be $11.9B per year for these four device types. Furthermore, using Grennan and Swanson (2017)’s estimate on how surplus is split, the total loss in consumer surplus is $10.6B per-year and the loss in producers’ gross profit is $1.2B per-year.\footnote{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.}

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.

These calculations are only illustrative and should not be over-interpreted since they may over- or under-estimate the potential loss.\footnote{For example, the National Hospital Discharge Survey focuses on only inpatient implant surgeries and do not include outpatient surgeries. Furthermore, 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 has increased.} As discussed above, these welfare estimates do not fully account
for the potential social gains from fewer product failures and greater safety. Nonetheless, they suggest that the decline in innovation documented by our regressions could potentially have a large 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. 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 and that the inputs themselves are not dangerous or defective. BAAA is one of few federal liability reforms, an area of legislation typically reserved for the states (Kerouac, 2001). 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 that for non-implant patents) and that four or five years later, it was restored to a level comparable

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38 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).

39 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.

40 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.
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 results show that, relative to the default years (before 1990), implant patenting decreased significantly between 1990 and 1998 (the coefficient of the interaction term is -0.339, and the p-value < 0.001, confirming our main result), and it recovered after the BAAA (the coefficient is 0.034, but 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). Appendix Figure A5 plots the year-specific difference-in-differences coefficients of a regression analogous to that for Figure 2 (Panel B), but extended to 2010. The graph shows that the negative effect of our liability shock is sustained after 1995 and is similar in magnitude until the end of the 90s. The effect starts to become increasingly less negative two years after 1998 and turns small and positive in 2002. The coefficients afterwards are statistically similar to the baseline year 1989 (the year before our liability shock).

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 these results should not be taken as ‘causal’ evidence of the effect of the law. The industry also took other measures to address the shortage of material suppliers that might have contributed to the recovery of implant patenting—such measures included reallocating

\[^{41}\text{The difference-in-differences coefficients of later years are more noisily estimated. However, comparing the coefficients for years with the most negative impacts and the years after 2002 shows mostly statistically significant differences. For example, the p-value of the equality test for the two difference-in-differences coefficients of years 1995 and 2002 is 0.009 and that for a test for years 1994 and 2005 is 0.039.}\]

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resources to identifying alternative supply sources or substitute materials. Moreover, DuPont started to win lawsuits at the state level in 1993 and won decisive judgments in 1995 and 1997, which effectively stopped further TMJ lawsuits and might have helped to also reduce the uncertainty over supplier liability.\footnote{In January 1995, U.S. District Court Judge Paul Magnuson granted summary judgment in favor of DuPont in a consolidated case involving all 280 remaining federal TMJ cases. The judge further ordered that any future federal TMJ cases automatically be dismissed (Schmucki, 1999). As is shown in panel (a) of Appendix Figure 1, the number of TMJ lawsuits filed against DuPont drastically dropped starting in 1995. In 1997, the Court of Appeals (1st District) in Houston, Texas, ruled in favor of DuPont and sustained DuPonts summary judgment in the trial court against 161 TMJ Plaintiffs.} Regardless of the precise reasons for the recovery, we do not observe an overshoot of implant patenting in the longer run. This suggests that the decline in the intervening years was a real loss rather than a delay in investment.

### 8.3 Assessing alternative mechanisms

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. As discussed in Section 5.1, litigations over TMJ and breast implant failures may have led to an overall decline in implant innovation through other mechanisms—in particular, a drop in the overall demand for implants; an increase in the liability risk perceived by implant producers; or more-stringent oversight by the regulators. In this section, we collect a body of evidence—including results from prior sections and additional evidence—supporting the idea that market foreclosure driven by upstream suppliers’ concern over liability risk is an important, though not necessarily the only, mechanism behind the decline in innovation.

First, industry reports describing the status of the implant industry in general after Vitek’s bankruptcy, as well as the congressional testimonies of medical device manufacturers, large and small, reflect concerns about the lack of suppliers rather than about downstream litigation or the decline in demand. 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, we collect additional data measuring the demand for implants, and the results do not suggest any significant demand drop after 1990. In particular, we collected data for 32 procedures that are consistently reported throughout the period of 1987-1995 by the National Hospital Discharge Survey and identify those involving medical implants. Difference-in-differences regressions for the number of services and the rate (i.e., number per 100,000 population) do not show significant differences before and after 1990 between these two types of procedures. This evidence, albeit based on relatively coarse data, is inconsistent with the idea that demand drop is a key driver of the decline in innovation.

Third, as noted before, our analysis excludes TMJ and silicone breast implants, which were the source of most implant failures and where downstream litigation was concentrated. As reported in Section 6.5, data on the FDA’s approval time do not reveal significant regulatory concerns over implant safety in general. Furthermore, using adverse-events data that form the basis for lawsuits, we show that the large decline in implant innovation is not only robust to controlling for the extent of adverse events associated with a given product type, but also holds for product types for which there should be little concern about downstream liability (i.e., products with zero adverse events throughout 1985-1995). Overall, these findings help isolate the mechanism of a heightened downstream liability risk and support the conclusion that the upstream-supply mechanism plays an important role.

Fourth, as discussed previously, the triple-differences results presented in Section 6.3 show that higher liability risk significantly reduced patenting by US firms relative to foreign innovators. To the extent that this differential effect reflects a greater willingness of foreign polymer producers to continue supplying foreign device manufacturers, as the comprehensive industry report points out, this is additional support for our proposed mechanism.

Finally, as shown in Section 8.2, implant patenting did recover due to the implementation of the BAAA and other factors (such as decisive lawsuits won by DuPont in 1995/1996) that likely to have reduced upstream suppliers’ liability risk. We also conducted a triple-differences regression analysis to

\[ \text{The DID coefficient for the number of services (in thousands) provided is 41.9 (p-value is 0.40); and the DID coefficient for the rate is 0.13 (p-value = 0.548).} \]

\[ \text{We also confirm the patent results dropping two additional prominent patent subclasses—pacemakers and heart valves—which were associated with the highest numbers of adverse events (column 4 of Table 5).} \]
estimate the differential patterns of foreign and US innovation after 1998. The (unreported) estimates show a larger increase for US producers and confirm that implant patenting by US producers reached a level comparable to that before 1990 a few years after the BAAA was implemented. This reversal pattern is also consistent with our theoretical model and points to the importance of supply restriction 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) some of the critical inputs are supplied by large multi-market firms with deep pockets and the ability to foreclose a risky downstream segment; (ii) many downstream innovators are small and are likely to resort to bankruptcy when liability claims exceed firm values; and (iii) there exist sufficient informational frictions (including asymmetric information and uncertainty over the likelihood of product failures and the extent of harms) and transactions costs such that it is hard for downstream producers to be fully insured and for the parties to write complete contracts regarding the allocation of liability.

These 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 first 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 and quality.

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.\textsuperscript{45} 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 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 an important mechanism for this decline—the 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.

Our paper adds empirical evidence to the scarce body of empirical work on the impact of liability risk on innovation, and it also contributes to the industrial organization literature by studying a novel driver of vertical foreclosure and spillover effects throughout industry linkages. 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

\textsuperscript{45}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.
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 R&D investments. This insight may be particularly valuable for regulators evaluating the role of a country’s liability systems and the associated tradeoffs in its competitiveness, especially in emerging fields such as artificial intelligence and sophisticated robotics and their various applications (Agrawal, Gans and Goldfarb, 2018).46

References


46See Galasso and Luo (2018) for a discussion of the economic issues related to the product-liability regime and innovations in artificial intelligence; Marchant and Linder (2012) and Hubbard (2015) and the references within for details of tort law and an exploration of their applications to autonomous vehicles and sophisticated robots.

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[64] Robinson, Joan (1933) *The Economics of Imperfect Competition*, London McMillan.


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

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.

b. Patenting by US firms
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

<table>
<thead>
<tr>
<th></th>
<th>Obs.</th>
<th>Mean</th>
<th>Std. Dev.</th>
<th>Min</th>
<th>Max</th>
</tr>
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<td>3.340</td>
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<td>102</td>
</tr>
<tr>
<td>Year</td>
<td>29656</td>
<td>1990</td>
<td>3.160</td>
<td>1985</td>
<td>1995</td>
</tr>
<tr>
<td>Implant</td>
<td>29656</td>
<td>0.103</td>
<td>0.304</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

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

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

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

<table>
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<tr>
<th>Dependent variable</th>
<th>(1)</th>
<th>(2)</th>
<th>(3)</th>
<th>(4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patents</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implant x After 1990</td>
<td></td>
<td>-0.464***</td>
<td>-0.827***</td>
<td>-0.644***</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(0.052)</td>
<td>(0.105)</td>
<td>(0.140)</td>
</tr>
<tr>
<td>Non-implant x After 1990</td>
<td></td>
<td></td>
<td></td>
<td>-0.107</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(0.139)</td>
</tr>
<tr>
<td>Year effects</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Subclass effects</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Observations</td>
<td>29656</td>
<td>22033</td>
<td>6138</td>
<td>29051</td>
</tr>
<tr>
<td>Sample</td>
<td>drop assignees that patent in both implant and non-implant subclasses</td>
<td>implant and drug subclasses</td>
<td>implant and matched drug subclasses</td>
<td>non-implant and matched drug subclasses</td>
</tr>
</tbody>
</table>

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. Non-implant = 1 if less than 80 percent of all the patents in a medical device subclass are implant patents. Drug subclasses are based on USPTO patent classes 424 and 514, both titled ”Drug, bio-affecting and body treating compositions.”
<table>
<thead>
<tr>
<th>Dependent variable</th>
<th>(1)</th>
<th>(2)</th>
<th>(3)</th>
<th>(4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patents by US firms</td>
<td>-0.334***</td>
<td>-0.393***</td>
<td>-0.106***</td>
<td>-0.068***</td>
</tr>
<tr>
<td></td>
<td>(0.046)</td>
<td>(0.056)</td>
<td>(0.031)</td>
<td>(0.026)</td>
</tr>
<tr>
<td>Implant x After 1990</td>
<td></td>
<td></td>
<td>-0.344***</td>
<td>-0.305***</td>
</tr>
<tr>
<td>Implant x After 1990 X US firms</td>
<td>-0.334***</td>
<td>-0.305***</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patents by foreign firms</td>
<td>0.716***</td>
<td>0.812***</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(0.086)</td>
<td>(0.099)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>US firms</td>
<td></td>
<td></td>
<td>0.454***</td>
<td>0.261***</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(0.024)</td>
<td>(0.017)</td>
</tr>
<tr>
<td>After 1990 X US firms</td>
<td></td>
<td></td>
<td>0.567***</td>
<td>0.485***</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(0.038)</td>
<td>(0.031)</td>
</tr>
<tr>
<td>Implant X US firms</td>
<td></td>
<td></td>
<td>-0.331***</td>
<td>-0.199***</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(0.047)</td>
<td>(0.037)</td>
</tr>
<tr>
<td>Year effects</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Subclass effects</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Country status defined by</td>
<td>assignees</td>
<td>inventors</td>
<td>assignees</td>
<td>inventors</td>
</tr>
<tr>
<td>Observations</td>
<td>29656</td>
<td>29656</td>
<td>59312</td>
<td>59312</td>
</tr>
</tbody>
</table>

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

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

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

<table>
<thead>
<tr>
<th></th>
<th>(1)</th>
<th>(2)</th>
<th>(3)</th>
<th>(4)</th>
<th>(5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dependent variable</td>
<td>Applications</td>
<td>Applications</td>
<td>Applications</td>
<td>Applications</td>
<td>Applications</td>
</tr>
<tr>
<td>Implant x After 1990</td>
<td>-0.394*</td>
<td>-0.469**</td>
<td>-0.142***</td>
<td>-0.141***</td>
<td>-0.052**</td>
</tr>
<tr>
<td></td>
<td>(0.236)</td>
<td>(0.236)</td>
<td>(0.048)</td>
<td>(0.050)</td>
<td>(0.023)</td>
</tr>
<tr>
<td>Adverse events reports</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>-0.001</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(0.009)</td>
</tr>
<tr>
<td>Year effects</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Product code effects</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Matched Control</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Drop outliers</td>
<td>NO</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Product codes with zero</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>YES</td>
</tr>
<tr>
<td>injury/death reports 1985-1995</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Observations</td>
<td>3344</td>
<td>2486</td>
<td>2464</td>
<td>2464</td>
<td>1760</td>
</tr>
<tr>
<td>Mean (dependent variable)</td>
<td>0.267</td>
<td>0.308</td>
<td>0.152</td>
<td>0.152</td>
<td>0.065</td>
</tr>
</tbody>
</table>

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. Adverse events reports = the number of product code-associated reports on deaths, injuries, and malfunctions in a given year. Column 2 exploits a matched control group that minimizes pre-trend differences. Column 3 drops two outlier product codes. Column 5 includes only product codes with zero adverse event reports throughout 1985-1995.
Table 7. Heterogeneous effects

<table>
<thead>
<tr>
<th>Panel A. Firm size</th>
<th>(1)</th>
<th>(2)</th>
<th>(3)</th>
<th>(4)</th>
<th>(5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dependent variable</td>
<td>Patents</td>
<td>Patents</td>
<td>Patents</td>
<td>Patents</td>
<td>Patents</td>
</tr>
<tr>
<td>Firm size</td>
<td>Small</td>
<td>Medium</td>
<td>Large</td>
<td>Top 16</td>
<td>Top 6</td>
</tr>
<tr>
<td>Percent of patents</td>
<td>50%</td>
<td>25%</td>
<td>25%</td>
<td>10%</td>
<td>5%</td>
</tr>
<tr>
<td>Implant x After 1990</td>
<td>-0.170*** (0.039)</td>
<td>-0.113*** (0.021)</td>
<td>-0.150*** (0.027)</td>
<td>-0.046*** (0.010)</td>
<td>-0.015** (0.006)</td>
</tr>
<tr>
<td>Sample mean</td>
<td>0.795</td>
<td>0.382</td>
<td>0.396</td>
<td>0.166</td>
<td>0.084</td>
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</table>

<table>
<thead>
<tr>
<th>Panel B. Citation quintiles</th>
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</thead>
<tbody>
<tr>
<td>Dependent variable</td>
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<tr>
<td>Implant x After 1990</td>
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<tr>
<td>Sample mean</td>
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<tr>
<td>Observations</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Dependent variable</th>
<th>(1)</th>
<th>(2)</th>
<th>(3)</th>
<th>(4)</th>
</tr>
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<tbody>
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<tr>
<td>Patents</td>
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</tr>
<tr>
<td>DuPont's patents</td>
<td></td>
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<tr>
<td>DuPont's patents</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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
Mean dep. Variable: 0.679, 1.649, 0.016, 0.052

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
Harvard Business School
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. Estimated year-specific triple-interaction coefficients in a triple-differences regression

Year-specific version of the triple-differences regression in column 4 of Table 4, controlling for subclass and year fixed effects, a complete set of year-specific double-interaction terms, and a dummy variable indicating US patentees. The figures plot the year-specific triple-differences coefficients (and 95% confidence intervals).
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.
Figure A5. Estimated annual effects, extended to 2010

Difference-in-differences regression corresponding to the regression used in Figure 2 (Panel B) in the paper but extended to 2010, controlling for subclass and year fixed effects. The baseline year is 1989. 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.
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<tr>
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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 1972-1982). 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

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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

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<td>YES</td>
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<tr>
<td>Matched control</td>
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<td>Observations</td>
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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.