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.

The relationship among risk, uncertainty and investments is fundamental to understanding economic growth and technological change (e.g., Bernanke, 1983; Bloom, 2009; Fernandez-Villaverde and Rubio-Ramirez, 2015). A major source of risk faced by firms are product liability laws that are designed to protect customers from defective or dangerous products (Jarrell and Peltzman, 1985; Daughety and Reinganum, 1995; Hay and Spier, 2005). In 2016, product liability cases accounted for roughly 70 percent of the personal injury civil cases filed in US district courts. Cases such as these often make the headlines because of their

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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]

Theoretical models in law and economics suggest that the impact of liability risk on innovation is ambiguous (e.g., Daughety and Reinganum, 2013). On the one hand, higher liability may reduce innovation incentives by raising the costs of or chilling the demand for new technologies associated with greater risk. On the other hand, it may also increase the profitability of and the demand for risk-mitigating technologies and safer product designs that reduce the likelihood of injuries. This theoretical ambiguity highlights the importance of empirical research to identify conditions under which the liability system may incentivize or chill innovation and to examine the underlying economic mechanisms.

The dominant view in the policy debate has been that, for the U.S. liability regime, the chilling effect on innovation outweighs the positive incentivizing effect. 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 view is also 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 negative view does not seem to find support in the scarce empirical evidence linking liability risk and innovation. If anything, the two 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.

In this paper, we provide the first set of large-sample evidence of a substantial chilling effect in an economically and socially important sector. Importantly, we show that this effect is driven primarily by a specific mechanism—the surge in upstream liability that led to extensive vertical foreclosure by large suppliers, which, in turn, negatively affected downstream investments in innovation. Vertical production and distribution chains are common in many modern industries, and how liability burdens should be allocated across parties in these chains is a critical feature of tort law. Theoretical models have shown that, in many settings, different allocation rules matter for social efficiency (Marchand and Russell, 1973; Posner, 1986;

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

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

Hay and Spier, 2005), but empirical analysis of these questions is extremely limited. This paper provides novel evidence on how liability risk can percolate through the vertical chain and impact innovation by firms and in segments that are not directly targeted by litigation.

Our analysis exploits a quasi-exogenous surge in the liability risk faced by large, common input suppliers to medical implants in the early 1990s. Medical implants such as heart valves, pacemakers, replacement joints, and intraocular lenses save or improve the lives of millions of people every year. According to industry reports, the U.S. implantable device market was about $71 billion in 2016, and implants account for roughly 20 percent of medical device patenting and about 60 percent of Food and Drug Administration (FDA) Class III device applications.[3] Medical implants are manufactured using biomaterials that are direct or modified applications of common materials such as metals, polymers and ceramics. These raw materials are often produced by large companies that supply to a wide range of sectors in the economy. During the 1970s and 1980s, large firms, such as DuPont and Dow Chemicals, were the dominant suppliers of polymers and silicone used in many implants, including prostheses, body tissues, pacemakers, and heart valves (Aronoff, 1995). The standard policy for these large companies was to not withhold materials from the medical sector and to warn device producers that suppliers were not responsible for testing and determining the safety of implants (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 'deep-pocket' polymer supplier of Vitek's. 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 historical industry accounts, congressional hearings, discussions with industry insiders, courts dockets, and media mentions, documenting how Vitek's bankruptcy in 1990 and the TMJ and breast implant litigations against material suppliers dramatically raised liability concerns for all material suppliers (not just suppliers directly involved in these litigations) that sold to all implant manufacturers (not just the two types of devices). The focus of our analysis will be the impact that this surge in upstream suppliers' liability risk had on medical implant innovation overall (specifically, on types of implant products that were *not* involved in the litigations).

To illustrate the key mechanism at work, we propose a simple model in which innovation can take place at both the upstream and 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

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

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

Our main finding, based on a series of difference-in-differences regressions, is that medical implant patenting decreased by 35 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 effect was immediate but small and grew larger over time. The increasing magnitude is compatible with implant innovators gradually reducing their patent applications as an increasing number of polymer and silicone suppliers withdrew from the market.

We examine the extent to which our finding is driven by firms that could reallocate R&D resources from implant to non-implant technologies. Our estimates suggest that even if such within-firm substitution took place, its influence was likely to be small, implying an overall decline in medical device innovation. We then subject our data to a variety of tests to i) control for potential confounding factors, such as demand and technology trends that affect implant and non-implant innovation differently; and ii) 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. Among a collective body of evidence, 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, which supports the predictions of our theoretical framework.

Using FDA device approval data, we show that the significant decline in implant innovation is present

not only at the research stage, but also at the commercialization stage. 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 not only that the large decline in implant innovation is robust to controlling for the extent of adverse events associated with a given product type, but also that it holds for product types about 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.

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.

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 the inputs themselves were 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 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).

1 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). 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 a demand channel and also derive theoretically offsetting effects: higher liability exposure of physicians chills demand for new technologies associated with greater risk but increases demand for risk-mitigating technologies that reduce injuries. Empirically, they also show that the positive effect dominates: on average, states passing tort reforms that decrease physicians' exposure to medical malpractice liability experience a significant decrease in medical-device patenting.[4] 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; 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; Frakes and Jena, 2016). These studies tend to focus on the liability cost faced by a single party, with Hay and Spier (2005) and Helland et al. (2020) being the exceptions. 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 it may be optimal for manufacturers to share the residual liability under certain conditions, a consumer-only liability regime may be preferable when consumers are heterogeneous or possess private information. Helland et al. (2020) show that because drug companies' prices need to be uniform across jurisdictions, shifting liability towards them in a small jurisdiction will actually increase physicians' prescriptions of a potentially harmful product. Our paper differs from Helland et al. (2020) in its focus on vertical foreclosure and the effect of liability shift on innovation investments.

A related set of studies examines the safety-access trade-off generated by the FDA approval process:

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[4]Relatedly, Galasso and Luo (2021) show that following an increase in customers' (and physicians') perceived risk of radiation diagnostic devices, which was triggered by wide media coverage of a series of over-radiation accidents, CT producers increased innovation, in particular in features and technologies that mitigate radiation risk.

more-stringent regulations create value by inducing greater safety and higher quality, but they may also lead to fewer available products in the market. In an influential paper, Peltzman (1973) shows that the 1962 drug amendments requiring proof of efficacy in addition to safety led to a significant decrease in welfare. In contrast, Grennan and Town (2020) find that for coronary stents, the efficacy requirement in the U.S. is critical for reducing quality uncertainty and facilitating adoption. Their counterfactual analysis shows that the U.S. policy is close to optimal, while the European Union, which currently requires only safety, would benefit from additional efficacy testing. Our paper differs from the above papers in two aspects: we focus on product liability risk, which stems from an ex-post policy rather than from an ex-ante regulation; and we study how misallocation of liability risk across market players may matter.

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. In the health sector, Finkelstein (2004) finds that policy changes designed to increase the usage of pre-existing vaccines 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.

2 Medical implants, biomaterials, and liability risk

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

TMJ implants are intended to replace (entirely or in part) the temporomandibular joint (jaw). In the 1980s, Vitek was the leading producer of TMJ implants in the US. Its product obtained FDA approval in 1983 after expert panels reviewed a series of scientific reports and clinical trial results. Oral surgeons across the US liked Vitek's product, which quickly became the state-of-the-art device in the field (Schmucki, 1999). Several years later—unexpectedly and despite the initial positive response—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 more than 40 states (Schmucki, 1999). Eventually, DuPont won all the suits that went on trial, but the process took ten years and cost the company over $40 million.[5] This was a large sum compared to the revenue that DuPont obtained from TMJ implants (a few thousand dollars in total, as each device that Vitek produced contained only about 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).[6]

These litigations had significantly affected raw material producers' assessment of their liability when supplying to implant manufacturers. As a result, many suppliers changed their 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 markets accounted for only 0.005% of the total revenues from other industries for polymer producers. A common practice 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. Such supply policy relied on common law protections for component and raw-material suppliers.[7]

The TMJ and breast implant litigations implied that these industry practices may not have been sufficient to keep the suppliers' liability risk commensurate with their expected revenue. Following these events, many material producers dramatically changed their policy for supplying permanent implant producers (Service,

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[5]"Biomaterials Access Assurance Act of 1997," Hearing Before the Subcommittee on Commercial and Administrative Law of the Committee on the Judiciary, House of Representatives, One Hundred Fifth Congress, First Session, on H.R. 872, June 12 1997.

[6]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.

[7]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 would use the product and could not foresee and remedy the potential hazards. Similarly, if the buyer substantially altered the material, the material supplier would not be held liable to the ultimate consumer.

1994). In a new supply policy issued in January 1993 (see Appendix A), DuPont refused to sell materials to all manufacturers of permanently implantable medical devices and restricted the supply to temporary implants, while its old policy remained unchanged for non-implant devices. Because the use of polymeric materials is extremely common for implants and their components, and DuPont was a primary supplier, this affected a wide range of products, from sutures and fracture fixation devices to pacemakers and heart valves. A number of other major suppliers also exited the market around the same time (RAND, 2000). Notably, in 1990, Dow Chemicals announced that, starting in 1992, it would cease supplying materials to implant producers (Borzo, 1994).[8]

Prompted by the withdrawal of these large suppliers, the Health Industry Manufacturers Association (HIMA) commissioned a comprehensive report examining the status of the biomaterial market (Aronoff, 1995). A survey conducted for Aronoff's (1995) 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 well-established manufacturer of integrated circuits refused to supply its chips for implanted devices. On May 20, 1994, 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 in the hearings explained how device companies were responding to these shortages by stockpiling resources that were still available or by signing more-onerous contracts with the few suppliers willing to serve the market. Testifiers 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).

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[8]As a polymer supplier for medical implants, Dow Chemicals was not as dominant as DuPont, but its polymer products were used in leads and connectors for pacemakers, defibrillators, and similar devices (Borzo, 1994).

3 Theoretical framework

In this section, we describe a simple model that captures 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 3.2.

An upstream (polymer) producer may develop a new product that can be used by manufacturers in downstream market *A* (medical implants) and by many other industries (collectively denoted as 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* comprises 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 $\left[I^D, 1 + I^D\right]$. This implies that when the input is sold at price *p*, only users for which $v - p - I^D \geq 0$ buy the good, and that the downstream demand for market *A* is equal to $D^A(p) = 1 - F(p + I^D) = 1 - p$. Similarly, we denote the demand curve for market *B* by $D^B(p) = \theta(1 - p)$, where $\theta > 1$. We can think of market *B* as the collection of θ downstream markets, each with demand $1 - p$. The assumption that $\theta > 1$ implies that market *B* captures a larger share of the upstream firm's business. The upstream firm can charge different prices in different markets. Profit maximization by the upstream firm yields $p_A = p_B = 1/2$, which is intuitive because both markets have the same price elasticity. Thus, the total profit of the upstream firm is $\Pi^0 = (1 + \theta)/4$.

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; that is, $l = E(d)$, 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 and Ruffino (2013). We are agnostic about the exact nature of *l*, as Vitek's bankruptcy and the subsequent events increased both risk and uncertainty.

For simplicity, we assume that downstream firms cannot invest in R&D to identify substitute inputs or

to increase the safety of their products. This assumption is reasonable in our empirical setting, in which DuPont and other large suppliers that withdrew from the market provided the majority of the supply; and, even with substitute suppliers stepping in, medical implant producers were concerned about declining quality standards as suppliers shifted from "*large, sophisticated chemical companies with well-established quality procedures*" to "*smaller, undercapitalized, and less sophisticated supply sources*" (Citron, 1994). Moreover, marginal improvements in the safety of medical implants were unlikely to change large suppliers' foreclosure decisions, as the expected liability costs far exceeded their profits from this small market.

Incorporating the liability risk, the upstream firm's objective function in market A becomes $(p_A - l)(1 - p_A)$. Consider, first, 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 profit is

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

where $\Delta(l) = l(2-l)/4$, the profit difference 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.[9] 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 $\pi^B = \theta/4$.

3.1 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 market A firms, they are affected only through the input price. When the input is sold at price p_A, the total development cost sustained by downstream firms is

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

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

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

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

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

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

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

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.

3.2 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 2. 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.

Third, we show that the impact of liability risk may percolate throughout an industry's vertical chain. Even if only the upstream firm incurs the direct litigation costs, 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, missing significant effects taking place elsewhere in the value chain.

We intentionally make our model as simple as possible to illustrate the potential mechanism and its 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 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 downstream innovation incentives even more.[10]

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

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[10]TMJ and breast implant litigations and the bankruptcies of their leading producers may, indeed, increase the (perceived) liability risk faced by downstream firms directly. We aim to isolate this channel in our empirical analysis.

a stronger indemnification contract from the downstream firms or require larger product-liability insurance coverage. As mentioned in Section 2, 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 could still have been joined in the lawsuits and would have had to "*put up with the expense of discovery procedures and the great inconvenience it entails, as well as adverse publicity*."

We also assume that the upstream firm can charge different prices in different markets. Conversations with industry practitioners suggest that price discrimination was not common in our context for two main reasons: i) downstream firms could potentially access the homogeneous inputs in secondary markets, as distribution is often through large wholesalers; and (ii) transaction costs of writing different contracts with a large number of customers are generally high. If, instead, we 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, our framework assumes a continuum of downstream firms. Our results are robust to considering a downstream oligopoly market, the typical setting studied in the industrial organization literature on vertical foreclosure. When the increase in liability risk is moderate, it may affect the upstream monopoly's ability to commit to restricting supplies, especially when the contract is not observable (Rey and Tirole, 2007). When the liability increase is sufficiently large that market A becomes unprofitable, the upstream firm may exit market A entirely, as it does in our baseline model, and downstream innovation does not take place.

4   Data and methods

Our main source of data is the patent record database from the United States Patent and Trademark Office (USPTO) (USPTO, 2016). Each patent is classified 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 (USPTO, 2015). To identify medical device patents, we use the primary subclass to which each patent is assigned.

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 (FDA, 2015c), we retrieve a comprehensive list of device names, each corresponding to a unique product code that identifies the 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 20 medical specialties. Of these, 567 device names in 11 specialties are flagged as implanted devices. From these 567 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 226,624 medical device patents (in 2,712 subclasses) applied for between 1976 and 2015 for which these textual variables are available (USPTO, 2021). 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 19 percent of the patents in each subclass are identified as implant patents, but the variance is substantial. In roughly 67 percent of the subclasses, the fraction of implant patents is below 0.1, and in 17 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 roughly 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: 623/19.14 "Implantable humeral bone" (96.3 percent implant patents) and 623/14.11 "Artificial vocal cords" (87.5 percent implant patents). Three subclasses are associated with the jaw and breast implants involved in the litigations, and their fractions of implant patents are, respectively, 83, 88, and 92 percent.[11] Examples of subclasses with a minimal fraction of implant patents in-

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[11] As additional supporting evidence for our textual analysis, consider the primary patent class 623, titled "Prosthesis (i.e., artificial

clude: 128/201.21 "Respiratory devices using liquefied oxygen" (0 percent); 602/22 "Orthopedic bandages for fingers" (1.3 percent); and 606/36 "Surgical instruments for depilation" (3.1 percent).[12]

The main sample for our empirical analysis is a panel that tracks 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. 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 in 1995 and 1997, which eventually led to the passage of the BAAA in 1998, and partly because DuPont won critical lawsuits in 1995 (Schmucki, 1999). It is important to note that, as we discuss in Section 7.1, industry players still faced significant uncertainty after 1995. In that section, we extend the sample to 2010 for an analysis of the longer-run outcomes. To address potential endogeneity concerns, we drop the three patent subclasses related to jaw and breast implants from our analysis. The 11-year window includes 46,696 patents, with which we construct the panel dataset of our main sample. The total number of subclasses in our main dataset is 2,703, and the number of observations is 29,733.

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. Within-subclass variation in patenting (the standard deviation is 2.06) is slightly smaller than between-subclass variation (the standard deviation is 2.63). 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. This figure provides a first look at our main result; in the next section, we turn to regression analysis to control for other factors that might also contribute to the differential growth rates between the two groups.

In Section 5.3, we also use the FDA device application data as an alternative measure of innovation. Apart from a more accurate identification of implant devices, a strength of the FDA data is that they are more closely linked to the final products than the patent data are and that they potentially capture non-patentable technologies. Moreover, the adverse-events data linkable to product codes help to control for downstream direct liability risk. On the other hand, there are important merits associated with using the

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body members), parts thereof, or aids and accessories therefor," which includes 376 subclasses. About 14 percent of the patents in this class belong to subclasses that include only implant patents. Roughly 54 percent of the patents belong to subclasses in which the fraction of implant patents is greater than 0.8, and about 90 percent belong to subclasses in which the fraction of implant patents is above 0.5.

[12]We also 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.

patent data. First, relative to alternative measures, the application date of a patent probably captures the closest point to the origin of innovation activities; in practice, patent attorneys strongly recommend filing patent applications in advance of FDA filings (Arora and Schmidt, 2012), 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 (2020). Second, patents are more disaggregated and, hence, more likely to capture innovations about specific features of a product. In contrast, the FDA device applications are at the product level, making it more difficult to discern the amount of innovation associated with one device. Third, relatedly, patent data also capture innovation responses by firms specializing in research activities or the development of specific components. Finally, in Section 6, we also examine the effect of the liability shock on upstream innovation (polymers). Patenting data and similar textual algorithms allow us to generate an innovation metric that is consistent across upstream and downstream technologies, which would not be possible with FDA data because they capture only downstream medical devices. The availability of multiple innovation measures is a merit of the medical sectors, and our paper exploits both data types to provide a comprehensive picture of the impact of the liability shock.

4.1 Econometric model

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

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

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

$After1990_t$ captures the post-period in which the uncertainty about liability risk of supplying to medical implant producers became higher for material suppliers. Numerous industry and academic studies stress that the industry did not foresee the surge in litigation against DuPont in 1990 after Vitek's bankruptcy. We confirmed this in conversations 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.*" These conversations also suggest that after the surge of lawsuits, DuPont (and possibly its large wholesalers) became cautious

16

about supplying to new customers or for new products by existing customers, even though their supply policies towards existing customers and products did not officially change until January 1993. Moreover, as mentioned in Section 2, in 1990, Dow Chemicals announced its intention to stop supplying materials to implant producers, even though the implementation would not take place for another two years. To further examine the timing of the liability shift, we also manually collected litigation and media-mention data, focusing on DuPont, the primary supplier of a large variety of polymeric materials. Panel (a) of Appendix Figure A1 plots the timing of TMJ lawsuits involving DuPont as one of the defendants, collected from Bloomberg Law (Bloomberg Law, 2017). 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.[13]

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 $After1990_t$ 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 implant products began to fail more generally in the early 90s, leading to a disruption or a decline in demand. The second type of concerns are related to the interpretation of the identified effect. TMJ and breast implant litigations and the bankruptcies of the leading producers may also have 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

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[13]Furthermore, the wide media coverage supports the idea that information on DuPont's legal battle spread across all industry participants, affecting all participants' perception about liability risk.

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. Finally, in Section 7.2, we discuss 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. 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 use the implant fraction as a continuous treatment variable and also vary the threshold separating the two groups.

5 Downstream effect on implant innovation

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, after 1990, implant subclasses experienced a reduction of roughly 0.53 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 average decline in implant patenting after 1990 is about 35 percent.[14]

Column 2 interacts the treatment indicator After1990 with the fraction of implant patents of the subclass. Recall that the fraction of implant patents of a subclass is calculated using the data from 1976-2015 and, hence, is constant over time. The estimate confirms our baseline finding and shows that doubling the mean

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[14]The average number of patents for non-implant subclasses after 1990 is 2.03, and the pre-1990 difference between implant and non-implant subclasses is -0.51 patents per year. The 'hypothetical' average number of patents for implant subclasses would have been 1.52 per year after 1990.

value of the fraction of implant devices in the subclass, from 0.2 to 0.4, reduces patenting in implant classes by about 0.075 patents per year after 1990. Column 3 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.

As discussed in Section 4.1, if some medical device firms have shifted their research efforts from implant to non-implant technologies, the observed decline in implant patenting may not indicate an overall decline in innovation. In column 4 of Table 2, we exclude patenting by assignees active in both the implant and non-implant subclasses.[15] The estimated coefficient is -0.35 patents per year. This suggests that while within-firm substitution between implant and non-implant patenting may play some role, it accounts for a relatively small part of the decline in overall innovation.[16] In the appendix, we show that our result is also robust to using an alternative control group—patenting in subclasses that include only pharmaceutical drug innovations—for which contamination concerns are less severe.

In the Appendix, we provide additional robustness checks that confirm our findings. These include regressions that use different cutoffs to define the implant subclasses, that exploit alternative econometric models, and that use more-aggregate technology classifications by the USPTO. We also show that, while the effect is the biggest for the largest patent subclasses, it is also significant for the middle two quartiles of the pre-shock patenting distribution. 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 faced by upstream suppliers had a large chilling effect on downstream innovations. In the following, we subject this basic result to a number of additional tests.

5.1 Pre-treatment trend and time-specific treatment effects

To check the common-trends assumption, we estimate the year-specific differences between the treatment and control subclasses, β_t, in the following regression (1989 is the baseline year).

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

Figure 2 plots the estimated coefficients and their 95-percent confidence intervals. The estimated differences between the implant and non-implant subclasses are small before the liability shift; they bounce

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[15]Seven percent of the unique 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.

[16]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, 36 percent of the total effect estimated in the full sample.

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.

We also estimated a version of equation (2) in which the interaction terms are between year fixed effects and the fraction of implant patents in a subclass, as suggested by Finkelstein (2007). The estimates, reported in the Appendix, show a more gradual effect—the negative effect does not become statistically significant until 1992—but the overall pattern is similar to that in Figure 2, with the size of the negative effect becoming increasingly larger over time.

Even though the exact start differs by specification, the overall pattern of the effect is compatible with implant innovators gradually reducing their patent applications as an increasing number of suppliers withdrew from the market. Patent application costs are typically small relative to R&D expenditures, and patents provide the benefits of optionality; however, the quick but small reaction early on is consistent with the idea that, at the margin, the decrease in expected profits and increase in costs—in the face of increased uncertainty and diversion of resources and engineering time towards securing materials for existing products—are sufficient to lead some firms to give up or postpone their patenting applications and R&D. Consistent with what we might expect, we show in the Appendix that the early effect is driven by patent applications that are more likely to be at the margin—that is, by smaller firms and for less-valuable technologies.

5.2 Patents by foreign firms as the control 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.

We expect foreign firms to be less affected by the TMJ and breast implant litigations and the resulting disruption to the industry's supply chain for a number of reasons. 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 (Klerman, 2012).

Moreover, Aronoff (1995) (the HIMA-commissioned industry report) specifically points 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."[17] 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 US implant producers. These include 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 the results are similar when we classify patents using the information on the country of the first inventor, which is available for all patents.

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 3 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 3, we show that this result is robust to using the inventor's country of origin to categorize the patents.[18]

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 3. Column 3 reports the triple-differences results based on the assignees' country of origin. The coefficient of the triple-interaction term (-0.307) 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

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[17]This report was also cited in the legislative history of the Biomaterials Access Assurance Act that was enacted in 1998 to ensure the supply of biomaterials (which we will describe and analyze in Section 7.1): "75 percent of the suppliers of biomaterials required for implantable medical devices have banned sales to U.S. device manufacturers." H.R. Rep. No. 105-549, pt. 2, at 11 (1998).

[18]We re-estimated the time-specific treatment effects (equation 2) using only patents by US assignees as the dependent variable. The results, reported in the Appendix, appear to be sharper than those in Figure 2, which uses all patents.

innovators, this estimate captures the decrease in implant patenting by US firms. Column 4 of Table 3 replicates column 3, using the inventor's country of origin to categorize the patents, and the results are similar. In the Appendix, we plot the triple-interaction coefficients in a year-specific version of column 4 of Table 3. This figure illustrates a pattern that is qualitatively consistent with that in Figure 2; the estimated differential effects on implant patenting experienced by US firms are slightly smaller and slightly more delayed (the negative effect becomes significant in 1991). This is consistent with the idea that our liability shock had a substantially lower impact on foreign firms that commercialize in the US.

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 (European Patent Office , 2016). Different from foreign patentees of US patents, these foreign firms pool together firms that do and do not commercialize in the U.S. As an example, Appendix Figure A5 shows small and statistically insignificant differences between implant and non-implant subclasses for the UK data. These findings provide further support for the idea that the increase in liability risk affected mainly American patentees' innovation incentives.

Overall, the results in this section help 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 U.S. and foreign patenting reflects producers' differential access to materials. That said, this finding alone does not necessarily isolate the alternative mechanisms completely, and the fact that foreign and US device producers compete with each other may also entail a general equilibrium effect that potentially overestimates the relative decline in U.S. medical implant innovation. We provide additional evidence for assessing alternative mechanisms in the next section and collectively discuss the body of evidence in Section 7.2.

5.3 Liability risk and FDA applications

So far, we have used patents as our measure of innovation. In this section, we examine whether our baseline result holds when using the product-level innovation measure—the medical-device application data from the FDA (FDA, 2015a,b). 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 that 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; thus, the unit of analysis is the number of FDA applications in each product code-year. 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 4 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 the shock. 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.

Apart from confirming that implant innovation experienced a decline relative to non-implant medical device innovation, the FDA data also help us to address two potential downstream mechanisms. First, the FDA Medical Device Reporting Program (MDR) database provides reports on deaths, injuries and malfunctions that are associated with a specific FDA product code (FDA, 2017). 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. Column 4 of Table 4 shows that our results are robust to including *Adverse events reports*, which equal the total number of reports in year *t* for the product code. 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.[19] The finding of a large and significant negative effect on implant innovation, even for products that raise minimal concerns about direct liability risk, provides further evidence that the upstream supply channel is an important driver of the relative decline in implant innovation.

Second, we find that the amount of time the FDA takes to approve a device does not change differentially for implant versus non-implant product codes after 1990. In the Appendix, we report application-level regressions using devices applied between 1985 and 1995. The estimates indicate that application time is not significantly longer for implant devices than for non-implant devices. If anything, the coefficients suggest that implant devices, on average, experience a shorter approval time after 1990. This result is inconsistent with the alternative explanation that the drop in innovation is driven by a significant change in regulatory

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[19]Assuming 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.

scrutiny of medical implants.

Overall, our analysis using product-based measures of innovation shows that the relative decline in implant innovation took place not only in the early-invention stages but also the commercialization stages.

5.4 Heterogeneous effects

The preceding analysis shows that, on average, the liability shock affected patenting activity during our study period. In this section, we explore how the impact may depend on firm size and patent quality.

We use the number of medical device patents by each assignee between 1985 and 1995 to measure firm size. Because the distribution is skewed, we allocate patentees into three groups: 'small patentees' (assignees with one to four patents) cover 50.5% of the patents; 'medium patentees' (five to 40 patents) cover 24.2% of the patents; and 'large patentees' (more than 40 patents) cover the remaining 25.2% of the patents. We create two additional groups to capture the largest patentees: the 'Top 16 patentees' group covers roughly 10% of the patents, and the 'Top six patentees' group covers roughly 5% of the patents. Panel A of Appendix Table A8 estimates our baseline regression separately for these five groups of patentees. Taking into consideration the average level of patenting across different groups, the effect ranges from -16.5 to -38.8 percent, all economically large and statistically significant. Even though the effect is industry-wide, it is smaller for the six largest assignees than for the rest of the sample. This is 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 were less likely to be insolvent and more likely to honor their contractual obligations.

We next explore whether the shock had differential impacts across patents of different quality. The welfare interpretation would differ greatly, depending on whether it affected high-quality patents or only marginal patents with limited impact. The innovation literature has often used the number of citations that a patent receives as an indirect measure of patent value (Pakes and Griliches, 1980). We remove application-year and (two-digit) technology class effects and identify the (filtered) citation quintile to which each patent belongs. Panel B of Appendix Table A8 reports our baseline regressions using these quality-quintile subsamples. The coefficients are also negative and statistically significant across all five quality quintiles, with the magnitude of the effect being 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 and patenting activities that are more likely to result in the lowest-value patents are terminated. With risk-averse innovators and ex-ante uncertainty about the value of innovation, a higher development cost may discourage the exploration of risky projects, which may also lead to a reduction in breakthrough innovations (Aguiar and

24

Waldfogel, 2018).

Overall, these results indicate that the liability shock had a broad impact: its effects spanned the entire medical device industry, as well as technologies' quality distribution.

6 Upstream effect on 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 the 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 5. We start with the sample of 297,842 chemical patents that belong to the NBER patent subcategories of resins and organic compounds (NBER, 2006). 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 transcript 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 (House of Representatives, 1995). 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 5 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 1990. 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 subclasses chosen to minimize pre-trend differences. The coefficient remains statistically insignificant, confirming the finding of no effect on upstream innovation. Appendix Figure A6 illustrates the coefficient of a regression run on this sample, including separate dummies for each year before and after the change in liability risk. All coefficients are statistically insignificant and of small magnitude, further corroborating our finding of no effect. Columns 3 and 4 of Table 5 show that we also do not observe any decline in patenting in affected-

polymer subclasses relative to other subclasses by DuPont, the most important polymer supplier at the time and the target of the TMJ implant litigation.

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.

7 Discussion and policy implications

Our main empirical finding is that the increase in liability risk faced by upstream suppliers after 1990 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 at both the invention and the commercialization stages. This section complements our analysis by (i) examining the longer-run outcomes after a federal policy was implemented to address the shortage of biomaterials; (ii) providing additional support for the idea that restricted access to upstream suppliers was an important driver of the decline in downstream innovation; and (iii) discussing the external validity of our findings and their welfare implications.

7.1 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.[20] 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 the inputs themselves are not dangerous or defective.[21] 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 had 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*

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[20]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. "Biomaterials Access Assurance Act of 1997," Hearing Before the Subcommittee on Commercial and Administrative Law of the Committee on the Judiciary, House of Representatives, One Hundred Fifth Congress, First Session, on H.R. 872, June 12 1997.

[21]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.

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 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 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 used 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 -0.233, and the p-value < 0.001, confirming our main result), and it recovered after the BAAA (the coefficient is -0.091, but not statistically different from the default years before 1990). We see similar results with the FDA data: the coefficients of the two interaction terms are, respectively, -0.133 (p-value < 0.05) and 0.194 (statistically insignificant). In the Appendix, we plot the year-specific difference-in-differences coefficients; the graph shows that the negative effect of our liability shock is sustained after 1995 and remains similar in magnitude until the end of the 90s. The effect 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). Finally, notice that we do not observe an overshoot of implant patenting in the longer run, which suggests that the decline in the intervening years, which lasted more than a decade, was a real loss rather than a delay in investment. While we should not view these results as the causal effect of the law—as the industry also took measures to identify alternative supply sources or substitute materials, and DuPont's important wins in 1995 and 1997 might also have helped to reduce the uncertainty over supplier liability—it is plausible that without the policy intervention, industry self-adjustments would have taken a much longer time.

7.2 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 4.1, 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—results from prior sections as well as 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, 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 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.*"

To provide more-direct evidence for this mechanism, we further exploit the 1995 congressional hearing documents (House of Representatives, 1995), which include a list of implant devices that rely on polymers. Mapping the device names on this list to patent classes and to FDA product codes is not a straightforward exercise, and it is not entirely clear how exhaustive the list is. Moreover, as discussed in Section 2, the increasing reluctance to supply went beyond polymeric materials (Citron, 1994). Nonetheless, we show in the Appendix that implant patent subclasses and FDA product codes that are more likely to rely on polymeric materials are more negatively (marginally significant) affected than those that likely do not use polymers.

Second, we collect additional data measuring the demand for implants and show that there is no significant demand drop after 1990. In particular, we collect 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.[22] 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 5.3,

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[22]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).

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 not only is 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. 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.

Finally, as discussed previously, the triple-differences results showing 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. We also conducted a triple-differences regression analysis to estimate the differential patterns of foreign and US innovation after the BAAA in 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.

7.3 External validity and welfare implications

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 also apply 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.

Ex-ante regulations can play an important role in mitigating uncertainty over safety (e.g., Stern, 2017; Grennan and Town, 2020). In this respect, in 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)—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.[23] 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.

A full welfare analysis of our findings requires contrasting two forces: (i) the surplus lost from fewer new devices; and (ii) the social gains due to greater safety (either because fewer harmful products are developed or because the new products are safer). In the appendix, we leverage our estimates to assess the first force— the magnitude of the potential welfare costs associated with the decline in implant innovation. To do this, we exploit the estimates by Grennan and Swanson (2017) on the increase in total surplus per procedure when physicians have access to an additional medical device. Back-of-the-envelope calculations suggest that potential welfare costs associated with the lost devices could be between $4.1B and $11.9B per year for four prominent implant device types (pacemakers, catheters, and knee and hip prostheses).

The above estimates do not fully account for potential social gains from greater safety.[24] That said, it seems reasonable to expect that the negative impact on welfare dominates potential gains in our setting for a number of reasons. In practice, the extensive foreclosure by large suppliers appeared to have disrupted normal R&D activities by implant producers and limited their ability to develop new and safer products. Switching to smaller suppliers is associated with a higher cost (due to the lack of scale) and inconsistent quality control (Citron, 1994). More generally, the idea that a substantial increase in upstream liability may

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[23]For example, as mentioned in Section 2, 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 conversations 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.

[24]This is a limitation that our analysis shares with much of the prior research on the safety-access trade-off (Peltzman, 1973; Grennan and Town, 2020). Galasso and Luo (2021) take a first step in addressing this problem by examining innovation in radiation diagnostic devices, one setting in which it is possible to distinguish between new technologies affecting radiation risk and those affecting image quality.

have been inefficient is also consistent with the law and economics literature. 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 (Daughety and Reinganum, 2013). As we depart from the benchmark case and consider scenarios involving downstream insolvency, the allocation of liability begins to matter. When there are significant downstream firm heterogeneity, asymmetric information, and contractual frictions, downstream-only liability can be a preferable policy (Hay and Spier, 2005).

Asymmetric information and contractual frictions are important features in contexts like ours, where large upstream firms supply general-purpose inputs to a wide range of downstream markets. When upstream suppliers do not possess the specialized knowledge required to understand the features of all the applications using their inputs, information asymmetry 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. Moreover, as we show in our theoretical model, when the total profits from supplying a given risky market are sufficiently small relative to other revenue sources (as in the case of implants), upstream firms may resort to vertical foreclosure. Overall, this suggests that in environments like ours, an increase in upstream liability may inefficiently raise costs for all downstream firms, even those that are unlikely to be insolvent and whose products are safe.

8 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 the patenting of other medical devices, on the order of 35 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, indicate an important mechanism behind 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 have been industry-wide, involving firms of various sizes and patents of different values.

Our paper adds 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 sectors may prefer to foreclose market segments in which liability risk is the greatest, rather than face 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 (Galasso and Luo, 2018).

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Figure 1: Patenting over time

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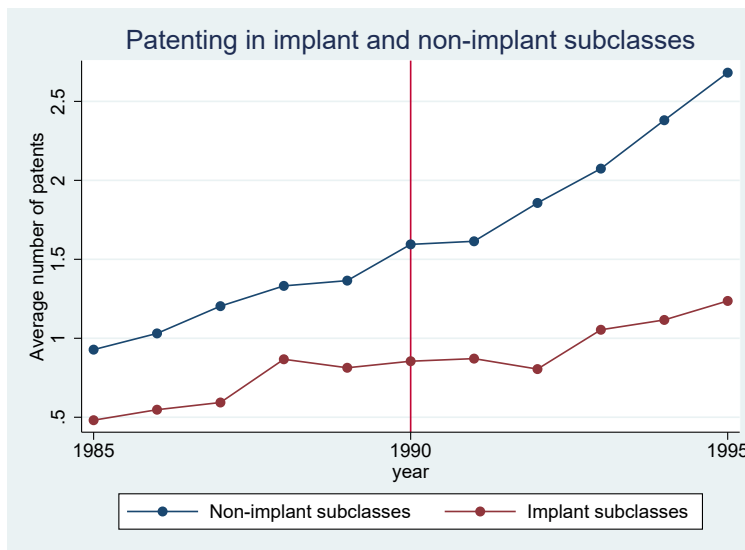
Note: Average number of patents over all implant and non-implant subclasses by application year. Implant subclasses (the treatment group) are subclasses for which at least 80 percent of all the patents between 1975 and 2015 are implant patents; non-implant subclasses are the remaining subclasses.

Figure 2: Estimated annual treatment effects

Note: This regression corresponds to equation (2) in the paper, controlling for subclass and year fixed effects. The figures plot the coefficients (and 95% confidence intervals) of the interaction terms between year dummies and the implant class dummy, which equals one if at least 80 percent of all the patents in the subclass are implant patents.

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

Patenting in implant and non-implant subclasses

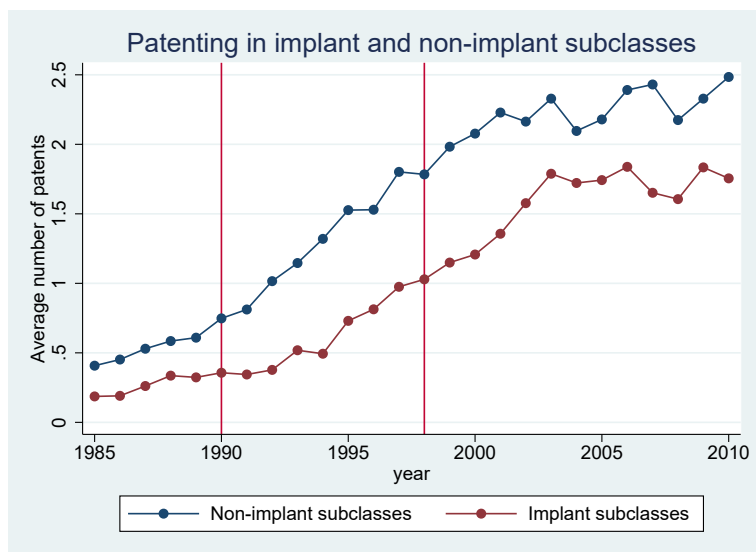*Note*: Average number of patents by US assignees over all implant and non-implant subclasses by application year. Implant subclasses (the treatment group) are subclasses for which at least 80 percent of all the patents between 1975 and 2015 are implant patents; non-implant subclasses are the remaining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

Table 1: Summary statistics

	Obs.	Mean	Std. Dev.	Min	Max
Patents	29,733	1.571	3.343	0	102
Year	29,733	1990	3.162	1985	1995
Implant	29,733	0.089	0.285	0	1

Note: 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

Dependent variable	Patents	Patents	Patents	Patents
	(1)	(2)	(3)	(4)
Implant × After 1990	-0.533***		-0.315***	-0.354***
	(0.088)		(0.090)	(0.026)
[1em] Implant fraction × After 1990		-0.374***		
		(0.110)		
Year effects	YES	YES	YES	YES
Subclass effects	YES	YES	YES	YES
Sample			Drop subclasses with implant-patent fraction between 0.02 and 0.8	Drop assignees patenting in both implant and non-implant subclasses
Observations	29733	29733	17985	29733

Note: OLS regressions. Patents = the number of patent applications in a subclass-year. Implant = 1 if the fraction of implant patents in a subclass exceeds 0.8. Robust standard errors clustered at the subclass level (in parentheses). * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

Table 3: Patents by foreign firms and triple differences

Dependent variable	Patents by US firms	Patents by US firms	Patents	Patents
	(1)	(2)	(3)	(4)
Implant × After 1990	-0.302***	-0.384***	-0.061**	-0.095***
	(0.047)	(0.061)	(0.029)	(0.034)
Implant × After 1990 × US firms			-0.307***	-0.343***
			(0.053)	(0.063)
Patents by foreign firms	0.399***	0.558***		
	(0.050)	(0.079)		
US firms			0.255***	0.443***
			(0.017)	(0.024)
After 1990 × US firms			0.480***	0.561***
			(0.031)	(0.037)
Implant × US firms			-0.176***	-0.292***
			(0.040)	(0.051)
Year effects	YES	YES	YES	YES
Subclass effects	YES	YES	YES	YES
Country status defined by	assignees	inventors	assignees	inventors
Observations	29733	29733	59466	59466

Note: OLS regressions. 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. Robust standard errors clustered at the subclass level (in parentheses). * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

Table 4: Liability risk and FDA applications

Dependent variable	Applications (1)	Applications (2)	Applications (3)	Applications (4)	Applications (5)
Implant × After 1990	-0.394*	-0.469**	-0.142***	-0.141***	-0.052**
	(0.236)	(0.236)	(0.048)	(0.047)	(0.022)
Adverse events reports				-0.001	
				(0.009)	
Year effects	YES	YES	YES	YES	YES
Product code effects	YES	YES	YES	YES	YES
Matched Control	NO	YES	YES	YES	YES
Drop outliers	NO	NO	YES	YES	YES
Product codes with zero injury/death reports 1985-1995					YES
Observations	3344	2486	2464	2464	1683
Mean (dependent variable)	0.267	0.308	0.152	0.152	0.065

Note: OLS regressions. 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. Robust standard errors clustered at the subclass level (in parentheses). * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

Table 5: Impact on polymer patenting

Dependent variable	Patents (1)	Patents (2)	DuPont's patents (3)	DuPont's patents (4)
Affected-polymer class × After 1990	0.201	0.214	-0.002	-0.025
	(0.151)	(0.191)	(0.022)	(0.025)
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	1.570	0.016	0.053

Note: OLS regressions. 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. Robust standard errors clustered at the subclass level (in parentheses). * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

Online Appendix

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

Alberto Galasso and Hong Luo

Appendix A: DuPont's revised supply policy

Below, we present 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 B: Back-of-the-envelope welfare calculation

This Appendix explains in greater detail the welfare calculation conducted in Section 7.3. 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 is, 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 as $10.6B per-year and the loss in producer gross profits as $1.2B per-year.[25]

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.

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[25]For reference, one industry estimate suggests that the total sales of implant devices was $43B in 2011 ("Understanding the market for implantable medical devices," by Keith Lind, AARP Insights, August, 1-15, 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.

Appendix C: Additional empirical analysis

C.1. Timing of the shock

Figure A1 provides additional evidence for the choice of our treatment timing—that is, years including and after 1990. Panel (a) plots the timing of TMJ lawsuits involving DuPont as one of the defendants, collected from Bloomberg Law.[26] The figure shows a sharp increase in the number of lawsuits DuPont faced starting from 1990, the year Vitek filed for bankruptcy. Panel (b) 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.

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

(a) TMJ lawsuits with DuPont among the defendants   (b) Media mentions of medical implants
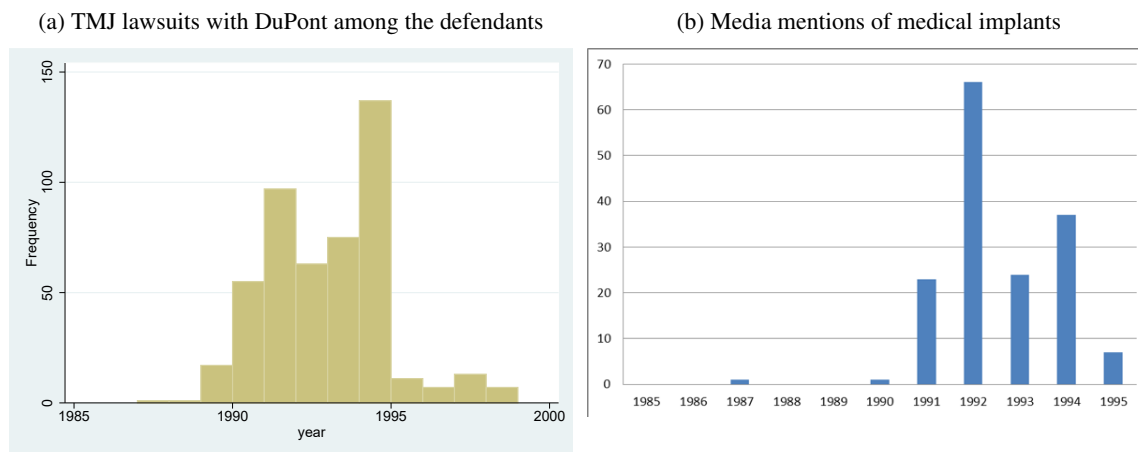
Note: Source: (a) Bloomberg Law; (b) Factiva (Dow Jones), search keywords are 'implant,' 'DuPont,' 'jaw,' and 'breast.'

C.2. Robustness of the baseline results

Recall that in the baseline analysis, we define a patent subclass as an implant subclass if at least 80 percent of the patents belonging to this class are implant patents. The first two columns of Table A1 show that our baseline result is robust to different thresholds of defining implant subclasses.

For about five percent of the subclasses in our sample, we observe no patenting during the entire sample period of 1985-95. In column 3 of Table A1, we show that our result is robust to dropping these subclasses. In column 4, 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

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[26]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 left us with 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.

Table A1: Robustness of baseline results

Dependent variable	Patents (1)	Patents (2)	Patents (3)	Patents (4)	Patents (5)
Implant x After 1990	-0.428***	-0.568***	-0.556***	-0.606***	-0.550***
	(0.092)	(0.116)	(0.096)	(0.100)	(0.093)
Year effects	YES	YES	YES	YES	YES
Subclass effects	YES	YES	YES	YES	YES
Drop observations	NO	NO	Subclasses with no patents	Subclasses with no patents & years before first patent	Pacemakers & heart valves
Implant subclass thresholds	0.5	0.9	0.8	0.8	0.8
Observations	29733	29733	27830	26819	28809

Note: OLS regressions. Patents = the number of patent applications in a subclass-year. In column 1, implant = 1 if the fraction of implant patents in the subclass exceeds 0.5; in column 2, implant = 1 if the fraction of implant patents in the subclass exceeds 0.9; and in columns 3-5, implant = 1 if the fraction of implant patents in the subclass exceeds 0.8 (as is in the baseline analysis). Column 3 drops subclasses with no patenting during our sample period. Column 4 exploits an unbalanced panel in which a subclass enters the sample in the first year of positive patenting. Column 5 drops subclasses involving pacemakers and heart valves. Robust standard errors clustered at the subclass level (in parentheses). * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

t. This approach, which excludes subclasses with no patenting before year t, gives an estimate very similar to that in column 2. In column 5 of Table A1, 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 greatest number of adverse events. Our estimates show that our results are robust in this subsample.

In Table A2, we confirm our findings using a number of alternative econometric models. Column 1 shows that 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. Column 2 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 5.4 on heterogeneous effects, citations are a common measure of patent value in the economics of innovation literature (Pakes and Griliches, 1980). Finally, we confirm our results with two Poisson models. Column 3 uses 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. Column 4 uses 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.

The USPTO subclass system follows a hierarchical nested structure in which subclasses are grouped into

Table A2: Alternative econometric models

Dependent variable	log(patents+1)	Citations	Patents	Patents
Model	OLS	OLS	Poisson	Poisson
				mean scaling estimator
	(1)	(2)	(3)	(4)
Implant x After 1990	-0.073***	-34.107***	-0.147*	-0.309***
	(0.012)	(10.631)	(0.077)	(0.054)
Year effects	YES	YES	YES	YES
Subclass effects	YES	YES	YES	NO
Observations	29733	29733	27830	29733

Note: Patents = the number of patent applications in a subclass-year. Implant = 1 if the fraction of implant patents in a subclass exceeds 0.8. Column 1 includes a dummy for subclasses-years with no patenting. Column 4 includes the log of pre-sample patenting as control. Robust standard errors clustered at the subclass level (in parentheses). * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

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). A potential downside is that subclasses cut the data quite thin, and many subclass-year observations have zero patents.

Table A3: Aggregation of patent subclasses

Dependent variable	Patents	Patents	Patents
Aggregated subclasses	1871	1184	462
	(1)	(2)	(3)
Implant x After 1990	-0.600***	-1.189***	-3.049**
	(0.182)	(0.392)	(1.279)
Year effects	YES	YES	YES
Subclass effects	YES	YES	YES
Observations	20581	13024	5082
Mean dep. Variable	2.269	3.585	9.189

Note: 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. Robust standard errors clustered at the subclass level (in parentheses). * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

In Table A3, 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 1,871 subclasses (aggregating associated 'children' subclasses, if applicable, up to indent level 3), 1,184 subclasses (up to indent level 2), and 462 subclasses (up to indent level 1). These aggregations increase the average

patenting activity per (aggregated) subclass and reduce the number of cases in which patenting is zero. In all aggregation levels, we find a strong negative decline in implant relative to non-implant technologies.

To further clarify how the estimated effect may vary by subclass size, Table A4 reports DID regressions that use subclasses for which the pre-treatment patenting level belongs to three different terciles of the distribution. Column 4 uses subclasses in the 25th-75th percentile range. The results show that the effect is small and statistically insignificant for subclasses in the first tercile of pre-treatment patenting (one patent or fewer in 1985-89), but it becomes significant for the upper two terciles of the distribution (2-5 patents and six patents or more). The last column shows that the effect remains significant when we drop the bottom and top quartiles of the distribution. Overall, the results show that the treatment effect is driven by relatively active patenting subclasses. Though it is largest in the most active classes, the treatment effect is not localized to these technologies. The effect is also present in the middle of the distribution.

Table A4: Effects by patent class size

Dependent variable	Patents	Patents	Patents	Patents
Sample	Below 33rd perc.	33rd-66th perc.	Above 66th perc.	25th-75th perc.
	(1)	(2)	(3)	(4)
Implant × After 1990	-0.003	-0.258***	-1.341***	-0.262***
	(0.081)	(0.086)	(0.433)	(0.070)
Year effects	YES	YES	YES	YES
Subclass effects	YES	YES	YES	YES
Observations	10032	10802	8899	17578

Note: Patents = the number of patent applications in a subclass-year. Implant =1 if the fraction of implant patents in a subclass exceeds 0.8. The first three columns include subclasses for which the pre-shock patenting level falls in the three terciles of the distribution, respectively. Column 4 includes subclasses for which the pre-shock patenting level falls in the middle two quartiles. Robust standard errors clustered at the subclass level (in parentheses). * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

C.3. Substitution toward non-implant patents

To examine the extent to which the effect of liability risk spills over to the control group, we exclude patenting by assignees active in both the implant and non-implant subclasses in the paper (column 4 in Table 2). In the following, we conduct a separate exercise to isolate the potential spillover effect. In particular, we contrast patenting in implant patent subclasses with an alternative control group—patenting in subclasses that include only pharmaceutical drug innovations and not medical device innovations.[27] 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 1 of Table A5 estimates equation (1) in the paper, using this alternative control group. To

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[27]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 one percent of the assignees).

address the concern that trends in patenting in drug subclasses may differ from those in implant subclasses, in column 2, 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 1 and 2 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.

Table A5: Drug patenting as an alternative control group

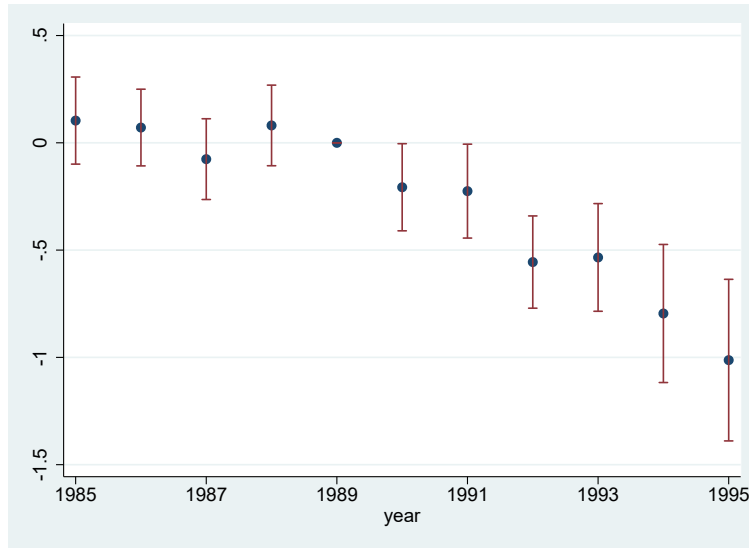| Dependent variable	Patents	Patents	Patents
	(1)	(2)	(3)
Implant x After 1990	-0.815***	-0.501***	
	(0.109)	(0.135)	
Non-implant x After 1990			0.031
			(0.125)
Year effects	YES	YES	YES
Subclass effects	YES	YES	YES
Observations	21626	5302	29733
Sample	implant and drug subclasses	implant and matched drug subclasses	non-implant and matched drug subclasses

Note: 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." Robust standard errors clustered at the subclass level (in parentheses). * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

The last column of Table A5 compares the two control groups—non-implant medical device subclasses and the (matched) drug subclasses used in column 2. 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.

C.4. Time-specific effects

Table A6 examines the timing of the effects for four separate subsamples, divided by patent value—patents with citations (after excluding subclass and application year fixed effects) above versus below the median—and by firm size (the six largest firms versus applicants outside the top six, including smaller firms, non-profit organizations, and individual inventors). Please see the definitions of patent citations and firm size in Section 5.4 "Heterogeneous effects." In these DID regressions, we define three treatment windows: 1990-1991; 1992-1993; and 1994-1995. The results show that for both below-median and above-median citation patents, top-6 firms experience greater delays than smaller firms, non-profit organizations, and individual

Figure A2: Estimated annual treatment effects

inventors. Within assignees of similar sizes, the effect is more immediate for less-important patents (those with below-median citations) than for more-important patents.

C.5. Patents by foreign firms and triple-differences regressions

Figure A3 plots the time-specific treatment effects (equation 2) using only patents by US assignees as the dependent variable. The results appear to be sharper than those in 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.

Figure A4 presents the triple-interaction coefficients in a year-specific version of the regression presented in column 4 of Table 3. This figure illustrates a pattern that is qualitatively consistent with that in Figures 2 and A3, suggesting that the liability shock had a substantially lower impact on foreign firms that commercialize in the US. The estimated differential effects on implant patenting experienced by US firms were slightly smaller and more delayed after controlling for the patenting trends by foreign assignees.

C.6. FDA and patent approval delays

The first two columns in Table A7 present FDA application-level regressions, in which the dependent variables are the number of months between the application date and the decision date and its logarithm. The regressions use applications that underlie the sample used in column 4 of Table 4; that is, control and treatment product codes are matched on the pre-trend, and two outlier product codes are excluded. The estimates

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Table A6: Timing-specific effects by firm size and patent value

Sample	Below-median citations		Above-median citations	
	Exclude top 6 firms	Top 6 firms	Exclude top 6 firms	Top 6 firms
Dependent variable	Patents	Patents	Patents	Patents
	(1)	(2)	(3)	(4)
Implant X (1990-1991)	-0.176***	-0.011	-0.032	-0.012
	(0.043)	(0.007)	(0.053)	(0.008)
Implant X (1992-1993)	-0.341***	-0.028**	-0.131**	-0.026**
	(0.058)	(0.011)	(0.051)	(0.012)
Implant X (1994-1995)	-0.566***	-0.027***	-0.227**	-0.023
	(0.071)	(0.008)	(0.098)	(0.014)
Year effects	YES	YES	YES	YES
Subclass effects	YES	YES	YES	YES
N	29733	29733	29733	29733
Sample mean	0.747	0.039	0.739	0.046

Note: 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. Robust standard errors clustered at the subclass level (in parentheses). * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

Figure A3: Year-specific DID coefficients using US patents

Note: This regression corresponds to equation (2) in the paper, using only patents by US assignees and controlling for subclass and year fixed effects. The figures plot the coefficients (and 95% confidence intervals) of the interaction terms between year dummies and the implant class dummy, which equals one if at least 80 percent of all the patents in the subclass are implant patents.

Figure A4: Year-specific triple-interaction coefficients in a triple-differences regression

Note: Year-specific version of the triple-differences regression in column 4 of Table 3, 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).

show that the amount of time required to obtain the FDA approval is not significantly longer for implant devices than for non-implant devices. If anything, the coefficient in column 2 suggests that implant devices, on average, experience a (marginally) shorter approval delay after 1990.

Table A7: Approval timing

	FDA applications		Patent applications	
	log(Time)	Time	log(Time)	Time
	(1)	(2)	(3)	(4)
Implant X After 1990	-0.292	-7.574*	-0.038*	-1.487**
	(0.382)	(4.464)	(0.020)	(0.711)
Adverse events reports	0.021	0.546		
	(0.086)	(0.615)		
Patent subclass/FDA product code FE	Yes	Yes	Yes	Yes
Year FE	Yes	Yes	Yes	Yes
Observations	374	374	46491	46491

Note: For the first two columns, time = number of months between the application date and the decision date of an FDA application, implant = 1 if the FDA identifies the product code as an implant, and adverse events reports = the number of product code-associated reports on deaths, injuries, and malfunctions in a given year. For the second two columns, time = the number of months between the application date and the grant date of a patent, and implant = 1 if at least 80 percent of all the patents in a subclass are implant patents. Robust standard errors clustered at the subclass level (in parentheses). * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

Figure A5: Estimated annual treatment effects using patents published by the UK patent office

Note: 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 cutoff 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.

In the second two columns of Table A7, we replicate the above analysis for patent grant delays (from the application date to the grant date) at the USPTO. We use the patents underlying our baseline sample and define implant subclasses as those with a fraction of implant patents above the 80-percent threshold, as we do in the baseline analysis. The regressions control for year and patent subclass fixed effects. The results also do not show any differential increase in grant delays for implant subclasses relative to non-implant subclasses. These results on FDA approval time and patent grant delays help mitigate the concern that our main results in the paper are driven by heavier regulatory burdens for implant technologies.

C.7. Heterogeneous effects

Panel A of Table A8 estimates our baseline regression across five groups of patentees. For each assignee in our sample, we construct a patent portfolio equal to the number of medical device patents between 1985 and 1995. Because of the skewness in the distribution of patent portfolios, we allocate patentees into three groups: 'small patentees' (assignees with one to four total patents) cover 50.5% of the patents; 'medium patentees' (assignees with five to 40 total patents) cover 24.2% of the patents; and 'large patentees' (assignees with more than 40 patents) cover the remaining 25.2% of the patents. In addition, we further examine the effect on patenting by the largest assignees, 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.

The coefficients are negative and statistically significant across all groups.

Table A8: Heterogeneous effects

(a) Firm size

Dependent variable	Patents	Patents	Patents	Patents	Patents
Firm size	Small	Medium	Large	Top 16	Top 6
Percent of patents	50%	25%	25%	10%	5%
	(1)	(2)	(3)	(4)	(5)
Implant × After 1990	-0.153***	-0.110***	-0.154***	-0.046***	-0.014**
	(0.042)	(0.023)	(0.027)	(0.010)	(0.006)
Year effects	YES	YES	YES	YES	YES
Subclass effects	YES	YES	YES	YES	YES
Sample mean	0.793	0.381	0.396	0.167	0.085
Observations	29733	29733	29733	29733	29733

(b) Citation quintiles

| Dependent variable	Patents	Patents	Patents	Patents	Patents
Quintile	Q1 (lowest)	Q2	Q3	Q4	Q5 (highest)
	(1)	(2)	(3)	(4)	(5)
Implant × After 1990	-0.081***	-0.098***	-0.046**	-0.032	-0.079***
	(0.022)	(0.015)	(0.021)	(0.022)	(0.026)
Year effects	YES	YES	YES	YES	YES
Subclass effects	YES	YES	YES	YES	YES
Sample mean	0.314	0.314	0.314	0.314	0.314
Observations	29733	29733	29733	29733	29733

Note: OLS regressions. Patents = the number of patent applications in a subclass-year. Implant = 1 if the fraction of implant patents in the subclass exceeds 0.8; and = 0, otherwise. In (a), small patentees if portfolio has fewer 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). Robust standard errors clustered at the subclass level (in parentheses). * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

Panel B of Table A8 presents results across patents of different quality. 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. The coefficients are also negative and statistically significant across all five quality quintiles, even though the magnitude of the effect appears to be the smallest for the intermediate-quality range.

C.8. Impacts on upstream patenting

Figure A6 plots the DID coefficients estimated from a regression similar to equation (2) in the paper but uses patents related to resin and organic compounds in 1985-1995. 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. The results show that upstream polymer patenting is not affected by the liability shock.

Figure A6: Estimated year effects on upstream innovation
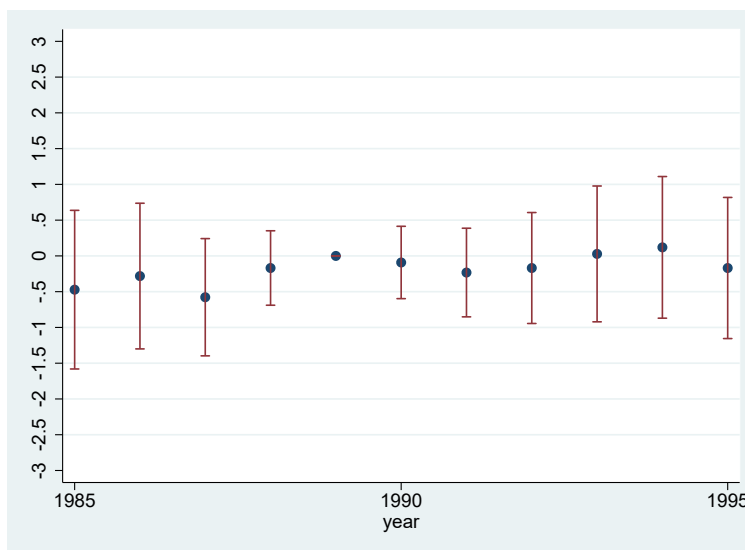
Note: The regression is similar to equation (2) in the paper, using patents related to resin and organic compounds in 1985-1995 and controlling for subclass and year fixed effects. The figure plots the coefficients (and 95% confidence intervals) of the interaction terms between year dummies and the affected-polymer class dummy, which equals one if at least 80 percent of all the patents in the subclass are affected-polymer patents.

C.9. Policy remedy: the 1998 Biomaterials Access Assurance Act

Figure A7 plots the year-specific DID coefficients estimated from a regression that uses patents by US assignees, analogous to that for Figure A3 but extended to 2010. The graph shows that the negative effect of our liability shock is sustained after 1995 and remains similar in magnitude until the end of the 90s. The effect starts to become increasingly less negative in 2000 and turns small and positive in 2002. The coefficients afterwards are statistically similar to the baseline year, 1989 (the year before our liability shock). The difference-in-differences coefficients of later years are more noisily estimated. However, comparing the coefficients for the years with the most negative impact and the years after 2002 shows mostly statistically significant differences.

Figure A7: Estimated annual effects, extended to 2010
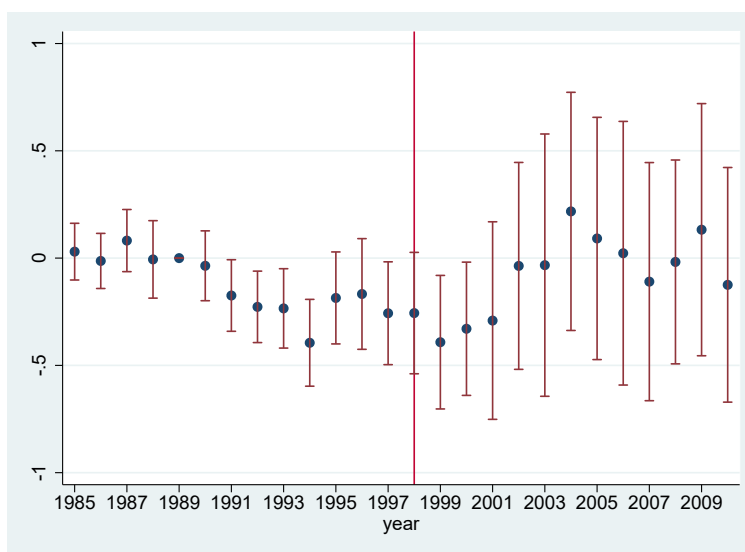
Note: The baseline year is 1989. The figures plot the coefficients (and 95% confidence intervals) of the interaction terms between year dummies and the implant class dummy, which equals one if at least 80 percent of all the patents in the subclass are implant patents.

C.10. Additional evidence for assessing alternative mechanisms

The primary mechanism we propose in the paper is due to input supply restrictions. The litigations primarily targeted polymer (including silicone) suppliers. In the following, we provide an analysis that intended to determine whether the impact is more negative for implant innovations that are polymer-based than for those that are not.

We exploit the 1995 congressional hearing documents that include a list of devices that rely on polymers. The list includes about 100 major product categories of implanted devices, ranging from sutures, to batteries, to cardiac material, to various types of orthopedic implants, to catheters, and to pacemakers. Matching this list to patent subclasses or FDA device codes is not a simple exercise. Some of these device names are easy to identify; however, some capture components or basic building materials (e.g., "molded component" or "cardiac material") that may be present in many devices and, thus, hard for us to match to patent applications or FDA codes. Other times, the device names in the congressional documents may be very general and refer to a broad set of products. For example, the list includes "neuro stimulator," which could refer to all types of stimulators in neurology.

We begin with the patent data by using textual information to identify patents in implant subclasses that appear to be polymer-based. Specifically, we classify a patent as a 'polymer-based implant' if the title, the abstract, or the first claim of the document contains these device names listed in the congressional hearing document. Then, we use this information to distinguish implant subclasses that rely heavily on polymers from those that do not. We label a subclass as a 'polymer-based implant subclass' if the fraction of polymer-based patents is greater than 80 percent, which leads 63% of implant subclasses to be defined as polymer-

15

based, and 37% as not polymer-based (consistent with the widespread use of polymers). The first column of Table A9 compares the polymer-based implant subclasses to non-polymer-based implant subclasses. The result shows that polymer-based implant subclasses, according our definition, are (marginally) significantly more negatively affected than non-polymer-based implant subclasses.

Table A9: Polymer-based implants versus non-polymer based implants

	Patents	FDA applications
	(1)	(2)
Polymer implant x After 1990	-0.394**	-0.082*
	(0.167)	(0.045)
Patent subclass/FDA product code FE	Yes	Yes
Year FE	Yes	Yes
N	2651	1232

Note: Patents = the number of patent applications in a subclass-year. FDA applications = number of FDA applications in a product code-year. In column 1, polymer implant = 1 if at least 80 percent of all the patents in an implant subclass are defined as polymer-based; and in column 2, polymer implant is defined based on manual matching. Robust standard errors clustered at the subclass level (in parentheses). * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.

We conduct a similar exercise for FDA device applications. To the best extent we can, we manually match the device names in the list provided to the congressional hearing with FDA device names. Our approach classifies about 70 percent of the implant product codes as using polymer. Similar to column 1, column 2 of Table A9 compares polymer-based implants to non-polymer-based implants using the FDA data. The coefficient also shows that polymer-based implant devices are (marginally) more negatively affected. Overall, the empirical evidence presented above is consistent with the idea that the relative decline in innovation is greater for medical implants that rely more substantially on polymers.

As we explain above, the classification is subject to substantial measurement error because detailed information indicating which devices or patents do not rely on polymers is not readily available. In addition, as we discuss in Section 2, input disruptions were not exclusively restricted to polymeric materials. Paul Citron (1994), a vice president at Medtronic at the time, stated that "while the impact has been greatest for implanted polymeric and elastomeric materials, it has not been restricted to them. The adverse experience with product liability has caused suppliers of essentially all components used in implants to assess their willingness to supply. For example, certain well-established manufacturers of integrated circuits have refused to supply their chips for implanted devices." Because of these issues, we do not want to over-rely on this specific heterogeneous effect but, rather, on the collective set of results discussed in Section 7.2 as evidence for our proposed mechanism.