

NBER WORKING PAPER SERIES

TORT REFORM AND INNOVATION

Alberto Galasso  
Hong Luo

Working Paper 22712  
<http://www.nber.org/papers/w22712>

NATIONAL BUREAU OF ECONOMIC RESEARCH  
1050 Massachusetts Avenue  
Cambridge, MA 02138  
October 2016

We thank James Dana, Deepak Hegde, Curtis Huttenhower, Mark Schankerman, Kathryn Spier, Ariel Stern, Scott Stern, Laurina Zhang and seminar participants at Duke University, Harvard Business School, the NBER productivity seminar, New York University Innovation and Strategy conference, and the Northwestern Searle Conference on Innovation Economics for helpful comments. We are also grateful to Kira Fabrizio and Ronnie Chatterji for sharing data on physician-inventors. Danielle Wedde and Esther Yan provided excellent research assistance. The views expressed herein are those of the authors and do not necessarily reflect the views of the National Bureau of Economic Research.

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NBER Working Paper No. 22712  
October 2016  
JEL No. I1,K4,O3

**ABSTRACT**

Current academic and policy debates focus on the impact of tort reforms on physicians' behavior and medical costs. This paper examines whether these reforms also affect incentives to develop new technologies. We find that, on average, laws that limit the liability exposure of healthcare providers are associated with a significant reduction in medical device patenting and that the effect is predominantly driven by innovators located in the states passing the reforms. Tort laws have the strongest impact in medical fields in which the probability of facing a malpractice claim is the largest, and they do not seem to affect the amount of new technologies of the highest and lowest quality. Our results underscore the importance of considering dynamic effects in the economic analysis of tort laws.

Alberto Galasso  
Rotman School of Management  
University of Toronto  
105 St. George Street  
Toronto, ON M5S 3E6  
CANADA  
and NBER  
[alberto.galasso@rotman.utoronto.ca](mailto:alberto.galasso@rotman.utoronto.ca)

Hong Luo  
Harvard University  
Morgan Hall 241  
Soldiers Field Road  
Boston, MA 02163  
[hluo@hbs.edu](mailto:hluo@hbs.edu)

# 1 Introduction

Economists have long recognized the crucial role of innovation for economic growth. A key feature of research and development (R&D) investments is their public-good nature, which generates under-investment in innovation relative to the socially optimal level (Arrow, 1962; Bloom et al., 2013). How to avoid such under-investment and how to provide greater innovation incentives are central questions in the macroeconomic and public policy literatures.

To increase R&D incentives, governments typically implement a variety of policies - such as patents and subsidies - directly targeted at innovation investments. To assess and quantify the effects of these policies is a key focus of the innovation literature. Only recently, economists have recognized that policies not directly targeted at innovation investments may also have large impacts on R&D incentives and the direction of technological progress (Finkelstein, 2004). Documenting and quantifying these indirect and dynamic effects is crucial not only to understanding the determinants of innovation activities, but also to evaluating the costs and benefits of policy reforms. The objective of this paper is to examine the innovation investment response to a prominently debated public policy: tort reform.

Torts are actions that injure someone and are recognized by law as grounds for a lawsuit. The role of the tort system is to deter people from injuring others. An important class of torts related to professional negligence is medical malpractice. A danger prominently voiced in public debates is that large settlements arising from medical malpractice litigation lead doctors to practice “defensive medicine” -i.e., to perform excessive tests and procedures because of concerns about malpractice liability. Policy debates typically contrast the high costs of defensive medicine procedures with their low expected benefits to patients. A number of studies have investigated the relationship between the tort system and treatment intensity or medical expenditures, and they provide evidence of the practice of defensive medicine (inter alia see Kessler and McClellan, 1996; and Avraham and Schanzenbach, 2015).

In addition to their effects on procedure use and malpractice claims, tort reforms may also impact R&D investments and technological change. In particular, a number of law scholars have warned about a possible “chilling effect” of the current tort system on innovation; that is, high damage awards and the court’s reliance on custom may reduce physicians’ willingness to adopt new, but riskier technologies, even if they are potentially superior to customary treat-

ments (e.g., Parchomovsky and Stein, 2008; Greenberg, 2009; and Priest, 2011). This idea that ‘liability retards innovation’ has become a key argument for tort reform advocates, and has gained substantial ground over the years in courts and Congress. A typical counter-argument is that high liabilities may also encourage innovation because they induce physicians to ‘defensively adopt’ innovative technologies that are themselves safer or help physicians manage risks. Despite these claims, the empirical literature on the relationship between liability risk and innovation is scarce. We aim to address this gap by studying the impact of tort reform on innovation in the medical device sector, a field of technology closely linked to malpractice litigation.

To illustrate the channels through which tort reforms may affect innovation incentives, we begin our analysis with a simple theoretical model. In our framework, physicians adopt medical technologies considering both their expected benefits to patients and their “riskiness” -i.e., the likelihood that adoption will lead to malpractice liability. A tort reform, such as the introduction of caps on malpractice damages, will affect physicians’ adoption decisions. Consistent with the idea that high liabilities chills innovation, our model predicts that a reduction in the cost associated with malpractice litigation will *increase* physicians’ propensity to use riskier technologies with high patient benefits. However, our analysis also shows an additional effect of tort reforms -i.e., they *reduce* the propensity of physicians to “defensively adopt” low-risk technologies with limited benefits to patients in order to avoid suits. These shifts in technology adoption affect upstream R&D investments, and the overall impact on the development of new devices depends on the relative strengths of the two effects.

While our theoretical framework shows that the overall effect of tort reforms on innovation is ambiguous, it provides a testable prediction. Tort reforms are more likely to reduce innovation incentives in technology fields characterized by high risk of malpractice claims. Intuitively, in these fields, it is likely that physicians adopt new technologies mainly for defensive reasons. Thus, if the expected liability cost is reduced, the incentives to use these technologies decrease, resulting in an overall decline in innovation incentives.

To test these predictions, we combine standard measures of innovation, based on US patent data, with data on state tort reforms from the American Tort Reform Association for the period 1985-2005. We use the inventor address information provided by the United States Patent and Trademark Office (USPTO) and the application year of a patent to link patents with U.S. state-years. We also exploit the USPTO 3-digit technology classification to identify

medical instrument patents. The class of tort reform central to our empirical analysis is the introduction of caps on non-economic damages -that is, damages other than monetary losses, such as pain and suffering. These damages typically comprise a substantial fraction of total awards and represent the main focus of tort reform advocates.

Our main result shows that patenting in medical instruments is reduced by roughly 14 percent in the presence of caps on non-economic damages. This negative effect suggests that, on average, the demand for new technologies that high liabilities generate through defensive-adoption exceeds their negative chilling effect on medical device innovation. This finding is robust to a wide variety of alternative specifications and controls. In particular, the synthetic control method by Abadie et al. (2010) provides clear graphical evidence that medical instrument patenting responds to tort reforms, mostly after five years. Results are similar if we exclude from the sample states for which caps on non-economic damages affect only medical malpractice rather than general torts. Moreover, we show that our findings are not driven by the largest states or by the largest medical device producers. Finally, we run a placebo test that indicates no effect of tort reforms in the sample of non-medical, measuring and testing instruments.

Because innovation activities may respond to demand changes beyond the local level, we also examine whether medical device patenting in a state is affected by policy changes in other states. We construct measures of economic linkages across states exploiting proxies for the relative demand and supply of medical device innovation and find that the effect is predominantly driven by local reforms. We show that such a local nature of the policy impact is related to a key feature of the medical device industry: the involvement of practicing physicians. Indeed, a sizable fraction of the negative impact of tort reforms appears to be driven by the patenting activity of physician innovators located in the state.

We extend these baseline results in several direction. First, to confirm the prediction of our theoretical model, we show that the effect of tort reforms is much more pronounced for patenting related to specialities with a high frequency of malpractice claims (such as surgery and orthopedics). Conversely, caps on damages have a small and statistically insignificant effect on patenting in medical fields with few malpractice claims (such as dental and optics). Second, exploiting patent citations as a proxy for technological value, we document a non-monotonic U-shaped relationship between the effect of tort reforms and innovation quality. Caps on damages have no statistically significant effect on innovation at the lowest and highest quality quintiles.

The effect is negative, statistically significant and of large magnitudes at intermediate quality levels.

Taken together, our findings indicate that tort reforms can have an impact on the level and direction of innovation and that an effective assessment of these policies should consider both their static impact on patients and their dynamic effects on medical technologies. While, on average, caps on damages appear to reduce the propensity to innovate, our analysis shows that this effect is highly heterogeneous and depends on the characteristics of both the devices and the medical fields.

The paper is organized as follows. Section 2 summarizes the related literature. In Section 3, we present a simple model that links tort reforms with innovation incentives. Section 4 describes the data and the econometric specification. Section 5 presents the baseline estimates of the average effect of tort reforms on medical device patenting. In Section 6, we show that the impact of tort reform is heterogeneous and depends on the characteristics of the field and the innovation. We conclude with a brief summary of the findings.

## **2 Related literature**

Our paper is related to studies that investigate the determinants and direction of innovation, in line with the induced-innovation and directed technical change literatures. In the context of pharmaceuticals, a number of papers have investigated the impact of variations in potential market size, exploiting shifts in population demographics (Acemoglu and Linn, 2004), the introduction of Medicare Part D (Blume-Kohout and Sood, 2013), and variations in effective patent life (Budish et al., 2015). More specifically, our paper is related to studies that examine how public policies focusing on achieving some social goal other than innovation affect innovation. In the health sector, Finkelstein (2004) exploits three different policy changes designed to increase the usage of preexisting vaccines and finds that these policies are associated with a 2.5-fold increase in clinical trials for new vaccines. Acemoglu et al. (2006) find that the introduction of Medicare was 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. In the energy and environment sector, Jaffe and Palmer (1997) conclude that environmental compliance standards increase R&D spending at the firm level.

Our analysis draws on the literature studying the relationship between legal liabilities

and medical practice.<sup>1</sup> Most studies in this literature exploit the variations provided by state tort reforms. Kessler and McClellan (1996) examine Medicare beneficiaries treated for serious heart diseases and find that tort reforms lead to reductions in medical expenditures of five to nine percent without substantial effects on mortality or medical complications. Similarly, Avraham and Schanzenbach (2015) find that the probability of heart patients receiving a major intervention drops by five percent after a state implements non-economic damage caps. These results provide evidence for the practice of defensive medicine when liability risks are high. Other papers provide more-nuanced evidence on the influence of liability risks on physician behaviors. Currie and MacLeod (2008) find that caps on non-economic damages increase, while the joint and several liability rule decreases the use of cesarean sections. Shurtz (2014) shows that the effects of tort reforms may depend on physicians' financial incentives. Frakes (2013) shows that states' utilization rates of various treatments and diagnostic procedures changed substantially following the adoption of a rule requiring physicians to follow national, as opposed to local, malpractice standards of care. Frakes and Jena (2016) show that changes in clinical standards can induce higher levels of health care quality.

The only empirical study that we are aware of linking liability and innovation is by Viscusi and Moore (1993), who show that, on average, liability costs increase firms' R&D intensity. Their paper differs from ours in a number of dimensions. Theoretically, they study the direct effect of product liability on firms' R&D investment, whereas, in our model, changes in liability risks affect innovation indirectly, as they first influence physicians' demand for new technologies. Empirically, they study the impacts of the cost of product-liability insurance using a cross-industry dataset covering large firms in the period 1984-1987. We focus on the effects of state tort reforms on medical device patenting for all firms in the period 1985-2005.

Our paper relates to the literature on innovation and technology diffusion in the medical device industry. Clemens (2013) finds that the introduction of Medicare and Medicaid had a positive effect on U.S.-based medical equipment patenting. Chatterji and Fabrizio (2014) study the role of users in medical device innovation. Grennan and Town (2015) examine the impact of regulatory testing requirements for medical devices on innovation diffusion. Stern (2015) shows that medical device innovation incentives are shaped by the regulatory approval process.

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<sup>1</sup>Another stream of studies examines the effects of tort reforms on malpractice claims such as the frequency and severity (e.g., Danzon, 1984; and Avraham, 2007), and malpractice insurance-related outcomes, such as insurers' reported losses, mean payments, and insurance premiums (e.g., Barker, 1992; and Viscusi and Born, 1995). For an overview of the malpractice system and the effects of tort reforms, see the survey by Kessler (2011).

Nistor and Tucker (2015) show that the Food and Drug Administration’s (FDA) decision to allow for third-party certification of medical devices led to more adverse medical events.

Finally, our work is related to the literature on the determinants of state and regional innovation. For example, Agrawal and Cockburn (2003) report evidence in support of the anchor tenant hypothesis that large, local, R&D-intensive firms have a positive impact on regional innovation. Marx et al. (2009) show that regional non-compete regulations affect inventor mobility and knowledge spillovers. Galasso et al. (2013) show that state-level taxes strongly impact knowledge diffusion through the decision to trade patent rights. Vakili and Zhang (2015) show that liberalization policies are associated with an increase in the level of state innovation.

### 3 Theoretical model

In this section, we develop a simple theoretical model to explore the effects of tort reforms on innovation incentives. In our framework, innovations are characterized by multidimensional heterogeneity, as in Weyl and Tirole (2012). Policy reforms affect technological progress through their impact on downstream technology adoption, which, in turn, shapes upstream R&D investments, as in Aghion et al. (2015).

#### 3.1 Basic framework

We consider a medical field with a representative (consumer) physician. We assume that the physician’s utility from adopting a medical technology includes the patient’s expected benefits and the expected cost of medical malpractice liability, as in Schurtz (2014). A medical technology,  $i$ , is thus characterized by two parameters:  $b_i \in [0, 1]$  and  $r_i \in [0, 1]$ , where  $b_i$  is the expected benefit to the patient, and  $r_i$  is the technology-specific malpractice liability risk (e.g., the probability of a bad patient outcome). The expected liability cost is  $H$ , which captures the probability that a bad patient outcome would result in a malpractice claim (or even a suit) and the costs that the physician expects to face if involved in such a dispute. The literature on medical malpractice points out that even when physicians are insured against claims for monetary damages, they still suffer from malpractice disputes due to additional costs such as time loss, stress, and damage to the physician’s reputation.<sup>2</sup> We model a tort reform as a

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<sup>2</sup>As discussed in Currie and MacLeod (2008), payments made on behalf of a physician to settle malpractice claims are registered in the National Practitioners’ Data Bank (NPDB), which hospitals, health care professionals and lawyers often access. Seabury et al. (2013) analyze data from 40,916 physicians covered by a nationwide



decrease in  $H$ , which may operate through two channels: (i) a reduction in the frequency of malpractice claims given bad patient outcomes,<sup>3</sup> and (ii) a reduction in the expected costs associated with malpractice disputes.

The physician’s utility, when she adopts technology  $i$  is

$$U_i = b_i - r_i H. \tag{1}$$

For a simple micro-foundation of our setting, consider an environment in which each innovation  $i$  is characterized by a distribution of potential patient outcomes  $y \sim G_i$ , with mean  $\mu_i$  and support  $[0, 1]$ . If a dispute between the patient and the physician arises when the realized outcome is below a certain threshold  $\underline{y}$ , the utility of the physician is  $U_i = \mu_i - G_i(\underline{y})H$ , which is equivalent to equation (1) once we set  $\mu_i = b_i$  and  $r_i = G_i(\underline{y})$ .

There is an innovator with an idea for a new patentable technology, which we denote as  $N$ . The medical field is characterized by a dominant standard technology  $O$ , which is freely available to physicians. We model the idea-generation process following Scotchmer (1999) and assume that  $b_N$  and  $r_N$  are independent draws from the uniform distribution over the interval  $[0, 1]$ . We assume that  $b_O$  and  $r_O$  are exogenously given and that  $U_O > 0$  and  $U_O < 1 - H$ . These assumptions rule out extreme outcomes and ensure that there are no regions in which the old technology is dominated or dominant for all values of  $r_N$ .

An idea can be developed into a new technology through an R&D process. Successful development takes place with probability  $p(x) = x$  if the innovator incurs a research cost  $C(x) = x^2/2$ . As in Aghion et al. (2015), we refer to  $x$  as the “innovation intensity,” which captures the likelihood of successfully developing a new technology.

The timing of the game is as follows. The innovator draws the idea, observes  $b_N$  and  $r_N$  and decides whether and how much to invest in R&D to develop the new technology. If the new technology is developed, the innovator makes a take-it-or-leave-it offer to the physician, who then decides whether to adopt  $N$  or  $O$ . If  $N$  is not developed, the physician adopts  $O$ .

For an illustrative example of how liability risks influence the physician’s choice between alternative technologies, consider the case of heart-attack patients. Avraham and Schanzenbach (2015) show that the probability of receiving a major intervention in the form of either an

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insurer and find that the average physician spends 50.7 months (about 11% of a forty-year career) with an unresolved, open malpractice claim.

<sup>3</sup>For example, Avraham (2007) finds that caps on non-economic damages enacted in a state significantly decrease the number of cases per 1,000 doctors by 10-15 percent.

angioplasty or a bypass, instead of drug management and monitoring, declines by 1.25 to two percentage points after non-economic damage caps are enacted. This provides evidence that damage limitations can reduce treatment intensity. Furthermore, they also find evidence of substitution between major interventions. Angioplasty declines by roughly two percentage points after caps are imposed, while bypass surgery, which is more invasive and remunerative than angioplasty, rises by 0.5-0.6 percentage points.

More broadly, we can also interpret the two technologies as complements. When bundled together, the new technologies help the physician improve the patient outcome and/or better manage the risk. In other words,  $U_N$  is the utility of the bundle combining the old and the new technologies, and the innovator is rewarded with the extra utility generated to the physician when the new technology is included in the bundle. Examples include a surgical device allowing for an easy delivery of the fetus during a cesarean section when fetal head is deeply wedged in the pelvic cavity; an apparatus and method that position a patient for rapid and effective endotracheal intubation; and a device delivering bioactive materials that help wound recovery after surgeries.

### 3.2 Tort reforms and innovation incentives

If technology  $N$  is developed, the innovator makes a take-it-or-leave-it offer to the physician for a transfer,  $t$ . The physician decides whether to accept the offer, which yields a payoff of  $U_N - t$ , or to adopt the old technology, which yields  $U_O$ . This implies that the payoff of the innovator will be either  $U_N - U_O$  or zero, depending on whether the new technology offers the physician lower utility than the old technology.<sup>4</sup>

The physician will adopt the new technology if  $U_N \geq U_O$ , which occurs when  $b_N$  is above the following threshold:

$$b_N^* = b_O - H(r_O - r_N). \quad (2)$$

Figure 1 illustrates the parameter region in which the new technology is adopted and the shift associated with tort reforms (i.e., a decrease in  $H$ ). For a fixed level of liability,  $H$ , physicians trade off technology quality with the risk of malpractice litigation. Riskier technologies ( $r_N > r_O$ ) are adopted as long as their quality ( $b_N - b_O$ ) is large enough. Conversely, safer technologies are adopted only if their quality is not too low. A decrease in  $H$  rotates the

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<sup>4</sup>Our results are robust to replacing the take-it-or-leave-it offer with a Nash bargaining protocol in which the surplus is split between the innovator and the physician.

adoption threshold clockwise. The result highlights that a tort reform has different effects on adoption, depending on the characteristics of the new technology. First, there is an increase in the adoption of high-quality but riskier technologies. This is consistent with tort reforms mitigating the concern that high liability exposure makes physicians reluctant to adopt new technologies (i.e., the ‘chilling effect’ of the current tort system on innovation suggested by Parchomovsky and Stein, 2008). Second, in contrast, there is a reduction in the adoption of low quality and safer technologies. This is consistent with the argument that high liability exposure motivates physicians to use low-risk technologies even if their benefits to patients are limited, and that tort reforms help mitigate this ‘defensive-adoption’ incentive. Finally, there is no effect on the adoption of high-quality/low-risk or low-quality/high-risk technologies.

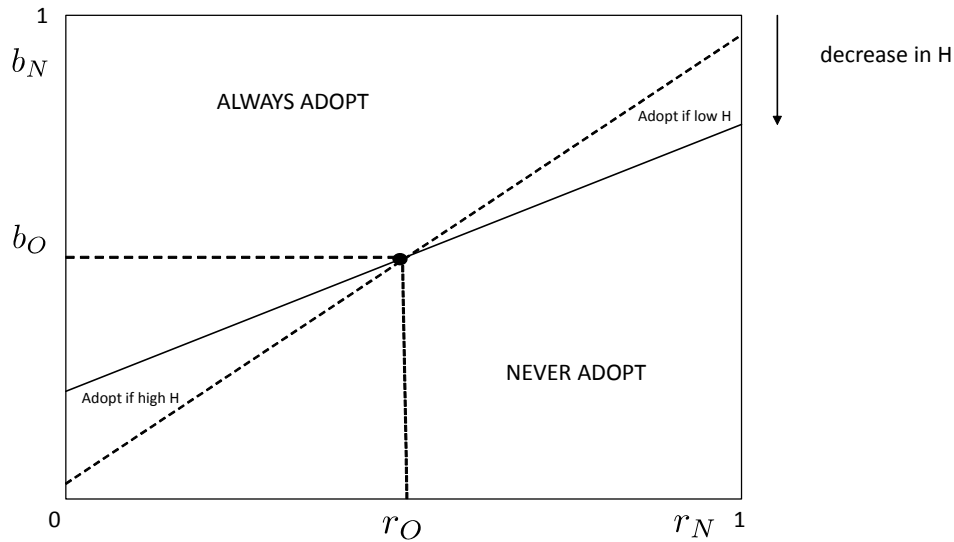


Figure 1: Tort reform (reduction in  $H$ ) and technology adoption

The overall effect of a tort reform on technology adoption is, therefore, ambiguous. The following proposition shows that when the old technology is sufficiently risky, in the absence of tort reforms, the incentive to avoid malpractice claims by defensively adopting safer technologies dominates the chilling effect of high liabilities. As a result, a tort reform would result in an overall decrease in the propensity to adopt new technologies. That is,

**Proposition 1** *A decrease in  $H$  generates an overall decrease in the propensity to adopt new technologies if and only if the old technology is sufficiently risky (i.e.,  $r_O > 1/2$ ).*

**Proof.** See Appendix. ■

So far, our analysis has focused on the effect of tort reform on technology adoption. The overall impact of a tort reform on innovation combines its impact on adoption with the effects on the incentives to invest in R&D. For technologies that are going to be adopted ( $U_N \geq U_O$ ), the profits from a successful innovation are  $U_N - U_O$ , and the innovator will invest in R&D,  $x$ , to the point at which the marginal cost of R&D equals its marginal benefits.

Generally speaking, tort reforms may have a positive or a negative effect on innovation incentives, depending on the type of the new technology. At the extensive margin, because tort reforms affect the physician's adoption decisions, some technologies become profitable after the reform while others are no longer profitable. The former experience an increase in the innovation intensity while the latter experience a drop. At the intensive margin, for technologies that are adopted regardless of the liability regime, tort reforms affect their profit incentives. Recall that the profit from a successful innovation is equal to  $b_N - b_O - H(r_O - r_N)$ . Therefore, a reduction in  $H$  increases innovation intensity for technologies with  $r_N > r_O$  and decreases innovation intensity for those with  $r_N < r_O$ . Finally, the relative magnitudes of the opposing effects (extensive and intensive margins combined) on innovation incentives would depend on how the patient benefit of the new technology compares to the old technology, as the relative importance of safety consideration is different. The characterization of the optimal R&D intensity shows that the overall effect of a tort reform on innovation incentives depends on the risk level of the existing technology.

**Proposition 2** *The impact of a decrease in  $H$  on innovation intensity is negative when the old technology is sufficiently risky ( $r_O > 1/2$ ) and ambiguous otherwise (i.e., when  $r_O \leq 1/2$ ).*

**Proof.** See Appendix. ■

In the proof of Proposition 2, we show that, when  $r_O > 1/2$ , the negative impact of tort reform on innovation dominates regardless of the level of patient benefit and, hence, the overall net effect is negative. Intuitively, when the risk level of the old technology is high enough, a large number of new technologies are developed and generate high profits mainly for defensive reasons. Thus, if a reduction in  $H$  is implemented, the profitability of these technologies declines and this reduces innovation incentives. When the risk level of the existing technology is relatively low ( $r_O < 1/2$ ), we show that the positive impact of tort reform on innovation intensity dominates for technologies that convey high enough patient benefit, rendering the overall net effect of tort reform ambiguous.

To summarize, our simple model shows that tort reforms have an ambiguous effect on innovation. Moreover, it generates a testable prediction: the effect of tort reform on innovation is more likely to be negative in technology fields characterized by a higher risk of malpractice litigation.

### 3.3 Discussion of the main modeling assumptions

The model builds on a number of assumptions that warrant additional discussion. First, in describing the idea-generation process, we assume that parameters are drawn from uniform distributions. Uniform distribution is a common assumption when modeling ideas, given the abstract nature of the creative process (Scotchmer, 1999). An important feature of our model is that, even though ideas are uniformly drawn, the distribution of ideas developed into technologies is not restricted to being uniform. The innovator chooses endogenously how much to invest in development, and she invests more when ideas are more profitable.

Second, our framework assumes that  $b$  and  $r$  are independently distributed. A priori, there is no reason to impose correlation between  $b$  and  $r$  in the idea space. Under the interpretation of  $b$  and  $r$  as features of a distribution of patient outcomes, correlation between  $b$  and  $r$  requires restricting the shapes of the outcome distributions across ideas. For developed ideas, correlation between  $b$  and  $r$  arises endogenously in our model and depends on  $H$ .<sup>5</sup>

Third, for simplicity - and different from Schurtz (2014) - our model does not include physicians' financial incentives. Therefore, the parameter  $b$  should be interpreted as a combination of the utility that the physician attaches to patients' benefits and the financial incentives associated with the adoption of the medical technology. These financial incentives typically depend on patients' insurance plans, and in our empirical analysis, we will show that our estimates do not change when we control for the extent of public and private insurance coverage by a state.

Finally, in our model, physicians act as users of medical devices, not as inventors. Our theoretical results generalize to the case in which physicians are also innovators, as long as they can appropriate in part or fully the rents from commercialization.

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<sup>5</sup>If we extend the model by imposing a negative correlation between  $b$  and  $r$ , we would expect a lower impact of a tort reform on innovation incentives. This is because negative correlation renders more likely ideas with high benefit and low risk (which are developed independently of the malpractice regime) and ideas with high risk and low benefits (which are not developed even in the presence of caps on damages). Conversely, we would expect positive correlation between  $b$  and  $r$  to amplify the impact of tort reforms.

## 4 Data and methods

We begin with a U.S. state-year panel dataset measuring tort reforms during the period 1985-2005. The main source of data on tort reforms is the American Tort Reform Association (ATRA), which lists information on reforms implemented since 1986. We complement these data with additional information collected by Currie and MacLeod (2008) on the pre-1986 status quo and on laws overlooked by ATRA because they were overturned.

We merge this panel with the United States Patent and Trademark Office (USPTO) patent dataset to measure patenting activity across U.S. states during our sample period. We use the address information of the first inventor and the application year of a patent to aggregate patents to the state-year level. Each patent is classified by the USPTO using 3-digit technology classes, and we exploit this detailed classification system to identify medical instrument patents.<sup>6</sup> We also obtain data on the gross product, the population and the number of physicians in a state.<sup>7</sup>

USPTO patents offer a unique source of data for large-scale studies on innovation. Nonetheless, certain qualifications should be kept in mind. First, not all inventions are patented, but the innovation literature has shown that technologies with greater impact on social welfare and economic growth are more likely to be patented (Pakes and Griliches, 1980). Second, innovation is a process for which it is impossible to measure the origin. Relative to alternative measures, such as an FDA-approved device and the location information of its manufacturer, the application date of a patent and the location of the inventors are probably the best available measures to capture the timing and location of the origin of the invention.

It is unlikely that the tort law changes that we exploit in the paper are driven by, or systematically correlated with, trends in medical device innovation for the following reasons. First, most of the law changes in the ATRA sample are modifications of the general tort statutes and are not aimed directly at medical malpractice. As described in Currie and MacLeod (2008), there is little evidence that tort laws were passed in response to specific developments in the health sector, and most laws apply to all torts. Priest (1987) argues that an important driver of early tort reforms was a doctrinal change in the interpretation of tort law, leading some

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<sup>6</sup>Specifically, we follow a list provided by the USPTO indicating patent classes related to medical devices: <http://www.uspto.gov/web/offices/ac/ido/oeip/taf/meddev.htm>.

<sup>7</sup>These data are obtained from the US Census and the BEA. Information on the number of physicians is not reported in the US Census Statistical Series for the years 89, 91 and 93 and are imputed by interpolation.

courts to increase injury compensations substantially. Moreover, a number of more recent tort reforms were influenced by the extensive media coverage of the 1992 *Liebeck v. McDonald's Restaurants* case, in which a woman was awarded more than two million dollars when she accidentally spilled hot coffee in her lap. Finally, it is important to note that our data also include instances in which state courts overturned laws because of constitutionality issues. As we show later, analysis focusing on these reforms alone provides results that are consistent with our baseline results.<sup>8</sup>

Our paper focuses on the demand channel of liability risks (that is, changes in malpractice liability risks affect physicians' demand for new technologies) instead of on the direct effect of product liability risk on manufacturers for the following reasons. First, different from many other sectors, medical devices are subject to national regulation. Specifically, manufacturers of medical devices reviewed by the FDA are subject to the Medical Device Amendments to the Federal Food and Drug and Cosmetic Act passed in 1976, which preempts state tort claims (Bivans, 1995). This implies that changes in state tort laws exploited in this paper are likely to affect manufacturers through their impact on downstream users rather than through product liability costs. Second, the product-liability risk channel seems too narrow to capture the phenomenon in our context. For example, technologies that are demanded for defensive reasons (e.g., diagnostic and monitoring technologies; devices that aid smooth delivery of babies during cesarean sections; or a small diameter steerable guidewire for use in procedures in narrow arteries) are unlikely to be targets of liability claims, rendering the product-liability channel irrelevant.

The class of tort reforms central to our empirical analysis is the introduction of caps on non-economic damages -i.e., damages other than monetary losses, such as pain and sufferings. As discussed in Avraham et al. (2012), these damages comprise a substantial fraction of total awards and have often been the main focus of tort reform advocates. Consistent with the literature, we capture tort reforms using a dummy variable, *Damage Caps*, which equals one if caps on non-economic damages are in place. In our setting an indicator variable is preferable to the actual level of caps for two reasons. First, for some of the reforms, it is difficult to identify a precise dollar amount (i.e., they do not impose a cap of a fixed dollar amount and

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<sup>8</sup>Moreover, Deng and Zanjani (2015) do not find evidence of an influence of private interest groups - such as doctors or insurance industry professionals - on tort reform adoption. Similarly, Avraham and Schanzenbach (2015) exploit a detailed dataset of patients experiencing heart attacks and show that passages of tort reforms do not appear correlated with pre-existing trends in treatment intensity.

use a multiplier of the economic damages). Second, and more importantly, with fixed-effects models, changes in the presence of a cap within a state provide more meaningful identification variations than cross-state variations in the level of caps. While caps on non-economic damages are a common state-level tort reform, we also control for other (less common) tort reforms, such as caps on punitive damages or changes in the joint-and-several liability rules.

During our sample period, 25 states experienced changes in caps on non-economic damages. Of these states, 16 switched from no caps to a cap, whereas the remaining nine states experienced multiple shifts (e.g., caps were instituted and then rescinded, and in some cases, reinstated). About half of the reforms took place in the late 1980s. In terms of 1985 medical device patenting, population and gross state product, the states in which caps on damages were not implemented for the entire sample period are not statistically different from states in which caps were present in some years.

Table 1 provides summary statistics. Caps on non-economic damages were present in about 34 percent of the state-year observations of our sample. On average, inventors in a state applied for roughly 1,700 patents (eventually granted), and about 100 of these patents were classified by the USPTO in one of the medical device technology classes.

#### 4.1 Econometric specification

Our main econometric model focuses on the relationship between measures of innovative activity  $Y_{jt}$  in state  $j$  and period  $t$  and the indicator for the presence of caps on non-economic damages in state  $j$  and period  $t$ . Our baseline specification is:

$$\log Y_{jt} = \beta \text{Damage Caps}_{jt} + \lambda' X_{jt} + \theta_t + \mu_j + \varepsilon_{jt}, \quad (3)$$

where  $X_{jt}$  is a vector of control variables, and  $\mu_j$  and  $\theta_t$  are, respectively, the state and year fixed effects. The coefficient  $\beta$  captures the effect of tort reforms on patenting in the state: for example,  $\beta < 0$  means that innovators located in a state reduce their patent applications when damage caps are in place. We cluster the standard errors at the state level.

Our identification comes primarily from changes in damage caps over time within a state. The controls  $X_{jt}$  and state effects  $\mu_j$ , therefore, play an important role in our analysis. As discussed previously, there is little evidence that the tort reforms used in our analysis are driven by, or systematically correlated with, trends in medical device innovation. Nonetheless, we perform several robustness checks designed to placate remaining endogeneity concerns and to



isolate confounding factors. For example, we construct better controls to each of the states affected by a tort reform using the synthetic control method developed by Abadie et al. (2010). We also exclude large states and large device companies to confirm that the results are not driven by states that may have implemented pro-innovation policies or by large companies that were particularly innovative during the sample period.

Because innovation activities may respond to changes in demand beyond the local level, we also examine whether innovative activity  $Y_{jt}$  in state  $j$  and period  $t$  is affected by tort reforms in other states. This requires extending the baseline model to include non-local effects

$$\log Y_{jt} = \beta \text{Damage Caps}_{jt} + \gamma \text{Non-Local Reforms}_{jt} + \lambda' X_{jt} + \theta_t + \mu_j + \varepsilon_{jt}, \quad (4)$$

where  $\text{Non-Local Reforms}_{jt}$  is a weighted average of tort reforms in other states

$$\text{Non-Local Reforms}_{jt} = \sum_{i \neq j} w_{ij} \text{Damage Caps}_{it}. \quad (5)$$

## 5 Baseline empirical results

In this section, we report the overall effects of the presence of non-economic damage caps on patent applications in the medical device fields. In the next section, we explore the heterogeneity in the data to further test the predictions of our model. The regressions in Table 2 show a strong negative correlation between medical device patenting by innovators located in the state and the presence of caps on non-economic damages. All the specifications include year and state effects. These results are consistent with the idea that, in the absence of tort reforms, the defensive-adoption effect of high liabilities dominates the chilling effect, on average.

Column 1 presents the estimates of an OLS regression with the number of medical patents as the dependent variable. The coefficient implies an average reduction of roughly 30 patents in years in which damage caps are present. Column 2 shows that the results are similar with an OLS regression with log of patents as the dependent variable. Exponentiation of the coefficient implies that in periods when caps on damages are in place, innovation is reduced by roughly 14 percent. Evaluated at the median level of patenting for state-years without damage caps (i.e., 28 patents), this effect is equivalent to a reduction of roughly four medical device patents per year.<sup>9</sup>

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<sup>9</sup>The difference between the average effect presented in column 1 and the effect evaluated at the median is due to the skewness in the distribution of patenting across state-years. In Section 5.2, we report the estimated effects separately for each treated state.

In column 3, we show that results are not affected if we introduce a variety of controls: lagged total patenting; population; and the number of physicians in the state.<sup>10</sup> Column 4 controls for other changes in tort law: cap on punitive damages; modifications of the collateral-source rule; and modifications of the joint-and-several liability rule. The coefficients on these dummies are all statistically insignificant and small in magnitude, confirming the predominance of non-economic damages. Finally, column 5 shows that results are robust to excluding from the sample states for which caps on non-economic damages pertained only to medical malpractice rather than to torts more generally. This helps to address the concern that the effects might be driven by legislation passed in response to specific incidents of malpractice.<sup>11</sup>

We perform a variety of robustness tests to confirm our main finding. First, there is the concern that our regressions ignore the count nature of our dependent variable. To address this issue, we show that our results are robust to estimating the effect of caps on damages using a Poisson regression model with fixed effects (column 1 in Appendix Table A1).

A second series of extensions demonstrates that our main results are robust to including extra covariates. First, Table A1 shows that the results are similar when we allow for dynamics and use a multiplicative feedback model that controls for the logarithm of lagged patenting in medical instruments. Also in Table A1, we extend our baseline model to include additional controls for gross state products (GSP), the percentage of the state’s population with medical insurance coverage, and the percentage of the population with private medical insurance. These variables are proxies for the demand for new medical technologies in the state, and their inclusion reduces the concern that tort reforms are correlated with other unobservable demand shocks affecting innovation. The coefficient on tort reform is stable, and the coefficients on the insurance variables are small and statistically insignificant.<sup>12</sup> In unreported regressions, we also confirm that our results are robust to including a control, constructed by Frakes (2013), for the adoption of rules requiring physicians to follow national, as opposed to local, standards.<sup>13</sup>

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<sup>10</sup>As an alternative approach, instead of controlling for the population and the number of physicians in the state, we run a weighted regression with weights constructed from the pre-sample (year 1981) population in each state. The estimated coefficient on Damage Caps is equal to -0.116 with p-value below 0.01. We find a very similar coefficient when weights are constructed from the pre-sample number of practicing physicians in the state. For both coefficients we cannot reject equality with the estimate in column 3 of Table 2.

<sup>11</sup>Currie and Macleod (2008) identify these states as Montana, Nevada and Alaska.

<sup>12</sup>The insurance variables are obtained from the US census, which only reports data for the period 1987-2005. We extrapolate the time series to construct the data for the two missing years.

<sup>13</sup>The coefficient on tort reform is stable, whereas the dummy on national standardization is negative, small

We also examine whether our results are robust to: (i) excluding the five states with the largest number of medical device patents in 1984; and (ii) dropping the ten largest patentees over our sample period. The regressions reported in Table A1 indicate that the estimated effect is not driven by the largest states or the largest firms. These findings mitigate a number of concerns over confounding factors (e.g., that large patenting firms happen to be located in control states or that large control states happen to have implemented pro-innovation policies).

Finally, in the last column of Table A1, we present a placebo test that estimates our baseline model using the sample of non-medical measuring and testing instruments (USPTO class 073). The estimated coefficient is statistically insignificant and small in magnitude, suggesting that tort reforms have not affected patenting in this technological field. This finding help to address the concern that the impact of cap-on-damages on medical device patenting may reflect omitted variables (e.g., pro-innovation policies) or pre-trends in patenting correlated with tort reforms.

We turn next to two extensions that are of independent interest.

## 5.1 Non-local effects of tort reforms

Our empirical analysis thus far has assumed that the impact of tort reforms on innovation is localized -i.e., it affects innovators only in states with policy changes. In this section, we extend our baseline model and examine the effects that tort reforms have outside the state in which they are implemented. There are a number of possible channels through which a cap on damages imposed by one state can impact innovation incentives in other states. For example, if caps on damages in one state substantially reduce the demand for certain technologies in the state, they may decrease R&D investments in these technologies by local innovators, as well as by innovators located in other states. This would lead us to underestimate the impact of tort reform on innovation. More complex spillover effects may also arise through competitive interaction between medical device firms in treated states and those in control states.

To examine whether market forces generate effects of tort reforms beyond the focal state, we extend our baseline model including a new variable  $\text{Non-Local Reforms}_{jt}$ , which is a weighted average of tort reforms in other states. The first set of weights we construct aims to be a proxy for the relative demand of medical instruments in each state  $i \neq j$ . To

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and insignificant. A priori, it is not clear how standardization of physician practice may impact innovation incentives, because it may combine a positive demand effect for devices used in national standard procedures, and a negative impact for devices employed in local procedures which deviates from the standard.

this end, we exploit the American Medical Association (AMA) publication titled “Physician characteristics and distribution in the U.S.” that provides detailed information on the number of practicing physicians in the US by state and compute the share of physicians in each state  $i$  in the pre-sample year 1981, which we label  $s_i$ . We then generate weights  $w_{ij} = s_i/s_j$  to use in the construction of Non-Local Reforms $_{jt}$  as defined in equation (5). This approach gives higher weights to tort reforms in bigger states and, at the same time, allows us to compare the magnitudes of the estimated effects of reforms in the focal state and other states. We add this new control to our baseline in column 1 of Table 3. The result is striking, we find no evidence of a significant effect of tort reform in other states on medical device patenting in the focal state.

Our second approach constructs weights which take into account both the demand for specific categories of medical devices in each state and the innovation supply of the focal state across these categories. Exploiting the AMA’s data, we construct a vector with the pre-sample (year 1981) number of practicing physicians in each state across three main speciality groups: surgery, orthopedics and others. We then use the USPTO patent classification system to identify pre-sample (years 1980-82) medical instrument patents in three technology areas which parallel these speciality groups: surgery, orthopedics and others. We exploit these data to construct

$$\varpi_{ij} = \sum_k pat_{jk} doc_{ik}$$

where  $k \in \{\text{surgery, orthopedics, others}\}$  captures specialities/technology areas,  $pat_{jk}$  is the fraction of US patenting in technology area  $k$  accounted by state  $j$  and  $doc_{ik}$  is the fraction of US physicians in speciality area  $k$  accounted by state  $i$ . The construction of this variable is consistent with a simple supply/demand model for medical instruments innovation. Intuitively, the number of doctors in each state  $i$  and speciality area  $k$  is a proxy of its demand for innovation in technology area  $k$ . Similarly, the level of patenting in state  $j$  and technology area  $k$  is a proxy of its supply of medical innovation to doctors in speciality area  $k$ . The Non-Local Reforms $_{jt}$  variable is then constructed using  $w_{ij} = \varpi_{ij}/\varpi_{jj}$  as weights. Column 2 of Table 3 shows that adding this, more sophisticated, control does not change our conclusion. Also in this case the coefficient is very small in magnitude and statistically insignificant, suggesting that non-local effects do not play a central role.<sup>14</sup>

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<sup>14</sup>In unreported regressions, we also considered a weighted average of the tort reforms in other states, in which weights are constructed from the state-to-state migration flows data in the 2005 American Community Survey

The above two sets of weights do not take into account the geographic distance between demand and supply, which may influence factors such as shipping costs and regional scale effect of sales force. We next investigate the effects of tort reforms in other states by geographic distance directly. First, in column 3 of Table 3, we extend our baseline model by adding a dummy for damage caps implemented in bordering states. The result shows that a tort reform in a bordering state does not have a significant impact on the focal state’s innovation incentives, with an estimated coefficient being negative but statistically insignificant. Column 4 of Table 3 introduces a flexible specification that allows for non-linear effects of distance. Specifically, we employ five dummy variables for reforms within 500Kms, 500-750Kms, 750-1,000Kms, 1,000-1,250Kms and 1,250-1,500Kms from the focal state. The distance is constructed from the latitude and longitude coordinates of states’ population centroids provided by the Census Bureau. The only coefficient statistically significant (at the 0.1 level) and with magnitude substantially larger than the others is the one for reforms within 500Km. In all regressions, the coefficient of the direct effect of a tort reform within the focal state is stable and similar in magnitude to the baseline regression. Overall, the data suggest that geographical spillover effects appear to be small and concentrated within 500Kms of the focal state.

*Explaining the local nature of the effect*

We showed that the effect of tort reforms on medical device innovation is concentrated among local innovators. Various features of the medical device industry may explain this finding. Specifically, the medical device innovation process is characterized by the substantial involvement of practicing physicians. Chatterji et al. (2008) find that roughly 20 percent of medical device patents list a licensed physician among their inventors. This occurs because physicians often develop new technologies and either patent them directly or collaborate with manufacturing firms to protect and commercialize the technologies (Chatterji and Fabrizio, 2014). This widespread user-innovation paradigm suggests that the local nature of the effect of tort reforms on innovation may be explained by changes in patenting by local physicians who are directly affected by the policy change. On top of doctors’ involvement in patenting, the local effect of tort reforms can also be explained by an informational advantage of local innovators. Medical device innovators geographically located closer to physicians affected by

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of the US Census Bureau as in Moretti and Wilson (2014). The larger the population flow from state  $j$  to state  $i$ , the greater is the weight of a reform in state  $j$  for state  $i$ . The coefficient on this variable is also small and statistically insignificant.

tort reforms may be better suited to understand and address doctors' technological needs.<sup>15</sup>

It is hard to observe feedback from physicians systematically. We can, however, examine the user-patenting channel more directly. We exploit data from Chatterji et al. (2008) and identify the patents in our sample that list a licensed physician as inventor for the period 1990-1996. We find that 19.1 percent of the 1990-96 medical device patents in our sample are classified as invented by doctors or with the participation of doctors, a figure very similar to that in Chatterji et al. (2008). In column 1 of Table 4, we show that our main finding is robust to focusing on the 1990-96 sub-period. In columns 2 and 3, we contrast the effect of tort reforms for patents involving practicing physicians and other patents. The negative impact of tort reforms appears statistically significant only for patents involving physicians, with a coefficient twice as large as that for the other patents. This result supports the idea that a sizable fraction of the tort reform effect is driven by local physician innovators who are directly affected by tort law in a state.<sup>16</sup>

## 5.2 Synthetic control method

Our analysis so far has focused on the average effect (across treated states and over time). In this section, we use the synthetic control method (Abadie et al., 2010) to obtain a clear graphical representation of the effect of adopting the damage cap. By investigating each treated state separately, this method also allows us to see which states drive the average results and the timing and magnitude of the effect for each state.

Specifically, for each of the 16 states that transitioned from no cap to adopting a cap, we construct a synthetic control using the 23 states that did not have a cap throughout our sample period (donor states). The predictor variables used to construct the synthetic controls are the number of medical patents, the total number of patents, population, GSP, and physicians per population. The weights on the donor states are reported in Table A2 for the top six treated

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<sup>15</sup>Thomas Fogarty, inventor of the embolectomy balloon catheter, states: “Physicians are the ones who recognize the need, and very often, the physician is capable of conceiving what may satisfy that need. . . . The physician plays a key role, followed by the engineer and other specialties who have knowledge in the development of technology related to the medical field” (in *Endovascular Today*, March 2013). This idea is also confirmed by Shaw (1985). In a study of British medical innovations he finds that, for half of the devices in his sample, a prototype was developed and produced by a user. In another third of the cases, the idea was transferred directly from the user to the manufacturer at the user’s initiative.

<sup>16</sup>As we discuss in Section 3.3, in our model, physicians act as users of medical devices, not as inventors. Our theoretical results generalize to the case in which physicians are also innovators, as long as they can appropriate in part or fully the rents from commercialization. For Table 4, we control only for state and year effects because of the smaller size of this sample.

states (as explained below).<sup>17</sup>

The treated states vary substantially in their inventive activities. For example, the total number of medical patents applied for between 1974 and 1986 ranges from three to 416. We report, in Figure 2, the results for the top six treated states (according to their pre-1987 patent stock).<sup>18</sup> Before adopting the cap, the number of medical patents in the treated state is similar to the corresponding synthetic control state, while patenting decreases relatively after the tort reform. The treatment effect, defined as  $(N_{\text{treated,after}} - N_{\text{treated,before}}) - (N_{\text{control,after}} - N_{\text{control,before}})$  where  $N$  is the yearly average, ranges from -51.7 to -22.4 patents per year for these six states. The mean and the median are, respectively, -36.7 and -36.1. Visual inspection shows that, when tort reforms make a difference, the magnitude increases over time and starts to become meaningful after five or six years.

The treatment effects for the other ten smaller states that switched from no cap to a cap (not reported graphically) are small, ranging from -7.8 to 4.1 patents per year, with the mean and median being both about -1. We confirm robustness of these results to excluding large patenting states, top ten assignees, or states that are less than 500Kms from the control.

We use the placebo tests suggested by Abadie et al. (2010) for inference. For each treated state, we iteratively apply the synthetic control method to every state in the donor pool. Specifically, we reassign the adoption of the cap to each of the 23 donor states and shift the treated state to the donor pool. This iterative procedure provides a distribution of estimated treatment effects for states in which no intervention took place. The results for the top six treated states, presented in Figure A1, show that the estimated effect for the true treated state is among the most negative in this distribution.

Exploiting this methodology, we also examine two large states, Texas and Ohio, which eliminated their damage caps off during the sample period. The estimated treatment effects of eliminating the cap are positive, and equal to 48.2 and 62.7, respectively, for Texas and Ohio. These results are consistent with our theoretical model, confirming that the negative effect of the presence of a cap on patenting activities is unlikely to be caused by the general trend of

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<sup>17</sup>Because the method requires a relatively long pre-treatment period, we extend the sample back to 1977. We obtain the weights on the donor states by minimizing the distance between the average values of the predictor variables in the pre-treatment period for a treated state and those for its synthetic control, subject to: (i) all weights must be non-negative, and (ii) they sum to one.

<sup>18</sup>The top six treated states are Colorado, Maryland, Michigan, Missouri, Utah and Wisconsin. There is a discrete drop in the pre-1987 patent stock between the sixth and the seventh states: the number is 221 for the former and 89 for the latter.

increasing inventive activities in the control state.<sup>19</sup>

## 6 Heterogeneous effects

Our baseline analysis has documented an average negative effect of tort reforms on medical device patenting. In this section, we examine the heterogeneity in the impact of tort reforms: (1) by the extent of malpractice risk of a particular medical field; and (2) by the quality of an invention.

### 6.1 Malpractice risk and innovation incentives

The model predicts that the impact of tort reforms is more likely to be negative in technology fields characterized by frequent malpractice risk (i.e., high  $r_O$ ). Intuitively, in these fields, it is likely that physicians adopt new technologies mainly to manage liability risk. Thus, if caps on damages are implemented, the incentives to use these technologies decline and, thus, reduce the overall innovation incentives.

Jena et al. (2011) study US malpractice data from 1991 through 2005. They show that the proportion of physicians facing litigation risk varies substantially across medical specialties. The likelihood of facing a malpractice claim is the largest in surgery (especially in neurosurgery and thoracic-cardiovascular surgery) and orthopedics, where the annual probability of facing a claim is about 20 percent. Conversely, malpractice claims are not frequent in specialties such as psychiatry, optics or dentistry, where the annual probability of a claim is below 3 percent. Building on these findings, we exploit the detailed USPTO patent classification system and identify medical instrument patents related to four technology fields: surgical, orthopedics, optics, and dental.<sup>20</sup>

Table 5 provides the estimates for the effect of tort reforms on patenting in each of these four fields. As our model predicts, there is a large negative effect for medical instrument patenting related to specialties in which the frequency of malpractice claims is high (surgery and orthopedics). Conversely, the effect is small and statistically insignificant for devices associated with specialties with fewer malpractice claims (dental and optics). While we cannot reject that the effects on surgical and orthopedic devices have the same magnitude ( $p = 0.97$ ),

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<sup>19</sup>Both Texas and Ohio reinstated the cap in 2004, and we do not use 2004 and years after that in our analysis. Ohio also had a brief one-year reinstatement in 1999, which we ignore in the analysis.

<sup>20</sup>We use the following 3-digit classes: 128 and 600-607 for surgical; 433 for dental; 351 and 356 for optics; and various sub-classes of class 623 for orthopedics.



we can strongly reject that the effect for surgery is equal to the effect for optics ( $p < 0.01$ ) or to the effect for dental ( $p < 0.01$ ).

## 6.2 Tort reform and innovation quality

Our baseline regressions indicate a negative effect of tort reforms on medical device patenting. Such a reduction in the number of patent applications may have very different impacts on welfare depending on whether it affects high-quality patents or marginal patents with limited impact on the technology field. To unbundle the heterogeneous effect of tort reforms across different quality levels, we exploit information on the citations received by each patent. Patent citations identify prior knowledge upon which a patent builds. USPTO patent examiners are responsible for insuring that all appropriate prior art has been cited, and this delimits the scope of property rights granted to the patentee. Because of this important legal function, the economics of innovation literature has often employed the number of citations received by a patent as an indirect measure of patent value (Pakes and Griliches, 1980). Since citation counts are inherently truncated, and levels may differ across technology areas, we filter citations by removing grant-year and 3-digit technology class effects. We then identify the (filtered) citation quintile in which each patent belongs.

In Table 6 we present the estimates of our baseline model for each of the quality quintiles. The estimates show a non-monotonic relation between damage caps and patenting across patents of different quintiles. The effect is not statistically significant for innovations in the lowest quintile of innovation quality. The effect becomes negative and significant in the second quintile, and the magnitude of the negative effect is larger as innovation quality increases (with the largest being in the fourth quintile). The effect, again, becomes small and insignificant for innovations in the top quality quintile.

We perform a variety of tests to confirm robustness of this finding. First, we re-estimate the relationship between damage caps and patenting disaggregating at the finer level of citation deciles. The (unreported) estimates are in line with those from the quintile analysis and show a U-shaped relationship between tort reform and innovation. There is a statically significant negative impact only for patents from the 4th to the 9th deciles, with the largest effects on the 7th decile of the distribution. Second, we confirm that the pattern is robust to using alternative measures of patent quality. In Appendix Table A3, we construct quintile bins exploiting residuals obtained from regressing citations against year effects, technology effects and the number of claims. This alternative measure - which captures normalized citations per

patent claim – yields results very similar to those obtained in Table 6.<sup>21</sup>

*Explaining the U-shaped effect*

The non-monotonic impact of tort reforms illustrated in Table 6 is predicted by our model when we perform comparative statics in  $b_N$ , which is the expected benefit to the patient from the new technology. This result is formally proved when we derive the main result of Proposition 2, and it is illustrated in Appendix Figure A2. Intuitively, physicians do not adopt low-quality technologies independent of the malpractice liability regime and, hence, tort reforms have little impact in that quality bin. As the value of a new technology increases and gets closer to the value of the old technology, adoption becomes more likely mainly to manage risk. In this quality bin, the effect of tort reforms on innovation incentives is negative because the physician’s willingness to pay for a safer technology decreases after the reform. For new technologies with value greater than the old technology, tort reform has two opposing effects: It decreases innovation incentives for safer devices, but increases innovation incentives for riskier devices. Furthermore, the positive effect of the reform gets stronger than its negative effect as the value of the new technologies becomes higher. This explains why the negative effect of tort reform is mitigated at higher quality bins and we find an insignificant effect for patents of the highest quality.

Note that the model generates a non-monotonic relationship between tort reform and  $b_N$ , which is the expected benefit to the patient from the new technology. In performing this comparative statics, we let  $r_N$  (the expected risk level of the new technology) vary endogenously for each level of  $b_N$ . To empirically disentangle  $b_N$  from  $r_N$  is very challenging with our data, and citations are a measure of quality available for a variety of different medical technologies. While it is likely that the lowest quintile of the citation distribution captures innovations with very low  $b_N$  and that patents in the top quintile capture technologies with very large  $b_N$ , intermediate quintiles may contain technologies with mixed levels of  $b_N$  and  $r_N$ . Despite the presence of such measurement error, the estimates are consistent with the model’s predictions, suggesting that citations may be a reasonable proxy for  $b_N$ .

We perform an additional test of the prediction of the model exploiting the fact that in the U.S. medical devices are subject to the FDA regulatory process. One of the FDA’s regulatory pathways to bring a device to market is the Pre-market Approval (PMA) process,

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<sup>21</sup>We also obtain similar results: (i) filtering citations removing only the grant year effects; and (ii) measuring quality with the number of patent claims filtered by 3-digit technology effects.

which requires detailed product information and evidence of safety from clinical trials (Stern, 2015). The FDA requests PMAs for “high-risk” devices that are used to support or sustain human life, and the expenditure required to complete PMAs is substantial (75 million dollar per device according to survey evidence in Makower et al., 2010). This high cost, combined with the “high-risk” nature of the medical devices involved in PMAs, suggests that data on PMAs may provide a reasonable window on technologies with high  $b_N$  and  $r_N$ . Our theoretical framework suggests that tort reforms will not strongly affect innovation incentives for these devices. The model predicts an ambiguous effect for these technologies, with a magnitude (positive or negative) lower than the one for devices with lower  $b_N$ .

Exploiting the data released by the FDA for PMA requests as a measure of innovation, we run a variety of (unreported) regressions estimating the impact of tort reforms. Coefficients are small and statistically insignificant across the various specifications. While this insignificant effect is in line with our theory, two key qualifications should be kept in mind. First, FDA applicants are often manufacturers that are not necessarily the innovators. Second, there is evidence of strategic delays in the introduction of medical devices in the U.S. market relative to the European markets (Grennan and Town, 2015). Both of these issues may generate substantial measurement errors for innovative activities and geographic locations and, hence, bias the coefficients toward zero.

## 7 Conclusions

This paper investigates how tort reforms affect the development of new medical device technologies by exploiting state tort reforms and patent data for the period 1985-2005. We develop a theoretical model in which tort reforms increase physicians’ propensity to adopt riskier technologies by mitigating the “chilling effect” of high liabilities emphasized by legal scholars. At the same time, we show that tort reforms also reduce physicians’ propensity to defensively adopt low-risk technologies in order to avoid malpractice liability, even when their benefits to patients are limited. These shifts in technology adoption affect upstream R&D investments, and the overall impact on the development of new devices depends on the relative strengths of the two effects.

Our empirical analysis shows that the introduction of caps on non-economic damages is associated with an average decline in patenting for medical instrument technologies. This suggests that, on average, the demand for new technologies generated by high liabilities exceeds

the negative chilling effect that damages have on medical device innovation. Consistent with the model's predictions, we find that tort reforms have a greater negative effect in specialities with a high frequency of malpractice claims (and, hence, stronger defensive-adoption effects when damages are high). Moreover, we find that the effect is the most negative for patenting at intermediate quality levels, while it is insignificant for patenting at the top and the bottom of the quality distribution. For the most valuable medical technologies, the insignificant effect of tort reforms indicates that, empirically, the positive effect of caps on damages on medical innovation counterbalances their negative effect.

More broadly, our paper provides empirical evidence that tort reforms can affect the rate of technological change, indicating that these policies have dynamic effects on innovation incentives that go beyond their short-term impact on patients and health costs. As Finkelstein (2004) stresses, recognizing and estimating these dynamic effects is crucial to evaluating the costs and benefits of tort reforms.

There are several useful directions for further research. Our paper infers the differential effects of tort reforms on different types of technologies without directly categorizing the technologies. With patent textual analysis, it may be possible to more precisely measure the impact of tort reforms across finer classes of medical devices. Second, our paper does not evaluate the welfare effect of tort reforms on innovations. This would require a more structural analysis of the value of safer technologies versus riskier, but potentially more effective, technologies to physicians and to patients, as well as the spillover effects of these technologies to other sectors of the economy.

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## Appendix

### Proof of Proposition 1

The area in the  $(b_N, r_N)$  space in which technology is adopted is equal to

$$\begin{aligned}
 AD &= \int_0^1 (1 - b_O + H(r_O - x)) dx \\
 &= 1 - b_O + H\left(r_O - \frac{1}{2}\right),
 \end{aligned}$$

with derivative  $\frac{dAD}{dH} = r_O - \frac{1}{2}$  which is positive if  $r_O > 1/2$ .



## Proof of Proposition 2

The optimal innovation intensity for an innovator with idea  $(b_N, r_N)$  solves

$$\max_x x (b_N - b_O - H(r_N - r_O)) - \frac{x^2}{2}$$

which is equal to  $x^* = U_N - U_O$ . Consider an innovator with an idea with expected benefit  $b_N$ . She will invest in R&D as long as

$$b_N - b_O - H(r_N - r_O) \geq 0$$

or

$$r_N \leq \frac{b_N - b_O}{H} + r_O \equiv \bar{r}.$$

The innovation intensity for firms at  $b_N$  is

$$\int_0^{\bar{r}} b_N - b_O - H(x - r_O) dx = \frac{H\bar{r}^2}{2}. \quad (6)$$

Considering the corner solutions when  $\bar{r}$  is outside the unit interval in (6), we obtain the expected innovation intensity for a fixed level of  $b_N$ :

$$i(b_N, H) = \begin{cases} 0 & \text{if } b_N < b_O - Hr_O \\ \frac{H}{2} \frac{b_N - b_O}{H} + r_O^2 & \text{if } b_O - Hr_O < b_N < H + b_O - Hr_O \\ b_N - b_O + H(r_O - \frac{1}{2}) & \text{if } b_N \geq H + b_O - Hr_O. \end{cases} \quad (7)$$

We exploit formula (7) to study the impact of tort reforms on innovation as well as the heterogeneity in the impact across technologies with different levels of expected benefits. To compute the total expected innovation investment we integrate  $i(b_N, H)$  for each value of  $b_N$ . The total effect comprises three parts. The first part is

$$\int_0^{b_O - Hr_O} 0 db_N = 0.$$

The second part is

$$\int_{b_O - Hr_O}^{H + b_O - Hr_O} \frac{H}{2} \frac{b_N - b_O}{H} + r_O^2 db_N = \frac{1}{6} H^2$$

The third part of the innovation intensity is

$$\begin{aligned} & \int_{H + b_O - Hr_O}^1 \left( b_N - b_O + H(r_O - \frac{1}{2}) \right) db_N \\ &= \frac{1}{2} H^2 r_O^2 - \frac{1}{2} H^2 r_O - H b_O r_O + \frac{1}{2} H b_O + H r_O - \frac{1}{2} H + \frac{1}{2} b_O^2 - b_O + \frac{1}{2}. \end{aligned}$$

Which implies that the expected innovation intensity as function of  $(b_O, r_O)$  is equal to

$$I(H, b_O, r_O) = \frac{1}{2}H^2r_O^2 - \frac{1}{2}H^2r_O + \frac{1}{6}H^2 - Hb_Or_O + \frac{1}{2}Hb_O + Hr_O - \frac{1}{2}H + \frac{1}{2}b_O^2 - b_O + \frac{1}{2}$$

The following derivative captures the impact of a tort reform:

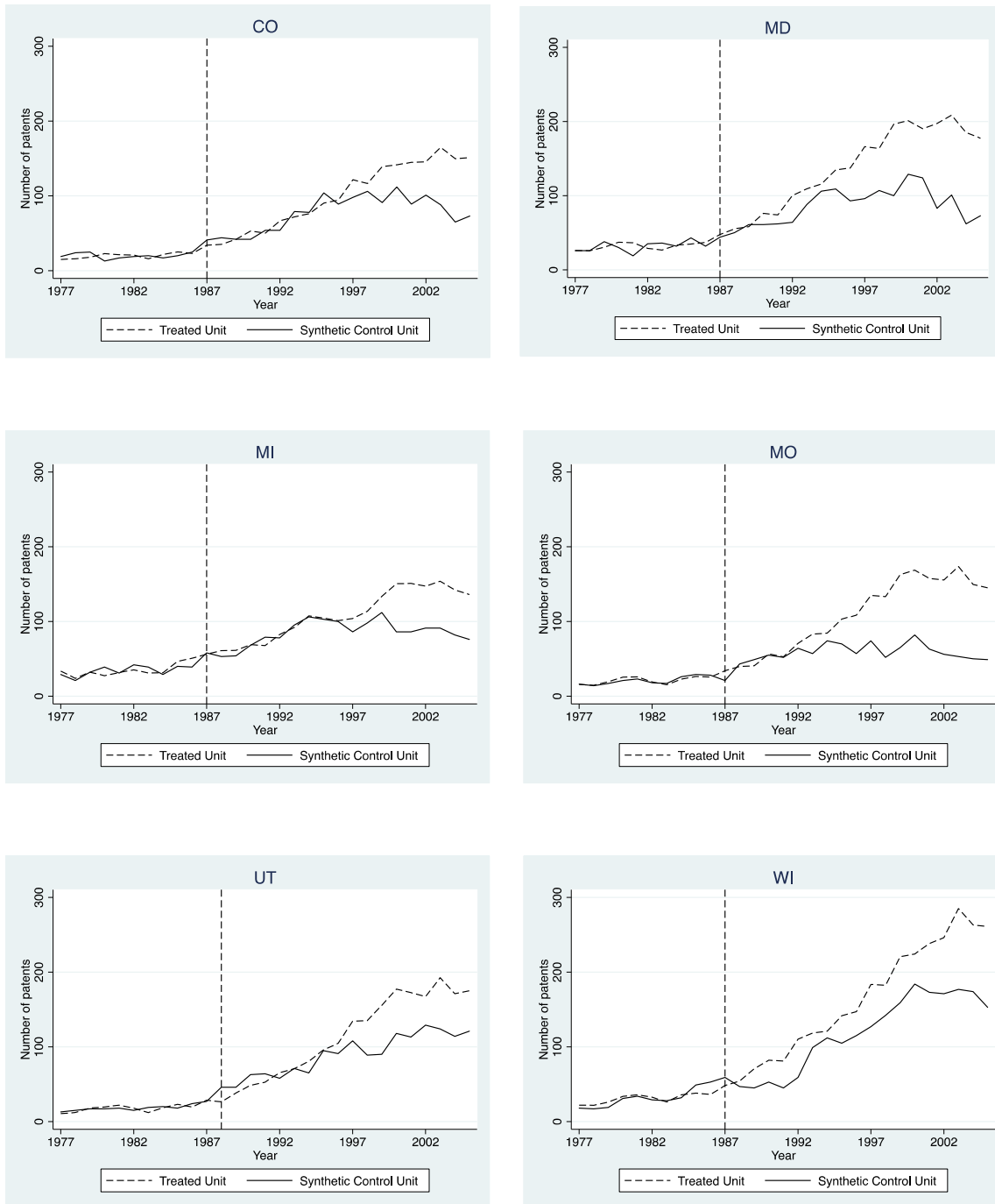
$$\frac{\partial I}{\partial H} = \frac{1}{3}H + \frac{1}{2}b_O + r_O - Hr_O - b_Or_O + Hr_O^2 - \frac{1}{2}.$$

When  $r_O = 0.5$  we have that  $\partial I/\partial H = H/12 > 0$ . Moreover,  $\frac{\partial^2 I}{\partial H \partial r_O} = 1 - H - b_O + 2Hr_O$  which is increasing in  $r_O$  for every value of  $b_O$  if  $r_O \geq 1/2$ . We now look at the effect across various levels of  $b_N$ . When  $b_N < b_O - Hr_O$ , we have that  $\frac{\partial i}{\partial H} = 0$  and  $\frac{\partial^2 i}{\partial H \partial b_N} = 0$ . When  $b_O - Hr_O \leq b_N \leq H + b_O - Hr_O$  we have that

$$\frac{\partial i}{\partial H} = \frac{r_O^2}{2} - \frac{(b_N - b_O)^2}{2H^2} \geq 0.$$

The positive inequality follows because  $b_O - Hr_O < b_N$  implies  $b_O - b_N < Hr_O$  which in turn implies  $(b_N - b_O)^2 < (Hr_O)^2$ . Moreover  $\frac{\partial^2 i}{\partial b_N \partial H} = -\frac{b_N - b_O}{H^2}$  which is increasing when  $b_N - b_O < 0$  and decreasing when  $b_N - b_O > 0$ . Thus the derivative is maximized at  $b_N = b_O$ . Finally, when  $b_N \geq H + b_O - Hr_O$ , we have that  $\frac{\partial i}{\partial H} = (r_O - \frac{1}{2})$  and  $\frac{\partial^2 i}{\partial H \partial b_N} = 0$ . Notice that the maximum value that  $\frac{\partial i}{\partial H}$  can take is  $\frac{r_O^2}{2}$  because  $\frac{r_O^2}{2} > r_O - \frac{1}{2}$  for any  $r_O \leq 1$ . Figure A2 illustrates these findings.

**Figure 2. Medical patenting in treated states and synthetic controls**



NOTES: This figure plots the number of medical patents by the application year for a treated state and its synthetic control. These six states had the largest pre-1987 medical-patent stock among the 16 states that switched from having no cap to imposing a cap on non-economic damages between 1977 and 2005. The control is generated using the same 23 states that did not impose a cap throughout the sample period. Vertical lines separate the pre- and post-cap periods.

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**Table 1. Summary statistics**

	<b>Obs.</b>	<b>Mean</b>	<b>Std. Dev.</b>	<b>Min</b>	<b>Max</b>
Total Patents	1071	1697.8	3110.4	21	28383
Medical Device Patents	1071	98.8	210.4	0	2070
Damage Caps	1071	0.3	0.5	0	1
Year	1071	1995	6.1	1985	2005
Population (1,000)	1071	5189.2	5753.1	453.5	35827.9
Physicians per 1,000 population	1071	2.3	0.9	1.2	7.9

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NOTES: Unit of observation is U.S. state-year. Total Patents is the total number of patents applied for (and eventually granted) in a year in the state. Medical Device Patents are applications classified by the USPTO in one of the medical device patent classes. Damage Caps is equal to one if the state has a cap on non-economic damages. Data on population and physicians are from the US Census and the Bureau of Economic Analysis (BEA).

**Table 2. Damage caps and medical device patenting**

	(1)	(2)	(3)	(4)	(5)
Dependent Variable	Med Pats <sub>t</sub>	log(Med Pats <sub>t</sub> )	log(Med Pats <sub>t</sub> )	log(Med Pats <sub>t</sub> )	log(Med Pats <sub>t</sub> )
Damage Caps <sub>t</sub>	-29.708** (12.52)	-0.150** (0.06)	-0.159*** (0.06)	-0.152*** (0.06)	-0.162** (0.07)
log(Population)			1.134*** (0.44)	1.400*** (0.43)	1.094** (0.42)
Physicians per 1,000 population			0.130 (0.16)	0.119 (0.162)	0.112 (0.17)
log(Total Patents <sub>t-1</sub> )			0.045 (0.13)	0.030 (0.13)	0.083 (0.14)
Punitive Damage Cap				-0.084 (0.07)	
Collateral-source rule				0.053 (0.09)	
Joint and Separate Liability				-0.030 (0.07)	
Year Effects	YES	YES	YES	YES	YES
State Effects	YES	YES	YES	YES	YES
Drop states with malpractice-focused reform					YES
Observations	1071	1071	1071	1071	1008

NOTES: OLS estimation. \* significant at 10 percent, \*\* significant at 5 percent and \*\*\* significant at 1 percent. Med Pats = number of patent applications in medical device fields in the state. Damage Caps =1 if a cap on non-economic damages is present in the state. Total Patents = total patent applications in the state. Other reform dummies are indicator variables for cap on punitive damages, modifications of the collateral-source rule and modifications of the joint-and-several liability rule. Robust standard errors clustered at the state level. In columns 2-5, we add 1 to Med Pats and include a dummy that equals one for state-years without patenting.

**Table 3. Non-local effects of tort reforms**

	(1)	(2)	(3)	(4)
Dependent Variable	log(Med Pats <sub>t</sub> )	log(Med Pats <sub>t</sub> )	log(Med Pats <sub>t</sub> )	log(Med Pats <sub>t</sub> )
Damage Caps <sub>t</sub>	-0.161*** (0.06)	-0.161*** (0.06)	-0.161*** (0.06)	-0.147*** (0.05)
Non-Local Reforms (Demand)	-0.002 (0.01)			
Non-Local Reforms (Demand-Supply)		-0.001 (0.01)		
Cap in border state			-0.086 (0.06)	
Cap within 500 Km				-0.119* (0.07)
Cap in 500 to 750 Km				0.093 (0.07)
Cap in 750 to 1000 Km				-0.001 (0.06)
Cap in 1000 to 1250 Km				-0.003 (0.09)
Cap in 1250 to 1500 Km				0.093 (0.06)
Control variables	YES	YES	YES	YES
Year Effects	YES	YES	YES	YES
State Effects	YES	YES	YES	YES
Observations	1071	1071	1071	1071

NOTES: OLS estimation. \* significant at 10 percent, \*\* significant at 5 percent and \*\*\* significant at 1 percent. Med Pats = number of patent applications in medical device fields in the state. Damage Caps =1 if a cap on non-economic damages is present in the state. We add 1 to Med Pats and include a dummy that equals one for state-years without patenting. Non-Local Reform (Demand) = weighted average of Damage Caps in other states with weights constructed from pre-sample distributions of practicing physicians. Non-Local Reform (Demand-Supply) = weighted average of Damage Caps in other states with weights constructed exploiting both pre-sample distributions of practicing physicians across specialities and pre-sample patenting across technology fields. Cap in border state = 1 if caps are present in border state. Other dummies =1 if caps are present within geographical distance. Control variables include log(Population), Physicians per 1,000 population, and lagged log(TotalPatents).

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**Table 4. Damage caps and physicians' patents**

	(1)	(2)	(3)
Dependent Variable	log(Med Pats <sub>t</sub> )	log(Med Pats <sub>t</sub> ) by physicians	log(Med Pats <sub>t</sub> ) by other inventors
Damage Caps <sub>t</sub>	-0.268* (0.13)	-0.426*** (0.15)	-0.210 (0.13)
Year Effects	YES	YES	YES
State Effects	YES	YES	YES
Observations	357	357	357

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NOTES: OLS estimation. \* significant at 10 percent, \*\* significant at 5 percent and \*\*\* significant at 1 percent. Med Pats = number of patent applications in medical device fields in the state. Damage Caps =1 if a cap on non-economic damages is present in the state. Robust standard errors clustered at the state level. Data on medical patenting by physicians are from Chatterji et al. (2008).

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**Table 5. Damage caps and litigation risk**

	(1)	(2)	(3)	(4)
Dependent Variable	log(Med Pats <sub>t</sub> ) in surgery	log(Med Pats <sub>t</sub> ) in orthopedics	log(Med Pats <sub>t</sub> ) in optics	log(Med Pats <sub>t</sub> ) in dentistry
Damage Caps <sub>t</sub>	-0.190*** (0.05)	-0.192** (0.08)	-0.013 (0.04)	0.058 (0.06)
Control variables	YES	YES	YES	YES
Year Effects	YES	YES	YES	YES
State Effects	YES	YES	YES	YES
Observations	1071	1071	1071	1071

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NOTES: OLS estimation. \* significant at 10 percent, \*\* significant at 5 percent and \*\*\* significant at 1 percent. Med Pats = number of patent applications in medical device fields in the state. Damage Caps =1 if a cap on non-economic damages is present in the state. Robust standard errors clustered at the state level. We add 1 to Med Pats to include state-years with no patenting. Regressions control for lagged total patenting, log(Population), Physicians per 1,000 population, and a dummy that equals one for state-year without patenting.

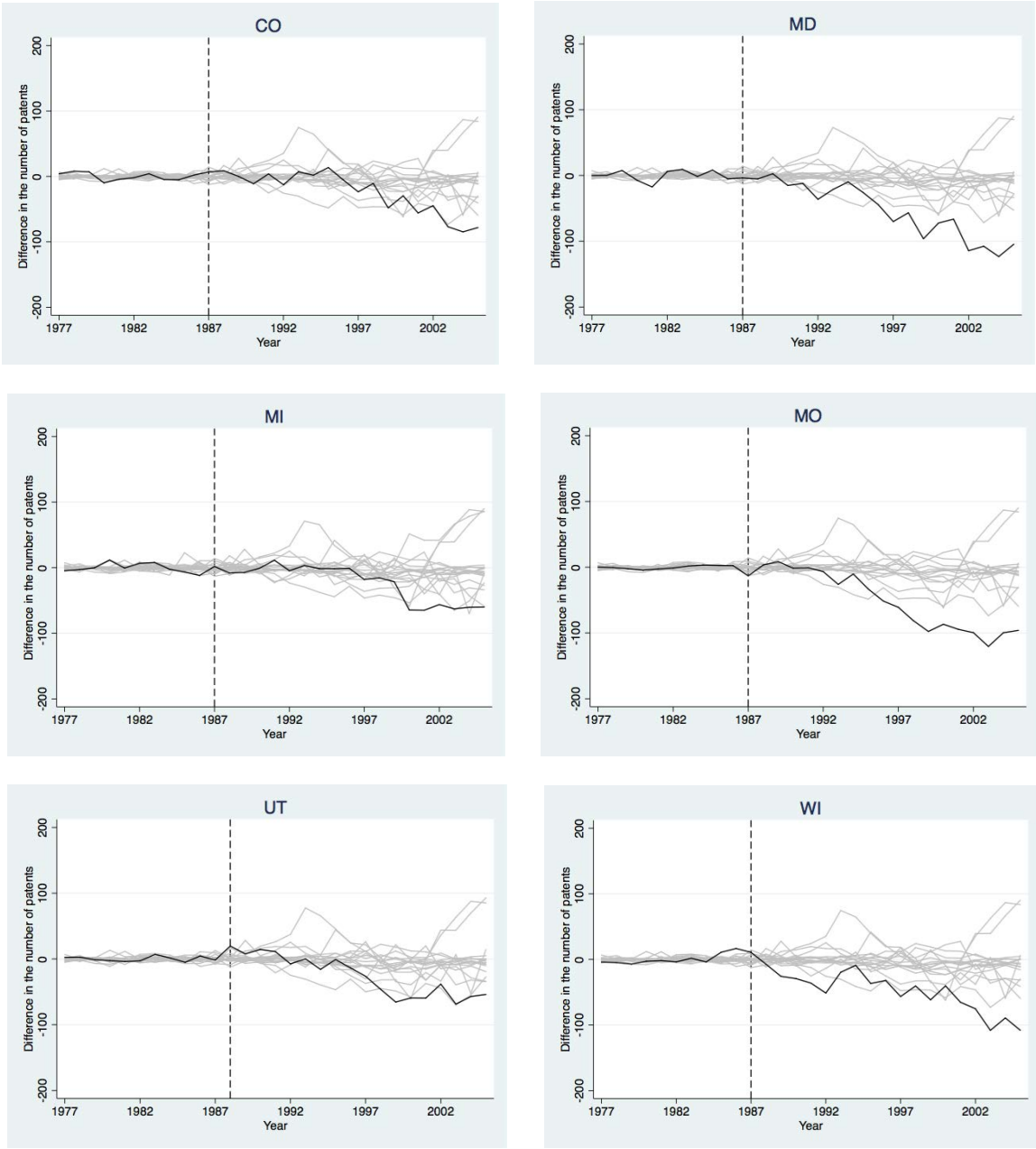


**Table 6. Damage caps and patent quality**

	(1)	(2)	(3)	(4)	(5)
Dependent Variable	log(Med Pats <sub>it</sub> ) in 1st citation quintile	log(Med Pats <sub>it</sub> ) in 2nd citation quintile	log(Med Pats <sub>it</sub> ) in 3rd citation quintile	log(Med Pats <sub>it</sub> ) in 4th citation quintile	log(Med Pats <sub>it</sub> ) in 5th citation quintile
Damage Caps <sub>t</sub>	0.312 (0.21)	-0.399** (0.16)	-0.603*** (0.18)	-0.810*** (0.16)	-0.177 (0.14)
Control variables	YES	YES	YES	YES	YES
Year Effects	YES	YES	YES	YES	YES
State Effects	YES	YES	YES	YES	YES
Observations	1071	1071	1071	1071	1071

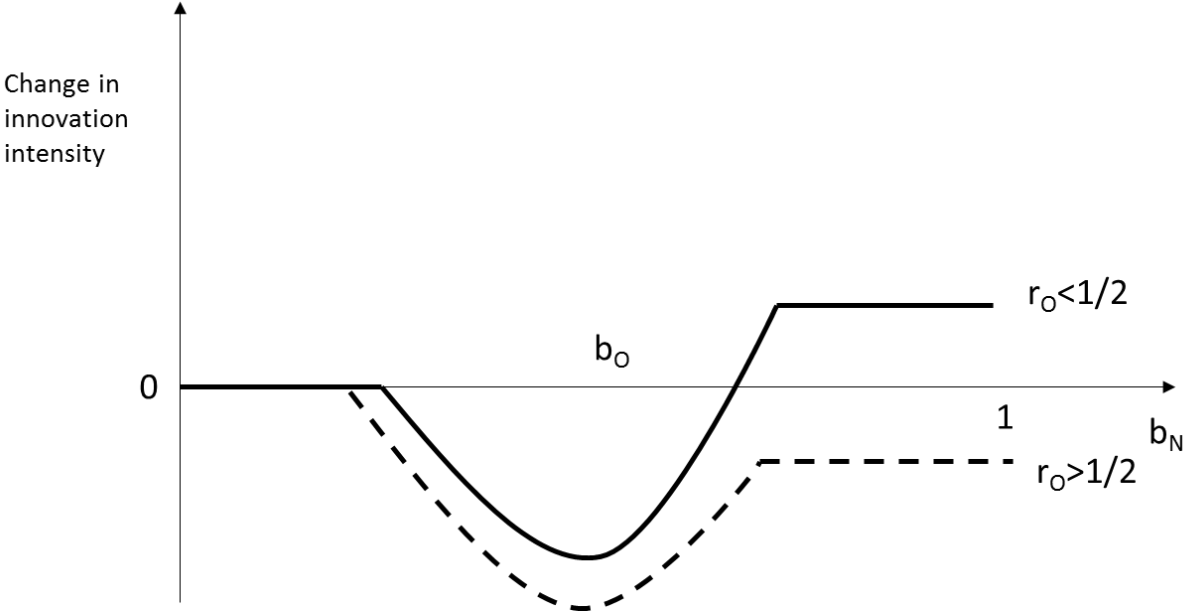
NOTES: OLS estimation. \* significant at 10 percent, \*\* significant at 5 percent and \*\*\* significant at 1 percent. Med Pats = number of patent applications in medical device fields in the state. Damage Caps =1 if a cap on non-economic damages is present in the state. Citations quintiles constructed from citations filtered by grant-year and technology-class effects. Robust standard errors clustered at the state level. We add 1 to Med Pats to include state-years with no patenting. Regressions control for lagged total patenting, log(Population), Physicians per 1,000 population, and a dummy that equals one for state-years without patenting.

**Figure A1. Effect of damage caps in treated and placebo states**



NOTES: For each of the six largest states switching from no caps on non-economic damages to a cap, we apply the same synthetic control method to each of the same 23 donor states (i.e., states that do not impose a cap throughout the sample period). During each iteration, this particular treated group is allocated to the donor pool. We follow Abadie et al. (2010) and exclude the placebo states for which the pre-intervention MSPE is more than twice as large as that of the treated state.

**Figure A2. Effect of a reduction in  $H$  on innovation intensity for different levels of  $b_N$  and  $r_O$ .**



**Table A1. Robustness of baseline specification**

	(1)	(2)	(3)	(4)	(5)	(6)
Dependent Variable	Med Pats <sub>t</sub>	log(Med Pats <sub>t</sub> )	log(Med Pats <sub>t</sub> )	log(Med Pats <sub>t</sub> )	log(Med Pats <sub>t</sub> ) dropping largest assignees	log(Mesurement Pats <sub>t</sub> )
Estimation Method	Poisson	OLS	OLS	OLS	OLS	OLS
Sample	full	full	full	drop largest states	full	full
Damage Caps <sub>t</sub>	-0.097** (0.04)	-0.132*** (0.05)	-0.186** (0.09)	-0.154*** (0.06)	-0.163*** (0.06)	-0.027 (0.06)
log(MedPats <sub>t-1</sub> )		0.231*** (0.06)				
Percentage of population with insurance coverage			-0.008 (0.01)			
Percentage of population with private insurance			-0.002 (0.01)			
log(GSP)			0.255 (0.312)			
Control variables	YES	YES	YES	YES	YES	YES
Year Effects	YES	YES	YES	YES	YES	YES
State Effects	YES	YES	YES	YES	YES	YES
Observations	1071	1071	1071	966	1071	1071

NOTES: OLS estimation. \* significant at 10 percent, \*\* significant at 5 percent and \*\*\* significant at 1 percent. Med Pats = number of patent applications in medical device fields in State. Damage Caps =1 if a cap on non-economic damages is present in the state. GSP= Gross State product. Robust standard errors clustered at the state level. We include a dummy that equals one for state-years with zero patenting. In column 4, we drop states with the largest patenting in medical devices in 1984 (CA, DE, NY, NJ and FL). In column 5, we drop the ten largest patentees in medical instruments over our sample period. In Column 6, we conduct a placebo test using the measuring and testing (patent class 73). Columns 2-6 also control for lagged total patenting, log(Population), and Physicians per 1,000 population.

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**Table A2. Weights of donor states used to construct the synthetic controls**

<b>Donor States</b>	<b>CO</b>	<b>MD</b>	<b>MI</b>	<b>MO</b>	<b>UT</b>	<b>WI</b>
AZ	0.005	0	0	0.011	0	0.009
AR	0	0	0	0.006	0.023	0.006
CT	0.007	0	0	0.008	0	0.009
DE	0.004	0	0.015	0.003	0	0.002
DC	0.124	0.2	0	0.021	0	0.013
GA	0.144	0.467	0	0.53	0	0.153
IN	0.139	0	0	0.017	0	0.417
IA	0.36	0	0	0.001	0	0.008
KY	0.008	0	0	0.008	0	0.01
ME	0	0	0	0.003	0.657	0.004
MA	0.005	0.01	0	0.007	0	0.006
MN	0.143	0.154	0	0.112	0.246	0.228
NE	0.002	0	0	0.004	0	0.005
NJ	0.006	0	0	0.006	0	0.005
NY	0.003	0.116	0	0.003	0	0.001
NC	0.007	0	0.537	0.193	0	0.075
PA	0.004	0	0.447	0.004	0	0.003
RI	0.002	0	0	0.004	0	0.004
SC	0.001	0	0	0.011	0	0.009
TN	0.005	0.053	0	0.03	0	0.016
VT	0.001	0	0	0.003	0	0.003
VA	0.01	0	0	0.014	0	0.009
WY	0.02	0	0	0.002	0.074	0.003

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NOTES: This table reports the weights of the 23 donor states used to construct the synthetic controls for the largest six states that changed from having no non-economic damage cap to having one. See Figure 3 for the estimates of the synthetic control method.

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**Table A3. Damage caps and patent quality - Robustness to extra-filtering**

	(1)	(2)	(3)	(4)	(5)
Dependent Variable	log(Med Pats <sub>t</sub> ) in 1st citation quintile	log(Med Pats <sub>t</sub> ) in 2nd citation quintile	log(Med Pats <sub>t</sub> ) in 3rd citation quintile	log(Med Pats <sub>t</sub> ) in 4th citation quintile	log(Med Pats <sub>t</sub> ) in 5th citation quintile
Damage Caps <sub>t</sub>	0.234 (0.18)	-0.404** (0.19)	-0.678*** (0.18)	-0.733*** (0.17)	-0.193 (0.13)
Control variables	YES	YES	YES	YES	YES
Year Effects	YES	YES	YES	YES	YES
State Effects	YES	YES	YES	YES	YES
Observations	1071	1071	1071	1071	1071

---

NOTES: OLS estimation. \* significant at 10 percent, \*\* significant at 5 percent and \*\*\* significant at 1 percent. Med Pats = number of patent applications in medical device fields in the state. Damage Caps =1 if a cap on non-economic damages is present in the state. Citations quintiles constructed from citations filtered by grant-year effects, technology-class effects and number of claims. Robust standard errors clustered at the state level. We add 1 to Med Pats to include state-years with no patenting. Regressions also control for lagged total patenting, log(Population), and Physicians per 1,000 population.