Unintended Consequences of Products Liability: Evidence from the Pharmaceutical Market*

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We explain a surprising effect of tort liability in the market for prescription drugs. Greater punitive damage risk seems to increase prescription drug utilization in states without non-economic damage caps but decrease utilization in states with such caps. We offer an explanation for this puzzle. The vertical production process for drugs involves national upstream producers (drug companies) and local downstream producers (doctors). When a single state reallocates liability from downstream to upstream producers, national drug companies see little reason to alter their nationwide output decisions, but local physicians have incentives to increase their prescriptions in that state. The net result is higher local output. We show how this dynamic can explain our puzzle by demonstrating that punitive damages shift liability upstream from doctors to drug companies, but not when non-economic damages caps limit physician malpractice liability. We provide evidence explaining when, how, and why this type of liability shifting occurs (JEL K13, I11, I18).

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1. Introduction

Tort liability plays a significant role in the healthcare system and the economy as a whole. Payments in products liability suits—even excluding legal fees and other indirect costs—account for 1.74% of GDP (Towers Watson 2010). In health care, lawsuits against doctors represent 1%–2% of physician expenditures (Mello et al. 2010), and suits against drug companies amount to 2.26% of all drug expenditures.

Yet, direct tort liability payments represent only one channel through which the legal regime influences economic outcomes. Different liability rules have the potential to interact with each other and produce unintended consequences. In states with punitive damage caps, the average number of prescriptions per physician visit is about 2.3% lower than in states without such caps. On its own, this might suggest that punitive caps lower drug manufacturer's cost of promoting and selling its products. However, a closer look at the data reveals an important anomaly. This decline is driven entirely by states that do not cap non-economic damages. Among these states, punitive damage caps lower prescribing by 7.4%. This contrasts with the prior empirical literature on products liability,² which consistently shows that punitive damage caps expand output. In states that do cap non-economic damages, prescriptions actually rise.³ This raises a further question about why drug companies respond so differently in states with and without non-economic damage caps, when noneconomic damages are relatively insignificant in judgments against drug manufacturers.

^{1.} This estimate is derived from all settlement special items reported in the income statement. For pharmaceutical companies, this represents provisions to alter reserves for litigation and settlement. For other companies, the amount would include insurance payments from the firm's general liability policy, but pharmaceutical firms do not typically have insurance against loses in litigation. As such the sum of the settlement special items represents unexpected payments in litigation. Although some of this litigation is likely not related to product liability the majority of loses in excess of reserves is likely major product liability cases—a fact reflected by disclosures in the 10,000 statements. We sum the total special reserves incurred from 2002 to 2008 and divide this by total sales over the same period to get the ratio of 2.26%.

^{2.} A number of studies find that higher tort liability reduces quantity of output (Kessler et al. 2005; Klick and Stratmann 2007; Matsa 2007; Currie and MacLeod 2008; Helland and Showalter 2009; Helland and Tabarrok 2012; Malani and Reif 2015). Other studies find that higher liability is associated with higher output due to defensive medicine (Kessler and McClellan 1996), though subsequent analysis has cast doubt on this result (Sloan and Shadle 2009; Paik et al. 2017).

^{3.} We calculated the average number of prescriptions per outpatient visit at the drugstate-year level for all 50 states plus the District of Columbia from 1998 to 2007. Data on prescriptions are from Optum's Touchstone database, described in Section 5.1.1. Data on punitive and non-economic damage caps are from Avraham (2019) and our own review of state statutes; more details appear in Section 4.2. We measured the average number of prescriptions for all state-years with and without punitive damage caps, and then stratified this calculation by state-years with and without non-economic damage caps.

The existing theoretical literature is hard-pressed to account for these findings. Current thinking emphasizes two countervailing theoretical effects. Imposing tort liability on producers increases their costs and reduces supply. At the same time, if consumers value the insurance or deterrence effects of liability, tort liability boosts demand. Since supply falls and demand rises, tort liability always raises prices, but it has ambiguous effects on equilibrium quantity (Polinsky and Rogerson 1983). However, it is difficult to understand why quantity should systematically fall in states with non-economic damage caps but rise in states without them.

We argue that the interaction between two different liability rules affecting different actors in the pharmaceutical supply-chain—account for these fact patterns. The pharmaceutical production process is vertical. An upstream pharmaceutical manufacturer produces the drug and markets it nationally. Downstream doctors use the drug as an input and prescribe it to patients in their local markets. 4 When a patient is injured while taking a prescription drug, she typically sues both the downstream physician for medical malpractice and the upstream drug company under products liability to maximize her chance of recovery.

Punitive damages are relatively rare in suits against physicians, but more common in suits against drug manufacturers (Vidmar and Holman 2009). In contrast, non-economic damages are more salient in malpractice lawsuits against physicians than in products liability suits against drug manufacturers. These institutional details begin to outline our proposed explanation. When malpractice risk is uncapped, liability is shared between physicians and drug companies. Punitive damage caps shift liability onto physicians, who respond by limiting their prescribing behavior. On the other hand, when non-economic damage caps limit malpractice risk, punitive damage caps reduce the liability of drug manufacturers without shifting as much additional risk onto physicians. In this simpler context, the reduction in manufacturer risk may lead to more prescriptions or no change in prescriptions, depending on the extent to which local punitive damage cap laws affect the incentives of a pharmaceutical company that operates nationally.

We develop our explanation in a series of steps. First, we present the institutional details of the pharmaceutical industry and the legal rules that surround pharmaceutical products liability. Notably, when a plaintiff

^{4.} It is true that, in the United States, a patient obtains her prescription drug from a pharmacy and that she may have health insurance that helps her finance its purchase. These do not negate the basic economics of vertical production. First, the patient cannot obtain the prescription drug without the physician's prescription. The pharmacy is best thought of as simply a retail distributor. Likewise, the fact that the insurance company finances the drug does not negate the physician's power over the patient's access to drugs. The insurance company can choose not to cover a prescription. However, this only increases the price of the drug to the consumer. It does not bar access. Ultimately, the physician must issue a prescription for the consumer to be able to buy the drug. Moreover, the drug company must produce the drug for the physician to prescribe it.

injured after taking a drug has access to punitive damages, she often offers the physician a deal: if the physician testifies against the drug company in her products liability case, the plaintiff will reduce the economic and non-economic damages that the physician must pay to settle a malpractice claim by up to the expected value of additional punitive damages.⁵ Physician testimony raises the probability that the patient will successfully obtain punitive damages from the company, and it leads to a more favorable settlement for the physician. These agreements are so common that they are frequently formalized and often enforced in court. When that occurs, they are called "Mary Carter" agreements, named after the defendant in the case that made them enforceable. In drug cases, the doctor typically remains a defendant to avoid diversity and testifies as an adverse witness without admitting personal liability.

Second, we present a stylized game-theoretic model of Mary Carter agreements between plaintiffs and physicians. The model formalizes the intuition above for why punitive damage caps work differently in states with and without high medical malpractice liability. To validate this model, we present empirical evidence that punitive damage caps shift liability onto physicians in the manner we predict.

Finally, we develop our primary empirical framework and present our estimated relationship between punitive damage caps and prescription drug utilization, stratifying across states with and without non-economic damage caps. Non-economic damage caps make it harder to shift liability from drug companies to physicians. We exploit this fact to test the validity of our "liability-shifting" explanation. As an additional test, we also use another stratifying variable that influences the degree to which liability can be shifted from drug companies to physicians. FDA boxed warnings,

^{5.} Patients make this deal with the physician rather than the drug company because they are likely to obtain greater punitive damages from those companies than the physician. This increase is due to the fact that punitive damages punish bad behavior by the drug company against all consumers, not just the plaintiff, and the national drug company sells to many more consumers than the local physician.

^{6.} Booth v. Mary Carter Paint Co. 226 Cal. App. 2 d 8 (Fla. Dist. Ct. App. 1967.). Mary Carter Agreements originally and most commonly arise in joint and several liability settings where multiple defendants are liable under a common legal theory (Kornhauser and Revesz 2009; Loh and Lesser 2019). Moreover, they sometimes take the form of loans from one defendant to the plaintiff to enable the plaintiff to sue other defendants (thereby reducing the damages owed by the first defendant). However, they can also arise in the drug injury context where the doctor and drug company are being sued under different theories—negligent medical practice and strict products liability—and involve reduced payments from the defendant to the plaintiff. While empirical data on Mary Carter agreements are hard to come by because the plaintiff and cooperating witnesses want to hide their agreements from defendants and courts, a number of papers provide examples of these agreements (Bernstein and Klerman 1994; Loh and Lesser 2019).

^{7.} In some states, explicit Mary Carter agreements are prohibited and thus not enforceable through the court. However, whether or not the formal trade occurs, in practice these agreements are enforced through the reputation of plaintiffs' attorneys (who have to agree to lower damages for physicians who agree to testify).

more commonly known as black-box warnings, of side effects make it harder to shift liability from physicians to drug companies because drug companies are typically found liable as a result of "failure-to-warn" about adverse effects.

The analysis in this paper expands the economics literature on tort liability and products regulation, which has largely neglected the implications of vertical production for tort rules.⁸ The majority of the literature assumes a single producer operating in one jurisdiction (Spence 1977; Polinsky and Rogerson 1983; Landes and Posner 1985). The economics literature on joint and several liability does tackle the problem of multiple tortfeasors (Landes and Posner 1980; Sykes 1984; Kornhauser and Revesz 1989, 1994; Miceli and Segerson 1991; Currie and MacLeod 2008). However, it typically abstracts from the contracting between upstream and downstream firms that is central to vertical production. A partial exception is Hay and Spier (2005), which discusses optimal allocation of tort liability between a producer and a consumer when the consumer's use of a product may injure third parties, a problem that is isomorphic to tort liability with vertical production. However, Hay and Spier (2005), like previous articles, assumes that all actors operate in one jurisdiction. Moreover, its model assumes the consumer (or, by analogy, the downstream firm) can directly contract on quality. This strong assumption contrasts with the large literature on incomplete contracts (Bolton and Dewatripont 2005). A working paper precursor (Helland et al. 2018) of this paper provides a more general model of vertical production with limited contracting between upstream and downstream producers. This paper specializes that paper to the pharmaceutical sector and explicitly models the interesting litigation dynamics between the vertical producers in that sector.

The remainder of the paper can be outlined as follows. Section 2 lays out the institutions in the US pharmaceutical market and explains our conjecture that punitive damages shift liability upstream and thus increase output. Section 3 presents a theoretical model of Mary Carter agreements. Section 4 presents empirical evidence supporting the model's implications for liability-shifting. Section 5 describes the data, lays out and justifies the identification strategy, and presents our main empirical results. Section 6 concludes.

^{8.} This modeling choice contrasts, for example, with the economic literatures on tax and regulatory competition, which assumes that legal rules vary across jurisdictions and that firms can operate in multiple jurisdictions and can change jurisdictions to avoid regulation (Oates and Schwab 1988). The regulatory competition literature does not address the exact analog of the case we consider here: the effect of a single jurisdiction's liability rules when firms operate in that and other jurisdictions.

^{9.} This contracting has an important effect on welfare: it may be possible by allocating liability asymmetrically among tortfeasors to achieve the first best. This welfare effect is similar to the insight that contracting between agents can address moral hazard in teams without a budget breaker (Legros and Matthews 1993).

2. Background on the Pharmaceutical Sector and Related Tort Liability Rules We begin by describing the institutions of the pharmaceutical market and the liability rules that govern it. We explain how and why drug manufacturers and physicians share liability.

2.1 The Organization of the Pharmaceutical Sector

Upstream, the pharmaceutical industry in the US sells to a national market in which there is little purely geographic dispersion in prices (Lakdawalla and Yin 2015, footnote 10). Wholesalers, distributors, and national pharmacy chains virtually eliminate opportunities for price discrimination across states or localities. Moreover, upstream drug manufacturers cannot easily control the quantity of drugs utilized within a given state, because they cannot set a state-specific price, and they cannot directly control the behavior of prescribing physicians.

Downstream, pharmaceuticals must be prescribed by physicians, who are licensed at the state level. Nearly, all physicians practice within a single state. State-specific licensing laws make it costly to practice in multiple states, even setting aside the logistical difficulties of maintaining separate practices in different geographic locations (Kocher 2017). As a result, while drug pricing does not vary much from one state to the next, physician prescribing decisions can. Thus, physicians will play a significant role in driving local variation in prescription drug utilization from one state to the next.

2.2 Tort Liability in the Pharmaceutical Sector

Tort liability for prescription drugs is determined by several cross-cutting liability regimes. Pharmaceutical companies themselves are exposed to state-level products liability laws. In addition, physicians may be exposed to state-level malpractice liability for prescribing a pharmaceutical that results in harm. Liability is thus allocated across drug companies and physicians in ways that might vary from one state to the next.

2.2.1 Failure-to-Warn Liability in Pharmaceuticals. Products liability is a primary driver of the pharmaceutical industry's legal liabilities (Viscusi 1991). To illustrate this point, we present descriptive statistics on damages in products liability cases against drug companies using data from the LexisNexis book Guide to Drugs in Litigation, from 1990 to 2009. This book, commonly referred to as the "Grey Book," is updated annually and covers all drug suits in LexisNexis's extensive database of litigated cases. Like all publicly available litigation data, its sample frame is limited to cases that go to trial and generate a written opinion and/or trials and settlements discussed in other public sources. We present data from 665 trials in Table 1. The average award in this sample was \$6.49 million. Among the 41% of cases involving a damage award, the average award was \$15.85 million. Note that these numbers reflect only a fraction of the total costs of products liability to pharmaceutical manufacturers, as the majority are paid in out-of-court settlements and are not included in these

Table 1. Outcomes From Pharmaceutical Products Liability Trials, 1990–2009

Variable	Mean	Standard deviation
Had punitive damages (fraction)		
All cases	0.04	0.19
Cases with award	0.11	0.31
Punitive damage award (2008 \$ millions)		
All cases	1.37	14.05
Cases with any damage award	3.18	21.05
Cases with a punitive damage award	43.09	66.70
Compensatory award (2008 \$ millions)		
All cases	5.16	47.94
Cases with a compensatory damage award	12.64	74.43
Total award (2008 \$ millions)		
All cases	6.49	50.91
Cases with any damage award	15.85	78.68
Doctor named as defendant	0.56	0.50
Total number of trials		665

Data report outcomes of pharmaceutical products liability trials from the LexisNexis Drugs in Litigation (2008 edition) from 1990 to 2009. Data on award amounts mostly come from jury verdict awards in trials, which could have been adjusted on appeal or in settlement. Settlement amounts were unknown except in rare cases (N=121) and are not included in the award amounts.

figures. In contrast to doctors, who purchase liability insurance against medical malpractice cases, drug companies are typically self-insured against products liability.

Drug companies' products liability damages result from so-called "failure to warn" suits. These suits subject companies to damages if they fail to disclose to physicians all drug side effects about which they should have known and if the patient suffers a non-disclosed side effect. Drug companies are not subject to design defect liability, because courts believe that drugs are inherently unsafe and companies cannot reformulate them to eliminate side effects (Restatement [Second] of Torts, §402 A, comment K; see also Restatement [Third] of Torts §6(c)) (Restatement [Third] of Torts; Restatement [Second] of Torts) (Restatement [Third] of Torts; Restatement [Second] of Torts). Drug companies occasionally face liability for defects that arise during the manufacturing of a drug. Such cases are not thought to create significant liability, however, because the Food and Drug Administration (FDA) regulates companies' manufacturing processes, reducing the frequency of manufacturing defects.¹⁰

Since manufacturer liability is based on a failure-to-warn about side effects, prior warnings about side effects may mitigate the manufacturer's products liability risk. The most extreme versions of such warnings are so-

^{10.} For our empirical analysis, our predictions about the impact of liability on the quantity of drugs sales will be the same regardless of whether the source of liability is from failure to warn or manufacturing defects, though the predictions about the impact on safety could differ.

called "black-box warnings." If trials or other data show there are significant safety risks from a drug, the US FDA may choose to require the manufacturer to issue a black-box warning for the drug. Black-box warnings limit the ability of plaintiffs (and physicians) to assert that drug company failed to warn doctors and patients of drug risks. In other words, they limit the scope for plaintiff-physician agreements that push liability on manufacturers. Therefore, they also reduce the impact that punitive damages or damages caps have on drug company liability.

Damages for products liability include both compensation for harms (economic and non-economic damages) and punitive damages to punish or deter intentional or reckless misconduct. However, punitive damages are frequently responsible for the largest verdicts in products liability (Eisenberg et al. 2006), and they are an important source of liability in failure-to-warn suits against pharmaceuticals. Table 1 shows that \$1.37 million (21%) of the average award in all pharmaceutical products liability cases were for punitive damages. Punitive damages are only granted in 4% of cases and 11% of cases with an award, but when they are granted, they average \$43 million.

2.2.2 Medical Malpractice Liability of Physicians When Prescribing Drugs. Physicians are subject to medical malpractice liability for injuries caused by the drugs they prescribe. 11 Generally speaking, if a physician does not prescribe drugs in a manner that a reasonable physician would and if the patient suffers harm from that drug, the physician is liable under a theory of negligence in common law tort (Edersheim and Stern 2009). The patient can recover both compensatory and punitive damages, though punitive awards against physicians tend to be both rare and small for at least three reasons (Mello et al. 2010). First, while most medical malpractice awards are covered by liability insurance, such insurance does not cover punitive damages (Malani and Reif 2015). In addition, punitive damages are intended to punish bad behavior, and the bad behavior of doctors affects far fewer people than the bad behavior of drug companies. Finally, physicians have fewer resources than drug companies and so cannot be punished by juries as much as drug companies can.

2.2.3 Allocation of Liability Between Pharmaceutical Manufacturers and Both drug companies and physicians are potentially liable when a patient suffers harms from a prescription drug. Plaintiffs often

^{11.} The fact that different theories of liability are used against upstream drug companies and downstream physicians does not affect our analysis. All our theory requires is either that there is upstream and downstream liability for the same transaction and that they can trade-off. In the pharmaceutical context, compensatory damages cannot exceed harm to patients. Thus, an increase in upstream compensatory damages must reduce downstream compensatory damages. While this limit does not apply to punitive damages, we shall show in the next subsection that increases in upstream punitive damages are associated with reductions in downstream damages.

simultaneously sue both drug companies (under products liability) and physicians (under medical malpractice) for a few reasons. First, naming the doctor as one of the defendants allows plaintiffs to sue in state court, which is often more favorable for plaintiffs. The doctor is local, but the drug company is often out of state. Therefore, suing the company directly would give rise to diversity jurisdiction and move the case to federal court (Willig 1985). Second, a failure-to-warn case hinges on doctor's testimony. Because the doctor is a so-called "learned intermediary," the adequacy of the warning depends on what the doctor knew rather than what the patient knew. The medical malpractice suit gives the patient leverage to get the doctor to testify against the drug company. Consistent with this logic, our review of the Grey Book data suggests that 56% of suits against drug companies involved a doctor named as a co-defendant (Table 1).

The tort regime and litigation process influences the way liability is allocated across physicians and manufacturers. We will show in particular that punitive damage caps and non-economic damage caps systematically influence the relative amount of liability each face. We will also discuss how black-box warnings affect the allocation of liability.

Punitive damage caps. One factor influencing the allocation of liability is the presence of punitive damages. While punitive damages can be claimed from physicians, they are—as we explained above—disproportionately obtained from drug companies. Significantly, the probability that a plaintiff obtains punitive damages from the drug company rises if the physician testifies on the patient's behalf (Willig 1985).

These two facts encourage plaintiffs to offer physicians the following deal in drug cases: the patient will settle with the doctor for lower medical malpractice damages if the doctor agrees to testify against the drug company. As a result of this deal, which is called a Mary Carter agreement, the physician will pay a lower amount than she otherwise would, and the drug company will pay a higher amount than it otherwise would.

The amount by which the doctor's settled damages falls depends on the bargaining power between the plaintiff and physician, but it cannot be larger than the expected increase in the drug company's punitive damages. If the physician had all the bargaining power, she would extract the entire increase in manufacturer punitive damages for herself. In this case, total damages against both the physician and the drug company would remain the same, but a greater share would be allocated to the drug company. Under incomplete physician bargaining power, some of the increase in damages goes to the plaintiff, and total paid damages might rise.¹²

This logic implies that punitive damages caps, which reduce drug companies' liability for punitive damages, should reduce the value of physician

^{12.} Focusing on the relatively small subset of cases in the Grey Book that break out total payments in drug cases into portions paid by doctors and pharmaceutical companies, it appears that doctors typically settle for very small amounts and often no payment at all.

testimony to plaintiffs. That, in turn, would increase the amount of damages physicians are left holding as physicians cannot trade their testimony for as large a reduction in their own damages. We explore this settlement dynamic in Section 3.

Non-economic damage caps. When physicians are protected against malpractice liability by means of non-economic damages caps, doctors directly pay less in damages in both drug and non-drug cases. In addition, punitive damage caps will have a more muted effect on physician damages settlements. Conceptually, if the physician's malpractice damages are lower to start with, a deal with the patient will necessarily have a smaller effect on the physician's damages. Thus, we hypothesize that noneconomic damage caps limit the potential for punitive damage caps to shift risk onto physicians. In other words, we expect punitive damage caps to increase physician liability by less in those states where non-economic damages are capped.

Black-box warnings operate as the inverse of non-Black-box warnings. economic damages. Non-economic damage caps make it harder to shift liability from drug companies to physicians. In contrast, black-box warnings make it harder to shift liability from physicians to drug companies. Under our explanation of liability-shifting, black-box warnings would mitigate the effect of repealing a punitive damage cap, because it becomes harder to shift liability back onto a manufacturer that has already issued a warning. In Section 3, we explore how this might work in theory, and in Section 5.3, we present evidence that punitive damage caps have weaker effects on prescriptions for drugs with one or more black-box warnings in place.

3. The Economics of Mary Carter Agreements and Damages Caps

Here, we present a stylized model of the litigation dynamics that we discussed in the prior two subsections, so that we may present empirical evidence in favor of its auxiliary implications in the next section. Suppose a patient is injured after using a prescription drug. She sues the prescribing physician under a medical malpractice theory and the pharmaceutical manufacturer under a failure-to-warn products liability theory.

Let $V_{\rm MD}(\vec{r})$ be the expected value to the patient of a medical malpractice suit against the physician. Define $V_{Rx}(\vec{r}, b)$ as the expected value to the patient of a products liability suit against the drug company. We assume both patients and physicians have the same expectations about these suit values. 13 The expected value of the medical malpractice and the products liability lawsuits depend on the local legal regime, \vec{r} . The legal regime may include a punitive damage cap, which mainly reduces the value of a

^{13.} Our basic point about the impact of legal regime or disclosure on settlement does not depend on difference in beliefs or on those differences driving settlement.

successful suit against the drug company, and a non-economic damages cap, which mainly lowers the value of a successful malpractice suit against the doctor. In addition, the expected value of the products liability lawsuit—but not the malpractice lawsuit—depends on whether the drug company issued a black-box warning, b. Such a warning reduces the scope of potential liability claims by forewarning about a set of use cases in which patients are likely to be harmed by the drug. The drug company can no longer be held liable for failure-to-warn in these use cases. Since the blackbox warning also correspondingly shrinks the number of clinically appropriate uses for the drug, the liability reduction trades off against lost revenues.

We shall focus on the negotiated settlement of the medical malpractice suit. We model settlement as a simple bargaining problem without information asymmetries (Landes 1971; Gould 1973; Posner 1973). To keep the focus on the effect of damages caps and disclosure, we assume the desire to settle is driven simply by legal costs. Specifically, we assume each side in the medical malpractice litigation bears legal costs $\lambda \in [0, 1)$ proportional to the expected size of the award. Including litigation costs, the physician expects to pay $(1 + \lambda)V_{\text{MD}}$ in malpractice damages, while the patient expects to receive $(1 - \lambda)V_{\rm MD}$, where we have suppressed the legal regime variables for notational convenience. 14 To arrive at a specific settlement amount, we study a Nash-bargaining model where the physician's bargaining weight is $\gamma \in [0, 1]$.

We do not model litigation costs or the settlement process in the products liability suit, because neither affects the malpractice settlement negotiations. Thus, the expected value of the products liability suit against the drug company, V_{Rx} , could be determined by either actual litigation or settlement of that suit.

Before deciding the malpractice settlement amount, the patient and physician must decide whether to cooperate in the patient's lawsuit against the drug company or whether to proceed with malpractice litigation independently of the product liability litigation. Cooperation entails the physician testifying that she was not warned by the manufacturer about the dangers of the drug. This bolsters the patient's failure-to-warn suit against the company. Let V_{Rx}^{NC} be the expected value of the products liability suit if there is no cooperation. We assume cooperation raises the value of the suit to $V_{\rm Rx}^{\rm C} > V_{\rm Rx}^{\rm NC}$ and define $\Delta V_{\rm Rx} = V_{\rm Rx}^{\rm C} - V_{\rm Rx}^{\rm NC}$ as the benefit of the physician's cooperation. We also assume, however, that testifying imposes the marginal cooperation cost MC > 0 on the physician. Costs include extra preparation and time, and potentially also the legal and psychic costs of exaggerating or hiding relevant facts.

Because each party can unilaterally decide not to cooperate, the parties cooperate only if it makes both weakly better off. We formulate this

^{14.} Treating legal costs as equal across physicians and patients sacrifices no generality in our context and simplifies notation.

problem as a two-stage game. In the first stage, the physician and patient decide whether to cooperate in the patient's products liability suit. In the second, the two players decide on a settlement amount. We analyze this game using backward induction. We use the Nash bargaining framework to determine a second-stage settlement amount conditional on the cooperation decision. We allow for a settlement to be reached even if the players choose not to cooperate in a suit against the drug company. We now study whether and when the players will decide to cooperate.

3.1 Malpractice Settlement in Absence of Cooperation on Products Liability Suit We first examine the second-stage settlement of the malpractice suit when the physician does not cooperate with the patient on the products liability suit. Defining γ as the physician's Nash-bargaining weight, the equilibrium non-cooperative settlement S^{NC} solves

$$\max_{\mathbf{S}} \left((1+\lambda)V_{\mathbf{MD}} - S \right)^{\gamma} \left(S - (1-\lambda)V_{\mathbf{MD}} \right)^{1-\gamma}.$$

In this equation, the first term $(G_{\text{MD}} \equiv (1 + \lambda)V_{\text{MD}} - S)$ is the doctor's gain from settling, and the second term $(G_{PT} \equiv S - (1 - \lambda)V_{MD})$ is the patient's gain from settling. Taking a natural logarithm of the objective function simplifies optimization. The resulting first-order condition implies an optimal settlement of

$$S^{\text{NC}} = \left[(1 - \gamma)(1 + \lambda) + \gamma(1 - \lambda) \right] V_{\text{MD}} > 0. \tag{1}$$

When the expected malpractice award $(V_{\rm MD})$ rises, so does the settlement, because the patient gains more leverage in the negotiation. Since the parties avoid litigation costs when settling, the total surplus from the no-cooperation settlement is $G^{\rm NC}=2\lambda V_{\rm MD}$. The physician and patient's shares of this surplus are $G^{\rm NC}_{\rm MD}=\gamma G^{\rm NC}$ and $G^{\rm NC}_{\rm PT}=(1-\gamma)G^{\rm NC}$, respectively.

3.2 Malpractice Settlement With Cooperation on Products Liability Suit Next, we examine the malpractice settlement when players cooperate in prosecuting the products liability suit. This settlement is called a Mary Carter agreement, though we will also call it a *cooperation* settlement to distinguish it from the prior settlement. Because the physician pays the costs of cooperation and the patient obtains the benefit of a higher expected products liability award, the optimal cooperation settlement $S^{\mathbb{C}}$ solves

$$\max_{S\geq 0} \left((1+\lambda)V_{\text{MD}} - S - \text{MC} \right)^{\gamma} \left(S + \Delta V_{\text{Rx}} - (1-\lambda)V_{\text{MD}} \right)^{1-\gamma},$$

where we subtract MC from the doctor's gain to reflect the marginal cost of cooperating, and we add ΔV_{Rx} to the patient's gain to capture the marginal benefits of cooperating.

The cooperation settlement is subject to the further constraint that, for the physician's testimony against the drug company to be credible, it

cannot be that the patient simply paid for it. Therefore, the patient's payment to the physician must be masked by some positive settlement payment, that is, S > 0, from the physician to the patient.

Assume for a moment that this non-negative settlement constraint does not bind. The *unconstrained* optimal settlement under cooperation is

$$S^{\text{CU}} = (1 - \gamma)[(1 + \lambda)V_{\text{MD}} - \text{MC}] + \gamma[(1 - \lambda)V_{\text{MD}} - \Delta V_{\text{Rx}}]$$

= $S^{\text{NC}} - [(1 - \gamma)\text{MC} + \gamma \Delta V_{\text{Rx}}].$ (2)

Because $S^{CU} < S^{NC}$, cooperation lowers the unconstrained optimal settlement. Intuitively, the physician provides cooperation in exchange for a lower settlement. As before, the settlement rises with the expected malpractice award, because it increases the patient's outside option. On the other hand, the settlement falls when the value of the physician's cooperation (ΔV_{Rx}) rises. The total surplus from settlement is $G^{\rm C} = 2\lambda V_{\rm MD} + \Delta V_{\rm Rx} - {\rm MC}$. The physician gets $G_{\rm MD}^{\rm CU} = \gamma G^{\rm C}$ and the patient gets $G_{\text{PT}}^{\text{CU}} = (1 - \gamma)G^{\text{C}}$.

Now consider the alternate case where the non-negative settlement constraint binds. The constrained cooperation settlement must be $S^{CC} = 0$. Now the physician's gain is given by her saved malpractice litigation damages (including costs) minus her cost of cooperation, $G_{MD}^{CC} =$ $(1+\lambda)V_{\rm MD}$ – MC. The patient's gain is his higher damages in the products liability suit minus malpractice damages (after costs) that she does not get, $G_{PT}^{CC} = \Delta V_{Rx} - (1 - \lambda) V_{MD}$.

3.3 Decision to Cooperate in Products Liability Suit

Now we turn to determining whether the physician and patient will cooperate in the patient's products liability suit. For there to be cooperation, each party must weakly gain from the malpractice settlement under cooperation. If the non-negative settlement constraint does not bind in the cooperation settlement case, these conditions collapse into a single one, namely that cooperation increases total surplus, that is, $\Delta V_{\rm Rx}$ - $MC \ge 0.15$ The parties reach a settlement if and only if cooperation increases total surplus.

On the other hand, if the non-negative settlement constraint does bind on the cooperation settlement, then the physician's condition for cooperation becomes MC $\leq S_{\rm MD}^{\rm NC}$ and the patient's condition is $\Delta V_{\rm Rx} \geq S_{\rm PT}^{\rm NC}$. The zero settlement wipes out the physician's liability payment, but it leaves her with the cost of cooperation. The physician will cooperate so long as her costs with cooperation are not larger than what she would have to pay in settlement without cooperation. Likewise, with a zero

^{15.} The doctor cooperates if her gain from cooperation is greater than her gain from not doing so, that is, $[(1 + \lambda)V_{MD} - MC] - S^{CU} \ge G_{MD}^{NC}$. Likewise, the patient does do if $S^{CU} - [(1 - \lambda)V_{MD} + \Delta V_{Rx}] \ge G_{PT}^{NC}$. Plugging in the optimal unconstrained Mary Carter settlement into these constraints reveal that each collapses to $\Delta V_{\rm Rx} - {\rm MC} \ge 0$.

settlement the patient gets no liability payment. The patient will cooperate so long as the additional products liability award due to cooperation is greater than the settlement she would receive in the no-cooperation case.

3.4 Predictions

We now turn to the impacts of damages caps and black-box warnings on physicians' incentives to prescribe drugs.

Our first prediction is that a punitive damage cap increases the physician's malpractice settlement payment and thus weakens her incentive to prescribe drugs. A punitive cap makes the physician's testimony less valuable to the patient, who offers less favorable settlement terms in response. A higher malpractice settlement amount, in turn, increases the cost of prescribing medication.

A punitive damages cap makes testimony less valuable because it likely reduces the patient's gain from the physician's testimony, $\Delta V_{\rm Rx}(\vec{r},b)$. We say "likely" because this result requires that caps do not differentially lower the probability of victory under cooperation. This assumption seems plausible, even if not self-evident. 16 If this holds true, caps either reduce the gain from cooperation or have no effect. A cap that exceeds the potential judgment will have no effect. A cap that binds, however, will likely reduce the gain from cooperation. Since the products liability verdict is higher with cooperation than without, the cap will likely reduce the cooperative verdict by more than the non-cooperative one.

A reduction in the gain from cooperation produces two effects on the physician's incentives. First, it increases the unconstrained Mary Carter settlement. With less gain, there is less surplus from cooperation to split between the physician and patient. This increases the physician's expected liability costs and discourages her from prescribing. Moreover, it also decreases the likelihood of cooperation, because it reduces the additional surplus, ΔV_{Rx} – MC, that cooperation unlocks. When cooperation is less likely, the physician sees a further increase in expected liability costs, because cooperation reduces the physician's expected liability. Both effects discourage prescribing.¹⁷

^{16.} Consider the simple example where a plaintiff either wins \$X or ends up with nothing. If punitive caps do not have first-order effects on the probability of victory, they will weakly reduce the expected award in this case.

^{17.} To be thorough, we must examine two cases: one where the parties cooperate even after caps are imposed and another where the parties do not cooperate after the cap is imposed. First, consider the case where the parties cooperate before and after the cap. The cooperation constraint obviously does not bind, but the non-zero settlement constraint might bind. Suppose the latter does not. The unconstrained settlement S^{CU} increases when the gain from cooperation $\Delta V_{\rm Rx}$ falls. If the non-zero constraint does bind before the cap, the optimal settlement still rises. After the increase, either the constraint does not bind, in which case there is no effect of the cap, or the constraint does not bind, which represents an increase in the settlement amount. Second, consider the case where the parties do not cooperate after the cap. This means that the parties move from S^{CU} to S^{NC} . According to (2), this represents an increase in the settlement amount.

Our second prediction is that a non-economic damages cap weakly lowers the physician's malpractice settlement payment and thus weakly increases her incentive to prescribe drugs. This cap directly reduces the physician's expected liability $V_{\rm MD}(r,b)$ and thus her settlement, regardless of whether the physician cooperates with the patient or not. Reduced malpractice liability, in turn, decreases the physician's costs of prescribing drugs. 18

Our third prediction is that non-economic damage caps can sometimes—but not always—attenuate the effect of punitive damage caps on physician liability and prescribing. Consider a situation where cooperation is optimal in a state with neither non-economic nor punitive damages caps. A non-economic damages cap reduces the optimal settlement. In some cases, the settlement falls far enough that the non-negativity constraint binds for some or all physicians. Since the constraint binds, a new punitive damages cap can do one of two things: (1) make non-cooperation optimal by reducing the gains to cooperation or (2) leave the zero settlement cooperative equilibrium unchanged. In the first case, the punitive cap continues to discourage prescribing by increasing the physician's settlement payment. In the second case, the punitive damages cap is rendered neutral.

Finally, we predict that black-box warnings increase the physician's expected liability and reduce her incentive to prescribe. The logic proceeds along exactly the same lines as our proof that punitive damage caps increase physician liability. Both black-box warnings and punitive damage caps reduce the drug company's liability and make the physician's testimony less valuable. In addition, black-box warnings may mitigate the effect of punitive damage caps on prescribing. To take a stylized case that illustrates the latter point, suppose that black-box warnings perfectly insulate the drug company from liability, so that $V_{Rx}(\vec{r}, b) = 0$ in the presence of a black-box warning b. If this is true, then the legal regime has no effect on $\Delta V_{\rm Rx}$ for drugs with black-box warnings. In reality, black-box warnings may not perfectly immunize every manufacturer. However, they never increase the manufacturer's failure-to-warn liability, and may reduce it in at least some cases.

^{18.} Our formal argument considers two cases: either the parties do not or they do cooperate before a non-economic damages cap. This cap does not affect the additional surplus from cooperation, $\Delta V_{\rm Rx}$ – MC, and thus the propensity to cooperate. Therefore, we need not consider the effects of a cap on cooperation. If the parties do not cooperate, equation (1) says that a cap that lowers the expected malpractice award $V_{\rm MD}$ reduces the settlement amount S^{NC} . If the parties do cooperate but the constraints on settlement do not bind, equation (2) says a cap will lower the also reduce the settlement amount S^{CU} . If the parties cooperate but the settlement is constrained, then the non-economic damages cap will have no effect on settlement. If the non-negative settlement constraint binds, it will bind even more because, if anything, a cap will lower the expected malpractice aware V_{MD} and, thus, the settlement amount in equation (2). If one of the cooperation constraints bind, then they will continue to bind since, as we explain above, those constraints collapse to $\Delta V_{Rx} - MC$, which does not depend on the expected malpractice award.

4. Empirical Evidence on the Impact of Punitive Non-economic Damage Caps on Physician Liability

Before we study the effects of liability rules on prescribing patterns, we first provide additional support for our theory of litigation dynamics by testing two auxiliary hypotheses of the model: (1) Punitive damage caps increase physician liability risk and (2) Non-economic damage caps reduce physician liability risk. We use data on medical malpractice liability payments by physicians in cases that do or do not involve medication.

4.1 Physician Liability Payments Data

Our dependent variable is the level of damages paid by a physician via judgment or settlement. Our data on physician liability payments come from the National Practitioner Data Base (NPDB), a nationwide database of payments in malpractice cases. The NPDB includes payments that result from settlements and plaintiff wins at trial and for payments made directly by physicians or by insurers on a physician's behalf. The database contains information on over 200,000 medical malpractice payments made on behalf of practitioners in all 50 states and the District of Columbia. 19 We aggregate these data to the state-year level. We employ data from the period 1992 to 2007 in our analysis.²⁰

The NPDB is the most comprehensive, publicly available database on malpractice claims, including both out-of-court settlements and jury awards. Nonetheless, it suffers from some known limitations. First, it has some problems with incomplete reporting (Government Accounting Office 2000). Since it is unlikely these reporting issues vary systematically with state tort regime or type of claims (e.g., medication-related or other), the incomplete reporting in itself is unlikely to bias our results. Second, we utilize information on medication error cases in determining the impact of punitive damage caps on physician liability. This will be a broader set of cases than simply "failure to warn," and it will include other cases involving known drug interactions, prescribing the wrong medication or the wrong dose. Nonetheless "failure to warn" cases would fall into this category. As such our results will again be biased toward zero, since there is no reason to think that punitive damage caps should increase physician liability in cases that do not involve a pharmaceutical company. Finally, the NPDB only includes information on claims where there is liability paid by or on behalf of physicians; any liability paid by the manufacturers is not included, nor is there information on any cases where physicians are completely shielded from liability.

^{19.} These data have been used for research many times and are discussed in more detail elsewhere (cf., Chandra et al. 2005; Helland et al. 2005; Helland and Lee 2010).

^{20.} The NPDB is the most comprehensive, publicly available database on malpractice claims, but also has some problems with incomplete reporting (Government Accounting Office 2000). However, for our purposes, it is important to note that it is unlikely these reporting issues would be differentially affected across states or across types of claims (e.g., medication-related or other).

4.2 Damages Caps Data

There are two treatment variables of interest. HighPL $_{it}$, or "high products liability," is a dummy variable that is one if there is no punitive damage cap in state i and year t. HighMM_{it}, or "high medical malpractice," is a dummy equal to one of there is no non-economic damage cap in state i and year t. The data on punitive and non-economic damage caps come from Avraham's data (Avraham 2019). In the case of punitive damages, we utilize only legislative changes that apply to products liability. Since Avraham's data focus primarily on medical malpractice litigation, we supplemented these data with our own search using state statutes to determine the rules governing products liability.

Table 2 describes the legislative changes that occurred during the timing of our study sample. During our sample period, six states (AL, AK, AR, ID, MS, MO, and OH) adopted punitive damage caps that applied to products liability cases, while two states (PA and IL) repealed caps. During this same period, eight states (FL, GA, IL, MS, NV, OH, OK, and TX) adopted non-economic caps for medical malpractice cases.

4.3 Empirical Strategy

Let D_{pit} represent the malpractice damage settlement or award in case p that occurred in state i in year t. We estimate the regression model as follows:

$$D_{pit} = \theta_{PD} HighPL_{it} + \theta_{PD-D} (HighPL_{it} \times RX_{pit}) + \theta_{D}RX_{pit} + \theta_{NED} HighMM_{it} + \alpha_i + \alpha_t + \alpha_x X_{it} + \epsilon_{niit}.$$

We argue that HighPL_{it} directly affects drug companies but not physicians and that HighMM_{it} primarily affects physicians. Our game-

Table 2. Adoption and Repeal of Punitive Damage Caps for Products Liability Cases and Noneconomic Damage Caps in Medical Malpractice Cases by State (1997–2008)

	Law was adopted or implemented	Law was repealed or no longer in effect
Caps on punitive damages	AK (1998), AL (2000), AR (2003), ID (2004), MO (2005), MS (2003), OH (1997, 2005)	IL (1998), OH (1998)
Caps on non-economic damages	FL (2004), GA(2005), IL(2005), ME (2000), MS (2003), NV (2005), OH (1997), OH (2003), OK (2004), SC (2005), TN (2005), TX (2004)	AK (2006), <i>IL (1998), MI</i> (2004), <i>OH (1998)</i> , OR (2000)

Laws in italics apply to all tort cases; all other laws apply only to medical malpractice cases. These were compiled from McCullough, Campbell, and Lane LLP's Summary of United States Medical Malpractice Law, Ronen Avraham's Data Base of State Tort Law Reforms (First Edition), the American Tort Reform Association Tort Reform Record (First Edition), and state statutes.

theoretic analysis implies that punitive damage caps can increase physician malpractice damages in drug cases. Therefore, we include an indicator variable for cases involving drug errors (RXpit) and interact it with high products liability. Our regressions also include a vector X of other characteristics of the state in which the case occurred (including the fraction male, the fraction nonwhite, income per capita, and the share of the population in 5-year age ranges). We identify the impacts of tort rules on malpractice payments using a difference-in-difference approach. Specifically, we estimate changes in damages paid within states adopting specific damages caps and compare these to the corresponding changes in damages within states that do not adopt. We implement this by including state (α_i) and year (α_t) fixed effects. We assume that $E[\epsilon_{viit}|\text{HighPL}_{it}]$ $\operatorname{HighMM}_{it}, \operatorname{RX}_{pit}, X_{it}] = 0.$

4.4 Results

Results of this regression are reported in Table 3. The first two rows report the effects of high medical malpractice damages and high products liability damages, respectively, on the log malpractice payment per case, where malpractice payments data are taken from the NPDB. The third row reports the interaction term between products liability and cases involving medication errors.

In sum, the results demonstrate three points. First, consistent with prior work, high medical malpractice liability regimes increase reduce physician malpractice payments. 21 This is consistent with the notion that noneconomic damages play a significant role in malpractice liability. We find that high medical malpractice regimes are associated with higher average payments across all specifications. The impacts range from a 9% increase when controls are included to a 13% increase when state, year, and malpractice type fixed effects are included.

Second, products liability rules have no significant effect on physician malpractice payments in the aggregate, when one includes non-drug cases. Among all types of medical malpractice cases, high products liability regimes have a small and insignificant effect on damages physicians pay. This is also sensible because punitive damages are rare in malpractice cases (Moller et al. 1999; Seabury et al. 2004).

Third, high products liability regimes reduce physician malpractice payments in drug cases. This is consistent with the prediction that high products liability raises the value of Mary Carter agreements between plaintiffs and physicians, but only in drug cases. We find that high products liability regimes actually reduce damages paid by physicians by 13%–14%.

In an additional sensitivity analysis, we tested for the existence of preperiod trends in malpractice payments among states changing their products liability or medical malpractice liability regimes. We found little

^{21.} See, for example, Seabury et al. (2014).

Table 3. Effect of Punitive and Non-economic Damages Caps on Medical Malpractice Payments

	(1)	(2)	
Dependent Variable: Log of payments in medical malpractice cases (2008 \$s)			
High malpractice liability (i.e., no non-economic	0.128**	0.0875**	
damages caps)	(0.0443)	(0.0241)	
High products liability (i.e., no punitive	0.0179	0.00931	
damages caps)	(0.0439)	(0.0299)	
High products liability * Drug Case	-0.146*	-0.145*	
	(0.0618)	(0.0606)	
Fixed effects	State, year, type of alleged malpractice		
State demographic variables	No	Yes	
Observations	215,010	215,010	
R ²	0.110	0.111	

The table reports results of an OLS regression of payment in a malpractice case on the liability environment and case features. Malpractice payment data are from National Practitioner Data Bank and span 1992–2007. Robust standard errors clustered at the state level are reported in parentheses. Punitive Cap is defined as state-years with a punitive damage cap in place; Noneconomic Cap is defined as state-years with a noneconomic damage cap in place. **, *, or * indicates statistical significance at the 1%, 5%, or 10% level, respectively.

evidence of pre-period trends in the payments variable. The details of this analysis appear in Appendix B.

5. Empirical Evidence on Physician Prescribing Behavior

5.1 Data

We now turn to the analysis of tort rules and prescribing patterns. Here, we describe our data on drug quantity and characteristics.

5.1.1 Quantity of Drug Sales. Our outcome variable is the number of prescriptions written by doctors per office visit. There is no single, nationally representative source for such drug utilization data. We derive measures of the utilization of prescription drugs from a large database of private-sector health insurance claims, the Touchstone database created by Optum, a healthcare consulting firm. We obtained information on all pharmacy spending and utilization for all covered patients from 1997 to 2007. These data have been used in a number of prior analyses of pharmaceutical utilization (Joyce et al. 2002; Goldman et al. 2004, 2006). Using these data, we construct aggregate measures of utilization by drug, state, and year. To normalize prescribing behavior according to population size and utilization of health care, as well as to mitigate the impact of possible sampling differences in the Touchstone database, ²² we focus on the

^{22.} While the Touchstone data track national numbers reasonably well, they are not designed to be a nationally representative sample.

number of prescriptions for each drug per 1000 total outpatient physician visits in a state and year.²³

In our regression analyses, we control for 5.1.2 Drug Characteristics. characteristics of drugs that could affect utilization. These include the generic status of the drug, as well as the number of generic competitors within the same therapeutic class. We use the 2007 Red Book²⁴ to provide information on generic status and therapeutic class by drug. Broadly speaking, the therapeutic class is a means for grouping drugs according to their use in clinical settings (e.g., "beta-blockers" or "ACE-inhibitors"). Our data included 74 different therapeutic categories. ²⁵ To construct the number of generic competitors, we sum across drugs within class for all the drugs in our sample by year.

While generic drugs are older on average, the age of a drug could have an independent effect on demand. Older drugs have more established track records of real-world use, potentially generating more information on safety or real-world efficacy that cannot be gleaned from clinical trials of a few thousand patients. We use information on a drug's age, defined as current year minus the year of approval, which we obtain from the FDA's Orange Book database.

Finally, we use information on black-box warnings on the package inserts of prescription drugs. As described earlier, "black-box warnings" represent official disclosures from the manufacturer of adverse event risks. If manufacturers disclose safety risks in the form of trial or other data, the FDA may choose to require the issuance of a black-box warning for the drug. Data on black-box warnings were gathered by hand from archived MedWatch reports available on the FDA website. Our black-box warning data cover the warnings in effect between 1996 and 2009.

Table 4 summarizes the quantity and other drug utilization statistics. In total, we have data on up to 1227 drugs for up to 10 years in 50 states and the District of Columbia. Since some drugs are introduced or withdrawn from the market during the sample, we end up with 510,969 observations (approximately eight years per drug per state). There are about 1.8 prescriptions per 1000 visits on average, with an average price per prescription of about \$198. The share of observations with high products liability and high malpractice liability is almost the same, about 60%, but this

^{23.} Note that not every prescription requires a visit to a physician. Some prescriptions could be written at hospitals or in emergency departments. Also, we focus on 30-day equivalent prescriptions, so any refills count as separate physicians. So, this measure should not be interpreted as the probability that a prescription is filled conditional on a visit.

^{24.} The Red BookTM is a database on pharmaceutical produces published by Truven Health Analytics that includes a comprehensive set of identifiers on all brand, generic, and over-the-counter products.

^{25.} This includes a category in which we pooled together relatively rare drugs where there were insufficient observations to include class fixed effects separately (about 5% of drugs fell in this category).

Variable	Mean	Standard deviation	
Prescriptions per 1000 outpatient visits	1.83	5.95	
Fraction in high products liability state	0.59	0.49	
Fraction in high malpractice liability state	0.60	0.49	
Price per prescription (\$s)	198	1028	
Fraction generic	0.36	0.48	
Fraction with black-box warning in place	0.11	0.32	
Number of generic competitors in class	11.20	11.47	
Number of branded competitors in class	47.57	30.34	
Age of drug (years)	13.65	6.55	
Number of drugs		1227	
Observations	510.969		

Table 4. Summary Statistics

The table reports means and standard deviations of selected variables. Observations are at the drug-state-year level. High products liability is defined as states with no punitive damage cap in place; high malpractice liability is defined as states without a noneconomic damage cap in place.

masks considerable variation across states. About 22% and 24% of observations are states and years with only high products liability or malpractice liability, respectively, and 36% of observations have both.

5.2 Empirical Strategy

5.2.1 Difference-in-Difference Design. We test the hypotheses generated by our stylized model of drug litigation dynamics using a difference-in-difference design that compares drug sales in a state that changes liability rules from year t to t+1 to a state that does not change during that span. Let Y_{gcit} be the sales of drug g in state i in year t, where drug g is a member of therapeutic class c. Our regression specification is

$$Y_{gcit} = \beta_{P} \text{HighPL}_{it} + \beta_{N} \text{HighMM}_{it} + \beta_{PN} \text{HighPL}_{it} \times \text{HighMM}_{it} + \gamma_{\sigma} + \gamma_{t} + \gamma_{t} + \gamma_{M} M_{ct} + \gamma_{G} G_{ct} + \gamma_{X} X_{gct} + \epsilon_{igct},$$
(3)

where $E[\epsilon_{igjt}| \text{HighPL}_{it}, \text{HighMM}_{it}, M_{ct}, G_{ct}, X_{gct}] = 0$. The regression includes fixed effects for drug (γ_g) , state (γ_i) , and year (γ_t) . Identification is based on variation in the number of prescriptions per office visit for a given drug in a state and year, relative to the national level of prescriptions per visit for that drug, the average level of prescriptions per visit for that state, and the national level of prescriptions per visit that year.

The primary treatment variable is the indicator for a high products liability regime, $HighPL_{it}$, measured by an indicator for the absence of punitive damages cap in state i at time t. A secondary treatment variable is the indicator for a high medical malpractice liability regime, $HighMM_{it}$, measured by the absence of a non-economic damages cap.

In addition to the fixed effects and liability indicators, our empirical model controls for the effect of competition by including the number of branded competitor drugs (M_{ct}) and the number of generic competitor drugs (G_{ct}) in the same therapeutic class c. Note that drugs are nested within classes, so we do not include separate fixed effects for class.

Finally, the regression equation includes various controls X_{gct} to address measurement issues and potential confounders.

Our liability shocks occur at the state level, so it is important to allow for correlation in the error terms across states (i.e., clustering). However, we also observe the same drug across states and years, and it is unlikely that the error terms are independent across drugs. Therefore, we estimate standard errors using the two-part clustering approach of Cameron et al. (2011) to allow for clustering across states and therapeutic classes. Because drugs are nested within class, this approach allowed for a more flexible combination of possible correlations.

5.2.2 Exogeneity of Tort Liability Rules. Our identification strategy assumes that the adoption of tort reform is exogenous with respect to the pharmaceutical market in a state. There are two reasons to believe this is plausible. Since drugs are sold on a national market, any given state has a very limited impact on the profitability of a product, so producers have less incentive to invest lobbying efforts in any particular state. Moreover, since the products liability regime tends to affect many types of cases, these are more likely to be driven by general business interests than by pharmaceuticals alone.

To buttress this identifying assumption further, we conduct two sets of validity tests. First, we test whether changes in the liability regime—that is, adoption of damage caps—are correlated with prescription drug utilization, prescription drug prices, or outpatient physicians, in the first year of the sample, 1997. We bin the states into quintiles based on prescriptions per outpatient visit, total number of prescriptions, mean drug price, or outpatient visits in 1997, respectively. Figure 1 plots the number of states switching products and malpractice liability regimes in each quintile. Each outcome variable is reported in a separate panel of the figure. Importantly, we find no obvious relationship between these outcomes and the change in the liability regime. Using Wilcoxon rank-sum tests, we fail to reject the equality of the distribution of the liability regime changes across quintiles for any of the outcome measures.

As a second validity check, we test for the presence of pre-existing trends in drug sales leading up to changes in either products or malpractice liability regimes (or both together). Specifically, we estimate equation (3) including policy leads of one, two, and three years prior to the change in policies. If changes in the pharmaceutical market are driving the adoption of tort reform, we would expect to see significant effects in the preperiod of magnitudes similar to our "post-period" coefficients of interest. The results of this test are discussed at the end of Section 5.3, but we note here that we find no evidence of pre-existing trends.

5.3 Results

In the introduction, we documented the puzzle that punitive damage caps lower prescription drug utilization, but only when states do not cap

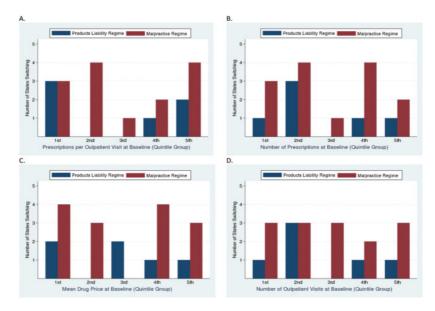


Figure 1. Distribution of changes in products liability and malpractice regimes by state characteristics. (A) By number of Prescriptions per Outpatient visit. (B) By number of Prescriptions. (C) By Mean Drug Price. (D) By number of Outpatient Visits.

non-economic damages. We presented some raw, unadjusted numbers to support this hypothesis. Estimating equation (3) provides more robust evidence. Specifically, we test whether $\beta_{\rm p} > 0$, that is, higher products liability is associated with higher output, and whether $\beta_{PN} > 0$, that is, the products liability effect is larger when malpractice liability is greater.

Table 5 presents the associated regression results. The top two rows in panel A report the main effects of products liability and malpractice liability, respectively, and the third row reports the interaction effect. Panel B aids in the interpretation of these coefficients by reporting the predicted change in prescribing behavior that would result from higher products liability, stratified by states with low and high malpractice liability. The first column of results presents coefficient estimates for a specification that includes the treatment variables (liability rules) and the fixed effects (state, year, and drug) that implement our difference-indifference design, but no drug or therapeutic class level covariates. The second column presents coefficient estimates for a specification that adds in these drug and therapeutic class covariates. We have tried specifications that include other fixed effects (state and year only, and state, year, and therapeutic class) but do not present them here. Although they do not change our basic finding, these alternative specifications are mis-specified and risk omitted variable bias, given our preferred specification of covariates (Gelbach 2016).

Table 5. Regression Estimates of the Effects of Products Liability (upstream) and Medical Malpractice Liability (downstream) Rules on Drug Quantity

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The table reports the results of regression of the number of prescriptions per outpatient visit against the products liability and malpractice regime of the state. High products liability is defined as states with no punitive damage cap in place; high malpractice liability is defined as states without a noneconomic damage cap in place. Each column reports the results of a different regression based on the inclusion of covariates. Data are at the drug-state-year level. Robust standard errors are reported in parentheses, computed to allow for two-level clustering within states and within therapeutic classes. **, *, or + indicates statistical significance at the 1%, 5%, or 10% level, respectively.

Averaging over all states, higher products liability regimes are associated with up to 6% higher prescription rates, though the effect is statistically insignificant in the aggregate. However, we find 11%-20% higher prescription rates in states with higher malpractice liability, where we predict the effects of products liability ought to be highest. Further consistent with our explanation, we also find that the effects are much smaller in magnitude, and statistically insignificant, in states with lower malpractice liability. Finally, the table supports our conclusion that malpractice liability exposure reduces prescribing by 16%–20%. As predicted, this effect runs in the opposite direction of the products liability effect, that is, $\beta_N < 0$ while $\beta_P > 0$. Moreover, these effects are centered in states with low products liability; in states with high products liability, higher malpractice liability has no statistically significant effect on prescribing. These opposing effects rule out a simpler supply-side story that damages liability—whether from products or malpractice—increases costs and thus reduces output.²⁶

A second test of our liability-shift hypothesis relies on the impact of black-box warnings. "Failure-to-warn" products liability risk is mechanically higher when drug manufacturers have failed to warn. However, if drug companies have already disclosed the most serious risks from their drugs via black-box warnings, it is harder to shift liability from doctors to drug companies. Thus, higher products liability damages may have smaller effects on drugs with black-box warnings than those without those.

We test this hypothesis by stratifying our estimates for drugs with and without black-box warnings. Our results are reported in panels I and II, respectively, of Table 6. Table 7 helps with interpretation by calculating the implied effect of punitive damages in states with high versus low noneconomic damages exposure. If our explanation for the puzzle is correct, β_{PN} should be larger in absolute value for the drugs without black-box warnings. Consistent with the results in Table 5, we find that the main effect of high products liability is small and insignificant and that malpractice liability reduces prescription rates among both drugs with and without black-box warnings. However, the interaction effect (β_{PN}) is much larger and only significant for drugs with no black-box warnings; this is consistent with our explanation.

As expected, Table 7 shows that in our preferred specification (with state and drug fixed effects), high products liability is always associated with statistically insignificant effects on sales in states with low malpractice liability due to non-economic damage caps. Focusing on our preferred specification (with state and drug fixed effects), in states with high noneconomic damage liability, higher punitive damages boosts sales by 20.9% for drugs without a black-box warning, but just 12.3% (which is also insignificant) for drugs with a black-box warning. These results suggest that non-economic damage caps limit the possibilities for shifting risk from drug companies to doctors, while black box warnings limit the shifting of risk in the other direction.

A concern with the results in Table 5 and Table 6 is that our difference in difference (DD) estimates rely on treatment that (imposition of damages caps) that is adopted at different times in different states. Recent work by Goodman-Bacon (2018) has shown that such estimates tend to

^{26.} We also estimated an event study specification that included only an indicator for no punitive damages cap but was run separately on a sample with and without non-economic damages caps. We find that there is a positive effect of having no punitive cap only in the sample with no non-economic cap, but the effect is only statistically significant in years 2 and 3 post elimination of a punitive cap.

Table 6. Regression Coefficient Estimates of the Effects of State Liability Regimes on Drug Quantity Stratified by the Presence of a Black-Box Warning.

	(1)	(II)				
Dependent variable: Log number of prescriptions per outpatient visit						
A. Drugs with a black-box warning in place						
High products liability (i.e., no punitive	-0.0339	0.0701				
damages cap)	(0.0779)	(0.0725)				
High malpractice liability (i.e., no non-economic	-0.216*	-0.109				
damages cap)	(0.0791)	(0.0668)				
High products liability × high malpractice liability	0.0344	0.0527				
	(0.0708)	(0.0761)				
B. Drugs without a black-box warning in place						
High products liability (i.e., no punitive	0.00374	0.0544				
damages cap)	(0.0474)	(0.0538)				
High malpractice liability (i.e., no non-economic	-0.169**	-0.151**				
damages cap)	(0.0571)	(0.0508)				
High products liability × high malpractice liability	0.110	0.155*				
	(0.0733)	(0.0616)				
Fixed effects		Year, state, drug				
Other covariates	None	Generic status, black-box				
		warnings, number				
		of brand competitors,				
		number of generic				
		competitors, drug age,				
		state demographics				

The table reports the results of regression of the log number of prescriptions per outpatient visit against the products liability and malpractice regime of the state. High products liability is defined as states with no punitive damage cap in place; high malpractice liability is defined as states without a noneconomic damage cap in place. Data are at the drugstate-year level. Robust standard errors are reported in parentheses, computed to allow for two-level clustering within states and within therapeutic classes. **, *, or + indicates statistical significance at the 1%, 5%, or 10% level, respectively.

overweight the impact of treatments adopted in the middle years of our sample. In the Appendix, we show that applying the decomposition in Goodman-Bacon (2018) to test the balance of our covariates across groups of states that adopted treatment at different times fails to reject that the baseline levels of the covariates we employ are balanced across treatment states. Moreover, we find that balancing our DD design produces essentially the same inference as our baseline DD design.

In Table 8, we report the results of an additional validity test for preexisting trends in prescription rates prior to the adoption of reforms. Reporting results only for the preferred specification (with state and drug fixed effects), columns I, II, and III report the estimated effects for high products liability, high malpractice liability, and their interaction, respectively. The top row reports the main effect while the next rows report the one-, two-, and three-year leads. These results confirm the basic findings and suggest no evidence of pre-existing trends. The lead variables are generally smaller in magnitude and inconsistent in sign compared with the main effects, and none of them is statistically significant. This, combined

Table 7. Implied Effects of State Liability Regimes on Drug Quantity Stratified by the Presence of a Black-Box Warning

	(1)	(11)				
Dependent variable: Log number of prescriptions per outpatient visit						
A. Drugs with a black-box warning in place						
Mean of the dependent variable (levels)	1.78 prescriptions per 1000 visits					
Effect of high products liability when malpractice liability is low	-3.4%	7.0%				
Effect of high products liability when malpractice liability is high	0.1%	12.3%				
B. Drugs without a black-box warning in pla	ce					
Mean of the dependent variable (levels)	2.20	prescriptions per 1000 visits				
Effect of high products liability when malpractice liability is low	0.4% 5.4%					
Effect of high products liability when malpractice liability is high	11.4%+	20.9%**				
Fixed effects		Year, state, drug				
Other covariates		Generic status,				
		black-box warnings,				
		number of brand competitors,				
		number of generic competitors,				
		drug age, state demographics				

The table reports the results of regression of the log number of prescriptions per outpatient visit against the products liability and malpractice regime of the state. High products liability is defined as states with no punitive damage cap in place; high malpractice liability is defined as states without a noneconomic damage cap in place. Data are at the drugstate-year level. **, *, or + indicates statistical significance at the 1%, 5%, or 10% level, respectively. Variance estimates were computed to allow for two-level clustering within states and within therapeutic classes.

with the findings reported in Figure 1, support the case for the exogeneity of our policy variables.

6. Conclusion

This paper examines a puzzling relationship between tort liability rules and production in the pharmaceutical sector. Our inquiry begins with the observation that states with higher punitive damages exposure experience higher prescription rates, but only in those states with high non-economic damages exposure.

Our explanation relies on the interactions among patients, their providers, and drug manufacturers. Liability for prescription drug harms is shared by providers and drug manufacturers, both of whom are targets for litigation. When punitive damages are high, patients have stronger incentives to implicitly pay their physicians to cooperate in a lawsuit against the drug company. This payment can be made through so-called "Mary Carter" agreements between physicians and their patients. The Mary Carter behavioral effect may be mitigated in states with low malpractice damages because physicians have less to gain from settling with their patients.

Table 8. Test for Pre-existing Trends in Drug Quantity Leading Changes in Products Liability or Malpractice Regimes

	(1)	(11)	(III)			
Dependent variable: Log number of prescriptions per outpatient visit						
,	Main effect of high	Main effect of high	Interaction effect			
	products liability	malpractice	of high products			
	(i.e., no punitive	liability (i.e., no	liability and high			
	damages cap)	non-economic	malpractice			
		damages cap)	liability			
Main effect of the policy	0.0820	-0.180*	0.197*			
	(0.0952)	(0.0728)	(0.0870)			
Policy leads						
1 year	-0.0594	0.0829	-0.121			
	(0.0915)	(0.0959)	(0.107)			
2 years	-0.0371	0.0716	-0.0946			
	(0.0800)	(0.0845)	(0.0942)			
3 years	0.0624	-0.0163	-0.0631			
	(0.164)	(0.0583)	(0.0882)			
Fixed effects	Year, state, drug					
Other covariates	Generic status, black-box warnings, number of brand					
	competitors, number of generic competitors, drug age,					
	state demographics					

The table reports the results of regression of the number of prescriptions per outpatient visit against the products liability and malpractice regime of the state. High products liability is defined as states with no punitive damage cap in place; high malpractice liability is defined as states without a noneconomic damage cap in place. Data are at the drugstate-year level. Robust standard errors are reported in parentheses, computed to allow for two-level clustering within states and within therapeutic classes. **, *, or + indicates statistical significance at the 1%, 5%, or 10% level,

We provide empirical support for this behavioral explanation in three ways. First, we show in Table 3 that increases in products liability exposure—via the absence of punitive damages caps—reduce physician damages payments, even though punitive damages have little direct bearing on physician malpractice risk. Table 3 also shows that reductions in malpractice liability mitigate this effect of products liability on physician payments. Both these findings support our emphasis on patient-physician settlement dynamics. Second, we show that these effects on physician payments appear to influence prescribing as well. Higher products liability results in more prescribing, and this effect too is mitigated in states with lower malpractice liability. Finally, we exploit black-box warnings as an alternative mechanism for mitigating the products liability effects: when drugs have black-box warnings that reduce failure-to-warn products liability, the reallocative effect of products liability exposure is also mitigated.

Our study suggests the value of investigating how the interaction of multiple independent firms, operating across multiple independent jurisdictions, complicates the effectiveness of tort liability rules. Further

research may investigate interactions across goods markets, where multiple risky goods are used to produce a given output. More research is also needed on how these considerations affect the political economy of tort reform at the state and national level. A competitive, complex, and vertically disintegrated economy appears to have important implications for how we study tort reform, and how the economic analysis of tort reform should continue to evolve.

Conflict of interest statement. D.L. owns equity in Precision Medicine Group, which provides consulting and research services to firms in the pharmaceutical and biotechnology industries. In addition, D.L. has received consulting payments from Novartis, Genentech, Pfizer, GRAIL, and Otsuka. S.S. has consulted for Precision Health Economics, a consulting firm for the biopharmaceutical industry.

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Appendix A: Description of Claims Data

The data include enrollment files, medical and pharmacy claims and health plan benefits, and span 1997–2007. Enrollment records allow us to track who is eligible for services as well as basic demographics (age, gender, three-digit zip code of residence, and relationship to sponsoring employee). Pharmacy claims in the data include all outpatient pharmaceutical purchases. Each claim includes the type of drug, drug name, National Drug Code (NDC), dosage, days supplied, place of purchase (retail or mail-order), payments by patients and health plans, type of drug dispensed (generic, multi-source brand, single-source brand), type of pharmacy (retail, mail-order), and type (new/refill). The number of health plans contributing data varies each year, with more than 40 plans contributing in the last two years. Thus, there are 421 plan-years of data in the existing data set. About 44% of these plan-years (n = 187) cover retiree benefits, so there is substantial representation of older Americans in the data. Plans also vary in the length of time they appear in the data. Currently, there are 28 plans with five or more years of data.

The data are also representative of all major plan types (health maintenance organizations, HMOs; preferred provider organizations, PPOs; point-of-service, POS, plans; and fee-for-service, FFS, plans) with members in all 50 states. In 2005, approximately 41% of the sample was enrolled in HMOs; 25%, in PPOs; 24%, in POS plans; and the remainder in FFS plans. Geographically, 43% of enrollees resided in the South,

32% in the North Central region, 14% in the West, and 11% in the Northeast.

In the claims data, pharmacy claims are coded by NDC, a unique product identifier created by the FDA. However, the same "drug" could be assigned multiple NDCs according to different strength, dose, or differences in the packaging or labeling of the product. For example, a search of the drug Lipitor on the FDA website reveals more than 75 different NDC codes.²⁷ We aggregate these claims to the drug level according to the active ingredient (also referred to as the molecule name or "generic name"). We linked the data by NDC code to the 2007 Redbook and aggregated all claims according to the active ingredient name by the state, year gender, and age-category level. Of course, even after adjusting for the national representativeness of the sample, some of the variation in quantity across states and years could be driven by variation in the size of the population or the utilization of medical services. Thus, we also computed the number of outpatient visits—the encounter most likely to results in a prescription—for each state, year gender, and age category in Ingenix. Using the weights constructed by comparing Ingenix enrollment to the CPS population, we constructed weighted averages of prescriptions per outpatient visit at the drug, state, and year level.

Appendix B: Supplementary Empirical Analyses

We tested for the existence of different pre-adoption trends in malpractice payments for states adopting punitive and non-economic damages caps. Define NonEconCap_{st0} as an indicator variable that equals unity if state shas a cap on noneconomic damages at time t and zero otherwise. Define NonEconCap $_{stn}$ as an indicator variable that equals unity if the state sfirst adopted a non-economic damages cap in year t + n, and zero otherwise. Define PunitiveCap_{st0} and PunitiveCap_{stn} similarly. Define P_{cst} as the payment made in malpractice case c, in state s, at time t. We run the following regression:

$$P_{cst} = \beta_0 + \beta_1 \text{NonEconCap}_{st0} + \sum_{n=1}^{5} \beta_{1n} \text{NonEconCap}_{stn} + \beta_2 \text{PunitiveCap}_{st0} + \sum_{n=1}^{5} \beta_{2n} \text{PunitiveCap}_{stn} + \epsilon_{cst}$$

The results appear in Table A1. The results are consistent with our basic findings and do not suggest a pre-adoption trend. High malpractice liability is associated with higher liability in all case types, while high products liability is associated with lower malpractice liability in drug cases and uncorrelated with it in other cases. There is a slight evidence of

^{27.} See http://www.accessdata.fda.gov/scripts/cder/ndc/proprietaryname.cfm, accessed on December 1, 2013.

a pre-trend in malpractice cases, although these are almost exclusively in the non-drug cases, which are less central to our analysis. There does appear to be an anomaly in year 3 prior to adoption, although the preperiod effect runs counter to our estimated effect and would thus bias against our findings.

As noted in the text, a potential concern with DD estimation arises when it relies on treatment that (in our case, the imposition of damages caps) is adopted at different times in different states. Goodman-Bacon (2018) has shown that such estimates tend to overweight the impact of treatments adopted in the middle years of our sample. We apply the decomposition method developed in Goodman-Bacon (2018) and use it to test the balance of our covariates across groups of states that adopted treatment at different times. We also compare how different our estimate would be if we used an estimate that balanced weights across all treatment adoptions.

Our balancing tests (not reported) do not reject balance in baseline levels of any of the covariates we employ. Moreover, we find that our full DD estimates are remarkably close to estimates from a balanced set of 2×2 DD estimates. As shown in Figures A1 and A2, estimates that weight state changes the same continue to show that high products liability regimes increase prescribing.

Note that the estimates showing unequally weighted changes differ from those in Table 5 and Table 6 (in the text) because they do not include controls (other than the state- and year-fixed effects). This is because the latest version of Goodman-Bacon (2018)—at the time of this writing—did not incorporate controls or interaction effects into its formulas for a balanced set of DD estimates. As a result, we had to exclude our control variables when performing this test. In addition, instead of using interaction effects, we had to stratify our regressions across states with high and low malpractice liability. The uncontrolled baseline results in this exercise are not our preferred specification. However, this analysis does demonstrate that balancing our DD design produces essentially the same inference as our baseline DD design.

Appendix C: Tables and Figures

Table A1. Tests for Pre-existing Trends in the Adoption of Damage Caps as a Function of Malpractice Payments, Overall and for Drug and Non-drug Cases

	(1)	(4)	(2)	(5)	(3)	(6)
		practice ses	,	g malprac- cases		tice drug ses
High malpractice liability		0.133*** (0.0414)	0.109*** (0.0344)	0.127*** (0.0409)	0.230** (0.105)	0.164 (0.111)
High malpractice liability	sate in ye	ears prior t	o adoption	1	,	,
1 year	•	0.0831* (0.0457)	·	0.0931* (0.0467)		-0.0780 (0.141)
2 years		0.0452 (0.0424)		0.0473 (0.0441)		-0.00929 (0.118)
3 years		-0.0226 (0.0349)		-0.00568 (0.0355)		-0.264** (0.113)
4 years		0.0340 (0.0513)		0.0379 (0.0511)		-0.0545 (0.198)
5 years		0.0359 (0.0475)		0.0414 (0.0479)		-0.0921 (0.120)
High products liability	0.0159	0.0356 (0.0509)	0.0365 (0.0336)	0.0482 (0.0489)	-0.212* (0.117)	-0.0754 (0.101)
High products liability sa	. ,	. ,	. ,	(0.0400)	(0.117)	(0.101)
1 year	,	-0.00741 (0.0525)	шорион	-0.00410 (0.0576)		0.0308 (0.234)
2 years		0.0457 (0.0532)		0.0373 (0.0524)		0.213 (0.196)
3 years		0.0772 (0.0818)		0.0361 (0.0777)		0.538** (0.207)
4 years		0.0764 (0.0756)		0.0551 (0.0676)		0.268 (0.314)
5 years		0.0319 (0.0699)		0.0281 (0.0702)		0.136 (0.186)
Observations R^2	214,048 0.110	214,048 0.110	202,472 0.109	202,472 0.109	11,576 0.085	11,576 0.086

Robust standard errors in parentheses; ****p<0.01, ***p<0.05, *p<0.1.

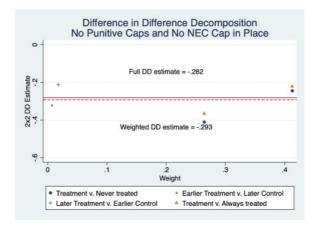


Figure A1. Goodman-Bacon (2018) decomposition for Table 6, comparing effect of no punitive caps on samples with and without non-economic caps.

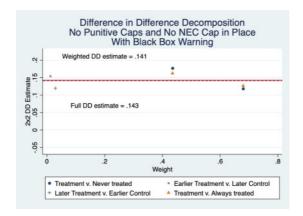


Figure A2. Goodman-Bacon (2018) decomposition for Table 8, comparing effect of no punitive caps on samples with and without drugs with BBW warnings. All sample include only states without non-economic damages caps.