Tort Liability and the Market for Prescription Drugs

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Abstract

Recent events have led to considerable debate over the issue of tort liability on the part of pharmaceutical manufacturers. Critics of the liability system claim that FDA regulations guarantee that all reasonable steps are taken to ensure consumer safety, and that liability simply drives up costs and restricts patient access to life-altering or life-saving therapy. Advocates of tort liability argue that FDA oversight has gaps and the tort system merely discourages manufacturers from bringing unsafe products to market, without limiting patient access. In this study, we consider the implications of tort liability for static and dynamic welfare. On the cost side, we estimate the causal impact of tort liability on prices and access, along with the implied effects on innovation. On the benefits side, we assess the impact of tort liability on the safety of drugs on the market.

Background

Recent events have led to considerable debate over the issue of tort liability on the part of pharmaceutical manufacturers. Critics of the liability system claim that FDA regulations guarantee that all reasonable steps are taken to ensure consumer safety, and that liability simply drives up costs and restricts patient access to life-altering or life-saving therapy. Advocates of tort liability argue that FDA oversight has gaps and the tort system merely discourages manufacturers from bringing unsafe products to market, without limiting patient access.

Naturally, the imposition of more stringent tort liability rules has costs and benefits for the pharmaceutical market, as for other markets. On the positive side, more stringent rules discourage the introduction of dangerous drugs, and improve the safety profile of the marginal drug. On the cost side, however, liability imposes costs on all drug manufacturers, including those producing relatively safe products. For the marginal drug, these costs will be fully borne by consumers in the form of a price increase. For inframarginal drugs, the cost will be shared by manufacturers and consumers. Across the board, the result will be higher prices and reduced utilization for consumers. Finally, by reducing revenue, the reduction in utilization also imposes a dynamic cost by reducing the number of new innovations. A critical issue for welfare is the equilibrium correlation between safety and profitability. E.g., if the marginally profitable drug is as safe or safer than average, the dynamic costs of tort liability will be higher.

In this study, we consider the implications of tort liability for static and dynamic welfare. On the cost side, we estimate the causal impact of tort liability on prices and access, along with the implied effects on innovation. On the benefits side, we assess the impact of tort liability on the safety of drugs on the market. [In this draft, we only report the effects of tort liability on drug prices. Our next draft, which will be prepared for our presentation, will include results on access and side effects.]

Liability and Firm Behavior

In the context of the pharmaceutical market, most liability suits are for "failure to warn" of adverse side effects. For every drug, there are known and unknown side effects. Manufacturers make decisions regarding which known side effects to warn against. There remains uncertainty about the emergence of unknown side effects, and about the potential for adverse outcomes from known side effects that are not disclosed.

Manufacturers are not supposed to be held liable for the emergence of unknown side effects that could not have been anticipated. However, if courts cannot perfectly discriminate between known and unknown effects, firms face some risk. This, however, is a uniform risk that applies to all drug launches equally.

When it comes to known side effects, disclosure insulates a firm from lawsuits, but also depresses demand. Moreover, the riskiest side effects both incur the greatest legal costs, and depress demand by the most. It is thus unclear whether firms will choose to disclose the biggest risks or the smallest risks. However, we can assess how the size of risks, and the severity of the liability regime, affect the optimal pricing strategy, and the launch decision.

The Pricing Decision

In reality, there are always some undisclosed risks, since manufacturers will never disclose every conceivable side effect. Whenever any undisclosed side effect is retained as a risk by the firm, liability rules will affect prices. To fix ideas, suppose there exists a single undisclosed side effect known to the firm. This side effect is characterized by the fraction of potential users affected, ϕ , along with the probability of legal discovery, δ . Assume that in the event of discovery, every affected user is able to recover damages. Finally, the per capita liability costs recovered, λ , vary according to legal rules. Defining Q as the number of users, expected liability costs will equal $E(Q\phi\delta\lambda)$.

Given this undisclosed side effect, expected profits equal:

$$\max_{P} E[\pi] = P \cdot Q(P) - Q(P) \cdot \phi\delta E(\lambda) \qquad (1)$$

The price of the drug is P , and the demand is $Q(P)$. For simplicity, we presume that marginal costs of production are zero, so that liability represents the only production cost. We also assume that λ is the only random variable.

The solution to this problem is the standard monopoly pricing rule, where the Lerner index is set equal to the inverse of the price elasticity of demand:

$$\frac{[P - (\phi\delta E(\lambda))]}{P} - \frac{1}{e} = 0$$

where $e = \frac{Q(P)}{PQ_P}$ is the price elasticity of demand.

Consider a constant elasticity of demand function. Abstracting in this way from changes in the elasticity, it is straightforward to differentiate the equilibrium condition and obtain:

$$\frac{dP}{dE(\lambda)} = \frac{P}{E(\lambda)} \qquad (2)$$

In other words, prices change proportionally with expected per capita liability cost.

When expected liability costs are hard to observe, this expression provides a means of recovering them. Suppose we can identify “high” liability cost and “low” liability cost

areas. Low-cost areas have expected per capita costs equal to L, while high-cost areas have costs equal to $L + \Delta$, where $\Delta > 0$. If we can observe changes over time in the fraction of high-cost areas, α, it will be the case that:

$$\frac{dP}{d\alpha} = \frac{\Delta P}{E(\lambda)} \tag{3}$$

Taking logarithms of the price, we can simplify further:

$$\frac{d\ lnP}{d\alpha} = \frac{\Delta}{E(\lambda)} \tag{4}$$

Therefore, the coefficient on α in a log-price equation yields the percentage difference in liability costs between the high-cost and low-cost areas.

The Launch Decision

The analysis above presumes that firms continue to market the drug in response to changes in liability risk. This will generally be true, but changes in the liability environment may cause firms to forego launches, or to disclose risks they might not have otherwise disclosed.

Obviously, failure to launch results in profits of zero – at least, treating all development costs as sunk. Disclosure of the risk lowers profits. In particular, suppose that in the event of disclosure, all susceptible individuals refrain from using the product, but there is no longer any liability risk. Assuming susceptibility is uncorrelated with willingness-to-pay, the firm's profit in this case equals:

$$\max_{P} E[\pi] = P*(1-\phi)Q(P) \tag{5}$$

On the extensive margin, increases in liability costs lower profits from equation . If these profits fall below the maximum profits available under equation 5, the firm will choose to disclose. If they fall below zero, the firm will refuse to launch. Note that, if there are fixed costs of launch, the profits under disclosure may be negative. In this case, the firm will refuse to launch, whenever non-disclosure yields negative profits.

Since drugs vary in demand and other characteristics, the set of "marginal" drugs, with zero or near-zero expected profit, is likely to be diverse. The question is thus what types of drugs will be foregone as the result of changes in liability. The envelope theorem implies that $\frac{dE[\pi]}{dE(\lambda)} = -Q^*\phi\delta$. Growth in liability costs will tend to discourage the entrance of: (1) Higher-selling drugs; (2) drugs with higher risk of adverse effects; and (3) drugs with more easily discovered adverse effects.

Empirical Approach

Framework

The theory posited jurisdictional variation in liability exposure. In particular, some states impose caps on punitive damage awards payable to plaintiffs. Although punitive damages are rare, they are frequently responsible for the largest verdicts in products liability (Eisenberg et al 2006). They are an important source of liability in failure to warn suits against pharmaceuticals. For example, in the Vioxx litigation against Merck, state court juries in Texas and New Jersey have made large awards of punitive damages, over $200 million in at least one Texas case.[]

The theoretical model also presumed that firms sell their goods in a national market. As a result, geographic variation affects prices, to the extent that the sale of a good varies geographically. Goods sold primarily in uncapped states face greater liability exposure than goods sold primarily in capped states. Specifically, suppose that Q_{igt} is the quantity of good g sold in state i at time t, and U_{igt} is an indicator for whether state i is an uncapped state at time t. In our framework, the term α_{gt} measuring liability exposure for good g at time t is calculated as:

$$\alpha_{gt} = \frac{\sum_i Q_{igt} U_{igt}}{\sum_i Q_{igt}} \qquad (6)$$

One may be concerned that relative demand changes within a state are driven by changes in liability exposure. In this case, the measure α_{gt} may be endogenous with respect to punitive damage caps. As a sensitivity test in some specifications, we fix quantity shares at a baseline time $\bar{t}$, and calculate:

$$\alpha_{gt} = \frac{\sum_i Q_{ig\bar{t}} U_{igt}}{\sum_i Q_{ig\bar{t}}} \qquad (7)$$

The within-drug variation in this measure is generated exclusively by the adoption and repeal of punitive damage caps over time.

Defining P_{gt} as the time t price of drug g in therapeutic class c, the primary regression specification takes the form:

$$P_{gt} = \gamma + \beta * \alpha_{gt} + \delta_g + \delta_t + t * \delta_c + \epsilon_{cgt} \qquad (8)$$

The regression includes drug and year fixed-effects, along with (in some specifications) linear therapeutic class-specific time trends.

Identification

The primary identification concern is whether punitive damage cap adoption is exogenous with respect to the pharmaceutical market. From a theoretical point of view, this concern is mitigated by a free-rider problem across states. Since drugs are sold on a national market, a given state has a very limited impact on the price charged. Outside of the largest few states, no state can expect to see tangible returns from the passage of a cap. Therefore, there is little reason to expect that the passage of a cap is prompted by high pharmaceutical prices. Moreover, failure of exogeneity will tend to bias down the estimates we obtain, since high-price drugs are more likely to draw punitive damage caps. As a result, we obtain a lower bound on the true effect.

Data Sources

The analysis requires information on prescription drug utilization, total population, and punitive damage caps.

Prescription Drug Utilization Data

We use a large database of private-sector health insurance claims, based on the Ingenix Touchstone database, linked to proprietary data on insurance benefit design. These data include enrollment files, medical and pharmacy claims and health plan benefits, and span 1997 to 2007. They have also been used in a number of prior analyses of pharmaceutical utilization {Goldman, 2006 #1490;Goldman, 2004 #1562;Goldman, 2006 #1558;Goldman, 2007 #1560}. Over the balance of the paper, we refer to this as the Multiplan Integrated Dataset, or MIDas.

Pharmacy claims in the data include all outpatient pharmaceutical purchases. Each claim includes the type of drug, drug name, 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).

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). These data are provided to us through an ongoing arrangement with Ingenix Inc, a benefits consulting firm.

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 percent 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 proivder organizations, PPOs; point-of-service, POS, plans; and fee-for-service, FFS, plans) with members in all 50 states. In 2005, approximately 41 percent of the sample was enrolled in HMOs; 25 percent, in PPOs; 24 percent, in POS plans; and the remainder in FFS plans. Geographically, 43 percent of

enrollees resided in the South, 32 percent in the North Central region, 14 percent in the West, and 11 percent in the Northeast. The data supplier has also indicated that, going forward, recent acquisitions of health plans will increase enrollment in the Northeast and West, which will make the data more regionally representative.

A major strength of our data is the very large sample sizes, which allow us to conduct analysis for specific classes of medications and conditions. The data allow us to carefully track prescribing patterns and link them to clinical outcomes in ways that survey data cannot. Even the Medical Expenditure Panel Study (MEPS), which was designed to provide representative data on health care spending nationwide, suffers from a serious undercount of health care spending—anywhere from 6 percent to 40 percent (Selden et al., 2001). The MCBS is also known to undercount prescription drug spending, for example, by both the Congressional Budget Office and the CMS (Christensen and Wagner, 2000).[1] Still, a comparison with nationally representative data provides a useful benchmark.

Table 1 compares mean drug spending in 2003 from our data to a comparable MCBS sample of elderly with employer-provided supplemental coverage. After accounting for the MCBS undercount and regional differences in spending, there is a close correspondence in estimated spending by age and gender. Overall, mean drug spending in 2003 for our sample was $2,317, compared with $2,400 estimated from the MCBS (after adjusting for the known undercount), a difference of 3.5 percent.

Data on State-Level Punitive Damage Caps

[To be completed]

Measurement

Utilization

If we had a single, nationally representative source for drug utilization data, it would be straightforward to calculate α, but such data do not exist. The MIDas data, while they track national numbers reasonably well, are not designed to be nationally representative, stratified probability samples.

To address this problem, we reweight the MIDas utilization data so as to be nationally representative by gender and age category.[2] We begin by calculating state-level utilization figures from Ingenix by gender, and 8 age categories (0-10, 11-19, 20-29, 30-

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[1]The Congressional Budget Office, for example, inflated MCBS prescription drug spending by 15 percent to produce its official forecast of the cost of Part D.

[2] Drugs are identified in MIDas by linking its NDC code field to drug name and therapeutic class information contained in the 2007 Redbook.

39, 40-49, 50-59, 60-64, 65+). Throughout, we take the number of users as the utilization measure, rather than the number of prescriptions.

Next, we use the Current Population Survey (CPS) to calculate total US population by state, gender, and age cells. The CPS data are used to weight the MIDas calculations and construct state-level figures for total utilization.

In our baseline specifications, the utilization of drugs is allowed to vary across years, in the construction of α_{gt}. In specifications where we hold drug utilization fixed over time, we use mean utilization figures estimated across all MIDas years.

In every case, we separately estimate utilization for branded and generic drugs within a therapeutic class.

Price

The dependent variable is the price of a (branded or generic) prescription. We conceive of drugs as being sold in a national market. Therefore, we calculate mean nationwide prices for branded and generic versions of a product, using the pricing information in MIDas. These data measure the total payment made by consumers and insurers to the manufacturer, but not including any unobservable rebates paid from manufacturers to insurers. For each (branded or generic) drug, we calculate total payments, divided by total prescriptions, to calculate mean expenditure per prescription. This is taken as our measure of the mean nationwide price.

Results

Descriptive Statistics

Considerable variation in liability exposure comes about as a result of geographic variation in the prevalence of disease. This point is illustrated by Figure 1 and Figure 2. The figures show, for a number of different diseases, the percent growth in the share of patients living in a capped state. This can be taken as a simple proxy for $(1-\alpha)$, where the proxy is perfect if per capita utilization is constant.

Figure 1 makes the point that exposure to caps has risen much more rapidly among patients with neurological and mental disorders and with diabetes, as compared to cancer or heart disease patients. Exposure to caps roughly doubled from 1996 to 2005 for patients with neurological or mental disorders. The corresponding increase was just 20% for cancer patients. Figure 2 repeats this analysis within cancer patients, for different types of cancer. The figure indicates that exposure to caps has risen by about 50% for prostate cancer patients, but by just 10% for breast cancer patients.

Finally, Figure 3 presents a simple tabulation that foreshadows our empirical results. The figure shows growth in prices for drugs that are above or below the median growth in exposure to punitive damage caps. The average drug saw a 5% increase in exposure to caps from 1996 to 2005. The pairs of curves in the figure plot the mean growth in prices for drugs facing growth in exposure above or below this level. Particularly from the year

2000 onwards, branded drugs facing higher growth in punitive damage caps exhibited significantly slower price growth. Specifically, the "capped" drugs saw price growth around 190% over this period, while the "uncapped" products saw corresponding growth of around 225%. This implies annual rates of price growth for uncapped drugs of around 12.5% versus 11.2% for uncapped drugs.

On the other hand, generic prices are not very much different across capped or uncapped drugs. Indeed, due to a sharp movement in the last year of our data, the uncapped generic drugs actually end up experiencing less price growth than the capped generic drugs. This is consistent with the fact that generic drug manufacturers are extremely unlikely to be sued for failure to warn about side effects.

Table 2 presents simple summary statistics at the drug level, for mean nationwide prices, fraction of users exposed to punitive damage caps, and counts of drugs. For both branded and generic drugs, approximately half of users are exposed to caps. Mean prices are about twice as high for branded drugs, compared to generics. In total, we have data on 7836 drugs, 5729 of which are branded.

Regression Analysis

Table 3 presents our baseline results. Each column in the table corresponds to a different regression model. Column (1) reports results from models without linear therapeutic class-specific time trends, while column (2) adds these. The three rows report results for samples that include all drugs, branded drugs only and generic drugs only.

Calculated across all drugs, exposure to punitive damage caps lowers pharmaceutical prices by 8.5% to 13.8%, although this effect loses significance when the class-specific time trends are added. This should be interpreted as the total price effect of moving from zero nationwide exposure to complete nationwide exposure. The second and third rows confirm the result in Figure 3: the effects of damage caps on price are concentrated among the branded drugs. Here, exposure to caps lowers prices by 11% to 17%. In contrast, there are no statistically significant effects on the prices of generic drugs, regardless of the specification.

Table 4 repeats these analyses using measures of α_{gt} that fix state-level utilization shares across time. As a result, the only source of variation in α remains the adoption or repeal of punitive damage caps. Confining the source of variation in this manner raises the estimated effect sizes. This would be expected if demand is rising faster in capped states than uncapped states. Using constant demand shares, exposure to caps lowers branded prices by 12% to 20%, but again has no statistically significant effect on generic prices.

Table 5 explores the presence of lagged effects, by regressing prices on the past year's exposure to punitive damage caps. Since this analysis uses drug utilization numbers varying over time, it should be compared to the results in Table 3. The two sets of coefficients are extremely close, indicating a relatively slow rate of decay in the impact of caps on prices.

Conclusions

Our analysis suggests that punitive damage caps have significant negative effects on pharmaceutical prices. Approximately half of all patients in our data are currently covered by caps. Implementing a nationwide cap is predicted to lower branded pharmaceutical prices by 5 to 10%. This would save tens of billions of dollars annually.

To be sure, punitive damage caps may have costs, in the form of compromised incentives for safety. Nonetheless, the price-reductions are substantial, and suggest that pharmaceutical manufacturers respond quite strongly to liability risk when setting prices.

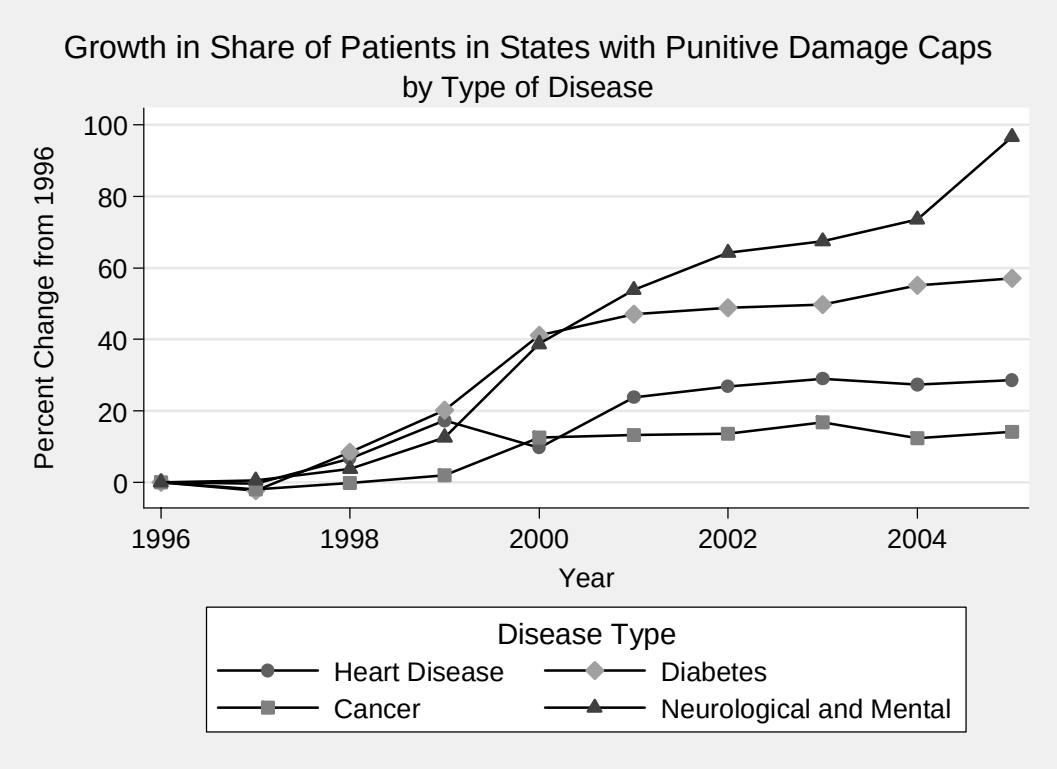

Figure 1. Growth in the Exposure to Liability Reform by Type of Disease, 1996-2005*

* Note: The figure illustrates the percent growth in share of patients living in a state with a cap on punitive damages in civil trials by type of disease and year. The share of patients in each state is estimated using the fraction of all MCBS patients self-reporting having the disease who live in the state in the year. Percent growth is defined relative to 1996, the first year in the sample.

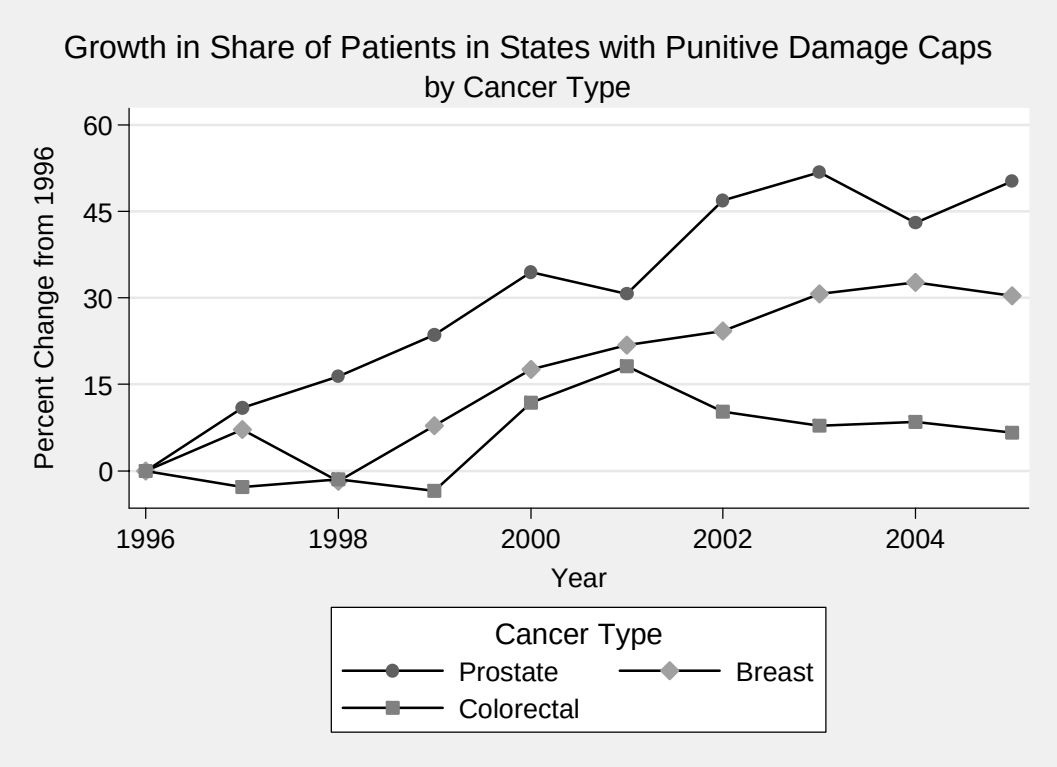

Figure 2. Growth in the Exposure to Liability Reform by Type of Cancer, 1996-2005*

* Note: The figure illustrates the percent growth in share of cancer patients living in a state with a cap on punitive damages in civil trials by type of cancer and year. The share of cancer patients in each state is estimated using the fraction of all MCBS patients self-reporting having a specific type of cancer who live in the state in the year. Percent growth is defined relative to 1996, the first year in the sample.

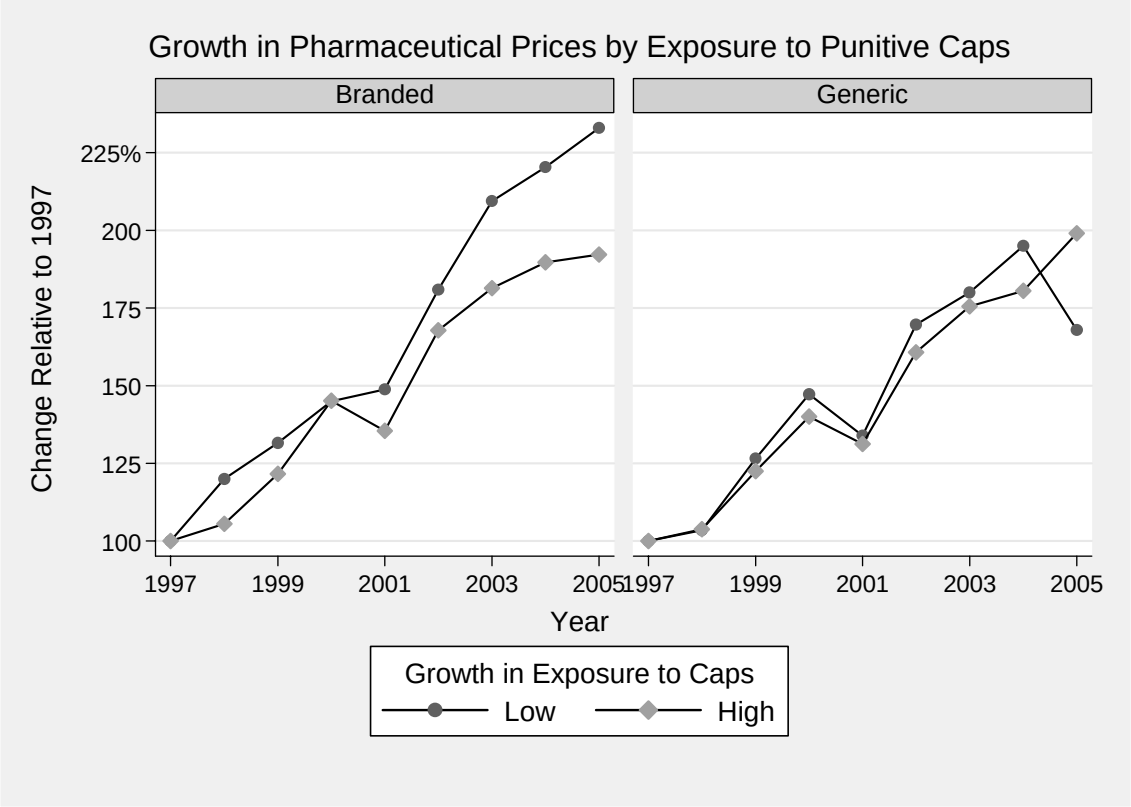

Figure 3. Trends in Pharmaceutical Prices by Growth in Exposure to Punitive Damage Caps, 1997-2005

* Note: The figure illustrates the percent growth in average pharmaceutical prices by generic status and exposure to punitive damage caps. Percentage change in prices is defined relative to the base year (1997). High or low growth in exposure to the caps is defined relative to the median within-drug growth in exposure from 1997 to 2005, which is approximately 5%. That is, drugs with low growth either had their exposure fall or grew by less than 5%, while drugs with high growth had their exposure rise by more than 5%.

Table 1: Comparison of Rx Spending, Privately-Insured Elderly Only.

Characteristic		Proportion Of Population[1]	Mean Rx Spending ($) MCBS[2]	Our Plans
Age[3]				
	65 to 74	0.56	2,248	2,244
	75 to 84	0.35	2,460	2,443
	85+	0.09	2,262	2,259
Gender[4]				
	Female	0.53	2,487	2,395
	Male	0.47	2,303	2,230
Region				
	Northeast	0.19	2,191	2,311
	Midwest	0.25	2,301	2,632
	South	0.37	2,543	2,286
	West	0.18	2,052	1,925
Overall[4]		1.00	2,400	2,317

[1]Elderly with employer-provided supplemental coverage (65+)

[2]Adjusted for the 15% undercount of drug spending in the MCBS

[3]Our data adjusted to reflect the regional distribution in MCBS

[4]Our data adjusted for age and region distributions in the MBS

Table 2: Summary Statistics

	All Drugs	Branded Drugs	Generic Drugs
Total Expenditure per RX	116.51	119.75	55.24
	(196.24)	(200.44)	(55.37)
Fraction of Patients in States with Punitive Damage Caps	0.47	0.47	0.49
	(0.04)	(0.04)	(0.06)
Number of observations	7,836	5,729	2,107

Note: Table reports mean values at the drug-year level, with standard deviations reported in parentheses. Data are weighted by the total number of patients prescribed the drug.

Table 3. The Estimated Impact of Exposure to Punitive Damage Caps on the Price of Prescription Drugs

	(1)	(2)
	Dependent Variable: Total Expenditures per RX	
	All Drugs	
Fraction of Patients in States with Punitive Damage Caps	-0.138	-0.085
	(0.052)**	(0.051)
	Branded Drugs	
Fraction of Patients in States with Punitive Damage Caps	-0.168	-0.106
	(0.052)***	(0.052)*
	Generic Drugs	
Fraction of Patients in States with Punitive Damage Caps	0.066	0.065
	(0.066)	(0.072)
Therapeutic Class-Specific Time Trends?	No	Yes

Notes: Table reports estimates of the elasticity of the price of a prescription drug with respect to a change in the exposure of that drug to caps on liability for punitive damages in civil lawsuits. Each column represents a separate regression. The unit of analysis for all regressions is a drug-year. All regressions include fixed effects for year and drug, as well as a dummy indicator for a branded (i.e., on-patent) drug, and controls for the total number of different branded and generic drugs in the therapeutic class in the year. The data are weighted by the total number of patients prescribed the drug in the year.

Liability exposure is defined as the fraction of patients prescribed the drug in a year residing in states with a cap on punitive damage in civil suits (so a high exposure to caps indicates low exposure to liability). Therapeutic class-specific time trends are specified linearly. Robust standard errors are reported in parentheses, adjusted to allow for correlation (clustering) within the therapeutic class. A * or ** represents statistical significance at the 10% or 5% level or better, respectively.

Table 4. Estimated Price Effect of Exposure to Punitive Damage Caps Defining Liability Exposure Using a Fixed Share of Demand by State

	(1)	(2)
	Dependent Variable: Total Expenditures per RX	
	All Drugs	
Fraction of Patients in States with Punitive Damage Caps	-0.158	-0.095
	(0.062)**	(0.055)*
	Branded Drugs	
Fraction of Patients in States with Punitive Damage Caps	-0.202	-0.124
	(0.062)***	(0.057)**
	Generic Drugs	
Fraction of Patients in States with Punitive Damage Caps	0.089	0.107
	(0.073)	(0.072)
Therapeutic Class-Specific Time Trends?	No	Yes

Notes: Table reports estimates of the elasticity of the price of a prescription drug with respect to a change in the exposure of that drug to caps on liability for punitive damages in civil lawsuits. Each column represents a separate regression. The unit of analysis for all regressions is a drug-year. All regressions include fixed effects for year and drug, as well as a dummy indicator for a branded (i.e., on-patent) drug, and controls for the total number of different branded and generic drugs in the therapeutic class in the year. The data are weighted by the total number of patients prescribed the drug in the year. In this model liability exposure is defined as the fraction of patients prescribed the drug residing in states with a cap on punitive damage in civil suits, using the average share of

demand for each state across all years. Therapeutic class-specific time trends are specified linearly. Robust standard errors are reported in parentheses, adjusted to allow for correlation (clustering) within the therapeutic class. A * or ** represents statistical significance at the 10% or 5% level or better, respectively.

Table 5. The Estimated Impact of Exposure to Punitive Damage Caps in the Previous Year on the Price of Prescription Drugs

	(1)	(2)
	Dependent Variable: Total Expenditures per RX	
	All Drugs	
Fraction of Patients in States with Punitive Damage Caps	-0.130	-0.077
	(0.047)***	(0.046)
	Branded Drugs	
Fraction of Patients in States with Punitive Damage Caps	-0.154	-0.092
	(0.045)***	(0.046)*
	Generic Drugs	
Fraction of Patients in States with Punitive Damage Caps	0.041	0.075
	(0.071)	(0.067)
Therapeutic Class-Specific Time Trends?	No	Yes

Notes: Table reports estimates of the elasticity of the price of a prescription drug with respect to a change in the exposure of that drug to caps on liability for punitive damages in civil lawsuits. Each column represents a separate regression. The unit of analysis for all regressions is a drug-year. All regressions include fixed effects for year and drug, as well as a dummy indicator for a branded (i.e., on-patent) drug, and controls for the total number of different branded and generic drugs in the therapeutic class in the year. The data are weighted by the total number of patients prescribed the drug in the year. Liability exposure is defined as the fraction of patients prescribed the drug in the previous year residing in states with a cap on punitive damage in civil suits (so a high

exposure to caps indicates low exposure to liability). Therapeutic class-specific time trends are specified linearly. Robust standard errors are reported in parentheses, adjusted to allow for correlation (clustering) within the therapeutic class. A * or ** represents statistical significance at the 10% or 5% level or better, respectively.