Product Liability Litigation and Innovation: Evidence From Medical Devices

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Motivation

Health and safety concerns are critically important for firms introducing new products

Product liability cases account for over 70% of civil personal injury cases in the U.S.

Often make newspaper headlines due to large damage awards and salient nature of pains, sufferings, and death

Current policy debates over safety of AI, sophisticated robotics, and digital platforms in US and EU

How does the product liability system affect the rate and direction of technological progress?

Dominant view

"In the United States product liability is so extreme and uncertain as to retard innovation. The legal and regulatory climate places firms in constant jeopardy of costly and, as importantly, lengthy product liability suits."

This negative view:

- is shared by several legal scholars: Huber (1989); Parchomovsky and Stein (2008)
- has shaped high-profile judicial decisions
- is a key argument for tort reforms

Michael Porter (1990)

Available empirical evidence

Limited evidence with ***mixed findings***. Current assessments: either (i) ***indirect measures*** *of product liability risk* (ii) or ***narrowly focus*** *on one particular litigation event*

This paper: examines the effect of product liability litigation exploiting the universe (>200,000 cases) of federal product liability litigation in the medical device industry during the past 25 years.

Empirical context: medical devices

The medical device industry is a dynamic and research-intensive setting. New products can have substantial impact of social welfare (Grennan and Town, 2020)

Medical devices and drugs account for the majority of liability cases (~55%), all of the top-20 defendants

Intense debate on need to reform liability system:

- Advamed: "*Corrosive impact of litigation on medtech innovation and patient access to medtech*"…"*The vast majority of product liability litigation… compromises patient interests and chills innovation*."
- Public Citizen: without high damages "*manufacturers would be more likely to put dangerous drugs and medical devices on the market with little concern for patients' safety*"

Theoretical considerations

Canonical model of timing of technology introduction/product obsolescence (e.g. Katz and Shapiro, 1992; Waldman, 1993, Fishman and Rob, 2000):

$$\Pi_t^N - c > \max_{\hat{t}>t} \left\{ \sum_{j=t}^{\hat{t}-1} \delta^{j-t} \pi_j^O + \delta^{\hat{t}-t} (\Pi_{\hat{t}}^N - c) \right\}$$

Being target of product liability litigation reduces profits from existing product offering (π_j^O) which leads to earlier introduction of new product (Henry et al., 2022). Consistent with law and economics interpretation of new products as a 'remedial action' (Chen and Hua, 2012)

Litigation also shifts demand: safety as 'demand pull' increasing willingness to pay for new safer products (Π_t^N) (Schmookler, 1966; Galasso and Luo, 2022)

These channels point to ***positive effect*** of liability litigation on the introduction of new products. Appendix shows this in formal model based on Waldman (1993).

Chilling effects of litigation

There are also channels through which litigation may slow down the introduction of new products

1. Re-direction of research efforts may be required, and this may take time. In some cases, safer products may not be feasible (Rosenberg, 1974)
2. Monetary and non-monetary costs of litigation may increase the cost of R&D:
   - high legal costs and damage/settlement payments
   - tax on time of executives and R&D personnel
   - litigation may percolate throughout the vertical chain and increase input costs (Galasso and Luo, 2022)
3. Litigation generates regulatory and legal uncertainty (FDA banned silicone breast implants, litigation reveals information). Firms have incentives to wait for uncertainty to be resolved before introducing new products

Overall effect of product liability litigation on innovation is **ambiguous** as it depends on features of the firm and the technology. Empirical analysis is essential to inform policy

Data: sample

Our sample includes 45 leading medical device firms

- Top 30 companies based on Compustat sales 2000-20 + others from trade magazine rankings
- Challenges: M&As and subsidiary names that are not the same as parent firms
  - Recover ownership structures and their changes using WRDS Company Subsidiary Data, Refinive M&A data, the FDA registration, and news
  - Clean up firm names to be consistent with various FDA datasets

Merge with FDA data on device applications, adverse events, and recall data. FDA classifies devices using product codes. Codes distinguish generic types devices (e.g. pulmonary valves)

Final sample:

- 86,741 firm-code-year between 1995 and 2020
- A firm-code enters the sample in the year of first application (or acquisition) in code

Data: litigation

Multiple sources:

- Federal Judicial Center's integrated database
- Lex Machina
- Judicial Panel on Multidistrict Litigation (JPML) data for MDL cases

Identify cases involving product liability litigation and our sample firms

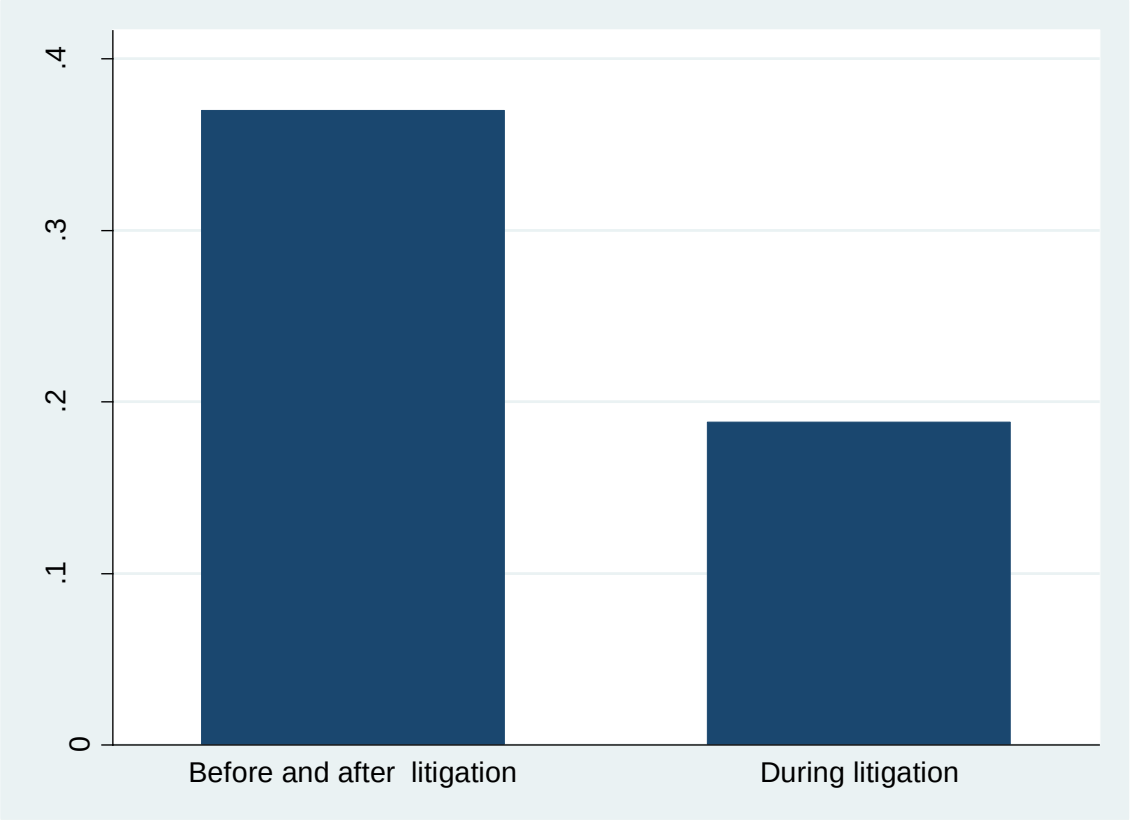
Identify medical devices litigated based on court documents

Identify product codes by finding 510k and PMA applications of each litigated device

Ultimately 215,483 total cases in 1995-2020 against sample firms

Descriptives stats

	N	Litigated	Percentage
Firms	45	16	35.6%
Product codes	2089	28	1.3%



Baseline Regressions

	(1)	(2)	(3)
	Application Dummy	Application Dummy	Application Dummy
Litigation	-0.132***	-0.155***	-0.162***
	(0.046)	(0.046)	(0.045)
log(Adverse Events)		0.010***	0.010***
		(0.002)	(0.002)
Firm-code effects	YES	YES	YES
Year effects	YES	YES	YES
Firm-year effects	NO	NO	YES
Observations	86741	86741	86551

A roughly 40% drop in the propensity to file an FDA application in a product code during the years in which litigation takes place

Paper shows several robustness:

DV - #applications, adjust for M&As….

Model - Poisson, lagged stock

Controlling for product recalls

	(1)	(2)
	Application Dummy	Application Dummy
Litigation	-0.168***	-0.171***
	(0.048)	(0.055)
log(Adverse events)	0.004*	0.013***
	(0.002)	(0.002)
log(Recalls)	0.007	0.006
	(0.007)	(0.007)
log(Recalls t-1)		0.009
		(0.007)
log(Recalls t-2)		0.009
		(0.007)
log(Recalls t-3)		-0.002
		(0.007)
log(Recalls t-4)		-0.011
		(0.007)
Sample	after 2002	after 2002 and lags defined
Observations	71465	57133

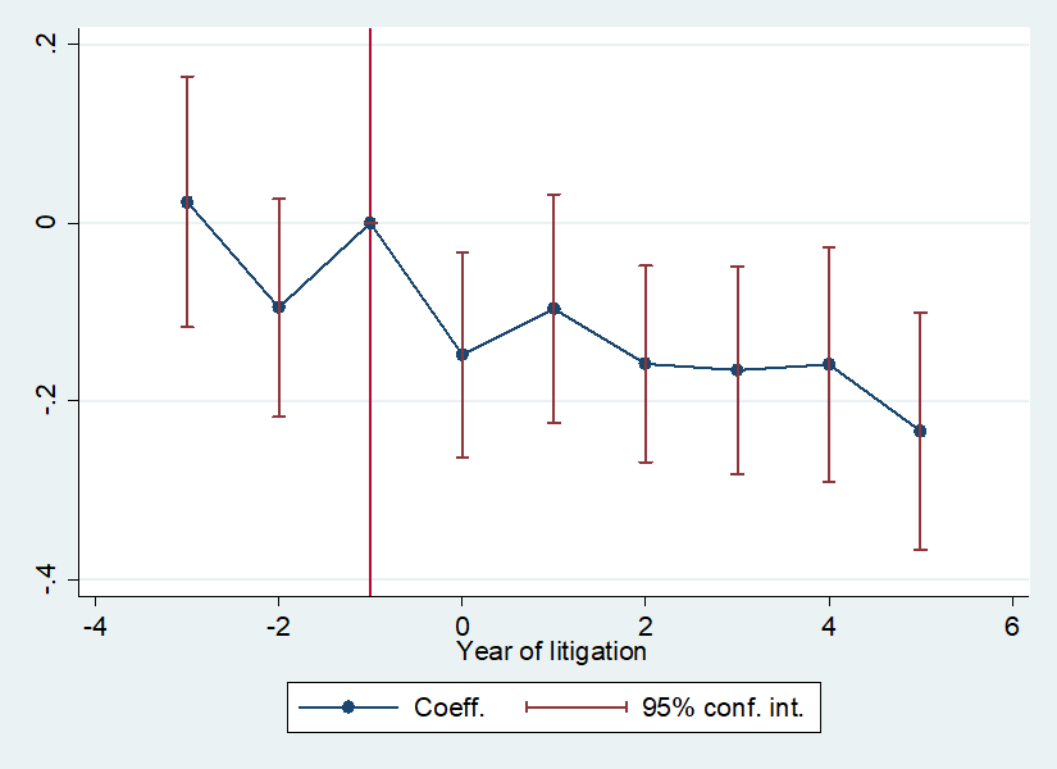
Concern that recalls may have direct chilling effects

Recall data only available after 2002, use it to construct measures of recalls (# or dummy)

Recalls 10 times more frequent than litigation

No chilling effect of recalls (consistent with Ball, Macher and Stern, 2018)

Dynamic effects



	Application Dummy	Application Dummy
Litigation	-0.161***	-0.161***
	(0.049)	(0.050)
After Litigation	-0.041	
	(0.064)	
After litigation year 1		-0.118*
		(0.066)
After litigation year 2		-0.041
		(0.085)
After litigation years 3+		-0.001
		(0.081)

Relatively quick drop and stable effects during the litigation spell. Filing reverts to pre-litigation levels about 1 year after litigation (but only a few post-litigation spells in our data!)

Omitted variables

Correlation between innovation and litigation may be biased by unobservable variations within a firm-code that correlates with litigation and innovation. The direction of the bias is ambiguous:

- Products with high demand may stimulate innovation but increase litigation → under-estimate the effect of litigation on innovation
- Media coverage of product failures may trigger litigation and chill innovation → over-estimate the effect of litigation on innovation

Constructing time-varying controls at the firm-code level is challenging. E.g. ECRI offers sales data on medical devices but: expensive, only 5-8 years and in some cases less detailed than code level

Firm-tech-year effects

Exploit Code of Federal Regulation hierarchical structure.

E.g.: hip prosthesis product codes

Part of CFR classifications

3 digits (orthopedics)

4 digits (orthopedics therapeutic)

5 digits (hip and knees prosthesis)

7 digits (metal hip prosthesis)

	(1)	(2)	(3)	(4)
	Application Dummy	Application Dummy	Application Dummy	Application Dummy
Litigation	-0.166***	-0.197***	-0.177***	-0.096*
	(0.046)	(0.058)	(0.064)	(0.055)
Firm-technology-year effects	16 tech areas	73 tech areas	371 tech areas	938 tech areas
Digits	3	4	5	7
Firm-code effects	YES	YES	YES	YES
Year effects	YES	YES	YES	YES
Observations	84620	74223	58820	34445
Average # codes	100	32	4.9	1.9

Regulatory environment and litigation

We identified two key changes in the regulatory environment that took place during our sample period:

1. implementation of the ***Alternative Summary Reporting*** (ASR) program, which affected the amount of public information on device malfunctions

2. Supreme Court decision ***Riegel v. Medtronic*** in 2008 which changed the boundaries between federal regulation and state laws

Use these in two ways: (i) study the impact of these institutional features on product liability litigation and (ii) exploit the quasi-exogenous nature of these changes (not specific to tech-firm) to confirm baseline finding

ASR

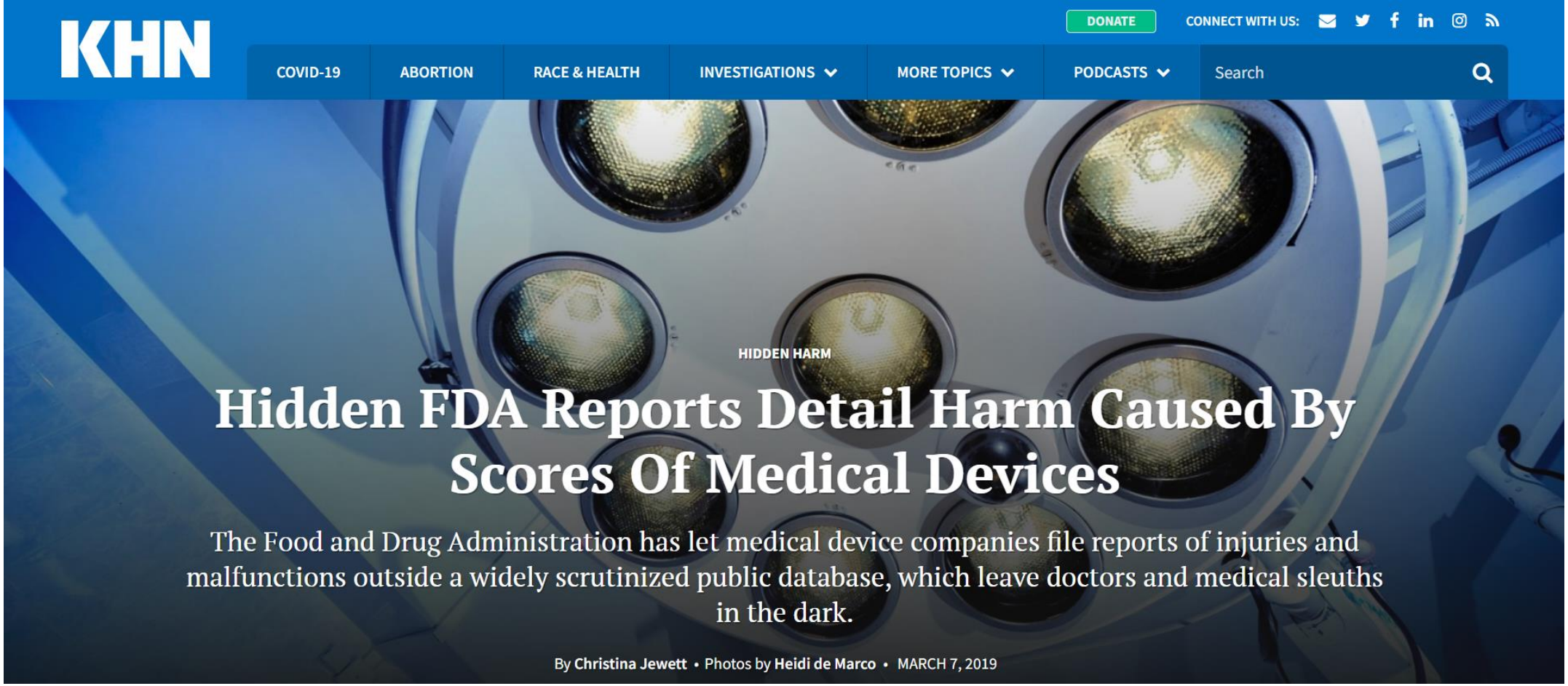
Adverse reports released by FDA using Manufacturer & User Facility Device Experience (MAUDE) database

Initial guidelines (1984) required submission of separate reports for each malfunction. Increase administrative burden to FDA and lack of staff led to ***Alternative Summary Reporting (ASR)*** program, which enabled manufacturers of certain devices to submit quarterly summary reports of specific events instead of individual reports

Selected manufacturers informed in 1997, FDA began receiving reports in 1999. Designed for events which were "*well known to the FDA and have been reported for years to the agency*." Initially restricted to 12 product codes, but subsequent guidelines did not specify the set of products

ASR hidden from the public until 2019 whereas MAUDE is public. Our interview with former FDA manager:

"*a single person at the FDA was managing ASR data and they were on sick leave for a long time….the intention was not to hide the data*" but to facilitate the work for the 15 FDA staff members dealing with malfunction reports



"so obscure that it is unknown to many of the doctors and engineers dedicated to improving device safety. Even a former FDA commissioner said he knew nothing of the program"

Public information shapes litigation

	(1)	(2)	(3)
	Litigation	Litigation	Litigation
Estimation	OLS	OLS	OLS
Private Reports	-0.004**		
	(0.002)		
Adverse events	0.004**		
	(0.002)		
log(ASR Ratio)		-0.006***	-0.006***
		(0.002)	(0.002)
log(Adverse events)		0.006***	0.006***
		(0.001)	(0.001)
Sample	Full	Full	2003-2018 non original ASR codes
Observations	86741	86741	60144

Hidden reports reduce the likelihood of litigation

Practitioner publications and the academic law literature: info on malfunctions used by lawyers to identify opportunities for lawsuits

Useful to

"*identify plaintiffs (product users) that have had adverse experiences. Plaintiffs' attorneys know that even without a single `strong' case, life sciences companies may be amenable to settling when faced with a multitude of potential lawsuits*" (Medmarc, 2022)

Quasi-exogenous variation

We do not exploit actual use of ASR

Drop 12 original codes and use ‘awareness of the system’ and composition of adverse events to predict litigation

IV estimate confirm chilling effect. Larger in magnitude (but conf. int. overlap with OLS)

	(1)
	Application Dummy
Estimation	2SLS
Litigation (instrumented)	-1.133***
	(0.396)
Instruments	Aware X log(Adverse events), Aware X log(NonSerious events)
First stage F-stat	19.43
Sample	2003-2018 non original ASR codes
Observations	59863

Riegel vs Medtronic

Boundaries between federal regulation and state laws uncertain since the Medical Device Amendments of 1976

Riegel vs Medtronic (2008): PMA go through more stringent screening process by federal agency, and this pre-empt several state tort claims. Not the case for 510k

Supreme Court decision increases the burden required to win a liability case against PMA manufacturer

Effects on innovation

Interplay between federal and state laws affects pattern of litigation

Riegel vs Medtronic reduced the litigation for PMA relative to 510k

In turn this affects commercialization of new devices

IV larger than OLS (but conf. int. overlap)

	(1)	(2)	(3)
	Litigation	Application Dummy	Application Dummy
Estimation	OLS	OLS	2SLS
PMA x After 2008	-0.031***	0.044**	
	(0.012)	(0.021)	
Litigation (instrumented)			-1.411**
			(0.564)
First stage F-stat			38.82
Sample	PMA vs 510k with high event frequency	PMA vs 510k with high events frequency	PMA vs 510k with high event frequency
Observations	12412	12412	12398

Spillovers within firms

	(1)
	Application Dummy
Litigated code	-0.148***
	(0.046)
Other codes in specialty	0.016*
	(0.008)
Other codes in sub-group	
Codes outside specialty	0.006
	(0.004)
Observations	86741

No evidence of generalized chilling effect for entire technology area

Spillovers across firms

	(1)
	Application Dummy
Litigated firm-code	-0.160***
	(0.046)
Other firms in code	-0.058**
	(0.025)
Other firms in sub-group	0.013
	(0.011)
Other firms in specialty	-0.001
	(0.007)
Observations	86741

Some evidence of spillover to non litigated firms but ***highly localized***

No evidence of spillover effects outside litigated code, even within subgroups

Robust to restricting the sample to firms never litigated

Litigation and safety

FDA data

- Construct forward looking measure of adverse-events associated with the 510ks/PMAs of the devices that are applied for in each year. Captures the safety profile of products launched in each cohort
- Devices commercialized during and after litigation are safer. Effects begins during litigation but intensifies after.

Patent data

- Construct panel using patent classes rather than FDA codes. No evidence of negative effect of litigation on patenting.
- But higher likelihood of filing risk-mitigating patent during and after litigation

Conclusion

Litigation is common among medical devices firms but highly concentrated in a few tech areas

Litigation has a significant chilling effect on commercialization by litigated firms and on related firms

- contained within the narrow product markets
- innovation intensity tends to recover after the litigation
- there is evidence suggesting an increase in product safety after litigation

Regulatory regimes—public availability of adverse information and federal preemption— affect litigation risk

Combined with Galasso and Luo (2017; 2022): complex link between liability and innovation

Thank you!