Routledge
Taylor & Francis Group

Economics of Innovation and New Technology

ISSN: 1043-8599 (Print) 1476-8364 (Online) Journal homepage: www.tandfonline.com/journals/gein20

Vaccine production and innovation: insights from tort reform and Medicare expansion

Myongjin Kim, Firat Demir, Ahmed El Fatmaoui, Qi Ge, Pallab Ghosh & Junying Zhao

To cite this article: Myongjin Kim, Firat Demir, Ahmed El Fatmaoui, Qi Ge, Pallab Ghosh & Junying Zhao (29 May 2025): Vaccine production and innovation: insights from tort reform and Medicare expansion, Economics of Innovation and New Technology, DOI: 10.1080/10438599.2025.2511865

To link to this article: https://doi.org/10.1080/10438599.2025.2511865

View supplementary material

Published online: 29 May 2025.

Submit your article to this journal

View related articles

View Crossmark data

Full Terms & Conditions of access and use can be found at
https://www.tandfonline.com/action/journalInformation?journalCode=gein20

ECONOMICS OF INNOVATION AND NEW TECHNOLOGY
https://doi.org/10.1080/10438599.2025.2511865

Routledge
Taylor & Francis Group

Check for updates

Vaccine production and innovation: insights from tort reform and Medicare expansion

Myongjin Kim[a], Firat Demir[a], Ahmed El Fatmaoui[a], Qi Ge[b], Pallab Ghosh[a] and Junying Zhao[c]

[a]Department of Economics, University of Oklahoma, Norman, OK, USA; [b]Department of Economics, Vassar College, Poughkeepsie, NY, USA; [c]Department of Health Administration and Policy, University of Oklahoma Health Sciences Center, Oklahoma City, OK, USA

ABSTRACT

Leveraging a unique dataset on vaccine production and development, this paper assesses the effectiveness of two policy interventions in stimulating firms' output and innovation, including (1) a tort reform that reduces vaccine manufacturers' product liability; and (2) an expansion of Medicare's coverage of vaccine products. A difference-in-differences analysis indicates that both policies significantly boost vaccine production, with the impact of Medicare coverage expansion being 3–6 times larger in magnitude. There is also evidence suggesting that vaccine manufacturers are more likely to invest in R&D in response to this expansion, and the effect is likely driven by the underlying market structure.

ARTICLE HISTORY
Received 31 October 2024
Accepted 8 May 2025

KEYWORDS
Innovation; production; vaccine; tort reform; Medicare; market structure

JEL CODES
I18; L11; O31; K13

1. Introduction

Vaccines generate substantial positive externalities and have far-reaching impacts on public health, labor market outcomes, technological progress, and economic growth (Atwood 2022; Carpenter and Lawler 2019). The vaccine industry has historically been shaped by numerous (de)regulations and subsidies aimed at boosting production and innovation. Curiously, despite significant policy attention, vaccine supply shortages have remained a long-standing concern for policymakers and health professionals in the U.S. (Hinman et al. 2006; U.S. Government Accountability Office 2021). The COVID-19 pandemic and recent global supply chain disruptions have further brought this pressing issue to the forefront and highlighted the urgency to assess policies that can effectively promote vaccine production and development.[1]

Our paper contributes to these dialogues by evaluating and contrasting the effectiveness of two policy interventions with distinct incentives for vaccine manufacturers in stimulating their output and innovation, including (1) a tort reform that subsidizes manufacturers by reducing their product liability; and (2) an expansion of Medicare's coverage that subsidizes consumers for selected vaccine products. We also explore an

CONTACT Myongjin Kim mjkim@ou.edu Department of Economics, University of Oklahoma, Norman, OK 73019, USA

Supplemental data for this article can be accessed online at http://dx.doi.org/10.1080/10438599.2025.2511865.

© 2025 Informa UK Limited, trading as Taylor & Francis Group

understudied but important channel in stimulating production and innovation through the interaction between the type of policy intervention and the underlying market structure.

More specifically, we focus on the National Childhood Vaccine Injury Act (NCVIA) of 1986, a legislation enacted in 1986 and fully implemented in 1988 (National Childhood Vaccine Injury Act 1986). This tort reform effectively functions as a subsidy for vaccine production by providing liability protections to manufacturers of childhood vaccines from vaccine-related injuries, thereby lowering the number of vaccine injury lawsuits and the associated liability and production costs. As is common with public financing of injury compensation programs for specific products, the NCVIA finances compensation for vaccine injuries through an excise tax on vaccines, a cost ultimately passed on to both manufacturers and consumers (Drake and Tieman 1994; Thompson, Orenstein, and Hinman 2020).

Meanwhile, starting in 1981, Medicare Part B began offering full reimbursement for certain preventive vaccines to beneficiaries aged 65 or older. Our study specifically examines the following two expansion episodes of Medicare vaccine coverage, including (1) the 1984 coverage of co-payments for hepatitis B (HBV) vaccinations for beneficiaries at high or intermediate risk, and (2) the 1993 provision of full coverage of seasonal influenza vaccination (MedPAC 2021). The expanded vaccine coverage is funded through subsidies by the federal government (about 72% through tax revenues) and consumers (about 26% through Medicare Part B monthly premiums) (Cubanski, Neuman, and Freed 2019). Compared to the NCVIA of 1986, by significantly subsidizing consumers of specific vaccine products and freeing the manufacturers from bearing the financial burden, the expansion episodes of Medicare's coverage of vaccine products thus reflect more salient policy shocks on the demand for vaccines and would likely present a larger incentivizing effect on production and innovation.

Our study leverages a unique manually compiled dataset on vaccine production and development for 25 different vaccines between 1980 and 1995. The data contain information on the number of gross and net doses distributed from the Centers for Disease Control and Prevention (CDC) Biologics Surveillance and each vaccine's clinical trial information from the New Drug Application (NDA) Pipeline. Our empirical strategy exploits a quasi-experimental design, where the implementation of a given policy only impacts certain vaccines but not others, allowing us to distinguish between the treatment and control groups of vaccine types. In particular, four vaccines – diphtheria-tetanus (DT), diphtheria-pertussis-tetanus (DPT), measles-mumps-rubella (MMR), and oral poliovirus vaccine (OPV) – constitute our treatment group affected by the 1986 tort reform. Four other vaccines – hepatitis B and three variants of influenza – belong to the treatment group affected by Medicare's expanded coverage of vaccine products in 1984 and 1993. For each policy shock, our difference-in-differences (DID) specification compares the changes in production and investment outcomes of manufacturers producing the treated vaccine types against those producing the control vaccine types during the same pre- and post-policy shock periods.

Our DID estimates suggest that both types of policy interventions lead to a significant increase in vaccine production. However, the impact of Medicare coverage expansion can be 3–6 times greater than that of the tort reform with the gap widening over time. Additionally, vaccine development appears to only respond to Medicare coverage

expansion. Moreover, when analyzing subsamples by market structure, we observe that under the 1986 NCVIA tort reform, investment responses are limited to monopoly markets where consumers carry much of the excise tax burden. In contrast, under the 1984/93 Medicare coverage expansion, both monopolistic and oligopolistic firms are incentivized to invest, and the level of investment tends to increase with the intensity of product market competition.

A potential explanation for our findings lies in the interaction between the type of policy intervention and the underlying market structure. In particular, the tort reform can help lower affected manufacturers' liability and production costs and in turn present positive externalities on output and investment. However, such positive externalities are met with two offsetting channels, namely, uncertainty about future lawsuits and shared excise tax burden between manufacturers and consumers (Allcott and Rafkin 2022). Increased product market competition in an oligopolistic market may further reduce firms' profit margins and therefore disincentivize innovation. In contrast, while the expansion of Medicare's coverage of vaccine products also presents positive externalities on output and investment, it does not encounter as many opposing channels that can offset its impact on innovation. This in turn explains the divergent effects between the two types of policy interventions. Furthermore, most vaccine purchases are made by a few large institutional buyers, such as hospitals and the federal government, who prioritize vaccine quality. Expanded Medicare's coverage of vaccine products may further stimulate such concentrated demand, prompting manufacturers to emphasize quality competition and stimulate their R&D investment.

There are several unique aspects of our paper. Firstly, our study adds to a growing body of literature examining the link between tort reform, product liability, and innovation, such as the theoretical contribution of Henry, Loseto, and Ottaviani (2022) and empirical works of Galasso and Luo (2017), Galasso and Luo (2022) and Galasso and Luo (2024). Much of the existing literature in this strand tends to focus on innovation in medical devices and technologies. In contrast, our paper analyzes R&D investment in vaccine products, which present significant positive externalities and policy implications. Our finding regarding the limited innovation effect of a tort reform that eliminates product liability also helps inform the ongoing debate concerning the tradeoffs between regulation and litigation (e.g. Grennan and Town 2020; Philipson, Sun, and Goldman 2010; Rogers 2023, particularly in terms of the efficiency implications of preemption, which grants pharmaceutical companies immunity from state law lawsuits upon FDA approval.

Next, prior related studies tend to evaluate large-scale policy interventions that subsidize either firms or consumers (e.g. Cabral, Geruso, and Mahoney 2018; Danzon and Sousa Pereira 2011; Finkelstein 2004). For instance, similar to our paper, Finkelstein (2004) also considers the 1993 Medicare subsidy for co-payments of seasonal influenza vaccinations and documents an overall positive effect in boosting vaccine product development. Because of our unique dataset on vaccine production and development, our study departs from the existing literature by not only examining a broader set of outcome variables that capture firms' output, investment, and pricing decisions, but also contrasting the independent effects of policy shocks that affect firms' costs (e.g. through legal liability mitigation) versus those that influence consumers' willingness to pay (e.g. through direct subsidies). Indeed, our results indicate that the impact of a consumer subsidy policy on boosting vaccine production can be 3–6 times greater than that of a tort reform centered on liability protection.

Furthermore, our study explores how the interaction between the type of policy intervention and the underlying market structure shapes the effectiveness of government policies in stimulating firms' output and innovation. To our knowledge, this paper is the first to specifically examine this important channel that helps shed light on the long-standing puzzle of persistent supply shortages and limited innovation in the vaccine industry, despite extensive policy interventions and subsidies.

Lastly, our work contributes to the discussion on the relationship between competition and innovation as well as the broader literature on the effectiveness of incentive policies on innovation (e.g. Guerzoni and Raiteri 2015; Hall and Van Reenen 2000; Leahy and Neary 1997; Pindyck 1993). Aghion et al. (2005) document an inverted U-shaped relationship between innovation and competition for non-perishable goods. However, Goettler and Gordon (2011) argue that this relationship depends on industry characteristics that vary across sectors and over time, leading firms to reduce innovation as competition intensifies. Our results from the vaccine industry, on the other hand, suggest that the link may also depend on the types of policies implemented, with the relationship potentially decreasing (increasing) under policies prioritizing liability protections (consumer subsidies).

2. Institutional background and related literature

2.1. NCVIA tort reform

The 1970s and early 1980s saw a significant increase in civil litigation concerning vaccine injuries.[2] Combined with rising production costs and a relatively small market size compared to the therapeutic drug market, many vaccine manufacturers chose to exit the market (Manning 1996; Sloan and Hsieh 2007). By 1986, the market had dwindled to just one manufacturer for the polio vaccine, one for the measles-mumps-rubella vaccine, and two for the diphtheria-pertussis-tetanus vaccine (National Childhood Vaccine Injury Act 1986).

In response to concerns over vaccine shortages and their potential long-term economic and social impacts, the U.S. Congress enacted the National Childhood Vaccine Injury Act of 1986 to mitigate manufacturers' liability costs for childhood vaccines, such as DPT, MMR, DT, and OPV.[3] In particular, the NCVIA of 1986 established a federal administrative compensation program called the Vaccine Injury Compensation Program (VICP, or Vaccine Court). Located within the U.S. Court of Federal Claims, the VICP grants immunity to vaccine manufacturers from civil liability in cases where injuries resulting from vaccination were deemed unavoidable and provides a mechanism for consumers to file claims against the federal government for such unavoidable injuries (National Childhood Vaccine Injury Act 1986). Victims may sue manufacturers in civil courts only if the case has been appealed or if the injury was avoidable and caused by the manufacturer's negligence or willful misconduct.

The VICP is funded through a nominal excise tax on each vaccine dose sold (National Childhood Vaccine Injury Act 1986), a common approach to publicly financing injury compensation programs for specific products. Since liability immunity for manufacturers and subsequent victim compensation are tied to specific vaccine products, applying product-specific excise taxes means both manufacturers and consumers share the costs and avoids

the spread of financial burden to all taxpayers (Drake and Tieman 1994). Between 1988 and 1992, the per-dose excise tax amounted to $4.56 for DPT, $4.44 for MMR, $0.29 for OPV, and $0.06 for DT. Since 1993, the federal excise tax has remained at permanent nominal levels, and following the Taxpayer Relief Act of 1997, nominal excise tax rates for covered vaccine-preventable diseases have been reduced to $0.75 per dose (Thompson, Orenstein, and Hinman 2020). The revenue from the excise tax is deposited into the Vaccine Injury Compensation Trust Fund, which is then used to cover administrative expenses, attorney fees, and compensation for vaccine injury claims.

The tort reform and its associated excise tax represent a policy intervention designed to reduce manufacturers' liability costs from vaccine injury lawsuits while providing injured consumers with compensation through an administrative process. Depending on the magnitude of the offsetting effect from the excise tax, the combined impact of this policy shock on incentivizing for-profit vaccine manufacturers to remain in the market and continue producing critical childhood vaccines is theoretically ambiguous.

2.2. Medicare coverage expansion

The original Medicare statute, a federal health insurance program for individuals 65 or older and certain younger people with disabilities or specific health conditions, did not include coverage for preventive care. However, starting in 1981, Medicare Part B began fully reimbursing beneficiaries aged 65 and older for selected preventive vaccines, including pneumococcal disease.[4] Our study specifically focuses on the following two expansion episodes of Medicare vaccine coverage, including (1) the 1984 coverage of co-payments for hepatitis B vaccination for beneficiaries at high or intermediate risk,[5] and (2) the 1993 full coverage of seasonal influenza vaccination (MedPAC 2021).[6]

The expansion of vaccine coverage entails substantial public subsidies. For example, in 2019, Medicare Part B covered 16.6 million doses of seasonal flu vaccines, 3.9 million doses of pneumococcal vaccines, and 300,000 doses of hepatitis B vaccines, resulting in a total payment of nearly $1.4 billion (MedPAC 2021). Compared to the 1986 NCVIA tort reform, by subsidizing consumers of specific vaccine products and relieving manufacturers of the associated financial burden, the expansion episodes of Medicare's coverage present a more salient policy shock on the demand for vaccines.[7] We therefore posit that such a consumer subsidy policy would likely improve vaccine manufacturers' expected revenue and profit, in turn incentivizing firms to increase production and innovate. Indeed, Figure 1 presents preliminary evidence on the contrasting effects of the tort reform and the Medicare coverage expansion on the number of clinical trials for vaccines affected by each policy.

2.3. Related literature

Our study contrasts two types of policy interventions that offer distinct incentives for vaccine manufacturers and is most closely related to two strands of literature. First, a growing body of empirical literature examines the relationship between tort reform, product liability, and innovation. For example, Galasso and Luo (2017) study how state-level tort reforms that introduce caps on non-economic damages affect innovation in medical device technologies and find that such tort reforms are associated with a

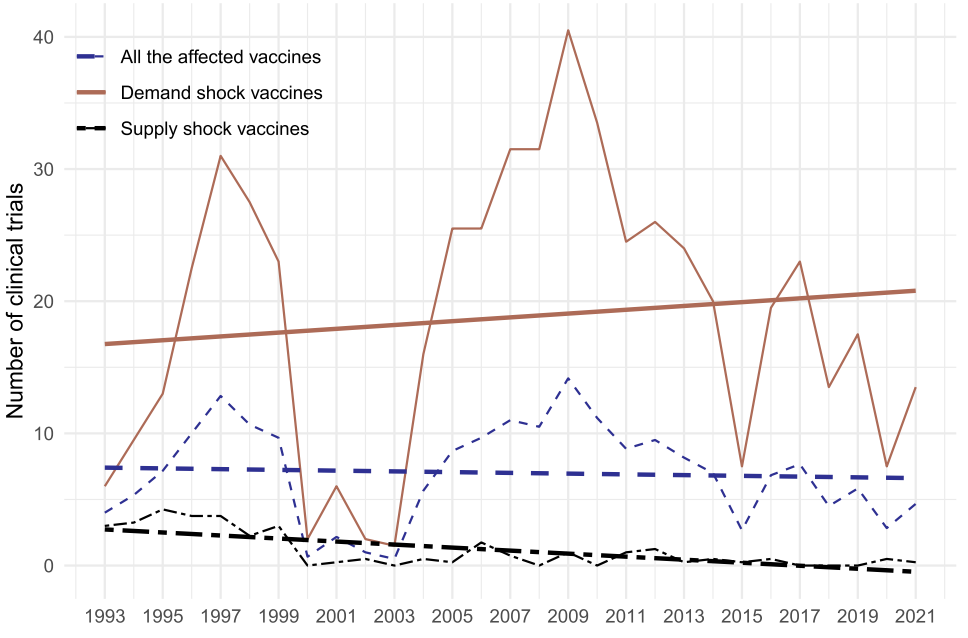

Figure 1. Vaccine investments: NCVIA tort reform vs. Medicare coverage expansion.

Note: The figure depicts the number of clinical trials for vaccines affected by each policy. The straight lines represent linear trends. The 'supply shock' refers to the enactment of the NCVIA of 1986, while the 'demand shock' refers to the expansion episodes of Medicare's coverage of vaccine products in 1984 and 1993.

significant decline in patenting, particularly in fields with a high risk of malpractice claims. Galasso and Luo (2022) show that increased liability risk for suppliers of polymers used in implants suppresses downstream innovation while leaving upstream patenting largely unaffected. Galasso and Luo (2024) find that product liability litigation reduces new product introductions and redirects innovation toward safer devices. In contrast to these existing studies that primarily focus on innovation in medical devices and technologies, our paper analyzes R&D investment in vaccine products, which present significant positive externalities and policy implications. Our finding regarding the limited innovation effect of a tort reform that reduces product liability also contributes to the ongoing debate over the tradeoffs between regulation and litigation (e.g. Grennan and Town 2020; Philipson, Sun, and Goldman 2010; Rogers 2023), particularly with respect to the efficiency implications of preemption, which grants pharmaceutical companies immunity from state law lawsuits upon FDA approval.

The other stream of literature closely related to our work concerns the impact of Medicare on innovation. Podemska-Mikluch (2018) provides an overview of this literature and argues that Medicare has driven major investments in hospital infrastructure, increased medical device patenting, and accelerated the diffusion of imaging technologies. As an example, Acemoglu and Finkelstein (2008) study the 1983 introduction of the Medicare Prospective Payment System (PPS), which shifted reimbursement from full to partial cost coverage and raised the relative price of labor for hospitals. They find that this reform encouraged the adoption of a range of new medical technologies, including

blood banks, open-heart surgery facilities, and CT scanners. Podemska-Mikluch (2018) further points out that Medicare's fee-for-service structure tends to promote the development of high-cost technologies while discouraging more disruptive, cost-effective innovations and experimentation in healthcare delivery.

Our study is akin to the seminal work by Finkelstein (2004), which investigates how public policies aimed at increasing vaccination rates affect vaccine innovation. Finkelstein (2004) finds that such policies can lead to a substantial rise in clinical trials and eventual approvals for vaccines targeting the affected diseases, although the resulting innovation is largely incremental, with limited impact on more fundamental advances. While the policy shocks that we examine, namely the 1986 NCVIA tort reform and the 1993 Medicare coverage expansion, overlap with some of those studied by Finkelstein (2004), our analysis extends this work by considering a broader set of outcome variables that capture vaccine manufacturers' output, investment, and pricing decisions. Furthermore, we explicitly contrast the production and innovation impacts of a consumer subsidy policy with those of a liability-reducing tort reform. More importantly, our study explores how the interaction between the type of policy intervention and the underlying market structure shapes the effectiveness of government policies in stimulating firms' output and innovation. To our knowledge, this paper is the first to specifically examine this important channel that can offer insight into the long-standing puzzle of persistent supply shortages and limited innovation in the vaccine industry, despite extensive policy interventions and subsidies.

3. Data and descriptive evidence

3.1. Sample construction

We collect data on vaccine output from the CDC Biologics Surveillance spanning from 1980 to 1995.[8] The data contain two key metrics reported by vaccine manufacturers: gross doses distributed and net doses distributed, which are the gross doses minus any returned doses. The CDC publication encompasses 25 types of vaccines. Four of these vaccines, including DT for children, DPT, MMR, and OPV, belong to our treatment group that is affected by the 1986 NCVIA tort reform. Meanwhile, four other vaccines, including hepatitis B and three variants of influenza, fall under the treatment group affected by the Medicare coverage expansions in 1984 and 1993. A full list of vaccine types as well as their treatment and control group assignments can be found in Table A1 in the Appendix.

Next, following Finkelstein (2004) and Yin (2008), we use the number of clinical trials, which represent the final and most expensive stage of vaccine development, as an indicator for product innovation.[9] Similar to Finkelstein (2004), we do not rely on patent approvals as a measure for innovation because a relatively low proportion of vaccine research is successfully patented. The vaccine clinical trial data are obtained from the NDA Pipeline, which is an annual paper-based publication by the FDA Development Corporation on drug products and clinical trials before 2002.[10] The database contains a 'Drug in Research' table that provides information, listed in alphabetical order by the manufacturer, on each clinical trial conducted. We manually extract the relevant information for each vaccine type and aggregate the counts across manufacturers to obtain the annual total number of clinical trials for each vaccine type.[11]

In addition, we obtain data on vaccine prices from two widely-used annual pharmaceutical catalogs, the American Druggist Blue Book and the Drug Topics Red Book. For each catalog, we calculate the price per dose for each vaccine product and take the average across all products belonging to the same vaccine type. We then take the average of the resulting prices from the two catalogs to determine the average wholesale price per dose per vaccine type in a given year. Each vaccine manufacturer is identified by a unique National Drug Code (NDC) assigned to each product, as reported in the drug catalogs.[12]

Product liability costs depend on the scale of production and consumption, as a higher volume of vaccine use increases the likelihood of injuries and, in turn, raises liability costs. As a result, cost savings stemming from the 1986 NCVIA tort reform can partially reduce marginal costs and increase profits, which can affect vaccine manufacturers' investment and production decisions. To measure product liability costs, we utilize Westlaw, a lawsuit database frequently used by legal scholars and practitioners, to extract information on vaccine-related private product liability lawsuits during our sample period. Additionally, we obtain publicly available data on VICP cases and compensation payments between 1988 and 1995 from the Public Access to Court Electronic Records (PACER).

To alleviate potential omitted variable concerns related to product characteristics, we incorporate controls for vaccine-related adverse events in our robustness checks because they could directly affect liability costs and investment decisions. These events, which can range from mild to severe reactions, vary across vaccine types and over time. We acquire data on annual vaccine-specific adverse events from the Vaccine Adverse Event Reporting System (VAERS), a federal database available since 1990, and from paper-based surveillance reports for years prior to 1990.

Lastly, we collect information on FDA approvals for each vaccine type from the electronic FDA Purple Book and the paper-based FDC Report. Data from these sources are cross-checked for accuracy by three independent pharmaceutical or medical experts. Monetary values are reported in nominal terms in most regression specifications, but we also obtain consistent results when converting to 1999 USD using the CPI inflator from the Bureau of Labor Statistics.

3.2. Summary statistics and data patterns

Table 1 presents the summary statistics for our main variables of interest, separated by the type of policy intervention.[13] All observations are at the vaccine type-year level. We find that vaccine types in the NCVIA tort reform sample appear to have fewer gross and net doses, fewer clinical trials, and lower prices compared to those in the Medicare expansion sample. They also tend to experience more adverse events and more lawsuits per vaccine type. Figure 2 further plots the evolution of our main variables of interest. All four variables exhibit a more consistent upward trend and a larger overall change during our sample period in the Medicare expansion sample (as shown in Panel B) compared to the NCVIA tort reform sample (as shown in Panel A).

As will be discussed in the next section, our empirical strategy follows a difference-in-differences design, and a key identification assumption is that vaccine types in the treatment and control groups follow similar pre-policy shock common trends across our outcome variables of interest. In Figure 3, we plot the average gross number of doses

Table 1. Summary statistics: regression sample.

	N	Mean	S.D.	Median	Min	Max
Panel A: NCVIA Tort Reform (1986)						
Gross number of vaccine doses	200	6.197	7.457	1.891	0	24.968
Net number of vaccine doses	200	6.056	7.347	1.791	0	24.474
Price per dose	227	10.920	10.241	8.886	0.268	57.630
Real price per dose	227	14.402	12.249	13.440	0.480	63.190
Clinical trials	240	0.379	1.003	0	0	6
Adverse events	186	420.361	860.918	29.500	0	4,253
Lagged lawsuits	240	0.620	2.791	0	0	27
Lagged FDA approvals	240	0.029	0.169	0	0	1
Lagged FDA trials	240	0.013	0.111	0	0	1
Number of firms	240	1.858	1.549	1	0	7
Panel B: Medicare Coverage Expansion (1984/93)						
Gross number of vaccine doses	197	4.982	9.412	0.611	0	63.116
Net number of vaccine doses	197	4.529	7.978	0.625	1.334	56.485
Price per dose	241	22.794	46.816	9.482	0.271	341.190
Real price per dose	241	29.254	54.105	13.570	0.480	392.880
Clinical trials	286	0.444	1.243	0	0	8
Adverse events	180	158.840	581.573	24	0	3,790
Lagged lawsuits	286	0.070	0.445	0	0	5
Lagged FDA approvals	286	0.038	0.193	0	0	1
Lagged FDA trials	286	0.021	0.166	0	0	2
Number of firms	286	1.626	1.373	1	0	7

Note: All observations are at the vaccine type-year level. The policy shocks are based on the enactment of the NCVIA of 1986 and the expansion episodes of Medicare's coverage of vaccine products in 1984 and 1993. *Lawsuits* refer to the number of lawsuits of each vaccine type each year. *Lagged FDA approvals* and *Lagged FDA trials* represent one-year lagged FDA approvals and trials, respectively, for each vaccine type.

and average price separately for the treatment and control groups of vaccine types for each of the policy samples. The solid red line indicates vaccines affected by the policy, and the dashed blue line shows vaccines not affected by the policy. Overall, we do not observe noticeable trend differences between the treatment and control groups of vaccines prior to either policy shock. This in turn provides suggestive visual evidence supporting the common trends assumption. In the next section, we detail our empirical strategy and present regression estimates that will further quantify the production and innovation effects of each policy intervention.

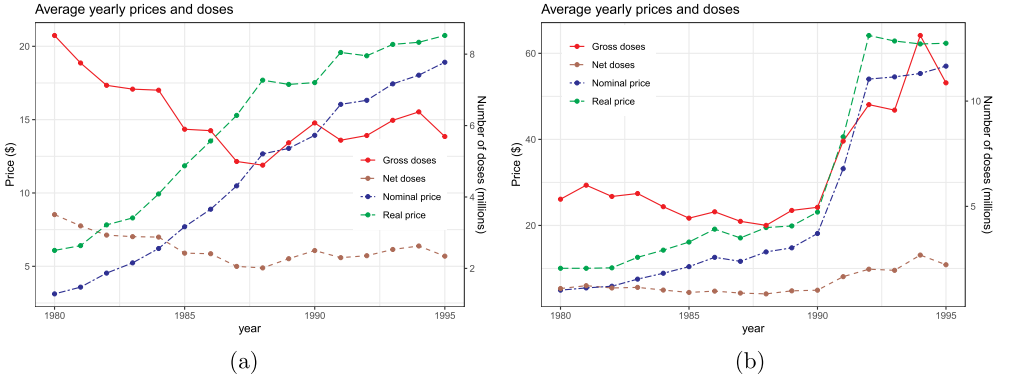

Figure 2. Evolution of vaccine quantity and price. (a) 1986 NCVIA Tort Reform and (b) 1984/93 Medicare Coverage Expansion.

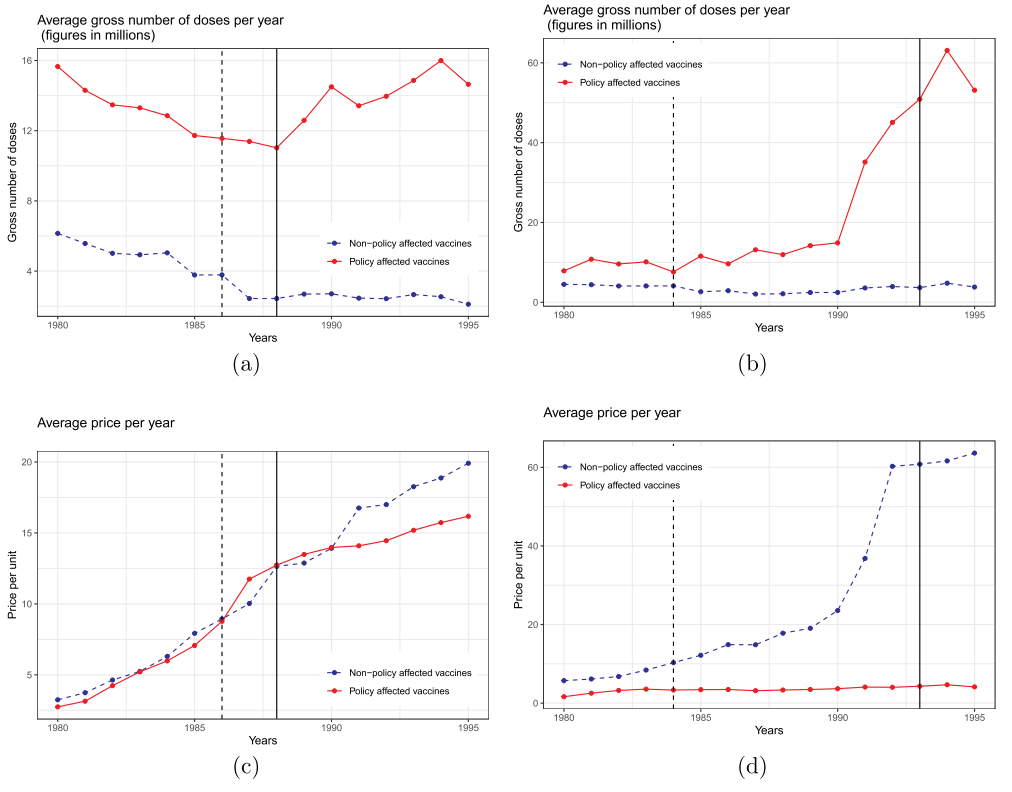

Figure 3. Vaccine quantity and price by treatment and control groups. (a) 1986 NCVIA Tort Reform: Quantity. (b) 1984/93 Medicare Coverage Expansion: Quantity. (c) 1986 NCVIA Tort Reform: Price and (d) 1984/93 Medicare Coverage Expansion: Price.

4. Production and innovation effects of tort reform and Medicare coverage expansion

4.1. Empirical strategy

To examine how vaccine manufacturers respond to the NCVIA tort reform and the Medicare coverage expansion, we follow Finkelstein (2004) and employ a DID design that compares changes in the production and investment decisions of manufacturers of treated vaccine types to those of manufacturers of control vaccine types over the same pre- and post-policy shock periods.[14] We separately estimate the following DID specification for each of the policy shock samples:

$$Y_{jt} = \alpha + \beta Adopt_{jt} + \delta X_{jt} + \gamma_j + \theta_t + \epsilon_{jt}, \tag{1}$$

where Y_{jt} represents the outcome variables for vaccine type j at time t, including gross doses produced, net doses produced, number of clinical trials, and nominal/real average vaccine prices. $\mathbf{X}_{jt}$ is a vector of vaccine-specific and time-varying covariates that could affect the quantity produced and vaccine prices, such as lagged number of lawsuits, number of adverse events, lagged clinical trials, and lagged clinical approvals. In particular, the numbers of lawsuits and adverse events are expected to dampen firms'

production, while the lagged clinical trials and FDA approvals are measures of firms' past investment efforts, which could be correlated with current investment.[15] γ_j and θ_t capture the vaccine type and year fixed effects, respectively. Standard errors are clustered at the vaccine type-level across all specifications.

$Adopt_{jt}$ is our main variable of interest that takes a value of one if the vaccine type belongs to the treatment group during the post-policy period. Specifically, for the NCVIA tort reform policy sample, *Adopt* equals one for the four vaccine types affected by the 1986 tort reform upon its implementation in 1988, including (1) DT (pediatric), (2) DPT, (3) MMR, and (4) OPV. Likewise, for the Medicare expansion sample, *Adopt* equals one if the affected vaccine is hepatitis B in or after 1984, or influenza (monovalent, bivalent, and trivalent) in or after 1993.[16] The coefficient on *Adopt*, β, therefore captures the change in manufacturers' production and investment decisions for the treated group of vaccines after the relevant policy was implemented, relative to the control group of vaccines within the same pre- and post-policy periods.

A potential endogeneity concern in our DID specification arises if the assignment of vaccines to the treatment group is correlated with unobserved factors that also influence production or investment outcomes. For example, if manufacturers anticipated the NCVIA tort reform or Medicare coverage expansion and adjusted their production or clinical trials before the policy implementation, this could violate the common trends assumption, leading to biased estimates of β. To address this, we formally assess whether treated and control vaccines follow similar pre-trends in Section 5.1. Additionally, we perform a randomness test of the tort reform and consider alternative control groups in Section 5.2 to further alleviate concerns about anticipatory behavior affecting our estimates.

One may also be concerned that vaccines in the treatment group may differ systematically from control vaccines in characteristics such as market size and growth potential. Our baseline DID specification already includes vaccine type and year fixed effects, along with vaccine-specific and time-varying covariates, $\mathbf{X}_{jt}$ which help partially address this issue. To further mitigating this concern, in Section 5.2, we also refine the control group to include vaccines from firms with manufacturing experience comparable to those in the treatment group.

Another consideration is that the vaccine industry has been subject to various other health policies of varying scales targeting different vaccine types. As a result, vaccines previously impacted by these policies could inadvertently be included in the control group, potentially exaggerating the long-term treatment effect on vaccine production and investment. To alleviate this issue, our control groups consist of vaccine types unaffected by other policies throughout our sample period as well as during the five years preceding and following it.[17]

4.2. Baseline results

Tables 2 and 3 report the estimates based on Equation (1) for the NCVIA tort reform and Medicare expansion samples, respectively. The dependent variables here include the number of gross doses produced (in millions), nominal price per dose, as well as the number of clinical trials conducted for each vaccine type.[18] Given the focus of our study, our discussion will center on the estimated coefficient on *Adopt*, which is a

Table 2. Impact of NCVIA tort reform on production, prices, and innovation.

	Gross doses (in millions)					Price per dose ($)					Clinical trials	
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
Adopt	3.730**	3.687**	3.691**	3.503**	3.511**	−1.408	−1.521	−1.637	−1.710	−1.776	1.366	1.402
	(1.655)	(1.630)	(1.631)	(1.634)	(1.640)	(3.949)	(3.957)	(3.904)	(3.987)	(3.937)	(0.905)	(0.946)
Lagged lawsuits		0.058	0.058	0.069	0.069		0.168	0.171	0.181*	0.181*		−0.053***
		(0.045)	(0.045)	(0.044)	(0.044)		(0.105)	(0.105)	(0.104)	(0.104)		(0.011)
Lagged FDA approvals			−0.072		−0.303			2.003		1.800		
			(1.091)		(1.013)			(1.268)		(1.376)		
Lagged FDA trials				2.056***	2.136***				2.371	1.891		
				(0.626)	(0.661)				(3.039)	(3.368)		
Observations	200	200	200	200	200	227	227	227	227	227	240	240

Note: All observations are at the vaccine type-year level. The policy shock is based on the enactment of the NCVIA of 1986. Vaccine type and year fixed effects are included in all specifications. Clustered standard errors at the vaccine-type level are in parenthesis. *$p < 0.1$; **$p < 0.05$; ***$p < 0.01$.

Table 3. Impact of Medicare coverage expansion on production, prices, and innovation.

	Gross doses (in millions)					Price per dose ($)					Clinical trials	
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
Adopt	19.888**	19.880**	20.197**	19.900**	20.275**	−22.918	−22.852	−24.368	−22.231	−23.880	3.224***	3.224***
	(9.944)	(9.889)	(9.780)	(9.944)	(9.783)	(19.598)	(19.458)	(19.812)	(19.343)	(19.545)	(0.217)	(0.216)
Lagged lawsuits		−0.510	−0.512	−0.509	−0.507		1.063	1.143	1.136	1.189		−0.047
		(0.647)	(0.659)	(0.641)	(0.652)		(2.025)	(2.028)	(2.097)	(2.094)		(0.066)
Lagged FDA approvals			−1.982***		−2.074***			9.392		9.017		
			(0.684)		(0.784)			(6.125)		(5.582)		
Lagged FDA trials				−0.172	−0.554				−4.958	−3.402		
				(0.910)	(0.983)				(9.554)	(8.871)		
Observations	197	197	197	197	197	241	241	241	241	241	286	286

Note: All observations are at the vaccine type-year level. The policy shock is due to the expansion episodes of Medicare's coverage of vaccine products in 1984 and 1993. Vaccine type and year fixed effects are included in all specifications. Clustered standard errors at the vaccine-type level are in parenthesis. $^{*}p < 0.1$; $^{**}p < 0.05$; $^{***}p < 0.01$.

dummy that equals one if a given vaccine type belongs to the treatment group during the post-policy shock period.

In Table 2, we observe that compared to the control group of vaccines, those vaccine types affected by the enactment of the NCVIA of 1986 experience a significant increase in the number of gross dosses produced by approximately 4 million doses per year. The tort reform also results in a negative and positive impact on the vaccine price and the number of clinical trials, respectively, but the corresponding estimates are not precisely estimated.[19]

Turning to Table 3, we find that manufacturers affected by the expansion of Medicare's coverage of vaccine products would significantly increase their vaccine production by as much as 20 million gross doses. We also document a significant increase in the average number of clinical trials by approximately 3 trials for vaccines in the treatment group. When comparing these estimated coefficients against their counterparts in Table 2, we find the differences to be statistically significant at the 1% level. This implies that compared to a tort reform that mitigates product liability, a consumer subsidy policy can lead to 3–6 times larger production and investment responses from vaccine manufacturers. Lastly, we continue to observe a negative price effect due to the expansion of Medicare's coverage, but the estimates are again not statistically significant.[20]

Overall, our baseline results establish a consistently positive effect of both policy interventions on the quantity of vaccines produced, with the magnitudes of the impact being significantly larger when responding to the Medicare coverage expansion. In addition, the Medicare coverage expansion also help stimulate vaccine investment as measured by the average number of clinical trials, which is consistent with the findings in Finkelstein (2004).

5. Robustness checks

In this section, we conduct a number of tests to assess the robustness of our baseline DID estimates, including verifying the common trends assumption, assessing the randomness of policy implementation timing, considering alternative control groups, estimating a dynamic panel model, and examining heterogeneity in short-term vs. long-term responses.[21]

5.1. Common trends assumption test

The key identification assumption behind our DID specification is that vaccine types in the treatment and control groups follow similar pre-policy common trends across our outcome variables of interest. While Figure 3 presents some preliminary visual evidence, we adopt a formal approach to further assess the validity of the common trends assumption. Specifically, following Abadie (2005) and Prince and Simon (2017), we test for conditional common trends by restricting our data to the period prior to the policy's effective date (i.e. using only the years preceding the implementation of the relevant policy intervention) and adding linear time trends (years) and their interaction with the *Adopt* dummy to our main DID specification. The resulting estimates on production outcomes, as presented in Table A5 in the Appendix, indicate that the coefficients on the interaction term

Adopt × *TimeTrend* are insignificant across all specifications and both policy shock samples. This suggests that vaccines in the treatment and control groups likely follow similar pre-policy shock time trends, lending support to the common trends assumption behind our DID specification.

5.2. Randomness test and alternative control groups

While the tort reform as a policy shock is less likely to raise endogeneity concerns compared to the Medicare coverage expansion, potential selection issues may still arise from control variables such as adverse events and FDA approvals. To mitigate this concern, we assess the randomness of the tort reform by estimating a linear probability regression on the likelihood of a given vaccine type being in the treatment group.[22] As shown in column 3 of Table A6 in the Appendix, the coefficients for all covariates in the full specification are not statistically significant, supporting the timing of the tort reform being plausibly exogenous.

Nevertheless, there could still be concerns that the vaccines in the treatment group may be systematically different from those unaffected by the tort reform. As an additional check, we therefore consider alternative ways to define the control group of vaccines. We report the resulting estimates in Table A7 in the Appendix.[23] In column(s) 1, to test for potential anticipation effects, we exclude years likely affected before the policy implementation: 1986 and 1987 for the tort reform sample, and 1990 for the Medicare expansion sample. In column(s) 2, we restrict the control group to vaccines produced by firms with manufacturing experience comparable to those in the treatment group, based on the number of years since the manufacturer's first recorded production through 1995. Thus, the control group comprises vaccines from manufacturers within 1.5 standard deviations of the treatment group's mean age, using the nearest neighborhood matching based on the characteristics of vaccines. This matching technique ensures that the treated and control vaccines are similar in terms of manufacturer's experience. Our findings remain consistent across both columns. In addition, the estimates from the tort reform sample remain unchanged when expanding the sample to include adult vaccines.

5.3. Dynamic panel specifications

It is possible that the effects of past vaccine production and clinical trials could affect current production and innovation outcomes. To account for this, one could control for past lags of gross doses and clinical trials and estimate a dynamic panel model. On the other hand, Nickell (1981) shows that when introducing lagged dependent variables as independent variables, the demeaning process in fixed effect models can potentially lead to biases as the demeaned error may still be correlated with the explanatory variables. A common solution found in the literature employs dynamic panel techniques, such as the Arellano-Bond (AB) GMM estimator (Arellano and Bond 1991). As another robustness check, we thus control for lagged dependent variables and estimate the corresponding dynamic panel specifications using the Arellano-Bond estimator. The results, as reported in Table A8 in the Appendix, are qualitatively similar to our baseline estimates in Tables 2 and 3.

5.4. Short-term vs. long-term effects

The output and innovation effects of policy shocks may vary over time. To explore this possibility, following Prince and Simon (2017), we assume that the policy interventions are permanent and adjust Equation (1) to distinguish between short-term and long-term effects. Specifically, we separately estimate the following DID model for each of the policy samples:

$$Y_{jt} = \alpha + \phi Adopt02_{jt} + \xi Adopt3_{+jt} + \delta X_{jt} + \gamma_j + \theta_t + \epsilon_{jt}, \quad (2)$$

where $Adopt02_{jt}$ is a dummy that denotes whether vaccine type j belongs to the treatment group and it is within two years after the relevant policy shock (i.e. 1987 and 1988 for the tort reform sample; 1985 and 1986, or 1994 and 1995, for the Medicare expansion sample). $Adopt3_{+jt}$ is a similarly defined dummy that denotes whether vaccine type j belongs to the treatment group and it is three years after the relevant policy shock (i.e. 1989 and after for the tort reform sample; 1987 and after for the Medicare expansion sample). The coefficients on *Adopt02* and $Adopt3_{+}$ thus respectively capture the short-term (2 years) and long-term (3+ years) impact of the policy shocks on vaccine manufacturers' production and investment decisions.

We report the estimated coefficients in Table 4 with Panels A and B focusing on each of policy intervention samples. In Panel A, we notice that while the overall patterns of the estimated coefficients are analogous to those reported in Table 2, only the coefficients on $Adopt3_{+}$ in the output response regressions are statistically significant. This implies that much of the quantity response to the 1986 NCVIA tort reform, as observed in Table 2, is likely driven by the long-term, rather than short-term, impact of the tort reform.

In Panel B, we again find the estimates to agree with those presented in Table 3 in terms of the overall directions and magnitudes. On the other hand, judging by the differences in the magnitudes of the coefficients on *Adopt02* and $Adopt3_{+}$, it also appears that the long-term impact of the Medicare coverage expansion becomes smaller for production responses but larger for investment responses, where the number of clinical trials almost doubles in the three years after the Medicare coverage expansion.

Taken together, we conclude that our baseline DID estimates are consistent and robust to a range of sensitivity tests, and the impact of the policy interventions may also depend on the time frame of the impact.

6. Heterogeneity by market structure

While data limitations do not allow us to fully parse the mechanisms at play, this section evaluates the underlying market structure as a potential explanation for our baseline findings. We first examine the heterogeneity of the production and innovation impact by market structure. Next, we present a simple conceptual framework that highlights the theoretical justifications for the differential investment incentives by market structure. We then offer some discussion to further connect the stylized empirical evidence with our theoretical framework.

6.1. Empirical evidence

It is worth noting that each of the treatment or control vaccine products in our sample features (time-varying) monopolistic or oligopolistic market structure. As will be discussed

Table 4. Robustness check: short-term vs. long-term effects.

	Gross doses (in millions)					Price per dose ($)					Clinical trials	
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
Panel A: NCVIA Tort Reform (1986)												
Adopt02	1.449	1.063	1.066	0.996	0.998	0.799	0.328	0.313	0.250	0.250	0.750	0.905
	(1.222)	(1.105)	(1.096)	(1.106)	(1.096)	(3.141)	(3.046)	(2.992)	(3.072)	(3.024)	(0.463)	(0.559)
$Adopt3_+$	4.530**	4.557**	4.568**	4.377**	4.390**	−2.144	−2.106	−2.261	−2.359	−2.451	1.572	1.559
	(1.994)	(1.982)	(2.000)	(2.024)	(2.040)	(4.569)	(4.562)	(4.517)	(4.610)	(4.566)	(1.098)	(1.087)
Lagged lawsuits		0.108**	0.108**	0.115**	0.116**		0.132**	0.132**	0.144**	0.142**		−0.043***
		(0.052)	(0.052)	(0.050)	(0.051)		(0.060)	(0.059)	(0.062)	(0.062)		(0.008)
Lagged FDA approvals			−0.183		−0.373			2.118		1.891		
			(1.077)		(1.030)			(1.293)		(1.403)		
Lagged FDA trials				1.689**	1.787**				2.659	2.165		
				(0.858)	(0.845)				(2.938)	(3.275)		
Observations	200	200	200	200	200	227	227	227	227	227	240	240
Panel B: Medicare Coverage Expansion (1984/93)												
Adopt02	24.858***	24.806***	24.882***	24.910***	25.048***	−24.258	−24.101	−24.600	−23.104	−23.887	2.313***	2.311***
	(9.422)	(9.371)	(9.391)	(9.310)	(9.257)	(19.281)	(19.012)	(19.198)	(19.146)	(19.138)	(0.330)	(0.329)
$Adopt3_+$	15.997**	16.026**	16.396**	16.057**	16.476**	−21.907	−21.911	−24.188	−21.587	−23.875	4.351***	4.352***
	(7.233)	(7.207)	(7.171)	(7.194)	(7.115)	(19.619)	(19.613)	(20.510)	(19.532)	(20.281)	(0.307)	(0.306)
Lagged lawsuits		−0.449	−0.454	−0.440	−0.440		1.051	1.139	1.125	1.188		−0.053
		(0.599)	(0.609)	(0.594)	(0.604)		(2.035)	(2.042)	(2.112)	(2.113)		(0.066)
Lagged FDA approvals			−1.508***		−1.643***			9.376		9.016		
			(0.496)		(0.537)			(6.250)		(5.699)		
Lagged FDA trials				−0.548	−0.840				−4.891	−3.401		
				(0.883)	(0.924)				(9.735)	(9.072)		
Observations	197	197	197	197	197	241	241	241	241	241	286	286

Note: All observations are at the vaccine type-year level. The policy shocks are based on the enactment of the NCVIA of 1986 and the expansion episodes of Medicare's coverage of vaccine products in 1984 and 1993. Vaccine type and year fixed effects are included in all specifications. Clustered standard errors at the vaccine-type level are in parenthesis. $^{*}p < 0.1$; $^{**}p < 0.05$; $^{***}p < 0.01$.

in the next section, different market structures may entail different investment incentives for the involved manufacturers. We thus divide our sample based on the underlying market structure and re-estimate the baseline DID specifications to examine how the effects of policy interventions might vary between monopolistic and oligopolistic vaccine product markets.

We report the results in Table 5. Panels A, B, and C correspond to specifications that respectively employ gross doses, price per dose, and number of clinical trials as the dependent variable. Across all specifications for the tort reform sample (i.e. columns 1–4), recall that *Adopt* equals one if the vaccine type is affected by the relevant policy and the year is after 1987. Analogously, *Adopt* for the Medicare expansion sample (i.e. columns 5–8) is a dummy variable that is equal one if the vaccine is hepatitis B and the year is after 1983 or if the vaccine is influenza and the year is after 1992.

The regression estimates in Table 5 reveal intriguing patterns with respect to market structure and firms' innovation incentives. In particular, we find that under the policy intervention due to the enactment of the NCVIA of 1986, monopoly manufacturers experience a statistically significant increase in clinical trials but such impact does not translate to gross doses or price per dose. Meanwhile, oligopoly markets do not appear to be affected by the tort reform. In contrast, we observe a much stronger effect on the number of clinical trials and gross doses in both monopoly and oligopoly markets following the expansion episodes of Medicare's coverage of vaccine products.

6.2. A simple conceptual framework

We now highlight a simple conceptual framework to motivate the observed empirical patterns outlined in the previous section. In Figures 4 and 5, we illustrate the theoretical justifications for the potential differential investment incentives between monopolistic and oligopolistic product markets following the 1986 NCVIA tort reform and the 1984/1993 Medicare coverage expansion, respectively.

Focusing on Figure 4, Panel (a) indicates that before the tort reform, monopoly profit is given by the light grey rectangle *abef*, which would incentivize the monopoly to invest in R&D. The tort reform reduces the manufacturer's liability costs and thus the marginal cost and average total cost, leading to an even bigger profit depicted in the dark grey rectangle *ghij*. In contrast, Panel (b) suggests that after the tort reform, the same-sized cost reduction would in fact lead to a negligible change in profit from *abef* to *ghij* in oligopoly markets, which may present inadequate incentives for the oligopoly to invest in new vaccine products. This prediction is consistent with our observation in Table 5 that only monopoly markets, not their oligopoly counterparts, appear to be affected by the enactment of the NCVIA of 1986.

To evaluate the impact of an equivalent sized policy shock due to the Medicare coverage expansion, we impose a same-sized vertical shift of the demand curve in Panels (a) and (b) of Figure 5 as that of the cost curves in Panels (a) and (b) of Figure 4. Panel (a) of Figure 5 suggests that monopoly profits will increase from the light grey area *abef* to the dark grey area *ghif* following the expansion of Medicare's coverage of vaccine products. Similar increases in profits also occur in oligopoly markets as illustrated in Panel (b) of Figure 5. In other words, policy shocks that target consumers' willingness to pay, such

Table 5. Heterogeneity by market structure.

	NCVIA Tort Reform (1986)				Medicare Coverage Expansion (1984/93)			
	Monopoly		Oligopoly		Monopoly		Oligopoly	
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
Panel A: Gross doses (in millions)								
Adopt	4.485	4.534	2.441	2.031	3.479***	3.790***	17.607	18.116
	(2.717)	(2.655)	(2.808)	(2.657)	(0.766)	(0.805)	(10.177)	(9.829)
Lagged lawsuits		0.313		−0.007		−0.213		−1.132
		(0.473)		(0.026)		(0.428)		(1.056)
Lagged FDA approvals		1.776***		−0.103		0.378		−2.154
		(0.505)		(1.120)		(0.620)		(1.681)
Lagged FDA trials		0.000		2.502**		−2.302		−1.124
		(.)		(0.897)		(1.912)		(1.991)
Observations	124	124	76	76	141	141	81	81
Panel B: Price per dose ($)								
Adopt	−0.371	−0.486	4.640	3.571	−6.121	−7.058	2.340	1.979
	(3.736)	(3.747)	(4.446)	(3.792)	(7.141)	(8.145)	(3.255)	(2.531)
Lagged lawsuits		0.100		0.199***		1.513		−0.295
		(0.553)		(0.049)		(2.782)		(0.903)
Lagged FDA approvals		-6.210**		2.131*		2.957		1.950
		(2.116)		(1.024)		(5.289)		(2.097)
Lagged FDA trials		0.000		2.335*		−1.336		5.059***
		(.)		(1.125)		(3.274)		(1.022)
Observations	147	147	80	80	184	184	92	92
Panel C: Clinical trials								
Adopt	0.798**	0.803**	2.004	2.084	2.896***	2.895***	3.550***	3.549***
	(0.318)	(0.330)	(1.865)	(1.988)	(0.187)	(0.189)	(0.309)	(0.314)
Lagged lawsuits		−0.046		−0.052**		0.017		−0.010
		(0.063)		(0.017)		(0.042)		(0.105)
Observations	160	160	80	80	194	194	92	92

Note: All observations are at the vaccine type-year level. The policy shocks are based on the enactment of the NCVIA of 1986 and the expansion episodes of Medicare's coverage of vaccine products in 1984 and 1993. Vaccine type and year fixed effects are included in all specifications. Clustered standard errors at the vaccine-type level are in parenthesis. $^{*}p < 0.1$; $^{**}p < 0.05$; $^{***}p < 0.01$.

as Medicare coverage expansion, will generate investment incentives in both monopoly and oligopoly markets, which is again consistent with our observation in Table 5.

Next, we consider several institutional features that help further strengthen the theoretical justifications above. As noted by Berk and DeMarzo (2016), firms base their investment decisions on the discounted expected profit of a potential investment, which is driven by (1) the size of discounted expected revenue and cost, and (2) the associated risk. For the purpose of our discussion, we will focus on the first factor in explaining why firms may have varying investment responses to policy shocks.

In our context, the difference in the expected revenue brought about by the consumer subsidies in 1984 and 1993, as opposed to the expected cost savings from the tort reform in 1986, can be attributed to differences in the target population sizes. The 1986 NCVIA tort reform targeted only 22–24 million children, whereas the 1984/93 Medicare coverage expansion focused on over 30 million elderly Medicare beneficiaries. Moreover, the population size of the latter group has grown even faster in subsequent decades due to a projected aging population (U.S. Census Bureau 2017). Such a trend is expected to widen the gap in expected revenue between the two types of policy interventions, resulting in even larger expected profits under the 1984/93 Medicare coverage expansion (as shown in Figure 5(a,b)) compared to those under the 1986 NCVIA tort reform (as shown in Figure 4(a,b)). This may further magnify firms' heterogeneous responses to the two types of policies.

Additionally, while the tort reform may have spurred innovation in vaccines, these vaccines were typically administered to children only once in their lifetime. On the other hand, vaccines affected by the 1984 and 1993 Medicare coverage expansion are administered universally to adults, and in some cases, even seasonally. Analogous to the discussion on innovation in durable vs. non-durable products (see Waldman 2003 for a review of related literature), this key difference in vaccine administration frequency may contribute to the widening disparity in anticipated revenue and, consequently, the incentives for innovation.

It is also worth noting that the effect of the excise tax may present an offsetting impact on the tort reform. This is because the burden of the excise tax shared by both firms and consumers would increase firms' expected tax costs, thereby offsetting the aforementioned increase in expected profits. As a result, there would be a negligible change in profits among oligopoly firms (as shown in Figure 4(b)) compared to a significant increase in profits among monopoly firms (as shown in Figure 4(a)). This could in turn discourage oligopoly firms from investing following the tort reform.

6.3. Discussion

Our baseline estimates and the subsample analysis by market structure deliver the following three key takeaways: (1) combining the tort reform with increased competition does not lead to increases in R&D investment, while (2) policy shocks due to the Medicare coverage expansion generally result in increased investment, and moreover, (3) combining the Medicare coverage expansion with more product market competition leads to even greater R&D spending. We detail below how the interaction between policy intervention and market structure, facilitated through the specific institutional features of the vaccine industry, can help guide our understanding of the potential mechanisms at play.

As outlined in Section 6.2, the tort reform may lower the affected manufacturers' costs and present positive externalities on innovation. However, the positive externalities are also met with two offsetting channels, including that (1) despite the liability immunity, there is still uncertainty about future lawsuits due to avoidable injuries or manufacturers' negligence; and (2) as discussed in Section 2.1, the tort reform is funded via an excise tax whose burden is borne by both consumers and manufacturers, which can lower firm's profitability and therefore dampen the incentives for innovation. Moreover, greater product market competition – for example, in an oligopoly rather than a monopoly – could further reduce a firm's profit margin and investment incentives. Our first main empirical takeaway regarding the impact of the tort reform can thus be traced back to the interaction of the saved costs and positive externalities from the tort reform against the offsetting channels of uncertainty, excise tax, and competition intensity.

While the expansion of Medicare's coverage of vaccine products also presents positive externalities on innovation and investment, it does not encounter as many counteracting factors that might dampen its influence on innovation. As such, our second empirical takeaway can be attributed to the increased demand and positive externalities from a consumer subsidy policy, similar to the impact of health policies analyzed in Finkelstein (2004).

Our third takeaway could be explained by concentrated demand and quality competition, as discussed in Danzon and Sousa Pereira (2011). Specifically, the demand side in

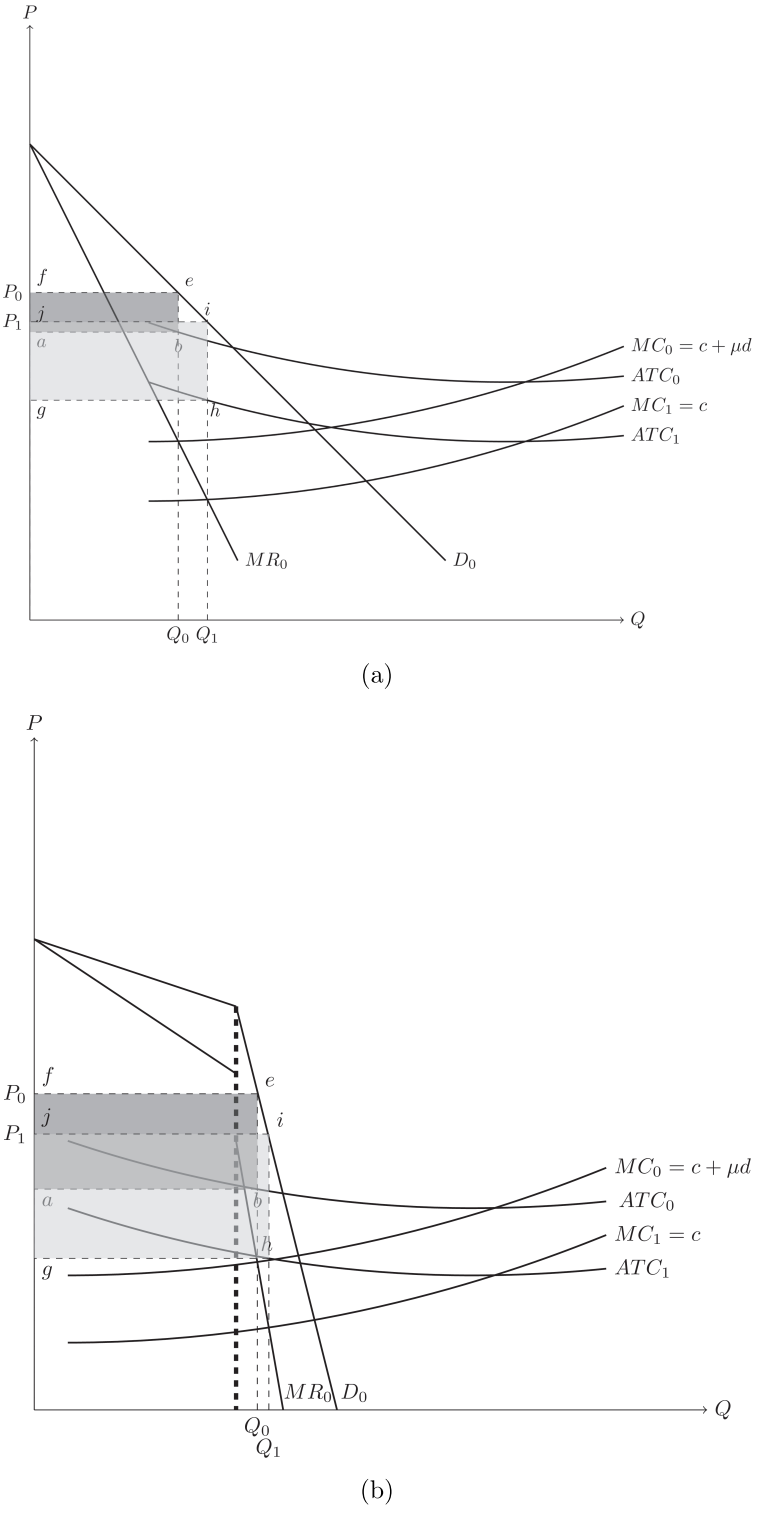

Figure 4. Policy shock and market structure: 1986 NCVIA tort reform. (a) Monopoly and (b) Oligopoly.

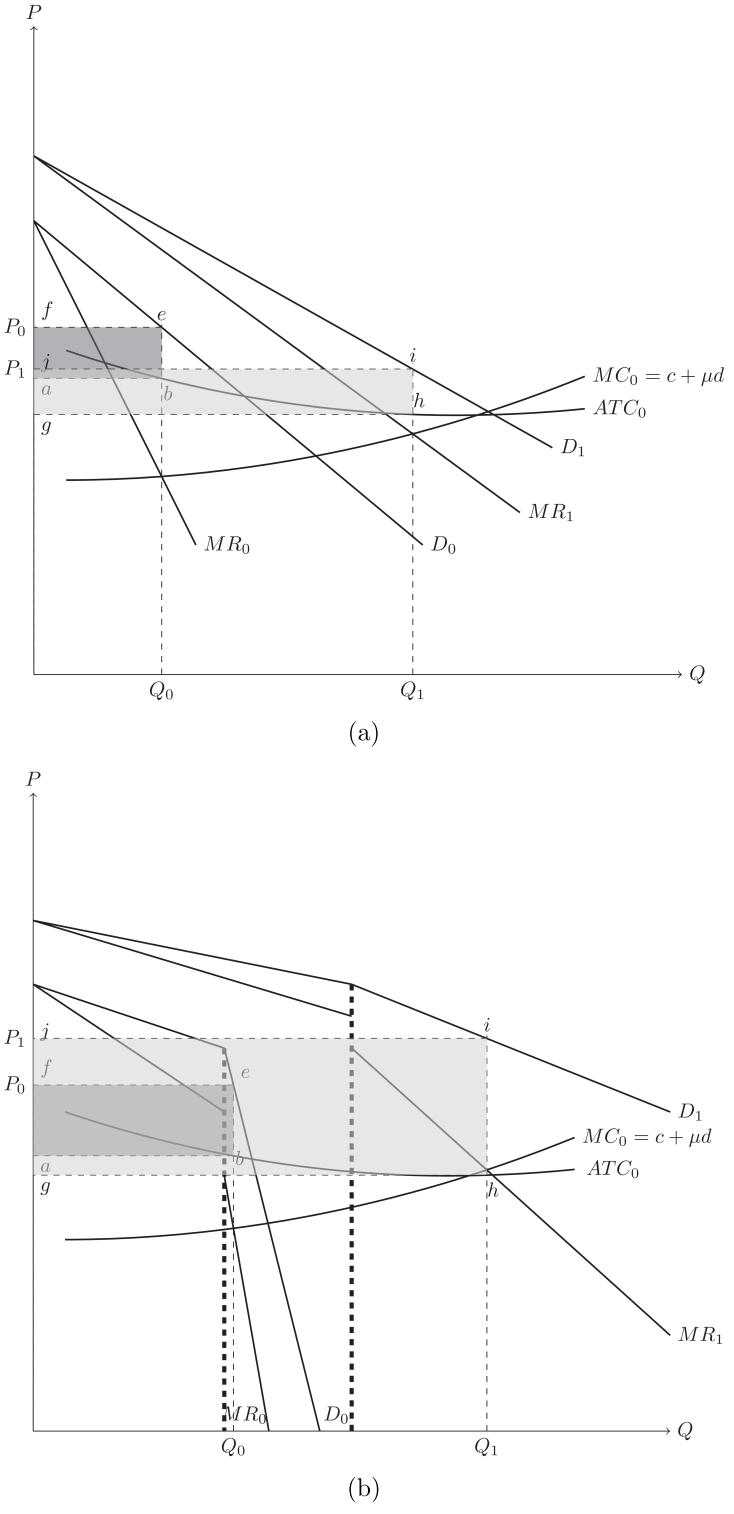

Figure 5. Policy shock and market structure: 1984/93 Medicare coverage expansion. (a) Monopoly and (b) Oligopoly.

our context primarily consists of institutional buyers, such as hospitals, vaccine distributors, and the federal government, who place a high value on vaccine quality. The expected increase in output due to the expanded Medicare's coverage of vaccine products would strengthen such concentrated demand and pressure producers to compete on quality. In the case of a monopoly when facing the Medicare coverage expansion, as discussed above, R&D investment would rise due to the increased firm value and the significant positive externality. On the other hand, under an oligopolistic market structure facing the same policy shock, firms may invest even more due to the large positive externality and the added pressure from quality competition. Despite the decrease in profit margins resulting from competition, investing in R&D and improving product quality would likely continue to represent a dominant strategy for those oligopolistic vaccine manufacturers.

Lastly, we notice that vaccine prices do not seem to respond to either policy intervention across all of our specifications. This could be attributed to the aforementioned theory of concentrated demand, where a small number of institutional buyers, such as the federal or local government, make most of the purchases. Consistent with Danzon and Sousa Pereira (2011), government purchasing contracts tend to lower vaccine prices. Therefore, while the Medicare coverage expansion may push up vaccine prices (e.g. via increased demand for vaccine products), this price impact could also be offset by the downward pressure created by large-scale government purchasing contracts. The lack of price responses thus also helps corroborate our theoretical justifications.

7. Conclusions

In this paper, we examine the impact of different policy interventions on vaccine manufacturers' investment and production decisions. By leveraging a unique manually compiled dataset on vaccine production and development, we analyze the effects of a tort reform that reduces manufacturers' product liability and a consumer subsidy policy via the Medicare coverage expansion that stimulates vaccine consumption. Our DID estimates suggest that both policies lead to a significant increase in vaccine production. However, we also find evidence that vaccine manufacturers are more likely to invest in R&D following the Medicare coverage expansion, and the effect is likely driven by the underlying market structure.

Considering the substantial positive externalities of vaccines, it is crucial to design an incentivizing policy that optimizes social welfare while also accounting for the distribution of the policy's social burden. To this end, our findings present several important policy implications. For one, the heterogeneous effects by market structure can help further our understanding of and potentially address the long-standing issue of vaccine underdevelopment. For example, we find that subsidizing firms via liability immunity generate fewer incentives for innovation, possibly due to the offsetting effects of greater uncertainty and tax incidence from excise taxes. In contrast, consumer subsidy policies tend to stimulate both output and R&D investments, particularly in markets with concentrated demand. This implies that subsidizing consumers could be more cost-effective than subsidizing firms via product liability protections. On the other hand, if the government continues to subsidize the supply side via liability protections, our results also imply that such a policy is more likely to be effective in a monopoly market than an oligopolistic one.

These insights are particularly relevant in light of recent congressional efforts to promote vaccine production and innovation by further strengthening manufacturers' liability protections (Lewis et al. 2020), and they may also help inform similar tort reforms aimed at mitigating product liability in other industries.

Our study opens up several avenues for future research. For instance, our analysis is largely descriptive and does not account for firms' endogenous entry and exit decisions as a result of policy interventions. Because the dynamics of entry and exit can help shape the competitive landscape of the industry, it remains important to distinguish whether investment decisions are directly affected by policy shocks, or whether they are indirectly influenced through changes in market structure. In addition, similar to Finkelstein (2004), our data are collected at the product-year level. The use of more granular firm-level data could thus help further uncover the output and innovation responses of individual firms to policy shocks, and we will leave this investigation to future research.

Notes

1. For instance, there have been major delays and shortages in producing seasonal influenza, hepatitis A, and COVID-19 vaccines, as discussed in Kremer and Snyder (2020) and reproduced in Figure A1 in the Appendix.
2. For example, between 1980 and 1984, three manufacturers of the DPT vaccine experienced a surge in the number of lawsuits filed against them, increasing from 4 to 73, with the average amount claimed per suit rising from $10.8 million to $46.5 million (Hinman 1986).
3. The legislation was subsequently expanded in 1995 to include additional childhood vaccines (e.g. human papillomavirus) and adult vaccines (e.g. seasonal influenza). To avoid potential confounding effects, we limit our sample period up to 1995.
4. Vaccines not covered under Part B are instead covered under Part D, a prescription drug plan. Whether a vaccine is covered by Part B or Part D of Medicare can have significant implications for access and health equity, e.g. vaccines covered under Part B typically feature lower out-of-pocket costs for beneficiaries compared to vaccines covered under Part D.
5. Note that the CDC also recommended in 1991 that all infants be vaccinated against Hepatitis B. Our results remain robust under two alternative scenarios: (1) treating the policy as occurring in 1991 by replacing the 1984 shock with the 1991 CDC recommendation; and (2) assuming that the 1984 policy was inactive after three years and reactivated in 1991.
6. Also note that since our sample period begins in 1980, we are not able to evaluate the 1981 Medicare coverage expansion for the pneumococcal vaccine.
7. It is worth pointing out that even with subsidies, consumers' actual uptake of vaccines may still be influenced by their behavioral biases and learning (Jin and Koch 2021).
8. Unfortunately, due to proprietary concerns, the publication of this data was discontinued after 1995.
9. In our study, the term 'development' refers to both the creation of new variants of existing products and the production of entirely new products. It is also worth pointing out that a company's investment in developing and innovating new vaccines may be evident in their research and development expenses. Nonetheless, as R&D expenses are proprietary information, they are not publicly accessible.
10. A more recent database on clinical trials is ClinicalTrials.gov published by the National Library of Medicine (https://clinicaltrials.gov/).
11. For seasonal influenza vaccines where the valence is not specified and for combined vaccines that are combinations of multiple vaccine types, there may be different approaches to counting their clinical trial numbers. One approach is to count a trial of a flu vaccine as a trial of each mono-, bi-, and tri-valent vaccine types, respectively (FA), or as no trial for each type (FN). Another method is to count a trial of a combined vaccine as a trial of each relevant

vaccine type, respectively (CA), or as no trial of each type (CN). As a result, there are four potential methods of counting the number of clinical trials, and we adopt the CN-FA approach in our study.

12. Table A2 in the Appendix presents a breakdown of our main outcome variables of interest by vaccine type and year.
13. We present additional summary statistics for our robustness check sample in Table A3 in the Appendix.
14. We exclude vaccine types from the control group if they were affected by other government policies and experienced any external shocks during the sample period.
15. As a robustness check, we also control for the number of firms for each vaccine type in a given year in our main specifications, and our results remain identical. We use the number of firms as a proxy for the intensity of competition within a vaccine type. However, due to potential endogeneity concerns, our preferred specifications exclude this variable from the set of controls. In addition, as shown in the summary statistics in Table 1 and Table A12 in the Appendix, the number of firms does not vary significantly over time, largely due to the extremely high fixed costs of vaccine production (Danzon and Sousa Pereira 2011), which supports our specification choice.
16. Note that we exclude the anthrax, diphtheria toxoid, and rabies vaccines from the control group for the 1986 NCVIA tort reform sample because they are intended exclusively for use in adults.
17. It is also possible that the effects of past vaccine production and clinical trials could affect current production and innovation outcomes. Section 5.3 presents a robustness check based on a dynamic panel model.
18. As a robustness check, we also estimate specifications using net doses produced and real price per dose as the dependent variables. The results based on these alternative production and price measures are presented in Table A4 in the Appendix, and we find them to be in line with our baseline results. Moreover, we re-estimate our specifications using the natural logarithm of gross doses as the dependent variable, and the results remain qualitatively similar to our baseline findings.
19. The estimates remain comparable when we control the adverse events instead of the number of lawsuits.
20. We should note that the results are qualitatively similar when we replace the 1984 shock with the 1991 CDC recommendation on vaccine usage and instead assume that the policy shock occurred in 1991. The corresponding estimates are reported in Table A9 in the Appendix. When we assume that the 1984 policy was inactive after 3 years and reactivated in 1991, the results are again comparable with caveat that in this case, the reference group for the second policy shock includes vaccines that were previously exposed to other shocks. These results are available upon request.
21. We also present a series of additional robustness checks in the Appendix, including considering alternative policy implementation years (Tables A9 and A10), adopting alternative control groups for the Medicare coverage expansion (Table A11), and accounting for the evolution of market structure (Table A12). We find our results to remain consistent.
22. Note that instead of vaccine-related lawsuits, we consider adverse events in the randomness check since, by definition, lawsuits can be correlated to the tort reform. We also perform the randomness test using a probit model and find the results to be comparable.
23. The summary statistics of the sample used in this robustness check is presented in Table A3 in the Appendix. Note that for the tort reform, which primarily targets childhood vaccines, we present results using two samples: a full sample that includes both adult and childhood vaccines, and a baseline sample restricted to childhood vaccines only. The results are consistent across both samples.

Acknowledgments

We are grateful to the editor and two anonymous referees for their insightful comments and suggestions. We thank Haizhen Lin, Ginger Zhe Jin, Andrew Sweeting, Byoung Park, and Marc Rysman

for constructive discussions and feedback. We also thank Shari Clifton, Hibah Malik, Victoria Jones, Elizabeth Wells, Aleeze Malik, and Steven Pan for data collection assistance.

Disclosure statement

No potential conflict of interest was reported by the author(s).

Funding

Myongjin Kim thanks financial support from Data Institute for Societal Challenges (DISC) and Oklahoma Aerospace & Defense Innovation Institute (OADII). Firat Demir thanks financial support from the Carnegie Corporation of New York (grant number, G-20-57642 and G-22-59079), the Fulbright Commission and Vilnius University for his Fulbright visit in spring 2022. Junying Zhao acknowledges support from the National Institutes of Health Grant (3U54GM104938), Presbyterian Health Foundation Grant (20221535) and University of Oklahoma. All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest or non-financial interest in the subject matter or materials discussed in this manuscript.

References

Abadie, A. 2005. "Semiparametric Difference-in-differences Estimators." *The Review of Economic Studies*72 (1): 1–19. https://doi.org/10.1111/0034-6527.00321.

Acemoglu, D., and A. Finkelstein. 2008. "Input and Technology Choices in Regulated Industries: Evidence from the Health Care Sector." *Journal of Political Economy* 116 (5): 837–880. https://doi.org/10.1086/595014.

Aghion, P., N. Bloom, R. Blundell, R. Griffith, and P. Howitt. 2005. "Competition and Innovation: An Inverted-U Relationship." *Quarterly Journal of Economics* 120 (2): 701–728.

Allcott, H., and C. Rafkin. 2022. "Optimal Regulation of E-Cigarettes: Theory and Evidence." *American Economic Journal: Economic Policy* 14 (4): 1–50.

Arellano, M., and S. Bond. 1991. "Some Tests of Specification for Panel Data: Monte Carlo Evidence and an Application to Employment Equations." *The Review of Economic Studies* 58 (2): 277–297. https://doi.org/10.2307/2297968.

Atwood, A. 2022. "The Long-Term Effects of Measles Vaccination on Earnings and Employment." *American Economic Journal: Economic Policy* 14 (2): 34–60.

Berk, J., and P. DeMarzo. 2016. *Corporate Finance*. 4th ed. Boston, MA: Pearson.

Cabral, M., M. Geruso, and N. Mahoney. 2018. "Do Larger Health Insurance Subsidies Benefit Patients or Producers? Evidence from Medicare Advantage." *American Economic Review* 108 (8): 2048–2087. https://doi.org/10.1257/aer.20151362.

Carpenter, C. S., and E. C. Lawler. 2019. "Direct and Spillover Effects of Middle School Vaccination Requirements." *American Economic Journal: Economic Policy* 11 (1): 95–125.

Cubanski, J., T. Neuman, and M. Freed. 2019. *The Facts on Medicare Spending and Financing*. San Francisco: Henry J. Kaiser Family Foundation.

Danzon, P. M., and N. Sousa Pereira. 2011. "Vaccine Supply: Effects of Regulation and Competition." *International Journal of the Economics of Business* 18 (2): 239–271. https://doi.org/10.1080/13571516.2011.584429.

Drake, B., and A. M. Tieman. 1994. "National Childhood Vaccine Injury Act of 1986: Using Tax Revenues to Assure Vaccine Availability." *Public Budgeting & Finance* 14 (2): 54–64. https://doi.org/10.1111/pbaf.1994.14.issue-2.

Finkelstein, A. 2004. "Static and Dynamic Effects of Health Policy: Evidence from the Vaccine Industry." *Quarterly Journal of Economics* 119 (2): 527–564. https://doi.org/10.1162/0033553041382166.

Galasso, A., and H. Luo. 2017. "Tort Reform and Innovation." *The Journal of Law and Economics* 60 (3): 385–412. https://doi.org/10.1086/694337.
Galasso, A., and H. Luo. 2022. "When Does Product Liability Risk Chill Innovation? Evidence from Medical Implants." *American Economic Journal: Economic Policy* 14 (2): 366–401.
Galasso, A., and H. Luo. 2024. "Product Liability Litigation and Innovation: Evidence from Medical Devices." National Bureau of Economic Research Working Paper No. 32215.
Goettler, R. L., and B. R. Gordon. 2011. "Does AMD Spur Intel to Innovate More?" *Journal of Political Economy* 119 (6): 1141–1200. https://doi.org/10.1086/664615.
Grennan, M., and R. J. Town. 2020. "Regulating Innovation with Uncertain Quality: Information, Risk, and Access in Medical Devices." *American Economic Review* 110 (1): 120–161. https://doi.org/10.1257/aer.20180946.
Guerzoni, M., and E. Raiteri. 2015. "Demand-Side Vs. Supply-Side Technology Policies: Hidden Treatment and New Empirical Evidence on the Policy Mix." *Research Policy* 44 (3): 726–747. https://doi.org/10.1016/j.respol.2014.10.009.
Hall, B., and J. Van Reenen. 2000. "How Effective Are Fiscal Incentives for R&D? A Review of the Evidence." *Research Policy* 29 (4–5): 449–469. https://doi.org/10.1016/S0048-7333(99)00085-2.
Henry, E., M. Loseto, and M. Ottaviani. 2022. "Regulation with Experimentation: Ex ante Approval, Ex post Withdrawal, and Liability." *Management Science* 68 (7): 5330–5347. https://doi.org/10.1287/mnsc.2021.4164.
Hinman, A. R. 1986. "DTP Vaccine Litigation." *American Journal of Diseases of Children* 140 (6): 528–530.
Hinman, A. R., W. A. Orenstein, J. M. Santoli, L. E. Rodewald, and S. L. Cochi. 2006. "Vaccine Shortages: History, Impact, and Prospects for the Future." *Annual Review of Public Health* 27 (1): 235–259. https://doi.org/10.1146/publhealth.2006.27.issue-1.
Jin, G. Z., and T. G. Koch. 2021. "Learning by Suffering? Patterns in Flu Vaccination Take-up." *American Journal of Health Economics* 7 (1): 68–94. https://doi.org/10.1086/711564.
Kremer, M., and C. M. Snyder. 2020. "Strengthening Incentives for Vaccine Development." *NBER Reporter* 4:7–11.
Leahy, D., and J. P. Neary. 1997. "Public Policy towards R&D in Oligopolistic Industries." *American Economic Review* 87 (4): 642–662.
Lewis, K. M., J. T. Lobert, W. W. Shen, and J. O. Shimabukuro. 2020. "COVID-19 Liability: Tort, Workplace Safety, and Securities Law." Tech. rep., Congressional Research Service.
Manning, R. L. 1996. "Is the Insurance Aspect of Producer Liability Valued by Consumers? Liability Changes and Childhood Vaccine Consumption." *Journal of Risk and Uncertainty* 13 (1): 37–51. https://doi.org/10.1007/BF00055337.
MedPAC. 2021. "Report to the Congress: Medicare and the Health Care Delivery System." Chapter 7: Medicare vaccine coverage and payment. Tech. rep.
National Childhood Vaccine Injury Act. 1986. "42 U.S.C. §§300aa-1–300aa-34".
Nickell, S. J. 1981. "Biases in Dynamic Models with Fixed Effects." *Econometrica* 49 (6): 1417–26. https://doi.org/10.2307/1911408.
Philipson, T. J., E. Sun, and D. Goldman. 2010. "The Effects of Product Liability Exemption in the Presence of the FDA." In *Regulation vs. Litigation: Perspectives from Economics and Law*, edited by D. P. Kessler, 137–164. Chicago: University of Chicago Press.
Pindyck, R. S. 1993. "A Note on Competitive Investment under Uncertainty." *American Economic Review* 83 (1): 273–277.
Podemska-Mikluch, M. 2018. "Understanding Medicare's Impact on Innovation: A Framework for Policy Reform." *Annals of Computational Economics*George Mason University, Mercatus Center, June. https://www.mercatus.org/research/research-papers/understanding-medicares-impact-innovation.
Prince, J. T., and D. H. Simon. 2017. "The Impact of Mergers on Quality Provision: Evidence from the Airline Industry." *The Journal of Industrial Economics* 65 (2): 336–362. https://doi.org/10.1111/joie.2017.65.issue-2.
Rogers, P. 2023. "Regulating the Innovators: Approval Costs and Innovation in Medical Technologies." Working Paper.

Sloan, F. A., and C.-R. Hsieh. 2007. *Pharmaceutical Innovation: Incentives, Competition, and Cost-Benefit Analysis in International Perspective*. Cambridge, UK: Cambridge University Press.

Thompson, K. M., W. A. Orenstein, and A. R. Hinman. 2020. "Performance of the United States Vaccine Injury Compensation Program (VICP): 1988–2019." *Vaccine* 38 (9): 2136–2143. https://doi.org/10.1016/j.vaccine.2020.01.042.

U.S. Census Bureau. 2017. "2017 National Population Projections Tables." Census.gov. Accessed March 12, 2023.

U.S. Government Accountability Office. 2021. "Vaccine Development Capabilities and Challenges for Addressing Infectious Diseases".

Waldman, M. 2003. "Durable Goods Theory for Real World Markets." *Journal of Economic Perspectives*17 (1): 131–154. https://doi.org/10.1257/089533003321164985.

Yin, W. 2008. "Market Incentives and Pharmaceutical Innovation." *Journal of Health Economics* 27 (4): 1060–1077. https://doi.org/10.1016/j.jhealeco.2008.01.002.