What Spurs Production and Innovation in the Vaccine Industry? Insights from Policy Interventions in the US*

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Abstract: This paper investigates the impact of supply- and demand-side policy interventions on firms' output and innovation. Leveraging a unique dataset on vaccine production and development, we evaluate the effectiveness of a tort reform, a supply-side policy intervention that reduces vaccine manufacturers' product liability, and a demand-side policy intervention, the expansion of Medicare coverage of select vaccine products. Our difference-in-differences analysis indicates that while both interventions result in significant increases in vaccine production, the impact of the demand-side policy can be 3-6 times greater in magnitude. There is also evidence suggesting that vaccine manufacturers are more likely to invest in R&D when facing the demand-side policy intervention, and the effect is likely driven by the underlying market structures.

Keywords: innovation; production; vaccine industry; market structure; policy intervention
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1 Introduction

The Covid-19 pandemic and ongoing geopolitical conflicts have led to significant disruptions in global supply chains and just-in-time production processes, including factory closures, transportation delays, labor shortages, production slowdowns, and trade disputes (see, for example, Helper and Soltas (2021)). Besides highlighting the vulnerability of global production and distribution networks, these disruptions also underscore the importance of enhancing supply chain resilience and increasing public and private investments in research and development (R&D) to mitigate the fallout (Parast, 2020). These concerns in fact echo longstanding queries posed by economists and policymakers alike on how to devise effective policies that can incentivize firm production and innovation in both short and long terms (Bown et al., 2022).

We contribute to these discussions by examining the output and investment effects of policy interventions that boost demand versus those that mitigate supply-side costs in the US domestic vaccine industry. We also explore how policy interventions interact with market structures and identify key factors that help promote the effectiveness of policies in stimulating production and innovation.

Vaccines offer substantial positive externalities. Besides the far-reaching impact on public health (Carpenter and Lawler, 2019), labor market outcomes, technological advancements, and economic growth (Atwood, 2022), the vaccine industry also presents an ideal empirical context to study the impact of government policies on firms' output and R&D investment. This is because the industry has historically been subject to various government regulations and policy interventions, including significant subsidies from both supply and demand sides,[1] aimed to boost vaccine production and development. Curiously, despite significant policy attention, vaccine supply shortages remain a longstanding concern for policymakers and health professionals in the US (Hinman et al., 2006; U.S. Government Accountability Office,

[1]According to Cleary et al. (2020), between 2000 and 2019, the NIH provided an average of $23 billion annually in funding directly or indirectly associated with the development of new drugs, representing approximately one-third of the annual R&D expenditures by pharmaceutical companies in the U.S.

2021). Recent events have brought this issue to the forefront and highlighted the urgency to evaluate policies that can effectively promote the production and distribution of vaccines.[2]

The puzzle of extensive policy support coexisting with persistent vaccine supply shortages may be explained by the inherent differences in incentives that supply- and demand-side policies offer to manufacturers, in turn affecting their effectiveness in boosting output and innovation. Recent congressional efforts, for example, have tried increasing liability protections, a supply-side intervention, to facilitate vaccine production and innovation (Lewis et al., 2020). Despite their potential cost-effectiveness in achieving similar objectives, demand-side policies, however, have received significantly less attention in recent policy discussions. For instance, Finkelstein (2004) documents that the consumer subsidy from Medicare for the copayment of seasonal influenza vaccination since 1993, a demand-side policy, has stimulated vaccine investments through increasing the number of clinical trials.

Rather than examining demand- and supply-side policies in isolation, our study evaluates large-scale policy interventions on both fronts and explores an understudied but important channel in stimulating production and innovation through the interaction between the types of policy interventions and market structures. Specifically, we analyze the supply-side policy shock due to the enactment of the National Childhood Vaccine Injury Act (NCVIA) of 1986, which became fully implemented in 1988 (National Childhood Vaccine Injury Act, 1986). This tort reform 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. The NCVIA funds compensation for vaccine injuries through an excise tax on vaccines, which is ultimately borne by the manufacturers and consumers of vaccines (Drake and Tieman, 1994; Thompson et al., 2020).

As for demand-side policies, starting in 1981, Medicare Part B provided full reimburse-

[2]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.

ment to beneficiaries aged 65 or older for certain preventive vaccines, such as those for pneumococcal disease. Our study focuses on 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 government revenue) and consumers (about 26% through Medicare Part B monthly premiums) (Cubanski et al., 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 coverage thus reflect salient policy shocks on the demand side 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 types of vaccines between 1980 and 1995. The data contain information on the number of gross and net doses distributed from the CDC Biologics Surveillance and each vaccine's clinical trial information from the NDA Pipeline. We employ a difference-in-differences (DID) design and exploit a quasi-experimental setup, where a given (supply- or demand-side) policy intervention impacts only specific vaccines, allowing us to distinguish between the treatment and control groups of vaccine types. More specifically, four vaccines – DT for children, DPT, MMR, and OPV – are in our treatment group impacted by the 1986 supply-side policy shock from the tort reform. Four other vaccines, including hepatitis B and three variants of influenza, fall under the treatment group affected by the demand-side policies due to Medicare's expanded coverage of vaccine products in 1984 and 1993.

Our DID design then 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 baseline estimates suggest that both policies lead to a significant increase in vaccine production. However, the impact of the demand-side policy can be 3-6 times greater than that of the supply-

side policy with the gap widening over time. Additionally, vaccine development appears to only respond to the demand-side policy. These results are robust to a range of sensitivity tests, including the common trends assumption test, randomness test, and alternative control groups. Moreover, when analyzing subsamples by market structures, we observe that under the 1986 supply-side policy, investment responses are limited to the monopoly market where consumers carry much of the excise tax burden. In contrast, under the 1984/93 demand-side policies, both monopolistic and oligopolistic firms are incentivized to invest, and the level of investment tends to increase with the intensity of product market competition.

We also explore the potential mechanisms at play by considering the interaction between the types of policy interventions and market structures. In particular, the tort reform (a supply-side shock) can lower affected manufacturers' costs and present positive externalities on investment and production. 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 could further reduce firms' profit margins and therefore incentives for innovation under the supply-side policy. In contrast, while the expansion of Medicare coverage on select vaccine products (a demand-side shock) also presents positive externalities on investment and production, it does not encounter as many opposing channels that may offset its impact on innovation, which in turn explains the divergent effects between supply- and demand-side policies. Furthermore, most vaccine purchases are made by a few large institutional buyers, such as the federal government and hospitals, who prioritize vaccine quality. Expanded Medicare vaccine coverage may further stimulate this concentrated demand, prompting manufacturers to emphasize quality competition and boost their R&D investment.

There are several unique aspects of our paper. Firstly, prior related studies tend to focus on the impact of either supply- or demand-side policy on R&D investments (e.g., Finkelstein 2004; Danzon and Sousa Pereira 2011; Cabral et al. 2018). Because of our unique dataset

on vaccine production and development, our study departs from the existing literature by evaluating large-scale policy interventions on both the supply and demand sides and by examining their differential effects on a broad range of outcome variables capturing firms' output, investment, and pricing decisions. Indeed, our results indicate that the magnitudes of the demand-side policies can be 3-6 times greater than those of the supply-side policies.

Next, our study explores the interaction between the types of policy interventions and market structures in explaining the effectiveness of (supply- and demand-side) policy interventions in stimulating firms' output and innovation. To our knowledge, this paper is the first to specifically examine this important channel that can help guide our understanding of the long-standing puzzle regarding the supply shortage and lack of innovation in the vaccine industry despite numerous government policy measures and subsidies.

Lastly, our work contributes to the discussion on the relationship between competition and innovation. 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 industries and over time, and they find that firms tend to innovate less when competition intensifies. Our results from the vaccine industry suggest that such a relationship may also depend on the types of policy interventions, e.g., we find a decreasing (increasing) relationship under supply-side (demand-side) policy interventions. Our paper thus also adds to the broader literature on the effectiveness of incentive policies on innovation (e.g., Pindyck 1993; Leahy and Neary 1997; Hall and Van Reenen 2000; Guerzoni and Raiteri 2015).

2 Institutional Background

2.1 National Childhood Vaccine Injury Act of 1986

The 1970s and early 1980s saw a significant increase in civil litigation related to vaccine injuries.[3] 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, only one manufacturer of the polio vaccine, one manufacturer of the MMR vaccine, and two manufacturers of the DPT vaccine remained, creating a significant public health risk (National Childhood Vaccine Injury Act, 1986).

In response to concerns about vaccine shortages and their potential long-term economic and social impacts, Congress enacted the National Childhood Vaccine Injury Act (NCVIA) of 1986 to mitigate manufacturers' liability costs for childhood vaccines, such as diphtheria-tetanus (DT), diphtheria-pertussis-tetanus (DTP), measles-mumps-rubella (MMR), and oral poliovirus vaccines (OPV).[4] More specifically, the NCVIA of 1986 established a federal administrative compensation program called the Vaccine Injury Compensation Program (VICP, or Vaccine Court). Located within the US 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 thus only sue manufacturers in civil courts if the dispute has been appealed or in cases of injuries that were avoidable and caused by the manufacturer's negligence or willful misconduct.

The VICP is funded via a nominal excise tax on each vaccine dose sold (National Childhood Vaccine Injury Act, 1986), a commonly used means for publicly financing injury com-

[3]For example, between 1980 and 1984, three manufacturers of the DTP 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).

[4]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.

pensation programs for specific products. Given that liability immunity for manufacturers and subsequent victim compensation are product-specific, using (product-specific) excise taxes ensures that both manufacturers and consumers bear the cost, rather than distributing the burden across all taxpayers, including those who do not consume the product in question (Drake and Tieman, 1994). From 1988 to 1992, this excise tax amounted to $4.56 for DPT, $4.44 for MMR, $0.29 for OPV, and $0.06 for DT vaccines sold, and since 1993, the federal excise tax has remained at permanent nominal levels (Thompson et al., 2020). Additionally, following the passage of the Taxpayer Relief Act of 1997, nominal excise tax rates for covered vaccine-preventable diseases have been reduced to $0.75 per dose (Thompson et al., 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.

Taken together, the duo of the tort reform and the associated excise tax presents a supply-side policy intervention to reduce manufacturers' vaccine injury lawsuits and the associated liability costs while protecting injured consumers through administrative compensation. Depending on the magnitude of the offsetting effect from the excise taxes, there is an ambiguous combined impact of this policy shock on incentivizing for-profit vaccine manufacturers to remain in the business and continue producing critical childhood vaccines.

2.2 Expanded Medicare Coverage on Vaccine Products

The original statute of Medicare, a federal health insurance program that provides health coverage to people who are 65 or older, as well as to certain younger people with disabilities or specific health conditions, did not include coverage of preventive care, but Congress has since amended it to include coverage of various vaccines. Beginning in 1981, Medicare Part B began to fully reimburse beneficiaries aged 65 or older for specific preventive vaccines, including pneumococcal disease.[5] Our study specifically focuses on the following two expan-

[5]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

sion episodes of Medicare vaccine coverage, including 1) the 1984 coverage of co-payments for hepatitis B (HBV) vaccination for beneficiaries at high or intermediate risk,[6] and 2) the 1993 full coverage of seasonal influenza vaccination (MedPAC, 2021).[7]

The expanded vaccine coverage unsurprisingly involves significant 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 NCVIA of 1986 that acts as a supply-side policy intervention, by significantly subsidizing consumers of specific vaccine products and freeing the manufacturers from bearing the financial burden, the expansion episodes of Medicare coverage thus present salient policy shocks on the demand side.[8] We therefore posit that such demand-side shocks would improve vaccine manufacturers' expected revenue and profit, in turn incentivizing firms to increase production and innovate. Indeed, Figure 1 presents some preliminary visual evidence illustrating the contrasting effects of supply- and demand-side policies on innovation, as indicated by the number of clinical trials.

3 Data and Descriptive Evidence

3.1 Sample Construction

We collected data on vaccine output from the CDC Biologics Surveillance spanning from 1980 to 1995.[9] 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

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.

[6]Note that the Centers for Disease Control and Prevention (CDC) also recommended in 1991 that all infants be vaccinated against Hepatitis B. Our results are quantitatively and qualitatively similar in both scenarios: 1) we assume the policy took place in 1991 and replace the 1984 shock with the 1991 CDC recommendation shock; 2) we assume that the 1984 policy turns off after 3 years and back on in 1991.

[7]Also note that since our sample period begins in 1980, we could not evaluate the 1981 Medicare policy for pneumococcal vaccine.

[8]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).

[9]Unfortunately, the publication of this data was discontinued after 1995 due to proprietary concerns.

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 supply-side policy intervention due to the enactment of the NCVIA. Meanwhile, four other vaccines, including hepatitis B and three variants of influenza, fall under the treatment group affected by the 1984 and 1993 demand-side policies due to Medicare's expanded coverage of vaccine products. 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 vaccine clinical trials, which represent the final and most expensive stage of vaccine development, as an indicator for innovation.[10] Similar to Finkelstein (2004), we do not rely on patent approvals as a measure of innovation because a relatively low proportion of research in vaccines 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.[11] 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 extracted the relevant information for each vaccine type and aggregated the counts across manufacturers to obtain the annual total number of clinical trials for each vaccine type.[12]

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

[10]In our study, the term "development" encompasses the creation of new variants of existing products as well as 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 (R&D) expenses. Nonetheless, as R&D expenses are proprietary information, they are not publicly accessible.

[11]A more recent data source on clinical trials is the federal clinical trial electronic database (`https://clinicaltrials.gov/`).

[12]When it comes to clinical trials 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 trial numbers. One approach is to count a trial of such 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 trials, and we adopt the CN-FA approach in our study.

catalog, we calculate the price per dose of 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 per year. Moreover, the drug catalogs report a unique National Drug Code (NDC) for each product, which we use to identify the corresponding manufacturer.

The costs associated with product liability depend on the number of products produced and consumed, as an increase in production and consumption of a vaccine raises the probability of injuries occurring, in turn increasing the liability costs. As a result, cost savings stemming from the 1986 tort reform can partially reduce marginal costs and increase profits, which may affect the investment and production decisions made by firms. To measure product liability costs, we use 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 from the Public Access to Court Electronic Records (PACER) for the years 1988-1995.

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 vaccine injury-associated 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 that has been available since 1990, and from paper-based publications on adverse events following immunization surveillance for years prior to 1990.

Lastly, we collected information on FDA approvals for each vaccine type from two sources: the electronic FDA Purple Book and the paper-based FDC Report. All data from these sources were entered and cross-checked for accuracy by three independent pharmaceutical or medical experts. Monetary values are primarily reported in nominal terms in most re-

gressions, but we also obtain consistent results when adjusting to 1999 USD using the CPI inflation calculator 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 nature of the policy intervention.[13] All observations are at the vaccine type-year level. We find that vaccine types in the supply-side policy sample appear to have fewer gross and net doses, fewer clinical trials, and lower prices compared to those in the demand-side policy sample. They also tend to experience more adverse events and more lawsuits per vaccine type than their counterparts in the demand-side policy sample. 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 demand-side policy sample (as shown in Panel B) compared to the supply-side policy 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 and average price separately for the treatment and control groups of vaccine types for each of the supply- and demand-side policy samples. The solid red line represents policy-affected vaccines, while the dashed blue line represents non-policy-affected vaccines. Additionally, the dashed vertical line indicates the year 1986 as the effective year for the policy, while the solid vertical line indicates the year 1988 as the effective time for the policy. Overall, we do not observe noticeable trend differences between the treatment and control groups of vaccines prior to either the supply-side or demand-side policy shock. This in turn provides preliminary visual evidence supporting the common trends assumption. In the next section, we detail our em-

[13] We present additional summary statistics for our robustness check sample in Table A2 in the Appendix.

pirical strategy and present regression estimates that will further quantify the production and investment impact of supply- and demand-side policy interventions.

4 Impact of Supply- and Demand-Side Policies on Vaccine Output and Development

4.1 Empirical Strategy

To examine how vaccine manufacturers respond to policy interventions, in the form of a tort reform affecting the supply side and a Medicare subsidy affecting the demand side, we follow Finkelstein (2004) and employ a DID design that exploits a quasi-experimental setup, where a given (supply- or demand-side) policy intervention impacts only specific vaccines, allowing us to distinguish between the treatment and control groups of vaccine types. Our DID design compares the changes in production and investment decisions of manufacturers producing the treated vaccine types against those producing the control vaccine types during the same pre- and post-policy shock periods.[14] Specifically, we separately estimate the following DID specification for each of the supply- and demand-side policy 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

[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.

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. To account for the possible correlation of standard errors over time for each vaccine type, we include clustered standard errors by vaccine types 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 intervention period. More specifically, for the supply-side policy sample, *Adopt* assigns a value of one for the four vaccine types that were affected by the 1986 policy upon its implementation in 1988, including 1) Diphtheria and Tetanus Toxoid (pediatric),2) Diphtheria and Tetanus Toxoid with Pertussis, 3) Measles, Mumps, Rubella, and 4) Poliomeylitis Vaccine, Live, Oral. Likewise, for the demand-side policy sample, *Adopt* equals to one if the affected vaccine is hepatitis B in or after 1984; or Influenza Virus Vaccine (Monovalent), Influenza Virus Vaccine (Bivalent), and Influenza 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 concern with our empirical design 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

[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. The number of firms serves as a proxy for competition intensity within a vaccine type. But because of potential endogeneity concerns, our preferred specifications do not control for the number of firms. In addition, as shown in the summary statistic Table 1 and Table A7 in the Appendix, the number of firms do not significantly vary over time due to the extremely high fixed cost (Danzon and Sousa Pereira (2011)). This supports our specification choices.

[16] Note that the control group of vaccines for the 1986 supply-side policy shock includes the following eleven vaccine types: Measles, Measles/Rubella, Meningococcal, Mumps, Mumps Rubella, Pertussis, Polio Inactivated, Rubella, Smallpox Vaccine, Tetanus and Diphtheria Toxoid (Adult), Tetanus Immune Globulin (Human), and Tetanus Toxoid. The control group of vaccines for the demand-side policy shocks include all the aforementioned vaccine types, as well as Anthrax, Diphtheria Toxoid, and Rabies, which we exclude from the control group for the 1986 policy sample because they are intended exclusively for use in adults.

production and investment. To alleviate this concern, our control groups comprise vaccine types that were not affected by other policies during our sample period, as well as five years before and after that period.

4.2 Baseline Results

Tables 2 and 3 report the estimates based on Equation (1) for the supply-side and demand-side policy 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.[17] Given the focus of our study, our discussion will center on the estimated coefficient on *Adopt*, which is a 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 supply-side policy intervention 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.[18]

Turning to the demand-side policy sample in Table 3, we find that compared to the control group, manufacturers affected by the expansion episodes of Medicare coverage on 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 supply-side policy shock, the

[17] As a robustness check, we also estimate specifications using net doses produced and real price per dose as dependent variables. The results based on these alternative production and price measures are presented in Table A3 in the Online Appendix, and we find them to be in line with our baseline results.

[18] The estimates are qualitatively the same and quantitatively similar when we control the adverse events instead of the number of lawsuits.

demand-side policy shock can lead to 3-6 times larger production and investment responses from vaccine manufacturers. Lastly, we continue to observe a negative price effect in the demand-side policy sample, but the estimates are again not statistically significant.[19]

Overall, our baseline results establish a consistently positive effect of both the demand-side and supply-side policies on the quantity of vaccines produced, with the magnitudes of the impact being significantly larger when responding to demand-side interventions. In addition, the demand-side policies 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 perform a range of robustness checks on our baseline DID estimates, including the common trends assumption test, randomness test, alternative control groups, and heterogeneity by short-term vs. long-term responses.[20]

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 intervention 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.,

[19] We should note that the results are qualitatively similar if we replace the 1984 shock with the 1991 CDC recommendation on vaccine usage and instead assume the policy shock took place in 1991. The corresponding estimates are reported in Table A4 in the Appendix. When we assume that the 1984 policy turns off after 3 years and back on in 1991, the results are again comparable with caveat that the reference group for the second policy shock, in this case, includes vaccines that were previously exposed to other shocks. These results are available upon request.

[20] We also present a series of additional robustness checks in the Appendix, including considering alternative policy implementation years (Tables A4 and A5), adopting alternative control groups for demand-side policies (Table A6), and accounting for the evolution of market structures (Table A7). We find our results to remain consistent.

using only the years preceding the implementation of the supply- or demand-side policy) 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 4, indicate that the coefficients on the interaction term $Adopt \times TimeTrend$ are insignificant across all specifications and both samples of policy shocks. 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 there may be less endogeneity concern regarding the tort reform as the source of a supply-side policy shock, there could be a potential selection issue related to the set of control variables such as adverse events and FDA approvals, unlike the demand-side policy intervention. 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.[21] In Table 5, the estimates from the full specification in column (3) suggest that the timing of the policy appears relatively random, 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 6.[22] In column(s) (1), to test for any potential anticipation of the policy by vaccine manufacturers, we omit years possibly impacted pre-policy: 1986 and 1987 for the supply-side policy sample, and 1990 for the demand-side policy sample. In column(s)

[21] We also perform the randomness test using a probit model and find the results to be comparable. The probit estimates are available upon request. Note that instead of vaccine-related lawsuits, we consider adverse events in the randomness check since lawsuits can be correlated to the tort reform by definition.

[22] The summary statistics of the sample used in this robustness check is presented in Table A2 in the Appendix. Note that for the supply-side policy that primarily focuses on childhood vaccines, we present results from both a full sample incorporating adult vaccines and a baseline sample with just childhood vaccines. The results remain consistent regardless of the sample chosen.

(2), we narrow the control group to vaccines produced by firms with similar manufacturing experience as those in the treatment group. We measure this experience by the firm's age, defined as the years from its first evidence of production until 1995. That is, the control group includes vaccines from firms within 1.5 standard deviations of the treatment group's mean age. This matching technique ensures that the treated and control vaccines are similar in terms of manufacturing age. Our findings remain consistent across both columns. Moreover, the estimates from the supply-side policy sample remain unchanged when expanding the sample to include adult vaccines.

5.3 Short-Term vs. Long-Term Effects

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

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

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 supply-side policy sample; 1985 and 1986, or 1994 and 1995, for the demand-side policy 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 supply-side policy sample; 1987 and after for the demand-side policy 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 7 with Panels A and B focusing on the supply-side and demand-side policy samples, respectively. 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 from the supply-side policy shock, as observed in Table 2, is likely driven by the long-term, rather than short-term, impact of the supply-side policy intervention.

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 demand-side policy shocks becomes smaller for production responses but larger for investment responses, where the number of clinical trials almost doubles in the three years after the expansion of the Medicare coverage on selected vaccine products.

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

6 Potential Mechanisms

In this section, we assess the potential mechanisms underlying our baseline findings. We first examine the heterogeneity of the production and innovation impact by market structures. Next, we present a simple conceptual framework that highlights the theoretical justifications for the differential investment incentives by market structures. We then offer some discussions to further connect the stylized empirical evidence with our theoretical framework.

6.1 Role of Competition: Empirical Evidence

Each of the treatment or control vaccine products in our sample features (time-varying) monopolistic or oligopolistic market structures. As will be discussed in the next section, different market structures may entail different investment incentives for the involved manufacturers. We thus separate our sample by market structures and re-estimate the baseline DID specifications to examine whether and how the impact of supply- and demand-side policy interventions may differ between monopolistic and oligopolistic vaccine product markets.

We report the resulting estimates in Table 8. 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 supply-side shock sample (i.e., columns 1-4)), recall that *Adopt* equals to one if the vaccine type (Diphtheria and Tetanus Toxoid (pediatric); Diphtheria and Tetanus Toxoid with Pertussis; Measles, Mumps, Rubella; or Poliomeylitis Vaccine, Live, Oral) is affected by the relevant policy and the year is after 1987. Analogously, *Adopt* for the demand-side policy shock sample (i.e., columns 5-8) is a dummy variable that is equal to one if the vaccine is hepatitis B and the year is after 1983 or if the vaccine is Influenza Virus Vaccine (Monovalent), Influenza Virus Vaccine (Bivalent), or Influenza, Trivalent and the year is after 1992. All specifications include vaccine and time-fixed effects with standard errors clustered by vaccine types.

The results, as presented in Table 8, reveal intriguing patterns with respect to market structures and firms' innovation incentives. Specifically, we find that under the supply-side 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 supply-side policy. In contrast, the demand-side policy interventions following the expansion episodes of Medicare coverage of vaccine products present a much stronger effect on the number of clinical trials and gross doses in both monopoly and oligopoly markets.

6.2 Role of Competition: A Simple Conceptual Framework

We now present a simple conceptual framework to motivate the observed empirical patterns as 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 supply-side and the 1984/1993 demand-side policy interventions, respectively.

Focusing on Figure 4, Panel A indicates that before the supply-side policy shock, 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 as 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 8 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 demand-side policy shock, 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 following the demand-side shock due to the expansion episodes of Medicare coverage on vaccine products, monopoly profits will increase from the light grey area $abef$ to the dark grey area $ghif$. Similar increases in profits also occur in oligopoly markets as illustrated in Panel B of Figure 5. In other words, the demand-side policy shocks will generate investment incentives in both monopoly and oligopoly markets, which is again consistent with our observation in Table 8.

Next, we consider several institutional features of our empirical context that help further strengthen the theoretical justifications above. As highlighted 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 demand subsidies in 1984 and 1993, as opposed to the expected cost savings from the supply-side policy shock in 1986, can be attributed to differences in the target population sizes. The 1986 policy targeted only 22-24 million children, whereas the 1984/93 policies targeted over 30 million elderly Medicare beneficiaries. Moreover, the population size of the latter group has grown even faster in subsequent decades due to an aging population as projected by (U.S. Census Bureau, 2017). Such a trend is expected to widen the gap in expected revenue between the two types of subsidies, resulting in even larger expected profits under the 1984/93 demand-side shock (as seen in Figures 5a and 5b) compared to profits under the 1986 supply-side shock (as seen in Figures 4a and 4b). This may further magnify firms' heterogeneous responses to the two types of policies.

Additionally, while the 1986 supply-side policy might have spurred innovation for vaccines, such vaccines were typically administered to children just once in their lifetime. On the other hand, Vaccines affected by the 1984 and 1993 demand-side policy interventions are administered universally to adults, and in some cases, even seasonally. 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 supply-side policy shock. This is because the burden of the excise tax shared by 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 4b) compared to a significant increase in profits among monopoly firms (as shown in Figure 4a). This could in turn discourage oligopoly firms from investing when facing a supply-side policy intervention.

6.3 Discussion

Our baseline estimates and the subsample analyses by market structures deliver the following three key takeaways: 1) combining supply-side policy with increased competition does not lead to increases in R&D investment, while 2) demand-side policy generally results in increased investment, and moreover, 3) combining demand-side policy with more product market competition leads to even greater R&D spending. We detail below how the interaction between the types of policy interventions and market structures, facilitated through specific institutional features of the vaccine industry, can help guide our understanding of the potential mechanisms at play here.

As outlined in our conceptual framework above, 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 as a result of the tort reform, 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 producers, which can lower firm's profitability and therefore dampen incentives for innovation. Moreover, increased product market competition, e.g., in an oligopoly as opposed to a monopoly, could further reduce a firm's profit margin and investment incentives. Our first main empirical takeaway regarding the impact of the supply-side policy shock 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 coverage on selected 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 thus be attributed to the increased demand and positive externalities from the demand-side policy interventions, similar to the impact of health policies analyzed in Finkelstein (2004).

Our third takeaway can be attributed to concentrated demand and quality competition, as discussed in Danzon and Sousa Pereira (2011). The demand side in our context primarily consists of institutional buyers, such as hospitals, vaccine distributors, and governments, who are highly concerned about vaccine quality. The expected increase in output due to the expanded Medicare coverage of vaccine products would strengthen such concentrated demand and pressure producers to compete on quality. In the case of a monopoly under the demand-side policy, 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 demand-side policy shock, firms may invest even more due to the large positive externality and the added pressure from quality competition. Despite the decrease in firm value 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 supply-side or demand-side policies across all of our specifications. This could be attributed to the aforementioned theory of concentrated demand, where a small number of large buyers, such as the federal government, make most of the purchases. Consistent with Danzon and Sousa Pereira (2011), purchasing contracts from the federal or local government tend to lower vaccine prices. Therefore, while the demand-side policies may push up vaccine prices (e.g., via increased demand for vaccine products), the impact could also be offset by the downward pressure on prices 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 government policies on the demand and supply sides 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 policy on the supply side that removes vaccine manufacturers' product liability and a consumer subsidy policy on the demand side 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 when facing demand-side policy intervention, and the effect is likely driven by the underlying market structures.

Vaccines are a public good with significant externalities. It is therefore 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 significant policy implications. For one, the heterogeneous effects and potential mechanisms we have identified can help further our understanding of and potentially address the long-standing issue of vaccine underdevelopment. For example, we find that supply-side subsidies generate fewer incentives for innovation, possibly due to the offsetting effects of greater uncertainty and tax incidence from excise taxes. In contrast, demand-side 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 tort reforms. On the other hand, if the government continues to subsidize the supply side via a tort reform, our results also imply that such a policy is more likely to be effective in a monopoly market than an oligopolistic one. We envision that these insights could also be instrumental in addressing similar tort reform issues related to product liability in many other industries.

Our study also 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 supply- and/or demand-side policies. 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 structures. 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.

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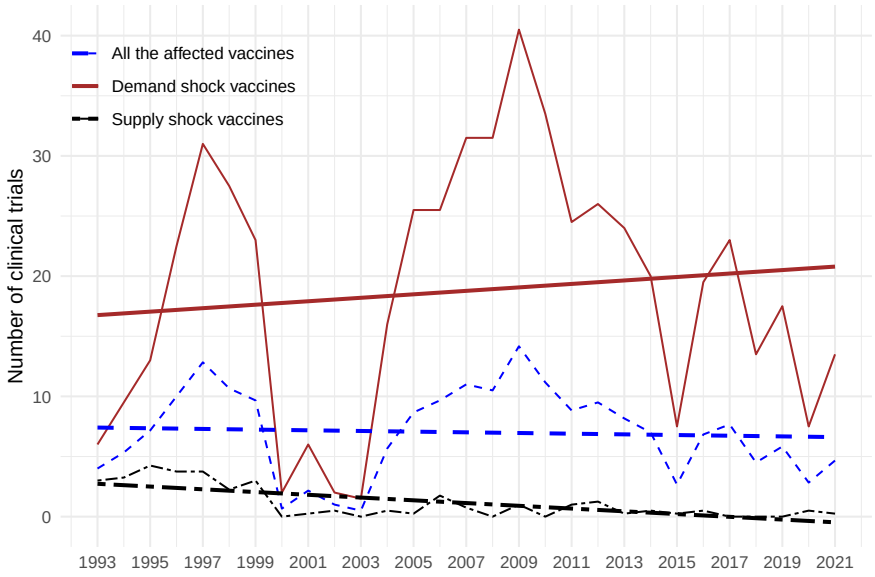
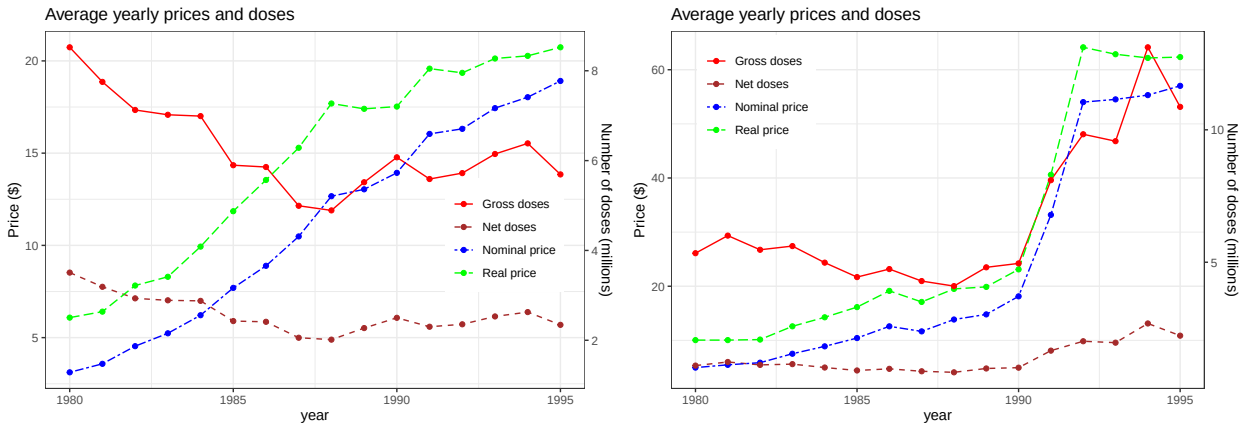
Figure 1: Vaccine Investments: Supply- vs. Demand-Side Policy



Note: The figure depicts the number of clinical trials for policy-affected vaccines. The straight lines represent a linear trend and the curved lines refer to a quadratic linear trend. The supply-side policy is based on the enactment of the National Childhood Vaccine Injury Act of 1986. The demand-side policy is based on the expansion episodes of Medicare coverage on hepatitis B and seasonal influenza in 1984 and 1993.

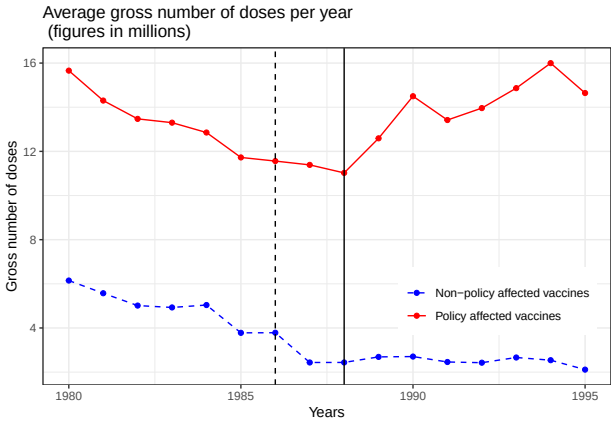
Figure 2: Evolution of Vaccine Quantity and Price



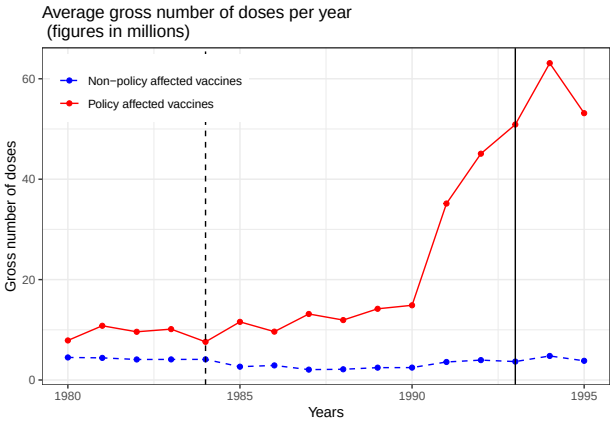
(a) 1986 Supply-Side Policy

(b) 1984/91-93 Demand-Side Policy

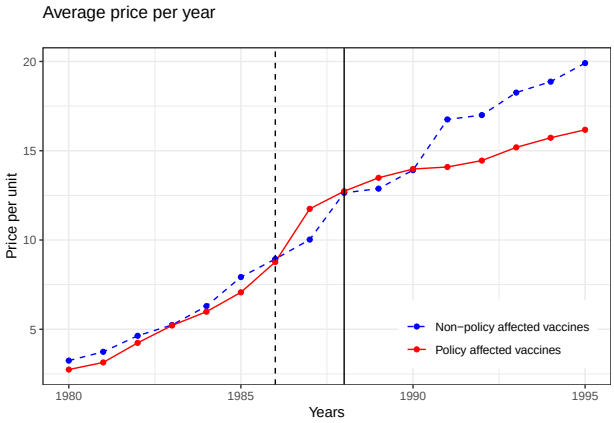
Figure 3: Vaccine Quantity and Price by Treatment and Control Groups



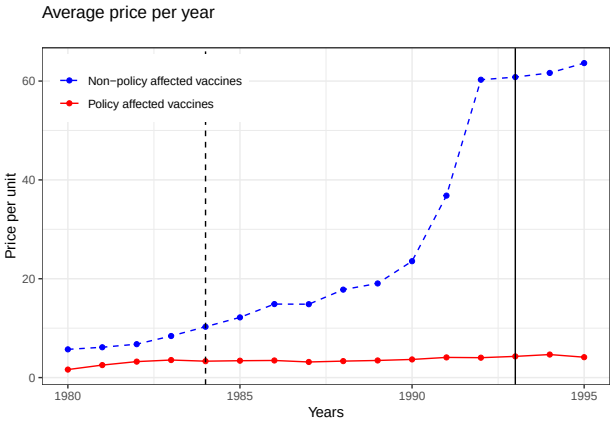
(a) 1986 Supply-Side Policy: Quantity



(b) 1984/91-93 Demand-Side Policy: Quantity

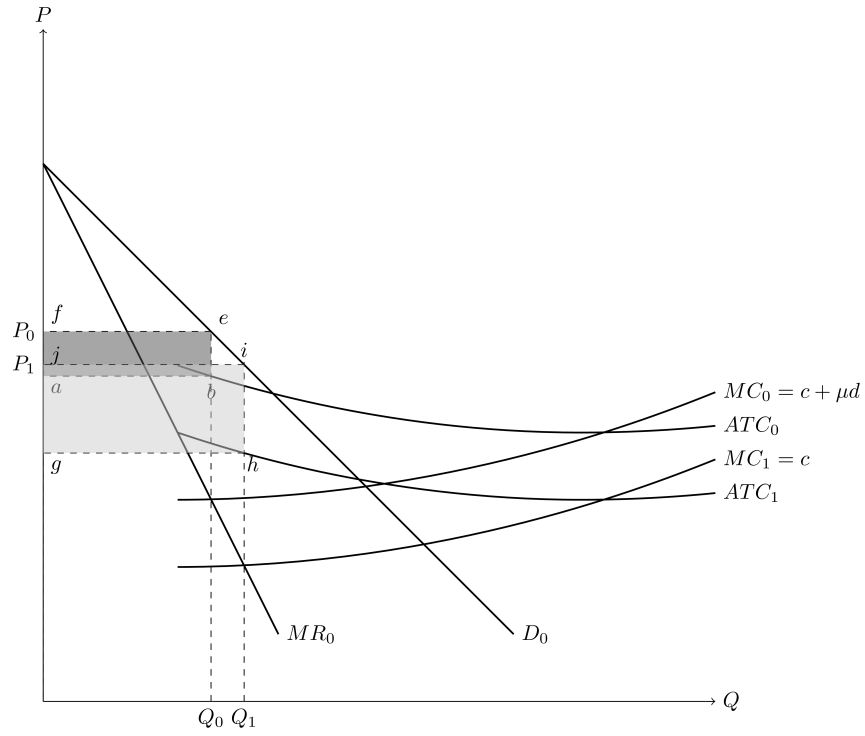


(c) 1986 Supply-Side Policy: Price

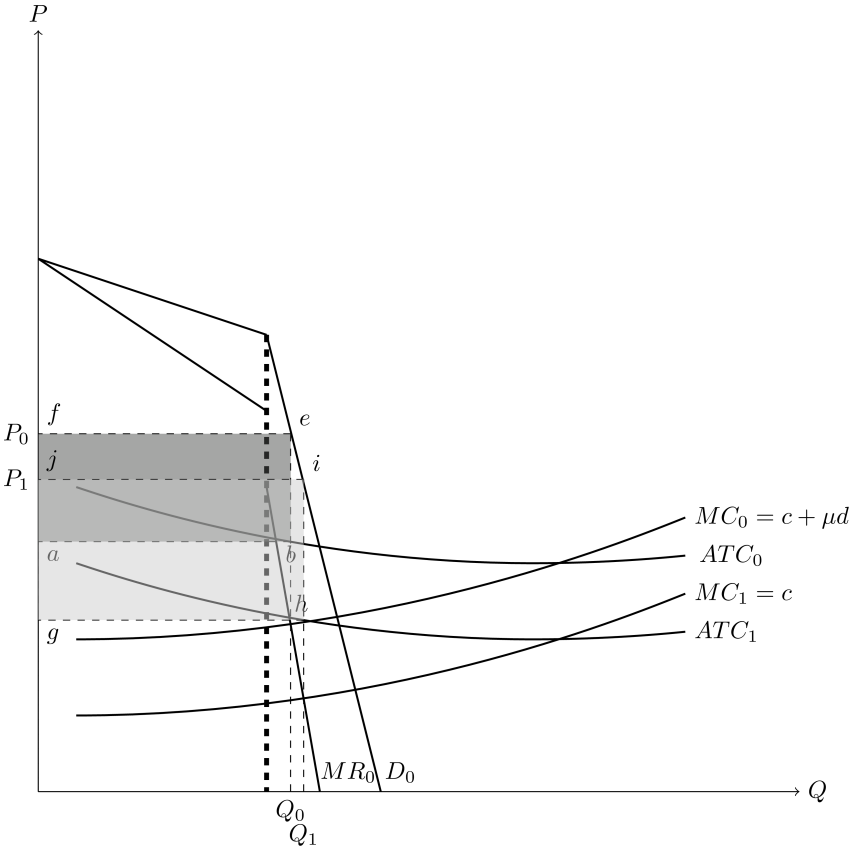


(d) 1984/91-93 Demand-Side Policy: Price

Figure 4: Policy and Market Structure: 1986 Supply-Side Policy

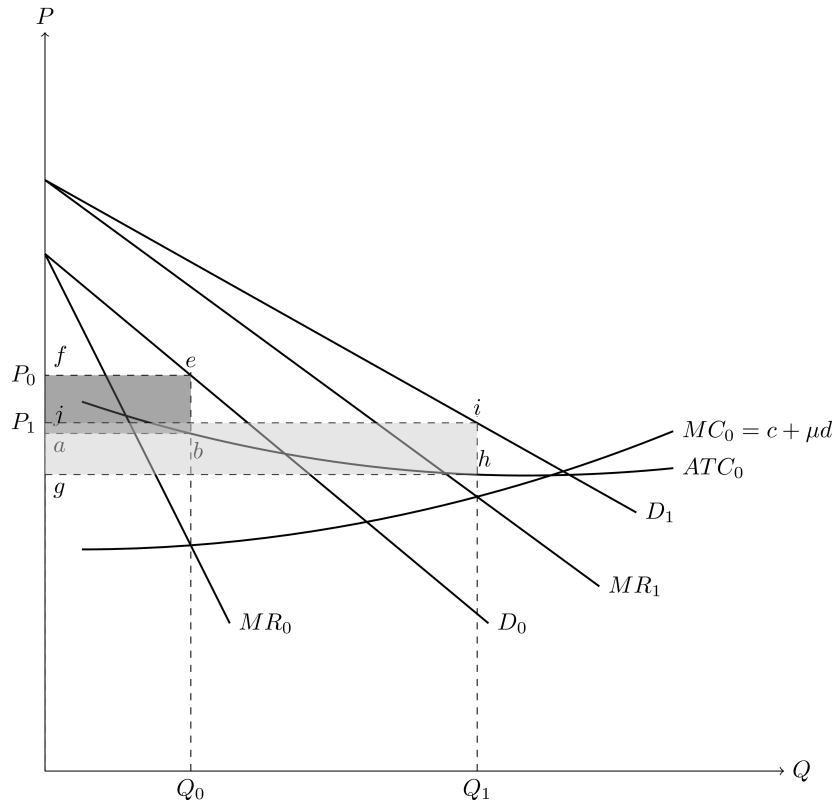


(a) Monopoly

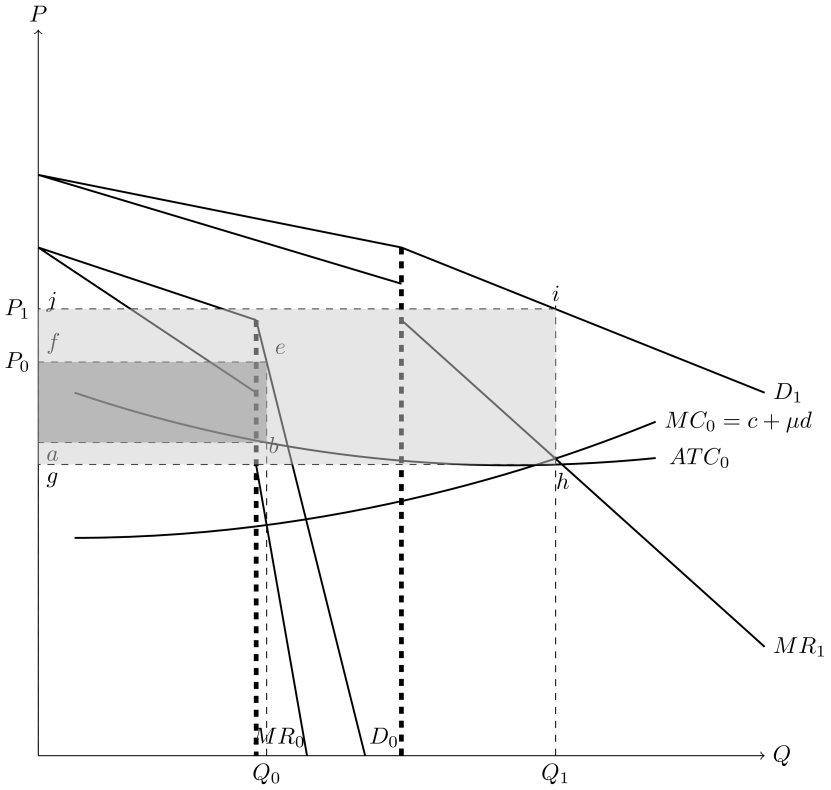


(b) Oligopoly

Figure 5: Policy and Market Structure: 1984/93 Demand-Side Policy



(a) Monopoly



(b) Oligopoly

Table 1: Summary Statistics: Regression Sample

Panel A: Supply-Side Policy (1986)

	N	Mean	S.D.	Median	Min	Max
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 unit of vaccine	227	10.920	10.241	8.886	0.268	57.630
Real price per unit of vaccine	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: Demand-Side Policy (1984/93)

	N	Mean	S.D.	Median	Min	Max
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 unit of vaccine	241	22.794	46.816	9.482	0.271	341.190
Real price per unit of vaccine	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 supply-side policy shock is based on the enactment of the NCVIA of 1986, while the demand-side policy shock is due to the expansion episodes of Medicare coverage on 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.

Table 2: Impact of Supply-Side Policy 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 supply-side policy shock is based on the enactment of the NCVIA of 1986. Vaccine-fixed effects 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 Demand-Side Policy 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 demand-side policy shock is due to the expansion episodes of Medicare coverage on vaccine products in 1984 and 1993. Vaccine-fixed effects 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 4: Robustness Check: Common Trends Assumption Test

	Gross doses (in millions)		Net doses (in millions)	
	(1)	(2)	(3)	(4)
Adpot	−153.632	−2,089.937	357.194	−2,287.597
	(549.319)	(1,316.609)	(892.548)	(1,527.057)
Time trend	−0.488***	−0.411	−0.436**	−0.373*
	(0.164)	(0.250)	(0.173)	(0.219)
Adpot × Time trend	0.073	1.049	−0.185	1.149
	(0.277)	(0.664)	(0.450)	(0.771)
Constant	977.691***	825.833*	876.222**	750.041*
	(325.727)	(496.078)	(343.039)	(434.381)
Observations	96	40	96	40
Supply-side policy sample	✓		✓	
Demand-side policy sample		✓		✓

Note: All observations are at the vaccine type-year level. The sample is restricted to the period prior to the policy's effective date (i.e., using only the years preceding the implementation of the supply- or demand-side policy). Clustered standard errors at the vaccine-type level are in parenthesis. *p<0.1; **p<0.05; ***p<0.01.

Table 5: Robustness Check: Randomness Test for Supply-Side Policy

		Adopt	
	(1)	(2)	(3)
Adverse events	0.031***	0.011*	0.010
	(0.004)	(0.006)	(0.006)
Lagged FDA approvals		0.049	0.025
		(0.154)	(0.187)
Lagged FDA trials		0.361	0.343
		(0.232)	(0.248)
Number of firms			0.022
			(0.051)
Constant	-1.133**	-1.118**	0.129*
	(0.502)	(0.514)	(0.069)
Observations	184	184	184
R^2	0.132	0.231	0.244

Note: All observations are at the vaccine type-year level. Clustered standard errors at the vaccine-type level are in parenthesis. *p<0.1; **p<0.05; ***p<0.01.

Table 6: Robustness Check: Alternative Control Groups

Panel A: Supply-Side Policy (1986)

	Gross doses (in millions)				Price per dose ($)			
	(1)	(1)	(2)	(2)	(1)	(1)	(2)	(2)
Adopt	3.483*	3.486*	3.741**	3.452**	−1.496	−22.399	−4.821	−31.588
	(1.806)	(1.802)	(1.854)	(1.743)	(4.501)	(17.294)	(5.256)	(22.127)
Lagged lawsuits	0.020	0.018	0.078	0.071	0.167	0.819	0.199	0.663
	(0.070)	(0.069)	(0.055)	(0.048)	(0.165)	(0.673)	(0.154)	(0.474)
Lagged FDA approvals	−0.181	−0.120	0.414	0.036	1.871	5.137	1.286	2.903
	(1.079)	(0.958)	(0.844)	(0.619)	(1.336)	(4.974)	(1.923)	(5.189)
Lagged FDA trials	2.202***	2.180***	1.752	1.554***	1.796	0.543	−1.173	−17.823
	(0.688)	(0.668)	(1.118)	(0.507)	(3.570)	(12.185)	(2.771)	(15.320)
Sample	Child	Full	Child	Full	Child	Full	Child	Full
Observations	173	186	130	157	199	227	147	205

	Clinical trials			
	(1)	(1)	(2)	(2)
Adopt	1.529	1.550	1.218	0.934
	(1.008)	(0.994)	(1.008)	(0.993)
Lawsuits	−0.036	−0.038	−0.055***	−0.061***
	(0.028)	(0.028)	(0.012)	(0.017)
Sample	Child	Full	Child	Full
Observations	210	252	160	224

Panel B: Demand-Side Policy (1984/93)

	Gross doses (in millions)		Price per dose ($)		Clinical trials	
	(1)	(2)	(1)	(2)	(1)	(2)
Adopt	32.386***	31.001***	−24.047	−34.033	3.220***	3.087***
	(1.078)	(1.501)	(19.814)	(27.773)	(0.234)	(0.255)
Lagged lawsuits	−0.291	−0.223	1.342	2.263	−0.048	−0.058
	(0.481)	(0.497)	(2.187)	(3.131)	(0.066)	(0.058)
Lagged FDA approvals	−0.946**	−0.651	9.557	11.636		
	(0.470)	(0.608)	(5.846)	(7.614)		
Lagged FDA trials	2.272***	2.087**	−3.455	−13.573		
	(0.654)	(0.850)	(8.945)	(13.478)		
Observations	179	127	225	173	268	190

Note: All observations are at the vaccine type-year level. The supply-side policy shock is based on the enactment of the NCVIA of 1986, while the demand-side policy shock is due to the expansion episodes of Medicare coverage on vaccine products in 1984 and 1993. Vaccine-fixed effects 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 7: Robustness Check: Short-Term vs. Long-Term Effects

Panel A: Supply-Side Policy (1986)

	Gross doses (in millions)					Price per dose ($)					Clinical trials	
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
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: Demand-Side Policy (1984/93)

	Gross doses (in millions)					Price per dose ($)					Clinical trials	
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
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 supply-side policy shock is based on the enactment of the NCVIA of 1986, while the demand-side policy shock is due to the expansion episodes of Medicare coverage on vaccine products in 1984 and 1993. Vaccine-fixed effects 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 8: Heterogeneity by Market Structures

Panel A: Gross doses (in millions)

	Supply-Side Policy (1986)				Demand-Side Policy (1984/93)			
	Monopoly		Oligopoly		Monopoly		Oligopoly	
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
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 ($)

	Supply-Side Policy (1986)				Demand-Side Policy (1984/93)			
	Monopoly		Oligopoly		Monopoly		Oligopoly	
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
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

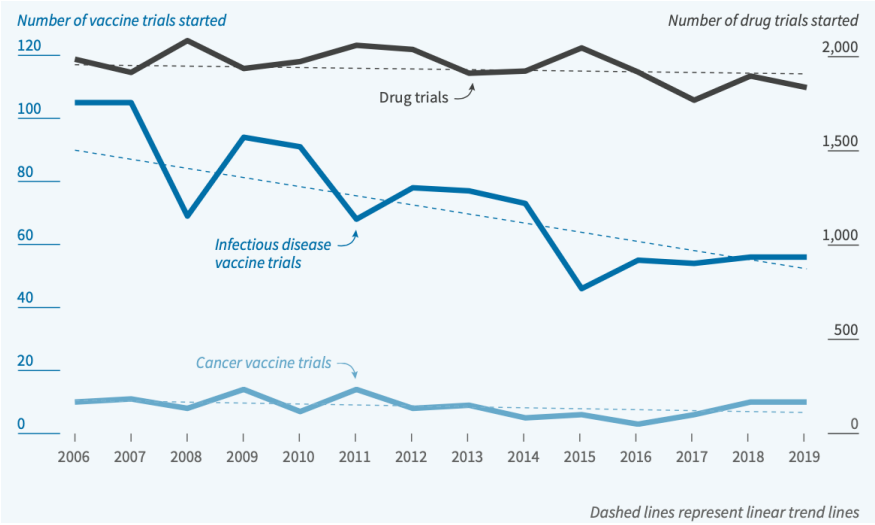
Panel C: Clinical trials

	Supply-Side Policy (1986)				Demand-Side Policy (1984/93)			
	Monopoly		Oligopoly		Monopoly		Oligopoly	
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
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 supply-side policy shock is based on the enactment of the NCVIA of 1986, while the demand-side policy shock is due to the expansion episodes of Medicare coverage on vaccine products in 1984 and 1993. The demand monopoly (columns 5 and 6) policy coefficients are missing because the restricted sample happens to include only control vaccines; that is, all the treated demand side vaccines are manufactured by an oligopoly structure market. Vaccine fixed effects 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.

Appendix: Additional Figures and Tables

Figure A1: Vaccine Investment by Kremer and Snyder (2020)



Note: This figure is sourced from Kremer and Snyder (2020) and highlights disparities between drug and vaccine phase three trials. The authors argue that, despite the life-saving significance of vaccines, manufacturers exhibit considerably less innovation in this domain compared to pharmaceutical drugs. As depicted in the figure, the persistently sluggish investment in vaccines has been a consistent concern for policymakers, in turn resulting in delays in development and shortages during production.

Table A1: Vaccines and Treatment/Control Assignment

Vaccine Type	Demand-Side Policy	Supply-Side Policy
Anthrax	Y	N
Diphtheria Toxoid	Y	N
Hepatitis B	Y (Treated)	N
Influenza Virus Vaccine (Monovalent)	Y (Treated)	N
Influenza Virus Vaccine (Bivalent)	Y (Treated)	N
Influenza, Trivalent	Y (Treated)	N
Measles	Y	Y
Measles/Rubella	Y	Y
Meningococcal	Y	Y
Mumps	Y	Y
Mumps Rubella	Y	Y
Polio, Inactivated	Y	Y
Rabies	Y	N
Rubella	Y	Y
Smallpox Vaccine	Y	Y
Tetanus Immune Globulin (Human)	Y	Y
Tetanus Toxoid	Y	Y
Tetanus and Diphtheria Toxoid (Adult)	Y	Y
Diphtheria and Tetanus Toxoid (pedatric)	N	Y (Treated)
Diphtheria and Tetanus Toxoid with Pertussis Vaccine	N	Y (Treated)
Measles, Mumps, Rubella	N	Y (Treated)
Poliomeylitis Vaccine, Live, Oral	N	Y (Treated)

Note: We excluded vaccine types from the control group if they were affected by any other government policies and experienced any external shocks during the sample period.

Table A2: Summary Statistics: Robustness Check Sample

Panel A: Supply-Side Policy (1986)

	N	Mean	S.D.	Median	Min	Max
Gross number of vaccine doses	130	6.918	8.478	1.626	0	24.968
Net number of vaccine doses	130	6.760	8.346	1.494	0	24.474
Price per unit of vaccine	147	11.822	11.035	9.528	0.268	57.630
Real price per unit of vaccine	147	15.502	13.063	13.580	0.480	63.190
Clinical trials	160	0.569	1.185	0	0	6
Adverse events	118	614.525	1,024.106	50.500	0	4,253
Lagged lawsuits	160	0.906	3.377	0	0	27
Lagged FDA approvals	160	0.038	0.191	0	0	1
Lagged FDA trials	160	0.013	0.111	0	0	1
Number of firms	160	1.594	1.314	1	0	6

Panel B: Demand-Side Policy (1984/93)

	N	Mean	S.D.	Median	Min	Max
Gross number of vaccine doses	127	6.413	11.264	0.842	0.000	63.116
Net number of vaccine doses	127	5.753	9.483	0.787	−1.334	56.485
Price per unit of vaccine	173	27.563	54.313	8.818	0.490	341.190
Real price per unit of vaccine	173	35.151	62.614	12.290	0.960	392.880
Clinical trials	190	0.668	1.477	0	0	8
Adverse events	125	218.865	689.913	28.667	0	3,790
Lagged lawsuits	190	0.084	0.497	0	0	5
Lagged FDA approvals	190	0.058	0.234	0	0	1
Lagged FDA trials	190	0.026	0.191	0	0	2
Number of firms	190	1.668	1.191	1	0	5

Note: All observations are at the vaccine type-year level. The supply-side policy shock is based on the enactment of the NCVIA of 1986, while the demand-side policy shock is due to the expansion episodes of Medicare coverage on vaccine products in 1984 and 1993. The above table lists pertinent summary statistics based on the age sample as shown in Table 6.

Table A3: Robustness Check: Alternative Production and Price Measures

Panel A: Supply-Side Policy (1986)	Net doses (in millions)					Real price per dose ($)				
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
Adopt	4.065***	4.008***	4.016***	3.839***	3.849***	−1.437	−1.601	−1.725	−1.863	−1.931
	(1.515)	(1.484)	(1.486)	(1.487)	(1.494)	(3.955)	(3.943)	(3.864)	(3.923)	(3.862)
Lagged lawsuits		0.077	0.077	0.086*	0.087*		0.244*	0.246*	0.262**	0.262**
		(0.049)	(0.049)	(0.048)	(0.048)		(0.133)	(0.134)	(0.131)	(0.131)
Lagged FDA approvals			−0.155		−0.370			2.154		1.854
			(1.095)		(1.033)			(1.532)		(1.698)
Lagged FDA trials				1.888***	1.986***				3.290	2.796
				(0.585)	(0.621)				(2.884)	(3.310)
Observations	200	200	200	200	200	227	227	227	227	227

Panel B: Demand-Side Policy (1984/93)	Net doses (in millions)					Real price per dose ($)				
	(11)	(12)	(13)	(14)	(15)	(16)	(17)	(18)	(19)	(20)
Adopt	15.116**	15.110**	15.382**	15.066**	15.371**	−27.757	−27.729	−29.651	−26.602	−28.640
	(6.886)	(6.842)	(6.733)	(6.935)	(6.794)	(19.472)	(19.380)	(20.015)	(19.136)	(19.608)
Lagged lawsuits		−0.387	−0.389	−0.396	−0.391		0.465	0.565	0.595	0.661
		(0.529)	(0.539)	(0.525)	(0.535)		(2.419)	(2.399)	(2.460)	(2.443)
Lagged FDA approvals			−1.702***		−1.689***			11.920		11.140
			(0.561)		(0.603)			(7.249)		(6.797)
Lagged FDA trials				0.385	0.074				−8.984	−7.062
				(0.675)	(0.725)				(10.916)	(10.200)
Observations	197	197	197	197	197	241	241	241	241	241

Note: All observations are at the vaccine type-year level. The supply-side policy shock is based on the enactment of the NCVIA of 1986. Vaccine-fixed effects 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 A4: Robustness Check: Alternative Demand-Side Policy Implementation Year (1984/1991)

Panel A: 1984 as Year of Policy Shock

	Gross doses (in millions)					Price per dose ($)					Clinical trials	
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
Adopt	3.157***	3.141***	3.651***	2.178***	2.720***	−10.289	−10.362	−10.995	−7.509	−8.938	4.321***	4.328***
	(0.240)	(0.237)	(0.344)	(0.308)	(0.499)	(11.649)	(11.846)	(12.130)	(8.829)	(9.343)	(0.110)	(0.100)
Lagged lawsuits		0.147	0.141	0.129	0.127		0.510	0.607	0.601	0.664		−0.050
		(0.333)	(0.338)	(0.329)	(0.335)		(1.981)	(1.969)	(2.032)	(2.017)		(0.075)
Lagged FDA approvals			−1.567*		−1.208			9.530		8.910		
			(0.843)		(0.786)			(6.055)		(5.530)		
Lagged FDA trials				2.037***	1.722***				−6.528	−4.612		
				(0.262)	(0.401)				(10.858)	(10.258)		
Observations	164	164	164	164	164	211	211	211	211	211	240	240

Panel B: 1991 as Year of Policy Shock

	Gross doses (in millions)					Price per dose ($)					Clinical trials	
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
Adopt	2.980***	2.957***	2.179**	1.817***	1.017	−24.532	−24.794	−22.522	−26.176	−24.167	1.301***	1.312***
	(0.471)	(0.482)	(0.985)	(0.515)	(1.007)	(23.375)	(23.939)	(23.449)	(23.623)	(23.086)	(0.120)	(0.122)
Lagged lawsuits		0.122	0.124	0.119	0.121		0.910	0.926	0.904	0.918		−0.040
		(0.328)	(0.337)	(0.329)	(0.337)		(2.217)	(2.196)	(2.225)	(2.204)		(0.067)
Lagged FDA approvals			−0.981		−0.995			6.354		6.431		
			(0.970)		(0.943)			(5.209)		(5.269)		
Lagged FDA trials				1.416***	1.429***				1.929	2.335		
				(0.433)	(0.400)				(6.128)	(6.299)		
Observations	164	164	164	164	164	211	211	211	211	211	240	240

Note: All observations are at the vaccine type-year level. In panel A, *Adopt* is the dummy variable of the main effect, a binary variable that equals one if vaccine type (hepatitis B) is affected by policy and the year is after 1983. *Adopt* in panel B is the same as the latter but the effective treatment year is assumed to be 1991 based on CDC recommendation. Vaccine-fixed effects 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 A5: Robustness Check: Alternative Demand-Side Policy Implementation Year (1993)

	Gross doses (in millions)					Price per dose ($)					Clinical trials	
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
Adopt	31.690***	31.633***	31.746***	31.853***	31.907***	−33.434	−33.244	−33.750	−33.976	−34.319	2.925***	2.924***
	(1.044)	(1.083)	(1.073)	(1.013)	(1.020)	(21.547)	(21.244)	(21.560)	(22.113)	(22.326)	(0.245)	(0.243)
Lagged lawsuits		−0.289	−0.301	−0.305	−0.312		0.777	0.845	0.896	0.939		−0.018
		(0.497)	(0.504)	(0.497)	(0.502)		(1.941)	(1.938)	(1.996)	(1.992)		(0.084)
Lagged FDA approvals			−1.418***		−0.951**			7.954		7.148		
			(0.526)		(0.478)			(5.334)		(4.793)		
Lagged FDA trials				2.529***	2.286***				−8.420	−7.131		
				(0.590)	(0.660)				(11.782)	(11.340)		
Observations	192	192	192	192	192	243	243	243	243	243	288	288

Note: All observations are at the vaccine type-year level. *Adopt* is the dummy variable of the main effect–a binary variable that is assigned one if vaccine type (Influenza Virus Vaccine (Monovalent), Influenza Virus Vaccine (Bivalent), and Influenza, Trivalent) is affected by policy and the year is after 1992. We exclude the vaccines that were affected by the 1986 policies from our data. Vaccine-fixed effects 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 A6: Alternative Control Group for Demand-Side Policy

	Gross doses (in millions)					Price per dose ($)					Clinical trials	
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
Adopt	20.097*	20.063*	20.065*	20.310*	20.311*	−19.546	−19.519	−19.365	−18.873	−19.104	3.118***	3.118***
	(10.626)	(10.595)	(10.628)	(10.485)	(10.529)	(17.563)	(17.503)	(17.609)	(17.317)	(17.462)	(0.140)	(0.140)
Lagged lawsuits		−0.474	−0.474	−0.463	−0.464		1.092	1.159	1.129	1.173		−0.042
		(0.598)	(0.595)	(0.589)	(0.590)		(2.056)	(2.066)	(2.110)	(2.113)		(0.069)
Lagged FDA approvals			0.053		−0.244			7.198		7.095	−0.235**	−0.233**
			(0.885)		(0.679)			(5.079)		(4.867)	(0.112)	(0.113)
Lagged FDA trials				−1.408	−1.471				−2.282	−0.930		
				(1.366)	(1.315)				(8.892)	(8.578)		
Observations	192	192	192	192	192	243	243	243	243	243	288	288

Note: All observations are at the vaccine type-year level. *Adopt* is a binary variable that is assigned one if either of the following conditions is met: vaccine type is hepatitis B and the year is after 1983 but before 1989, vaccine type is hepatitis B and the year is after 1990, and the vaccine is an influenza type (Influenza Virus Vaccine (Monovalent), Influenza Virus Vaccine (Bivalent), and Influenza, Trivalent) and the year is after 1992. Note that all the 1984 vaccines are excluded from this sample. We exclude the vaccines that were affected by the 1986 policies from our data. Vaccine fixed effects 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 A7: Robustness Check: Accounting for Evolution of Market Structures

Panel A: Log Number of Firms (OLS)

	(1)	(2)	(3)	(4)	(5)	(6)
Adopt 84	0.180**			0.215***	0.196***	
	(0.077)			(0.082)	(0.066)	
Adopt 88		0.108*		0.077		0.098*
		(0.058)		(0.062)		(0.055)
Adopt 93			−0.119		−0.137	−0.121
			(0.224)		(0.225)	(0.218)
Lagged lawsuits	−0.010	−0.015***	−0.027	−0.013***	−0.015	−0.016***
	(0.016)	(0.002)	(0.017)	(0.002)	(0.019)	(0.002)
Lagged FDA approvals	0.013	0.044	0.042	0.008	0.018	0.063
	(0.073)	(0.084)	(0.092)	(0.057)	(0.063)	(0.072)
Lagged FDA trials	0.152***	−0.147**	−0.073	0.078	0.149**	−0.157***
	(0.055)	(0.072)	(0.086)	(0.103)	(0.060)	(0.059)
Observations	240	288	272	304	288	336

Panel B: Firm Entry Dummy (Probit)

	(1)	(2)	(3)	(4)	(5)	(6)
Adopt 84	4.172***			2.366*	5.590***	
	(1.443)			(1.302)	(0.920)	
Adopt 88		−0.796		−2.051		−0.908
		(0.759)		(1.311)		(0.596)
Adopt 93			−0.784		−0.785	−0.509
			(0.765)		(0.701)	(0.758)
Lagged lawsuits	−0.0002	0.018	−6.959***	0.159	−0.677	0.023
	(0.314)	(0.048)	(0.593)	(0.225)	(1.389)	(0.029)
Lagged FDA approvals	0.910	2.711*	−4.576***	2.763**	−0.099	2.122
	(1.315)	(1.520)	(0.897)	(1.355)	(0.767)	(1.351)
Lagged FDA trials	1.342*	−4.351***	−6.101***	2.367**	0.483	−6.023***
	(0.793)	(0.618)	(0.784)	(1.064)	(0.772)	(1.329)
Observations	225	270	255	285	270	315

Panel C: Firm Exit Dummy (Probit)

	(1)	(2)	(3)	(4)	(5)	(6)
Adopt 84	−4.172***			−2.366*	−5.590***	
	(1.443)			(1.302)	(0.920)	
Adopt 88		0.796		2.051		0.908
		(0.759)		(1.311)		(0.596)
Adopt 93			0.784		0.785	0.509
			(0.765)		(0.701)	(0.758)
Lagged lawsuits	0.0002	−0.018	6.959***	−0.159	0.677	−0.023
	(0.314)	(0.048)	(0.593)	(0.225)	(1.389)	(0.029)
Lagged FDA approvals	−0.910	−2.711*	4.576***	−2.763**	0.099	−2.122
	(1.315)	(1.520)	(0.897)	(1.355)	(0.767)	(1.351)
Lagged FDA trials	−1.342*	4.351***	6.101***	−2.367**	−0.483	6.023***
	(0.793)	(0.618)	(0.784)	(1.064)	(0.772)	(1.329)
Observations	225	270	255	285	270	315

Note: All observations are at the vaccine type-year level. *Adopt* 84 is the dummy variable of the main effect, a binary variable that equals one if vaccine type (hepatitis B) is affected by policy and the year is after 1983. *Adopt* 88 is the dummy variable of the main effect, a binary variable that equals to one if vaccine type (Diphtheria and Tetanus Toxoid (pediatric)", Diphtheria and Tetanus Toxoid with Pertussis", "Measles, Mumps, Rubella", and Poliomeylitis Vaccine, Live, Oral") is affected by policy and the year is after 1987. *Adopt* 93 is the dummy variable of the main effect, a binary variable that equals to one if vaccine type (Influenza Virus Vaccine (Monovalent)", Influenza Virus Vaccine (Bivalent)", and "Influenza, Trivalent") is affected by policy and the year is after 1992. We exclude the affected vaccines of the eliminated policies in each column. For instance, in column 1, we excluded the affected vaccines by the 1988 and 1993 policies. The firm entry dummy equals one if the number of firms for each vaccine increased in the next period and zero otherwise. The firm exit dummy equals one if there is no change or fewer number of firms in the subsequent years for each vaccine. Note that the initial year, 1980, is dropped to create these firm dummies. Vaccine-fixed effects 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