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Regulatory Paradox and Market Restructuring: Unintended Effects of the Two-Invoice System on Pharmaceutical Prices and Their Micro-Mechanisms

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Abstract: The Two-Invoice System, designed to curb inflated drug prices and disrupt gray-market profit chains in pharmaceutical distribution, has effectively rationalized drug circulation. However, it has not achieved the anticipated price-reducing effect. Instead, a regulatory paradox of rising ex-factory prices has emerged. To explain this paradox, this paper proposes a theoretical framework of front-loading the distribution functions and cost internalization to formulate a series of testable hypotheses, which are then empirically examined using data from Chinese listed pharmaceutical companies and industrial and commercial registration records from 2014 to 2022. The research finds that: The Two-Invoice System formally reduces the distribution tiers, but the inherent distribution functions such as marketing promotion and client relationship management have not disappeared. Instead, they are shifted upstream to manufacturers through either vertical integration (in-house, self-operated model) or outsourcing (CSO model), and are internalized as sales costs, ultimately pushing up the ex-factory price. Heterogeneity analysis indicates that the regulation has a more significant impact on enterprises with a higher product-portfolio concentration, weaker R&D capabilities and smaller scales. This restructuring of the distribution ecosystem inhibits the entry of traditional pharmaceutical wholesalers and gives rise to new organizational forms, especially medical consulting firms, creating new regulatory blind spots. This paper provides micro-level evidence for regulatory economics on how formal regulation can be rendered ineffective by substantive restructuring efforts of market participants. It reveals the internal logic of how firms adjust their boundaries when institutional change alters transaction costs.

Keywords: Two-Invoice System; pharmaceutical price regulation; regulatory paradox; transaction costs; market restructuring

JEL Classification: L51; I18; L65; D23; L22

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Declaration of competing interests

The authors have no competing interests to declare that are relevant to the content of this article.

Data availability

The data that support the findings of this study are drawn from CSMAR, WIND, and publicly available annual reports. Restrictions apply to data obtained from commercial databases. Publicly available annual-report data and processed data used in the analysis are available from the corresponding author upon reasonable request, subject to applicable licensing restrictions.

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1. Introduction

As a heavily regulated sector inherently tied to public well-being, the pharmaceutical market presents a fundamental tension between pricing efficiency and consumer welfare. When high drug prices impose heavy burdens on patients (Oldfield et al., 2025) and impede health equity (Hu et al., 2008), dissecting the underlying price formation mechanism becomes a central concern and an empirical challenge for both economists and policymakers (Cameron et al., 2009). In China, the multi-layered, elongated distribution chain for pharmaceuticals has long been identified as a key driver of inflated prices (Yuan et al., 2021). Under the prevailing multi-invoice model, drug prices are subject to cumulative double-marginalization and sequential markups across intermediate layers. This structure not only raised retail prices and increased healthcare spending but also generated rent-seeking opportunities and compliance risks in an opaque chain that eroded market order and public interest.

To address this market failure, the Chinese government introduced the Two-Invoice System nationwide in 2017. The policy mandates that only two invoices may be issued across the entire distribution chain: one from the manufacturer to the distributor, and a second from the distributor to the healthcare institution. By strictly limiting the number of permissible invoices, the reform aimed to formally eliminate redundant intermediaries, compress distribution costs, and push prices toward competitive levels.

Several years into implementation, the policy has achieved some distribution-related objectives. A large number of uncompetitive small and medium-sized distributors exited the market, industry concentration rose, and distribution practices became more standardized. Yet the expected price effect has not materialized. Retail prices did not decline as anticipated (see Figure 1), and---starkly---ex-factory prices in the pharmaceutical manufacturing sector accelerated upward over the same period (see Figure 2). This poses a puzzle: why did prices move in the opposite direction from what the policy intended? Does this pattern reflect a failure of policy transmission, or does it represent a rational strategic response by market actors adapting to new institutional constraints? Were distribution costs genuinely eliminated, or merely shifted across organizational boundaries and accounting categories? And did the post-reform distribution landscape generate new regulatory blind spots that warrant policy attention?

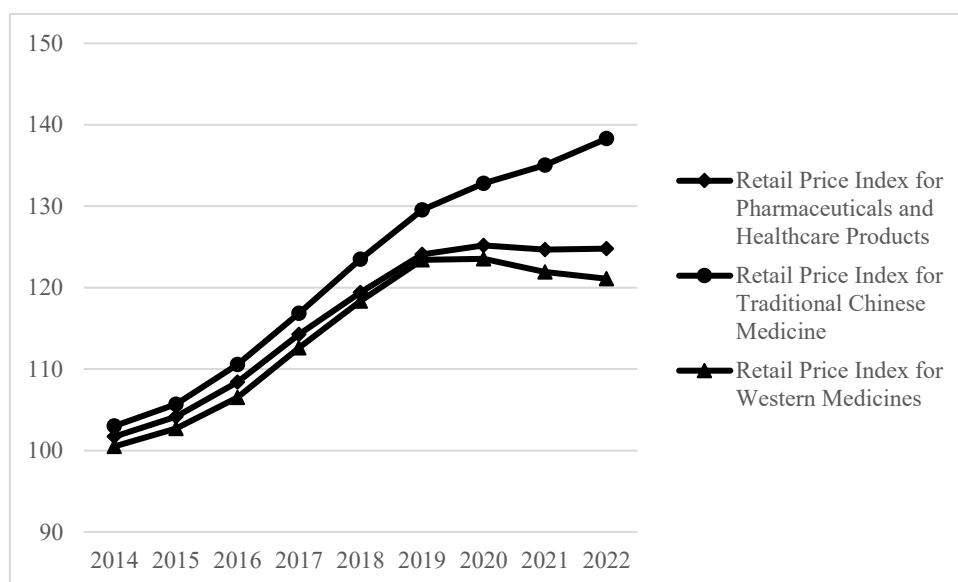


Fig.1 Pharmaceutical Retail Price Index (2013 = 100)

Source: National Bureau of Statistics of China

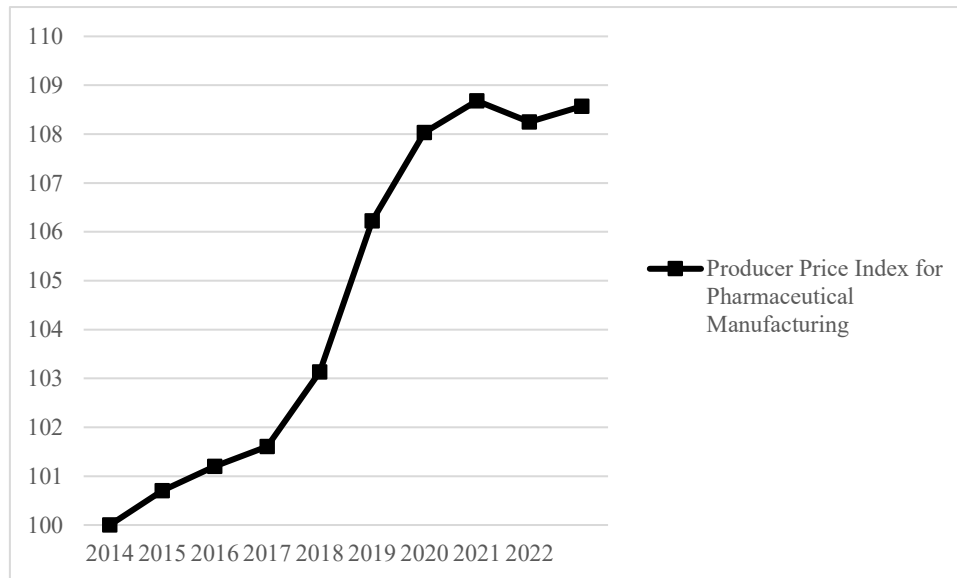


Fig.2 Producer Price Index for Pharmaceutical Manufacturing (2013 = 100).

Source: National Bureau of Statistics of China

To resolve this puzzle, we propose a forward integration and cost internalization hypothesis. The Two-Invoice System, as a market regulation, serves usually as a *de jure* regulation, which restricts the number of invoices---and hence the nominal number of transactions---but cannot eliminate the economic functions that pharmaceutical distribution necessarily entails, including marketing, client relationship management, and academic promotion (Becker and Lillemark, 2006). Regulation can reshape the formal structure of transactions, but it cannot extinguish the substantive economic activities those transactions support. Drawing on transaction cost economics, we argue that when the old multi-tier agency model becomes prohibitively costly under the new rules, manufacturers had to assume responsibility for these displaced functions (e.g., building in-house sales forces) or new contractual arrangements (e.g., partnerships with contract sales organizations) (Klein et al., 1978; Williamson, 1985). This reorganization of firm boundaries effectively converts what were previously external transaction costs into internal production costs. Because these forward-shifted distribution activities are incurred before the ex-factory pricing point, they are naturally absorbed into the ex-factory price, giving rise to a "high-invoicing, high-rebate" pricing model. In short, distribution regulation compressed the formal chain, but the underlying functions and their associated costs did not vanish; they migrated upstream through functional transfer and cost internalization.

We test this hypothesis using a difference-in-differences (DID) design applied to a panel of listed Chinese pharmaceutical manufacturers from 2014 to 2022. We find that, following the policy, affected firms' operating revenue---a proxy for ex-factory price---increased significantly, while net profits were unaffected. This pattern is consistent with a shift toward the "high-invoicing, high-rebate" pricing model, under which higher revenue suggests internalized distribution costs rather than genuine profitability gains. To ensure that this empirical revenue surge captures a pure price effect rather than a concurrent expansion in sales volume, we further consolidate this channel by validating a corresponding increase in gross profit margins. Empirically, the reform led to a concomitant surge in both selling expense ratios and the proportion of sales staff, providing direct empirical support for the hypothesized cost-internalization mechanism. Further decomposition of selling expenses reveals significant increases in marketing, promotion, and service commission expenditures, indicating that manufacturers absorbed distribution functions previously performed by intermediaries, employing both in-house teams and outsourced arrangements. Finally, using negative binomial regressions on provincial firm registration data over the same period, we show that the policy raised entry barriers for traditional pharmaceutical wholesalers while increasing registrations of medical consulting firms---direct micro-level evidence of structural transformation in the distribution ecosystem.

This paper makes three contributions. First, it contributes to the economics of regulation literature by documenting the limits of formal regulation when confronted with complex market functions. We provide a detailed case of how firms respond to regulatory constraints through internal strategic restructuring---cost internalization and functional transfer---thereby illuminating the micro-mechanisms underlying regulatory failure. Second, we contribute to the industrial organization literature on firm boundaries by exploiting a policy-driven natural experiment. Our evidence shows how the make-or-buy decision responds systematically when external transaction costs are artificially reshaped by regulation. Third, this study offers rigorous evidence for evaluating a major Chinese healthcare reform. By unpacking the underlying economic mechanisms, we identify new regulatory blind spots---notably the rise of contract sales organization (CSO) arrangements---and provide a

theoretical foundation for designing public policy that targets economic substance rather than formal structure.

The remainder of the paper proceeds as follows. Section 2 reviews the historical evolution of China's pharmaceutical distribution system and analyzes the institutional background and policy logic of the Two-Invoice System. Section 3 surveys the theoretical literature on regulation and firm responses, and develops our core hypothesis of forward integration and cost internalization. Section 4 specifies the empirical model and tests the hypothesis using listed pharmaceutical firm data. Section 5 conducts pre-trend and placebo tests to ensure robustness and explores heterogeneous treatment effects. Section 6 draws on detailed selling-expense data from firm annual reports and business registration records to provide supplementary evidence on the shift in sales models and the structural transformation of the distribution ecosystem. Section 7 concludes with policy implications.

2. Institutional Background and Reform Rationale

2.1 Institutional Background

The evolution of China's pharmaceutical distribution system since 1949 falls into four distinct phases.

Phase I: Planned Economy (1949--1978). To remedy the price gouging and supply shortages that characterized the pre-1949 private pharmacy system, the state established China Pharmaceutical Corporation in 1950, vesting it with unified authority over national drug procurement and allocation. Governments at all levels created state-owned drug distribution agencies, and private pharmaceutical firms were absorbed through socialist transformation. The result was a three-tier supply network spanning urban and rural areas: eight primary stations in major cities (Tianjin, Beijing, Shanghai, Guangzhou, among others), secondary stations at the provincial level, and tertiary stations at the county level. Drugs were allocated hierarchically by administrative jurisdiction and ultimately delivered to hospitals and pharmacies. This unified procurement-and-distribution model curbed early postwar disorder and expanded drug access, but it suppressed competition and generated substantial inefficiency.

Phase II: Market Liberalization (1979--1999). The pharmaceutical distribution sector underwent rapid market-oriented reform. In May 1981, the State Council issued the "Decision on Strengthening Pharmaceutical Administration", requiring that pharmaceutical products be produced and supplied according to demand. The 1984 Pharmaceutical Administration Law dismantled the rigid three-tier station system: collective and private entities meeting basic qualifications could now enter drug distribution and establish pharmaceutical trading companies. Mandatory production-and-sales quotas were gradually abolished, allowing manufacturers and distributors alike to sell directly to hospitals and pharmacies. The introduction of contracted management responsibility systems further boosted industry profitability. Liberalized entry and rising profits attracted a flood of new firms: by 1997, China housed 16,519 pharmaceutical wholesalers (China Pharmaceutical Yearbook).

This explosion in the number of distributors improved circulation efficiency but also generated excessive competition, multi-layered agency chains, and invoice-based fraud and money laundering. Each additional layer of distribution added a markup, and these cumulative costs were ultimately borne by patients. According to the Ministry of Health's 1993 First National Health Services Survey, average per-visit outpatient expenditure rose from 4.4 yuan in 1986 to 23.3 yuan in 1993, while inpatient costs surged from 167 yuan to 1,021 yuan. Drug expenditure accounted for 70 percent of outpatient spending and 55 percent of inpatient spending, outpacing both GDP growth and household affordability.

Phase III: Regulatory Consolidation (2000--2008). Authorities moved to tighten industry standards. In November 2001, the State Drug Administration issued a directive requiring all distributors to obtain Good Supply Practice (GSP) certification and complete GSP-compliant facility upgrades. The 2004 Measures for the Administration of Pharmaceutical Trading Enterprise Licenses mandated that distributors employ licensed pharmacists in numbers commensurate with their scale and maintain temperature-controlled storage facilities, raising barriers to entry for wholesale operations. In 2006, the State Food and Drug Administration began piloting electronic drug monitoring for controlled substances, assigning unique barcodes at the smallest package level. These tighter regulations reduced the number of distributors, which stabilized at approximately 13,000 from 2009 onward---still far above the level in advanced economies. The sector remained fragmented, with a long tail of small, weakly competitive firms.

Phase IV: New Medical Reform and the Two-Invoice System (2009--present). China's "New Medical Reform," launched in 2009, explicitly called for rationalizing drug distribution, raising industry concentration, and developing modern logistics and chain operations. In 2012, Sanming City in Fujian Province pioneered the Two-Invoice reform in drug distribution, achieving measurable reductions in circulation costs. The model was scaled nationwide starting in 2017.

2.2 Reform Rationale

2.2.1 The Multi-Invoice System: Rationale and Limitations

Under the multi-invoice regime, a drug passes through multiple layers of distributors between factory and hospital. Each intermediary issues a separate invoice and adds a markup. This system persisted in China for structural reasons.

First, China's vast geography and its large, stratified network of healthcare facilities posed an immense distribution challenge, especially given the country's historically underdeveloped logistics and information infrastructure. Manufacturers lacked the capacity to reach hospitals and clinics at every administrative level on their own. The multi-tier agency system delegated this last-mile distribution to specialized intermediaries, facilitating geographic penetration.

Second, most Chinese pharmaceutical firms were production-oriented enterprises whose portfolios consisted largely of generic drugs with limited ability to earn rents from innovation or patents. Competitive advantage therefore hinged heavily on sales effort. Manufacturers excelled at R&D and production, whereas distributors possessed specialized marketing capabilities and established hospital-channel relationships. The division of labor inherent in the multi-invoice system---manufacturers producing, distributors selling---allowed each party to focus on its core competency, raising aggregate productivity (Liu et al., 2020).

Third, the long-standing drug-markup compensation mechanism, also known as the distortion of cross-subsidizing hospital operations through drug markups, created powerful demand for multi-layer distribution channels. The Chinese government priced public hospital services below cost to preserve their welfare function. As household incomes rose and demographic shifts intensified demand for healthcare, fiscal subsidies proved increasingly insufficient. As a result, hospitals were permitted to resell drugs at a markup over wholesale prices, with the margin covering operating costs. This drug-markup pricing scheme alleviated hospital budget shortfalls but gave hospitals strong incentives to exploit prescribing authority for revenue (Currie et al., 2014; Zhao et al., 2021). The multi-invoice system provided the operational space and financial conduit to satisfy these incentives.

Fourth, hospitals---the dominant buyers in the pharmaceutical market---held substantial monopsony power. Budgetary constraints and delays in medical-insurance settlement meant that hospitals frequently failed to pay suppliers promptly, leaving drug manufacturers with chronic receivables. Under the multi-invoice system, manufacturers could sell to distributors, who in turn absorbed the collection risk. For small and mid-sized manufacturers with limited capital and financing capacity, this arrangement was critical to maintaining cash flow and operational continuity.

Despite its historical rationale, the multi-invoice system generated serious distortions. First, successive markups drove retail prices far above ex-factory levels. A widely reported online database launched in December 2011 publicly disclosed the ex-factory and retail prices of over 700,000 pharmaceutical products, revealing that retail prices routinely reached five to six times the corresponding ex-factory prices¹. Second, the multi-layer structure harbored illegal practices. Invoice fraud referred to the practice whereby unlicensed agents operated under the credentials of certified distributors, using legitimate invoices to sell drugs to downstream agents or hospitals and then extracting the margin between high selling prices and low purchase prices as slush funds to bribe prescribing physicians and hospital administrators. According to an investigative report by CCTV-13, kickbacks and bribes accounted for 20--40 percent of final drug prices². Third, the fragmented, atomized structure of the distribution industry precluded scale economies. In advanced economies, a handful of large distributors cover the national market, spreading fixed costs across warehouses and IT systems while competing margins down to thin levels. Data from the HDA Foundation show that U.S. pharmaceutical distributors recorded \$758 billion in sales in 2023, yet operated on a gross margin of just 1.7 percent and a net profit margin of 0.3 percent. By contrast, China's multi-invoice regime sustained thousands of under-capitalized distributors, producing a disordered market incapable of realizing comparable scale advantages.

2.2.2 Policy Objectives of the Two-Invoice System

The Two-Invoice System aimed to address the pathologies of the multi-invoice system through three channels. First, by capping the number of permissible distribution links to two, the policy sought to mechanically reduce transaction costs that accumulated across successive layers of intermediation. Second, by limiting the total number of invoices to two, the policy aimed to render the flow of funds across the supply chain transparent, eliminating the opaque spaces that facilitated invoice fabrication, illicit invoicing collusion and bribery. Third, by imposing higher professional and financial requirements on distributors, the policy intended to accelerate industry consolidation, drive out uncompetitive firms, and promote a more concentrated and better-regulated distribution sector.

Fujian Province served as the policy's laboratory. The Two-Invoice system was first piloted there in 2009, covering selected drugs in selected regions, and was extended to all drugs in all public hospitals province-wide by 2012. Implementation required hospitals to procure drugs by directly tendering to manufacturers;

¹ <https://china.huanqiu.com/article/9CaKrnJtwjg>

² <https://tv.cctv.com/2016/12/25/VIDEJMeyrhiUneWIE2PXfAvW161225.shtml>

manufacturers issued one invoice to the designated distributor, and the distributor issued a second invoice to the hospital. Distributors were further required to present their procurement invoices from manufacturers to hospitals, creating a verifiable paper trail. The Fujian pilot delivered measurable results: by 2017, the number of drug distributors in the province had fallen from over 200 to 62, industry concentration had risen, and distribution fees had declined from 5--8 percent to 3--5 percent.

The success of the Fujian pilot provided the empirical foundation for national rollout. In December 2016, the State Council's Medical Reform Office issued the "Implementation Opinions on Promoting the Two-Invoice System in Drug Procurement by Public Medical Institutions", defining the Two-Invoice rule as follows: one invoice from the manufacturer to the distributor, and one invoice from the distributor to the medical institution---with no additional invoices permitted across the entire distribution chain. In January 2017, the National Health and Family Planning Commission issued a formal Notice that the Two-Invoice System will be gradually implemented in drug procurement of public medical institution. With this, the Two-Invoice System was officially launched at national scale.

3. Literature Review and Research Hypotheses

3.1 Literature Review

3.1.1 Regulation and Firm Strategic Response

Regulation refers to government intervention in the conduct of microeconomic agents, undertaken to correct market failures, restore efficiency, and protect the public interest (Uekusa, 1992). It is especially common in natural-monopoly industries—public utilities, for example—or in sectors where social welfare is directly at stake, such as pharmaceutical markets (Vogelsang and Finsinger, 1979). From the 1930s through the 1970s, Keynesian orthodoxy dominated Western economic thought, and a proliferation of new regulatory instruments accompanied expanding state intervention in the economy. Yet even in natural-monopoly industries and public utilities, where regulation is arguably most warranted, prolonged regulatory oversight may itself give rise to regulatory failure. Against the backdrop of Western stagflation in the 1970s, economists began to examine the limitations of government regulation more systematically. The economics of regulation holds that government agencies, as the implementers of regulation, are themselves fully rational economic agents who make decisions based on their own economic or political interests rather than solely on considerations of the public interest (Stigler, 1971; Peltzman, 1976; Becker, 1983). When regulatory measures are systematically adjusted in favor of powerful interest groups—regulatory capture—the result is regulatory failure and welfare losses (Krueger, 1974). As political and economic systems have evolved, regulatory capture has assumed more subtle forms, including cognitive capture and cultural capture (Carpenter and Moss, 2013; Chen and Xu, 2025). The new economics of regulation, for its part, acknowledges that governments may regulate with the genuine intention of safeguarding the public interest; however, severe information asymmetry between the government and regulated firms can prevent the design of optimal regulatory policies, thereby leading to regulatory failure (Laffont and Tirole, 1993).

Whether regulation in fact fails depends crucially on how targeted firms respond (Lyon and Maxwell, 1999). Oliver (1991) advanced the foundational insight that firms are not passive rule-takers; rather, they deploy a range of strategic actions to resist, reshape, or even co-opt the institutional environment. Oliver's typology classifies firm responses to institutional pressure into five categories—acquiescence, compromise, avoidance, defiance, and manipulation—and subsequent empirical work has validated this framework (Goodstein, 1994; Milliken et al., 1998; Clemens and Douglas, 2005). Building on Oliver's framework, later scholars have enriched the analysis of organizational responses to regulation under varying conditions. Pache and Santos (2013) proposed a strategy of selective coupling, in which organizations selectively combine specific elements from complex institutional demands, thereby avoiding the high costs of full compliance or full decoupling. Durand et al. (2019) argued that firms adopt one of five response strategies—ranging from substantive compliance to inaction—depending on issue importance and the cost–benefit calculus of action. Aluchna and Kuszewski (2022) classified firm strategies into two broad categories—acceptance and rejection—each further differentiated into three or four subtypes, with the choice of strategy contingent on institutional pressure, organizational characteristics, and managerial cognition.

Firm strategic responses can themselves precipitate regulatory failure. Shapiro and Matson (2008) document how influential firms, through avoidance, defiance, and manipulation, successfully blocked a government proposal requiring all listed companies to evaluate and publicly report on their internal controls over financial reporting. Faulconbridge and Muzio (2016) show that multinational enterprises engage in field re-settling—reconfiguring business scope, adjusting operational scale, and reorganizing personnel—to maintain normal operations while evading complex host-country regulations. Heese et al. (2016) find that healthcare regulators selectively apply more lenient standards to charitable hospitals, and that these hospitals exploit this favorable treatment by engaging in fraudulent pricing to offset the financial shortfalls created by uncompensated charitable care.

The empirical literature on regulatory failure and firm strategic response has concentrated heavily on environmental regulation. Rugman and Verbeke (1998) and Wu et al. (2017) find that polluting firms relocate production to jurisdictions with weaker environmental standards, lowering their own compliance costs but potentially degrading environmental quality and public health in the receiving regions. Monogan III et al. (2017) show that air-polluting firms engage in strategic siting, disproportionately locating plants near state borders at downwind positions so that pollutants drift into neighboring states, thereby reducing local residents' exposure. Li et al. (2022) document greenwashing behavior in response to environmental regulation: firms issue voluminous environmental reports to project a pro-environment image, yet the information disclosed may substantially exaggerate their actual environmental performance. Wang et al. (2024) provide evidence supporting the pollution haven hypothesis, showing that industrial firms relocate production activities to administrative boundary areas to evade environmental regulatory pressure, with the concomitant effect of significantly increasing pollution levels at those boundaries.

The foregoing literature has usefully catalogued the repertoire of firm responses to regulation and enriched Oliver's (1991) five-category typology. Yet existing studies tend to focus on the types of responses firms adopt, paying less attention to the micro-mechanisms through which strategies such as avoidance or manipulation are actually implemented—the specific action paths firms follow. Building on this literature, and drawing on Peng's institution-based view, the present paper examines how pharmaceutical firms evade the constraints imposed by the Two-Invoice System, tracing the implementation pathway in detail, including internal organizational restructuring and the transformation of sales models. Moreover, the existing literature on regulation and firm response has been applied predominantly in the domain of environmental regulation, with limited attention to pharmaceutical markets—a sector of central importance to social welfare. By treating the Two-Invoice System as a natural experiment and combining regulation-and-response theory with in-depth analysis of the policy's effects and underlying causes, this paper provides empirical support for extending regulatory economics to pharmaceutical markets.

3.1.2 Pharmaceutical Market Regulation

Because pharmaceuticals are directly linked to human life and safety, many governments regulate drug prices to protect public health and improve access. Common instruments include price caps, profit controls, and reference pricing (Danzon et al., 2005). Whether such regulation achieves its objectives, however, remains contested. Some studies conclude that price regulation lowers drug prices and benefits patients. Granlund (2010) finds that a generic-substitution reform reduced pharmaceutical prices by roughly 10 percent on average. Brekke et al. (2011) show that when parallel imports are present, price regulation significantly reduces pharmaceutical expenditure. Kaiser et al. (2014) find that an internal reference-pricing reform lowered retail prices, reference prices, and patient co-payments simultaneously. Dubois and Lasio (2018) estimate that price regulation saved approximately 2 percent of anti-ulcer drug expenditures relative to a free-pricing counterfactual.

A second strand of research, however, finds that pharmaceutical price regulation often fails to achieve its stated goals and may generate unintended consequences that harm patients' long-term welfare. First, regulation may not succeed even on its own terms of reducing prices. Abbott (1995) finds that price-cap regulation paradoxically led pharmaceutical firms to raise launch prices by about 50 percent. Danzon and Chao (2000) show that price regulation weakens competition among generic manufacturers, curtailing the potential for voluntary price reductions in the off-patent segment. Yip et al. (2019) find that after the elimination of pharmaceutical markups, the intended cost savings were muted and short-lived because healthcare providers' income remained linked to drug prices. Second, because new drug development requires enormous financial and temporal investments, entails great technical difficulty, and has a low probability of success (Dierynck and Joos, 2020), price regulation can dampen pharmaceutical innovation. Vernon (2004) argues that regulation reduces R&D investment through both a profit effect and a cash-flow effect; simulating the impact of price regulation in the United States, the author estimates that such measures would reduce industry R&D spending by 23.4 to 32.7 percent. Brekke et al. (2007) compare several reference-pricing regimes and find that therapeutic reference pricing yields the lowest drug prices but also the lowest returns to patent-holding firms, making it the least conducive to new drug entry. Bardey et al. (2010) find that reference pricing reduces firm profits, shifting the mix of launched drugs toward high-profit projects and away from low-profit ones—suggesting that the long-run consequences of price regulation warrant careful assessment. Finally, price regulation may produce other unintended adverse effects. Jaikumar et al. (2024) find that regulation reduced pharmaceutical firms' spending on market promotion, disproportionately harming disadvantaged populations—particularly the poor—who rely heavily on informal healthcare providers for prescriptions, even though these are precisely the groups the regulation was intended to benefit.

This literature has analyzed both the beneficial effects and the limitations of pharmaceutical price regulation in considerable depth. However, existing research has primarily examined instruments that directly target drug prices—price caps, reference pricing, and the like. The Two-Invoice System represents a distinctively Chinese approach to price regulation that operates not by controlling prices directly but by restricting the number of

permissible transactions in the distribution chain, and it has received scant scholarly attention. Moreover, in developed countries, pharmaceutical distribution chains are relatively simple, and price regulation primarily affects manufacturers; the existing literature accordingly focuses on manufacturer-side responses. China, as a large emerging market, has a far more complex distribution process involving extensive promotion, marketing, logistics, and warehousing functions. Whether regulation in such a complex market may trigger additional unforeseen consequences is the question this paper addresses.

3.2 Research Hypotheses

Prior to the Two-Invoice System, most Chinese pharmaceutical manufacturers employed a low-invoicing pricing model. Under this model, manufacturers, which typically lacked independent promotion and distribution capabilities, sold their products at low prices to distribution agents, who then handled downstream sales activities. A minority of firms adopted a high-invoicing model, undertaking sales in-house and setting factory prices that covered both production and distribution costs, resulting in ex-factory prices much closer to the final retail price. Before the reform, the low ex-factory invoice pricing model was dominant. According to the pharmaceutical ex-factory price index published by the National Bureau of Statistics, this index exhibited a marked upward trend after 2017—precisely when the Two-Invoice System was being rolled out nationally—suggesting a systematic shift from low-invoicing to high-invoicing pricing.

Given that pharmaceutical manufacturers derive their core cash flows from drug sales, changes in operating revenue closely track changes in ex-factory prices. We therefore use operating revenue as a proxy for the ex-factory price. At the same time, we examine changes in net profit following the reform. If operating revenue rises significantly while net profit remains unchanged or declines, the implication is that higher revenue is being driven by higher ex-factory prices, but that additional costs or expenses are absorbing the price-induced revenue gains. We thus propose:

Hypothesis 1: The Two-Invoice System significantly increases the operating revenue of affected firms, reflecting a shift toward higher ex-factory prices.

Hypothesis 2: The Two-Invoice System fails to improve, or conversely reduces, the net profitability of affected firms due to the offsetting burden of internalized selling expenses.

Because changes in revenue may also reflect changes in sales volume rather than price alone, we use the gross profit margin as an alternative dependent variable in robustness checks to isolate the price channel from the quantity channel.

Price regulation that attempts to substitute administrative mechanisms for market price signals often induces behavioral distortions among regulated firms. In the pharmaceutical sector, such distortions may take the form of reduced R&D investment, a shift toward low-cost generic production, or reliance on regulatory loopholes to sustain operations (Cheung, 1974). Peng's institution-based view holds that firms' strategic choices are shaped not only by industry conditions (Industry-based View) and firm resources and capabilities (Resource-based View) but also by the institutional environment (Institution-based View). Institutions are of two kinds: formal institutions, which encompass laws, regulations, and government policies; and informal institutions, which include culture, business conventions, and relational networks. In transition economies, when formal institutions undergo change or leave institutional voids, firms rely on informal institutional arrangements to substitute for or complement the formal rules (North, 1990; Peng et al., 2009). This dynamic is especially pronounced during periods of policy transition: old institutional arrangements are dismantled, yet the construction of new formal institutions requires time and entails adjustment costs. In the interim, firms continue to depend on informal institutional arrangements to maintain operational continuity (Peng et al., 2008).

To cope with the constraints imposed by the reform, some manufacturers launched in-house sales models, building in-house teams to handle market promotion, academic conferences, and other commercial activities that had previously been outsourced to distributors. However, establishing an in-house sales organization demands substantial financial resources and managerial capability—capacities that many manufacturers lack. Many firms therefore opted instead for a "high-invoicing, high-rebate" model: raising the ex-factory price to incorporate distribution costs, then channeling funds back to distribution agents through rebates and service fees to sustain downstream promotion. This model effectively internalizes distribution costs into the manufacturer's cost structure.

Based on this mechanism, we propose two additional hypotheses:

Hypothesis 3: The Two-Invoice System significantly increases the selling-expense ratio of affected firms, reflecting the internalization of distribution costs.

Hypothesis 4: The Two-Invoice System leads to a significant increase in the share of sales personnel among affected firms' employees, reflecting vertical integration in sales organization.

4. Empirical Analysis

4.1 Identification Strategy and Model Specification

The Two-Invoice System reform constitutes an exogenous policy shock that offers a quasi-natural experiment for evaluating how distribution regulation shapes firm behavior. In January 2017, the National Health and Family Planning Commission issued the notice mandating adoption of the Two-Invoice System in drug procurement by public medical institutions, after which provinces progressively implemented the reform at the provincial level; the final batch—Heilongjiang, Tibet, and Xinjiang—began execution on January 1, 2018. Because the sample consists of listed pharmaceutical manufacturers that typically operate across multiple regions and whose decisions respond to the national policy environment rather than to province-specific rollout timing, we treat 2017 as a uniform treatment date and employ a difference-in-differences (DID) framework to test the hypotheses developed above.

A critical feature of this policy is that it does not affect all pharmaceutical firms equally. The reform primarily constrains firms that depend heavily on hospital sales channels and market relatively undifferentiated products. In contrast, firms whose products are sold primarily through retail pharmacies or other non-hospital outlets (the so-called "third terminal"), as well as those handling specialty drugs that already operate under flat, professionally managed distribution chains, are far less exposed. Simply classifying treatment and control groups by industry would fail to capture the true intensity of exposure to the Two-Invoice System and would likely introduce endogeneity bias. To construct more accurate treatment and control groups, we exploit firm-level variation along two dimensions using pre-policy (2016) data.

Hospital dependence. We first consider each firm's dependence on hospitals as a sales terminal. By definition, the Two-Invoice System applies only to drugs sold to hospitals; products sold through retail pharmacies or other non-hospital outlets are not directly affected. The greater a pharmaceutical manufacturer's reliance on hospitals, the higher its exposure to the policy. We therefore assign firms with higher hospital dependence to the treatment group and those with lower dependence to the control group. Specifically, we use Python to analyze the descriptions of product characteristics, client profiles, and sales models contained in each firm's 2016 annual report, generating a composite hospital-dependence score.

From the perspective of product characteristics, certain pharmaceutical products—blood products, narcotic and psychotropic drugs, and prescription drugs—can be used only in hospital settings. The more frequently such product names appear in the annual report, the higher the firm's hospital-dependence score. Conversely, OTC products and general health products, which are sold primarily through pharmacies or the third terminal, reduce the score in proportion to their frequency of appearance. From the perspective of client profiles, this study examines the names of each firm's top-five clients or top-five accounts receivable as disclosed in the annual report. The more frequently hospital names (e.g., XX Hospital) or procurement center names (e.g., XX Procurement Center) appear, the higher the hospital-dependence score; the more frequently pharmacy names (e.g., XX Pharmacy) appear, the lower the score. From the perspective of sales models, keywords associated with hospital-oriented sales—such as bidding, medical insurance catalog listing, academic promotion, and clinical trials—raise the score. Keywords associated with non-hospital sales—such as advertising, branding, and pharmacy-terminal promotion—lower the score.

Because the product names and client names appearing in annual reports are objective and verifiable, whereas firms' descriptions of their sales models may be relatively subjective and potentially overstated, we weight the three dimensions unequally: product characteristics receive a weight of 0.4, client profiles a weight of 0.4, and sales models a weight of 0.2. The weighted sum yields the final hospital-dependence score. Descriptive statistics for this score are reported in Table 1.

Table 1. Descriptive Statistics of Hospital Dependence Score		Mean	SD	Min	Max	Median
	Hospital Dependence Score	56.388	16.962	18.700	92	57.3

Product type. Second, we consider each firm's primary product type. A central objective of the Two-Invoice System is to eliminate the layers of costs that accumulate during multi-tier distribution, particularly the gray-market fees generated through illicit practices such as invoice fraud. Prior to the reform, such elevated distribution costs were concentrated among generic drugs with broad indications, high substitutability, and intense market competition. Specialty drugs—products targeting specific diseases that require specialized handling and professional promotion—had already established flat, transparent distribution channels before the reform, and their sales and distribution models were therefore unlikely to change in response to the policy. We accordingly use Python to analyze product-type information from each firm's 2016 annual report and classify firms into three categories. Firms whose primary products are antibiotics, generic cardiovascular drugs, traditional Chinese medicine injections, and similar generics are classified as generic-drug firms; these face high policy exposure and are assigned to the treatment group. Firms whose primary products are blood products, vaccines, or innovative biologics are classified as specialty-drug firms, and those whose primary products are OTC drugs are classified as OTC firms; both categories face low policy exposure and are assigned to the control group. Firms that produce products across multiple categories are classified as diversified-product firms. Because diversified-product firms do manufacture generic drugs, their sales and distribution models are affected by the policy, and we therefore

assign them to the treatment group as well. The distribution of firms across these three categories is reported in

Table 2. Firm Distribution by Primary Product Type	Primary Product Type	Generic Drugs	Diversified Product Portfolio	Specialty or OTC Drugs
	Share of Firms	18.4%	40%	41.6%

Combining these two dimensions, we define the treatment group as firms whose hospital-dependence score exceeds 50 and whose primary products are generic drugs or a diversified product portfolio; all remaining firms constitute the control group. The DID model is specified as follows:

$$Y_{it} = \beta_0 + \beta_1 Treat_i Post_t + \beta Control_{it} + \mu_t + \gamma_i + \varepsilon_{it}, \quad (1)$$

where Y_{it} denotes the four outcome variables for firm i in year t : operating revenue (OR), net profit (NP), the share of sales staff in total employment (PSS), and the ratio of selling expenses to operating revenue (RES). The dummy variable $Treat_i$ equals 1 for firms assigned to the treatment group and 0 otherwise; $Post_t$ equals 1 for years post 2017 and 0 pre 2017. The $Control_{it}$ contains firm-level controls. We control for firm size (SIZE), financial leverage (DAR), short-term solvency (CR), profitability (ROA), ownership type (SOE), production efficiency (PE), capital intensity (CD), and the share of fixed assets (FA). To mitigate scale differences across variables and reduce heteroskedasticity, we take logarithms of operating revenue, net profit, and total assets. Because net profit takes negative values, we apply a shift transformation (net profit + |minimum net profit| + 1) before taking logarithms. All continuous variables are winsorized at the 1st and 99th percentiles. Variable definitions are provided in Table 3.

Table 3. Variable Definitions	Variable Type	Denotation	Meaning	Definition
	Outcome Variables	OR	Operating Revenue	Log of operating revenue
		NP	Net Profit	Log of net profit (shifted)
		PSS	Share of Sales Staff	Sales staff / Total employees
		RES	Selling Expense Ratio	Selling expenses / Operating revenue
	Treatment Variable	DID	TREAT	1 = treatment group, 0 = control group
			POST	1 (year > 2017), 0 (year < 2017)
	Control Variables	SIZE	Firm Size	Log of total assets
		DAR	Financial Leverage	Total liabilities / Total assets
		CR	Short-Term Solvency	Current assets / Current liabilities
		ROA	Profitability	Net profit / Total assets
		SOE	Ownership Type	1 (state-owned enterprise), 0 (otherwise)
		CD	Capital Intensity	Fixed assets / Number of employees
		FA	Fixed Asset Share	Fixed assets / Total assets
		PE	Production Efficiency	Operating revenue / Total employees

The sample comprises all listed pharmaceutical manufacturing firms. Data are drawn from the CSMAR and WIND databases, with missing observations manually supplemented from annual reports filed with the Shanghai and Shenzhen stock exchanges. To ensure clean identification of the policy effect, we drop observations from the implementation year (2017), exclude firms listed after 2014, and remove firms flagged with special treatment (ST) status during 2014–2022. The final sample consists of 125 listed pharmaceutical firms with 1,000 firm-year observations.

4.2 Descriptive Statistics

Table 4 presents the descriptive statistics. Even after logarithmic transformation and winsorization, the key variables exhibit substantial variation, indicating rich informational content. Notably, the selling expense ratio (RES) and the share of sales staff (PSS) display wide ranges between their minimum and maximum values, reflecting considerable heterogeneity across firms in business models and sales strategies—a feature that suggests the Two-Invoice System regulation likely had differential effects across firms.

Table 4. Descriptive Statistics	Variable	Obs.	Mean	SD	Min	Median	Max
	OR	1,000	21.613	1.095	19.292	21.597	24.328
	NP	1,000	21.849	0.219	21.294	21.787	22.656
	RES	1,000	0.263	0.164	0.014	0.251	0.656
	PSS	1,000	0.260	0.178	0.014	0.227	0.648
	treat	1,000	0.336	0.473	0	0	1
	post	1,000	0.625	0.484	0	1	1
	SIZE	1,000	22.328	0.946	20.375	22.277	24.700
	ROA	1,000	0.058	0.064	-0.152	0.055	0.219
	DAR	1,000	0.324	0.172	0.045	0.304	0.781
	SOE	1,000	0.300	0.458	0	0	1
	CR	1,000	3.169	3.017	0.572	2.249	18.747
	CD	1,000	405,469.689	261,902.575	88,230.170	331,034.222	1,448,282.288
	PE	1,000	1,002,625.811	646,602.768	311,109.508	830,594.158	4,026,905.272
	FA	1,000	0.220	0.111	0.044	0.205	0.517

4.3 Empirical Results

4.3.1 Price Effect of Regulation

The price effect is the most direct consequence of the Two-Invoice System. As argued earlier, the regulation compels affected drug manufacturers to shift from the low-invoicing to the high-invoicing distribution mode, which increases reported revenue per unit sold. Controlling for both firm and year fixed effects, the DID estimate in column (1) indicates that the Two-Invoice System is associated with a statistically significant increase in operating revenue, with a coefficient of 0.087. This finding is consistent with Hypothesis 1. Column (2) of Table 5 reports the effect on net profit. The DID coefficient is insignificant, consistent with Hypothesis 2. After the implementation of the Two-Invoice System, the operating revenue of pharmaceutical manufacturing enterprises increased significantly, reflecting that the ex-factory prices of drugs have shifted from low to high. At the same time, there was no significant change in net profit, reflecting that the additional operating revenue brought about by the increase in ex-factory prices was absorbed by other costs or expenses.

Table 5. Price Effect of Regulation		(1)	(2)
		OR	NP
	DID	0.087***	-0.006
		(0.023)	(0.010)
	Constant	4.593***	18.390***
		(0.706)	(0.357)
	Controls	Yes	Yes
	Firm FE	Yes	Yes
	Year FE	Yes	Yes
	Observations	1,000	1,000
Robust standard errors are reported in parentheses. ***p < 0.01, **p < 0.05, *p < 0.1.		R-squared	0.980
			0.890

4.3.2 Structural Effect of Regulation

We now examine whether the Two-Invoice System induced structural changes in firm organization. Column (1) of Table 6 reports the effect on the selling expense ratio. The DID estimate is 0.037, confirming Hypothesis 3. Although the regulation formally eliminated multi-tier distribution, the sales and promotional activities previously performed by intermediaries remain essential for moving pharmaceutical products into hospitals. In practice, these functions have been shifted upstream to the manufacturer, and the associated costs are now borne directly by the firm, manifesting as a higher selling expense ratio. Column (2) of Table 6 examines the share of sales staff in total employment. The DID coefficient is 0.026, supporting Hypothesis 4. Following the reform, treated firms significantly expanded their sales workforce as a share of total employees. This result is consistent with vertical integration along the distribution chain: unable to rely on external distributors to the same extent as before, affected firms built up in-house sales capacity to manage the promotional, logistical, and relationship-management tasks that the intermediaries previously handled.

Table 6. Structural Effect of Regulation		(1)	(2)
Robust standard errors are reported in parentheses. ***p < 0.01, **p < 0.05, *p < 0.1.		RES	PSS
	DID	0.037***	0.026***
		(0.011)	(0.008)
	Constant	1.958***	-0.005
		(0.306)	(0.253)
	Controls	Yes	Yes
	Firm FE	Yes	Yes
	Year FE	Yes	Yes
	Observations	1,000	1,000
	R-squared	0.824	0.899

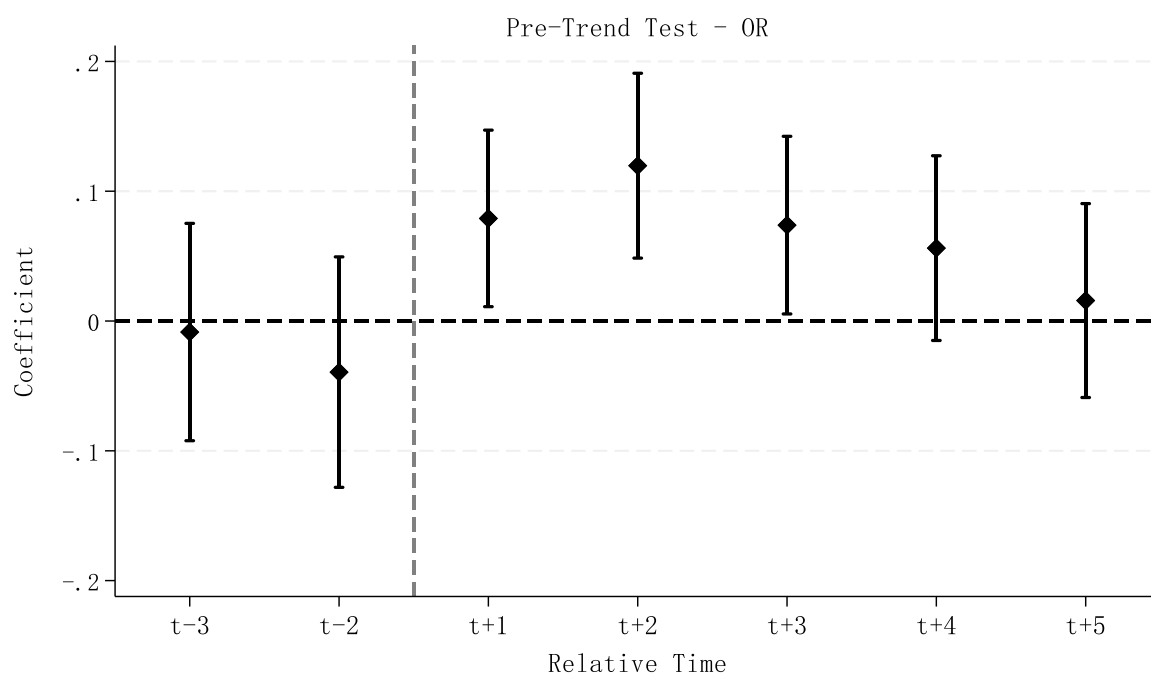
5. Robustness Checks and Heterogeneity Analysis

5.1 Robustness Checks

5.1.1 Pre-Trend Test

A key identifying assumption of the difference-in-differences (DID) estimator is that treatment and control groups would have followed parallel trends in the absence of treatment. Because the counterfactual post-treatment trajectory of the treated group is unobservable, researchers typically assess pre-treatment trends for indirect evidence in support of this parallel-trends assumption. To conduct this test, this paper interacts year dummies with the treatment-group indicator, replacing the single DID estimator in model (1), and use period $t - 1$ (2016) as the reference period. If the coefficients on the pre-treatment interactions are statistically insignificant, the data fail to reject the parallel-trends assumption.

Because the baseline regressions using net profit as the dependent variable yielded uniformly insignificant results, the pre-trend analysis focuses on the three responsive outcome variables: operating revenue, the share of sales personnel, and the selling-expense ratio. As Figure 3 shows, none of the pre-treatment coefficients are statistically significant, whereas the post-treatment coefficients align closely with the baseline estimates. The data are therefore consistent with parallel pre-treatment trends.



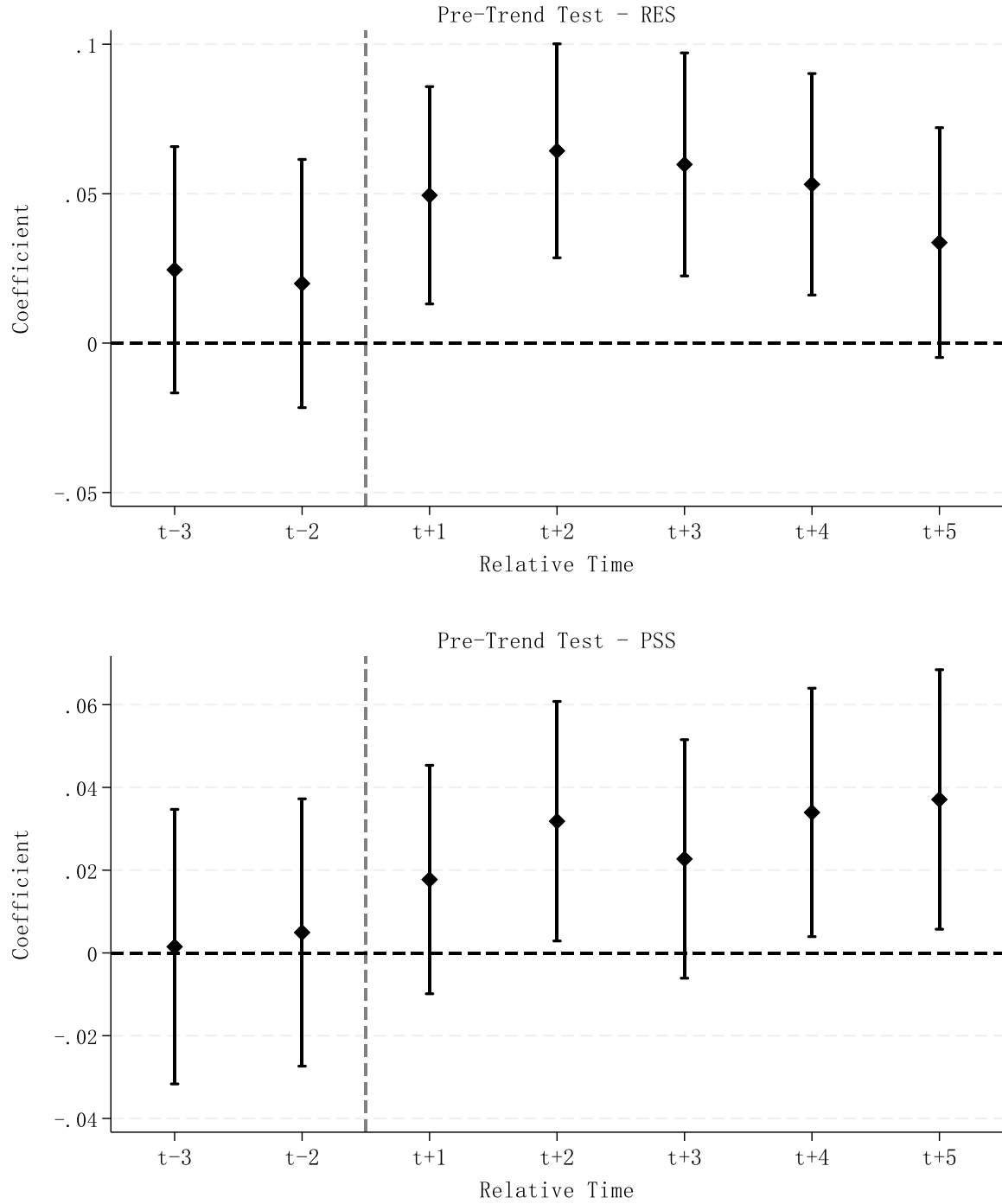
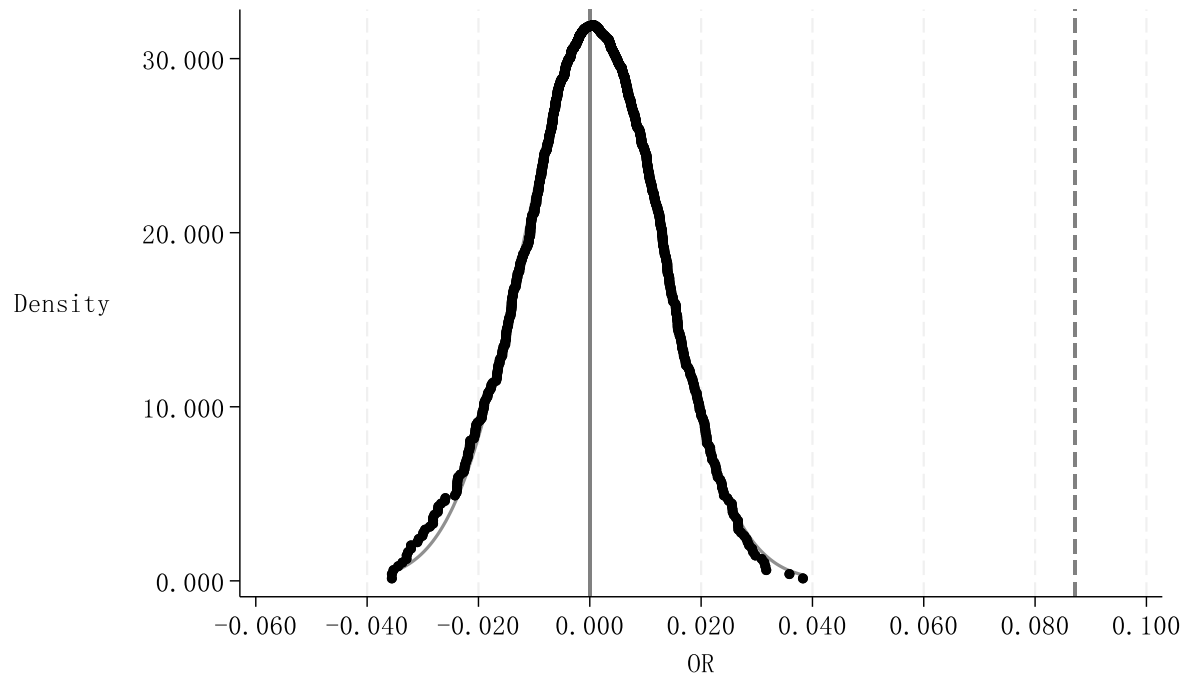
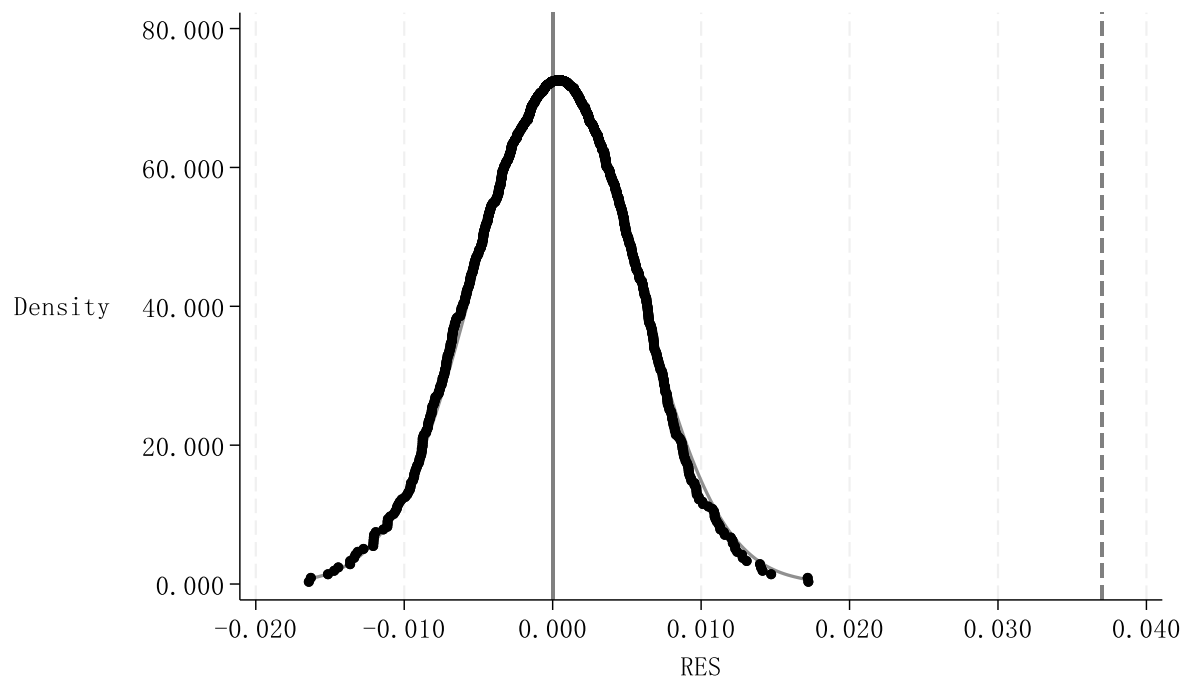


Fig.3 Pre-Trend Test Results

5.1.2 Placebo Test

A placebo test provides a further check against spurious inference. This section implements the test by randomly reassigning the treatment indicator across firms: from the full sample, we draw a pseudo-treated group at random, designate the remaining firms as the pseudo-control group, and estimate the DID regression on these fictitious assignments. Repeating this procedure 1,000 times produces the distribution of placebo estimates shown in Figure 4. The 1,000 placebo coefficients are centered tightly around zero and follow an approximately normal distribution, standing in stark contrast to the true estimate (indicated by the vertical dashed line). Because the true coefficient lies far in the tail of the placebo distribution, the baseline result passes the placebo test and is unlikely to be an artifact of chance.



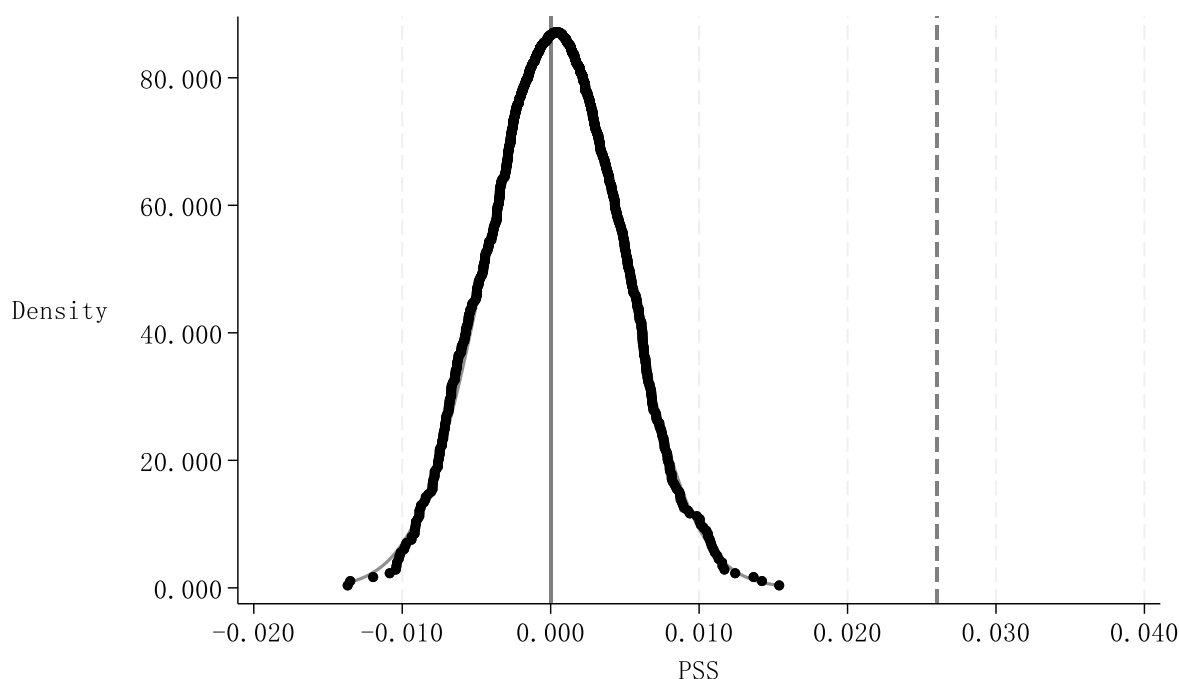


Fig.4 Placebo Test Results

5.1.3 Excluding Sales Volume Effects

The preceding analysis uses operating revenue as a proxy for ex-factory prices. Because revenue equals price times quantity, a revenue increase could in principle reflect greater sales volume rather than higher prices. To distinguish the pure price effect from potential compounding volume adjustments, we replace operating revenue with gross margin (GP), defined as $(\text{operating revenue} - \text{operating cost}) / \text{operating revenue}$. If the revenue increase were driven by volume growth, costs would rise proportionally and the gross margin would remain largely unchanged. If instead the increase reflected higher ex-factory prices, gross margin should rise appreciably. As column (1) of Table 7 reports, the Two-Invoice System led to a statistically significant increase in gross margin, confirming that the revenue effect operates through prices rather than volumes.

5.1.4 Excluding Other Major Reform Interference

A valid policy evaluation must guard against confounding by concurrent reforms. Since the launch of China's "New Medical Reform" in 2009, the government has implemented several major nationwide policies aimed at reducing drug prices. The four most consequential are: the zero-markup reform for hospital drug sales, the National Reimbursement Drug List (NRDL) negotiations, the Two-Invoice System, and centralized volume-based procurement (VBP). We address each potential confound in turn.

The zero-markup reform, piloted from 2009 and extended to all county-level public hospitals by 2015, predates the Two-Invoice System. If this earlier reform continued to generate differential effects across treatment and control groups during the Two-Invoice rollout, it would confound the estimates. The pre-trend test presented in Section 5.1.1, however, revealed no significant differential pre-trends, implying that the zero-markup reform had not caused systematic divergence between the two groups by the time the Two-Invoice System took effect.

The NRDL negotiations, conducted on a regular basis beginning in 2017, target expensive, exclusive, insufficiently competitive innovative drugs or patented drugs, using strategic purchasing to improve price accessibility. Although the NRDL negotiations overlap temporally with the Two-Invoice System, the two policies operate on distinct segments of the pharmaceutical market: the NRDL negotiations primarily affect innovative drugs, whereas the Two-Invoice System targets highly competitive generic drugs. Because innovative and generic drugs differ markedly in their sales models, distribution channels, and price formation mechanisms, the NRDL negotiations are unlikely to confound the estimated effects of the Two-Invoice System.

Centralized volume-based procurement (VBP) poses a greater threat to identification because it shares substantial overlap with the Two-Invoice System in both policy objectives and scope. The VBP pilot launched in November 2018 across 11 cities and was extended nationwide by the end of 2019. Following Li et al. (2026), we address this confound by truncating the sample window to exclude observations after 2019, when the two policies were jointly in force. As columns (2)-(4) of Table 7 show, the key results persist in this restricted sample. These findings confirm that the baseline estimates are not driven by other reforms.

Table 7. Robustness Checks Excluding Sales Volume Effects and Concurrent Medical Reforms		(1)	(2)	(3)	(4)	(5)
		GP	OR	NP	RES	PSS
	DID	0.026***	0.116***	-0.018	0.038***	0.019**
		(0.009)	(0.027)	(0.012)	(0.013)	(0.010)
	Constant	1.010***	5.613***	18.901***	1.984***	-0.336
		(0.336)	(1.132)	(0.421)	(0.456)	(0.278)
	Controls	Yes	Yes	Yes	Yes	Yes
	Time FE	Yes	Yes	Yes	Yes	Yes
	Firm FE	Yes	Yes	Yes	Yes	Yes
	Observations	1,000	625	625	625	625
Robust standard errors are reported in parentheses. ***p < 0.01, **p < 0.05, *p < 0.1.		R-squared	0.866	0.981	0.884	0.831
					0.831	0.916

5.1.5 Related Party Transaction Evidence

Related-party transactions are pervasive and large-scale in China's pharmaceutical industry. If the Two-Invoice System induced manufacturers to internalize previously outsourced distribution functions, this structural shift should be reflected in the composition of their related-party transactions. This study examines changes in two categories of related-party transactions—goods-related (RPT_G) and services-related (RPT_S)—around the policy rollout. Specifically, we estimate the following model:

$$RPT_C_{it} = \alpha_0 + \alpha_1 Treat_i Post_t + \alpha Control_{it} + \mu_t + \gamma_i + \varepsilon_{it}, \quad (2)$$

where RPT_C_{it} is the natural logarithm of either goods-related or services-related related-party transaction volume for firm i in year t , and all other variables are as defined previously. Data on related-party transactions are obtained from the CSMAR database.

Column (1) of Table 8 shows that the Two-Invoice System had no significant effect on goods-related related-party transactions. This result is plausible because most goods-related transactions involve the procurement of active pharmaceutical ingredients, which lie outside the policy's scope. Column (2) reveals a large and statistically significant increase in services-related related-party transactions. This finding is consistent with the mechanism documented above: once the Two-Invoice System took effect, manufacturers absorbed distribution functions in-house and required substantially more professional sales labor—commission-based services, promotional activities, and related outsourced tasks—provided by subsidiaries and affiliated entities, thereby driving up services-related related-party transaction volume.

Table 8. Related Party Transaction Evidence		(1)	(2)
		RPT_G	RPT_S
	DID	0.600	3.225***
		(0.760)	(0.684)
	Constant	-50.610***	-49.913***
		(17.765)	(15.351)
	Controls	Yes	Yes
	Firm FE	Yes	Yes
	Time FE	Yes	Yes
	Observations	1,000	1,000
Robust standard errors are reported in parentheses. ***p < 0.01, **p < 0.05, *p < 0.1.		R-squared	0.658
			0.525

5.2 Heterogeneity Analysis

5.2.1 By Product Concentration

Product concentration measures the degree to which a pharmaceutical firm's revenue derives from a small number of core products. Firms with high product concentration rely heavily on a few key drugs, giving them deep therapeutic expertise and strong market influence in specific niches but also exposing them to greater downside risk from adverse policy shocks. Firms with low product concentration spread their revenue across many product lines, which dampens the impact of shocks to any single product and confers greater resilience.

We measure product concentration using the Herfindahl–Hirschman Index of product-level revenue shares:

$$PCI = \sum_{k=1}^N (S_k)^2, \quad (3)$$

where S_k is the share of product k in firm i 's total operating revenue and N is the total number of products the firm sells. Because product portfolios vary widely across firms, we hand-collected product-level revenue breakdowns from the annual reports of all listed pharmaceutical companies, identified individual products and their corresponding sales, computed each firm's HHI, and then split the sample at the median into high-PCI and low-

PCI groups. Firms with incomplete product-level disclosures were excluded from this subsample analysis.

Table 9 reports the price-effect heterogeneity results. For both high- and low-concentration firms, the Two-Invoice System significantly increased operating revenue while leaving net profit unaffected, consistent with the baseline findings.

Table 9. Heterogeneous Price Effects by Product Concentration		(1)	(2)	(3)	(4)
		High-PCI		Low-PCI	
		OR	NP	OR	NP
	DID	0.088**	-0.014	0.145***	0.004
		(0.040)	(0.016)	(0.025)	(0.013)
	Constant	5.990***	18.882***	2.754***	17.711***
		(1.130)	(0.518)	(0.818)	(0.513)
	Controls	Yes	Yes	Yes	Yes
	Time FE	Yes	Yes	Yes	Yes
	Firm FE	Yes	Yes	Yes	Yes
	Observations	464	464	464	464
	R-squared	0.972	0.881	0.986	0.906

Robust standard errors are reported in parentheses.

***p < 0.01, **p < 0.05, *p < 0.1.

Product concentration also shapes how firms organize their sales activities. High-concentration firms, whose product lines are narrow and specialized, tend to adopt in-house sales models to ensure effective promotion of their core products. Low-concentration firms employ more diversified sales strategies, combining agency and in-house models and tailoring the approach to each product's characteristics. Table 10 reveals a sharp contrast: after the Two-Invoice System, high-concentration firms experienced a significant increase in their selling-expense ratio but no significant change in the share of sales personnel. Because their specialized products require domain-specific promotion expertise, these firms responded to the policy by purchasing professional sales services externally rather than by expanding their in-house sales workforce. Low-concentration firms, by contrast, exhibit significant increases in both the selling-expense ratio and the share of sales personnel, reflecting a broader restructuring of their sales operations through both internal hiring and external service procurement.

Table 10. Heterogeneous Structural Effects by Product Concentration		(1)	(2)	(3)	(4)
		High-PCI		Low-PCI	
		RES	PSS	RES	PSS
	DID	0.064***	-0.002	0.041***	0.061***
		(0.018)	(0.014)	(0.014)	(0.012)
	Constant	2.169***	-0.267	1.854***	0.302
		(0.477)	(0.338)	(0.385)	(0.324)
	Controls	Yes	Yes	Yes	Yes
	Time FE	Yes	Yes	Yes	Yes
	Firm FE	Yes	Yes	Yes	Yes
	Observations	464	464	464	464
	R-squared	0.830	0.906	0.814	0.890

Robust standard errors are reported in parentheses.

***p < 0.01, **p < 0.05, *p < 0.1.

5.2.2 By R&D Investment

Research and development and sales are the two core functions of pharmaceutical manufacturers. Firms with high R&D spending tend to possess more proprietary technologies and differentiated products, which confer stronger competitive advantages and greater resilience to adverse regulatory shocks. Firms with low R&D investment are more likely to produce homogeneous, easily substitutable generics and must therefore compensate through more aggressive marketing to maintain market share. Because the Two-Invoice System primarily targets the elimination of redundant distribution layers and associated costs, its impact is likely to differ across firms depending on their reliance on sales-intensive versus R&D-intensive strategies.

We split the sample at the median R&D expenditure to form high-R&D and low-R&D groups. The results, reported in Tables 11 and 12, reveal a clear pattern. For high-R&D firms, the policy's only significant effect is an increase in operating revenue; net profit, the selling-expense ratio, and the share of sales personnel all remain unchanged. For low-R&D firms, by contrast, operating revenue rises, the selling-expense ratio increases, the share of sales personnel expands, and net profit declines significantly. These findings confirm the intuition that innovation-capable firms, endowed with stronger core competitiveness, absorb the policy shock more smoothly. Low-R&D firms, whose products face greater substitution pressure, must escalate both personnel and financial commitments to sales, and the resulting cost increases erode profitability.

Table 11. Heterogeneous Price Effects by R&D Investment		(1)	(2)	(3)	(4)
		High R&D		Low R&D	
		OR	NP	OR	NP
	DID	0.052*	0.005	0.122***	-0.026**
		(0.028)	(0.015)	(0.036)	(0.013)
	Constant	3.519***	17.954***	6.712***	18.570***
		(0.779)	(0.545)	(1.173)	(0.433)
	Controls	Yes	Yes	Yes	Yes
	Time FE	Yes	Yes	Yes	Yes
	Firm FE	Yes	Yes	Yes	Yes
Robust standard errors are reported in parentheses. ***p < 0.01, **p < 0.05, *p < 0.1.		Observations	504	496	496
		R-squared	0.984	0.897	0.978

Table 12. Heterogeneous Structural Effects by R&D Investment		(1)	(2)	(3)	(4)
		High R&D		Low R&D	
		RES	PSS	RES	PSS
	DID	0.021	0.011	0.048***	0.042***
		(0.016)	(0.011)	(0.013)	(0.013)
	Constant	2.391***	-0.374	1.300***	0.389
		(0.447)	(0.314)	(0.442)	(0.372)
	Controls	Yes	Yes	Yes	Yes
	Time FE	Yes	Yes	Yes	Yes
	Firm FE	Yes	Yes	Yes	Yes
Robust standard errors are reported in parentheses. ***p < 0.01, **p < 0.05, *p < 0.1.		Observations	504	496	496
		R-squared	0.793	0.919	0.856

5.2.3 By Firm Size

Large pharmaceutical firms possess stronger financial resources and managerial capacity, enabling them to choose between in-house and agency sales models as circumstances dictate. Most small and mid-sized firms, by contrast, lack the scale to build their own sales teams and therefore relied on agency models prior to the Two-Invoice System. The policy's regulatory burden is thus likely to fall differentially across the firm-size distribution. We split the sample at the median total assets to form large-firm and small-firm groups.

Tables 13 and 14 present the results. For large firms, the pattern mirrors the baseline: operating revenue rises significantly, the selling-expense ratio increases, the share of sales personnel expands, and net profit is unaffected. Small firms also experience significant increases in operating revenue and the selling-expense ratio, but they additionally suffer a significant decline in net profit, with no significant change in the share of sales personnel. These results indicate that small firms, unable to sustain their pre-reform sales channels, must divert substantial resources to purchasing professional promotional services from third-party providers. The higher ex-factory prices they obtain are fully offset by these additional costs, resulting in lower profitability. Moreover, for resource-constrained small firms that cannot afford to expand their in-house sales workforce, the adjustment necessarily takes the form of outsourcing rather than internal hiring—hence the significant increase in the selling-expense ratio but not in the share of sales personnel.

Table 13. Heterogeneous Price Effects by Firm Size		(1)	(2)	(3)	(4)
		Large Firms		Small Firms	
		OR	NP	OR	NP
	DID	0.111***	-0.013	0.096***	-0.021***
		(0.028)	(0.013)	(0.035)	(0.007)
	Constant	3.691***	15.748***	3.137***	20.894***
		(1.030)	(0.472)	(1.094)	(0.276)
	Controls	Yes	Yes	Yes	Yes
	Time FE	Yes	Yes	Yes	Yes
	Firm FE	Yes	Yes	Yes	Yes
Robust standard errors are reported in parentheses. ***p < 0.01, **p < 0.05, *p < 0.1.		Observations	504	496	496
		R-squared	0.973	0.929	0.952

Table 14. Heterogeneous Structural Effects by Firm Size		(1)	(2)	(3)	(4)
		Large Firms		Small Firms	
		RES	PSS	RES	PSS
	DID	0.041***	0.023**	0.040**	0.014
		(0.012)	(0.011)	(0.018)	(0.012)
	Constant	2.038***	0.982***	1.105**	-0.435
		(0.373)	(0.359)	(0.431)	(0.301)
	Controls	Yes	Yes	Yes	Yes
	Time FE	Yes	Yes	Yes	Yes
	Firm FE	Yes	Yes	Yes	Yes
Robust standard errors are reported in parentheses. ***p < 0.01, **p < 0.05, *p < 0.1.	Observations	504	504	496	496
	R-squared	0.839	0.906	0.818	0.907

6. Further Analysis

The preceding sections established that the Two-Invoice System pushed distribution costs upstream into manufacturing firms, raising ex-factory prices and selling-expense ratios. This section probes two deeper consequences: how the policy reshaped firms' sales models and how it restructured the broader distribution ecosystem.

6.1 Sales Model Transformation

Selling expenses comprise multiple subcategories -- staff compensation, marketing and promotion outlays, consulting fees, and depreciation, among others. Shifts in the internal composition of these expenses can illuminate adjustments in a firm's sales model, warranting closer examination.

The Two-Invoice System rendered the traditional multi-tier agency model infeasible. Pharmaceutical manufacturers responded by transitioning toward one of two alternative sales models -- or a combination of both. Under an in-house model, firms build their own sales forces to conduct marketing campaigns, organize academic conferences, and manage client visits, which should manifest in higher marketing, conference, and business-development expenditures. Under an outsourcing model, firms contract with specialized sales-service providers, paying service fees, agency commissions, or similar charges. In practice, many firms adopt elements of both approaches simultaneously.

Hypothesis 5. The Two-Invoice System induces pharmaceutical manufacturers to shift toward in-house and/or outsourced sales models, increasing total selling-related expenditures.

To test this hypothesis, we estimate the following specification:

$$TSE_{it} = \rho_0 + \rho_1 Treat_i Post_t + \rho Control_{it} + \mu_t + \gamma_i + \varepsilon_{it}, \quad (4)$$

where TSE_{it} denotes the natural logarithm of total selling-related expenditures for firm i in year t . We construct this variable by scraping annual reports for four categories of expenditures: market expansion, conferences, marketing, and service fees. The scraping procedure identifies relevant line items using keyword lists for each category -- market expansion (market, development, business, promotion, expansion, entertainment); conferences (conference, meeting, exhibition, exhibition participation, booth, expo, academic); marketing (publicity, advertising, marketing, promotion, branding); and service fees (consulting, intermediary, service, labor, commission, agency, institution). Annual amounts across all four categories are summed to obtain total selling-related expenditures. All other variables are defined as in the preceding sections.

Table 15 reports the results. The coefficient on the treatment indicator is positive and statistically significant, confirming Hypothesis 5. These estimates imply that the Two-Invoice System prompted pharmaceutical manufacturers to transition from multi-tier agency distribution toward in-house and/or outsourcing sales models, thereby internalizing previously externalized distribution functions.

Table 15. Effect of Regulation on Sales Model Transformation		(1)
		TSE
	DID	0.202*
		(0.118)
	Constant	13.436***
		(2.940)
	Controls	Yes
	Time FE	Yes
	Firm FE	Yes
	Observations	1000
Robust standard errors are reported in parentheses. ***p < 0.01, **p < 0.05, *p < 0.1.	R-squared	0.802

6.2 Distribution Ecology Transformation

Under the pre-reform multi-invoice regime, distribution intermediaries profited handsomely from their control over sales channels and networks. Each year, large numbers of newly registered pharmaceutical wholesalers and sole proprietorships entered the market to engage in wholesale distribution, sub-distribution, and agency activities. The implementing rules of the Two-Invoice System in most provinces explicitly target pharmaceutical wholesale enterprises and public medical institutions. After the reform, the pharmaceutical wholesale sector faced heightened regulatory scrutiny, raising operational barriers and squeezing out small and medium-sized wholesalers that lacked core competitive capabilities.

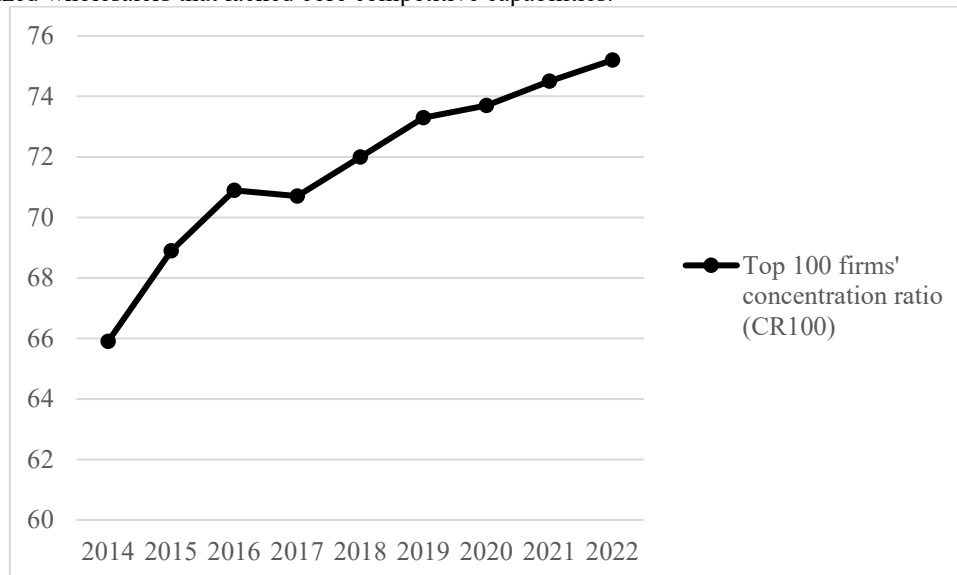


Fig.5 illustrates the evolution of concentration in the pharmaceutical wholesale industry.

Source: Statistical analysis report on the operation of China's pharmaceutical distribution industry

As documented in earlier sections, many pharmaceutical manufacturers adopted outsourced sales models following the reform, partnering with specialized sales-service firms. These entities are typically Contract Sales Organizations (CSOs), which possess professional marketing expertise and dedicated teams, often maintaining long-standing relationships with their clients. CSOs do not participate in the physical procurement or resale of pharmaceutical products; rather, they provide outsourced marketing and sales services to manufacturers, including pharmaceutical consulting, market research, promotional campaigns, and academic conference organization.

Hypothesis 6. The Two-Invoice System restructures the distribution ecosystem: it significantly reduces new registrations of traditional pharmaceutical wholesale enterprises while promoting new registrations of pharmaceutical consulting and service firms, reflecting a structural transformation of the distribution landscape.

To test this hypothesis, we draw on business registration records and estimate a negative binomial regression model, which is appropriate because the dependent variable -- the count of newly registered firms -- is overdispersed (variance exceeds the mean). The Poisson model is likewise suited for count data but is inferior here due to the overdispersion in the data, so only negative binomial results are reported. The specification is:

$$Count_C_{mt} = \varphi_0 + \varphi_1 Post_t + \varphi Control_{mt} + \mu_t + \gamma_m + \varepsilon_{mt}, \quad (5)$$

The dependent variable is the number of newly registered pharmaceutical commercial enterprises in province m in year t . Pharmaceutical commercial enterprises span two industry classifications: firms in the pharmaceutical and medical equipment wholesale category (industry code F) and CSO-type service firms, which are typically registered under the leasing and business services category (industry code L). Accordingly, we construct two dependent variables: (1) the annual count of newly registered enterprises in the pharmaceutical and medical equipment wholesale industry in each province, and (2) the annual count of newly registered enterprises in the leasing and business services industry whose business scope includes consulting-related keywords (consulting, medical, pharmaceutical, health, drugs, healthcare, health, and health products), filtered from the full set of registrations in that industry category from 2014 to 2022.

The key independent variable is a post-policy indicator, equals 1 for years post 2017 and 0 pre 2017. Control variables include the natural logarithm of provincial GDP, the natural logarithm of population, the natural logarithm of per capita disposable income, local government size (general budget expenditure divided by GDP), financial development (year-end outstanding loan balances divided by GDP), healthcare capacity (the natural logarithm of the number of beds in healthcare institutions), province fixed effects, and year fixed effects.

The business registration data cover all newly registered enterprises since 1949, including firm name, date of establishment, industry classification, and business scope. The data encompass a large proportion of small and medium-sized enterprises, providing strong representativeness. Control variables are from the CSMAR database.

Table 16 presents the results. The Two-Invoice System significantly reduced new registrations of pharmaceutical wholesale enterprises (column 1) while significantly increasing new registrations of pharmaceutical consulting and service firms (column 2). These findings support Hypothesis 6: the reform imposed stricter and more standardized oversight on the pharmaceutical wholesale sector, raising barriers to entry and reducing the number of new wholesale registrants. Simultaneously, as manufacturers increasingly contracted with CSOs and other service providers, new sales models and channels emerged, producing a structural transformation of the distribution ecosystem.

Table 16. Effect of Regulation on Distribution Ecology Restructuring		(1)	(2)
		Count C	Count L
Robust standard errors are reported in parentheses. ***p < 0.01, **p < 0.05, *p < 0.1.	POST	-3.040***	2.189***
		(0.718)	(0.543)
	Constant	-27.599*	29.645***
		(14.226)	(10.555)
	Controls	Yes	Yes
	Time FE	Yes	Yes
	Province FE	Yes	Yes
	Observations	248	248
	Inalpha	-2.108***	-2.857***
		(0.108)	(0.103)

7. Conclusion and Policy Implications

In this study, we document and examine the unintended consequences of the Two-Invoice System and the micro-mechanisms through which they arise. The central finding is that although the reform compressed the number of invoicing transactions in the pharmaceutical distribution chain, it did not eliminate the underlying marketing, client relationship management, and promotional functions that intermediaries had previously performed. Confronted with the regulatory shock, pharmaceutical manufacturers undertook organizational and strategic restructuring—either vertically integrating distribution by expanding their in-house sales forces or outsourcing to contract sales organizations (CSOs)—thereby internalizing previously external distribution functions and absorbing the associated costs. This process produced two reinforcing consequences. On the price dimension, the costs of internalized distribution functions were incorporated into ex-factory prices, giving rise to the high-invoicing model and effectively neutralizing the policy's intended price reductions. On the industry dimension, traditional wholesale enterprises were suppressed while medical consulting firms—the carriers of the new marketing functions—proliferated rapidly. Heterogeneity analyses further reveal that this distribution regulation had more pronounced effects on firms with lower product concentration, weaker R&D capabilities, and smaller scale, exposing the underlying reality that the regulatory burden falls most heavily on firms locked in price-based hypercompetition among undifferentiated products. Based on these findings, and with a view toward deepening the reform of China's healthcare and pharmaceutical system, we propose the following policy implications.

First, establish multi-agency coordinated penetrating audits to strengthen the governance framework. Our findings show that the CSO model flourished after the Two-Invoice System, becoming the primary vehicle for cost internalization and regulatory arbitrage. In response, the policy focus must shift toward regulating the substantive content of marketing activities and the authenticity of the functions they claim to perform. Regulatory authorities—including healthcare insurance, taxation, and market supervision agencies—should establish coordinated mechanisms to conduct penetrating audits of consulting fees, promotion fees, and similar expenditures, verifying that the corresponding academic promotion or market services are genuine, reasonable, and compliant, rather than disguised rent transfers.

Second, pursue multi-policy coordination to compress the space for high billing through volume-based procurement and payment reform. This paper reveals that the Two-Invoice System triggered widespread adoption of the high-invoicing model. The root cause lies in the fact that the price mechanism for pharmaceuticals was left untouched, necessitating coordination with the broader "three-medical linkage" reform, which refers to the coordinated reform of medical services, medical insurance, and the pharmaceutical sector³. On one hand, centralized volume-based procurement should continue to expand its coverage of drug categories, using pooled demand to negotiate directly with manufacturers over ex-factory prices and thereby compressing the margin from which high-invoicing markups can be extracted—allowing the channel-purifying effects of the Two-Invoice System to materialize. On the other hand, the transition to DRG/DIP payment systems should be accelerated to

³ In the context of China's health-care reform, the "three-medical linkage" refers to the coordinated reform of medical services, medical insurance, and the pharmaceutical sector. Its purpose is to align hospital incentives, insurance payment mechanisms, and drug pricing and procurement policies.

alter the fee-for-service profit motive of hospitals, incentivizing them to proactively control costs and standardize clinical practices, and thereby eliminating the demand-side driver behind the "high-invoicing, high-rebate" phenomenon.

Third, facilitate the transition from marketing-dependent to innovation-driven competition. Our heterogeneity analysis finds that firms with weaker R&D capabilities responded to the regulatory shock by escalating selling expenditures, a pattern that exposes the broader predicament of marketing involution (excessive sales-based competition) in China's pharmaceutical industry. The long-term remedy to inflated drug prices and kickback-based sales practices lies in shifting the basis of firm competition. When firms can sustain profitability through genuine technological innovation — building durable competitive advantages around clinically differentiated products—their reliance on gray-channel marketing activities will diminish endogenously, returning the industry to a trajectory of virtuous competition centered on therapeutic value.

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