ANTI-COMPETITIVE PRACTICES IN THE HEALTHCARE INDUSTRY: A COMPARATIVE ANALYSIS OF LEGAL IMPLICATIONS AND REGULATORY CHALLENGES IN THE UNITED STATES AND INDIA

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ABSTRACT

The healthcare industry plays a crucial role in public well-being and economic stability, yet it is increasingly dominated by anti-competitive practices that drive up costs, reduce consumer choice, and limit innovation. This research paper examines key anti-competitive behaviours in healthcare, including market monopolization, price fixing, pay-for-delay agreements, exclusive contracts, and Pharmacy Benefit Manager (PBM) manipulations. These practices significantly impact healthcare affordability and accessibility, particularly in the United States and India, where market structures differ but face similar regulatory challenges.

In the United States, hospital consolidations and mergers have led to regional monopolies, higher healthcare costs, and reduced competition, often without corresponding improvements in patient care. Pharmaceutical companies engage in price fixing and delay the entry of generic drugs through pay-fordelay agreements, costing consumers billions of dollars annually. PBMs manipulate drug pricing, prioritizing higher-cost medications that offer greater rebates, further inflating prescription drug costs. In India, corporate hospital chains, pharmaceutical pricing manipulation, and limited healthcare regulation contribute to inflated costs and restricted access to essential medicines. Price collusion and patent evergreening tactics by multinational pharmaceutical companies delay the availability of affordable generics. Weak enforcement and limited oversight by the agencies allow private entities to dominate the market.

This study proposes stronger antitrust enforcement, increased transparency in pricing, stricter regulations on PBMs and insurance providers, and greater investment in public healthcare infrastructure to combat these anti-competitive practices. International collaboration and policy reforms are

essential to promoting a fairer, more competitive, and patient-centred healthcare system.

Keywords: Healthcare industry, anticompetition, competition, market monopolization, price fixing.

INTRODUCTION

The healthcare industry is a vital sector that directly impacts the well-being of individuals and the economic stability of nations. Access to affordable and high-quality healthcare services is essential for maintaining public health and ensuring economic productivity. However, the industry is increasingly characterized by anti-competitive practices that reduce consumer choice, drive up costs, and stifle innovation. These practices, which include monopolization, price fixing, and restrictive contracts, undermine the principles of a free market and have significant implications for patient care and healthcare costs¹.

A competitive healthcare market promotes efficiency, innovation, and costeffectiveness, leading to better patient outcomes. However, market consolidation, particularly in hospital networks and pharmaceutical companies, has led to fewer choices for consumers and higher prices. Research indicates that hospital mergers and acquisitions often result in increased prices without proportional improvements in the quality of care². Similarly, pharmaceutical companies engage in strategies such as "payfor-delay" agreements, where brand-name drug manufacturers pay generic companies to delay introducing cheaper alternatives, thus maintaining monopolistic pricing³.

Health insurance markets also suffer from anti-competitive practices, such as the formation of narrow networks that limit patient access to certain providers and reduce competition among insurers. Pharmacy Benefit Managers (PBMs), intermediaries between drug manufacturers and insurers, often engage in opaque pricing mechanisms that favour higher-cost drugs while restricting access to lower-cost alternatives. These tactics not only increase healthcare spending but also limit patient access to essential medications and services⁴. This paper aims to analyse

¹ Martin Gaynor, Farzad Mostashari & Paul B. Ginsburg, Making Health Care Markets Work: Competition Policy for Health Care, 317 JAMA 1313 (2017)

² Zack Cooper, Stuart V. Craig, Martin Gaynor & John Van Reenen, The Price Ain't Right? Hospital Prices and Health Spending on the Privately Insured, 134 O.J. Econ. 51 (2019).

³ C. Scott Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. Rev. 1553 (2006), Colum. L. & Econ. Working Paper No. 306.

⁴ Neeraj Sood, Tanya Shih, Karen Van Nuys & Dana P. Goldman, The Flow of Money Through the Pharmaceutical Distribution System, USC Schaeffer Ctr. for Health Pol'y & Econ. Rep. (2017).

the various anti-competitive practices in the healthcare industry, their economic and social impacts, and potential policy solutions to foster a more competitive and fair healthcare market. By examining hospital consolidations, pharmaceutical pricing strategies, insurance market manipulations, and regulatory challenges, this study will provide a comprehensive understanding of the competitive landscape of the healthcare sector. The findings will also explore how stronger antitrust enforcement and policy reforms can help address these issues and create a more equitable healthcare system.

Anti-Competitive Practices

Anti-competitive practices refer to business behaviours that reduce competition, limit consumer choices, and create artificial barriers to market entry. In the healthcare industry, such practices distort market dynamics, often leading to higher costs, reduced quality of care, and decreased innovation⁵. Unlike other industries, where competition fosters efficiency and price reduction, healthcare markets are uniquely vulnerable to consolidation and restrictive agreements due to regulatory complexities, high entry costs, and the critical nature of medical services.

Types of Anti-Competitive Practices in Healthcare

1. Market Consolidation and Monopolization

Market consolidation and monopolization occur when healthcare entities merge or acquire competitors, reducing the number of independent providers, insurers, or pharmaceutical companies in a given market. While proponents argue that consolidation leads to greater efficiency and better coordination of care, empirical evidence suggests that it often results in higher prices, reduced competition, and limited access to care⁶.

Hospital consolidation has been a dominant trend in the U.S. healthcare system over the past few decades. Prices at hospitals that face little to no competition are significantly higher by as much as 54% compared to those in more competitive markets⁷. The lack of competition allows

⁵ Martin Gaynor, Kate Ho & Robert Town, The Industrial Organization of Health-Care Markets, 53 J. Econ. Literature 235 (2015).

⁶ Supra 1

⁷ Supra 2

dominant hospitals to set higher prices without necessarily improving the quality of care.

2. Price Fixing and Collusion

Price fixing occurs when competing firms agree to set prices rather than allowing market forces to determine them. In the pharmaceutical industry, price collusion has been documented in generic drug markets, where manufacturers coordinate to maintain high prices⁸. Such practices eliminate price competition, producing artificially inflated costs for consumers and insurers. Price fixing and collusion are among the most harmful anti-competitive practices in the healthcare industry. These practices occur when companies, including pharmaceutical manufacturers, hospitals, insurance providers, and healthcare suppliers, conspire to set prices at artificially high levels, preventing fair market competition⁹. Such conduct leads to inflated costs, reduced consumer choice, and financial strain on patients and government healthcare programs

3. Pay-for-Delay Agreements

Pay-for-delay agreements occur when brand-name pharmaceutical companies pay generic manufacturers to delay the entry of cheaper alternatives into the market. These settlements allow brand-name drugs to maintain monopolistic pricing beyond their patent periods. Pay-for-delay agreements, also known as reverse payment settlements, are anti-competitive deals in which brand-name pharmaceutical companies pay generic drug manufacturers to delay the release of cheaper alternatives. These agreements allow brand-name drug makers to extend their market exclusivity beyond patent expiration, keeping drug prices artificially high. The Federal Trade Commission (FTC) estimates that pay-for-delay deals cost consumers and taxpayers approximately \$3.5 billion annually 10.

4. Exclusive Contracts and Anti-Steering Clauses

Exclusive contracts and anti-steering clauses are anti-competitive practices used by hospitals, insurers, and pharmaceutical companies to limit competition and control market dynamics.

⁸ Michael A. Carrier & Steve D. Shadowen, Pharmaceutical Product Hopping: A Proposed Framework for Antitrust Analysis, 92 Notre Dame L. Rev. 167 (2017)

⁹ Fiona Scott Morton & Lysle Boller, Enforcement of Competition Law in the Pharmaceutical Sector, 81 Antitrust L.J. 195 (2017).

¹⁰ Fed. Trade Comm'n, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions (2010).

These practices restrict consumer choice, prevent cost reductions, and increase healthcare spending. Exclusive contracts between insurers and healthcare providers prevent competition by restricting providers from contracting with multiple insurers. Similarly, anti-steering clauses prohibit insurers from directing patients to lower-cost alternatives, maintaining higher prices for healthcare services¹¹.

5. Pharmacy Benefit Manager (PBM) Practices

PBMs play a significant role in determining drug pricing and access. However, their opaque rebate structures often lead to higher drug prices, as PBMs may favour highercost medications that offer more significant rebates rather than prioritizing affordability for consumers. PBM practices, including spread pricing, rebate walls, and formulary exclusion, often limit competition and drive-up costs for consumers and payers. Regulators and lawmakers have increasingly scrutinized these practices due to their impact on drug affordability and market competition.¹²

6. Barriers to Market Entry

High regulatory burdens, patent abuses, and complex licensing requirements create significant entry barriers for new healthcare providers and pharmaceutical companies. Evergreening, a common tactic in the pharmaceutical industry, involves making minor modifications to existing drugs to extend patent protections and delay generic competition.

These anti-competitive practices contribute to higher healthcare costs and reduced access to essential services. The following sections will examine specific case studies and their broader implications on the healthcare system.

Impact of Anti-Competitive Practices on Healthcare

Anti-competitive practices in healthcare, such as market monopolization, price fixing, pay-fordelay agreements, exclusive contracts, and Pharmacy Benefit Manager (PBM) manipulation, have significantly impacted healthcare systems worldwide. These practices have led to higher costs, reduced competition, limited access to essential medicines, and lower quality of care.

¹¹ Ginger Day, Anticompetitive Healthcare, 101 Wash. U. L. Rev. 1539 (2023).

¹² Supra 10

The healthcare system is largely privatized and dominated by large hospital chains, pharmaceutical companies, and insurance firms. India's system is a mix of public and private entities, with growing concerns over corporate dominance and restricted drug pricing regulations¹³.

Anti-competitive practices in the U.S. healthcare system drive up costs, limit patient access, and reduce innovation. Hospital mergers increase prices by 15%–30%, while pay-for-delay agreements cost consumers \$3.5 billion annually. Pharmacy Benefit Managers (PBMs) manipulate drug pricing, contributing to the insulin pricing crisis and delaying generic competition. Cases like Sutter Health's \$575 million antitrust settlement and Turing Pharmaceuticals' 5,000% price hike on Daraprim highlight monopolistic abuses. Additionally, insurer restrictions, such as Blue Cross Blue Shield's anti-competition policies, have led to billion-dollar settlements, underscoring the need for stronger regulations to protect consumers.

Whereas market manipulation in India's pharmaceutical sector keeps drug prices high and limits healthcare access. Indian drug companies collude to fix prices, while multinational firms use patent evergreening to block generics, as seen in Roche's delayed competition for Trastuzumab. Private hospital chains charge excessive fees, and insurers deny coverage, as highlighted by Fortis Healthcare's overbilling scandal. Trade agreements and corporate lobbying further drive up medicine costs, but legal rulings like the Novartis vs. India¹⁴ case has helped preserve affordable generics. These issues highlight the urgent need for stronger regulations to protect public health.

Anti-competitive practices in healthcare inflate costs, reduce competition, and limit patient access to essential treatments. While countries like the U.S. struggle with PBM driven pricing and hospital consolidation, India faces challenges in regulating private healthcare dominance and patent manipulation. Strengthening antitrust enforcement, increasing price transparency, and promoting generic alternatives are crucial to creating a more competitive and affordable healthcare system.

¹³ Sandeep Agarwala & Neha Jain, Anti-Competitive Practices and Healthcare Sector in India, 6 Int'l J. Health Sci. 5392 (2022).

¹⁴ Novartis AG v. Union of India, (2013) 6 SCC 1

Regulatory Framework and Legal Challenges in Addressing Anti Competitive Practices

in Healthcare

The healthcare industry is heavily regulated in both the United States and India, yet anti-

competitive practices persist due to legal loopholes, industry lobbying, and enforcement

challenges. Governments and regulatory bodies struggle to balance market competition,

innovation, and affordability while preventing monopolistic behaviour.

The U.S. healthcare market is regulated by federal antitrust laws, state rules, and industry-

specific regulations. The Sherman Antitrust Act (1890) bans monopolies and price-fixing, often

used to challenge anti-competitive hospital mergers. The Clayton Act (1914) prevents mergers

that reduce competition, while the Federal Trade Commission Act (1914) empowers the FTC

to penalize anti-competitive practices. The Affordable Care Act (2010) promotes price

transparency, restricts unfair insurer practices, and introduces Medicare payment reforms to

curb monopolistic behaviour.

India's healthcare sector is regulated by competition laws, pharmaceutical regulations, and

price control mechanisms, though weak enforcement limits their effectiveness. The

Competition Act (2002), enforced by the Competition Commission of India (CCI), aims to

prevent market dominance and cartelization in hospital chains, pharmaceutical firms, and

medical device manufacturers. The Drugs and Cosmetics Act (1940) oversees drug

manufacturing, pricing, and quality but lacks strong measures against anti-competitive pricing.

Additionally, the National Pharmaceutical Pricing Authority (NPPA) regulates drug prices

under the Drug Price Control Order (DPCO), but many essential medicines remain outside its

scope, leading to excessive pricing.

Despite strong regulatory frameworks, both the USA and India struggle with legal enforcement

against anti-competitive practices in healthcare. The USA faces challenges in controlling

hospital mergers, PBM influence, and drug pricing manipulation, while India grapples with

weak antitrust enforcement, price manipulation by hospital chains, and delayed generic

competition.

SUGGESTIONS

The persistent anti-competitive practices in the healthcare industry require comprehensive

regulatory reforms, stronger enforcement mechanisms, and increased transparency to ensure fair pricing, market competition, and consumer protection. Both the United States and India face challenges in tackling monopolization, price fixing, and collusive agreements in healthcare markets. Addressing these issues requires policy changes at multiple levels, including legislative action, enhanced regulatory oversight, and stronger penalties for violations.

One of the most effective ways to counter anti-competitive practices is by strengthening antitrust enforcement. In the United States, agencies such as the Federal Trade Commission (FTC) and the Department of Justice (DOJ) play a critical role in monitoring and addressing monopolistic behaviour. However, hospital consolidations, pay-for-delay agreements, and pharmaceutical pricing abuses often escape scrutiny due to legal loopholes and corporate lobbying. The agencies should be granted expanded authority to block anti-competitive hospital mergers more effectively, particularly in regions where consolidation leads to price hikes and reduced patient choice. Additionally, greater scrutiny should be placed on Pharmacy Benefit Managers (PBMs), which act as intermediaries between drug manufacturers, insurers, and pharmacies but often engage in practices that drive up drug prices. The authority should introduce stricter regulations on PBM rebate structures and pricing models, ensuring that consumers benefit from negotiated discounts rather than corporate profits.

Similarly, India's agencies must be empowered to take stronger action against hospital chains, pharmaceutical companies, and insurance providers engaging in monopolistic behaviour. Currently, CCI lacks the authority to impose stringent penalties or break up monopolies in the healthcare sector. Reforms should include higher financial penalties for violations, mandatory price disclosures by hospitals and pharmaceutical companies, and increased market monitoring to prevent cartelization. Additionally, authority must ensure comprehensive oversight of healthcare pricing and market dynamics.

Another crucial policy suggestion is eliminating pay-for-delay agreements and reducing patent abuse in the pharmaceutical industry. In the U.S., brand-name drug manufacturers delay generic competition by paying generic drug companies to postpone market entry, leading to prolonged high prices for essential medications. While the FTC v. Actavis (2013)¹⁵ ruling determined that such agreements could be challenged under antitrust laws, enforcement remains weak, and drugmakers continue to exploit patent loopholes. The agencies must be granted more authority

¹⁵ FTC v. Actavis, Inc., 570 U.S. 136 (2013).

to block anti-competitive patent extensions would help ensure faster entry of affordable generics into the market.

In India, patent evergreening has been partially addressed through Section 3(d) of the Indian Patents Act (2005)¹⁶, which prevents patents on minor modifications of existing drugs. However, multinational pharmaceutical corporations continue to challenge these provisions in court, delaying the availability of cheaper alternatives. The Indian judiciary and regulatory agencies must work together to strengthen the enforcement of patent laws and prevent undue delays in generic drug approvals. Additionally, the government should incentivize domestic generic manufacturers to increase competition and ensure drug affordability.

Another essential reform is enhancing price transparency and regulating hospital pricing structures. In both the U.S. and India, hospitals often engage in opaque pricing strategies, charging significantly different rates for the same procedures depending on insurance status, provider networks, and geographic location. In the U.S., the Hospital

Price Transparency Rule (2021) requires hospitals to publicly disclose prices, but compliance has been low, and penalties for non-compliance are weak. Stronger enforcement and increased penalties should be implemented to ensure hospitals comply with transparency mandates. Moreover, a national database of hospital prices should be created, allowing consumers to compare costs and make informed healthcare decisions.

In India, private hospitals often charge exorbitant fees, leading to financial distress among patients. Price caps on essential medical procedures should be introduced, similar to NPPA's price control mechanism for essential drugs. Additionally, hospital accreditation bodies should enforce standardized billing practices, preventing unethical overcharging and hidden fees. The government should also establish publicly accessible databases on hospital treatment costs, empowering patients with pricing information.

Regulating Pharmacy Benefit Managers (PBMs) and health insurers is also critical to reducing anti-competitive behaviour in healthcare markets. In the U.S., PBMs often engage in spread pricing, where they charge insurers higher rates than what they reimburse pharmacies, keeping the difference as profit. Requiring PBMs to operate with full pricing transparency, banning spread pricing, and ensuring that negotiated savings are passed on to consumers would

¹⁶ The Patents (Amendment) Act, 2005, § 3(d).

significantly lower drug costs. Moreover, allowing Medicare to negotiate drug prices directly with pharmaceutical companies a practice currently prohibited by law would enhance affordability for millions of Americans.

In India, the health insurance sector faces issues related to non-transparent pricing, policy exclusions, and limited competition. The Insurance Regulatory and Development Authority of India (IRDAI) should implement stricter consumer protection measures, requiring insurers to disclose pricing structures, claims approval processes, and hospital reimbursement rates. Additionally, expanding government-backed health insurance schemes such as Ayushman Bharat would enhance affordability and reduce dependence on private insurers.

A long-term solution to anti-competitive practices in healthcare is investing in public healthcare infrastructure to reduce reliance on private sector monopolies. In India, a large portion of healthcare spending is out-of-pocket, making patients vulnerable to price manipulation by private hospitals and pharmaceutical companies. The government should increase investments in public hospitals, expand access to affordable diagnostic facilities, and strengthen primary healthcare networks. A well-funded public healthcare system would increase competition, lower costs, and provide a reliable alternative to private sector dominance.

Similarly, in the U.S., expanding public healthcare programs such as Medicaid and introducing a public insurance option could counterbalance the pricing power of private insurers and hospital systems. By providing consumers with a lower-cost alternative, a public option would force private providers to lower prices to remain competitive. Additionally, expanding telehealth services and community-based healthcare models could enhance accessibility and affordability in underserved areas.

International cooperation and knowledge-sharing should also play a role in addressing anticompetitive practices. Both the U.S. and India can benefit from studying best practices in healthcare regulation from countries with well-regulated markets, such as Germany and Canada, where price controls and competition policies effectively prevent monopolization and ensure affordability. Collaborative efforts between regulatory bodies, researchers, and consumer advocacy groups can help develop more effective policies and enforcement strategies to protect patients from exploitative practices.

Addressing anti-competitive practices in healthcare requires a multi-faceted approach

involving stronger antitrust enforcement, regulatory reforms, price transparency, and public investment in healthcare infrastructure. The U.S. must focus on breaking hospital monopolies, regulating PBMs, and eliminating pay-for-delay tactics, while India needs stricter price controls, enhanced patent law enforcement, and expanded public healthcare funding. By implementing these recommendations, both countries can foster a more competitive, fair, and patient-centred healthcare system that prioritizes affordability and accessibility over corporate profits.

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