A STUDY ON THE IMPACT OF EXCESSIVE PRICING OF LIFE-SAVING DRUGS ON MARKET COMPETITION AND PUBLIC HEALTH

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ABSTRACT

This study explores the impact of excessive life-saving drug pricing on market competition and public health, focusing on a pressing issue in global healthcare systems. The escalating cost of essential medications has raised concerns about its effects on pharmaceutical market competition and the accessibility of treatments for various populations. The research delves into how monopolistic practices, such as patent extensions and "evergreening," restrict market competition, enabling pharmaceutical companies to set high prices for life-saving drugs. This lack of competition not only limits the availability of affordable alternatives but also obstructs the entry of generic drugs, worsening health inequities.

The study also examines the direct consequences of inflated drug prices on public health, showing how high costs reduce access to medications, particularly for low-income and vulnerable groups. The inability to afford necessary treatments often leads to poorer health outcomes, higher mortality rates, and increased financial strain on individuals and healthcare systems. Furthermore, the research highlights the role of regulatory measures, such as price controls and the promotion of generic drugs, in addressing the harmful effects of excessive pricing.

In addressing the ethical concerns, the study raises important questions about the responsibility of pharmaceutical companies to prioritize public health over profit, particularly for life-saving medications. The findings emphasize the need for a more balanced approach to drug pricing, one that fosters innovation while ensuring equitable access to essential medicines. Ultimately, this research advocates for comprehensive policy reforms and global cooperation to tackle the challenges posed by high drug prices, ensuring that life-saving treatments are accessible to all, regardless of economic means.

Keywords: Life-saving drugs, Excessive Price, Pharmaceutical industry, Drug Pricing, Public health, Monopoly, Generic drugs, etc.

CHAPTER I

INTRODUCTION

In recent decades, the rising cost of life-saving drugs has sparked widespread debate among policymakers, healthcare providers, and the general public. These medications are essential for treating chronic, life-threatening conditions such as diabetes, cancer, HIV/AIDS, and heart disease. However, as pharmaceutical companies continue to increase drug prices, millions of people are at risk of being unable to afford essential treatments. This issue not only affects individuals' health but also places a significant burden on healthcare systems globally. The high cost of life saving medications strains healthcare budgets, limiting the funds available for other vital public investments. In countries without universal healthcare, the problem becomes even more critical, with many individuals facing unaffordable out-of-pocket expenses. In the U.S., for example, roughly 25% of people struggle to afford life-saving drugs due to these high costs. While pharmaceutical companies argue that high drug prices are necessary to fund innovation, this pricing model may actually hinder the development of truly ground breaking treatments. It is often less risky and more profitable to create drugs that offer only minor improvements over existing ones, rather than pursuing innovative drugs with a higher chance of failure. On one hand, pharmaceutical companies argue that high drug prices are necessary to recoup the significant investments made in research and development (R&D), as well as to incentivize continued innovation. On the other hand, critics contend that such pricing strategies disproportionately benefit large pharmaceutical corporations while depriving vulnerable populations of access to critical treatments. Excessively high pricing of life-saving drugs stifles market competition by creating barriers to entry for generic and biosimilar manufacturers, ultimately limiting access and increasing costs for patients and healthcare systems, thereby impacting public health

This research seeks to explore the multifaceted impact of high drug prices on market competition and public health. It examines the ways in which monopolistic practices, pricing strategies, and market dynamics create barriers to access and affect the affordability of life-saving treatments. The ultimate goal is to understand how these pricing practices shape public health outcomes and to suggest potential regulatory and policy solutions.

SIGNIFICANCE OF THE STUDY

This study is significant as it explores the pressing issue of excessive pricing of life-saving drugs and its far-reaching consequences on market competition and public health. As drug prices soar globally, millions, especially in low- and middle-income countries, are unable to afford essential treatments, exacerbating health inequities. By analyzing the role of monopolistic pricing, patent protections, and the lack of competition, this research will shed light on how the pharmaceutical industry's pricing strategies impact affordability and accessibility. Additionally, the study will assess the effectiveness of current regulatory frameworks, providing actionable recommendations to improve drug pricing policies. It will highlight the public health implications, including the reduced access to necessary treatments and worsening health outcomes, advocating for more equitable access to life-saving medications. Ultimately, the study aims to inform policy discussions and offer solutions that balance the need for pharmaceutical innovation with ensuring affordable healthcare for all.

RESEARCH QUESTIONS

1. How does the excessive pricing of life-saving drugs influence market competition and the entry of generic drug manufacturers?

2. What role do patent laws and intellectual property protections play in the pricing strategies of pharmaceutical companies, and how do they affect market competition?

3. How effective are current regulatory measures, such as price controls and antitrust laws, in controlling the pricing of life-saving drugs and ensuring equitable access to medicines?

RESEARCH METHODOLOGY

This study adopts a doctrinal research methodology, emphasizing the analysis of legal frameworks, policies, and case law related to drug pricing. It will include a comprehensive literature review of scholarly works, government reports, and studies on market competition and public health. The research will examine patent and competition laws, price control regulations, and judicial decisions affecting drug pricing. Ethical and economic considerations, particularly the tension between market forces and public health access, will be explored. A

comparative legal analysis of different jurisdictions will highlight global trends and best practices, offering a thorough legal understanding of drug pricing regulation.

CHAPTER II

LIFE SAVING DRUGS

Life-saving drugs are essential medications that are used to treat severe, life-threatening conditions, preventing death, serious complications, or permanent disability. These drugs include a wide variety of treatments, such as antibiotics and antivirals to fight infections, chemotherapy and immunotherapy for cancer, insulin for diabetes, and heart medications for conditions like heart disease and stroke. Life-saving drugs are also crucial in managing chronic diseases such as HIV/AIDS, where antiretroviral therapies enable people to live longer, healthier lives. Additionally, vaccines like those for polio, measles, and influenza play a vital role in preventing infectious diseases from causing widespread harm. Emergency medications, including epinephrine for severe allergic reactions and naloxone to reverse opioid overdoses, are critical in urgent situations. Access to these medications is fundamental to improving global health and reducing mortality rates. However, high drug prices, especially for patented medications, can create significant barriers to access, particularly in low-income countries. This lack of affordability can lead to preventable deaths and exacerbate health inequalities. Ensuring that life-saving drugs are accessible to all, regardless of socioeconomic status, is crucial for public health, helping to save lives, reduce suffering, and promote well-being across populations worldwide.

EXCESSIVE PRICING

Various factors explain the level at which prices are set, including the degree of competition in the relevant market. If the market is competitive, it is expected that the price will be set close to cost. Prices will tend to be higher the further a market deviates from perfect competition. In situations of legal or de facto monopoly, economic theory predicts that a monopoly price will be imposed – i.e. the price at which the monopolist earns the most profits. For any higher price than the monopoly price, the monopolist would lose sales in excess of what he would gain by the price increase. As a result, economic theory predicts that prices will not be raised above the monopoly price. Given this, a prohibition against excessive prices is superfluous from a purely economic standpoint. Prices above the monopoly price are not possible, or are at least

irrational. If a prohibition against excessive prices amounts to a prohibition against monopoly pricing, this would mean that the prohibition of excessive prices would penalise the mere fact that a company holds a dominant position but this contradicts competition law, which does not prohibit dominant positions per se, but only their abuse. If, on the other hand, the prohibition catches all prices above the competitive price but below monopoly price, this would lead to a paradox – because monopoly prices would be allowed, while lower prices would be prohibited as excessive. Given the challenges identified above, it is unsurprising that excessive pricing is an area of limited competition enforcement around the world. Excessive pricing remained for a long time underdeveloped conceptually and underused in practice[1].

WORLD TRADE ORGANIZATION FRAMEWORK

The TRIPS Agreement acknowledges the fundamental tension between safeguarding intellectual property rights and ensuring affordable access to essential medicines. To reconcile these interests, it incorporates various flexibilities that empower nations to address public health challenges while maintaining respect for patent protections. Among the most significant of these is the provision for compulsory licensing under Article 31. This allows governments to authorize the manufacture or importation of generic versions of patented drugs without the consent of the patent holder, particularly in circumstances where public health is at risk or where drug prices are excessively high. Compulsory licensing serves as a powerful mechanism to lower the cost of critical medications and improve access for populations in need.

This flexibility has proven especially effective during health emergencies. For instance, during the HIV/AIDS crisis, countries such as Brazil and India utilized compulsory licensing to produce affordable generic antiretroviral drugs, dramatically expanding treatment access and reducing mortality. In broader health crises like pandemics, compulsory licensing becomes even more vital, enabling countries to provide timely, affordable treatments to their populations and curb disease spread.

Despite its public health benefits, the application of compulsory licensing remains contentious. Critics, particularly from the pharmaceutical industry and some developed nations, argue that it weakens intellectual property protections and diminishes incentives for innovation. In response, the Doha Declaration on the TRIPS Agreement and Public Health (2001) clarified

[1] For a thorough overview of enforcement against excessive prices, see (Jenny, 2018, pp. 2-20)

that the Agreement should be interpreted in a manner supportive of public health. It affirmed that countries have the right to use compulsory licensing to secure access to life-saving medicines without compromising patent rights.

Parallel importation, permitted under Article 6 of the TRIPS Agreement, allows countries to import patented medicines from nations where they are sold at lower prices, without needing the patent holder's consent. This helps reduce drug costs by leveraging international price differences, improving access to essential medicines. However, despite its potential, the use of parallel importation and compulsory licensing is often obstructed by political pressure, trade agreements, and fear of retaliation from wealthier countries. Developing nations may hesitate to use these measures due to legal complexities and concerns over diplomatic or economic consequences from powerful nations and pharmaceutical corporations.

The TRIPS Agreement also includes a mechanism for **transitional periods** (Article 65), allowing developing countries more time to comply with the provisions of the agreement, including the adoption of patent protections. This flexibility was introduced to provide countries with the time needed to develop their domestic pharmaceutical industries and gradually adapt to global patent standards. However, this transition period has been criticized for prolonging the challenges many low-income countries face in accessing affordable medicines, as it can delay the entry of generics into the market and maintain high prices for life-saving drugs.

In conclusion, the **TRIPS framework** established by the WTO provides essential mechanisms for balancing the protection of intellectual property rights with the need for access to affordable life-saving drugs. While the agreement includes important flexibilities like **compulsory licensing** and **parallel importation** to promote access to medicines, significant challenges remain in fully utilizing these tools due to **political pressures**, **trade retaliation**, and **legal complexities**.

The 2001 Doha Declaration on TRIPS and Public Health emphasized that the TRIPS Agreement should not hinder countries from protecting public health. It reaffirmed members' rights to use flexibilities like compulsory licensing and parallel importation to improve access to affordable medicines, particularly for diseases like HIV/AIDS and malaria.

CHAPTER III

LEGAL FRAMEWORK TO PROHIBIT THE EXECESSIVE PRICING

INDIA

The **Competition Act, 2002**, addresses anti-competitive practices in India, including the pharmaceutical industry. The Act prohibits unfair trade practices and aims to prevent companies from abusing their dominant position in the market.

Anti-competitive Agreements: Section 3 of the Act prohibits anti-competitive agreements, including price-fixing, which can be a concern in the pharmaceutical industry if large companies collaborate to keep drug prices high.

Abuse of Dominance: Section 4 of the Act prohibits abuse of dominant market positions. If a pharmaceutical company is found to have abused its market dominance by excessively raising drug prices or engaging in predatory pricing to eliminate competition, it can be penalized by the **Competition Commission of India (CCI)**.

The **Drug Price Control Order (DPCO)**, issued under the **Essential Commodities Act, 1955**, is the primary legal instrument that regulates the pricing of pharmaceuticals in India. DPCO provides the legal framework for price control of drugs and is periodically updated to adjust to changing market conditions.

UNITED STATES

Some jurisdictions do not prohibit exploitative excessive pricing as such. This approach was recently justified by the US Supreme Court, which held that: 'the mere possession of monopoly power, and the concomitant charging of monopoly prices, is not only not unlawful; it is an important element of the free market system[2].' These jurisdictions mainly take high prices as an indicator of underlying competition problems which need to be addressed, rather than as a variable on which competition agencies should intervene directly[3].

[2] Verizon Communications Inc. v Law Offices of Curtis v Trinko LLP 540 US 398, 407, 124 S Ct 872 (2004).
[3] (OECD, 2011, pp. 302-304[1]), US Contribution. But while excessive prices are not a competition abuse under Mexican law, the competition authority has various powers to determine whether excessive prices are being

The **340B Drug Pricing Program** allows certain hospitals and healthcare organizations serving low-income or underserved populations to purchase drugs at discounted prices. While this program helps mitigate high drug costs for certain groups, it does not address the broader issue of high prices for the general public and does not apply to all life-saving medications.

EUROPEAN UNION

Article 102(a) of the TFEU prohibits dominant firms from imposing unfair prices or trading conditions, covering both predatory and excessive pricing. In *United Brands*, the ECJ held that pricing is abusive when it lacks a reasonable link to the product's economic value, introducing a two-part test: excessive price-cost margin and unfairness. This standard, widely adopted across EU Member States, relies on cost comparisons, market benchmarks, or profitability analyses to assess excessive pricing.

GERMANY

Section 19(2) No. 2 of the German Competition Act also prohibits a dominant undertaking from charging "unreasonable terms and conditions". In principle, the same rules that apply as regards excessive pricing also apply to the determination of whether a company demands excessive terms and conditions[4].

UNITED KINGDOM

In the UK, the Competition Appeals Tribunal has recently held that a competition authority should consider a range of possible analyses when determining whether a price is excessive. If the authority identifies a relevant differential between the investigated price and the relevant benchmark price(s), it must also ensure that the differential is sufficiently significant and persistent to be excessive. When determining if the price is also unfair, the authority may conclude that the price is unfair in itself or unfair compared to competing products[5]. However, the authority must give due consideration to any objective justification advanced by the

charged in a market, in which case specific regulation can be imposed or extended – see (OECD, 2011, pp. 272-273[1]), Mexico's Contribution.

[4] Section 29 of the German Competition Act will only apply until 31 December 2022 because the German legislator considered its special rules to be necessary only for a transitional post-liberalisation period. The original deadline was 31 December 2012, but the legislator extended it twice, first to 31 December 2017, and then to the end of 2022.

[5] Flynn Pharma & Pfizer v CMA [2018] CAT 11, para. 443

defendant firm, and to any prima facie convincing argument that the pricing is actually fair in itself or in comparison to other products.

CHAPTER IV

CAUSES FOR THE EXCESSIVE PRICE

MONOPOLY

The high cost of life-saving drugs is largely due to monopolies. Many new drugs have no alternatives, and in cancer treatment, multiple drugs may exist, but price competition is absent since each drug is needed sequentially. Patients require every effective drug during their illness. Even older drugs can remain monopolized; in the U.S., insulin prices remain high due to control by Novo Nordisk, Sanofi-Aventis, and Eli Lilly. While generics should emerge post-patent, this rarely occurs in cancer and chronic diseases. By the time a drug runs out of patent life, it is already considered obsolete (planned obsolescence) and is no longer the standard of care[6].

A "new and improved version" with a fresh patent life and monopoly protection has already taken the stage. In the case of biologic drugs, cumbersome manufacturing and biosimilar approval processes are additional barriers that greatly limit the number of competitors that can enter the market. Clearly, all monopolies need to be regulated in order to protect citizens, and therefore most of the developed world uses some form of regulations to cap the launch prices of new life saving drugs. Unregulated monopolies pose major problems[7]. Unregulated monopoly over an essential product can lead to unaffordable prices that threaten the life of citizens.

SERIOUSNESS OF THE DISEASE

Life-threatening diseases pose severe risks due to their rapid progression and potential to cause irreversible harm or death if untreated. Conditions such as cancer, heart disease, diabetes, HIV/AIDS, and serious infections significantly affect individual health and strain healthcare systems. These illnesses often lead to long-term disabilities, high medical expenses, and emotional distress for patients and families. Timely diagnosis and immediate treatment are

[6] Siddiqui M, Rajkumar SV. The high cost of cancer drugs and what we can do about it. Mayo Clinic Proc. 2012;87:935–943. doi: 10.1016/j.mayocp.2012.07.007
[7] Ezekiel J. Emanuel, *Big Pharma's Deadly Pricing Practices*, N.Y. Times (Mar. 23, 2019).

critical, as delays can be fatal or result in permanent damage. While some diseases like HIV/AIDS are now manageable with proper medication, lack of access remains deadly. Patients facing such conditions are often willing to pay any amount to survive or extend life.

HIGH COST OF DEVELOPMENT

Developing a new drug is a lengthy and costly process, typically taking around 12 years from preclinical testing to approval, with estimated costs reaching nearly $3 billion. These high figures reflect the low success rate, as only 10–20% of drug candidates make it to market[8]. However, some experts argue that these estimates are overstated. Additionally, the greater the marginal benefit a drug provides, the more extensive and expensive the trials required for approval. Crucially, much of the foundational research is publicly funded, giving the public a justifiable stake in ensuring that life-saving drugs are priced affordably and accessibly[9].

REGULATORY AND APPROVAL PROCESSES

The regulatory and approval processes play a crucial role in the high pricing of life-saving drugs. The costly and time-consuming development, including clinical trials, is often cited by pharmaceutical companies to justify elevated prices. Regulatory compliance with agencies such as the FDA and EMA adds to these expenses. Patent laws grant exclusive marketing rights, limiting competition and enabling monopoly pricing[10]. Tactics like "evergreening" further prolong exclusivity. Delays in regulatory reviews increase costs as firms attempt to recover time and investment. Additionally, the absence of price control mechanisms in many regulatory systems allows unchecked pricing, making essential medicines unaffordable in many regions.

LIMITED ACCESS TO AFFORDABLE MEDICINES

High drug prices prevent many individuals, especially in low- and middle-income countries, from accessing essential treatments. As pharmaceutical companies set high prices, often citing R&D and patent costs, vulnerable populations face financial barriers, unable to afford critical medications. This lack of access leads to worsened health outcomes, increased mortality rates,

[8] DiMasi JA, Grabowski HG, Hansen RW. Innovation in the pharmaceutical industry: new estimates of R&D costs. J. Health Econ. 2016;47:20–33. doi: 10.1016/j.jhealeco.2016.01.012
[9] Almashat, S. Pharmaceutical research costs: the myth of the $2.6 billion pill.
[10] Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 Mich. Telecomm. & Tech. L. Rev. 345, 347 (2007).

and higher rates of preventable diseases, particularly for chronic conditions like cancer, diabetes, and HIV. The problem is compounded by insurance systems that may not fully cover expensive drugs or by the absence of government price controls, allowing companies to set inflated prices. As a result, the healthcare system bears the burden of poor health outcomes, leading to increased hospitalization costs and lost productivity. Ultimately, the excessive pricing of life-saving drugs exacerbates health inequities and undermines public health.

FINANCIAL BURDEN ON PATIENTS

Excessive pricing of life-saving drugs imposes a heavy financial burden on patients, especially those with chronic or life-threatening conditions. Many are forced to choose between essential medications and basic needs like food or housing. Uninsured and low-income individuals are particularly affected, often skipping treatment due to high costs. This deepens health disparities, as wealthier patients access necessary care while others suffer worsening health and increased long-term healthcare expenses.

LOBBYING POWER OF PHARMACEUTICAL COMPANIES

Pharmaceutical companies exert significant lobbying influence over drug pricing, access, and regulatory frameworks, particularly concerning life-saving medications. They invest heavily in lobbying to influence legislation, maintain patent protections, and secure pricing policies favorable to their interests. By extending patents, these companies delay the entry of generics, keeping drug prices high and limiting access, especially in low-income settings[11]. Additionally, lobbying efforts often target drug approval processes and health policies to align with corporate goals. While such lobbying can support innovation and R&D funding, it also raises ethical concerns about prioritizing profits over public health and equitable access to essential medicines[12].

CHAPTER V

REFORMS

LIMIT THE PATENT PROTECTION

[11] Robin Feldman, *May Your Drug Price Be Evergreen*, 5 U.C. Irvine L. Rev. 57, 75–78 (2015).
[12] Scutti, S. Big Pharma spends record millions on lobbying amid pressure to lower drug prices.

One of the main ways to limit the problem posed by monopoly is to limit the duration of patent protection. Current patent protections are too long, and companies apply for multiple new patents on the same drug in order to prolong monopoly. We need to reform the patent system to prevent over patenting and patent abuse[13]. Stiff penalties are needed to prevent "pay-for-delay" schemes where generic competitors are paid money to delay market entry[14]. Patent life should be fixed, and not exceed 7–10 years from the date of first entry into the market. These measures will greatly stimulate generic and biosimilar competition.

Limiting patent protection can help lower life-saving drug prices by enabling earlier entry of generics. Shortening patent terms and restricting evergreening where minor changes extend exclusivity encourages competition, reduces costs, and improves access to essential medications for broader populations.

FASTER APPROVAL OF GENERICS AND BIOSIMILARS

Streamlining the approval process for generics and biosimilars is key to lowering drug costs. A mutual recognition system among developed countries could reduce duplication by allowing automatic approval across jurisdictions[15]. Biologics, unlike generics, require clinical trials, making biosimilar adoption more complex due to provider reluctance and legal hurdles. Educating clinicians and implementing coordinated strategies are essential[16]. In the U.S., biosimilar uptake varies, though filgrastim's biosimilar reached 60% market share with 30–40% lower prices.

NON-PROFIT GENERIC COMPANIES

Nonprofit generic manufacturing offers a practical solution to lower the cost of life-saving drugs and address shortages. Initiatives like Civica Rx in the U.S. demonstrate how governments or philanthropic foundations can produce affordable, high-quality generics. Unlike profit-driven firms, these organizations focus on accessibility, supplying essential

[13] Amin, T. Patent abuse is driving up drug prices.
[14] Hancock, J. & Lupkin, S. Secretive 'rebate trap' keeps generic drugs for diabetes and other ills out of reach.
[15] Cohen, M. et al. Policy options for increasing generic drug competition through importation. Health Affairs Blog.
[16] Fein, A. J. We shouldn't give up on biosimilars

medicines for conditions like HIV/AIDS and malaria at reduced prices. Collaborating with governments and global agencies, they help advance health equity in underserved populations.

COMPULSORY LICENSING

Compulsory licensing is a vital mechanism that enables governments to lower the cost of life-saving drugs, especially when price negotiations with pharmaceutical companies fail or are unduly delayed. This legal provision allows a government to authorize third-party manufacturers to produce generic versions of patented medications without the patent holder's consent. It is particularly beneficial in low- and middle-income countries, where high drug prices often create significant barriers to access. By fostering competition, compulsory licensing can substantially reduce the cost of essential treatments, ensuring broader affordability and availability.

This tool becomes especially crucial during public health emergencies, such as pandemics or the HIV/AIDS crisis. For example, India effectively used compulsory licensing to manufacture affordable antiretroviral drugs, dramatically increasing access for millions of people[17]. The Doha Declaration on the TRIPS Agreement (2001) reaffirmed the right of WTO members to issue compulsory licenses when public health is at risk, stressing that patent flexibilities must support public health objectives.

Although critics argue that compulsory licensing could discourage innovation by weakening patent protections, proponents emphasize that access to essential medicines must take precedence.

VALUE-BASED PRICING

Unlike other developed nations, the United States does not use value-based pricing for new drugs, allowing companies to set excessively high prices regardless of clinical benefit. As a result, recent cancer drugs often exceed $100,000 annually. This undermines global price negotiations, as manufacturers rely on U.S. profits to offset concessions elsewhere. A regulatory body like ICER should be empowered to set ceiling prices based on value and

[17] Ellen 't Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health* 41–44 (2009).

oversee increases. Alternatively, capping prices using international reference pricing can help control excessive costs.

CAP ON PRICE INCREASES

The United States experiences a distinct challenge not common in other countries: significant price increases on existing drugs. Between 2012 and 2017, the U.S. spent $6.8 billion more on brand-name cancer drugs due to rising prices, while the rest of the world saw price reductions. The insulin price surge from $21 in 1999 to over $300 is a stark example. Additionally, over 250 drug prices rose by around 5% in early 2020. Federal or state legislation is essential to prevent such unjustified increases[18].

REMOVE INCENTIVE FOR MORE EXPENSIVE THERAPY

Reducing incentives for expensive therapies helps lower life-saving drug prices. Governments can promote generics, enforce price transparency, and link drug prices to health outcomes, shifting industry priorities toward affordable, effective treatments and improving access, especially in low- and middle-income countries.

MEDICARE NEGOTIATION

In addition to not having a system for value-based pricing, the United States has specific legislation that actually prohibits the biggest purchaser of oral life saving drugs (Medicare) from directly negotiating with manufacturers[19]. One study found that if Medicare were to negotiate prices to those secured by the Veterans Administration (VA) hospital system, there would be savings of $14.4 billion on just the top 50 dispensed oral drugs.

CHAPTER-VI

RECENT CASES

A number of cases against excessive pricing have recently been brought in the pharmaceutical sector as regards off-patent drugs. Given the absence of excessive pricing as an antitrust

[18] Prasad, R. The human cost of insulin in America

[19] Venker B, Stephenson KB, Gellad WF. Assessment of spending in medicare part D if medication prices from the department of veterans affairs were used. JAMA Intern. Med. 2019;179:431–433. doi: 10.1001/jamainternmed.2018.5874.

infringement in the US, excessive pricing cases have been brought elsewhere in the world, and particularly in Europe. Nonetheless, concerns about excessive prices of pharmaceuticals have led to a number of interventions in the US.

INDIA

Recent Indian cases have highlighted growing concern over the excessive pricing of life-saving medicines and the need for stronger regulatory interventions to ensure drug affordability. In **Novartis AG v. Union of India**, the Supreme Court denied a patent for the cancer drug Glivec, enabling generic production and significantly reducing treatment costs[20]. Similarly, in 2019, the Delhi High Court examined high insulin prices charged by multinational firms such as Sanofi and Novo Nordisk, prompting the National Pharmaceutical Pricing Authority (NPPA) to regulate insulin pricing[21]. In **Cipla Ltd. v. Union of India**, the Supreme Court upheld the government's authority to impose price controls on essential cancer drugs, reinforcing the legal basis for affordability measures[22]. A notable case involved Gilead Sciences' Hepatitis C drug Sofosbuvir (marketed as Sovaldi), which was initially priced at ₹1,00,000 per pill, making full treatment unaffordable for most Indian patients. Due to public pressure, the Indian Patent Office issued compulsory licenses to Natco Pharma and Hetero Drugs, allowing them to manufacture affordable generics priced at approximately ₹50,000 for the entire course. This case underscored the critical balance between intellectual property rights and public health needs, reinforcing the role of compulsory licensing in expanding access to essential medicines in India.

UNITED STATES

In the United States, there is no direct regulatory mechanism to address excessive drug pricing unless it involves a recognized violation of antitrust laws. Merely raising drug prices is not illegal; however, dramatic hikes have drawn increasing scrutiny. In 2016, Mylan's steep price increase of EpiPens led to an inquiry by the Federal Trade Commission into potential antitrust violations[23]. That same year, members of Congress urged the Department of Justice and FTC to investigate possible collusion among insulin manufacturers. One ongoing case involves a

[20] *Novartis AG v. Union of India*, (2013) 6 SCC 1.
[21] National Pharmaceutical Pricing Authority, *Price Control of Anti-Diabetic and Cardiovascular Drugs*, NPPA/19/2019-G.
[22] *Cipla Ltd. v. Union of India*, (2020) 2 SCC 386.
[23] Cecilia Kang, *Mylan to Offer Generic EpiPen at Half the Price*, N.Y. Times (Aug. 29, 2016).

pharmaceutical company accused under Section 2 of the Sherman Act of leveraging its dominant market position to exclude competitors. By controlling a key ingredient necessary for drug production and being the sole FDA-approved supplier, the firm allegedly inflated drug prices by 2,600%. The U.S. Senate Special Committee on Aging's 2016 report analyzed cases where companies exploited "gold-standard" off-patent drugs by creating closed distribution systems to block competition, enabling exorbitant pricing[24]. While these actions raised ethical and economic concerns, they did not clearly violate existing antitrust law. The case of Keytruda, Merck's cancer drug priced at $12,500 per dose, exemplifies the ongoing conflict between pharmaceutical innovation and the need for affordable access to life-saving treatments.

UNITED KINGDOM

In 2017, the UK Competition and Markets Authority (CMA) issued a decision on excessive pricing involving Epatunin, an anti-epileptic drug containing phenytoin. Although newly diagnosed epilepsy patients are rarely prescribed phenytoin, many long-term users rely on Epatunin for its stability. Due to guidance from the UK's Medicines and Healthcare Products Regulatory Agency (MHRA), patients stabilized on Pfizer's version were advised not to switch, creating barriers for competitors. This lack of substitutability allowed Pfizer to maintain pricing power[25]. Additionally, in 2001, the Office of Fair Trading (OFT) investigated a case concerning a sustained-release morphine product. While it involved excessive pricing in the community sector and exclusionary pricing in hospitals, it could have been framed as a single abuse rooted in a broader predatory pricing strategy.

ITALY

In 2016, Italy's competition authority condemned a price increase for a group of cancer drugs, known as "Cosmos drugs," as excessive. These drugs are essential and non-substitutable, used to treat cancer in specific patient groups, such as the elderly and children. They are preferred due to their low side effects compared to other treatments. The lack of alternatives and the need for consistent therapy make demand for Cosmos drugs price-inelastic, allowing for higher

[24] S. Special Comm. on Aging, *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model That Harms Patients, Taxpayers, and the U.S. Health Care System*, S. Rep. No. 114-429 (2016).
[25] Flynn Pharma Ltd and Flynn Pharma (Holdings) Ltd v Competition and Markets Authority [2018] CAT 11, para. 48.

prices.

SOUTH AFRICA

In 2002, the Competition Commission found that manufacturers of antiretroviral treatments for individuals infected with HIV/AIDS had abused their dominant positions by charging excessive prices, refusing to give competitors access to essential facilities, and engaging in exclusionary practices. At the conclusion of the investigation, the Commission announced that it was referring the matter to the Competition Tribunal for adjudication[26]. Before the referral and prosecution of the case, the manufacturers negotiated a settlement agreement under which they admitted no liability.

GERMANY

The German contribution discussed a number of cases concerning the excessive pricing of pharmaceutical products in the 1970s. The most representative case was the so-called Valium case[27]. Following comparisons of prices charged in Germany and in other European markets – complemented by a comparison of profits and costs – it was found that prices were excessive by approximately 35-40%. The decision of the Bundeskartellamt was appealed and upheld by the Higher Regional Court of Berlin (Kammergericht), which reduced the amount by which the prices were considered excessive on the basis of the benchmark price which the court considered most adequate for comparison. That decision was subject to a further appeal to the Federal Court of Justice (Bundesgerichtshof), which judged in favour of the company. A more recent case was brought in private proceedings. A pharmaceutical manufacturer had suddenly raised prices by 400%, after moderate price increases over several years. The court found that the claimant was entitled to damages amounting to the difference between the price paid by the claimant and the price that would have been charged under competitive conditions.

CHAPTER-VII

SUGGESTIONS

This research would explore how excessive pricing of life-saving drugs creates complex

[26] AIFA (Agenzia Italiana del Farmaco)'s scientific committee and expert oncologists.
[27] BGH [Federal Court of Justice], decision of 16. 12. 1976, KVR 2/76 – Valium; BGH [Federal Court of Justice], WuW/E 1445 ff., 1454 Valium II

challenges for both market competition and public health. The study would focus on understanding how high drug prices are often the result of monopolistic behaviors in the pharmaceutical industry, such as patent extensions, exclusive rights, and limited generic alternatives. By analyzing these pricing practices, the research would evaluate how they limit competition by reducing the number of market entrants and creating significant barriers for smaller or generic drug manufacturers. This reduced competition can lead to market concentration, where only a few companies dominate the supply of essential medications, allowing them to set inflated prices and reduce consumer choice.

On the public health side, the study would examine how excessive drug pricing impacts access to essential medications, particularly for low- and middle-income populations who are unable to afford life-saving treatments. The high cost of drugs, particularly in countries with limited healthcare resources, exacerbates health inequalities by creating a situation where only wealthier individuals or nations can access necessary treatments. This issue has severe consequences for public health, including higher mortality rates, prolonged illnesses, and the exacerbation of preventable diseases. The research would investigate the direct link between high drug prices and negative health outcomes, such as delayed treatments or inadequate healthcare for vulnerable populations.

The study would also address the ethical considerations surrounding excessive pricing. While pharmaceutical companies argue that high prices are necessary to recover the costs of research and development, the research would explore whether these companies have a moral responsibility to balance profit with accessibility. Furthermore, it would analyze the effectiveness of regulatory frameworks and government interventions, such as price controls, compulsory licensing, and the use of generics, to reduce the impact of excessive drug pricing on both market competition and public health. By comparing different national policies, the research would aim to propose strategies that ensure life-saving drugs are both affordable and widely accessible, without stifling innovation or investment in new treatments.

CONCLUSION

This study highlights the complex and multifaceted nature of excessive drug pricing and its significant impact on market dynamics and public health. Throughout the research, it has become clear that high drug prices pose a substantial challenge for policymakers, healthcare providers, and the global community. Excessive pricing disrupts market competition by

creating barriers for new entrants and encouraging monopolistic practices among pharmaceutical companies. This leads to market concentration, where a few dominant companies control the supply of essential medications. Such a lack of competition restricts consumer choice and results in inefficiencies within the healthcare system, ultimately driving up healthcare costs. Furthermore, reduced competition stifles innovation, as companies prioritize maintaining high prices for existing drugs over investing in new, potentially more affordable treatments. The public health consequences of excessive drug pricing are equally concerning. High prices limit access to critical medications for millions of people, particularly in low- and middle-income countries. Individuals who cannot afford life-saving drugs face increased risks of illness, complications, or death. Moreover, the pricing disparity deepens health inequalities, as wealthier populations can access necessary treatments while vulnerable groups remain without care. This inequality exacerbates public health disparities, leading to worsening health outcomes and long-term negative effects on both societal well-being and productivity.

The study also emphasizes the crucial role of regulatory frameworks and government policies in either mitigating or exacerbating the effects of excessive drug pricing. Countries with stronger price control mechanisms and robust competition laws tend to achieve better outcomes in balancing drug affordability and market competition. However, many nations still face challenges in creating regulations that effectively address the underlying causes of high drug prices while ensuring they do not hinder innovation or discourage pharmaceutical investment.

In conclusion, addressing the impact of excessive pricing of life-saving drugs on market competition and public health requires a multifaceted approach. Governments, pharmaceutical companies, and international organizations must collaborate to create fair pricing policies that ensure access to essential medications for all, while promoting a competitive market environment that fosters innovation. Policymakers must find a balance between safeguarding public health and incentivizing the development of new drugs, ensuring that life-saving treatments are both affordable and accessible to those who need them the most.

CHAPTER VIII

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