



THE MONOPOLY OF INSULIN AND EPIPEN

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INTRODUCTION

When Americans think of medicine, the first thought that comes to mind is money. In the realm of corporate healthcare, relationships between insurance, provider, and patient are bound by financial constraints. Often, Americans are unable to afford medications due to lack of insurance, unreasonable access, or perhaps, most critically, the root cause of excessive medicine pricing by pharmaceutical companies. While various factors control medicine pricing, the phenomenon of excessive prices are often caused by one thing: pharmaceutical monopolies.

In business terms, a monopoly is a market structure that consists of a single seller or producer assuming a dominant position in an industry or sector. They are discouraged in free-market economies due to stifling competition, which

limits consumer substitutes and therefore consumer choice. There are many types of monopolies, namely the natural monopoly, which results from unique raw materials, technology, or specialization. Usually, companies with patents – exclusive rights for a new product granted to the inventor – or extensive research and development (R&D) costs are considered to possess natural monopolies. Therefore, pharmaceutical companies would fall under the category of natural monopolies. Pharmaceutical companies research, produce, and market drugs for disease treatment; their role in drug discovery is so critical because certain drugs and medications can save lives and improve overall public health. However, when pharmaceutical companies have a monopoly over the market, it can inhibit innovation in drug development and restrict patient accessibility to treatment. Antitrust legislation is in place to regulate businesses and prevent monopolies, but is not effective when it comes to stopping pharmaceutical monopolies due to the unique nature of drug patents, which allow the company exclusive rights to develop and sell a drug for twenty years.

THE “WHY?” AND “HOW?” OF PHARMACEUTICAL MONOPOLIES

The market exclusivity granted by drug patents is one of the major factors allowing for pharmaceutical companies to gain a monopoly over the market. However, these companies employ other strategies to maintain their advantage. One is “evergreening”, in which companies make very minor modifications to a drug, such as slightly changing its chemical composition or adding a stripe to the pill, to obtain a new patent that extends their exclusive rights to the drug for another twenty years. Another such strategy is “thicketing”, which involves a company filing many patents, often with overlapping claims, on various aspects of a drug and flooding the U.S. Patent and Trademark Office and courts with them. This creates a “thicket” of patents that is difficult for competitors to navigate and challenge, preventing competitors from securing their own patents. Aside from patent protection, “Big Pharma” maintains control by lobbying to influence legislation, filing lawsuits against generic drug manufacturers to delay market entry, and funding research and advocacy groups to shape research agendas and public perception.

INSULIN AND EPIPEN MARKET MONOPOLY STUDY

While the issue of pharmaceutical monopolies spans across various industries, perhaps the most pervasive and well-studied monopolies remain the insulin monopoly and the EpiPen monopoly.

Insulin, naturally, is a biological hormone found in the human body that moves glucose from the bloodstream into the cells—thus, turning food into energy and regulating blood sugar levels. In the pharmaceutical world, insulin is instead pharmaceutically prepared to replace a lack of natural insulin in the body. As such, it’s usually administered as an injection and used to treat both Type 1 or 2 Diabetes, a chronic disease where the body doesn’t produce enough insulin, resulting in high blood sugar.

As of 2022, 8.4 million, or 11% of Americans, rely on insulin to survive; yet, despite the sheer number of people who desperately need it, there are only 3 companies in the United States that produce insulin: Eli Lilly, Novo Nordisk, and Sanofi. There are no true generic competitors available, and under the monopoly of these 3 companies, average costs have risen to \$450 per month. Globally, the US insulin monopoly remains an outlier, representing only 15 percent of the global insulin market but generating almost half of the global pharmaceutical industry's insulin revenue. Even government insurance reflects the burden of monopolies; in the 1990s, Medicaid paid between \$2.36 and \$4.43 per unit of insulin; by 2014, those prices more than tripled (depending on formulation).



Trends in Medicaid Reimbursement Rates from 1991 to 2014 for Insulin; JAMA Internal Medicine | Source: Vox

The EpiPen market is similarly just as bleak as the insulin industry, with only 1 company running the show in the US: Mylan, now renamed Viatris.

EpiPens, also known as Epinephrine auto-injectors or EAs, are used to treat anaphylaxis, a severe allergic reaction that involves the airways swelling up. Epinephrine, more commonly called "adrenaline," is dispersed through the pen device in the body, relaxing the airways quickly. Over 1 million Americans are prescribed EpiPens, but Mylan increased the prices of EpiPens from \$100 in 2007 to \$600 in 2016. In fact, various class action lawsuits came out against Mylan, one in which the lawsuit claimed that Mylan and Pfizer engaged in an illegal scheme to monopolize the EpiPen market. In 2022, Mylan settled the lawsuit for \$264 million.

They also settled for \$465 million in 2017, as the U.S. Attorney's Office announced that Mylan settled to resolve allegations that they violated the False Claims Act by knowingly misclassifying EpiPen as a generic drug to avoid paying rebates owed to Medicaid.

Currently, certain states such as New York and Illinois have implemented price caps to limit the exorbitant price of EpiPens.

IMPACTS ON PATIENT ACCESSIBILITY

As discussed earlier, inaccessibility of patients is the most deadly crime of pharmaceutical monopolies, as exemplified in the insulin and EpiPen industries. Clearly, the prices exceed reasonable pricing—14% of insulin users have insulin classified as an “extreme financial burden,” as insulin consumes 40% of their available income. In 1996, when the insulin company Eli Lilly debuted its brand of insulin, a vial cost \$21. Now, that same vial is 10 times that, a trend that is unexplainable by inflation.

A 2017-2018 Medical Expenditures Panel Survey found that nearly 1 in 7 Americans who filled an insulin prescription experienced extreme spending on insulin. That finding doesn’t include other costs typically shouldered by patients, including other medications, glucose monitors, and insulin pumps.

It underestimates the extreme financial toxicity that these individuals experience because diabetes and other comorbid conditions come along with many other health expenses. The worst part about it is that the majority of people who use insulin are insured through either private insurance, Medicare, Medicaid, or other. Only 2% were left uninsured, but the out-of-pocket costs remain excessive for all.

Similar trends occur for EpiPen users; on average, with no health insurance or a high-deductible one, a pack of 2 EpiPens can cost around \$710. With insurance, it’s around \$400. Multiple allergy patients are constantly at risk.

High out-of-pocket costs for insulin and EpiPen users result in less adherence to treatment—essentially opening the door to rationing, lack of access, and skipping of refills. Either unable to get the medication or unable to use it correctly, when patients begin purposely misusing medications to avoid financial burden, hospitals witness higher mortality rates, poorer outcomes, and more disability for highly preventable conditions. Costs of hospitalizations rise and hospital resources become concentrated away from sectors that address less preventable conditions.

Overall, such high costs inhibit patients’ ability to access medication, harm financial stability, and prevent correct usages of medication, while also increasing stress on the healthcare system. The way current pricing is continuing, it is inevitable that hospitals and individuals will continue suffering the most.

IMPACTS ON PHARMACEUTICAL INNOVATION

When pharmaceutical companies possess a monopoly, they become complacent as they do not have any competition. In the 20th century, also known as the golden era of R&D, manufacturers invested large amounts of money into R&D in hopes of discovering life-saving medications. R&D was expensive and risky, but had a high payout and would save millions of lives if successful. Now, the 21st century model of drug development prioritizes strategies aimed at minimizing risk and monetizing easy wins. A recent report found that 9 in 10 major drug companies spend more on marketing and sales than on R&D. Instead of dedicating funds to discovering novel treatments with higher efficacy, pharmaceutical companies work to erode the competition through patent manipulation rather than continually evolving their drugs to make them more effective. Removing competition allows for monopolies, which make companies complacent as they possess exclusive rights to sell their drug and do not have to compete with others to win over the consumer.

There is no competition in the insulin market since insulin’s protein structure is more complex than most small-molecule drugs; this prevents the FDA from approving patents filed by generic drug manufacturers for interchangeable versions. This removes the incentive for Eli Lilly, Novo Nordisk, and Sanofi to continue innovating and evolving their insulin medications. In regards to EpiPen, many complain of design flaws, namely the cap being on

the opposite end of the needle tip. This design flaw confuses consumers and inhibits user accessibility, potentially causing accidental finger injections. Between 1994 and 2007, there were over 15,000 unintentional injections from EpiPens, including by trained healthcare professionals attempting to deliver the medicine to others. Additionally, the epinephrine solution is not very shelf-stable, and can degrade at extreme temperatures. Other flaws are that EpiPens are bulky and expire after a year. Despite consumer complaints about these flaws, Pfizer has no incentive to alter the design as the company is the sole supplier for Mylan, another company that maintains exclusive rights to market and sell the EpiPen brand.

FUTURE OUTLOOK

The fundamental issue of pharmaceutical monopolies gaining traction are patents: evergreening prevents free market competition in a capitalistic healthcare economy. Worst of all, the US patent office is notoriously lax for patent granting. The pharmaceutical patent law must be reformed to withstand such corporate actions by implementing stricter qualifications for patents and allowing generic competition by reducing the 20 year patent protection duration. The US patent office must be held accountable with rigorous procedure to prevent the interests of excessive profiting over patient access.

It doesn't mean that innovation has to be sacrificed either: fundamentally, big pharma aren't the ones responsible for true innovation. While they hold a critical role in the end stages of drug development (like funding and running clinical trials), 2/3rds of true innovation usually comes from university studies or small startup companies funded by the National Institute of Health (NIH).

To ensure innovation keeps up, money from pending drug-payment reform policies can be reallocated into NIH-partnered research; not only would that benefit drug innovation, but it could also encourage big pharma to compete. Usage of federal funds can also be redistributed to making clinical trials more efficient and speedy. Operation Warp Speed, in which the US federal government funded research to make mRNA vaccines for the COVID-19 pandemic and also assumed some financial risks from the vaccines' clinical trials proves that redistribution of federal funds can tangibly benefit the stagnancy of pharmaceutical innovation in the status quo.

With critical patent reform and financial reallocation, the problems within pharmaceutical monopolies like the insulin and EpiPen markets can be mitigated. In doing so, not only will pharmaceutical innovation increase, but the quality of life for the American people will be exponentially improved.

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