Global Affordability and Availability of Vital Medications

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“I pledge that I have neither given nor received any aid on this work."

Vital medications needed by patients can be exceedingly difficult to afford. This problem is underscored in developing countries such as Pakistan, where drug availability is constrained by socioeconomic status (Saeed & Saeed et al., 2019). Anticompetitive behaviors prevent affordable generic medications from entering the market. Patents prevent or slow biosimilar drugs, which only hurts consumers forced to pay high prices (Carrier 2019). Some countries with socialized healthcare shoulder high drug costs; to accomplish this, drugs on the market are screened for cost-effectiveness. Globally, common health problems such as "hypertension, diabetes, ulcers, and arthritis" are challenging to treat due to economic constraints (Saeed & Saeed et al., 2019). A good illustration is global insulin affordability, a quagmire commonly mentioned anecdotally in discussions of drug prices. Insulin is a primary treatment for diabetes, and with price increases of 555% between 2001 and 2015, it is a focal point of the drug availability debate. This debate has erupted to such an extent; it has compelled researchers to devise an insulin analog and release instructions to the public (Gallegos & Pauwels et al., 2018). Daraprim entered the spotlight for its 5000% price increase is another shining example of affordability in pharmaceuticals (Carrier & Levidow et al. 2016). Drug prices and availability need to be tackled through well-constructed policies. Capitalistic motivations cannot be allowed to price drugs for shareholder profits. Political leaders can address some of these issues keeping drug prices high; however, changes should not be at the cost of innovation.

Rising drug prices are a global problem, primarily affecting lower-income countries and those on the low end of the socioeconomic ladder. To find out how we got here, we must elucidate why pharmaceutical companies price their products so outrageously. As one researcher points out, the blame passes onto a large group of stakeholders. "Patients, the insurance industry, employers, legislators, the board of directors of pharmaceutical companies, the CEO of pharmaceutical companies as well as shareholders" are culpable (Baker 2017). Affordable versions of brand-name prescription or even over-the-counter (OTC) medications are known as generic drugs. These drugs are bioequivalent to the more expensive brand names (Harvard Health 2021). Unfortunately, generic versions are not released as soon as we would like. There are many reasons for this. First, pharmaceutical brands apply to push back to the generic manufacturers by prohibiting generic makers from obtaining samples. This prolongs taking a brand-name drug, making a biosimilar, and bringing it to market. This is known as a "Risk

Evaluation and Mitigation Strategy" or REMS (Carrier 2019). What is worse, pharmaceutical brands intentionally delay by paying off generic manufacturing companies. Another strategy that brand manufacturers enlist to stave off generics, brands switch between different formulations. An example of this "product hopping" is switching from tablets to capsules or dosage sizes (Carrier 2019). Changing small details in the branded products slows generic duplication by forcing them to reformulate. Patents are an extraordinary tool that prevents duplication, which is somewhat effective. AbbVie's 130 or so patents on Humira, with some being filed before the primary one expired, extends the original patent many years into the future.

Availability of drugs with a high price tag raises eyebrows for those countries where medicine is socialized. One such example is the autoimmune medication, Etanercept (Enbrel). The Australian government subsidizes pharmaceuticals in Australia to keep consumer prices low. However, medications must pass a "Pharmaceutical Benefits Advisory Committee" to ensure cost-effectiveness is met (Lu et al., 2004). A prescription for Etanercept is expensive and costs the Australian government approximately 23000 AUD per year per patient. Fortunately, the autoimmune medication was found to be acceptable. This example exemplifies the benefits of socialized medicine but does not solve the high cost of medicine. Paying the high cost through government subsidies continues to enable drug companies to charge the current prices. High costs of drugs make common conditions difficult to treat for patients who have no resources. Developing countries lack the economic wherewithal to fund programs to provide much-needed medications to their populations. Pakistan, for instance, has a third of the population living below the national poverty line and therefore must use public health system resources (Saeed & Saeed et al., 2019). This puts certain essential medications out of reach for a large portion of the population; with Pakistan being one of the most highly populated countries globally, this is a substantial global burden. Like Australia, Pakistan's public health system approves the pricing of certain medications using a committee formed under the Drug Act of 1976 (Saeed & Saeed et al., 2019).

Insulin prices have been a common point of conflict, often a talking point in American politics. Politically, debates have been ongoing regarding insulin pricing. Former President Donald Trump attempted to address this by implementing executive law to help curb pricing. The Executive Order on Access to Affordable Lifesaving Medications was signed on July 24,

2020. With this order, federally qualified health centers must pass their 340B discounts to insulin patients (Rangavajla et al., 2021). Incumbent President Joe Biden delayed this order pending further review. This order was not thought to be beneficial for patients due to its narrow application. The number of patients potentially affected by this bill only amounts to 9% of Americans (Rangavajla et al., 2021). Furthermore, federally qualified health centers ensure patients receive the best price possible for their patients.

The insulin problem has given rise to a biohactivism movement driven to make the drug more affordable. The collaboration of these guerrilla professionals founded the Open Insulin Project (Gallegos et al., 2018). This project brings together specialists and small laboratories to focus on novel protocols allowing insulin production without violating current patents. If successful, the price of insulin will no longer be dictated by the small group of market makers. Instead, individuals, small pharmacies, and labs would be able to manufacture insulin themselves. Outside of the United States, insulin can be found at much more affordable prices. Biohactivism is a concerning movement; once the Open Insulin project concludes and releases the protocols for producing insulin at an individual level, there is a risk of harm. If a patient produces insulin without quality control measures, they may inject a risky product to themselves, thereby creating an ethical concern. However, passing the protocol onto hospitals or regulated laboratories would have a profound impact on patients.

Pyrimethamine (Daraprim) is an anti-malarial drug that recently gained prominence in 2015 due to Turing Pharmaceuticals corporate executive officer Martin Shkreli raised the drug's price by 5000%. Seen as a callous move, it caused understandable anger and confusion. The company's distribution for the drug became confined when originally it was more widely available (Carrier & Levidow et al., 2016). Because of its monopoly power over the drug's manufacturing, biosimilars would not be possible as its distribution system prevents that. With no competition, Turing pharmaceuticals are free to price its products as it sees fit. Pharmaceutical companies defend high prices in the United States due to price controlling policies in other countries abroad (Halpenny, 2016). The returns on their investment from American consumers are reinvested into research and development. If the United States were to apply cost-sharing measures as other countries have, it might stifle innovation in the pharmaceutical space. Canada passed the Patent Act in 1987, which kept companies' drug prices

in check by capping research and development expenditures at a percentage of sales. Canada also compares drug prices with other developed nations and addresses issues of excessive price schemes. India applies similar policies to research and development expenditures through transparency (Halpenny, 2016).

Addressing this issue will need to be a multipronged approach, focusing on patent laws, distribution chains, and subsidies. Researchers need to be paid for their work to create a novel pharmaceutical, especially when treating rare or hard-to-treat diseases. Without financial incentives, innovation will be stunted. Research is a time and labor-intensive profession with much trial and error. Each step is orchestrated to abide by current regulations so that potential side effects do not harm humans. Extensive experimental trials spanning multiple phases must report successes and failures that may impact whether a drug is approved. In the United States, only rarely is a drug given under Expanded Access, also known as "compassionate use" (Expanded Access 2021). A drug may be given to patients in emergent situations while still undergoing experimental trials. If the drug fails to work, it must be reported and expose to rejection from organizations such as the Food and Drug Administration (FDA). This illustrates the guarded nature of pharmaceutical companies and their products.

More often than not, pharmaceutical companies have a monopoly on specific drugs, especially those with active patents. Patent abuse by these multinational corporations should be investigated under antitrust laws (Halpenny, 2016). When a company also continuously blocks biosimilar generic drugs from being manufactured, it is unfair to market practice. When a drug is vital to many patients, but those patients have no choice but to pay excessive prices due to patents, it is abusive. Patients are consumers, and so, therefore, antitrust laws would be applicable to this situation. Interestingly, Italy took a stand against pharmaceutical company Aspen for abusing its market dominance. Specifically, it imposed a 1500% markup for anti-cancer drugs. Italy's Italian Competition Authority (ICA) fined 5 million euros for Aspen's unfair practices (Danieli, 2020). In 2016, United Kingdom's Competition and Market Authority (CMA) fined Pfizer and Flynn Pharma 89 million pounds for abusing their market dominance by charging inflated prices for phenytoin sodium capsules. Because of the narrow market and patient pool, there were no options for consumers to switch to a generic. As long as pharmaceutical companies are held accountable for their ruthless business practices, we may

bring prices under control. Furthermore, fair pricing would increase availability and access globally.

High-cost medications are a complex issue with a multi-faceted explanation and an even more complex solution. Pharmaceutical companies' unfair business practices, monopolies, patent abuse, is one measure that keeps prices high (Carrier 2019, Halpenny, 2016). However, these companies argue that this is necessary for some markets where health care is privatized. This allows the companies to reinvest those high returns into research and development, which pays for innovation. Many socialized health care systems globally ensure their citizens do not have to pay high prices for medications. Instead, stringent criteria are used to select the most cost-effective medication for cost-sharing and subsidization by the nation's government. Unfortunately, the United States does not have a socialized health care system, so Americans are forced to pay high prices. Well-constructed policies or a more socialized pharmaceutical program may help those in lower socioeconomic positions. This does not help everyone, and perhaps the burden ought to be on the pharmaceutical companies, governments, and stakeholders. Innovation is a good cause to raise drug prices; however, patients need to afford the medications. Innovation may continue, but only if patients are financially supported, or the pharmaceutical companies are provided subsidies to continue research and development efforts.

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