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Time to Lift Big Pharma’s Closed Curtains

“A brief overview of healthcare pricing, its inefficiencies, and possible future consequences.”

Seven years ago, Turing Pharmaceuticals C.E.O. Martin Shkreli acquired the U.S. rights to toxoplasmosis drug Daraprim and subsequently boosted its price from $13.50 a tablet to an eye-whopping $750. The drug is prescribed to patients with compromised immune systems due to parasitic infections and is the most efficient medication on the market that prevents seizures, blindness, birth defects among babies of infected mothers, and death caused by toxoplasmosis (Saba and Tucker). With the humongous price hike of Daraprim, patients had no choice but to stop using the drug or search for less efficient alternatives. The notorious villain Martin Shkreli indeed forced the world’s attention onto controversial drug pricing, but more so issues of access to medicine and the balance between commercial interests and health outcomes. Access to quality medicine is impeded due to the trade-off between health outcomes and affordability of medicine, which is worsened by the inefficiencies of the free-market healthcare system in the U.S..

Though the 5455% increase in the price of Daraprim had wide negative consequences, it allowed us to take a step back and come to an incredibly valuable realization, that the lawful drug price increase was only a symptom but not the illness itself. The root cause of such an illness lies in the broken healthcare system in the United States. The paradox of American healthcare is perfectly illustrated by the fact that it is renowned for its leadership in biomedical research and cutting-edge medical technology and is also the most expensive in the world, yet its health outcome is among the worst among other high-income, developed countries (Schneider et al., 2021). According to a 2021 study conducted by The Commonwealth Fund, a private U.S. foundation specializing in healthcare research and dedicated to promoting a high-performing healthcare system, U.S. healthcare underperforms in almost all health-related metrics, including “Access to Care”, “Care Process”, “Administrative Efficiency”, “Equity”, and “Healthcare Outcomes”. While the highest increase in healthcare expenditure as a share of gross domestic product (GDP) for the past 30 years in the other 10 studied countries is 3.7%, spending growth in the U.S. stands at 8.8%, despite it being the worst overall performer (Schneider et al., 2021). These statistics show the sheer inefficiency of

healthcare spending in the U.S. and a huge sum of wasted money. Being ranked at last in every single tested attribute apart from "Care Process" also tells us that the problems are much more likely to be systematic rather than random or external, as these metrics infiltrate all aspects of health care. With this in mind, we then turn to the fundamental differences between the healthcare system of the United States and some other top-performing countries, which exacerbate the poor access to quality medicine.

In contrast to most other high-income, Western countries that provide their citizens with a nationalized system of care and insurance coverage, the United States relies on a free-market, direct-fee healthcare system. Under this healthcare system, patients under the age of 65 (patients above 65 are covered by Medicare) or those not eligible for Medicaid (patients with an annual income lower than a certain threshold that varies by state) have to supply their own medical-related expenditures, with different levels of aid from private health insurance (Levine and Buntin, 2013). Without adequate, privately-funded coverage, out-of-pocket payments can be so high that it is simply unrealistic to receive care. Even among those with public health insurance, which only accounted for 34.8% of the population in 2020, healthcare services are often underused (Cha, 2022). With Medicare, covered patients have to pay hundreds or thousands of dollars for coinsurances, copayments, deductibles, and premiums. With Medicaid, different eligibility standards across states create further difficulties for low-income families to receive stable and consistent healthcare services (Cha, 2022). All of these contribute to poor health insurance coverage in the U.S.. According to the United States Census Bureau, 8.6% of people, or 28.0 million, did not have health insurance at any point during 2020. Because of the prevalence of private insurance, the free-market healthcare system in the U.S. also creates significant administrative inefficiencies and wastes of money. Billing and excessively cumbersome book-keeping tasks are so immense that they cost about $600 billion to $1 trillion annually, or 15% to 25% of all U.S. healthcare costs in 2019 (Chernew and Mintz, 2021). Further, the fee-for-service model for private insurance incentivizes unethical medical practices where practitioners perform more diagnostic tests or procedures than necessary to charge more from patients (Levine and Buntin, 2013). The administrative inefficiencies and fee-for-service model then pass on the high costs into payments paid by patients. In essence, the poor healthcare coverage compounds with high out-of-pocket costs of care created by the inefficient free-market healthcare system, rendering people who are not adequately covered extremely susceptible to otherwise preventable yet deadly conditions and illnesses like cancer.

Without a national body to oversee drug pricing and promote extensive pricing control, the free-market healthcare system in the U.S. maximizes freedom and opportunities for companies like Turing Pharmaceuticals to blatantly increase drug prices, making access to quality medicine extremely difficult. In 2016, The New England Journal of Medicine described Turing Pharmaceuticals' price increase of Daraprim as an emerging business model, one in which companies take advantage of niche-market drugs with few or no alternative therapeutics to maximize profits (Schoen et al.). Such a business model is extremely lucrative yet unethical, as it severely impacts the availability of Daraprim for patients desperately in need. Moreover, society as a whole ended up paying more as insurance companies that cover Daraprim's costs increased their rates,

and hospitals with low inventory for the drug drove up demand for it. Even stockholders of pharmaceutical companies were negatively affected as Hillary Clinton claimed that she would back legislation that would open up branded drugmakers to much fiercer competition and give more negotiating power to government programs. Other lawmakers were pushing bills that would allow Medicare to directly negotiate drug prices and reimportation of cheaper alternatives from Canada. All of these made major U.S. and U.K. drugmakers suffer, dimming these companies' profitability and growth prospects (Saba and Tucker). This shows the scope of damage caused by price hikes of life-saving drugs and how such issues transcend time frames and negatively impact people today. Another systematic issue with U.S. healthcare is that the Food and Drugs Administration's (FDA) approval regulation of generic drugs creates substantial barriers for generic drug manufacturers to develop alternative drugs with lower prices. The FDA's generic drug application process requires that applicants "scientifically demonstrate that their product is bioequivalent (i.e., performs in the same manner as the innovator drug)"; this means that the generic drug must show equivalent absorption and concentration of active ingredients in volunteers' bloodstream in the same amount of time (Center for Drug Evaluation and Research, 2016). As drug companies like Turing Pharmaceuticals limit the market supply of specialty drugs like Daraprim by selling them exclusively in specialty pharmacies, generic drug manufacturers lack adequate study samples to develop bioequivalent alternatives. Without any competition from generic drugs, Turing Pharmaceuticals gained complete control over the price at which they want to sell Daraprim. Such excessive pricing power of pharmaceutical companies also creates issues when patients need prescription drugs. As any patent-protected drug monopolizes its niche market, prices are bound to be set high. Free-market conditions of U.S. healthcare and the unique characteristics of the pharmaceutical industry both contribute to frequent price hikes of essential drugs, creating huge affordability issues and high barriers to acquiring access to quality medicine.

As a result of pharmaceutical companies' immense pricing power in a free-market environment, drug prices are set at levels that fail to reflect their true value and mislead patients' purchasing decisions, further impeding access to and utilization of quality medicine. Under the free-market healthcare system in the U.S., drugs that offer important advantages over existing treatments are priced at levels that are almost indistinguishable from their near-equivalents (Conti et al., 2021). According to a 2021 study conducted by USC-Brookings Schaeffer Initiative for Health Policy, among newly launched drugs in the U.S. where effectiveness was evaluated relative to existing market options, only 37% of the new drugs are shown to be better than existing products while 43% of them offer no additional health advantages (Conti et al., 2021). Yet, these drugs are priced at almost identical levels. Under FDA's Accelerated Approval Pathway, drugs with uncertain or even worse efficacy and health outcomes are also sold at the same price levels as existing drug options. Aduhelm, a medication targeting Alzheimer's disease with a yearly price tag of $56,000, is a recent example of a drug that has weak clinical findings and unreasonably high prices (Conti et al., 2021). The fact that evaluation of drug effectiveness has virtually no effect on how drugs are priced eliminates drug price as a distinguishing tool for clinical advances and weakens patients' ability to access the most efficient medication. Therefore, given the pricing and bargaining power of

pharmaceutical manufacturers in the U.S. healthcare system, patients tend to overpay for products that are worth less and in turn are left with much less money to pay for what they really need. From a broader perspective, the public is suffering from poor access to quality medicine as they pay more than they need and underuse products that have significant health benefits.

Not only do high costs and misleading price tags lead to the under-utilization of high-quality medicine in the U.S., but the incentive mechanism within the pharmaceutical industry also does. According to research in Nature Reviews Drug Discovery, "there are few, if any, products in the pipeline to address antimicrobial resistance, tuberculosis, and opioid dependency despite the significant unmet need and disease burden." However, many new drugs on the market are merely slightly modified versions of existing products with lucrative sales, offering virtually no overt extra benefits (Karlsson, 2015). This unfortunate result shows that the entire pharmaceutical industry is highly tilted towards anything that generates huge returns and commercial interests, not innovative products that can truly resolve some of the most pressing health crises humanity faces today. The losses associated with the lack of quality medication for such serious illnesses can be quantified by the near 700,000 deaths per year worldwide due to antimicrobial resistance and a potential annual loss of $3.4 trillion by 2030 (Dadgostar, 2019). Even though it is established earlier that drugs targeting certain illnesses with serious health and economic burden are underdeveloped, the situation tends to change when companies project a great total addressable market, product sales, and profitability. Under these highly profitable circumstances, research and development (R&D) investments tend to be concentrated in developing blockbuster drugs with new therapeutic targets (Karlsson, 2015). The rationale is that even though these drugs are characterized by higher uncertainty and technical difficulties, they also have much lower expected future competition and higher product sales. Therefore, it can be concluded that under most circumstances, the incentive mechanism within the pharmaceutical industry does not prioritize health outcomes; they are only attached with tactical significance when high-return profiles are present.

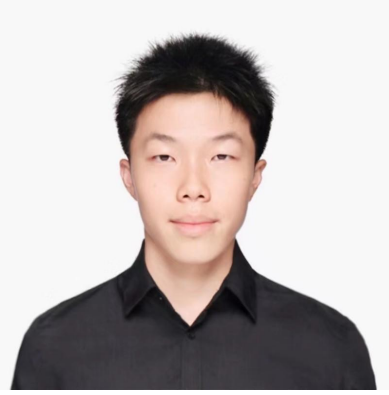
Understanding how the U.S. healthcare landscape and pharmaceutical industry-specific characteristics deter patients' access to quality medicine, we pivot our focus onto reasons for the inevitable conflict between health outcomes and the affordability of medicine from a pharma's perspective. According to the Information Technology and Innovation Foundation (ITIF), a pharma's revenue must pay for the long delays between initial research and the ultimate launch of a drug and also cover the high sunken costs of failed R&D efforts that yield zero revenue. More than that, since the pharma industry is the epitome of a dynamic high-tech industry, generating sufficient profits is indispensable for continuity in future innovation (Karlsson, 2015). Capital for operation and research may be quickly pulled away if there are no drugs under development in the pipeline, as investors respond to information like drug portfolio and pipeline development quickly. Given 90% of R&D failure rate and a 4.8% average rate of return on all assets, pharma companies need to make a 62.2% margin on their successful products (Karlsson, 2015). The chances are incredibly slim. Therefore, a huge sum of revenue in excess of costs that cover successful trials is required for a pharma company to merely survive. Only after its survival can a

pharma company take on more social responsibilities and continuously invest in new therapeutic targets and innovative drugs. This means that not only are costs of raw materials and all research and clinical trials covered in the prices of existing products, possibilities for future innovation and blockbuster drugs are also translated into their prices. Such a conflict between health outcomes and affordability is even worsened considering the free-market healthcare system in the U.S.. In other high-income countries with nationalized health insurance, policies that keep the price of their patent-shielded drugs low are pursued (Sommers et al., 2017). These don't exist in the U.S.. Consequently, multinational companies have to cover their lost revenue from the U.S. market by charging even higher prices to U.S. patients. According to ITIF, U.S. consumers paid approximately 70% of total global patented biopharma profits in 2019 (Dadgostar, 2019). Such a staggering figure further illustrates the health and financial burden on U.S. patients due to a combination of inefficient free-market healthcare systems and the tradeoff between health outcomes and drug affordability.

After examining the broken U.S. healthcare system and its interplay with the highly controversial pharmaceutical industry, we arrive at the conclusion that issues in healthcare are extremely complicated and challenging to solve. More specifically, access to quality medicine is very hard to promote because inefficiencies of the free-market healthcare system and medicinal innovation are both translated into drug prices. Long existing systematic issues like low public health insurance coverage and excessive pricing and bargaining power of pharma companies all make the matter worse. As a result, a collective societal effort is required to make life-saving, innovative drugs more accessible and affordable to everyone. Whether it is incorporating social value considerations into drug prices, the government negotiating for patented drugs that set prices too high, or benchmarking U.S. drug prices with International Reference Prices, the entire society needs to be mobilized to understand the root cause of the healthcare crisis and take appropriate actions.

About the Author

Oscar Zhang is a freshman from Shanghai, China majoring in Biochemistry and Quantitative Economics, minoring in Entrepreneurship. He is currently interning at Amundi US as an Equity Research Intern and is also an Equity ESG Analyst at Impending Bloom. He has also accumulated financial experience at an investment advisory fintech company. Outside of academia, he is a martial artist with 10+ years of experience, a black belt and amateur coach in Tae Kwon Do, and a backpacking fan.



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