Neoliberalism and Big Pharma:

The Impact of Free Market Capitalism on Public Health

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Global Illicit Drug Markets

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The emergence of synthetic chemistry enabled most epidemics and parasitic diseases to be under control in most countries worldwide. However, there are still two epidemics created by human behaviour which are smoking and prescription drug use. These habits are extremely deadly and have made drugs the third leading cause of death in Europe and the US, after heart disease and cancer (Gøtzsche, 2022). Unfortunately, the pharmaceutical industry has a long history of corporate crime and international corruption. Clinard et al (1979) found that pharmaceutical companies had more than three times as many serious or moderately serious law violations per firm as other companies in the study. Interestingly, the industry has undergone a complex and wide expansion in recent decades, driven by globalisation and its consequent increase in demand for drugs. Some academics showed that the largest pharmaceuticals extended their industrial empires through methods such as international price-fixing arrangements (Braithwaite, 2012).

However, this expansion has several more reasons, which have also brought with it a rise in costs and stronger incentives for fraud and corruption within the industry. These companies not only have a record of criminal negligence in drug manufacturing but also a history of corruption and bribery. Although the term "corruption" can have many meanings, interestingly, Gøtzsche (2022) defines it in his dictionary as "moral decay." He also defines bribery as a secret payment, usually in cash, for a service that would otherwise not be given or would be delayed. Given the high stakes involved in pharmaceutical products and their potential impact on public health, hard regulation is considered an essential topic to explore in this essay. As well as the lucrative nature of this type of product which can lead to dishonest incentives and pressures and therefore, bribery and corruption.

Moreover, conflicts of interest are a significant issue in the regulation of this industry, and marketing and fake communication with regulatory agencies such as the FDA create problematic areas. Finally, this paper will explore neoliberalism and its link with free-market capitalism and limited state intervention because it is an interesting and significant issue in the regulation of the industry. To contextualise these issues, this essay will examine two specific case studies: Thalidomide in Germany and Vioxx in the US, although it will also include small contextualisation from examples from companies such as Pfizer and Hoffman-La Roche, as all four cases highlight perfectly the harms caused by fraudulent and corrupt practices within the

industry, as well as the need for strong regulation to prevent similar tragedies from occurring in the future.

The current situation of pharmaceutical companies has a rapid rate of expansion while they are in a complex deviant position (Cooperstock, 1974). The point made by Gøtzsche (2022) is that pharmaceutical companies do not only sell drugs but also sell a false narrative about the benefits and drawbacks of their products. Braithwaite's (2012) study found extensive and global wrongdoing within companies resulting in social harm towards consumers (Baker, 2019). Pharmaceutical corporations often only promote the efficiency and safety of their products, without discussing their potential drawbacks. This creates a perception that taking these drugs will have only positive outcomes, when in fact, all medicine comes with some level of risk. Although this is evident, doctors and their patients often forget that medicine can harm us. The fact that we should take them with caution means that those who investigate and commercialise these products should possess ambitious standards of ethics and legality (Gøtzsche, 2022). In addition to illegal, unethical, and harmful behaviour such as bribing government officials, pharmaceutical companies also engage in dangerous manufacturing processes, negligence, and fraud in drug safety testing. Despite this claim, public expectations are that the industry will further research, develop and produce drugs ‘for the common good,’ ‘to improve rather than harm public health outcomes’ (Baker, 2019).

Nevertheless, the executive from a drug company ‘allowed his company to market a drug knowing that it may produce harmful side-effects for most individuals’ (Braithwaite, 2012). With that, establishing what is ethical or unethical, legal, or illegal, and other biases, is not that easy to do. Often, even the most lethal industry lies in the temptation of using financial resources to avoid stricter regulations (Passas, 2005). For instance, in 2012, Pfizer acceded to paying sixty million dollars to deter a federal investigation about bribery paid to foreigners, and now they are accused of paid bribery from foreign countries. The big image that multinational companies want to project is not something more than a popular method used by them. A disconnection between the ‘high ethical standards’ and the ‘legal imperatives’ (Gøtzsche, 2022). However, the connection between Pfizer and foreign countries is nothing else than another example of how corporate pharmaceutical harms have been occurring massively. But the reasons why the regulation of corporate pharmaceutical harms has been so difficult are a few.

One reason comes from what we know as globalisation, which has given to increasing demand, rising development costs led them to provide stronger incentives for new product development (Walker, 2019), which rotates inside a framework to protect patients by marketing drugs in various unethical ways. This industry and its intent the regulation is under their purpose of increasing sales by means such as falsifying research findings, deceptive advertising of drugs and even paying physicians to write prescriptions (Arnold et al., 2022). In the 60s, everything changed when national companies dominated the industry. However, these companies started exporting products across borders within Europe, leading to significant changes in the industry (Bauschke, 2010). This change involved a significant consolidation of the pharmaceutical industry that is primarily linked to global developments and fundamental improvements in the drug development process, which resulted in a substantial increase in development costs and higher sale prices.

Sometimes, this consolidation can be dangerous as it could lead to higher drug prices and less competition in the market, which may have less incentive to invest in research and development for new drugs (Scherer, 2000). The consolidation of this sector should not make us forget about the fact that drugs are dangerous. Their strategy of marketing, by spreading false information about their products, reflects their null social responsibility to deliberately kill millions of people every year who did not need the product in the first place (Gøtzsche, 2022). The act of prescribing drugs to individuals who do not require them, especially when the drugs are highly addictive and can significantly impact brain functions, has become a highly profitable business. Hoffman-La Roche is another big example of pushing Valium (diazepam) to become the top-selling drug at a price 25 times gold (Braithwaite, 2012). However, this enterprise is just another of the hundreds of companies that commit these crimes. For this, Gøtzsche (2022) in his study found that corporate crime is common, and the individuals behind these crimes are a blatant disregard for the deaths and other serious harms they cause. But this repetition and widespread are in an inescapable conclusion that they are committed deliberately because crime pays. The companies that have consolidated see fines as a marketing expense and carry on with their normal illegal activities as if no crime occurred.

Another reason, it has been shown that the pharmaceutical industry has been defined as causing numerous harms because it is particularly susceptible to fraud and corruption for several

reasons. In the first place, the sale of these types of products is lucrative, because the asymmetric information leaves patients more vulnerable to opportunism than other kinds of customers, and therefore pharmaceutical suppliers are profit maximizers (Cohen, Mrazek and Hawkins, 2007). Although some countries, like the US, have implemented robust checks and balances, there has still been a rise in fraudulent activities within the pharmaceutical sector. Moreover, the industry's dishonest activities have exposed legal loopholes, leading to a lack of transparency and regulatory oversight, which has allowed unethical behaviour to occur (Cohen, Mrazek and Hawkins, 2007).

The Thalidomide disaster serves as a valuable lesson, highlighting the critical need for better international communication among drug regulatory agencies. The lack of effective communication resulted in devastating consequences, including the birth of children with incomplete limbs, leaving them with only a head and a torso (Braithwaite, 2012). In Germany, this drug was endorsed as an anxiolytic but never was approved for marketing. Initially marketed as Contergan, was prescribed as a hypnotic sedative able to produce sleep without the risk of dependency. Florence (1960) may have begun to investigate certain symptoms associated with the toxic effects of thalidomide. However, it was not until 1961 that researchers established a link between thalidomide use during pregnancy and congenital malformations, which led to the substance being withdrawn from the market (Rehman, Arfons and Lazarus, 2011). The lasting impact of these tragic events has been on the drug regulation process, which is a positive outcome. Even though the Thalidomide substance was never approved by the Food and Drug Administration (FDA) in the 1950s (Reuters, 2021), the agency took steps to overhaul the regulatory process, enhance patient informed consent procedures, and demand more transparency from drug manufacturers.

Although Thalidomide is considered one of the ‘darkest episodes in pharmaceutical history,’ the Vioxx fiasco has been described as the worst disaster in drug history (Compton, 2022; Kruholz et al., 2007). This case was also seen as susceptible to causing harm as when Merck withdrew its COX-2 inhibitor, the US anti-arthritis drug Vioxx from the market. The drug was approved based on small, short-term trials that did not look for cardiovascular harm (Gøtzsche, 2013). Moreover, Merck's corporatized pharmaceuticals have caused severe harm, including a violation of human rights, as well as the handling of 'confidential' commercial

information (Washburn, 2005 cited in Brownlee, 2015). Further, the Vioxx scandal, as the industry itself, was seen engaged in sophisticated systems of fraud, but they face few, if any repercussions for their fraudulent behaviour (Eugene, 2019). The creator, Merck manipulated the science about the drug by skewing the results of clinical trials in favour of the drug and hiding the evidence that it can increase patients' risks (UCS, 2017) of serious cardiovascular events, including heart attacks, strokes or even death (Culp and Berry, 2007).

In the second place, pharmaceutical companies normally face various incentives and pressures that can affect their behaviour and decision-making towards acts such as bribery or corruption. The market is highly competitive which creates many companies to vie for market share and increase their profits. This competition can not only lead to aggressive marketing tactics and price wars (Zaret, 2016) but also can drive innovation and lower prices, which can benefit patients and healthcare systems (Morton and Boller, 2017). However, this sometimes brings with it the reliance on patents and similar forms of intellectual property protection to recoup their research and development costs, just with the final objective of earning profits. In the end, this creates an incentive that prioritises the development of substances that are more patentable and profitable, rather than more innovative or effective (Böhme, Frank and Kerber, 2021). Despite market competition and patents in the industry, regulatory requirements are necessary for pharmaceutical companies. However, regulating global pharmaceutical companies when they commit corporate crimes and harms is challenging. The standard justification for drug regulation is perceived as a market failure (Hägglöf and Holmgren, 2013). It is assumed that in unregulated markets, supplying firms would perform insufficient pre-market testing to avoid the inflated costs of testing. This market failure results from information imperfection. The inability to obtain full information about the benefits and risks of new drugs (Katz, 2007), leads firms to take advantage of the imperfection and apply less accurate information. Further, drug regulation can be seen as essentially paternalistic because it is necessary to ensure the safety and efficacy of drugs for the public (Dailey, 2007). Although, others argue that it seeks to protect the misinformed consumer from better-informed sellers (Sumner, 2020).

It has been seen that the regulation is not always foolproof and cases such as Thalidomide and Vioxx have marketed drugs that later have been found harmful. Most drugs are excessive marketing expenditures, and this creates a direct link towards persuading doctors and patients to

choose one drug over another, usually without a scientific basis for doing so, therefore, individuals used to put all their confidence in the pharmaceutics, until they realised that there have been in place toxic drugs and being marketed (Jarrett, 2021). Moreover, conflicts arise due to the varying regulatory requirements across different countries. These requirements are rights norms to global standards and working to ensure favourable marketing conditions, such as the cases of the Vioxx scandal and the Thalidomide disaster. Which aims to harmonise their regulations towards laws and policies brought from the International Council for Harmonisation of Technical Requirements for Pharmaceutical for Human Use (ICH). This intends to achieve compliance in medicines to be developed safely, in effective and high-quality ways (FDA, 2020). Nevertheless, pharmaceutical standards and regulatory systems across the world remain in many countries 'fragile, uneven, and highly dependent on aid and technical support from international donors' (Pezzola and Sweet, 2016:3). If regulatory requirements differ, and no harmonisation is seen, can create challenges for pharmaceutical companies that operate globally. Although every country has its regulations that apply to innovation, drug testing, manufacturing, and marketing (Agarwal and Karwa, 2018).

Furthermore, some conflicts of interest are a significant issue in the regulation of the pharmaceutical industry. These compromise the integrity of key parts of the pharmaceutical sector and the policies that it can encompass (Rodwin, 2019). They have always been a source of concern because of their potential to influence research, education, and clinical practice during the development of new pharmaceutical products. As Pezzola and Sweet found (2016), sometimes the quality of the regulation of the system appears to be highly correlated with the prequalification of suppliers. However, these influences can be handled by avoiding any pharmaceutical industry marketing advertisements or incentives (Alpert, 2005).

In the cases discussed, regulating the Vioxx company was critical. Despite substantial findings from reputable groups about the danger of the pharmaceutical, the data did not effectively move regulators to action (Nesi, 2008). Even more, Nesi (2008) examined Merck's communications efforts related to Vioxx which were focused on controlling the message around the drug's potential benefits and harms. Many lessons can be learned about how to generate valid post-marketing surveillance about the existing data of the drug. Although the FDA had a role in regulating Vioxx, the company saw itself subjected to criticisms and scrutiny. And Merck

decided not to conduct a single study solely to determine whether Vioxx might cause heart attacks and strokes, affecting the health of thousands of patients. Further, the Thalidomide case acted differently from Vioxx, and the tragedy led to the adoption of requirements for the systematic testing of pharmaceutical products for potential developmental toxicity before marketing (Nesi, 2008).

Another difficulty is found when discussing the impact of neoliberalism on pharmaceutical regulation. The presence of a 'state-pharma nexus' (Rawlinson, 2017) is seen in this relatively new political movement and ideology which has redefined the regulatory state to have much less power and to be more accommodating to industry interests, especially when it comes to those interests from the pharmaceutical sector (Abraham and Ballinger, 2012). Particularly, regarding accelerations and cost reduction of drug development and regulatory review. This means that drug regulatory agencies, such as FDA, have now lessened their adequate regulatory oversight over corporations that have a great deal of freedom to develop and market their products, which ends up increasing inequalities and causing social harm, as well as engaging in unethical practices such as promoting addictive drugs, hiding negative clinical trial data (Baker, 2019). Pharmaceutical companies have been involved in actions that claim to consider the well-being of society by offering financial support and engaging in corporate social responsibility (Dănescu and Popa, 2020), but in reality, the involvement of these companies contribution to corruption in the medical sciences, which as mentioned above, lead to the promotion of drugs that are not effective or even harmful, as well as aggressively marketing drugs (Sismondo, 2021). All this has been existing within the impact of neoliberalism which has been shifting the focus away from public health and safety towards the interests and incentives of the pharmaceutical industry.

The German thalidomide continues to reflect the complicity of the neoliberal state and the pharmaceutical industry in enabling these harms. The sedative thalidomide was nearly cleared for marketing in the US when the evidence became known about its harmful effects (Nik-Khah, 2016). However, the neoliberal response to the scandal reflects how deeply neoliberalism affects regulation. The disaster was a catalyst for a major change in federal drug safety laws, which increased regulation of drugs and gave the government more control over drug safety. Further, the industry's opposition to this increased regulation was surprisingly

overwhelmed by public demands for more government regulation and safer drugs (Dreier, 2015). On the other side, the American case of Vioxx highlights the potential conflicts of interests that can arise in the neoliberal privatisation of health care, when regulatory agencies are weakened, and corporations prioritise profit over public health and safety. All that mattered to Vioxx was obtaining quick regulatory approval and starting to get profits. However, this cost in the end 40,000 American lives due to too-rapid regulatory approval, and potential complicity within the FDA. This is something the U.S. used to get right: the epidemic of catastrophic birth defects in Europe due to Thalidomide was avoided in the U.S. because of slower regulatory approvals (Hull, 2016).

While Thalidomide and Vioxx are now bounded and removed from the market, their actions left a lasting scar on the pharmaceutical industry and the medical community. These practices contributed to the mistrust of pharmaceutical industries and the communities themselves: by committing acts of fraud and deceit, generalising data, and creating fake marketing. Stricter regulation and more constant revisions from both regulatory agencies and oversight by the federal governments or national parliament, as well as increased transparency and accountability, are potential solutions to the problem of its difficult regulation. Further, conflicts of interest within the medical community and deceptive research misconduct by the companies make it difficult to regulate the industry. Without sufficient controls, there is the risk that pharmaceutical corporations will transgress ethical boundaries, which is why, honesty and transparency and a limitation of a neoliberal state would ensure a stricter industry and prioritise individual health over corporate profits.

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