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Tackling Big Pharma: Checks and Balances in the Pharmaceutical Industry

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Abstract: **This summer I had the opportunity to intern at the Washington DC Veterans Affairs Medical Center observing physicians and cardiologists treat patients in real time. This experience has confirmed my desire to pursue medical school in the future. However, I know doctors work in a flawed healthcare system which has led me to research more about the medical field starting with the pharmaceutical industry. Beyond science, the more I researched, the politics and business aspects of medicine have stunned me. The profit-hungry pharmaceutical companies also known as "Big Pharma" have misguided the public regarding new drugs which have little to no health benefits. After reviewing medical journals, analyzing both quantitative and qualitative data, several researchers have consistently concluded that there is a lack of checks and balances between drug companies and governing authorities. The battle to secure unbiased, ethical drug developments has grown into one of the greatest controversies in American history. The profits are far too immense that the federal government has compromised its strict standards at the hands of drug merchants. Today, 4.5 million consumers visit their doctors regarding adverse prescription drug side effects due to false drug trials. Doctors are lured to prescribe one drug over another through gifts and vacations that affect their prescribing habits. For nearly a century, the pharmaceutical company's goal has been to reduce costs and earn profits rather than to provide life-saving and life enhancing medicine for patients. This paper aims to offer solutions to the problem at hand through policy modifications regarding drug trials and direct physician marketing.**

Keywords: **pharmaceutical companies, Big Pharma, Checks and Balances in the Pharmaceutical Industry.**

For nearly a century, integrity has been lost in the world of medicine. In effect, the term "Big Pharma" was coined to signify the abuses caused by pharmaceutical companies. Profit-hungry businesses have misinformed the public regarding new drugs that have little to no health benefits. One British drugmaker, GlaxoSmithKline, paid 3 billion dollars for selling two unapproved drugs to the mass market, the largest fraud settlement in US history (Sukhija 1). In the 90s, Merck was under fire for claiming that the MMR II was an effective vaccine for the mumps. Former Merck employees exposed how the supervisors of the company falsified the results of the drug trials (Sukhija 1). It is no surprise that due to a lack of checks and balances in the prescription drug industry, 4.5 million consumers visit their doctors regarding adverse prescription drug side effects (Drug Watch 1). Today, pharmaceutical firms are heavily controlled by the powerful and wealthy wherein each company depends on shareholders, healthcare providers, and other regulators who influence the development of new drugs (Fields 558). A firm's goal is no longer to provide life-saving and life enhancing new medicines for patients but rather, it is to reduce costs and earn profits. This paper aims to offer possible solutions to combat Big Pharma's unethical, profit-based activities through policy modifications regarding drug trial modifications and physician marketing. Such efforts are critical in order to provide checks and balances in America's prescription industry.

Since the early 1900s, Big Pharma's biggest influence was on the Food and Drug Administration (FDA). Their strategic moves have weakened the FDA's ability to protect the public from drugs with serious side effects. In spite of these clear cut warnings, the FDA has allowed billions in tax dollars to contribute to the research of new molecular entities (NME) or "innovations" by the pharmaceutical companies (Light, Lexchin, & Darrow 590). Many of these NMEs, however, provide little therapeutic gain and have done so for at least 35 years. From the 70s to the 90s, many experiments have been administered to test the validity of these new drugs. Many were found to be ineffective though "new" molecular variations

have been instilled. The cost and risks are less for manufacturers who then sell the drugs for their "newness" rather than its effectiveness. On average, pharmaceutical companies have spent 19 times more expenses on promotions than developing the drug itself (Light, Lexchin, & Darrow 592). In the name of business, prescription drugs are "packaged" and presented to coerce patients to buy a drug, whether it is effective or not.

A public outcry for Congress to regulate Big Pharma's corrupt activities has been on-going since the 1890s. However, pharmaceutical industry lobbyists fought against such regulations because exposing harmful or ineffective ingredients in the drugs could be detrimental to the business (Light, Lexchin, & Darrow 593). Although President Roosevelt created the 1906 Food and Drug Act in good faith that drug providers would list accurate ingredients on the label, the lack of reinforcement made it possible for drug companies to distort its labels. Congress made yet another attempt to secure safe drugs through the 1938 food and drug law when children began dying of antifreeze added to a sulfa drug for a sweet flavor. The law did not prove successful because once again, it was up to the companies to test the drugs in which the companies controlled the safety reports (Light, Lexchin, & Darrow 593). Throughout the 40s and 50s, the FDA approved drugs based on the pharmaceutical company's biased reports. Yet again, after the thalidomide tragedy in 1962, the FDA had no choice but to begin the National Research Council (Light, Lexchin, & Darrow 594). In response to serious casualties, drug companies were now required to submit evidence of effectiveness in order to prevent further deaths. This event has led to our modern drug testing system in which Big Pharma has found yet another way to yield profits rather than providing effective drugs for patients.

For the last 50 years, our modern drug testing system has functioned in three fundamental ways. First, new drugs are tested against placebos rather than treatments that have already been established (Gabriel and Goldberg 311). Second, companies test their own products. Researchers often tweak the data by combining favorable results in order to hide ineffective outcomes (Gabriel and Goldberg 311). Third, Big Pharma has manipulated research journals through ghostwriting as a tool to market drugs. Publication planning teams are hired to display "effectiveness" of drugs who are then forbidden from exposing any unfavorable outcomes. Research journals are then promoted to prove their drugs as effective, a powerful marketing tool used to convince physicians to prescribe their drugs.

Since physicians are required to prescribe drugs to patients, a pharmaceutical company's biggest clients are not the patients themselves but the doctors. Doctors have very little regard for the cost of drugs which is highly beneficial to Big Pharma (Gagnon 572). Hence, pharmaceutical companies have increased spending on promoting their new drugs. In America alone, about $42 billion was spent on promoting to physicians - free vacations, expensive dinners, gift baskets, and more - in order to affect their prescribing habits (Gagnon 572). About $61,000 was spent on each physician in America, a significant amount that proved quite effective with billions in profits.

This focus on profit instead of health has led to many health complications in America. Tamiflu, an anti-influenza drug, was administered to people around the world to prevent the "next major flu outbreak" caused 70 recorded deaths (Wolford 30). In one case, a 14-year-old who took Tamiflu jumped off a balcony and a 17-year- old boy ran in front of a truck (Wolford 30). These deaths could have been avoided if reports of drug trials were not partially concealed. Such negligence has caused millions of Americans to suffer from adverse reactions, both minor and major, requiring patients to return to their doctors. Such problems are highly preventable if accurate safety reports were provided in the first place.

This has been a major issue in the investigation of Merck's research on Vioxx in 2004. Although the trial of Vioxx reported that the drug "was easier on the digestive system," it also increased the risk of heart problems (Drug Watch 1). After passing the FDA approval in 1999, Merck, to defend its own drug, neglected FDA's order to report its harmful content on the drug label, and continued to promote and sell the drug to physicians without warning. What seemed like a small matter back then became monumental as patients began to die from heart problems caused by Vioxx. Before it was taken off the shelf in 2004, Vioxx caused 38,000 more deaths (Drug Watch 1).

While the FDA has made attempts to clean up the pharmaceutical industry through strict patent requirements, it still has room for advancements. Instead of taking unrealistic steps, early adjustments in the patent duration should be small enough in scale for Big Pharma to comply. Within each drug company, a patent is required for each drug it generates. The current patent law requires only new molecular entities of already existing drugs to be patented. Since the FDA deems drugs with significant therapeutic advances as priority, the patent law should be modified to incentivize proper research (Rodwin 513). One way is to offer varying durations based on the level of innovation of a drug. For instance, drugs that offer limited therapeutic improvements should be given the shortest patent duration while longer durations should be

offered to drugs that provide significant therapeutic advancements (Rodwin 513). Drug firms will then be incentivize to urge their research teams to develop drugs with therapeutic benefits.

Firms often hire pharmaceutical sales representatives (PSR) to follow a strict set of guidelines to sell their drugs to physicians including medical students. Amanda L. Connors states in her research, "Representatives are instructed to shake a doctor's hand for three seconds and when dining with physicians, to eat one small bite size piece at a time. Break off and butter bread one single piece at a time. Bread dipped in olive oil should also be broken off and eaten one single piece at a time" (Connors 257). For the purpose of receptivity, the pharmaceutical companies send cheap to expensive gifts to physicians so that they would be willing to see the sales representatives. The gifts include vacations, meals, coffee mugs, and other forms of cash awards. Despite their monetary value, the effect of these gifts is astounding. Although the criteria seems absurd to many, the impact that these fixed behaviors have on the physicians is surprising. Kaiser Foundation reported that "92% of physicians had received free drug samples, 61% had received meals, free access to entertainment, sporting events or travel, and [approximately 14%] had received financial benefits," demonstrating that the sales representatives tremendously influence physicians' prescription decisions (Connors 258). Connors reports 70% of patients believe that gifts significantly impact prescribing habits of a physician which often lead to suicide among patients (Connors 264). This conflict of interest must not be overlooked.

Medical detailers are employees of the drug firms who seek and educate physicians about newly developed drugs. Despite their educational purpose, these medical detailers are influenced by financial incentives, coerced to promote their own firms' drugs over others'. As Dr. Charles noted, "How can we trust any program sponsored by the industry as being educational rather than promotional?" (Rodwin 809). First and foremost, there must be a removal of "medical detailers" (Rodwin 809). Although this removal will leave many employees of the drug firms unemployed, the drug firms will have more cash in their hands to create new job sectors or develop new therapeutic drugs that will actually benefit patients. If such removal oversteps federal power, the way medical detailers are marketing the drug firms' products to physicians must be regulated through accountable measures such as a fine (Gagnon 572). To help doctors refocus on their patients' health, pharmaceutical companies should penalize companies for unethical conduct (Gagnon 472). The doctors will then have control over communication with pharmaceutical companies instead of constantly being tampered by pharmaceutical reps who affect the physician's prescribing patterns through lavish gifts.

Zeek Emanuel has revealed that the healthcare industry is currently evaluated at $2.8 trillion, the fifth largest economy in the world (Emanuel 1). It is no wonder that the battle to secure unbiased, ethical drug developments has grown into one of the greatest controversies in American history. The profits are far too immense, even beyond the federal government's control. While our market economy depends on these figures for economic growth, America is facing a deteriorating health care system with little traction towards progress. For nearly a century, Big Pharma has bullied governing authorities to work in their favor, all in the name of profit. It is essential that not only governing officials keep the drug industry accountable but the general public do so as well. While many non-profit organizations and other foundations are working hard to draw attention to this issue, the influence of Big Pharma today is extremely telling. The very people whose lives have been affected or are at stake must do more to expose Big Pharma and demand change. Without a collective voice in the political arena, small policy changes stirred by public interest groups will not be enough to tame the monster. Until then, our governing authorities must work towards practical and realistic policy modifications to keep checks and balances on Big Pharma. Solutions that are neither too far-fetched nor In doing so, we may save more lives.

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