Drug companies: Profiting at the cost of patients

At any given moment, nearly 50% of Americans hold at least one valid prescription (Qiuping, 2010). For many, the small stockpile of medication behind the cabinet seems commonplace. Every year, society, it seems, becomes more prone to medicalization—"when previously non-medical problems are defined and treated as medical problems." (Conrad & Leiter, 2004). It often appears as if there is a pill for everything. There are currently around 10,000 medications approved by the FDA for prescribing and sometimes many dozens of options for a single ailment (Huang et al, 2011). How do physicians decide what to prescribe? What sorts of factors influence a doctor's decision? Although there are many factors that influence doctors, drug companies are the main contributing influence to a doctor's choice of treatment. By exploiting their illnesses, Drug companies unethically profit from patients by fabricating demand for their drugs through: publication bias, the medicalization of illnesses, and unscrupulous marketing to doctors. Awareness of a prescriber's influences helps safeguard the public's interest by not allowing other motives or incentives to take precedence over one's health.

It's hard to believe that all people employed by drug companies and all the CEOs of these companies have an elaborate plan whose sole purpose is to harm and misuse patients and doctors. It's more probably that most of these individuals are average, well-intentioned human beings who don't set out to harm others. It's important to recognize the reasons why drug companies seem fit to justify their exploitation of patients' illnesses. Over the past 100 years, according to the World Climate Report (2011), life expectancy has steadily increased—with the exception of the Spanish Flu epidemic of 1918—from 47 years old to 78 years old. There are numerous factors that contribute to this, but one major factor is the

innovation and manufacturing of drugs by the pharmaceutical industry. Drug companies have provided a very important service for the entire human race in prolonging life and rightly should be rewarded for this service, but how much should they profit? Should their recompense be only limited at the discretion of the pharmaceutical industry itself? Although the pharmaceutical industry does bring about good, it uses this to justify unethical profit margins from its consumers.

There are other influences that effect a doctor's treatment plan—those being: patients, funders (insurance companies), and doctors—delineated by Ben Goldacre (2013) in his book *Bad Pharma: How drug companies mislead doctors and harm patients*; however, no other influence compares to the impact that drug companies have on prescribers (p. 240). Goldacre states that "For patients, things are simple: you want a doctor to prescribe the best treatment for your medical problem." (p. 240). Many patients consult and decide with their physician a treatment plan to follow, while many individuals trust in what their doctor first recommends. Insurance companies generally want the cheapest option, but will still pay for brand names drugs if physicians specify. Doctors often refer to others doctors' advice when choosing medical treatments. Most of the time a prescriber makes his/her decision based on what he/she is taught in medical school, what he/she reads on a given medication in publically available journals or trials, or from continued medical education services. All of these factors are influenced by the pharmaceutical industry, which will be shown hereafter, in various forms. There are many other influences as to what a doctor may prescribe, but the remainder of this essay will focus specifically how drug companies influence a doctor's decision in the route of treatment for patients.

Pharmaceutical companies alter the apparent effectiveness of a given drug through publication bias—which, according to Goldacre, means: "the process whereby negative results go unpublished." (p.7). To alter the statistics of any trial is unethical and is penalized by the federal government, but on the other hand, there is no penalty in not publishing trials that found negative or non-conclusive results; this is the basis of publication bias. The lack of incentive to publish negative results is common to both drug companies and academic journals alike. Why would a drug company publish an article that would diminish the potential sells of their product that they have heavily invested in when they don't have to? Why would an academic journal publish results that were non-conclusive, when they could just as easily publish something that is interesting and engaging to its audience? The answers to these questions find their roots in some form of financial incentive. What repercussions does this lack of information have? When a physician first reads about a new drug, he/she will most likely study the published, publically available academic journal articles written about the trials of the given drug. The Doctor will then use this information in conjuncture with previously acquired knowledge to make a final decision. In Goldacre's book, he compared this to flipping a coin a hundred times and not telling you about the times it lands on tails. Almost certainly, anyone would believe that he possesses a two-sided coin, with such information missing. When unpublished trials are never seen by doctors, drug companies can convince even the most knowledgeable in their field that a given drug is effective—whether or not it actually is (p. 8). This simple ploy by pharmaceutical companies to make their drugs more appealing through incomplete trial data, may have very harmful effects on patients.

In recent years, there have been attempts to fix the problems caused by publication bias through what is known as a trial registry. A trial registry requires that all trials, before they gather any subjects for testing, must publically register their trial, then afterwards state whether the findings were positive, negative, or inconclusive. Those involved in making the trials are motivated to comply with the registry because the International Committee of Medical Journal Editors (ICMJE) refuses to publish any trial that was not previously registered (Drazen, 2009). If a drug company does not register a trial and concludes with a positive result, they cannot get that particular trial information published, therefore, losing sales. Although this attempt is well intentioned, it fails to solve the fundamental problem: if a drug company doesn't want to publish an article, it doesn't have to. Although there is no way of actually forcing all trials to be registered, this does allow physicians to look in the registry and compare how many trails were registered to how many were actually published—however daunting a task that may be—thus giving them a more accurate idea of the effectiveness of the given medication. Even though this option exists, it is still not fully conclusive and most physicians won't go through the trouble of comparing and contrasting because it would most likely be extremely time consuming and complex.

The following examples, which are found in Goldacre's book, illustrate the potential effects that publication bias has in determining treatment options by doctors. The first drug, Lorcainide, is an anti-arrhythmic drug that was tested on 100 individuals with the hypothesis that if given to patients who had experienced heart attacks—since heart attack patients often experienced unusual heart arrhythmias—that it would reduce the risk of future heart attacks. The hypothesis seemed logical, so a trial was conducted and 50 people

received Lorcainide, while 50 others received a placebo. The results: out of the 50 that received the placebo, only one person died; out of the 50 that received Lorcainide, nine died. The trial obviously falsified the hypothesis and further trials on Lorcainide ceased. This study, conducted in the 1980's, was never published, and the information from this trial never reached the medical field. Not only did the trial falsify the original hypothesis, it was possible evidence that anti-arrhythmic drugs actually increased the risk of heart attacks; however, because this study was never published, no one else would know unless another trial was conducted. Several years later, again with the same logic that anti-arrhythmic drugs would reduce the risk of heart attacks, doctors began prescribing multiple kinds of anti-arrhythmic drugs to hundred of thousands of patients after having suffered a heart attack. According to Goldacre, more than 100,000 people died prematurely before the correlation of an increased risk of heart attack was noticed (pp. 10-11). This example is one of the more extreme cases, but effectively highlights the potential danger that missing data can have. Most cases are not so extreme.

The next example is of a drug called Reboxetine. Reboxetine is an anti-depressant drug that, according to the latest published journal articles, was just as effective as any other antidepressant drug on the market. This was based on one trial that was published, which showed that Reboxetine was more effective that a placebo, and just as effective as any other drug. A team of researchers later found, through searching registry files and calling manufacturers for trial information, that there were seven total trials conducted on Reboxetine. The researchers found that the six other trials actually found that Reboxetine was less effective than the other drugs, no more effective than a placebo sugar pill, and increased the frequency of negative side effects (Goldacre, pp. 6-7). This example more

accurately relates a more common effect that publication bias has on a doctor's treatment method and how missing data can harm patients. Had a physician known that Reboxetine actually did more harm than good, assuming this prescriber had the patient's best interest in mind, there would most certainly have been a considerable decrease in prescriptions of Reboxetine. This drug is a good example of a "Me Too" drug that will be discussed later in the essay.

Another equally powerful way that drug companies unethically profit from consumers is by creating demand for their drugs. There are many ways a drug company could go about doing this, but the focus will be specifically by marketing to doctors. Campbell et al (2007). from the *New England Journal of Medicine* in a survey conducted on the relationships between doctors and pharmaceutical representatives, found that 94% of all prescribers have some form of direct relationship with the pharmaceutical industry. These relationships include:

> "receiving food in the workplace (83%), receiving drug samples (78%), receiving reimbursement for costs associated with professional meetings or continuing medical education (35%), and more than one quarter (28%) received payments for consulting, giving lectures, or enrolling patients in trials." (Campbell et al, 2007).

This study shows that the pharmaceutical industry has a very active interest in keeping a close relationship and proximity to prescribers.

To better understand how the drug companies' profit from consumers, a basic understanding is needed of the total revenue and budget breakdown of the average drug company. Specific figures from the Pharmaceutical Research and Manufacturers of America

(PhRMA)—which is a group of 53 top drug companies based in America—in the year 2001 will be used to illustrate this point (PhRMA). Marcia Angell (2005)—former editor in chief of the *New England Journal Of Medicine*, physician, and time magazine's 25th most influential person in the world—states in her book titled: *The truth about the drug companies,* that PhRMA's annual revenue from 2001 was $179 Billion (2005, p. 120). PhRMA claimed that it spent $19.1 Billion of its budget on marketing and $30.3 Billion on research and development. These numbers come from the drug companies themselves (Angell, p. 120). Drug companies define marketing in one of four categories: "direct-to-consumer, sales pitches to doctors, free sample costs, and advertising in medical journals." (p. 121). PhRMA can accurately claim how much they spend on marketing when they define what marketing is. PhRMA is involved in many other practices to promote their products that do not fall under these four categories.

The business of creating new and innovative drugs is expensive. Research and Development costs can reach into the billions with just a single drug (Johar, 2013). The pharmaceutical industry, being a market business, is motivated by profit. The pharmaceutical industry has profit margins that rival those of many leading fortune 500 companies. Drug companies on average mark up their drugs an additional 30% (Angell, p. 11). Their reasoning for this is that it is needed to cover future research and development costs so they can continue to make innovative new drugs. Just how innovative is the pharmaceutical industry? In reality, drug companies today do not create many innovative drugs. Marc-Andre Gagnon (2013), a research professor in Carleton University declared that "In the last 20 years, fewer [new drugs] have been launched on the market every year, with the vast majority of new drugs offering little or no therapeutic advance[s] over

existing products." (Gagnon, 2013). The popular name given to these trite new drugs is "Me Too" drugs—as if to say, "he made a drug for depression, me too!" Of the total amount of new drugs manufactured each year, 77% are classified as "Me Too" drugs (Angell, p. 75). Since the majority of new drugs produced by drug companies cost close to nothing compared to truly innovative drugs, where does the 30% markup from sales go? Goldacre asserted that "the pharmaceutical industry overall spends about twice as much on marketing and promotion as it does on research and development." (p. 245). Drug companies claim to be innovative, but in reality they mostly create repeat drugs that are more cost effective. The money generated from these "Me Too" drugs gets funneled into their marketing departments, where it is spent fabricating demand through various marketing techniques and educational opportunities. All of the additional expenses come directly from the pocket of consumers in the form of higher drug prices.

There are additional practices used by drug companies to promote their products that are not considered marketing as defined by the pharmaceutical industry. According to Angell, the actual amount that drug companies in the United States spent on promoting their drugs in 2001 was around $54 billion (p. 122). One of the biggest promotional expenditures that aren't considered marketing by pharmaceutical companies are the educational costs they provide to physicians. In order for a doctor to keep licensure, he/she must have continued medical education hours. Many of the hours that each doctor must complete have to be live hours—like a conference or similar event with a live speaker. The cost to host these conferences is substantial, but just a small investment for any large pharmaceutical company. Drug companies have many regulations to abide by; one of these being that it's illegal for drug companies to market "off-label" uses for the drugs they

manufacture—"off-label" here just means that there isn't sufficient supporting evidence to allow FDA approval for these uses (Stafford, 2008). Doctors are not restricted to prescribe medication based on FDA approved treatments, so if drug companies can "educate" doctors about these uses, sales go up, and they turn a bigger profit; so that's exactly what they do (Angell, p. 136). In order for doctors to get continued medical education (CME) hours, the Accreditation Council of Continuing Medical Education (ACCME) must accredit the educational sponsor. Since the ACCME won't directly accredit a drug company, drug companies contract with different companies known as medical education and communication companies (MECCs). From there, they are free to "plan meetings, prepare teaching materials, and procure speakers." (Angell, p. 139). Angell summed up her opinion that the pharmaceutical industry educates physicians by these words: "No one should rely on a business for impartial evaluation of a product it sells", especially when this in turn affects the lives and health of most Americans (p. 135).

Although the pharmaceutical industry provides a great service to Americans, they use this to justify unscrupulous profit margins, which provides for the funding of their ambiguously defined marketing budget, in turn, creating more demand for their drugs and generating more profit for them. All of this is done at the cost of their consumers: anyone who has ever taken—or will take—a prescription medication. Many attempts to restrict the negative influence of drug companies on doctors have been made, but most of these restrictions have failed to meet their goal. Drug companies are still left to their own devices to profit as much as they see fit. A better understanding is needed of why these attempts to restrict pharmaceutical influence on doctors have not meet expectations— i.e. trial

registry, publication bias, and other factors—in order to effectively restrict pharmaceutical inveiglement.

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