

## **An Ethical Evaluation of the Modern Pharmaceutical Industry**

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**Lack of transparency, wrongdoings, and unlawful promotion characterize the healthcare industry; these are especially prevalent within the pharmaceutical industry. Consequently, an investigation into the evidence of the corruption and the ethical infringement is needed. In this paper, I will evaluate the pharmaceutical industry's adherence to the three major branches of ethics. The ever-increasing prices of pharmaceutical products, especially medications used for the combating of anaphylaxis and cancer, coupled with the compensatory-based medication promotion and research points to a major crisis in the realm of social justice. These examples, among many other current issues, lead to difficulties in individuals receiving the medications they truly need, either because they cannot afford them or the information is being withheld. Recent price hikes in medications also raise questions of whether this industry is truly providing for the health needs of all individuals or if it is merely preying on profit-generating opportunities.**

Over recent years, the healthcare industry has been under fire due to an ever-increasing realization of their lack of transparency, wrongdoings, and unlawful promotion – these things are especially evident within the pharmaceutical industry. The increased realization of corruption in this industry may have come about because of the increasing prevalence of high-deductible healthcare plans that allow the public greater exposure to the true cost of their medications. The astronomical prices of pharmaceuticals, especially for medications used for combating life-threatening events such as anaphylaxis and cancer, point to a major ethical dilemma as they restrict the number of individuals who can access the medications they need.

Public discontent with the pharmaceutical industry may also be due to the increasing prevalence of news stories that highlight unethical “marketing agreements” and the promotion of pharmaceuticals that may not even work for what they have been prescribed, as well as the existence of proprietary partnerships

between prescribing doctors and pharmaceutical companies. This combination of occurrences raises questions as to whether the industry is truly providing for the healthcare needs of all individuals; or, perhaps it is merely preying on profit-generating opportunities. The evident corruption surrounding pharmaceutical companies and the outlandish prices charged for their products warrant an investigation into the ethical infringements being made by the industry. The claims of corruption surrounding the pharmaceutical industry can be investigated through an evaluation of case studies and a discussion of ethical practices of this industry with consideration to the ethics, or lack thereof, displayed in the case studies.

### **Case Studies**

#### **EpiPen Price Increase**

A major ethical impingement of the pharmaceutical industry that has been a topic of great debate in recent months is the soaring cost of the EpiPen, which has undergone a 400% price increase since

being acquired by Mylan in 2007. While this device was originally developed as a nerve-gas antidote, it was discovered shortly thereafter to be exceedingly valuable as a treatment for life-threatening allergic reactions.<sup>1</sup> The dosage delivery mechanism found within the EpiPen has also been patented, making it the only immediate anaphylactic treatment with the capability to calculate the exact dose needed to be injected into the victim.<sup>2</sup> This patented mechanism and the device's life-saving value provide grounds which Mylan can use to further increase the price of the device as they are able to market this unique, life-preserving device. However, in the event of a life-threatening allergic reaction, two EpiPens are needed if the victim has not entered medical care within 15 minutes of the first dose. Due to not being able to predict the situation in which one will be at the onset of anaphylaxis, it is imperative that two EpiPens are always carried to prevent an event more serious than the onset of anaphylaxis, doubling the cost of an already expensive device so widely needed. For families with one or more anaphylactic children, an innumerable amount of devices are needed so that one is always within reach when the victim is exposed to an anaphylactic trigger.

With the price for a two-pack of EpiPens increasing from \$57 to \$608 in the decade that it has been owned by Mylan, the outlandish prices for such a crucial pharmaceutical are beginning to be felt more than ever as greater numbers of Americans transition into low-premium, high-deductible healthcare plans with higher out-of-pocket costs for prescription medications. Many are feeling as though they have no choice but to devise a way around the pharmaceutical industry to get the protection they need by buying pre-filled vials of

epinephrine inject themselves with, while other pharmaceutical industries, such as CVS, are attempting to design a product that does basically the same thing, but with a two-pack cash price a sixth of the cost of the Mylan brand.<sup>3</sup> This CVS-produced generic has been coined AdrenaClick and its convenient debut after the outlandish price of the Epi-Pen began getting national attention begs the question of if CVS is marketing this generic because they see a widespread need for it or because they saw the ability to capitalize on the exposure of Mylan's ridiculous pricing.

### **Orphan Drug Act of 1983**

Another recent event that brings ethical practices into question was the publishing of an article this February that outlines how individuals with rare diseases or in low-income brackets are unable to obtain the medication required for treatment due to exceedingly high prices.<sup>4</sup> The inability for those individuals with rare diseases to obtain the necessary medications proves excruciatingly difficult, even under the Orphan Drug Act of 1983. The Orphan Drug Act was enacted as a way for the government to provide incentives in the way of tax breaks to companies who have the capability to produce a drug needed and drive research for rare diseases, such as Huntington's disease or Amyotrophic Lateral Sclerosis (ALS), but do not have the financial capability to completely fund the costs associated with the research and development of these drugs. The costs associated with the research and development of new pharmaceuticals are partly due to the Kefauver-Harris Amendment, which mandates that companies prove the safety and effectiveness of pharmaceutical agents before marketing begins, setting forth

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<sup>1</sup> Rubin, 2016.

<sup>2</sup> Ibid.

<sup>3</sup> Pepperman, Westermann-Clark, & Lockey, 2016.

<sup>4</sup> Lathrop, 2017.

excruciatingly high standards for which drugs in research and development must pass. Despite these high standards, the number of orphan drugs produced prior to the Orphan Drug Act was less than 50 and now the number of available over drugs is well over 1,000.

While the combination of the Orphan Drug Act and the Kefauver-Harris Amendment have increased the availability of drugs for rare diseases as well as the safety and effectiveness of these drugs, they rarely increase the obtainability of the drugs as the resulting prices of drugs developed are far beyond the realm of affordability for many Americans. The government's jurisdiction in encouraging or regulating the production of these Orphan Drugs unfortunately does not extend into a capability for regulating the market price of these pharmaceuticals.<sup>5</sup> Since research and development far outweigh the potential profit from producing an orphan drug and the loss is not easily recouped through government incentives, pharmaceutical companies often charge more than 100 dollars per pill of an orphan drug. These prices often even extend into the several hundred dollars per pill range. This is an example of the pharmaceutical industry capitalizing on human illness. Also, when companies partake in these activities, they are acting against the Lord and withholding these medicines from those who need it most.<sup>6</sup>

### **Eli Lilly and Company**

A final case study on the topic of ethical deficiency in the pharmaceutical industry arises from a major pharmaceutical company, Eli Lilly, whose headquarters are in Indianapolis, Indiana. This company retains good standing in Indiana regardless of their questionable activity since it is often

overlooked with a preference for looking towards the good this company does in their home state. The Lilly Foundation, a division of Eli Lilly, strives toward making drastic improvements in global health during this century and the Lilly Endowment Scholarship Program awards almost 150 Indiana students with a full-ride scholarship to an Indiana state university of their choice every year. However, in recent years, this company has been involved in several corrupt acts, with one of the more major ones involving charges brought against Eli Lilly by the US Securities and Exchange Commission, or SEC.

Charges brought against Eli Lilly by the SEC arose after the discovery of off-shore "marketing agreements" made by subsidiaries of Eli Lilly and involved the transfer of large sums of money to off-shore, third-party accounts to individuals in Russia, Brazil, China, and Poland. The money transferred to these accounts was then being funneled to government officials to secure millions of dollars from the country's pharmaceutical markets.<sup>7</sup> During court proceedings, it was uncovered that Eli Lilly had known about their subsidiaries' corrupt actions and violation of the Foreign Corrupt Practices Act, or FCPA, yet chose to not take further action. During the same time that these charges and the proceedings were made public, Eli Lilly released a statement that they would be increasing the number of scholarships they provide by about 50 per year. Whether coincidence or a strategic ploy to take attention off their corruption, it successfully hid their wrongdoings from their immediate community.

### **Discussion of Ethics**

A critical evaluation of each of these three case studies within the framework of the three major forms of normative ethics

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<sup>5</sup> Lichtenburg & Waldfogel, 2003.

<sup>6</sup> Matthew 25:40, New International Version.

<sup>7</sup> "SEC Charges Eli Lilly and Company with FCPA Violations," 2012.

first warrants a discussion as to what exactly normative ethics are.<sup>8</sup> Normative ethics is the study of ethical actions and explores the way in which humankind ought to act. In simpler terms, normative ethics sets forth a framework for which actions are right and which actions are wrong, both with a sense of morality. The three major branches of normative ethics are eudaimonism, deontology, and consequentialism. Each of these branches deal with the determination of what is morally right and wrong in different ways. These three approaches leave out the relatively recent evolutionary ethics, but as this field is still developing and pulls most its points from the other three forms, its absence will not detract much from the discussion. The first approach of normative ethics to be investigated will be eudaimonism, or virtue ethics, which focuses largely on social justice. Next, deontology, or Kantian ethics, which puts forth the notion of universality in determining whether an action is good or bad. Lastly, discussion will be entered on consequentialism, or utilitarian ethics. This branch of ethics holds that the determination of whether an action is morally good or bad lies in whether it maximizes utility.<sup>9</sup>

### **Eudaimonism**

The first approach of normative ethics, eudaimonism, is an approach that emphasizes social justice. With the taking of the Hippocratic Oath and the integral nature of justice within the realm of public health, the entire health industry should maintain vision on the goal of helping those who need it, whether they can afford it or not.<sup>10</sup> Considering the three case studies delineated above, it appears that eudaimonism is not upheld within the pharmaceutical industry as social justice is often pushed aside to make way for capitalizing on human illness.

However, this form of ethics is not action guiding, but focuses on the end goal of an objective state of happiness with its primary concern on the agent's own character.<sup>11</sup> This industry continually finds new ways to capitalize on those who are in desperate need of medication as well as those who are incompetent about medications. Through the constant seeking for areas where capitalization is possible, pharmaceutical companies continually disregard the adherence to this form of ethics.

When CVS produced the Adrenaclick in response to the need plaguing the market, it is most likely that they saw the potential for profit and sprung to action. However, CVS could have wanted to truly fill a gap in the market to ensure the well-being of all those who suffer from life-threatening allergic reactions. The action taken by CVS could fit into the realm of eudaimonism and the end-goal of objective happiness as it allows for the survival of many who would be unable to afford this emergency medication otherwise. However, in the case of Eli Lilly's subsidiaries securing large portions of the pharmaceutical markets in foreign countries there is found a major violation of this form of ethics as the only benefit to arise from their behavior was the accruing of greater profits. Without a decrease in the price of pharmaceutical agents or increased availability, no progress was made toward an objective state of happiness as many that contain the will to live a full life were still unable to get the medications required to make their will a possibility. Lastly, in the case of the Orphan Drug Act, despite the efforts of the government to encourage the production of pharmaceutical agents for rare disease and the inability of the government to regulate the prices a major detraction from social justice is felt. If no one can

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<sup>8</sup> O'Toole, 2006.

<sup>9</sup> O'Toole, 2006.

<sup>10</sup> Gosten & Powers, 2006.

<sup>11</sup> O'Toole, 2006.

afford these medications, the individual in need is going to be unable to receive the medications they need and the company is going to be unable to make a profit, in no way are they going to add to reaching an objective state of happiness.

### **Deontology**

The next approach at ethics is deontology, or Kantian ethics, which focuses on the only intrinsically good thing as being a good will. This branch of ethics also puts forth that for an action to be permissible, it must be able to be applied to all people without contradiction as to if it is the right action.<sup>12</sup> While this is difficult to achieve, there are a few situations that can occur within the pharmaceutical industry that can be agreed upon as being the wrong action. As an example, doctors will prescribe medication to patients without certainty of its full effect to fulfill an agreement with a pharmaceutical or research company. This action not only goes against the Biblical command to treat others as one would want treated, but also impedes upon this form of ethics as many medical professionals would not want a pharmaceutical agent whose complete effects are not known to be used on them nor would they want to unknowingly be used as a subject in a study.<sup>13</sup> This approach to normative ethics also asserts that humans should not be used as means to an end, such as profit or an approved drug, because they are ends in themselves. Considering this, all three of the case studies discussed above violate this form of ethics, in some form or another, as they strive towards capitalizing human illness.

### **Consequentialism**

The last form of normative ethics to be discussed is consequentialism, or

utilitarian ethics. This approach to ethics believes that the best action to take is the one that maximizes utility, or the sum of all pleasure that can be derived from an action, to the greatest extent. Consequentialism also believes that the consequences of any action are the only by which one can measure whether it is morally right or wrong.<sup>14</sup> Utilitarianism shifts its focus outward and takes other's interests into account when making the decision between right and wrong, also, and can often be found being applied to social welfare economics and the crisis of global poverty. With pharmaceutical companies setting outlandish prices for medications needed by their customers, they are only thinking of themselves and recouping their expenditures or generating a profit, and are therefore in violation of this branch of ethics. This can be found to be true of Mylan, in their 400% price increase, as well as the astronomical prices of the drugs developed under the Orphan Drug Act. However, the competition provided by these high prices does allow space and motivation for the development of innovative pharmaceutical agents.

Aside from these case studies, a major point of concern within the ethical practices of the pharmaceutical industry is the ability of many powerful pharmaceutical firms to influence the research scientists and the publications on the medications they have developed. When the safety and effectiveness research of a pharmaceutical agent is funded by the producing company, there are three main ways that corruption can occur within the research, including the conflict of norms and the creation of dependency networks.<sup>15</sup> While the negative influence often occurs as the result of a monetary incentive from the pharmaceutical industry to the researchers, it could also arise from fear of what could happen to the

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<sup>12</sup> O'Toole, 2006.

<sup>13</sup> Luke 6:31, New International Version.

<sup>14</sup> O'Toole, 2006.

<sup>15</sup> Gray, 2013.

research firm should they disprove what the company is claiming the drug does.<sup>16</sup> This inadequacy in disproving those drugs which do not work, or the continual occurrence of Type I errors in their data, often leads to the distribution of misleading information and medical practitioners prescribing medications that are not the best fit for their patients.

### Conclusions

All of this is not to say that there have not been revolutionary advances in the ethics of the pharmaceutical industry in the recent years. Whether these have come about due to the enactment of new regulations or to provide better for the general welfare of society, they have nevertheless occurred. Increased transparency to companies' unethical practices for consumers, as well as the increasing calls for globalization, has called consumers to be more involved in the sourcing of their healthcare all-around, especially within the pharmaceutical industry.<sup>17</sup> In the past, there have been cases of agreements between prescribing doctors and pharmaceutical researchers that have led to individuals being prescribed a medication that they are not yet sure works. This has been mostly eradicated through the enactment of the Kefauver-Harris Amendment, which demands extensive testing to prove the effectiveness and safety of each pharmaceutical that is released. Introduced in 1981, the International Federation of Pharmaceutical Manufacturers and Associations, or IFPMA, has been devoted to moving the pharmaceutical industry to adopt a self-regulatory ethical compliance model and increase the number of transparent relationships between pharmaceutical companies and consumers.<sup>18</sup>

The end goal of the initiatives set forth by IFPMA is really the ability to provide effective care for its patients.

While the pharmaceutical industry has been under fire within the past several years for partaking in unethical behaviors, a lack of transparency amid globalization, and unlawful promotion and production of medications, it is truly in the process of minimizing the occurrence of these things. The unethical behaviors of the pharmaceutical industry are being combated through the Orphan Drug Act, despite its current shortcomings, the Kefauver-Harris amendment, and the work of the International Federation of Pharmaceutical Manufacturers and Associations. Unlawful promotion and production of pharmaceuticals is approaching a minimum as consumers have begun to take it upon themselves to become more informed as to the medications they have been prescribed. This is especially true through the continual technological advances that make almost everything accessible at an individual's fingertips. The monopoly held by Mylan with the EpiPen is coming to an end as the CVS-produced Adrenaclick available for a sixth of the cost allows anaphylaxis sufferers on low-premium, high-deductible plans to obtain a safer method of delivering the much-needed combatant into their system quickly without the use of a pre-filled adrenaline syringe. While there is truth behind the claims of corruption surrounding the pharmaceutical industry, efforts are continually being made to combat this corruption and the individuals behind the pharmaceutical industry are no less human than the rest of mankind are in a continual battle with sin, often in the forms of power and greed.

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<sup>16</sup> Rodwin, 2013.

<sup>17</sup> Shaw & Whitney, 2016.

<sup>18</sup> Ibid.

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