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Is the testing of unapproved pharmaceuticals on humans ethical science?

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Literature Review

Overview

Pharmaceutical, according to the United States Agency for International Development (2014), is defined as, “any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in humans.” The United States Agency for International Development is a leading proponent of ending global poverty, allowing societies to understand their potential, specializing in stabilizing countries through building respectable governments (Who We Are, 2015). The provided definition must take into account pharmaceuticals that have not yet been released to the general public as a commercial or approved drug to fully comprehend the term ‘unapproved pharmaceuticals’, and will be synonymous with the term ‘drug trial’ in the context of this paper. Patricia Bolton (2002) defines ethical science as, “the standards of conduct for scientists in their professional endeavors.” Patricia Bolton is a scholarly writer and author of the United States Department of the Air Force’s *Scientific Ethics*, an informative textbook about the scientific community, however no information was documented on her education (Bolton, 2002). With the provided contextual definitions, the controversial topic at hand is said to have many perspectives that must be explored. Author of the book *Bad Pharma: How Scientists Mislead Doctors and Harm Patients*, Ben Goldacre, takes a negative standpoint on using human beings as test subjects for unapproved pharmaceuticals and has an affinity for protecting human lives (Goldacre, 2012). His book was used throughout the research process. Goldacre is an Oxford graduate with a degree in preclinical studies, indicating his expertise in pharmaceutical trials (Ben

Goldacre Joins Oxford University, 2015). He is a member of the Royal College of Psychiatrists and research fellow at the Institute of Psychiatry and London School of Hygiene and Tropical Medicine, and has won numerous scholarly awards for his authorship (Institute of Psychiatry, Psychology, and Neuroscience, 2016). However, Ben Goldacre is predisposed in his belief that the pharmaceutical industry is corrupt, which makes the information in his book enormously one-sided. Pharmaceuticals as a whole are widely tested before being put on the shelf as a commercial drug (FDA, 2015). This is primarily due to the notion that before 1938, the United States had no drug trial phase before being made available to the public, causing extensive injury to the body (Animal Research, 2013). In 1938, the Food, Drug, and Cosmetic Act was passed to avoid this occurrence (Animal Research, 2013). In his book *Bad Pharma*, Ben Goldacre notes an important fact: most drug companies develop drugs from similar preexisting drugs (Goldacre, 2012). According to the Food and Drug Administration, a United States-based federal agency that is the lead regulatory body of public health and is responsible for ensuring safety through their widespread regulation and supervision of food and drugs (What We Do, 2015), clinical studies are administered for the following three reasons:

The NDA [new drug application] must provide sufficient information, data, and analyses to permit FDA reviewers to reach several key decisions, including:
Whether the drug is safe and effective for its proposed use(s), and whether the benefits of the drug outweigh its risks

Whether the drug's proposed labeling is appropriate, and, if not, what the drug's labeling should contain

Whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity (FDA, 2015).

The FDA also notes that before beginning clinical research, the new drug application must be submitted, review, and approved by a regulatory body (FDA, 2014). Drugs are

then developed and tested on laboratory animals before undergoing clinical trials (FDA, 2014). There are three phases of testing (I, II, and III) that are completed before being sent for approval and one phase that occurs once the drug is made commercial (phase IV) (US National Library of Medicine, 2008). Each phase is intended to answer a different question in the research process (US National Library of Medicine, 2008). Phase I, according to the US National Library of Medicine (2008), consists of a trial done on a small group of people or animals in order to “evaluate its safety, determine a safe dosage range, and identify side effects.” Phase II is conducted on a larger group of people to evaluate its efficacy and further the safety of the drug (US National Library of Medicine, 2008). In phase III trials, a large group of people receive the pharmaceutical to confirm the ability of the drug to carry out what it is intended to do, look for side effects, and accumulate data to ensure the drug’s safety (US National Library of Medicine, 2008). The final trial, phase IV, is conducted once the pharmaceutical has already been made commercial and aims to collect information on the global effect of the drug and any long-term side effects (US National Library of Medicine, 2008). The United States National Library of Medicine is a highly regarded medical archive founded in 1836 and the largest medical library in the world with a collection of over seven million medical publications (About the National Library of Medicine, 2015). Nevertheless, the USNLM is evidently only a United States archive, which shows its lack of global relevance in relation to the information it contains (About the National Library of Medicine, 2015).

Types of Pharmaceutical Testing

With the overview of pharmaceutical testing in mind, additional information in regards to the types of pharmaceutical tests must also be discussed. The controversial issue of using humans as test subjects for unreleased drugs instead of animals has been a debate for decades (Weaver, 1997). Information from Animal Research Info indicates that lawfully, pharmaceuticals must be tested on animals to protect the lives of humans who offer to undergo clinical trials (Animal Research Info, 2015). The further argument that side effects can be indicated at an early stage and help determine potential sources of problems with the drugs indicates the need for initial animal tests (Animal Research Info, 2015). However, in order for a drug's efficacy to be proven, it is essential to test on humans as they are the ones taking the medicines regularly (University of Illinois, 2015). Dr. Arthur Caplan was professor of Bioethics at the University of Pennsylvania and director of Medical Ethics at New York University as well as a member of multiple science-related committees and a graduate of Columbia University with a PhD in the Philosophy of Science (Arthur Caplan, PhD, 2016). In an interview conducted by the Public Broadcasting Service (PBS) about the appeal of conducting clinical trials on humans and the ethicality of doing so, Dr. Caplan answered the question, "Are there countries that have become go-to locations for pharmaceutical trials?" by saying:

India is certainly a go-to place — a lot of people, a lot of people eager to get into studies, a culture that is supportive of research.

Thailand — not desperately poor, but there are still a lot of people who don't have access to care, that's an attractive site for many studies.

Eastern Europe — again not desperately poor but people willing to sign on. You don't have to pay them much to be subjects and that sort of thing (Miller, 2011).

The answer demonstrates a few of the many areas that are frequently considered for clinical trials. From this information, it can be said that the topic definitely has a global relevance and can be researched in a multitude of places. Having obtained this information, the question “Is the testing of unapproved pharmaceuticals on humans ethical science?” still persists, and the types of trials that take place must additionally be identified.

Types of Trials

Alongside the above material, the controversy must be identified in terms of the type of trial. Government groups, private associations, or individual ambitious researchers can sponsor clinical trials conducted in various locations such as hospitals, colleges, and health clinics (US National Library of Medicine, 2006). A governmentally funded trial is known as one that is funded with the government’s money, while a privately funded trial is one funded by a company (Chopra, 2003). Sameer S. Chopra of JAMA notes in the article “Industry Funding of Clinical Trials: Benefit or Bias?” that, “Most clinical trials, however, are funded by pharmaceutical companies with enormous financial stakes in the products being evaluated” (Chopra, 2003). The article is furthered by the statement:

While grants from the National Institutes of Health fund most basic research in academic laboratories, it is largely industry that bears the cost of identifying new molecular entities and testing them in animal models and human subjects (Chopra, 2003).

Since large pharmaceutical companies provide financial support, it can be assumed that these trials have a predisposition to favor the companies' best financial interests in order to produce a large income, demonstrating the corruption in the industry.

Scientific Schools of Thought

As there are many differing schools of thought in the scientific field, these must be addressed in order to have a better understanding of the question. The aforementioned Dr. Arthur Caplan, as a professor of an erudite science class, possesses extensive knowledge on the philosophy of science (Arthur Caplan, PhD, 2016). He has a highly influential opinion when accounting for the medical standpoint on pharmaceutical trials. He was interviewed by PBS about the appeal of conducting clinical trials on humans and the ethicality of doing so. When asked what ethical concerns arise through trials on humans in less developed countries, he responded by saying,

There are a bunch of concerns. The first one is can you really follow Western ethical rules in very poor nations or among very poor populations in other countries? Meaning are they really giving you informed consent or will they sign up for anything that you show up with because they are desperate and have an overwhelming faith in anybody in a white coat? Second, can you collect data reliably in very poor countries, do people take the pills, do they do what they are told, are they getting other infections or diseases that make the data less reliable? The third issue is, for certain drugs, the more we learn about genetics, the more biological differences may determine the efficacy of a drug. So if you are testing only in Asian nations, is that a reliable predictor of what happens when you try it in Norway or when you try it in Greece or Utah? (Miller, 2011).

The American Medical Association whole-heartedly believes that regulations should be enacted in order to lessen conflicts of interest in clinical trials, namely those of privately funded trials sponsored by drug companies (AMA, 2000). A similar belief is held by Ben Goldacre, who starts his book *Bad Pharma: How Companies Mislead Doctors and Harm*

Patients by stating, “Medicine is broken,” an influential statement that confirms his ideology on the topic. (Goldacre, 2012). Goldacre takes a strong stance on the ethics of pharmaceutical trials and avidly believes that the industry has a large window for improvement (Goldacre, 2012). BMC Medical Education had physicians from Japan fill out a questionnaire with questions pertaining to their opinions on the ethics of pharmaceutical tests (Sumi et al., 2009). Out of a total 175 physicians, ninety seven answered yes when asked if they believed it was necessary to conduct pharmaceutical trials while seventy eight said no (Sumi et al., 2009). Only 5.7 percent responded that ethical problems were prevalent thoughts when clinical research was brought up (Sumi et al., 2009).

With the provided viewpoints, types of trials, differences in testing subjects, and definitions, it can be concluded that the question, “Is the testing of unapproved pharmaceuticals on humans ethical science?” is a highly controversial topic that must take into account all of this information. The types of pharmaceutical testing, types of trials, and scientific beliefs on this topic provide a wider facet that the dispute must recognize and will play a role in deciding whether pharmaceutical testing is considered an ethical science.

Ben Goldacre once wrote, “Medicine is broken,” (Goldacre, 2012). This seemingly hyperbolic, punctual sentence actually proves to be one of the most powerful in relation to the debate over the scientific ethicality of using humans as test subjects for unapproved pharmaceuticals. From previous research, it has been determined that the testing of unapproved pharmaceuticals on humans is not ethical science because harm is done to the human body from this testing, there is a distinct lack of consent from the patient to conduct these tests, and information is not published if unfavorable results are obtained. However, it can be asserted that pharmaceutical tests on humans is ethical science as they provide a platform for scientific advancements and the individuals targeted to take participate in these trials are critically ill. In order to fully grasp the question, the terms ‘ethical science’ and ‘unapproved pharmaceuticals’ must be defined. A pharmaceutical, as defined by the USAID (2014), is any substance used with intent in, “the diagnosis, cure, mitigation, treatment, or prevention of diseases in humans.” The definition of pharmaceutical must be considered in the context of those that have yet to be released as a commercial pharmaceutical (unapproved pharmaceutical), and will be synonymous with the words ‘drug’ and ‘medicine’ in this paper. Additionally, ethical science is to be known as, “the standards of conduct for scientists in their professional endeavors” (Bolton, 2002). These definitions can be utilized to evaluate these perspectives and aid in forming a conclusion.

To begin, human test subjects in clinical trials is not ethical science due to harm that occurs as a result of these trials. Boehringer Ingelheim, one of the top twenty pharmaceutical companies globally, has conducted a multitude of trials that result in bodily harm (Our Vision, 2016). Dr. Michel Pairet, a corporate board member of research

and nonclinical development at BI, has a multitude of knowledge in the pharmaceutical industry as he has served as the head of numerous research programs with a doctorate in Veterinary Science and a Ph.D. in Physiology and Pharmacology (Our Vision, 2016).

While his expertise is clear, it indicates the interest he takes in the subject, therefore making him a predisposed source. In one particular study, Boehringer Ingelheim states that

The overall frequency of mild AEs [adverse event] appeared to be higher in BIRB 796 BS treated patients compared to placebo. In the absence of a clear dose relationship, gastrointestinal and skin AEs showed a potential trend (Boehringer Ingelheim, 2003).

This quote outlines the regular occurrence of adverse events, or those not desired, of the variable group who consumed the actual drug as compared to the control group who took a placebo. With the quote explicitly stating the adverse events, including those of gastrointestinal and skin conditions showing an increasing trend, it effectively attests to the claim that harm is done to the body through clinical trials. This harm is further noted in a study directed by Sanofi (2007), which states that

A total of 97.7% of patients in the placebo group and all patients (100%) in the aflibercept group experienced at least 1 clinical TEAE [Treatment-Emergent Adverse Event] (regardless of relationship) and amongst them, 60 (69.0%) had Grade 3 or 4 TEAE, 44 (50.6%) had TEAEs that were SAEs [Serious Adverse Events], which led to death for 10 (11.5%) patients and to permanent or premature discontinuations for 18 (20.7%) patients.

The study, conducted in US, Denmark, Belgium, Germany, Italy, Romania, and Turkey, aimed to test the efficacy of the drug aflibercept in curing cancer patients (Sanofi, 2007). Sanofi is a major pharmaceutical company that has provided numerous key advancements in medicine (Our Company, 2016). The chairman of the Board of Directors, Serge Weinberg, has his bachelor's in law, proving he has a lack of expertise in the pharmaceutical industry (Our Company, 2016). However, he is a founder of the

Institute of Brain and Spinal Cord Disorders, proving he must have obtained a body of knowledge in the science community (Our Company, 2016). The statistics display the extent to which adverse events occur and adequately prove the harmful effects of using humans as test subjects for phase trials. It is important to discuss that almost exactly half of the treatment-emergent adverse events were considered serious (Sanofi, 2007). This is a statistic that most would consider shocking when taking into account the startling fact that over thirteen million people were living with cancer in the United States as of 2012, with only 66.5% of them surviving (Surveillance, Epidemiology, and End Results Program, 2016). As aforementioned in the Literature Review, Ben Goldacre wrote a book on medical ethics called *Bad Pharma: How Drug Companies Mislead Doctors and Harm Patients*. In this book, he references a specific trial, TGN1412, and the effects it has on patients of the study. Goldacre (2012) states:

In March 2006, six volunteers arrived at a London hospital to take place in a trial. It was the first time a new drug called TGN1412 had ever been given to humans, and they were paid €2,000 each. Within an hour these six men developed headaches, muscle aches, and a feeling of unease. Then things got worse: high temperatures, restlessness, periods of forgetting who and where they were. Soon they were shivering, flushed, their pulses racing, their blood pressure falling. Then, a cliff: one went into respiratory failure, the oxygen levels in his blood falling rapidly as his lungs filled with fluid. Nobody knew why. Another dropped his blood pressure to just 65/40, stopped breathing properly, and was rushed to an intensive care unit, knocked out, intubated, mechanically ventilated. Within a day all six were disastrously unwell: fluid on their lungs, struggling to breathe, their kidneys failing, their blood clotting uncontrollably throughout their bodies, and their white blood cells disappearing. Doctors threw everything they could at them: steroids, anti-histamines, immune-system receptor blockers. All six were ventilated on intensive care. They stopped producing urine; they were all put on dialysis; their blood was replaced, first slowly, then rapidly; they needed plasma, red cells, platelets. The fevers continued. One developed pneumonia. And then the blood stopped getting to their peripheries. Their fingers and toes went flushed, then brown, then black, and then began to rot and die.

This occurrence is one of many Goldacre mentions throughout the duration of his book. The harmful effects of clinical trials are unambiguously confirmed through Goldacre's comments on the occurrence. Ben Goldacre is an Oxford graduate with a degree in preclinical studies, indicating his expertise in pharmaceuticals (Ben Goldacre Joins Oxford University, 2015). He is a member of the Royal College of Psychiatrists and research fellow at the Institute of Psychiatry and London School of Hygiene and Tropical Medicine, and has won numerous scholarly awards for his authorship (Institute of Psychiatry, Psychology, and Neuroscience, 2016). However, Goldacre is predisposed in his belief that the pharmaceutical industry is corrupt, which makes the information provided in his book enormously one-sided. A fourth example of the immense harm done to partakers' bodies throughout the duration of clinical trials is noted in a Pfizer study in which eleven children died during Kano, Africa's worst meningitis epidemic (Smith, 2011). Throughout the trial, one hundred kids were told to take Trovan, an experimental pharmaceutical, while another hundred were to consume ceftriaxone, a commercial drug (Smith, 2011). Out of the total eleven who passed, five were consuming the experimental drug and six were taking the "gold-standard" drug (Smith, 2011). David Smith, author of the article published documenting this study, is The Guardian's Africa correspondent and a freelance writer (David Smith | The Guardian, 2016). He's an Oxford University graduate and has won multiple awards for his writing (David Smith | The Guardian, 2016). However, due to his degree in economics, he does not have expertise in the pharmaceutical industry (David Smith | The Guardian, 2016). It must be noted that this medicine was taken in the hopes of ending the meningitis epidemic, however quite the opposite occurred. The detrimental result of this trial supports the argument that harm is

done to the body; in this case, the harm that ensued was final. It can be concluded that serious harm is done to the human body from participating in pharmaceutical trials. This example, along with the examples above, illustrate the appalling effects of what most would consider to be harmless medications and prove the corruption in the pharmaceutical industry.

Furthermore, the lack of consent given from patients to doctors to conduct these trials also exemplifies the lack of scientific ethicality of conducting unapproved pharmaceutical trials on humans. The trial mentioned above in which eleven children died in Kano, Africa also raises ethical concerns on this topic. The Guardian's David Smith (2011) states

But later it was claimed that Pfizer did not have proper consent from parents to use an experimental drug on their children and questions were raised over the documentation of the trial.
This information confirms the lack of consent given to individuals in the medical field. As these children are minors, it is the parent's responsibility to give consent to the doctors and ultimately the drug provider, in this case Pfizer. The lack of consent given by the children's parents allows this example to sufficiently highlight the overall corruption of this trial and illustrates further how pharmaceutical tests on humans are not ethical science. A second example of this lack of consent is shown through Rama Lakshmi's article titled "India's Drug Trials Fuel Controversy." Lakshmi is a dependable staff writer for the Washington Post's India bureau and was part of a team that won a scholarly award for reporting (Rama Lakshmi, 2016). However, she graduated with a degree in museum studies, which shows she has a lack of knowledge on the ethicality of pharmaceutical trials (Rama Lakshmi, 2016). In her article, she verbalizes a major issue in Madhya Pradesh, India. The state government in Madhya Pradesh found that six doctors were not

obtaining consent from patients to participate in medical trials (Lakshmi, 2012). This violation is a clear example of how it is not ethical science to experiment on humans. It can be summarized from the two provided examples that there is a distinct lack of consent offered to partake in clinical trials, which satisfies the claim that drug tests are not ethical science.

In addition, the information obtained from human drug trials is not published if the results attained are not desirable for the pharmaceutical company. Before citing a specific example of this, it is essential to state that throughout the research process, it was indubitably challenging to acquire the information necessary to successfully argue the perspectives of this essay for this reason. A first example of this is shown through a quote from Deborah Cohen, a prolific, freelance writer and Harvard graduate who, despite having expertise that lies in history, has research funded by numerous reputable foundations that expresses her reliability (People – Deborah Cohen, 2012). Cohen (2011) says

Take the case of the drug lorcainide, used to regulate the heartbeat during a heart attack. In the early 80s, researchers in Nottingham carried out a study of the drug in 95 people using a method known as a randomised control trial. They noticed that nine out of the 48 people taking the drug died, compared to only one out of 47 who got a sugar pill, or placebo, instead. At the time, the researchers thought that the high number of deaths in those given lorcainide might have been due to chance rather than the drug itself. For commercial reasons, the drug was not developed any further and the results of the trial were never published. The results of this trial were posted thirteen years later by Iain Chalmers after the researchers recollected this incident in 1993 and were made available to show publication corruption (Cohen, 2011). This instance depicts the lack of information published for studies whose results do not generate favorable findings. According to the FDA, all clinical trials must be registered before beginning research with what is known as a

register, or an online regulatory body that aims to provide “basic results’... generally no later than one year after their Completion Date” (About the Results Database, 2015).

Bristol-Myers Squibb, a BioPharma company focused on scientific advancement to better the population with a clear expertise in the field that, however, has questionable reputability due to the lack of available results from their studies, embodies another example of this common occurrence despite the FDA’s regulation (Bristol-Myers Squibb, 2016). Bristol-Myers Squibb conducted a study on patients with Venous Thrombosis or Pulmonary Embolism in 148 locations globally, including the United States, Argentina, Australia, and Canada (Bristol-Myers Squibb, 2010). While this study was registered with www.clinicaltrials.gov, the most common United States register, the results of this were never posted (Bristol-Myers Squibb, 2010). Through this example, the corruption of the pharmaceutical industry is exposed. It is proven through both examples that drug testing is not ethical science because the interest of the pharmaceutical company is at stake if anticipated results are not achieved.

To counter this, drug trials are considered ethical science due to the fact that scientific advancements in medicine have been made from conducting these trials. In 2014, GlaxoSmithKline conducted a report to test the efficacy of benzoyl peroxide and clindamycin phosphate, two commonly used over-the-counter treatments for acne, in lessening the amount of lesions found on patients (GlaxoSmithKline, 2014). This study tested males and females between the ages of 12 and 45, with baseline checks at weeks one, two, four, eight, and twelve (GlaxoSmithKline, 2014). The results found that lesions were in fact reduced through the use of these products from an initial average of 492 lesions to an average of 438 lesions at the end of the twelve-week period

(GlaxoSmithKline, 2014). The statistic plainly describes how scientific advancement was bettered from human trials and subsequently proves they are ethical science. A second example of this is shown through another clinical trial that studied the effectiveness of Dutasteride on men who are at an increased risk of developing prostate cancer but have no detectable cancer at the commencement of the trial (GlaxoSmithKline, 2015). In this trial, conducted in 932 locations worldwide including Austria, Belgium, Lithuania, Mexico, and Poland, researchers had a control group who received a placebo drug in addition to a variable group who were instructed to take oral Dutasteride once daily for four years (GlaxoSmithKline, 2015). The results prove that scientific advancement is made through using humans as test subjects, as 3,390 of the total 4,049 men who took Dutasteride remained cancer free throughout the duration of the trial (GlaxoSmithKline, 2015). Of the men who took the placebo drug, 3,215 men remained cancer free while 858 developed cancer – roughly two hundred more than those who took Dutasteride (GlaxoSmithKline, 2015). Both of these examples are from GlaxoSmithKline, a science-based international healthcare corporation dedicated to aid people in becoming healthy (About Us | GSK, 2016). They are the first pharmaceutical company to campaign for research transparency, which exemplifies their belief in ethical research and further shows their reputability. Nevertheless, the company is predisposed to pose no negative study results in order to uphold this high reputation. The scientific advancements show the extent to which pharmaceutical testing is necessary and an ethical science.

Moreover, participants of these trials are critically ill before their involvement in pharmaceutical tests. A critical illness is defined as “a life-threatening condition” (Critical Illness, 2002). Pfizer, a leading pharmaceutical company that strives to provide

good health for the general population (About Pfizer, 2016), has many examples that prove the fatally ill are the only individuals who take part in their trials. Craig Lipset, head of clinical innovation at Pfizer, pursued partnerships to improve data use in Pfizer's business, indicating Pfizer's reliability (About Pfizer, 2016). However, the company has a prejudice to support the pharmaceutical industry in order to maintain the company. One example of Pfizer's use of those who are ill is emphasized in a trial done in Japan that tested the drug Apixaban to decrease bleeding during treatment as a blood thinner (Pfizer, 2013). A prerequisite of being part of this trial was to already be ill, as the trial would have no feasible effect on those who are healthy (Pfizer, 2013). An additional instance of this is from Sanofi, a leading pharmaceutical company that has provided several progressions in medicine (Our Company, 2016). Sanofi conducted an investigation in a multitude of countries including China, Hong Kong, Malaysia, the Philippines, Taiwan, and Thailand with hopes of controlling atrial fibrillation through the use of a developing drug (Sanofi, 2012). The criteria that needed to be met in order to participate include being a minimum of eighteen years of age and already suffering from atrial fibrillation, a critical illness (Sanofi, 2012). With these criteria and cases in mind, it can be affirmed that this prerequisite allows pharmaceutical tests to be deemed an ethical science.

Prior to beginning my research, I had preconceived notions about the topic of pharmaceutical testing on human beings. I believed that this was a tremendously unethical endeavor largely due to the notion that the human body can be depleted and, in extreme cases, result in death from partaking in these trials. This belief still holds true after completing my exploration of the topic; however, I now can empathize with the assertions that scientific advancements are furthered through clinical trials and critically

ill patients are the target group for the vast majority of these trials. I am now aware of a hard truth of this industry: scientific advancements cannot be made without going through phases of clinical trials to prove their effectiveness as a pharmaceutical before becoming a commercial drug. While I do feel that these trials are highly immoral and the pharmaceutical industry as a whole has a large window for improvement, I can also say that the amount of advancements that have been developed in the scientific community demonstrates the need for these tests. Further examination of the subject topic must be conducted to identify alternatives to clinical pharmaceutical trials on human beings, however I highly believe there are a multitude of alternatives that can be inaugurated to avoid the problems addressed through this research. It would be greatly beneficial to not base the salary of individuals in the pharmaceutical industry on the ability of their drug to perform well and to see that the previously mentioned registers are heavily monitored and require a detailed report of findings. I firmly believe that with these additions, there would be significantly less corruption in this industry and my opinion on the topic may shift to support that this is an ethical science. However, as of now, the testing of unapproved pharmaceuticals on humans is not ethical science because harm is done to the human body from this testing, there is a distinct lack of consent from the patient to conduct these tests, and information is not published if unfavorable results are obtained. However, it can be asserted that pharmaceutical tests on humans is ethical science because these tests provide a platform for scientific advancements and the individuals targeted to take participate in these trials are critically ill.

References

About Pfizer. (2016). Retrieved February 14, 2016, from [http://www\(pfizer.com/about](http://www(pfizer.com/about)

About the National Library of Medicine. (2015, June 12). Retrieved February 13, 2016, from <https://www.nlm.nih.gov/about/index.html>

About the Results Database. (2015, November). Retrieved Feburary 14, 2016, from <https://clinicaltrials.gov/ct2/about-site/results>

About us | GSK. (2016). Retrieved February 14, 2016, from <http://www.gsk.com/en-gb/about-us/>

AMA. (2000, December). Opinion 8.0315 - Managing Conflicts of Interest in the Conduct of Clinical Trials. Retrieved January 15, 2016, from <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion80315.page?>

Animal Research. (2013). Why do companies test cosmetics or other products on animals? Retrieved January 15, 2016, from <http://www.animalresearchcures.org/testing.htm>

Animal Research Info. (2015). FAQs. Retrieved January 15, 2016, from <http://www.animalresearch.info/en/resources/faqs/>

Arthur Caplan, PhD. (n.d.). Retrieved February 13, 2016, from <http://www.med.nyu.edu/pophealth/faculty/caplaa01>

Ben Goldacre joins Oxford University. (2015, March 24). Retrieved February 13, 2016, from <http://www.phc.ox.ac.uk/news/ben-goldacre-joins-oxford-university>

Boehringer Ingelheim Pharma GmbH & Co. KG BI Trial No.: 1175.11. (2003, June 6). Retrieved January 10, 2016, from http://trials.boehringer-ingelheim.com/content/dam/internet/opu/clinicaltrial/com_EN/results/1175/1175.11_U03-1389.pdf

Bristol-Myers Squibb: Home. (2016). Retrieved February 14, 2016, from <http://www.bms.com/ourcompany/mission/pages/default.aspx>

Bristol-Myers Squibb. (2010, February 27). BMS-562247 in Subjects Undergoing Elective Total Knee Replacement Surgery. Retrieved January 13, 2016, from https://www.clinicaltrials.gov/ct2/show/study/NCT00097357?term=eliquis&rank=14&show_locs=Y#locn

Buncombe, A., & Lakhani, N. (2011, November 13). Without consent: How drugs companies exploit Indian 'guinea pigs' Retrieved January 13, 2016, from <http://www.independent.co.uk/news/world/asia/without-consent-how-drugs-companies-exploit-indian-guinea-pigs-6261919.html>

Chopra, S. (2003, July 2). Industry Funding of Clinical Trials: Benefit or Bias? Retrieved January 15, 2016, from <http://jama.jamanetwork.com/article.aspx?articleid=196846>

Cohen, D. (2011, November 29). Drug study secrecy puts lives at risk - Index on Censorship. Retrieved January 13, 2016, from <https://www.indexoncensorship.org/2011/11/science-medicine-secrecy-drug-studies-lives-risk/>

Critical Illness. (2002, January). Retrieved February 14, 2016, from <http://www.financial-ombudsman.org.uk/publications/ombudsman-news/13/jan-critical-illness.htm>

David Smith | The Guardian. (2016, February). Retrieved February 14, 2016, from <http://www.theguardian.com/profile/davidsmith>

FDA. (2014, November 6). U.S. Food and Drug Administration. Retrieved January 15, 2016, from
<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm>

FDA. (2015, August 20). Drug Development and Review Definitions. Retrieved January 15, 2016, from
<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm176522.htm>

GlaxoSmithKline. (2014, September 11). GSK. Retrieved January 13, 2016, from
<http://www.gsk-clinicalstudyregister.com/study/114543#rs>

GlaxoSmithKline. (2015, April 23). "REDUCE" - A Clinical Research Study To Reduce The Incidence Of Prostate Cancer In Men Who Are At Increased Risk. Retrieved January 13, 2016, from
[https://clinicaltrials.gov/ct2/show/study/NCT00056407?term=cancer and africa&rank=15&show_locs=Y§=X01256](https://clinicaltrials.gov/ct2/show/study/NCT00056407?term=cancer+and+africa&rank=15&show_locs=Y§=X01256)

Goldacre, B. (2012). Missing Data. In Bad pharma: How drug companies mislead doctors and harm patients (p. 1, 8, 9, 101). New York City, New York: Faber and Faber.

Institute of Psychiatry, Psychology, and Neuroscience. (2016). Retrieved February 13, 2016, from <http://www.kcl.ac.uk/ioppn/index.aspx>

Lakshmi, R. (2012). India's drug trials fuel controversy. Retrieved January 13, 2016, from https://www.washingtonpost.com/world/asia_pacific/indias-drug-trials-fuel-controversy/2011/12/01/gIQAAcCrUP_story.html

Miller, T. (2011, August 23). 'Explosive' Growth in Foreign Drug Testing Raises Ethical Questions. Retrieved January 15, 2016, from
<http://www.pbs.org/newshour/rundown/sending-us-drug-research-overseas/>

NCBI. (1993, May). Streptokinase in acute myocardial infarction: A multicentric study in an Indian setting. Streptokinase Multicentric Trial Group. Retrieved January 13, 2016, from <http://www.ncbi.nlm.nih.gov/pubmed/8314272>

Our Company. (2016). Retrieved February 14, 2016, from
http://en.sanofi.com/our_company/our_company.aspx

Our Vision. (2016). Retrieved February 14, 2016, from http://www.boehringer-ingelheim.com/corporate_profile/our_Vision.html

People - Deborah Cohen. (2012). Retrieved February 14, 2016, from
<http://www.history.northwestern.edu/people/cohen.html>

Pfizer. (2013, April 23). A Phase 2 Study To Evaluate The Safety Of Apixaban In Atrial Fibrillation. Retrieved January 13, 2016, from
<https://www.clinicaltrials.gov/ct2/show/NCT00787150?term=B0661003&rank=1>

Rama Lakshmi. (2016). Retrieved February 14, 2016, from
https://www.washingtonpost.com/rama-lakshmi/2011/03/02/ABjxvmP_viewAll.html

Sanofi. (2007, October 5). Retrieved January 10, 2016, from
http://en.sanofi.com/img/content/study/TES10897_summary.pdf

Sanofi. (2012, February 12). The RECORD Asia-Pacific Atrial Fibrillation Registry (RECORDAF-AP). Retrieved January 13, 2016, from
<https://clinicaltrials.gov/ct2/show/study/NCT00995748?term=%22heart+attack%22+%22asia%22&rank=3>

Smith, D. (2011, August 12). Pfizer pays out to Nigerian families of meningitis drug trial victims. Retrieved January 13, 2016, from
<http://www.theguardian.com/world/2011/aug/11/pfizer-nigeria-meningitis-drug-compensation>

Sumi, E., Murayama, T., & Yokode, M. (2009, December 22). BMC Medical Education. Retrieved January 15, 2016, from <http://bmcmmeded.biomedcentral.com/articles/10.1186/1472-6920-9-75>

Surveillance, Epidemiology, and End Results Program. (n.d.). Retrieved February 13, 2016, from <http://seer.cancer.gov/statfacts/html/all.html>

US National Library of Medicine. (2006, October 11). FAQ: ClinicalTrials.gov - Who Sponsors Clinical Trials? Retrieved January 15, 2016, from <https://www.nlm.nih.gov/services/ctsponsor.html>

US National Library of Medicine. (2008, April 18). FAQ: ClinicalTrials.gov - Clinical Trial Phases. Retrieved January 15, 2016, from <https://www.nlm.nih.gov/services/ctphases.html>

USAID. (2015). USAID/OFDA Proposal Guidelines Pharmaceutical Annex A. Retrieved January 15, 2016, from <https://www.usaid.gov/sites/default/files/documents/1866/definitions.pdf>

University of Illinois. (2016). Advanced Applications of Ethics. Retrieved January 15, 2016, from <http://www.scs.illinois.edu/~eseebauer/ethics/Advanced/Drug.html>

What We Do. (2015, December 7). Retrieved February 13, 2016, from <http://www.fda.gov/AboutFDA/WhatWeDo/default.htm>

Who We Are. (2015, October 6). Retrieved February 13, 2016, from <https://www.usaid.gov/who-we-are>