

away from stigmatization.

But even with this guidance, the stigma persists. The stigma surrounding mental health is implicitly built into the minds of those who cannot comprehend what the illnesses actually are. The stigma you build up through news stories, movies, media, or family is what causes that other 80% of the mentally ill to not seek help. Your stigma is what builds that unnecessary wall of fear and caution. The taboo atmosphere that surrounds mental health perfectly represents people's tendency to avoid the unknown, focusing only on their physical health. "You're depressed? Oh, you must be unstable." "You're anxious? Wow, you really can't handle anything on your own, can you?" Discriminatory actions like these lead to the mentally ill convincing themselves that the stigma is justified and that the issue instead lies solely with them.

Like the depths of the ocean, the stigma is dangerous and immense. On the surface of the tide, there are those who put up a front of acceptance, of desire for change. Yet just below remains the polarizing beast. It silently waits, temporarily withholding its ferocious stereotypes and myopic ignorance. It waits for those who courageously make it past the surface, only to be repudiated once again by society. How can the mentally ill be expected to find any willpower to fight their illness, when they are not supported by society? How can we expect the mentally ill to recover when stigma and close-minded individuals make them feel like the problem? How can we expect the world's general health to improve, when we actively suppress and incorrectly label such a large part of it? Without a radical change in the way people view mental health issues, the mentally ill will continue to suffer, crash, burn, and inevitably be forgotten. Stigma is the vice that unnecessarily divides 'health' into two, leaving the mental side of it to eternally drown in false "insignificance".

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My name is Patrick Weir, and I am a current sophomore in the Morrissey College of Arts and Sciences studying Economics with a minor in Finance. I am 19 years old from Orangeburg, New York: a small town just north of New York City. Outside of school, I am a massive sports fan (mostly for the New York Rangers), an avid music listener of every genre, love the outdoors, and especially spending time with my family, friends, and dog, Guinness. As someone who has personally struggled with some of the issues discussed here, I am honored to be sharing this research paper with you all. My goal is to try and raise as much awareness on campus for the wrongful causes and effects of mental health stigmatization as I can.

Globalization and "Big Pharma": Roles, Relationships, and Testing Within Developing Countries

Sofia Zinis

The choices and methods of actions of large pharmaceutical corporations ("Big Pharma") can be reviewed in efforts to understand why the clinical drug trials that these companies carry out are overwhelmingly located within developing countries instead of the developed countries that house Big Pharma companies' headquarters.

Globalization and its Impact on Medicine

As the trend of globalization has developed over time, the way it has transformed the world along with the relationships between states, societies, and populations has developed and changed over time as well. The sphere of influence that globalization has today is constantly growing and extending into new territory. The premise of modern globalization is upheld on an international scale today by two principles: capitalistic market structures and the commodification of goods and services. For capitalism, in terms of economic prosperity and financial potential, the sky's the limit. The theory both requires and enables constant market expansion across all sectors of life. The commodification of materials, services, and anything the human mind can craft is a dominating way for individuals to contend with the constant need for growth that capitalism requires. Transnational corporations (TNCs) are products of capitalistic economies and global markets that allow businesses to continuously grow. They are the mega-businesses that use commodification to their advantage and treat capitalism as their ally in order to achieve economic success. TNCs have control over the majority (if not all) of global markets; medicine and science included.

Thanks to the primary factors of globalization - capitalism and commodification - medicinal cures and breakthroughs that are discovered have developed an additional importance outside of their medical benefits. For pharmaceutical companies, a large part of the motivation for medical successes can be attributed to the financial opportunity they possess.

The competition among pharmaceutical companies has produced top pharmaceutical empires that have spheres of influence that span beyond national borders. The effects that globalization has on the 'Big Pharma' industry can be seen in the geographical makeup of these transnational corporations. Pharmaceutical companies are primarily headquartered in developed countries within North America or Europe. Additional research institutions or facilities specific to companies' specializations are primarily located within these regions as well, depending on the type of pharmaceuticals a company is focused on synthesizing. Overall, pharmaceutical companies have their headquarters and administrative offices along with their synthesis labs and research facilities within nations within the most advanced societies that possess the most high tech equipment or machinery.

Meanwhile, pharmaceutical companies depend on developing countries for the mass reproduction of their medicines as opposed to the scientific creative processes of synthesizing the new compounds. Big Pharma relies on developing countries to provide resources for multiple different processes of drug production. This includes land to build factories

to mass produce and package the drugs as well as plants and ingredients needed for the medicine. The key factors of globalization are what led large pharmaceutical corporations to developing countries in the first place. Pharmaceutical companies see opportunity within the economic, social, and political struggles a developing nation may face and use their conditions to benefit their research. An additional resource pharmaceutical companies utilize within developing countries is the people, often through the borderline exploitation of local impoverished citizens. The vast majority of clinical trials for new drugs companies are looking to get approval for are conducted within developing countries on their citizens. Trials can be conducted in developing countries as well; however, there are a number of factors that pull pharmaceutical companies to developing countries instead.

Why Developing Countries?

There are a number of reasons that large pharmaceutical companies look to developing countries when deciding where to conduct clinical trials for a potential new drug. A common trend that can be identified across all developing countries regarding the overall conditions and state of medical matters can be summarized into this: the relatively low amounts of infrastructure to support necessary medical aid along with lack of funding leads to high numbers of sick populations. These sick populations exist in rural or urban areas and are made up of individuals of all different ages (depending on the disease type and who it affects). The large numbers and groups of people needing all types of medical care provide a prime location for companies to find a sufficient number of infected individuals to complete a successful clinical trial. Companies are likely to find individuals more immediately in need of treatment, which helps improve the efficiency and time period of the trials.

Additionally, the weak economic conditions that most developing states are in along with the poverty levels of the people within these countries is a critical pull factor for corporations. These less-than-ideal conditions allow pharmaceutical companies to come in and perform experiments for significantly

lower costs than if they were to be done within developed countries and regions of the world. As of 2013, The Confederation of Indian Industry made an estimate that “companies save up to 60 percent by undertaking the different phases of testing a new drug in India as compared to developed countries.”¹ Pharmaceutical companies are able to come in and conduct their trials while offering minimal benefits to the governments and populations agreeing to host them. Even if developing nations do offer medical services and treatments that could adequately benefit and care for their citizens, these are rare occurrences. The sparseness of necessary medications, treatments, or other necessary care factors can be due to the lack of funding available to the government to provide such care as well as a lack of funds on the patient end as well.

The types of medical care needed within developing countries differs greatly from the care needed by most medical patients in the developing world. Due to the disparities in medicinal and material resources, diseases and viruses that are not a threat to the populations in developed nations that have been ‘cured’ are still very much a problem for developing countries. For example, diseases like meningitis, HIV/AIDS, or other respiratory infections that children get vaccines for starting at a young age throughout the majority of the Global North are still major threats to populations within the developing world who do not have access to such treatments or do not have the funds to pay for the treatment options that may be available.² People flock to clinical trials out of desperation and hope for any possible treatment that has the potential to cure (or at least help) with their conditions. Sonia Shah, a write and expert on the ethics of drug testing, explained this as follows:

“Under-financed hospitals and clinics gain expertise, funding, and often new equipment when they conduct clinical trials. Patients who lack access to regular care can get treatments otherwise not available to them.”¹

Pharmaceutical companies understand that these patients really have no better options than participating in their studies and clinics, as the potential benefits of the treatment outweigh the

negative possibilities. Pharmaceutical companies and their research teams have the advantage of putting a smaller effort into finding patient candidates when individuals are desperate to seek anything that could help and comes at a low price.

Lastly, the biggest pull factor for clinical trials to be conducted within developing countries is corruption within official domestic institutions (such as government bodies) as well as a lack of legislation and inadequate regulations. Experiments can be done “cheaper and faster, and with less red tape.”³ Due to lacks in regulations protecting citizens from any potential harms they may experience through experimentation, the opportunities and methods open to pharmaceutical companies that may not be legal in the nation states that are home to these companies’ headquarters or potential patient populations. Researchers and doctors can cut corners, cross blurred lines, and tread into gray areas easily, and, more importantly, ‘legally’. Pharmaceutical companies conduct unethical trials in both developed and underdeveloped nations; however, the regulations and complexity of legislation surrounding the rights of patients within each country impacts how closely the trials are monitored and watched. Clinical trials completed in a developed nation with numerous precautionary protective measures in place have less room for error and malpractice in general. Phases of drug trials may be prolonged or experience setbacks due to violations governing authorities may find; whereas absences and gaps in regulations work to pharmaceutical companies’ benefit within developing states.

The same conditions that draw Big Pharma companies towards developing countries for clinical trials are factors that can allow for unethical or illegal trials to be conducted. Unethical trials can be conducted in developed countries too, but developing countries are much more susceptible to being conducted in illegal and unethical ways. An investigation conducted by the Washington Post “into corporate drug experiments in Africa, Asia, Eastern Europe and Latin America reveal[ed] a booming, poorly regulated testing system that is dominated by private interests and that far too often betrays its promises to patients and consumers.”⁴ For

example, over a two year time span, the number of deaths caused by clinical trials in India jumped from 288 deaths in 2008 to 668 deaths in 2010, and this upward trend has continued ever since.⁵ It just so happens that India relaxed its regulations on clinical trials and drug testing in 2005, just 3 years prior. Not all of these trials were conducted in an unethical or harmful manner, however, companies should make it their number one priority to make that number as close to zero as possible. Careful observation of the procedures used in clinical trials has increased exponentially within the last few decades as the universal call to protect human rights has transitioned into becoming a global norm.

Clinical Trials

The Declaration of Helsinki was formed in 1964 by the World Medical Association (WMA) with numerous amendments added on since then. The Declaration outlines ethical norms along with guidelines and ‘rules’ for how clinical trials and research should be conducted by pharmaceutical companies and scientific institutions in an ethical manner.⁶ The document extensively analyzes clinical trial ethics in hopes of reaching the ears of researchers setting out to experiment and research internationally and establish baselines that protect clinical subjects who are citizens of states that may not have the developed legislature to support the human rights of the citizens themselves. Four (of the numerous) key takeaways from the declaration can be summarized as:

1. The research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research.
2. Participation in a trial must be voluntary and participants must be informed.
3. Physicians should obtain freely-given informed consent from each participant.
4. Subjects who cannot provide informed consent themselves, for example children, should only be included if the research cannot be performed on other subjects instead.⁷

The declaration contains many more requests and amendments than described above and includes

the desire for transparency within clinical drug trials to be of the utmost importance for pharmaceutical companies conducting research. Unfortunately, more often than not, trials are not conducted under conditions anywhere near those listed above or those that make up the rest of the Declaration of Helsinki. The majority of unethical trials conducted by pharmaceutical companies remain unknown by the rest of the world; as there is no reason for corporations to ever seek to publicize their malpractice. The causal factor of the blanketed nature and secrecy of many clinical trials is a lack of transparency. Transparency within a clinical trial is of the utmost importance, but is most often the first thing forfeited by a company. Trials may not be properly recorded, patients' conditions could be inadequately documented, or failures and costly mistakes in a trial may fail to be included in 'detailed' reports and findings. Just as concerning, these pharmaceutical companies also frequently lack transparency with their test subjects.

The Centre for Research on Multinational Corporations (SOMO) is a Dutch non-profit research organization that observes ecological, economic, and social factors of multinational corporations and their role in sustainable development. SOMO released a detailed report in 2008 regarding a group of pharmaceutical corporations and unethical trials they have conducted fairly recently throughout the developing world. After analyzing and reviewing dozens of cases, author Irene Shipper outlined twenty-two individual cases that drew large amounts of attention around the world. Through the thorough observation over dozens of trials, Shipper concludes that "the lack of voluntary, informed participation and adequately informed consent are probably the most common problems [with ethical trial violations]".⁷ Lacks in the regulation of trials along with the limited transparency of corporations within both their documentation of the trials along with their communication with participants of the studies are two huge reasons that trials conducted by drug companies are deemed unethical.

Pfizer and Trovafloxacin Trials in Nigeria

Pfizer, one of the pharmaceutical supergiants in today's society, was in the process of creating a drug

called Trovafloxacin (Trovan) that, if approved, would have been used to battle a number of sicknesses. The drug could be prescribed for a number of small viruses or low scale sicknesses, but Trovan was created with the intention of combating meningitis. If approved, Trovane would have brought Pfizer over \$1 billion dollars in revenue⁸; so it is safe to say that the company was most definitely seeking to get the drug approved by the FDA for rollout and distribution as soon as possible. The company chose to conduct their trials in the city of Kano, Nigeria where cases of meningitis were rampant during the 1996 meningitis epidemic. Pfizer had 200 Nigerian children who all had intense to severe developments of meningitis to measure the effectiveness of Trovan compared to Ceftriaxone: a well-known treatment for meningitis that has been FDA approved for treatment in adults and children.

Pfizer conducted a first trial on animals to determine any side effects that may ensue. These tests showed "severe side effects, including degenerative joint disease, liver damage, and abnormal bone conditions" in animals. Even knowing this information, Pfizer decided to go on with the drug trials and begin administering the drug to children sick with meningitis. Within the trial, half of the children received Ceftriaxone while the other half received Trovan. It is explicitly stated in the records of the court case *Abudallah vs Pfizer* that this experiment was conducted without the patients' consent or knowledge that they were experiment subjects.⁹ Pfizer offered free treatment, so families believed that they were just getting medical help for their children and had no prior knowledge about the medicine they were being given. Not only did doctors fail to mention that this was an experiment, but the severe side effects that may occur were not addressed. Families and children not only were not aware that they had a 50/50 chance of receiving a medication that had potentially unknown detrimental effects, but receiving experimental medication also had the potential to have no effect on the patient at all; leaving patients in semi-critical condition without medical help at all when an effective and approved medication is readily available. Doctors failed to mention that regulated treatment (Ceftriaxone) was

offered free of charge at a hospital run by Doctors Without Borders nearby.

All of this information that was withheld along with the unethical way Pfizer conducted the trial resulted in 11 children dying and the permanent injuring of dozens of other children with conditions as severe as "paralysis, brain damage or permanent sight or hearing loss"⁸. The causes of these deaths and injuries were vastly due to side effects of Trovan. In a letter documenting his experience with the clinical trials, Dr. Juan Walterspiel notes that:

"Pfizer physicians administered the experimental drug without prior data on its gastro-intestinal absorption in pediatric patients and not knowing whether it would reach sufficient blood and cerebrospinal fluid concentrations in children after oral administration."¹⁰

Pfizer stopped the trials, but found that the low absorption rate of Trovan was limited to children, so still pushed for the drug to be approved for administration to adults. A secret Nigerian government report was conducted in hopes to understand what happened within the clinical trials, which concluded that the pharmaceutical company conducted an "illegal trial of an unregistered drug."⁸ When the results of the clinical trials and the conditions they were conducted under came to light after the Nigerian report was leaked to the Washington Post, Pfizer simply released a statement to the public addressing the issue after seeing the report saying that "Trovan unquestionably saved lives, and Pfizer strongly disagrees with any suggestion that the company conducted its study in an unethical manner."⁸

Results and Reasoning

The information revealed about this Trovan trial through the *Abdullahi* court case makes it a good example to follow. Pfizer is not the only Big Pharma to conduct unethical clinical trials by any means and this case is just one of hundreds of examples that have been exposed just within the last few decades. The decisions made by the company within this incident and the way Pfizer forfeited human rights for their own advancement and relative gain are the same decisions that have been made by numbers of Big

Pharma corporations across countless developing countries.

Pfizer argued that they "conducted this trial with the full knowledge of the Nigerian government and in a responsible way consistent with Nigerian law."⁸ When looking simply at the statistics of the conflict, this may be true. The reason such breaches of ethical practice occur is that pharmaceutical companies are fully aware of the flaws and regulation gaps within developing countries described before and use these to the advantage of the company. In the case of Kano, Nigeria, families of the children who died or were seriously injured tried to seek compensation or relief by bringing cases to court. One group sought to take action in a U.S. court while a second group brought their case to a Nigerian court. While legal action began to develop in New York through the *Abdullahi* case, the *Adamu* case in Nigeria was dismissed by the plaintiffs before it could even properly develop in Nigeria. The group had given up hope of any justice due to "alleged corruption in the Nigerian legal system and the plaintiffs' inability to obtain legal redress in Nigeria."⁹ The victims felt as if the chances of being seen or heard by authorities were so slim that they simply gave up. Luckily, those involved in the *Adamu* case were then incorporated into the *Abdullahi v. Pfizer* case occurring within the U.S.

This goes to show how the corruption and weak governing bodies of most developing countries significantly benefit the pharmaceutical companies coming in. Harmful environments with no repercussions are created, leaving Big Pharma companies to come in and do what they need to do. This avoidable expenditure of human lives for market and monetary gain is a horrible effect of globalization that has plagued these transnational corporations. In fact, it is made very clear that governments not only fully understand the corruption and regulation irregularities within the government branches of developing countries, but they proactively exploit these weaknesses and fuel the already ongoing corruption these nations contain.

The impact of the *Abdullahi v. Pfizer* case would have been significantly smaller if the information revealed in a letter from whistleblower Dr. Juan Walterspiel was not uncovered. The scale of the

corruption could not be properly understood if the information he exposed was not revealed. Dr. Walterspiel had worked for Pfizer during the Trovan clinical trials and knew what was happening in Kano. After raising objections to the methods used by Pfizer within the trials, Walterspiel was terminated from his position. In a letter written to Judge Pauley of the *Abdullahi v. Pfizer*, Walterspiel wrote:

“While the team was in Kano, (8) and (9), with (8) having refused to participate in the study, received a teleconference phone call from (10) reporting that Nigerian officials had shut down the study, needed to be paid off and that the team was under the threat of arrest. A courier with cash was dispatched by the intervention of (9) via KLM through Amsterdam. The study resumed about three days later. The law firm of Millberg Weiss is in possession of an affidavit by (8) in respect to this witnessed phone call concerning US federal subject matter bribing foreign officials.”⁹

An FDA and inspection had to be filed and be started under the suspicion of bribery, which happened to be mysteriously cut short later on. The Nigerian doctors and nurses conducting the experiment realized how illegal and harmful their actions were and only continued because they were paid off by head officials in charge of the trial. A Nigerian physician who was aware of what was occurring within the Trovan clinical trials said he knew what was going on was “a bad thing,” but he decided not to object because it appeared that Pfizer’s trials had been backed by the Nigerian government.

“I could not protest,” said the physician, Amir Imam Yola. “The system you have in America and the system we have here, there is a wide gap. Freedom of speech is still not here.”⁴

Corruption and governmental differences play a role in leading Big Pharma companies (like Pfizer) to conduct their testing in developing countries (like Nigeria), but they also play a role in what keeps the trials going; especially in an unethical manner.

While Walterspiel’s letter was not used as a source of evidence within *Abdullahi v. Pfizer*, he provides detailed insight into the breaches in ethics that occurred. The biggest injustice that had the

largest impact was the little to no knowledge patients and the families of participants received about the parameters and conditions of the trials. Pfizer claims that nurses gave information to the families of the patients involved and explained the research thoroughly; however, they can provide no physical proof of this consent.

“The patients did not know if it was research or not,” agreed a Nigerian laboratory technician who took part. “They just knew they were sick.”⁴

This is a common recurrence that is not unique to the Trovan trials in Kano. Similar cases expressing a lack of consent have been reported from all across the developing world. Patients are sometimes given forms to sign to signal their consent, but many of them are written in English.⁵ The literacy levels of the populations subject to clinical trials is markedly lower than the rest of societies; the chances of them knowing how to read formal English are negligible at best. Some patients are simply not offered any information or chance to express consent at all. A report discussing the ethics of different drug trials that have occurred in India states:

“... freedom of choice and individual agency is intrinsically important to well-being. This lack of free informed consent leads to a major deprivation of human capability. The participants are therefore deprived of their right to make an informed choice.... In most cases, they do not know about the recourse that is to be taken if they suffer from some injury or death due to the trial. Their consent also cannot be called free since the economic incentive obscures their thought process.”¹¹

This type of maltreatment by Big Pharma companies would not be tolerated if conducted in developed countries, so why is it okay for companies to conduct them in developing ones? “I take responsibility at the end of the day,” Dr. Dutse, a Nigerian physician largely involved in the Trovan trials, claimed. “Given their poverty and lack of access to decent medical care, honestly, did they have a choice?”⁴

Unfortunately, the maltreatment and exploitation of trial patients doesn’t end when their clinical trial comes to a stop, and individuals

have to deal with a plethora of complications and disadvantages moving forward. Typically, the medicines tested and introduced to test patients are not made available to them post-trial. The problem of the lack of medical resources, funds, and infrastructure is still faced by developing countries when Big Pharma companies leave. Sengupta describes this trend as she observed it occurring in India:

“... the participants of trials that are conducted in India are used for research while the benefits of the tested drugs are mostly reaped by developed countries... oppression occurs through a steady process of transfer of results of the trials on the impoverished for the benefit of people in developed countries.”⁴

The question is: why have these unethical practices not been stopped? The hard fact of the matter is clinical trials will always be needed to preserve the maximum safety of the global population. There is, however, absolutely no need for trials to continue to be conducted in an unethical manner. The drive for competition and supremacy within the Big Pharma industry is a primary motivator pushing companies to cut corners in any way they can, regardless of the effects.

Implications for the Future

The disparities between the treatment availability and care options in developing versus developed countries has been extremely evident since the start of the Covid-19 pandemic in 2020. As Big Pharma companies rush to create Covid-19 vaccines, clinical trials for vaccines have been occurring all across the globe in a hurried frenzy. Where clinical trials of this magnitude and importance are being conducted, one is sure to find at least one breach in ethical practice. The clinical trials conducted for Covid-19 vaccines were also conducted with urgency due to the time-sensitive nature of the pandemic; so the rushed pressure of clinical trials that often turns them unethical is definitely felt by Big Pharma companies and their test subjects. When discussing what clinical trials for Covid-19 vaccines look like and how they benefit populations: medical ethicist, Harriet Washington, shares her perspective on participating in clinical trials:

“People there are still taking a risk. And in my opinion, they often are taking a higher risk. What happens when drugs are tested, found efficacious and safe and then go on the market? These people who have been subjects are usually barred from the drug. It is priced beyond their ability to pay for it. So if the drug works, will they have access to it afterwards? Typically, the answer is no.”¹²

The vaccination rollout thus far has already proved Washington right. So far, developing countries have been far behind in their vaccination rollout due to lack of supply and access. The trials for Covid-19 vaccines potentially took enough of a toll on populations themselves. Because of the recency and ongoing nature of the trials, not enough documented information has been released about the methods employed by Big Pharma companies like Pfizer, Moderna, and others. Citizens within developing countries are not always so reluctant to accept Big Pharma companies into their lives based on the way they have been treated by the same or other big pharmaceutical companies in the past. For example, unethical trials lead to a distrust in medical efforts to combat epidemics and contagious diseases.¹² Within the *Abdullahi vs. Pfizer* case, the write up of the case results noted that:

“...Pfizer threatened international efforts to prevent the spread of contagious diseases across the international borders by fostering mistrust and opposition not only to future drug trials but also to vital public health programs organized by pharmaceutical companies. For example, after the reports about the Trovan medical trials resulting in alleged deaths of the children came out in Nigeria, the local population boycotted polio vaccination efforts in 2004, in part because of the Trovan drug experiments. The resistance to polio vaccinations in Nigeria resulted in the spread of the disease across Africa and the Middle East.”⁹

The impact these large pharmaceutical companies have on individuals goes far beyond unethical clinical trials within a developing state. Pfizer was one of the leading Big Pharma companies at the forefront of Covid-19 vaccination creation and

testing. It can be inferred that similar sentiments of resentment and skepticism are felt by Nigerian citizens today about vaccination trials, rollouts and approvals, and Pfizer itself. This shaky relationship is a relatively universal condition between developing countries and various Big Pharma companies (and is becoming increasingly apparent thanks to the 2020 pandemic).

The pandemic and the Covid-19 variants that have continued to pop up have put Big Pharma companies in the spotlight in uncharted ways. The time-sensitive worldwide need for Covid-19 vaccines has kept pharmaceutical companies plenty busy in their quest to discover new cures, and clinical trials are important now more than ever. The control and reduction of unethical drug trials has the potential to become an even larger issue as the world wrestles with the repercussions of the pandemic. Pharmaceutical companies will continue to depend on developing countries and their populations for drug trials to ensure safety and success for their patients. Big Pharma must recognize the utmost importance of prioritizing the human rights of well-being of their trial patients, no matter what country the drug trials take place in.

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