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“Pfizer Case Analysis, Nigeria - 1996”

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Dedication

The present dissertation is dedicated to all those humanitarian activists who devoted most of their lives to help people in need. In the same way, this paper seeks to pay tribute to the dedication of those who, through hard work and determination to achieve their objective, have been capable of denouncing large-scale extortion from governments and corporations. Lastly, I hope that this work will further contribute to future analyses of these types of issues which currently have such a profound impact on our planet, but are mostly inexplicably dismissed as serious subjects of analysis.

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Abstract

This dissertation aims to shed light on a clinical trial conducted by Pfizer in Nigeria during a meningitis epidemic that broke out in Sub-Saharan Africa in 1996. Initially, a general analysis of Africa's situation at that time regarding access to essential and generic medicines is presented. Next, an explanation about what the current WTO agreements are concerning patents and intellectual property laws is provided. To do this, cases involving well-known companies in which the enforcement of patents has generated conflicts between firms and states are used as examples.

Later, the clinical trial by Pfizer in Kano is explained chronologically from the planning stage of the drug until its market entry. It is important to stress that data from different publications and newspaper articles have been collected. These papers present a detailed study of the clinical trial and have contributed largely to bring the trial to the public stage. After this, an investigation report of the clinical trial by the Nigerian Federal Ministry of Health is reviewed and analysed.

Similarly, a court battle between the Pfizer Corporation and the Nigerian government is researched from three different lawsuits brought by Nigerian plaintiffs against the pharmaceutical firm both in United States District Courts and in the Nigerian Federal High Court. Finally, after investigating and analysing all of the above, several conclusions about the degree of responsibility of the pharmaceutical company and Nigerian authorities are established.

Introduction

The Pfizer case in Kano, Nigeria 1996, represents one of the major scandals of human right abuses involving a pharmaceutical company that called into question the ethical and moral principles of the most powerful pharmaceutical manufacturer in the world. This laboratory was accused of jeopardizing the lives of a large number of Nigerian children through the use of a new drug to fight meningitis called Trovafloxacin, whose side-effects proved to be fatal to patients.

However, before launching into the facts and actions that form the basis of this case study, it is necessary to take into consideration the situation of both Africa and Nigeria at the time of the clinical trial conducted by Pfizer, in light of economic indicators, access to basic health, access to essential medicines, principles regarding human experimentation, humanitarian situation, etc. This is because the Pfizer case is not an isolated event; rather, it is part of a serious set of irregularities that involved different state actors, non-government organizations, and transnational corporations, among other subjects of international law.

Thus, this type of analysis proves to be fundamental in answering questions such as: Why do pharmaceutical companies conduct clinical trials in African countries? Why is the vast majority of the world's diseased population concentrated in Africa? Is Access to essential medicines equitable anywhere in the world? What are the Nigerian health and human experimentation laws? Are intellectual property laws prioritized over human rights law?

Once these questions are settled, it will be easier to understand the background and context of the 1996 Pfizer case, and analysis of similar cases in the future as well.

CHAPTER ONE

1.1. Overall situation in Africa concerning the assignment of patents and supply of generic medicines

Every year infectious diseases kill approximately 6 million people in Africa and a large share of those fatalities corresponds to children under 10 years of age. “In Africa, the infectious and parasitic diseases account for 60 percent of all reported deaths.” (Cavanna, 2006). In contrast, if the same criteria is applied for the European Union countries, it may be concluded that infectious diseases represent 5% of total number of annual deaths, while fatalities caused by cancer, respiratory and cardiovascular diseases stand at 70%. “Of the estimated 14 million deaths caused by parasitic and infectious diseases that occurred in 1999, the vast majority of them were needy people from developing countries including 6.3 million in Africa and 4.4 in Southeast Asia”.

Those figures have caused certain pharmaceutical firms to meet with increasing criticism mainly because many detractors have argued that they have focused solely on developing medicines for diseases in developed countries while dangerously neglecting diseased people of poor countries who commonly die due to the lack of proper medication and the impossibility to acquire patent drugs.

As a result, one of the alternatives that various activists and non-government organizations have considered in order to relieve this crisis has been to promote and strengthen the marketing of generic drugs. In fact, during last decade, different regional integration initiatives and African governments have made an attempt to pass local laws that authorize the manufacturing and importing of generic versions of patented drugs.

In March 2014, various African leaders and international organizations met at the VII Joint Conference of the African Union held in Nigeria. During this conference, the different stakeholders succeeded in coordinating efforts and policies in order to increase local production of essential medicines on African soil, all within the framework of the Headline Goal. “The conference will aim to provide concrete proposals for the implementation of an accelerated industrial development agenda in Africa” (Oficina de Información y Prensa de Guinea Ecuatorial, 2014).

It is worth pointing out that organizations such as the Center for Environmental Studies and Projects (CEPA), United Nations Industrial Development Organization (UNIDO) and the Joint United Nations Programme on HIV and AIDS (UNAIDS) took part in the meetings held during the conference and joined local governments and regional organizational efforts.

The outcome of the VII Conference was quite successful. First off, every stakeholder acknowledged that Africa has to stop the import dependency of developed countries. “It is estimated that more than 80% of antiretroviral medicines (ARVs) medicines are imported from outside Africa” (ONUSIDA, 2014). Second, this initiative stands as an opportunity to promote sustainable and inclusive industrial development in Africa. Further, the implementation of this programme would eventually deliver more employment sources as well as benefits for public health.

However, despite success, important issues emerged at the time to implement the proposed programme of activities. Initially, a business model had to be carried out to attract the main African banks and thereby secure investment in the fledgling industry. Furthermore, certain pharmaceutical companies have shown total rejection of this new project and have filed cases with the aim of abolishing local laws in pursuit of generic manufacturing in Africa. “The applicant companies claim that laws in question affect their most valuable asset: patents” (Cooper, 2001).

Nonetheless, each WTO member state has the right to adopt specific measures in order to protect public health and likewise promote access to essential medicines, beyond its duty concerning intellectual property rights. This right was established in 2001 during the Doha round of negotiations, which resulted in the creation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This covenant meant a big step for the developing countries to initiate import and export programmes of generic versions of patent medicines.

The procedure states that if a country seeks to import generic versions of patent drugs, its government must give compulsory licenses which allow importation. In the same way, if there are current patents of the medicines concerned within an exporting country, the generic manufacturers are instead to receive compulsory licenses from its government allowing to produce and export generics.

In other words, the use of compulsory licenses is essential both for import and export of generics. However, in order for these operations to be carried out without any restriction, it is necessary for importers and exporters to ensure that operations comply with the appropriate standards referred to in Article 31 of the TRIPS Agreement. Under that article:

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected (World Trade Organization, 2001).

Although the World Trade Organization has considered it important to protect public health of states through the TRIPS Agreement, there are also regulations that allow laboratories worldwide to patent recently developed medicines with the aim of compensating research expenditure so that price fixing is at the drug manufacturer's sole discretion. For instance, the regulation specifies that pharmaceutical laboratories are free to market their drugs for twenty years, which is the patent term.

Beyond the time period established, any pharmaceutical company shall be free to market patent drugs, whose prices decrease drastically due to the patent expiration and become much more affordable for individuals. “Under the TRIPS Agreement, the available term of protection must expire no earlier than 20 years from the date of filing the patent application” (World Trade Organization, 2016). However, there are cases where allegations have been made by activists against certain laboratories which apparently sought to extend their monopoly by modifying some minor compound of the drug and thus acquire a new patent. Currently, every generic medicine must be provided with the assignment of a patent from the pharmaceutical laboratory that used the active ingredients.

Overall, the TRIPS Agreement represents a supportive legal framework to every member state. In other words, if any government considers that local intellectual property and patent laws do not protect public health, there is no legal impediment to carry out reforms to these laws. Nonetheless, although the WTO has promoted, through the Doha Declaration, a relaxed regulatory framework so that developing countries might be able to initiate drugs manufacturing schedules, there have been impediments that have represented serious drawbacks for the programs to such an extent that, in many cases, generic medicine laboratories have faced a considerable number of lawsuits.

In that regard, the modification of legislated provisions concerning patents and intellectual property have brought negative consequences for developing countries. To date, well-known pharmaceutical companies have openly declared their opposition to these types of policies promoted by some governments and have organized campaigns to curb their intentions. Furthermore, there are currently multilateral and regional agreements created in favour of intellectual property. These agreements, with no public health protection as a priority, might contribute to stopping the legal trade of generic drugs because many of them have no the copyright holder permission and might therefore be potential for confusion.

1.1.1. India and the emergence of the “Pharmacy of the Developing World”

India was one of the first states to develop generic manufacturing programmes. This was possible thanks to the fact that, since 1970, there had been a law (IN004) establishing that marketing of generic drugs by Indian laboratories does not need to be subject to the patent system, so medicines could be manufactured in any country with lower costs. The benefits of this law represented dramatic changes when it came to the possibility of successfully dealing with diseases that require costly treatments.

According to the 1970 law provisions, generic manufacturers were free to develop patent products by paying reasonable royalties. This would also achieve a reduction in the costs and a treatment simplification. “Thanks to this free competition that eliminated the patent system, the cost of an antiretroviral treatment had decreased from \$1,500 to \$150 per person a year in 2004” (Forcades, 2006).

On the other hand, this law stated that the Indian government had the power to authorize generic manufacturing in the event a health emergency arises, and likewise, imposed civil duties for society so that businesses were enable to oppose with the authorities as a result of patents applications before these were granted. In addition, it is important to stress that economic gain generated by this law would depend on the sales volume that drug manufacturers could achieve within a market with more than one billion people.

Since the adoption of law IN004 (1970), the results according to Indian leaders expectations have been quite encouraging. “Currently, India’s pharmaceutical industry burgeoned to become the fourth in the world concerning production and sales volumes and generic drugs have been exported to approximately 200 countries” (Devraj, 2005). Such growth led the Indian generic industry to gain the moniker “Pharmacy of the Developing World” and currently about 80 percent of drugs distributed in developing countries come from Indian laboratories.

The battle between brand-name drug companies and generic manufacturers has gained prominence especially when referring to HIV treatment. Logically, patients in developing countries with this disease cannot afford treatment with patented medicines; this is why Indian pharmaceutical laboratories have played a key role in the manufacturing of generic drugs to treat this disease.

Currently, the generic anti-HIV treatments require the combination of three different active ingredients in a same pill, which means that their cost is ten times lower than treatments with patent medicines. “Nevertheless, the percentage of the he HIV/AIDS positive population that benefits from the India’s pharmaceutical industry is less than 1%” (Forcades, 2006). Unfortunately, in March 2005, the Indian Parliament, under pressure by certain World Trade Organization Agreements, passed a Patent Act drastically amending the 1970 law since it established a different patent system for future generic drugs to be manufactured from that same year.

Nonetheless, the Indian Parliament stated a clause so pharmaceutical transnational corporations could not lodge new patents for those medicines which already had one. “Until that moment, in case of patent holders made abusive use of them, the Indian pharmaceutical laboratories might legally produce generic versions of medicines that were still protected by patents in developed countries” (Forcades, 2006).

“Between 1995 and 2005 there has been 8,926 patent claims in India which, owing to the new law imposed by the WTO, they must now be reviewed...” (Forcades, 2006). According to this information, approximately 80 percent of the total number of lawsuits came from pharmaceutical companies which claimed not to have assigned their patents to Indian laboratories. Well-known firms such as Roche, Novartis and Pfizer brought charges against the Indian generic industry.

Furthermore, there are currently various aid organizations that depend on the flow of low-priced medicines, examples are The President's Emergency Plan For AIDS Relief (PEPFAR), UNITAID, The Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), FARMAMUNDI, The United Nations Children's Fund (UNICEF), Doctors Without Borders (DWB), etc. It is important to stress that DWB has become an international player in this scenario by supporting Indian pharmaceutical firms as a result of the lawsuits made by transnational pharmaceutical corporations.

To date, speakers from Doctors without Borders have submitted official statements supporting Indian authorities' decisions about reforming the patent law. In this respect, DWB is the organization with more AIDS programmes than any other and their success has directly depended on the use of generic drugs. Doctors without Borders has condemned the initiatives taken by certain transnational laboratories and has turned to different international public-sector organizations in order to disprove their accusations. With the AIDS programmes as priority, the eventual plaintiffs' success would mean the end of AIDS programmes with generics and the consequences for patients would be disastrous:

If we couldn't get our hands on these generic drugs any more patients would die! And we would go back ten years to where we started, when treatment was too expensive to give to patients and all we could do was basically just treating the opportunistic infections that accompany HIV infection without being able to suppress the virus at all (Doctors Without Borders, 2010).

One of these lawsuits took place in January 2006 when the Swiss pharmaceutical company Novartis appealed the Indian government's decision not to extend its patent for an anti-cancer treatment called Glivec. It should be stressed that Indian patent law states that patent recognition shall only be granted to those medicines that are genuinely new and innovative. "Novartis aimed to challenge section 3(d) of the Indian patents act which disallow patents of products that are not considered innovations, but merely variants" (Farmacéuticos Mundi, 2007).

If the Novartis lawsuit had won the case in the Indian court at first instance, the anti-tumoral drugs with the Glivec's active agent no longer would have had an affordable price for leukaemia patients from developing countries. In the case of the drug Glivec, treatments turn out to be expensive even for patients in United States or Europe. "Novartis sells Glivec® at 2,500 dollars per patient a month in India" (Forcades, 2006).

"The generic versions of the drugs, manufactured by Indian laboratories, are sold for \$175 per patient per month within the Indian market" (Farmacéuticos Mundi, 2007). Further, if Novartis' request to challenge paragraph 3(d) of the Indian patents law had received a ruling in its favour; this would have meant the beginning of the end of generic manufacturing in India and the price competition as well, not only within this state, but also in other developing countries.

In 2012, Doctors without Borders prepared a report on this case in which the arguments presented by Novartis to bring charges are analysed. The report stated that the Indian court should to rule against the Swiss pharmaceutical company since the drug that it is intended to be patented could not be considered as an innovative medicine because it has the same active ingredients of already existing marketed drugs. In the words of (Druker, 2012):

Drug companies that have invested in the development of medicines should acquire a return on investment. But this does not mean that they may take advantage of these rights by setting high prices and trying to patent minor changes with a view to extend their monopoly.

Finally, in August of the same year, and after six years of legal battle, the Court ruled in favour of the Indian generic industry alleging that the properties of Glivec had not changed, hence it could not be considered an innovative medicine. This decision was applauded by the whole Indian pharmaceutical industry and by the developing countries that depended on it. In addition, the Indian court has set a precedent for other pharmaceutical companies who seek to bring charges similar to those alleged by Novartis in future.

On the other hand, Novartis responded through statements on their website in which company managers express their disagreement with the Court's decision arguing that patents must be licensed, thus contributing to the research, investment and medical innovation. "Without patents, there will not be new medicines for untreated illnesses and there will be neither new generics" (El Economista, 2013).

1.1.2. Pharmaceutical Industry in Strategic Crisis

Most of the sources consulted for this dissertation agree with the conclusion that the malfunctioning of pharmaceutical industry can be solved in favour of the sick people from both developed and developing countries. Firstly, after analysing the effects generated by patented drugs, especially within the African market, it can be said that pharmaceutical transnational companies manufacture many similar drugs and very few that are genuinely new.

Furthermore, pharmaceutical transnational companies have too much control over the clinical trials that are used to assess the safety and effectiveness of their own drugs. With regard to the patent process, medicines are often patented before the clinical tests that are necessary to confirm their efficiency and safety are carried out. The problem is, however, that the patent period begins to run before the start of the medicine's marketing.

Thus, the duration of patents referred to in some countries legislation should be reduced by two to four years to complete the clinical trials. "The patents and other monopoly rights have an excessive length and enjoy considerable flexibility" (Forcades, 2006). The legal technicalities often allow pharmaceutical laboratories that own a patent to block market entry for generic drugs for up to three years after the end of the patent term.

The Food and Drug Administration (FDA), considered as the most influential regulatory agency in the world, it is too closely linked to pharmaceutical industry so their obligation to regulate it has caused the actions that have been taken, sometimes too lenient towards pharmaceutical firms, to be considered as subject to criticism from activists and governments of developing countries. For instance, pharmaceutical laboratories commonly initiate trials with new products before obtaining the corresponding letter of approval from the FDA.

When it comes to scientific research undertaken by pharmaceutical firms, it is clear that these do not investigate those diseases that affect people in developing countries because it is not profitable for them. In other words, transnational pharmaceutical laboratories do not consider it convenient to allocate large amounts of money on research and manufacturing development if these products are sold at low prices once in the market.

In fact, a vast number of analysts point to the repowering of research capacity and generic manufacturing as one of the possible solutions for developing countries. It is necessary for governments from these countries to promote new policies that enhance the value of active ingredients of the drugs and not only the value of brand names. Also, each government can negotiate the duration of patents with the pharmaceutical companies in a way that patents can be maintained for a longer time in developed countries as long as the patent term in developing countries is reduced.

Another alternative to eliminate monopolies of pharmaceutical corporations lies in the establishment of new policies of active inclusion and citizens' participation in decision-making. Thus, citizens could get involved in the opening of tendering procedures within their country in accordance with the national needs concerning prices and patents monitoring and priority setting process in terms of research, resources allocation, etc. Finally, after seeing how WTO Agreements and intellectual property legislation have led to the consolidation of the big pharmaceutical companies, it becomes clear that politics regulates the economy, i.e. the market. However, politics must be fair and non-discriminatory in order to seek the common good involving everyone, not only those who find themselves in comfortable socio-economic positions.

1.2. Analysis of Nigerian and International Laws relating to medical research involving human subjects

Nowadays, there are different declarations and norms of international law concerning ethical principles that govern medical research involving human subjects. However, it is worth indicating that the enactment of these legislative frameworks was only possible after the end of World War II. . “Before WWII the vast majority of medical researchers and scholars conducted clinical trials without the patient’s consent and without any concern of their welfare” (Williams, 2015).

The first body of principles concerning human research was published on August 20 1947, and was one of the outcomes of Nuremberg Trials. This set of principles received the name of “Nuremberg Code” and includes ten principles that define legitimate medical research. Overall, the Nuremberg Code states that the absence of coercion and informed consent from the human subject is absolutely essential. Thus, experimentations cannot proceed until the patient agrees to undergo a medical procedure.

Later, new normative instruments that extensively address and develop the Nuremberg Code were adopted. These also present statutes about ethical duties of doctors. Furthermore, these instruments make informed consent principle more flexible, so that disabled patients can be treated only with the approval of their legal representatives. It should be stressed that without a relaxation of the informed consent principle, it would be difficult to be able to treat patients with medications for which they cannot grant their consent.

1.2.1. Declaration of Helsinki

It is a legal instrument developed for the medical community by the World Medical Association on June, 1964 and has a total of thirty-seven principles. These principles deal with risks, costs, benefits, vulnerable groups, scientific requirements, research protocols, ethics committees, informed consent, use of placebo, etc.

For instance, principle 23 states that any research protocol should be sent to the relevant ethics committee. “The committee must take into consideration the laws of the country in which the research is to be performed as well as applicable international norms but these must not be allowed to eliminate any of the protections for research subjects” (World Medical Association, 1964, p. 2192). In addition, this principle indicates that the aforementioned committee must be transparent in its functioning, independent of researchers and has the right to control the ongoing clinical trials.

Moreover, the informed consent covers the principles 25-32 contained in this declaration which state that individuals’ participation must be voluntary, provided that they are capable of giving informed consent. “For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorised representative” (World Medical Association, 1964, p. 2193). Equally, these principles indicate that in case of absence of patients representatives, the medical procedure might be carried out without the informed consent as long as the reasons to include disabled individuals are set forth in the research protocol which must be approved by the ethics committee.

1.2.2. International Code of Medical Ethics

Adopted by the General Assembly of the World Medical Association in London in 1949, it states the ethical principles of the physicians worldwide. Its creation, as well as the Nuremberg Code, occurred in response to experiments involving human subjects which were carried out during the first decades of the twentieth century. Currently, it constitutes a fundamental document of the World Medical Association since it represents one of the most important international ethical norms concerning medical and clinical research. This code is divided into four sections.

The first section refers to physicians’ duties in general. The second one explains their duties to their patients. Section three refers to their duties to their colleagues, and the last one points to the Declaration of Geneva. “The Declaration of Geneva was adopted by the General Assembly of the World Medical Association on September, 1948, constituting a revision of the Hippocratic Oath” (Reverte Coma, 1983).

1.2.3. The Food, Drug and Related Products Nigerian Decree No 19 of 1993

It is an Act enacted by the Nigerian government on January 27, 1993 to regulate the manufacture, importation, exportation, advertisement, sale or distribution of processed food, drugs and related products and registration thereof. It is divided into fourteen sections. However, it is section five which specifically refers to clinical trials. This section states that no person shall, in the course of his business, import or supply a drug, drug product, cosmetic or medical device or procure the manufacture or assembly of a drug, drug product, cosmetic or medical device for the purpose of a clinical test, unless this individual is a holder of a valid clinical trial.

Furthermore, in case of application for a clinical trial, a certificate shall be made to the Agency in such form and manner as the Agency may prescribe according to regulations, which shall request a series of requirements and conditions that allow to confirm the safety of the trial. In the case of Nigeria, the regulatory agency is The National Agency for Food and Drug Administration and Control (NAFDAC), which was formed in 1993 and is based in Abuja.

SECOND CHAPTER

2.1. Meningitis Outbreak in Africa and subsequent epidemic in Nigeria

In 1996, a meningococcal meningitis outbreak spread throughout much of sub-Saharan Africa, affecting eighteen countries and giving rise 15,783 deaths by the end of the year. According to the World Health Organization Regional Office for Africa the worst affected country by this epidemic was Nigeria with about 80,000 ill and more than 7,000 deaths. In March of the same year, the meningitis epidemic spread across the Kano state, which was already dealing with measles and cholera epidemics.

The geographical location of Nigeria is within the so-called African meningitis belt, which is a region in sub-Saharan Africa where the rate of incidence of meningitis is very high. It currently consists of sixteen countries. “The belt has an estimated 300 million people in its total area. This region is not only prone to meningitis, but also very prone to epidemics such as malaria” (World Health Organization, 2012).

Illustration 1: Geographical location of Nigeria



Source: (Mapa Mundial, 2012)
Obtained from mapamundial.co:
<http://mapamundial.co/a/mapadeNigeria>

As explained in Chapter 1, the drugs used to treat bacterial infections such as meningitis are marketed at a very high price on African soil. Furthermore, the generic supply of medicines is limited because of the enforcement of patents by transnational pharmaceutical companies, which significantly affects the promotion of public health. In the case of Nigeria, the situation was much more dramatic since it is a country with a GDP per capita of €466 in 1999. In other words, the families of patients who suffer

these kinds of diseases cannot afford the payments for the full cost of suitable treatments.

Given these situations, the World Health Organization (WHO) launched a call inviting pharmaceutical laboratories and non-government organizations which were keen to send aid missions in order to control the epidemic in Nigeria. One of the laboratories interested in this situation was Pfizer. In fact, this pharmaceutical firm prepared a plan which consisted in giving a new antibiotic called Trovan to ill children with meningococcal meningitis.

“At the same time, Pfizer was trying to win FDA’s approval to test Trovan directly on children” (Sampford, Zifeak, & Aydin Okur, 2015). In agreement with Pfizer’s internal documents, about 200 children suffering from meningitis were reportedly medicated in the Infectious Diseases Hospital wards requested by Pfizer’s researchers in Kano. “Meningococcal meningitis constitutes the only form of meningitis caused by bacteria which might lead to epidemics” (IPS Correspondents, 1996).

In the words of (Castro Castillo, 2007): “Half of them received the new Pfizer drug called Trovan while the other half was treated with a Ceftriaxone antibiotic to fight this disease.” However, soon after several of the children who received these treatments started showing serious side effects such as deafness, loss of consciousness, inability to move, arthritis, etc. On the other hand, the families affected by the experiment with Trovan required explanations about the health status of their children. As a result, Pfizer’s physicians argued that such reactions corresponded to a normal stage of the drug effects process and the children would improve over the days:

Maisikeli went to see the people of Pfizer. He was told that the children would improve in the following days. The strange loss of consciousness was aggravated at that time. The journalist tried to talk to the doctors again but the group had already left. His children died; one in the afternoon and one in the evening. (De Cózar, A torment called Trovan, 2009).

However, the result was that eleven children treated with Trovan and generics died while many others developed serious physical damage which left them handicapped for life. The parents' complaints were overheard by local authorities, non-government organizations and media. For this reason, investigations were initiated and Pfizer was subsequently reported in international courts as a result of its clinical trial conducted in Kano, Nigeria.

The allegations were aimed at obtaining a conviction for Pfizer and compensation after having used the medicine directly on children, when the drug had not yet obtained approval by the regulatory competent entities. There was also speculation that the Nigerian government did not demand strict fulfilment of national approval protocols to initiate the aid campaign to fight meningitis in Kano. "At the time, Nigeria was run by a military government that had one of the world's worst human rights and corruption records" (Stephens, Nelson, & Flaherty, *Where Profits and Lives Hang in Balance*, 2000, p. 1).

The first articles that shed light on the campaign with Trovan in the Kano hospital were published in 2000 under the name of "The Body Hunters" by the Washington Post. This publication recollected information through interviews with staff from Pfizer, non-government organizations and Nigerian physicians who participated in the clinical trial conducted by the transnational laboratory in African soil. These articles developed a chronological analysis ranging from the design stage of Trovan, its use during the trial in Kano and finally until its approval by the Food and Drug Administration (FDA).

2.2. Discussion of the experiment with the drug Trovan in Kano, Nigeria

The Body Hunters, designated as a series of research reports, was intensely disseminated by Nigerian media which gave rise contradictions and uncertainties in the local community and contributed to the decision of parents who, assisted by human rights lawyers, brought criminal charges against Pfizer. "The parents of children sued Pfizer under the Alien Tort Claims Act, alleging that there was no consent" (Sampford, Zifeak, & Aydin Okur, 2015). In addition, the parents demanded compensation of damages. "They also sought compensation for damages and continuing medical care

for the children involved, and an order restraining Pfizer from conducting illegal experimentation anywhere in the world” (Nwobike, 2006, p. 136).

In accordance to an article published by John Stephens in December 2000, Trovan was destined to be a great success. Wall Street analysts said Pfizer could reap \$1 billion a year if the drug won approval for all its potential uses. Furthermore, the company staff had indicated that Pfizer had been unable to capture enough patients with meningococcal meningitis in the United States so its researchers had to make their own way to Kano, Nigeria.

Indeed, experiments in developing countries that involve risky drugs proceed with little independent oversight. The pledges of quality medical care sometimes prove fatally hollow. “The majority of patients is poorly educated and they are sometimes tested without understanding that they are guinea pigs” (Stephens, Nelson, & Flaherty, *Where Profits and Lives Hang in Balance*, 2000, p. 4).

Certain pharmaceutical firms usually skip procedures as a result of weak governmental enforcement. These laboratories have been largely inspected by the Food and Drug Administration (FDA) which has limited authority and few resources to experiments abroad. “U.S. based drug companies are paying doctors to test thousands of human subjects in the Third World and Eastern Europe” (Stephens, Nelson, & Flaherty, *Where Profits and Lives Hang in Balance*, 2000, p. 4).

The laboratories use the tests to produce new products and new revenue streams, but they are also responding to pressure from regulators and stakeholders in order to develop medicines in a quickly way. Thus, by providing large amounts of human subjects, foreign trials help speed new drugs to the marketplace, where they will be sold mainly to patients in wealthy countries.

2.2.1. Trovan development and subsequent drug delivery to Nigeria

In 1996, Pfizer was trying to streamline the application process to submit Trovan for FDA approval. This drug, considered as a bacteria fighter, had shown promise against a broad range of infections such as sinusitis, gonorrhoea, pneumonia and bronchitis. As a result, thousands of patients had enrolled in international drug studies with the company, which represented the biggest testing program ever conducted by a pharmaceutical company.

Before the start of the clinical trial, American media analysts indicated that Trovan could be one of the most financially successful new drugs of its kind in decades for Pfizer. The company's main worry, however, was about possible side effects in children. "Trovan belonged to the quinolone class of antibiotics, and quinolones had caused joint damage in experiments on young rabbits and puppies" (Stephens, Nelson, & Flaherty, *Where Profits and Lives Hang in Balance*, 2000).

The Pfizer Research Team was aware that the company needed extensive, convincing tests that proved Trovan was safe and effective in order to gain approval for the drug's use on children. Nonetheless, illnesses such as meningococcal meningitis were relatively rare in the United States. Pfizer spokeswoman Betsy Raymond explained: "We had to move fast after detecting the epidemic in Nigeria since we would not be able to find those numbers of children with meningococcal meningitis in the United States" (Stephens, Nelson, & Flaherty, *Where Profits and Lives Hang in Balance*, 2000).

Trovan development was headed by Scott Hopkins, who proposed leading a six person team in Kano in an attempt to establish that Trovan in oral form could work in children with the same effect as a fast acting intravenous antibiotic. If successful, Trovan in oral form would mark a breakthrough in battling epidemics in developing countries. Children could simply swallow a pill once a day, thus avoiding risky injections.

A meningitis consultant named But McCracken, who later conducted Trovan tests for Pfizer, called the company's argument "a little bit disingenuous" since, from his perspective, the pharmaceutical company did obtain benefits from these kinds of experiments. "They obtain benefit from it. They gained knowledge about how Trovan works during the trials. It's not 100 % altruistic" (Stephens, Nelson, & Flaherty, *Where Profits and Lives Hang in Balance*, 2000, p. 3).

Despite disagreements and lack of understanding within Pfizer, the experiment rapidly won clearance in Nigeria after what company records called an "independent review" by the local authorities in that place and an alleged approval of a Kano Infectious Diseases Hospital ethics committee. Nonetheless, the verbal consent from the parents was never obtained. According to Scott Hopkins, Pfizer did not require FDA approval to conduct the trial in Kano. However, the company gave regulators a copy of their work plan so the agency granted permission to export the drug to Nigeria.

2.2.2. Arrive of the Pfizer team at Kano and beginning of the experiment

The Pfizer research Team that arrived in Nigeria confessed its surprise once in the city since they had expected a rural village, not a metropolis of at least 2 million inhabitants with huge urban chaos and squalor. Initially, the Pfizer team was told that Kano was formed by several rural settlements with early rural development and a moderate population density.

Once in the Infectious Diseases Hospital of Kano the Pfizer team and other international aid workers described it as one of the world's most fetid and overburdened hospitals they had visited. "In most of the wards there was no water nor electricity and patients had no access to toilets so the walls were encrusted with blood and excrement" (Stephens, Nelson, & Flaherty, *Where Profits and Lives Hang in Balance*, 2000, p. 2).

Hopkins stated that when the pharmaceutical staff learned that meningitis epidemic had reached northern Nigeria, they didn't imagine that deaths would occur massively. "By February 1996, 120 new patients arrived in Kano in critical health condition, they appeared at the hospital every day with serious infections" (Stephens, Nelson, & Flaherty, *Where Profits and Lives Hang in Balance*, 2000).

The research team had been recommended by Pfizer to require hospital management to vacate a certain number of beds in order to start the clinical trial. According to Kain de Jonge, a Belgian nurse and the Kano field coordinator at the time, there were sick people outside the hospital who could easily have had access to a bunk if it were not for the Pfizer research team's refusal, who wanted to keep the bunks available for the experiment with Trovan. Tensions within the hospital surfaced quickly due to not only the Pfizer team, but also volunteers from Doctors Without Borders. Its team had arrived weeks earlier with an advanced outline procedure to treat patients.

Pfizer speakers questioned about patient care during the trial said that it was not a duty of the research team. For them, the care of each patient should be provided by the support teams conformed by volunteers and local physicians. Scott Hopkins said that in order to initiate the trial, the research team wanted to work with children in stable health conditions and not with those in critical situations. "Noting the seriousness of the epidemic the Pfizer team began to treat any sick child who arrived at the hospital" (Perlroth, 2008).

During the first weeks of the experiment Pfizer assumed care of almost 200 children. The vast majority of them with high levels of malnutrition and some were only a few months old. The children presented various stages of meningococcal meningitis, which can escalate rapidly from fever to coma, seizures and death. In order to better identify children who entered the Pfizer ward, which was the place where the trial was conducted, the research team labelled each patient with a code.

As previously noted, the overall experiment plan consisted on giving Trovan to the first half of the patients, either by pills, oral form or intravenously. The other half would receive an intramuscular injection of Ceftriaxone, which represented an effective meningitis treatment that had already been tested in American children.

However, serious problems emerged as soon as the experiment began. Every child selected was required to have blood tests upon their arrival at the hospital and five days later. Unfortunately, these tests were left behind once researchers realized that the hospital did not have suitable medical equipment. Accordingly, Pfizer asserted that its team did issue a report in view of this situation.

On the other hand, Ceftriaxone had to be given by injection through a vein or intramuscularly. Nevertheless, due to the poor empowerment of the hospital staff, the researchers' report stated that the medicine was almost always injected into the youngsters' buttocks or thighs to save time and trouble. "The pricks were severely painful, so fear overcame children and sometimes lead to dangerous struggles with them" (Stephens, Nelson, & Flaherty, *Where Profits and Lives Hang in Balance*, 2000). Contrary to Trovan, Hoffmann-La Roche did not produce Ceftriaxone in oral form so that, as a relatively thick and high concentration the injections turned out to be quite annoying for the children.

In order to reduce the pain caused by the initial injections, the report stated that the Pfizer research team cut the volume of the antibiotic to one third of the recommended amount for children who were improving. The laboratory asserted that available data at that time indicated the dose remained more than sufficient, but the drug's manufacturer, Roche, through its medical director Mark Kunkel, said the reductions could have sapped the drug's strength and skewed any comparison to Trovan.

Furthermore, Kunkel also stated that in such types of treatment a high dose is essential so any form of clinical failure and even deaths of patients could have resulted from a too low dosage. A Nigerian physician who was present during the experiment in Kano declared in his testimony that he thought the trial was not good for the children; nonetheless, he did not object since the Pfizer trial had support from the Nigerian government.

“I could not protest, said the physician Amir Imam Yola. Between your system and the system we have here there is a wide gap. Freedom of speech is still not here” (Stephens, Nelson, & Flaherty, *Where Profits and Lives Hang in Balance*, 2000, p. 3).

Illustration 2: Infectious Diseases Hospital Entrance.



Source: (De Cózar, *La farmacéutica Pfizer conspiró para evitar un juicio en Nigeria*, 2010)
Obtained from El País:
http://internacional.elpais.com/internacional/2010/12/09/actualidad/1291849238_850215.html

2.2.3. Deaths following the Trial with Trovan in the Kano Hospital

“On January 1996, the rate of death in the Kano state reached 20 percent” (Doctors Without Borders, 2011). In the words of Scott Hopkins, in Pfizer’s wards the mortality rate was at least as low, if not lower, than in the wards of Doctors Without Borders which were improvised in the same hospital. From that moment the questions that arose focused on specific medical decisions, especially on the decision of using an unapproved oral antibiotic on very ill children. “It would never be used like that in the United States” (Stephens, Nelson, & Flaherty, *Where Profits and Lives Hang in Balance*, 2000, p. 3).

The Vice President of Pfizer at that time, Paul S. Miller, defended the decision through a written statement that he sent to a lawyer for Juan Walterspiel, a former Pfizer paediatrician who had publicly complained about the experiment before the media. According to Walterspiel, the oral formulation was safe. Nonetheless, he affirmed that researchers had given critically ill Nigerian children intramuscular antibiotic injections instead via oral.

Even though Pfizer physicians assured that the oral form of Trovan was effective, this was never tested on children, so the meningitis patients in Kano were the first to receive it. “Pfizer’s internal records revealed that there were children who died soon after having taken Trovan in oral form” (Stephens, Nelson, & Flaherty, *Where Profits and Lives Hang in Balance*, 2000). This report stated also that on April 6, 1996, a 7 year old boy with muscle paralysis entered a Pfizer ward. Doctors labeled him patient No. 0054 and proceeded to treat him with 50 milligrams of oral Trovan. Only nine hours after, the report said Patient 0054 was dead.

Something similar happened with a ten year old girl, which was labeled with number 0069. She grew worse over 72 hours while taking no antibiotic except Trovan in oral form. The mentioned girl weighed 41 pounds and upon being medicated with Trovan, her condition only worsened. Finally, three days after receiving treatment, she died. Within Pfizer records the only indications was that the dose continued unchanged due to death.

Local physicians and humanitarian aid staff who were in place when the deaths occurred expressed their rejection towards the procedure policy imposed by the Pfizer research team. According to Agwu Urundu, a Nigerian physician who was present at the Kano hospital, Trovan was an experimental drug for meningitis, so if something was not going well during the treatment, it would be necessary to change the medicine or even use a different drug to counteract the Trovan’s effects.

But McCracken stressed in interviews that when he provided advice to Pfizer on conducting further experiments with Trovan in United States and South America, he drew up written rules in order to protect patients who refuse medication. McCracken, when questioned by the Washington Post about the differences between the experiment in Kano and his experiments affirmed that, in the case of patient 0069’s treatment, none of that would have happened in his studies. “Commonly, if patients don't improve over the first 48 hours, they are switched out” (Stephens, Nelson, & Flaherty, *Where Profits and Lives Hang in Balance*, 2000, p. 5)

A Pfizer spokeswoman said in a written statement that the deadlines for observation of results were different in the Nigerian epidemic in Kano, where 48 hours was too early to judge a response to therapy. She also underlined that in the case of patient 0069, doctors gave the girl intravenous fluids in order to stabilize her. Therefore, she considered that Pfizer's researchers did satisfied industry guidelines that recommend changing a failing patient's treatment when he or she does not respond positively to medications given.

Pfizer also pointed out that the fatality rates in Nigeria were about equal among the patients who received Trovan in oral form, Trovan by injection and the drug developed by Roche (Ceftriaxone). Nevertheless, a Nigerian ethics committee would conclude a few years later that the doses of Ceftriaxone given during the clinical trial were of lower concentration than the recommended doses by the FDA to treat bacterial infections. This assertion would subsequently prompt suspicion that Pfizer sought to whitewash the Trovan results.

Scott Hopkins stressed that no child would have received Trovan in oral form unless he or she was sufficiently well to swallow the pill. Hopkins indicated that patient 0069 could have been relatively stable at the beginning and then suddenly worsened on the third day. On the other hand, industry guidelines for conducting meningitis trials never envisioned testing an antibiotic amid a dreadful epidemic in a precarious, short staffed medical camp lacking basic diagnostic equipment.

Pfizer speakers always maintained the same position with the media, that is, that the main goal was to study the safety and effectiveness of its antibiotic while a breakthrough treatment for the developing countries was proposed simultaneously. "The company argued that its practices were validated by the number of children who showed improvement and a mortality rate of around 6%" (Stephens, Nelson, & Flaherty, *Where Profits and Lives Hang in Balance*, 2000, p. 4). The mentioned figure compares favourably to those reported for bacterial meningitis victims treated at United States hospitals.

The Pfizer research team prepared the trial over six weeks instead of the year that usually lasts in the United States. Furthermore, American meningitis patients usually receive fast acting intravenous drugs. As indicated previously, the Pfizer team in Kano gave most of the Nigerian children an oral form of Trovan that the same company accepted had never been tested in paediatric population.

Pfizer hired local physicians in order to test Trovan during its experiment, one of the doctors was Abdulhamid Isa Dutse who, when interviewed by the Washington Post said that both local doctors and the Pfizer team agreed that in the event that a patient does not show symptomatic improvement it would be necessary to modify the medication. In this regard, Isa Dutse explained that Pfizer's researchers could have done a lot more for the patients with side effects who subsequently perished. Dutse also was in charge of writing the report describing patient 0069's death. "You can't jeopardize a patient's life. I don't know what happened. If a patient isn't doing well, you change the treatment. . . .Why we didn't do that, I don't know" (Rost, 2011).

The Nigerian physician named Imam Yola indicated that at the time of giving the medicine to patients, they did not understand they had been in an experiment since the only thing patients knew was that they were sick. In addition, the Pfizer research team quickly withdrew from Kano once the trial with Trovan was completed. It should be stressed that the pharmaceutical company did not monitor patients during their recovery.

As mentioned above, the childhood diseases expert Juan Walterspiel released his complaints concerning the experiment to The Washington Post, which he considered too risky. For Walterspiel, Trovan in oral form should never have been tested on children and just the fact of testing the drug given the adverse conditions in which children were constituted and assassination attempt. "Walterspiel was convinced that his company violated international standards that regulate these types of trials and also overlooked ethical standards" (De Cózar, A torment called Trovan, 2009). The Pfizer Company fired Walterspiel shortly after.

Illustration 3: View of one of the Pfizer's Wards at the Kano Hospital



Source: (Doctors Without Borders, 2011)
Obtained from Doctors Without Borders Web Site:
<https://www.msf.es/actualidad/msf-rechaza-las-acusaciones-falsas-y-enganosas-pfizer-acerca-la-participacion-msf-los>

2.2.4. Possible inconsistencies throughout the approval process of the clinical trial with Trovan in Kano

The Food and Drug Administration (FDA) requires that patients in these kinds of experiments, no matter where they live, express their total consent to clinical trials as long as the results are used in order to obtain marketing approval in the United States. And, in fact, the majority of clinical trials in developing countries are carefully conducted and help to accelerate the creation of life-saving medicines. “However, in certain cases in which new drugs are approved the law is poorly reinforced or ignored” (Stephens, Nelson, & Flaherty, *Where Profits and Lives Hang in Balance*, 2000, p. 5).

Trials of this type generally raise serious questions about corporate profits and ethics on a frontier of globalization where drug companies wield enormous influence, and where doctors paid by American companies sometimes perform experiments on patients in poorly informed authoritarian societies. In the United States, researchers are required to inform patients in great detail on the risks of an experimental drug.

They must describe its purpose and explain alternative treatments. Once this has been done, patients, parents of patients or impartial witnesses should sign a written statement of approval.

In Nigeria, researchers from Pfizer team developed a consent form, which according to the pharmaceutical firm, was approved by a local ethics committee. However, the drawback was that the vast majority of families of the children with meningitis were illiterate. This is why various local nurses were used by Pfizer's physicians in order to explain the form to the children's families. Next, the same Pfizer speakers affirmed that neither parents nor nurses signed the sheets annexed to the forms. Finally, the report by the Pfizer research team stated that they proceeded with the experiment based on verbal consent from the parents but not written consent.

In the words of doctors Dutse and Hopkins, the nurses did not even completely translate the approval forms given to the parents of children. "To be honest with you, it was a general explanation. It is very complicated for them. You explain to them it's a new medicine and you have a right to say no" (Stephens, Nelson, & Flaherty, *Where Profits and Lives Hang in Balance*, 2000, p. 4). Unfortunately for the media, it was an impossible task to contact the parents or family members of the victims since they were people coming from rural areas and without a permanent address.

The Nigerian physician Isa Dutse, when asked if he considered the experiment to be good or bad, stated that despite the problems, he believed that children benefited from Pfizer's visit, but also expressed his concern about it. "If a corporate giant landed in Kano again, I would want solid guarantees of continuing assistance from the company. In the future, we will have clear terms" (Stephens, Nelson, & Flaherty, *Where Profits and Lives Hang in Balance*, 2000, p. 5).

Illustration 4: Firdausi, one of the victims of Trovan with her mother.



Source: (De Cózar, A torment called Trovan, 2009)

Obtained from El País:

http://elpais.com/diario/2009/04/19/domingo/1240113154_850215.html

2.2.5. End of the experiment and follow-up inspections in the Pfizer Company from the Food and Drug Administration (FDA)

Pfizer's researchers left Kano after treating children for almost two weeks, leaving each child with a list of medications taken. The Pfizer speakers indicated that any child who remained ill was transferred to a better equipped hospital. Furthermore, the parents of the children were asked to return in four weeks to ensure their children remained healthy and free of side-effects. According to Isa Dutse, less than half showed up.

Despite general medical guidelines that regulate meningitis trials recommend long-term monitoring, in the case of Pfizer's clinical trial in Kano no additional control was required. The company affirmed that a six week monitoring period for the children diagnosed with meningococcal meningitis is mentioned in the records and there was no unusual side effect registered among patients who did return for check-up. Pfizer team's final report of the clinical trial concluded that both Trovan and the generic medicine were equally safe and effective. Moreover, the mentioned report disclosed that 45 children received treatment, thus deviating from the experiment's preapproved plan.

“By December 1996, Pfizer had tested oral and intravenous Trovan on 13,000 people in 27 countries” (Stephens, Nelson, & Flaherty, *Where Profits and Lives Hang in Balance*, 2000). Before the end of that year, the company applied to the FDA for approval to commercialize Trovan. Six months later, by mid-1997, FDA inspectors travelled to Pfizer's research headquarters located in Groton, Connecticut. The purpose of the trip was to examine documents from Nigeria. Once there, they sifted and sorted through raw results recorded in Kano and discovered nearly fifty discrepancies.

The FDA stressed that records confirmed that some laboratory tests had been conducted in Kano when they actually were done in Connecticut. The Pfizer Company could not distort these allegations since its speakers failed to recall who recorded some of the information. However, the pharmaceutical company said any discrepancies noted by FDA did not compromise the validity of the trial or its conclusions. When Pfizer applied FDA to approve Trovan marketing, the pharmaceutical firm included a document indicating an authorization from the ethics committee of the Kano Hospital to conduct the trial with Trovan in children who were sick with meningitis.

In 2000, the *Washington Post* revealed, through interviews with Nigerian physicians who took part in the experiment, that the approval letter issued by the ethics committee was drawn up a year after the trial finished but with an issue date preceding the beginning of the experiment. “The telephone interview further disclosed that the Kano Hospital did not have an ethics committee at the time of the clinical trial” (Nwabueze, 2003, p. 98).

In spite of the differences between FDA and the pharmaceutical company, the regulation agency authorized marketing Trovan for use against 14 adult illnesses on December. 19, 1997. Later, the European Union approved Trovan but specifically advised that Trovan in oral form should not be given to children. The drug rapidly became one of the most prescribed antibiotic brands in the United States. Pfizer reported that sales topped \$160 million in Trovan's first year and roughly 2.5 million individuals had taken it by mid-1999.

However, the FDA did not publicly indicate why Trovan marketing for children was not approved. The reasons why the authorization was not given are corporate secrets. Pfizer Company, in turn, affirmed that its application for Trovan use against meningococcal meningitis was withdrawn in October 1997 due to warnings issued by regulating entities to refuse authorization on the basis of a long list of inconsistencies founded after the respective inspections. The most relevant involved the implementation of plans to do appropriate monitoring tests which turned out to be dismal failures.

After sixteen months on the market, regulatory agencies announced bad news for Pfizer. According to the FDA, there had been 140 reports of liver problems in Trovan patients. Around 14 suffered liver failure and five died. “Hepatic side effects have included 5 deaths from liver toxicity and 4 patients requiring liver transplantation (one of which died) out of 140 cases of liver toxicity reported since the approval of Trovafloxacin in February 1998” (Drugsite Trust, 2009).

It is worth indicating that Pfizer speakers had argued to the media that during experiments, including the clinical trial in Kano, no serious liver problems had surfaced in patients. In this scenario, in 1999 American regulatory agencies advised doctors to restrict Trovan use to patients with serious diseases. “Concurrently, European regulators suspended Trovan sales as a result of the liver damages that emerged” (Castro Castillo, 2007).

In summary, even though Pfizer eventually obtained approval to sell the drug to adults, its desperate attempts to consolidate Trovan in the market proved to be unsuccessful. Finally, the collateral damage and subsequent child deaths caused by Trovan in Kano set a precedent that would lead to a long-term legal battle in international courts between the transnational pharmaceutical company, human rights lawyers, non-government organizations and even parents of the victims.

2.3. Report by Doctors Without Borders

When the Meningitis outbreak appeared in Africa, MSF was one of the first organizations who eagerly involved with the epidemic. In fact, this organization had not only deployed control programs in Nigeria but in several African countries within the African meningitis belt, such as Burkina Faso and Democratic Republic of the Congo. Furthermore, Doctors Without Borders and the World Health Organization collaborated together on stemming the outbreak.

2.3.1. Analysis of the trial with Trovan by Doctors Without Borders

As mentioned above, Doctors Without Borders was one of the non-government organizations that became closely involved in the analysis and study of the Pfizer's experiment in Kano. This is due primarily to during the time Pfizer sent its team of researchers to conduct the trial at the Kano Hospital, a DWB elite team was in the same place with the aim of providing medical aid. The team had arrived four weeks earlier and had started treating patients with infectious diseases through a cheap antibiotic called Chloramphenicol (front-line antibiotic useful for the treatment of different bacterial infections).

The DWB team was planning a prompt action plan consisted in a rapid patient screening, which meant grouping the sick by the severity of their illnesses. Those who were in stable conditions occupied mats in improvised tents pitched in the hospital wards. On the other hand, the sickest patients had access to battered beds inside in the compound.

When Pfizer's researchers moved to the assigned ward at the hospital, tensions surfaced rapidly due both the non-government organization and the pharmaceutical transnational company were applying different procedures concerning treatment and monitoring of patients. Additionally, it should be noted that the hospital facilities were quite poor and the global background consisted on an epidemic out of control. Further, the authorities of the hospital gave Pfizer's researchers two of the best-maintained beds of patient wards, including a comfortable workspace.

For volunteer activist Karin de Jonge, who served as field coordinator at the Kano Infectious Diseases Hospital, the situation became dire by indirect disputes between the Pfizer research team and other charitable organizations that were at the hospital during that time. According to de Jonge, Pfizer's researchers received special treatment from hospital officials causing patients treated by Non-government Organizations such as Doctors Without Borders to not receive proper care during their treatments.

On the other hand, Scott Hopkins, the head of the Pfizer team, stressed that its team enhanced the conditions to treat patients at the hospital on its own and called the Doctors Without Borders' complaints paranoid, saying this organization wanted sole credit for taming the epidemic. Additionally, Hopkins did not agree to use chloramphenicol to fight meningitis. "I wouldn't give my dog chloramphenicol because it has serious side-effects" (Stephens, Nelson, & Flaherty, *Where Profits and Lives Hang in Balance*, 2000).

Doctors Without Borders speakers described disturbances that took place in the Pfizer ward as very serious since they could have contributed to the death of patients. Regarding this situation, Karin de Jonge said: "In an epidemic, where you have a very high number of cases who will die, you don't go and experiment. We are talking about human beings, after all" (Bernard, 2007).

According to Doctors Without Borders, the arrival of the Pfizer research team caused only further chaos and uncertainty in the hospital. In the words of a DWB volunteer Evariste Lodi, the fact that Pfizer experimented with an unapproved drug in the midst of an epidemic was a very risky move. And in the event of failure, doctors would have had little room for immediate reaction, and so the fate of the patients would depend almost entirely on the drug efficacy. When Pfizer's researchers completed the report of the trial in Kano, this was read by a DWB physician.

The doctor in question was Marc Gastellu-Etchegorry who was outraged during interview and stated that the procedure carried out by the Pfizer research team was a huge mistake since as there were patients who did not show any improvement from certain drug therapy. It is a duty of all physicians to attempt to employ alternative

drugs, do not persist with the same dose and, if necessary, change the patient. Otherwise, if any patient dies, this may be considered as negligent assassination.

After the end of the experiment, the organization Doctors without Borders protested publicly stating that neither parents of children nor Nigerian children who took part in the clinical trial were aware of the fact that it was actually an experiment with a new drug that had not yet approved by the relevant regulatory entities or by a local ethics committee. Evariste Blondi said he believed that children did not understand what was going on.

Lodi indicated that he treated some children after Pfizer's researchers left the hospital. "All those patients and their families came back saying that they had never been informed that they were used in experimentation with an unproved medicine" (Stephens, Nelson, & Flaherty, *Where Profits and Lives Hang in Balance*, 2000, p. 5). Lodi also contended that Doctors Without Borders took care of some of the patients and did not find any clinical registers. For this reason, they could do nothing other than discover how the treatment had to continue.

2.3.2 Accusations from Pfizer against Doctors Without Borders

After a legal battle between the Nigerian government and Pfizer began as a result of the experiment conducted by the pharmaceutical laboratory at the Kano Hospital, the latter accused the NGO Doctors Without Borders of having used the drug "Trovan" during the time in which one of its teams was at the site. Doctors Without Borders answered through documentary evidence, whereby the non-government organization stated that Pfizer's allegations were false. The evidence indicated that the team deployed by Doctors Without Borders in Kano was in the same hospital but in a different ward that Pfizer and neither staff nor DWB's personnel had contact with the Pfizer's researchers at any point.

Furthermore, DWB indicated through the report that both its volunteers and physicians were completely against the initiative of conductING an experiment in the middle of an epidemic promoted by Pfizer. The non-government organization even indicated that they failed to understand how Pfizer dared to conduct such a trial in a disaster scenario. “Doctor Without Borders ´personnel in the site reported their concerns to Pfizer and local authorities” (Doctors Without Borders, 2011).

The president of Doctors Without Borders during the Kano epidemic in 1996, Jean Hervé Bradol, spoke to the media about the charges made by Pfizer and he strongly condemned those actions arguing that at no point did his organization test Trovan. In his view, chloramphenicol was the ideal medicine available at that time to treat patients with meningococcal meningitis. “It was not a time for a drug trial. They were panicking in the hospital, overrun by critically ill patients. The team were shocked that Pfizer continued the so-called scientific work in the middle of hell.” (Doctors Without Borders, 2011)

CHAPTER THREE

3.1. Analysis of the report issued by the investigation committee on the clinical trial of Trovafloxacin (Trovan) by Pfizer in Kano, 1996

In March 2001, a committee conformed by Nigerian specialist physicians concluded that Pfizer violated Nigerian and international laws during a meningitis epidemic that hit Nigeria in 1996 by testing an unapproved drug in sick children which were being treated at the Infectious Diseases Hospital in the city of Kano.

In doing so, a detailed report supported by the Nigerian government was issued and publicly disseminated thanks to the Nigerian Federal Ministry of Health. This document indicates that Pfizer never obtained authorization from the Nigerian government to test a drug called Trovan in around a hundred children. “Pfizer's experiment was an illegal trial of an unregistered drug, and a clear case of exploitation of the ignorant.” (Stephens, Panel faults Pfizer in '96 Clinical Trial in Nigeria, 2006, p. 3).

Pfizer had argued in the media that its researchers travelled to Kano solely with a philanthropic motive, which consisted of helping fighting the epidemic within the Kano state. However, the committee engaged to carry out the report rejected this allegation and noted that the Pfizer's physicians completed the trial with Trovan and left the place when the epidemic was still raging.

The investigation committee also established that the experiment violated laws such as Declaration of Helsinki which governs ethics in medical research and the United Nations Convention on the Rights of the Child. Furthermore, the group of experts recommended that Pfizer should be properly judged and it must be compelled to issue an apology without qualification to the Nigerian government and for the victims of this country

In this regard, the Nigerian government was recommended to enact reforms in order to prevent similar situations in future. “The company should also pay an unspecified amount of restitution” (Federal Ministry of Health, 2001). However, the report took longer than expected to come to light. In fact, it remained anonymous for several years still without knowing the reasons why the document classified as confidential. “I don't really know myself why the report was never released” (Stephens, Panel faults Pfizer in '96 Clinical Trial in Nigeria, 2006, p. 1).

3.1.1. Conformation of the Investigation Committee and analysis of interviews prior to the preparation of the report

At the beginning of 2001, the Nigerian Federal Ministry of Health constituted a committee of experts in order to start an investigation on the clinical trial carried out by the Pfizer laboratory in the framework of its 1996 campaign to fight meningitis in Nigeria. The establishment of the committee gained momentum among Nigerian authorities after various American and local newspapers disclose publicly the clinical trial with Trovan conducted at the Kano hospital five years before.

In order to appoint a head to be responsible for coordinating the functions and competencies of the Investigation Committee, the Ministry of Health named Doctor Abdulsalami Nasidi as chairman of the panel. Subsequently, once this body was constituted, its members contacted with the most individuals possible that were involved directly or indirectly to the Pfizer trial. To do this, different meetings were held in Kano and Abuja where senior managers and executives from organizations linked to the experiment were interviewed. The purpose of the interviews was to learn their tasks, roles and responsibility. In all, 26 individuals were interviewed by the committee.

On the other hand, although the committee was not able to interview any patient that received doses of the drugs tested during the clinical trial, mainly due to the difficulty in obtaining references on their location and address, the committee used any document with the signatures of the patients that was available. The panel of experts recollected different documents coming from the government and other international

legal papers with guidelines to follow in order to conduct of this type of trials with human subjects.

The interviews were conducted with Pfizer personnel, management staff of the National Agency for Food and Drug Administration and Control (NAFDAC), authorities from the Nigerian Federal Ministry of Health, officials of the Kano Infectious Diseases Hospital (IDH), members of the Federal Task Force for the control of the epidemic in Kano, representatives of Doctors Without Borders and other agencies involved in the case.

From among the 26 interviewees, the statements that stood out were by Dr. Idris Mohammed, Chairman of the Federal Task Force for Control of the Epidemic in Kano; Dr. Isa Dutse, Chief Consultant Physician and Chairman of the Medical Advisory Committee of the Kano Infectious Diseases Hospital (IDH); G.E. Osuide, Former General Director of the NAFDAC; Dr Sanda Mohammed, Former General Director of the Kano State Ministry of Health; Dr Suleiman Abdullahi, Principal medical Officer in charge of the IDH, Kano in 1996; Bawa Abubakar, Chief Regulatory Officer in charge of Registration of the NAFDAC, and others.

3.1.2. Interview with Doctor Abdulhamid Isa Dutse, Chairman of the Medical Advisory Committee of the Kano Infectious Diseases Hospital at the time of the experiment

One of the interviews that provided plenty of relevant information to the expert's panel was conducted with Doctor Isa Dutse. At the time of the interview, Dutse served as Chief Consultant Physician and Ag. Dean of Medicine at the Bayero University in Kano. Dutse confirmed to the committee that he was contacted on March 30, 1996, by the Medical Director of Pfizer Doctor Segun Dogunro because of his cooperation in a previous study for Pfizer a few years earlier. Additionally, the interviewee stated that during that meeting he talked to Scott Hopkins about the trial with Trovan in Kano which Pfizer was planning to do. So Hopkins gave Dutse a catalogue with all the product features and potential uses of the new drug.

In the words of Dutse, Pfizer representatives assured him that they had clearance from the NAFDAC to initiate the experiment and that the Nigerian Ministry of Health had assisted Pfizer in order to obtain a duty exemption waiver from the Federal Ministry of Finance:

The National Agency for Food and Drug Administration and Control (NAFDAC) is a Nigerian federal agency under the Federal Ministry of Health that is responsible for regulating and controlling the manufacture, importation, exportation, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, chemicals and packaged water. (National Agency for Food and Drug Administration and Control, 2013).

The physician also contended that the pharmaceutical company informed him that the clinical trial had obtained approval from the Kano State Ministry of Health. In addition, Dutse stressed that Pfizer representatives told him that, in that moment, there was no ethics committee in the hospital and he, as the chairman of the Medical Advisory Committee of the hospital, had to take immediate action to remedy the situation. Dutse affirmed to the committee that he was always in favour of the execution of the clinical trial with the drug Trovan since he believed in its potential, especially in oral form. Furthermore, Dutse stated that the Pfizer physicians had previously given him a brochure about Trovan which indicated that the drug had been already tested in approximately 500 people in other parts of the world.

On the other hand, Isa Dutse also said that during the initial stage of the trial he received a letter from the professor Idris Mohammed, who had asked him to discontinue the experiment urgently. “On April 11 1996, there was a letter from Prof. Mohammed specifically stopping the trial” (Federal Ministry of Health, 2001, p. 23). Dutse pointed out that he did not consider the request due to the experiment had just begun.

After having witnessed the deaths of some patients that took part in the trial, Dutse indicated that the action that he was most ashamed of was, once the trial had ended, having single-handedly provided an ethical clearance certificate to Pfizer supposedly issued by the ethics committee in order to conduct the trial which was dated before the

beginning of the experiment when, in fact, the mentioned committee was established after the end of the trial. “He regretting not constituting an Ethical Committee before and at the time of the trial” (Federal Ministry of Health, 2001, p. 23). Finally, Dutse stated that, from his perspective, the nature of the Pfizer research team’s arrival was anything but philanthropic.

The interview with Isa Dutse allowed the investigation committee to learn the fact that the Nigerian physician was named as the principal investigator of the clinical trial in a symbolic manner since he was neither in charge of the technical approach nor the administrative management of the experiment. In that regard, physician Scott Hopkins was who headed the investigation. Dutse also made no contribution to the development of the experiment protocol since he did not have sufficient time to study it due to the imminent beginning of the trial. Additionally, despite Dutse was acting as the principal investigator, he was never given the chance to keep patients records or reports elaborated by the researchers from the Pfizer team. Those reports and records evaporated together with the Pfizer research team as soon as the experiment was completed.

3.1.3. Interview with the senior staff from the Kano State Ministry of Health

Three officials who formed part of the Kano State Ministry of Health during the epidemic were interviewed by the Investigation Committee. Nonetheless, two interviews stood out and helped the committee to obtain new information which corroborated certain statements of other interviewees. These interviews were conducted with the Doctor Sanda Mohammed and Doctor Sulaiman Abdullahi.

a) Doctor Sulaiman Abdullahi

The interview with Dr. Abdullahi was fundamental for the deliberations of the Investigation Panel due to the interviewee served as Medical Officer in charge of the hospital where the clinical trial was conducted and he witnessed from beginning to end such test. Abdullahi indicated to the panel that he was aware of the clinical trial by Pfizer since the Kano State Ministry of Health had informed him previously that the laboratory was on its way to provide assistance and become participant in the treatment

of the patients. Furthermore, he assured that Pfizer informed the Infectious Diseases Hospital officials that they would use certain medicines including new drugs.

Moreover, Abdullahi was aware of the protest made by Idris Mohammed concerning the trial with Trovan and Ceftriaxone. It is worth indicating that Idris Mohammed was the chairman of the Federal Task Force for Control of the Epidemic in Kano. However, Abdullahi affirmed that before the beginning of the trial with Trovan and Rocephin (Ceftriaxone), which was the drug used simultaneously, he never received information about these drugs from Pfizer.

Sulaiman Abdullahi asserted that he was consciously aware that Profesor Idris Mohammed had requested Pfizer the respective permits that had to come from the NAFDAC, the Nigerian Federal Ministry of Health and the Ethics Committee, within a period of two days. Likewise, Abdullahi stated that Pfizer was unable to comply with the request, thus Idris Mohammed proceeded to suspend the clinical trial. Later, Abdullahi indicated that the General Director of the Kano State Ministry of Health, Doctor Sanda Mohammed, visited the hospital and oversaw the resumption of the experiment due to Pfizer allegedly presented documents containing the permits required. Nevertheless, when these were revised by Idris Mohammed, he considered them unacceptable.

As a result, Abdullahi explained that Idris Mohammed requested samples of Trovan from Pfizer to subsequently send them to the NAFDAC for examination. What was evident for Abdullahi were the disagreements between the General Director of the Kano State Ministry of Health and Idris Mohammed since when the former ordered the resumption of the trial he did not consult Mohammed or explain the reasons for the resumption of the clinical trial.

The investigation committee asked Abdullahi if he was aware of the presence of DWB in the hospital. He responded by saying that, in fact, the staff of this organization was treating patients within the Kano Infectious Diseases Hospital and the entire personnel was in disagree with the trial that Pfizer was conducting in the same building.

On the other hand, Abdullahi contended that at no point was he directly involved to the Pfizer trial due to he had to deal most of the time with logistic issues within the hospital, one of those tasks was to assign Pfizer an adequate ward. Lastly, to end the interview, Abdullahi affirmed that no kind of record or report concerning the clinical trial conducted by Pfizer remained in the hospital since the laboratory did not leave a single document as they left the hospital. Despite the resumption of the experiment was beyond the means of Abdullahi's attributions, he could better support the protests made by Professor Idris Mohammed. In that regard, Abdullahi could have delivered the Mohammed's letter to the senior executives and he did not.

b) Doctor Sanda Mohammed

Mohammed took office as General Director of the Kano State Ministry of Health in 1995, therefore he was the overriding authority of this ministry throughout the time that the trial by Pfizer lasted. Important data emerged from the Sanda Mohammed's statement which elucidated a little deeper the landscape of the Investigation Committee. The interviewee stated that at the beginning of the epidemic, the Kano State Ministry of Health did not have a committee which was responsible of controlling the outbreak. As a result, the Nigerian Federal government intervened instead of the mentioned ministry in order to take control of the epidemic. Furthermore, a meeting between Sanda and Idris Mohammed was arranged in which the latter informed Sanda that his mission was to provide assistance to the Ministry in the meningitis epidemic control.

When questioned about Pfizer's intention to donate drugs, Sanda Mohammed indicated that no organization contacted him directly in order to discuss the topic concerning the donation of drugs. He also affirmed that the Pfizer's physician Segun Dogunro donated some medicines to the Kano State Ministry of Health. Nevertheless, The Pfizer letter regarding the offering of donating drugs and the request to treat patients at the Kano hospital never made it to Mohammed's desk.

Sanda Mohammed further stated that during his encounter with Idris Mohammed, the latter never mentioned him anything about the clinical trial planned by Pfizer. Finally, when Mohammed coordinated meetings with the agencies in charge of the epidemic

control, these never notified Mohammed about the presence of possible drawbacks at the Kano Infectious Diseases Hospital, thus Mohammed called upon them to continue their job.

In analysing what Sanda Mohammed said during the interview, it can be said that his arguments were focused on not having been aware of the clinical trial conducted by Pfizer. However, his statements sometimes contradicted the statements of Doctor Isa Dutse, Idris Mohammed and Segun Dogunro from Pfizer, so it becomes difficult to believe that Sanda Mohammed was not aware of the experiment. The primary question that emerged was to determine if whether or not Sanda Mohammed had any knowledge of the clinical trial. If so, he would have been extremely responsible for deciding not to stop the experiment when Idris Mohammed filed his protest and for ordering its continuation afterwards.

3.1.4. Interviews with officials and staff from the Nigerian Federal Ministry of Health

a) Doctor Ihechukwu Madubuike

The Nigerian minister of health at the time of the Pfizer trial was Doctor Ihechukwu Madubuike. He was the one who provided the issuance of a duty exemption by the Federal Minister of Finance in order to give the green light for the importation by Pfizer of Trovan and other medical supplies and initiate the clinical trial to fight the meningitis epidemic.

Madubuike did not take the need of expert advisors seriously at the time of introducing a new drug into Nigeria in the middle of an epidemic. Furthermore, he dismissed the notices and reports from local physicians in which the trial with Trovan and Rocephin was required to stop and nor did he support the idea of creating an ad hoc committee in order to investigate the experiment subsequently. Unfortunately, in accordance with the report by the Investigation Committee, Doctor Madubuike never responded to the invitation to conduct an interview that the committee made him.

b) Doctor A.E. Ike

Doctor A.E. Ike did attend the interview as the former special assistant of Ihechukwu Madubuike, he stated during the interview that he sent a letter to Pfizer by direct order of Madubuike in which the completion of the shipment of certain drugs was required, including Altrofloxacin and Trovafloxacin. And all without seeking for the opinion of the Food and Drug department of the Ministry of Health. Ike also admitted having obtained no relevant information about the Trovan drug and he considered that a special committee must have been established in order to investigate the situation.

A physician named E.C Chidomere was also part of the interviewees and affirmed he was the successor of Doctor Ike as special assistant of Madubuike, the then Nigerian Minister of Health. Chidomere contended that it was during the exercise of his duties when a report on the Pfizer trial drafted by Professor Idris Mohammed reached his desk. The interviewee stated that he never communicate to Mohammed the responses received from Pfizer and NAFDAC requesting for his comments. Further, Chidomere admitted that the reply letter that he sent to Mohammed did not address the issues raised by the physician and it was written instead as a claim.

On the other hand, the Investigation Committee interviewed its own chairman, Doctor Abdulsalami Nasidi, who was the Chief Consultant Epidemiologist at the Nigerian Federal Ministry of Health.

a) Doctor Abdulsalami Nasidi

Nasidi stated that his division mobilized different teams to go out and assess the situation in several affected Nigerian regions where epidemic outbreaks had emerged. In addition, when he personally visited Kano found that there was a triple epidemic of measles, meningitis and cholera. Nasidi contended that the reports from the deployed teams were alarming so the Nigerian Ministry of Health established the controlling of the meningitis epidemic as priority on a national level.

As a result, this entity decided to set up a Task Force to tackle the epidemic which was composed of representatives from different university hospitals of the affected Nigerian states, members of the Kano State Ministry of Health and representatives from Doctors Without Borders. Furthermore, the group used the Kano Infectious Diseases Hospital as an operational base and filed every report directly to the Federal Ministry of Health.

Moreover, Nasidi explained to the committee that he was full aware of the trial with Trovan since during one of his visits to the Kano Infectious Diseases Hospital the Professor Idris Mohammed informed him that Pfizer. Instead of providing assistance for the control of meningitis, the company appeared to be testing the new drug in children. During that same visit, personnel from the Pfizer team met him and asked Nasidi to arrange a meeting in which Nasidi told them that what they were doing was wrong due to there was already a medicine that had proved to be effective to fight meningitis and that their drug had not the permits required.

Nasidi claimed to have advised hospital officials to discontinue the clinical trial after having been present in the Pfizer ward and watched the damaging side effects that children were experiencing. He tried to persuade Doctor Isa Dutse to desist from the experiment although the latter was convinced of the effectiveness of Trovan. The physician also stated having reported verbally the effects derivated from the experiment to the Ministry of Health, to which the institution replied and asserted that they were aware of the trial and would provide him much more detail.

Nasidi contended that he coupled with Professor Idris Mohammed in order to report the trial to Alhaji Ismaila Gwarzo, who held the position of National Security Adviser, and he did absolutely nothing. The report issued by Professor Idris Mohammed on the trial that was conducted was never referred neither was supported by an investigation process. Lastly, the Physician expressed strong concern since from the beginning of investigations about the experiment he had received threats against his physical integrity.

3.1.5. Interview with Professor Idris Mohammed

Mohammed manifested to the committee that during the clinical trial conducted by Pfizer he was the Chairman of the Federal Task Force for Control of the Epidemic in Kano. With regard to the 1996 epidemic, Mohammed stated that it was one of the worst epidemics in African history since it affected approximately 109,000 people causing a number of deaths greater than 11,000. “The epidemic started in Kano, Katsina and Bauchi spreading to other States including Plateau, and Osun” (Federal Ministry of Health, 2001, p. 51).

According to the findings of the Nigerian media, the epidemic started in February and the Task Force became involved in March. Furthermore, Mohammed stated having personally overseen both monitoring and efforts made during the trial in order to control the progression of disease. The committee learned from Mohammed that international organizations such as WHO and UNICEF supported the Task Force by sending qualified staff.

Mohammed stressed that he met with the Pfizer team at the Kano Infectious Diseases Hospital and was informed of the trial’s protocol before this began. He also stated that the Pfizer’s researchers communicated him that they believed that their new medicine was much better than existing antibiotics to fight meningitis and said the drug had been already tested on humans in the past. He argued having given his agreement to the trial on the condition that Pfizer provides him the permits and approval letters from the NAFDAC and the Kano State Ministry of Health during the course of the trial.

Later, in the absence of any replies from Pfizer, Mohammed decided to stop the trial by sending a letter addressed to the Principal Medical Officer in charge of the Kano Infectious Diseases Hospital. “Some time after the expiration of the eight days period of grace he terminated the trial via a letter to the Medical Officer-in-Charge, Dr Sulaiman Abdulahi.” (Federal Ministry of Health, 2001, p. 54). An incident that sparked Mohammed’s interest occurred when he witnessed how one of the Pfizer’s researchers withdrew about 10 cc cerebrospinal fluid from an ill child who died an hour later.

The committee was also informed by Mohammed that after the mentioned event and, to his surprise, the trial was resumed with the approval of the Kano Minister of Health. “Idris met Dr Sanda Mohammed and explained why the trial could not continue.” (Federal Ministry of Health, 2001, p. 53). According to the interviewee, the Minister Sanda Mohammed agreed with him, however reinforced his decision to continue with the experiment.

Illustration 5: A Nigerian child with Meningitis in Kano, 1996.



Source: (Montoya Villar, Vasquez Feijoo, Villarreal Albuja, & Vasquez Santos, 2012)
Obtained from <http://pfizertest.blogspot.com>:

Meanwhile, Idris Mohammed stated that during that time Doctors Without Borders and the International Red Cross threatened to withdraw from Nigeria if the trial continued. Subsequently, the professor sent a letter to the Federal Ministry of Health reporting what happened within the hospital. Nevertheless, he also sent his claims to the Advisor of National Security through a report prepared in partnership with Doctor Nasidi. For Idris Mohammed, the true Principal Investigator of the trial with Trovan and Ceftriaxone was Dr Scott Hopkins and not Dr Dutse.

All the above-mentioned statements led Idris Mohammed to assert to the committee that Pfizer's involvement in the fight against the epidemic was not humanitarian, but primarily to test its new drug. Moreover, Mohammed stated that his assumption was confirmed when the Pfizer team withdrew from Kano just finished the trial leaving no work scheme or plans for the continued management of patients who still were in the hospital wards. In conclusion, Idris Mohammed indicated that the Pfizer trial possibly had the support of the Federal Ministry of Health and the Kano State Ministry of health and that his only mistake was to have allowed the trial to take off at all without documentary evidence of authorization.

3.1.6. Interview with officials and senior staff from the NAFDAC

a) Professor G.E. Osuide

During 1996, Osuide served as General Director of the National Agency for Food and Drug Administration and Control (NAFDAC). Upon being asked by the investigation committee, several questions were asked to Osuide regarding his level of knowledge of the Pfizer's experiment and the actions taken by the agency that he was leading.

Firstly, professor Osuide indicated having been aware of the triple epidemic that was spreading in Kano, he had even witnessed the death of his personal assistant's son. However, Osuide stressed that NAFDAC did not have any knowledge of the trial by Pfizer. In fact, he argued that the pharmaceutical company did not request a formal approval to his institution before starting its experiment. Furthermore, for him this type of requests were usually made for special studies on animals or in vitro tests. At this point, Osuide stated that Pfizer made no formal application to NAFDAC in order to start a clinical trial.

However, what Pfizer did request was an authorization to import Trovan to Nigeria. Osuide indicated that during the time in which the Pfizer's request came to his building, he was outside of the country so the person in charge of the direction, E.U. Usoro, acted for him and analysed the paper. Later, Osuide said he had authorized him to process the application made by Pfizer so this was subsequently approved and immediately the same Usoro drafted a letter addressed to the Food and Drug

Administration (FDA) in United States in which green light was given for the importation of the drug Trovan. For Osuide, there was nothing out of the ordinary in the Pfizer's intention of seeking to import a medicine for research purposes.

Moreover, since Pfizer had already conducted clinical trials in Nigeria in past decades, Osuide believed that the company already knew what the procedures were to obtain the relevant consents in case they want to carry out a trial with human beings. If Pfizer had applied to NAFDAC for conducting a clinical trial, its request would have caught the attention within the institution so it would have been reviewed undoubtedly by a specialized committee. In fact, for Osuide the NAFDAC had during that time guidelines and procedures settled in order to conduct clinical trials, which Pfizer did not comply.

The then Director also contended having not received any document from Pfizer, and even less a paper that expresses the intention to use Trovan in order to fight meningococcal meningitis. Indeed, the only thing that came to his hands was a letter coming from the Nigerian Federal Ministry of Health drafted by Doctor Ike in which actions from NAFDAC regarding the Idris Mohammed's request to stop the clinical trial by Pfizer were required.

In accordance with the NAFDAC applicable regulations, every new drug that is not included on the Nigerian Essential Drugs List needs to be registered by the NAFDAC once this has been subject to multiple clinical trials in different medical centres. Nevertheless, in case of an emergency, a drug can be approved by the NAFDAC as long as it is supplied to a single patient. It is worth noting that this action could only be managed by the Nigerian Federal Ministry of Health.

Moreover, the assistant referred to the Trovan samples recollected by Idris Mohammed and subsequently sent to the NAFDAC for their analysis and stressed that the samples size were too small for analysis, as such they were not tested. Lastly, Osuide stated then that no license or permission was issued from the NAFDAC allowing Pfizer to conduct the clinical trial. "Prof. Osuide viewed the conduct of the trial by Pfizer as an act of deception and misuse of privilege" (Federal Ministry of Health, 2001, p. 40).

b) Doctor Bawa Abubakar

Abubakar joined the NAFDAC in 1996 as a Chief Regulatory Officer in charge of registration, and in parallel, he served as Deputy Director. Doctor Abubakar was interviewed by the investigation committee from a similar perspective to the one proposed for the interview of the General Director. Doctor Abubakar began his interview stating that Pfizer did apply to the NAFDAC since its research team sought to import various doses of Trovan from the United States. In fact, it was confirmed that the Former Director of Inspectorate Doctor E.U. Usoro, accepted the Pfizer's request and he therefore ordered the sending of an authorization that allows the import of Trovan to the Food and Drug Administration (FDA).

However, Abubakar stressed that the authorization issued by Usoro was special and only for research purposes. Regarding the development of the clinical trial, the panel learned from Abubakar that on June 17 1996 the NAFDAC received an application from Pfizer in which the pharmaceutical company requested to conduct a local clinical test with Trovan in order to fight meningococcal meningitis.

In the words of Abubakar, the NAFDAC's answer was negative so no permission was given. This was due to the application from the pharmaceutical laboratory did not comply with the rules and procedures established by the agency to carry out this type of trials. Later, Abubakar revealed to the committee that on July 3 1996 the NAFDAC had received a complaint about an illegal trial with an unapproved drug during the meningitis epidemic in Kano which was issued by Professor Idris Mohammed, who was the Chairman of the Federal Task Force for Control of the Epidemic in the said region.

The letter, dated July 1, 1996, was addressed to the then Minister of Health and copied to the General Director of the NAFDAC. According to the paper, the Director was directed to comment on the letter and likewise to confirm the registration status of the drug. In fact, despite his division was in charge to handle requests concerning the conduction of clinical trials, Abubakar obtained no record of any application or approval for importation or trial of a drug by the name Trovan from Pfizer before June

1996. Subsequently, his division did not guarantee Pfizer permit to import the drug or to conduct clinical trials with human subjects.

From the interviewee perspective, due to the short time interval between the application by Pfizer to the NAFDAC and Professor Idris Mohammed's petition, the pharmaceutical company could have drafted the application as an afterthought with a view to cover up the alleged illegality of the trial reported by the Chairman of the Federal Task Force for Control of the Epidemic. Moreover, after that Pfizer insisted with another application to the NAFDAC for permits to conduct local clinical trials on three different drug products: Cadura, Glucontrol and Trovan. However, as with the first application, Pfizer could not submit the permits and relevant origin certificates of the drugs within the stated deadline therefore no NAFDAC's approval was granted.

3.1.7. Interview with Pfizer representatives

The Pfizer delegation that appeared before the Investigation Committee was represented by Robert Tade, Lere Baale and Doctor Segun Dogunro. The first served as Managing Director of Pfizer Nigeria, Baale was the Pharmaceutical Director for Anglophone West Africa and Dogunro was working as Medical Director for Anglophone West Africa. In their initial statements, the three Pfizer speakers shared the view that it was unimaginable that a pharmaceutical company such as Pfizer would be involved in a clinical study without the approval of the relevant national and international agencies.

The information provided by the Pfizer representatives to the committee regarding the experiment development had a lot of similarities with Doctor Isa Dutse's statements or even the same Pfizer investigator Scott Hopkins. In other words, it was a Phase III random clinical trial in which two hundred patients with an average age of 10 were randomly selected in the Kano Infectious Diseases Hospital in order to be treated with the drugs Trovan and Rocephin (Ceftriaxone).

For Pfizer, the study consisted in a comparative test between Trovan and the ceftriaxone compound. The first was supplied to 99 children while the ceftriaxone was provided to 101. Later, the group of patients under Trovan medication had five deaths as mortality rate while the group medicated with ceftriaxone had six losses. Additionally, Pfizer representatives stressed that the said trial was the first through which Pfizer conducted a phase III clinical trial in Nigeria. It was also indicated that Trovan had already tested in countries such as South Africa and Egypt and that in every time the purpose of the trials was purely philanthropic.

On the other hand, Both Tade, Baale and Dogunro contended that their company did not send a request to NAFDAC in which permission to register the drug Trovan had been asked, since Pfizer had no intentions to register it. In addition, representatives stated that no report of the study was sent to any Nigerian authority. With regard to consent, Pfizer's representatives stressed that their group of researchers could not obtain written consent from the parents of the children treated. However, verbal consent was indeed achieved through the local nurses.

The assertions from the three Pfizer representatives allow to conclude several issues. Firstly, the company conducted a clinical trial with Trovan on the premise that NAFDAC's authorization to import Trovan for research purposes was enough to carry out the test in human subjects. Second, the clinical trial was conducted without an ethics committee's overview. Furthermore, Pfizer did not follow the necessary procedures for the conduct of the trial since there was no formal application to NAFDAC in which the supply of a new drug to children is required.

Thus, while Pfizer was allowed to use the Kano Infectious Diseases Hospital, such authorization was made on the basis of its charity policy and its goodwill to offer an intervention program in order to control the epidemic. Finally, despite Pfizer representatives kept repeating that their company informed the Nigerian Ministry of Health about the clinical trial, officials of the latter denied such allegations assuring that a clinical trial with Trovan was never mentioned in the letters.

3.2. Overall reflexions on Trovan use

Prior to the clinical trial with Trovan in Kano, reports had been made public by Pfizer which demonstrated that the mentioned drug had already been tested in normal volunteers who suffered from meningococcal meningitis. Those reports were submitted during the First International Paediatrics Infectious Diseases Conference in California in 1995. However, according to different testimonies from the principal actor linked to the Trovan clinical trial in Kano, the use of this drug during the test was apparently the first time that oral Trovan was tested directly on children.

Likewise, after the Pfizer clinical trial there was no evidence from entities such as the World Health Organization or the Nigerian Federal Ministry of Health in which Trovan use is recommended for the treatment of meningitis. Among the documents provided by the Pfizer representatives to the Investigation Committee, records and reports of the recruited patients for the trial were found. When analysing these papers, the committee found that Trovan adverse side effects caused serious damage to certain body systems. For instance, there were patients who presented arthritis, dizziness, headache, joint pain, motor nerve paralysis, etc.

In referring to the clinical trial protocol, it is worth noting that there were noticeable procedural biases, the most important among them being the one regarding the patient 0069's treatment. As detailed in previous chapters, this child received continuous oral doses of Trovan for three days, after which she died. In this case, deviation from the approved protocol consisted in not having changed therapy or implemented an alternative drug instead of having insisted with Trovan.

It must be pointed out that despite Pfizer research team being aware of the fact that during the tests with Trovan in animals prior to the clinical trial in Kano, significant liver damages emerged. However, the protocol did not include the possibility of conducting medical check-ups in order to verify the condition of the liver of the patients once the clinical trial had ended.

Moreover, although the fatality rate for the group of patients medicated with Trovan was relatively slow, 5.05% considering five deaths of the 99 children treated during the trial, the major concerns focus on the Trovan's collateral effects. The most common side effects associated not only with Trovan but with most antibiotics are usually nausea, diarrhoea, vomiting, skin rashes, fever, etc.

However, subsequent studies conducted in 1998, when Trovan had already been launched on the market, concluded that there was a high incidence of liver damages in patients, who required sometimes a liver transplant. "A 68-year-old man was treated with trovafloxacin for 7 days. One week after the end of antibiotic therapy, he presented because of a 3-kg weight loss, rash, pruritus, and dark urine. A liver biopsy specimen showed predominantly centrozonal necrosis" (Lucena, et al., 2000, p. 401).

In 2001, an article addressing the follow-up of an adult patient progression who had been medicated with Trovan was published. "We report the clinical course and computed tomography findings in a patient who developed acute liver failure shortly after commencing treatment with trovafloxacin. Extensive hepatic necrosis occurred and the patient ultimately died of her liver disease" (Pannu, Gottlieb, & Fishman, 2001).

On the basis of this type of findings, the Food and Drug Administration (FDA) alerted physicians on the possible liver damages that Trovan was causing, so the agency instructed that the drug should be prescribed only to patients who have not presented liver problems in the past. "Trovan should not be used for more than two weeks, and therapy should be discontinued if the patient experiences any clinical signs of liver dysfunction" (Federal Ministry of Health, 2001). As mentioned above, the Trovan marketing was banned in 1999 due to frequent drug adverse reactions. "The manufacturer withdrew trovafloxacin from the European markets on June 18, 1999. The drug remains available in the United States for very restricted indications" (Lucena, et al., 2000, p. 400)

3.3. Conclusions on the report issued by the Investigation Committee

The information gathered in the Investigation Committee's report further clarifies the overview on which of the actors involved in the experiment took greater responsibility for the 11 deaths. Furthermore, the mentioned report would contribute after the fact for Nigerian authorities to take legal action against Pfizer in international courts.

After analysing the different interviewees' statements that were compiled within the research report issued by the Investigation Committee, it can be asserted that:

- a) Pfizer's fundamental purpose to intervene in the Nigerian epidemic in Kano was only to test its new drug. Additionally, based on the arguments from the Pfizer representatives and the Infectious Diseases Hospital's officials, it can be said that the principal investigator of the trial was Doctor Scott Hopkins instead of Doctor Isa Dutse.
- b) The Pfizer research team treated 200 patients during the clinical trial, of an estimated total of 110,000 victims of the epidemic. Nevertheless, this team did not follow the internal procedures established in order to conduct clinical trials despite the team was well informed of the guidelines both from the Nigerian Federal Ministry of Health and the NAFDAC.
- c) The NAFDAC, as a Nigerian regulatory agency, failed in its duty to stop the clinical trial conducted by Pfizer and for having taken no concrete action once this was warned of the irregularities from the Chairman of the Federal Task Force for Control of the Epidemic in Kano.
- d) The alleged approval from the National Agency for Food and Drug Administration and Control NAFDAC to conducting the clinical trial with Trovan was in fact a permission to import this drug to Nigeria only for research purposes.

- e) The Nigerian Federal Ministry of Health neglected to safeguard the health of the Nigerian people by not giving appropriate follow-up to the letter addressed by the Chairman of the Federal Task Force Professor Idris Mohammed. Furthermore, this very institution erred in not strengthening the Federal Task Force for Control of the Epidemic neither administratively nor financially.
- f) Although representatives from the Kano State Ministry of Health stated having had no knowledge of any clinical trial, it is assumed that their General Director was aware of the experiment and could therefore have easily enforced the Professor Idris Mohammed's decision to stop the trial.
- g) The warnings issued by Professor Idris Mohammed about the Pfizer's trial did not receive the necessary attention from the Kano State Ministry of Health and the Nigerian Federal Ministry of Health, although he had indicated the possible damages to the health of patients who took part in the experiment.
- h) The clinical trial by Pfizer violated the Declaration of Helsinki on the Ethical Principles for medical research involving human subjects; the Food, Drug and Related Products Nigerian Decree No 19, and the United Nations Convention on the Rights of the Child adopted by the General Assembly on 20 November 1989.

3.4. Lawsuits against Pfizer Corporation as a result of its clinical trial in Nigeria

Both the articles published by American newspapers and the investigation report issued by the Nigerian Federal Ministry of Health on the Pfizer's experiment contributed to the families of the victims taking legal actions against the pharmaceutical laboratory. Since 2001, Pfizer has had to deal with a series of allegations which contained different charges. However, all of them coincided that the pharmaceutical corporation violated international instruments on medical research involving human subjects.

3.4.1. First Lawsuit: Abdullahi vs. Pfizer

On 29 August 2001 a group of parents of the victims from the clinical trial with Trovan sued Pfizer in the United States District Court for the Southern District of New York under the Alien Tort Claims Act. This Statute is a section of the United States Code and states that: "The district courts have original jurisdiction over any civil action by an alien for a tort only, committed in violation of the law of nations or a treaty of the United States" (Burley, 1989, p. 461).

Plaintiffs alleged that their children suffered grave injuries from an experimental antibiotic administered by defendant Pfizer without informed consent. Additionally, Pfizer was also accused of having violated the Nuremberg Code, the Declaration of Helsinki, the International Covenant on Civil and Political Rights and customary international law. It is worth stressing that this lawsuit was called Abdullahi vs. Pfizer, Inc.

In response, Pfizer filed a motion to dismiss the said allegations pursuant to Rule 12 of the Federal Rules of Civil Procedure, alleging that the Plaintiffs' fail to plead a violation of the law of nations, because their actions did not fit the narrow exceptions when a private party will be held liable for the law of nations. Nevertheless, the court denied this motion to dismiss on these grounds, due to the complaint sufficiently alleged that Pfizer had worked in concert with the Nigerian government, thereby the pharmaceutical corporation acted as a de facto state actor. Then, Pfizer sought dismissal on grounds of forum non conveniens, which establishes: "A court may refuse

to take jurisdiction over matters where there is a more appropriate forum available to the parties” (Barreth Jr, 1947, p. 387). In this case Pfizer was aiming that litigation is conducted in Nigerian courts.

Concurrently, plaintiffs claimed that the Nigerian court system was corrupt and could not be able to provide an adequate alternative forum. However, after a careful analysis, the court ultimately found that Nigeria did provide an adequate alternative forum and therefore accepted Pfizer’s motion and dismissed the applicant’s request. In other words, the court ruled in favour of transferring the case to Nigeria and granted the defendant’s motion to dismiss this action on grounds of forum non conveniens and Pfizer must consent to suit and acceptance of process in the said country. This decision led victims’ counsels to appeal from the District Court’s order of final judgment to the United States Court of Appeals for the Second Circuit. Once the appeal was issued, the Court of Appeals reviewed the forum non conveniens dismissal under the “clear abuse of discretion” standard.

The Court of Appeals then revisited the motion to dismiss on grounds of adequate alternative forum. In this instance, plaintiffs argued that under normal circumstances, Nigeria appeared to be an adequate forum. Nevertheless, there are situations in which the conditions in the foreign forum plainly demonstrate that plaintiffs are highly unlikely to obtain basic justice, so a defendant’s motion to transfer the case to Nigeria must be denied. Next, the Court for the Second Circuit noted that plaintiffs had submitted a certain number of affidavits from the American Ministry of Foreign Affairs and United Nations officials in order to buttress their claims about corruption in the Nigerian judiciary.

Subsequently, The Court of Appeals acknowledged that during the process, both parties had requested judicial notice of facts contained within the record of a parallel proceeding involving different claimants in a Nigerian Court. As a result, this court declined to take judicial notice of the case and opted instead to vacate the district court’s dismissal on grounds of the doctrine of Forum Non Conveniens and remanding again the litigation to that court to consider the implications of the case.

Once the Court of Appeals vacated and remanded the case, the United States District Court for the Southern District of New York addressed again the dual grounds from the dismissal motion. After conducting a comprehensive analysis, the Southern District Court granted Pfizer's dismissal motion under Rule 12 of the Federal Rules of Civil Procedure and found also that case Abdullahi vs. Pfizer was not going to be conducted in American courts.

Illustration 6: Zubairu Shaba shows a picture of his son, one of the 11 children who died during the Pfizer's clinical trial with Trovan.



Source: (De Cózar, 2010)

Obtained from El País:

http://internacional.elpais.com/internacional/2010/12/09/actualidad/1291849238_850215.html

3.4.2. Second Lawsuit: Adamu vs. Pfizer

In November 2002, a second lawsuit was issued in the United States against Pfizer. Plaintiffs were also a group of Nigerian minors affected by the clinical trial with Trovan. This demand was known as Adamu vs. Pfizer and the complaints were based likewise on alleged violations under the Alien Tort Claims Act and the Connecticut's law. "The Connecticut Unfair Trade Practices Act (CUTPA) allows the Commissioner of Consumer Protection to legally pursue persons or businesses who have used unfair or deceptive trade practices with consumers" (Connecticut Department of Consumer Protection, 2016).

The District Court started analysing the choice of applicable law principles. In doing so, Connecticut's qualified "lex loci delicti" doctrine was studied by the court, which refers to the law of the place where the tort was committed and stated that it is Nigerian law which governs over Connecticut law. In that regard, the plaintiff's claims were dismissed. Furthermore, besides the lack of subject matter jurisdiction, under both the Connecticut statutory and the Alien Tort Claims Act causes of action, the court also granted in 2005 the Pfizer's motion to dismiss on grounds of Forum Non Conveniens.

Thus, the Adamu vs. Pfizer litigation became the second of the total of lawsuits issued by Nigerian groups against Pfizer in American courts that were dismissed. "According to the judge, the plaintiffs had failed to show a sufficient legal source for an international prohibition of non-consensual medical treatment." (Business and Human Rights Resource Centre, 2014). However, in January 2009 the US court of appeals reversed the lower courts' dismissal of the Pfizer's lawsuits. The said court found that the prohibition of non-consensual medical experimentation on humans is binding under customary international law.

Later, in July 2009 Pfizer petitioned the US Supreme Court asking it to hear an appeal of the Court of Appeals' January 2009 ruling. As a result, in November of the same year the Supreme Court asked the US Solicitor General to submit a brief to the court in this litigation. In May 2010, the Solicitor General submitted this brief to the court urging the court to deny Pfizer's petition.

On February 23, 2011, the parties announced that they had reached a settlement in this case. The terms of the settlement remained confidential. Nonetheless, a joint statement issued by the parties explained that the plaintiffs will join the Meningitis Trust Fund process, which was ongoing and being managed by an independent board of trustees in Kano, Nigeria.

3.4.3. Third Lawsuit: Nigerian Government vs. Pfizer

On May 2007 the Kano state brought criminal charges and civil claims against Pfizer seeking over \$2 billion in damages and restitution. Most of accusations against the transnational corporation referred to criminal conspiracy and killing of innocent people. “The lawsuit claims 2 billion dollars in damages (El Mundo, 2007). Since November of the said year both parties established private settlement talks in order to reach an extrajudicial settlement. In late January 2009, the state court adjourned the case until late February to allow more time for the parties to reach a settlement out of court.

On the other hand, on June 2007 the Nigerian federal government filed suit against Pfizer and several of its staff members seeking specifically \$6.95 billion in damages for the deaths of children involved in the Trovan drug trial at the Kano Infectious Diseases Hospital. According to this lawsuit, Pfizer did not obtain approval from the relevant regulatory agencies. The case was adjourned until June 26 of that year.

In late January 2009, the Nigerian federal government informed the court that an agreement with Pfizer in order to settle the lawsuit out of court had been achieved. Further, in April 2009 the Kano state government and Pfizer announced that they have reached an agreement on the broad terms of an out-of-court settlement. “Pfizer and Kano state reached a final settlement in August 2009” (Business and Human Rights Resource Centre, 2014).

Both parties agreed to a settlement figure of \$75 million. The amount of the settlement would be paid as follows: \$35 million to create a fund for people who was recruited for the clinical trial, \$30 million that would underwrite health care initiatives in the Kano region and finally \$10 million that would be allocated to pay the state's legal

costs. Through this agreement, a series of litigations between Pfizer and the Trovan's victims were ended, thirteen years after the clinical trial in Kano was conducted.

Illustration 7: A mother of a victim of Trovan receiving a refund check



Source: (Redacción Pueblos, 2012)

Obtained from [revistapueblos.org](http://www.revistapueblos.org/?p=1567): <http://www.revistapueblos.org/?p=1567>

General Conclusions

As already stated at the beginning of this research paper, the present case study is not at all an isolated event. In fact, it may be argued that it is the result of a succession of significant errors and anomalies that appeared not only at the level of regulatory and control entities but also within government bodies and transnational corporations. Pfizer is the world's largest pharmaceutical laboratory and its researchers continually conduct tests with novel drugs, so the majority of the staff is completely familiar with all standard protocols required to conduct clinical trials.

With regard to the Trovan trial case, the body of principles that governs such practices is the Declaration of Helsinki and Pfizer Company violated articles from this set of principles, which refer to informed consent that must be given by patients. Nowadays, it is a fact that the major pharmaceutical companies make a profit from the health of millions of people around the globe. In 2006, Pfizer had declared net sales of \$48.37 billion, without considering the proceeds from the sale of its Consumer Healthcare Division acquired by Johnson & Johnson. "Johnson & Johnson reached an agreement for the acquisition of the Pfizer's consumer health care division, paying \$16.6 billion." (Saul, 2006).

Either way, whether or not the clinical trial with Trovan in Kano had informed consent from the patients, this caused an unacceptable number of deaths and irreversible physical damages to children. Furthermore, the impact of the experiment led many Nigerian sick Nigerian people to reject vaccination programmes headed by the World Health Organization in 1996. The Pfizer trial marked the start of a domino effect where more and more patients from developing countries became suspicious of Western medicine and prefer not to receive appropriate treatment rather than be intentionally infected with a disease.

As a result, many international aid agencies have described these attitudes and behaviour of patients as unintelligent or a result of ignorance but without analysing its own actions to such reactions. However, it should not be forgotten that Pfizer conducted its clinical trial with Trovan in the midst of a serious meningitis epidemic which extended all over sub-Saharan Africa, thus taking advantage from local physicians and authorities' desperation who streamlined approval procedures to conduct the trial possibly because they saw in Pfizer a helping hand.

Currently, due to the effects of cases such as that of Pfizer and others, the battles between countries and pharmaceutical corporations do not only happen as a result of the enforcement of patents, but also by existing mistrust towards drugs coming from these pharmaceutical transnational firms. This same distrust has also generated grave direct confrontations between corporations and countries. There has also been discussion on the close liaisons that inspection agencies maintain with the pharmaceutical industry which has caused the vast majority of pharmaceutical laboratories to move like a fish in water when it comes to request and obtain permits in order to test or market new products.

During the Pfizer's clinical trial, The Food and Drug Administration (FDA) was the agency that did not correctly overview the design stage, testing and marketing of Trovan. In fact, only after the said drug entered the market, the FDA established recommendations and restrictions pertaining to Trovan's application. The lack of regulation of pharmaceutical corporations not only have caused damage in developing countries. For example, the mere fact of having launched Trovan to the market while dismissing its side-effects caused several hundred cases in which patients from Europe and United States experienced serious liver damage in some cases irreversible.

On the other hand, the failure to comply with international human rights and children's rights treaties is considered a crime against humanity. The fact that a transnational pharmaceutical corporation uses child population from a foreign state as guinea pigs to test novel drugs represents a move that disregards fundamental rules of customary international law. Unfortunately, in most of litigations, where the parties hold different nationalities, the legal technicalities, applicable law and competent jurisdiction almost

always outweigh the need to properly sanction those who attempt against the life of defenceless and unprotected people.

Pfizer was sued by lawyers of the victims from the clinical trial in Kano. Nonetheless, these lawsuits could not be addressed in international or American courts. Although the pharmaceutical company compensated the Nigerian government, this action was the result of out-of-court negotiations between the parties, and not a Court decision. Additionally, if one compares the amount of \$75 million dollars which Pfizer paid to the local government, it can indeed be concluded that this figure represents less than 1 % of the company's total quarterly earnings.

To conclude, it turned out to be quite cheap for Pfizer to deliberately put hundreds of human lives at risk. Experiments such as Pfizer in Nigeria contribute to the increasing awareness of how the big pharmaceutical corporations use African countries as test scenarios without regard of the damage that they can inflict through their politics of ambition and greed:

So who has got away with murder? Not, of course, the highly respectable pharmaceutical firms, which have enjoyed record profits this quarter. No, there are no murders in Africa. Only regrettable deaths. And from those deaths we derive the benefits of civilization, benefits we can afford so easily... because those lives were bought so cheaply. (Williams & Meirelles, 2005).

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