

Case study on drug testing in nigeria

Business



Drug Testing in Nigeria Table of Contents Introduction3 Background3-4
Ethical Dilemma4-5 Situational Analysis5-6 Stakeholder Analysis6-7 Analysis
Based on Ethical Theories7-8 Conclusion and Recommendations8-9

References10 Drug Testing in Nigeria Introduction ' What if a drug company
experimenting on critically ill children does not get the proper Parental
consent, 11 of those children die and a whistleblower is fired? ' (Perlroth,
2008) This paper will discuss the issues caused by the actions taken
byPfizerPharmaceutical Company. First, we will discuss the ethical dilemmas
caused by the testing and identify the factors related to individuals involved;
companies and managerial practices and policies, as well as factors that
helped create the ethical dilemma. Then we will identify the stakeholders
and discuss how the factors that cause the dilemma affect them. Third, we
will analyze the ethical dilemma based on ethical theories.

Finally, the paper will conclude with analyzing whether Pfizer took the right
action and if not what action should have been taken. BackgroundA group of
Nigerian families has taken legal action against the pharmaceutical
company, Pfizer. The lawsuit, which was filed in a US court, claims that the
families' children were entered into a trial of Pfizer's Trovan (trovafloxacin)
for bacterial meningitis in 1996 without informed consent. The families
accuse the US-based drug company of violating " international law, federal
regulations, and medical ethics, in its zeal to carry out its test" (Ahmad,
2001). According to the Trovan Fact Sheet 1996 marked the beginning of the
most serious meningitis epidemic ever ecorded in Nigeria. The epidemic took
almost 12, 000 lives over a six-month period, affected close to 110, 000

people, and constituted a severe public health crisis for the government of Nigeria.

Amongst all recorded cases, the fatality rate was as high as 20% in the first weeks, and eventually decreased to 10.7%. There were hundreds of children brought to hospitals in the city of Kano on a daily basis. The Leading physician of Pfizer thought this epidemic presented a unique opportunity to test Trovan pills on children. Most of the patients in Nigeria were very sick, had no other medication and Trovan had a good chance of saving their lives (Spar and Day, 2006, p.

2) The Nuremberg Code of 1946 was the first international document to give guidance on the ethics of medical experimentation on human subjects. One of its core principles was that “ medical research involving human subjects is only justified if there is a reasonable likelihood that the population in which the research is carried out stand to benefit from the results of the research” (HHS, 2001). According to the Trovan Fact Sheet Pfizer obtained all required approval from federal and state government in Nigeria prior to conducting the Trovan study in Kano. Pfizer has at least 12 letters with dialogue between the company and Nigeria’s Ministry of Health and Ministry of Finance as well as the U. S.

Food and Drug Administration, discussing and approving the study. Ethical Dilemma Pfizer faced the ethical dilemma of whether to stay out of Kano or to run the clinical trials, because of the chaos of the meningitis outbreak the integrity of the clinical trial could not be guaranteed (Spar and Day, 2006, p.

1). Several things caused Pfizer this dilemma. On one hand, they had to decide whether the trial was worth the risks involved.

Risks such as conducting a clinical trial in the conditions of Kano as the condition of the facilities could undermine any valid medical research and the effort required to start a trial could take away resources from the sick. Then they had to decide whether they wanted to personally-conduct the trials or outsource it. They also had to obtain permission from a hospital ethics committee and complete the trial at a cost less than what they invested. There was also the risk of families suing if the drug did not work, the government could seek retribution, and the FDA could refuse to consider the results of the trial because of the condition of Kano. In addition, there was the pressure to finish testing and get FDA approval.

On the other hand, the children and people of Kano needed medical aid more than anything but only a few were receiving it, in the form of Intramuscular antibiotics that were difficult to administer. Trovan promised a quick cure with a bottle of pills (Spar and Day, 2006, p. 11). According to one drug researcher, it ' was kind of a desperate time for Nigeria, they were happy to have anyone come in and do just about any kind of work' (Stephens, 1996/7). Pfizer had already tested a combination of oral and intravenous Trovan successfully on two strains of bacteria known to cause meningitis. Scientific research strongly suggests that Trovan would be effective against the Nigerian bacteria (Spar and Day, 2006, p.

10). Another ethical dilemma could be conducting medical experiments without the consent of the Families as well as exploiting of a developing

country. Situational Analysis Several factors helped to create the ethical dilemmas addressed above. Pfizer pharmaceutical company has an estimated market value of Troval once the FDA approves all its uses. Upon approval, it would be worth \$1 billion. It was also critical for pharmaceutical companies to have an uninterrupted flow of new drug discoveries, as it was essential for growth and profitability (Spar and Day, 2006, p.

3). According to scientist, overseas research has many benefits. Infectious disease spread seasonally around the world, which allows pharmaceutical companies to test drugs by going to the disease rather than waiting for it to surface in a particular country (Spar and Day, 2006, p. 6). Nigeria's political state also had an effect on the ethical issues above. There standing in the international community was unstable due to a disbanding of government assembly.

Several nations imposed sanctions. There economic posture also was not very good. The country's public health network was also very poor; the government only spent US \$21 million on health care of the population. The worst part of this was that meningitis bacteria that were not easily treated struck Nigeria. There was no vaccine or oral treatment for the disease. Pfizer wanted to prove that Trovan was more effective and easier to administer (Spar and Day, 2006, p.

10) Stakeholder Analysis The ethical issues stated above affect the Nigerian Families, the pharmaceutical company, customers, communities, and stockholders. The Nigerian Families, customers, and communities are affected by Pfizer's decision to conduct trials in Nigeria using the drug

Trovan. There are two ways they could be affected. The medication could have had an adverse effect on them as it did with the 11 children killed mentioned in the lawsuit filed against Pfizer (Ahmad, 2001). There were also 14-recorded cases of active liver failure (1999). On the other hand, it could have had a positive effect such as curing their meningitis and preventing the spread of meningitis, which helps the community.

According to the Trovan fact sheet, Pfizer's contribution during the 1996 meningitis epidemic in Nigeria was not limited to treating patients in the Trovan clinical study. The company donated over \$18 million to Kano State in medicines, equipment, and materials to help fight the concurrent epidemics involving associated diseases, such as cholera and measles, ongoing at the time. The pharmaceutical company is also affected by the dilemma mentioned above. It can be affected in a positive or negative way. If the FDA accepted the test and approved the drug then the company gains another drug and increases its market value to \$1 billion, which benefits the company and stockholders (Spar and Day, 2006, p. 1).

The contributions that Pfizer made to Nigeria help the reputation of the company. Stockholders see that the company is committed to helping the community. The drug had a negative effect and caused death and illness, this is not good to the company's reputation. It affects the price of the company's stock in a negative way and it gives the company a bad reputation. This reputation will prevent customers from supporting the company and buying the products, therefore affecting profits, which also affect stockholders.

Analysis based on ethical theories According to lawsuits filed against Pfizer, some of their actions were not legal. Nigerian Families accused Pfizer of conducting a trial without formal consent, which the Families said violated international law, federal regulation, and medical ethics. They also accused Pfizer of manipulating the experiment leading to injury and death (Mokhiber, 2003). Pfizer responded to the suit stating that Nigerian authority approved the Trovan trial. In addition, they stated that they obtained consent from the Families involved in the trial as well as explained the specifics of the trial.

The study was well conceived, well executed, and saved lives" (Ahmad, 2001) In my opinion, society does not view the clinical trial of Trovan that was done with Nigerian children as acceptable. This is apparent in the lawsuits that were filed and the settlement that was rewarded. Society expects companies to help their community not cause pain on its members. Even though the pharmaceutical company stated in the Trovan fact sheet that it contributes to the community, the fact that 11 children died while conducting this experiment had a negative effect on the company as well as the community from which the children were killed. I also believe that Pfizer acted out of egoism. I believe that even though they contributed to the community and had some success with the FDA approval of Trovan, they acted purely out of self-interest.

They used the meningitis outbreak in Nigeria to do their final testing of Trovan. They needed to test Trovan pills on children and the outbreak in Nigeria was the perfect opportunity. According to the company, they obtained all necessary permission from the Nigerian government; however, that could be interpreted as them exploiting a developing country. At the <https://assignbuster.com/case-study-on-drug-testing-in-nigeria/>

time, the Nigerian government was unstable and did not care about health care (Spar and Day, 2006). Conclusion and Recommendation Did Pfizer take the right action by going to Nigeria to do their final test of Trovan on children that were suffering from meningitis? It is understandable that they had a drug that they thought might help the people of Nigeria, however they were not sure of the effect it would have on children.

The test they did on animals had negative result and so they could not be sure of the effect it would have on children. I am not sure if I would have taken that risk. My recommendation is that the company should not have used that opportunity to do the final test on Trovan. Mainly because it involved doing a test on children, especially when test that were ran on animals had negative results. My recommendation is that the company should have found some other means of doing their final testing of Trovan. Even if they were to use Nigerians, maybe it would have been ok at a different time.

At the time of the meningitis outbreak, there was mass confusion and it did not seem like a good time to make all the coordination for the trial. Also with the political and economical unrest, the timing was just bad. My recommendation for policies to prevent future dilemma is to have set policies that govern these situations. Policies that mirror current laws and systems in place that verify that all rules are followed which in turn covers the company and protect it from lawsuits. I would also make sure that stakeholders view the business as being responsible toward them and corporate citizens.

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