Ethical Considerations of Pharmaceutical Colonialism

Alexandra Lee

University of Kansas School of Nursing

Alexandra Lee is a native of Prairie Village, Kansas. While at the KU School of Nursing she obtained an Endowment Scholarship. Her scholarship achievements are recognized by receiving the Golden Key award. She is a member of Delta Chapter-Sigma Theta Tau International. Her future plans include becoming a neonatal nurse practitioner. While at the KU SON she was selected to travel to Johannesburg, South Africa where she participated in providing nursing care to the countries citizens. Alexandra wishes to recognize the support she has received from her family, especially her mother and father, in supporting her through her nursing and college education

Introduction

The complexity of the ethical issue being depicted is one that has transcended generations, bringing light to issues such as human rights, distributive justice, and the worldly effects of globalization. The subject termed 'pharmaceutical colonialism' is in part characterized by the colonization of developing countries in efforts of contributing to the sphere of pharmaceutical knowledge. The purpose of this descriptive essay is to enhance the readers knowledge of ethical considerations of importance to nursing regarding the conduct of clinical trials in developing countries. The significance of comprehending pharmaceutical colonialism is due to the gravity that the subject has on human rights globally. The human rights that are at greatest concern of being breached in medical testing include autonomy, nonmaleficence, respect for persons, and veracity. Considering that human rights do not only pertain to medical personnel, but to all persons globally, preserving the sanctity of these rights is imperative to continuation of the livelihood of each individual.

Nigerian Lawsuit Uncovers Modern Day Pharmaceutical Colonialism

During the past decade, the country of Nigeria filed a lawsuit against the North American drug company, Pfizer. This lawsuit was brought forward because research antibiotics were given to Nigerian children. The antibiotic in question is called Trovan, a medication that was approved by the Federal Drug Administration for adult use only under specific circumstances that included beginning therapy in health care settings and with treatment lasting no longer than 14 days (CNN, 1999). Due to Trovan's aggressive nature on fighting bacterial infections, Pfizer was anticipating a gross worth of $1 billion per year from its administration (Stephens, 2007). However, claims of extensive liver damage in adults were reported by use of Trovan, and the Federal Drug Administration restricted the use of the medication in 1999 (Stephens, 2007).

Meanwhile, an epidemic of meningitis was occurring in Nigeria and neighboring countries, causing countless deaths. In response, Pfizer conducted a clinical trial for the administration of Trovan and its hypothesized effectiveness in treating pediatric meningitis (Stephens, 2007). However, Trovan had never been approved for pediatric uses by the US Federal Drug Administration (FDA). The medication was administered in field hospital settings, in Kano, Nigeria. During the same time as Pfizer's clinical trial, Doctors without Borders were dispensing approved antibiotics, and, according to a Nigerian study, "Trovan had a survival rate that was at least as effective as the best treatment available at Kano's Infectious Disease Hospital" (Hladky, 2010, p. 2). Stephens reported that eleven children died during the experiment and 189 suffered blindness, deafness, and severe mental disabilities (2007).

Soon after Pzifer's claims of Tovan's survival rates, reports surfaced accusing Pfizer of fraudulent documents and inadequate consents pertaining to the study's methods. This was confirmed by the lead researcher, Abdulhamid Dutse, who admitted to forging letters after the experiment. Furthermore the Nigerian ethics committee never gave its consent to Pfizer to administer Trovan to pediatric patients (Stephens, 2007). Dutse stated that he, "then backdated the letter to March 28, 1996—a week before Pfizer's experiment began" (Stephens, 2007, p. 3). It has also been alleged that Pfizer failed to inform families of Trovan's side effects, and that a medical group, Doctors Without Borders, was concurrently administering "a conventional and effective treatment" free of charge at the same hospital (Richey, 2010, p. 3). The lawsuits also bring into question whether the physicians, during the clinical trial, administered high enough doses of the approved antibiotic to the children in the control group (Hladky, 2010).

Pfizer claims that the efforts by the Nigerian government to support claims that they mislead the country or families of Nigeria in any way is false. Pfizer goes on to state that the

company's intent "was to bring a life saving, innovative, and cost-effective form of antibiotics that could be used effectively in a meningitis epidemic in the developing country" (2007, p. 1). However, many others believe that Pfizer conducted the experiment and took advantage of the vulnerability of a country unable to defend its people from nonconsensual clinical trials. This was done to promote Western pharmaceutical expansion, and that this type of clinical trial would not have occurred with American children (Richey, 2010).

The United States Supreme Court allowed Nigerian families to sue Pfizer under the premise of the Alien Tort Statute, allowing for the trial to take place in the United States. Prior to this current lawsuit, the state of Nigeria brought legal claims against Pfizer from the damages during the clinical trial. Reports are that this claim was settled for $75 million. In part of the settled amount, Pfizer had agreed to grant a trust fund for the families and children involved in the lawsuit estimating at $35 million of the $75 million (Hladky, 2010, p. 4). However, "the Nigerian government's cases were not brought on behalf of those trial subjects and do not resolve Nigerian families' claims in the U.S. lawsuit" (Bollyky, 2009, p. 3).

Nursing Implications of Pharmaceutical Colonialism

One of the most relevant nursing implications of this ethically, controversial issue is that of cultural awareness. It is critical for nurses to be informed not only about the health care in their own country, but health care policies, or lack thereof, in other countries. Nursing as a profession treats people from a variety of cultural backgrounds, and for nurses to be considered culturally competent the profession must have an understanding of health issues in other countries.

The ineffectiveness of producing informed consents appears to be a consistent sub-issue of pharmaceutical colonialism. The definition of informed consent pertains to two

parts: that the participation is done voluntarily and that the participant is informed in entirety (Guido, 2010). Informed consent, even though the process has been established both nationally and internationally, still presents obstacles to researchers (Marshall, 2007). The participant's understanding is a key feature of informed consent, and even so, comprehension has posed various obstacles in ensuring adequate informed consent due to medical jargon and complicated experimental protocols (Marshall, 2007). For example, an HIV vertical transmission study, target population of South African women, found that even though consent was voluntary, many of the women participated in the study because they believed that they were not allowed to resign their participation, or that their child would therefore receive no prophylactic care (Marshall, 2007). Patricia Marshall noted that in order to ensure a participant's understanding of the informed consent process, that there should exist a process of testing the informed consent to ensure it's ability of comprehensiveness before the recruitment development commencement (2007).

Conclusion

As a result, it is our duty as nurses to be aware of the cultural differences that may arise when presenting a document of informed consent to the patient, and to allow for any interventions, such as a translator, to be present in order to ensure that the patient not only understands the procedure, but also alternative treatments, side effects, and expected outcomes. Thus, in essence, being a patient advocate.

The accepted definition of nonmaleficence is to do no harm. The condition is not whether a clinical trial originated out of deceit or humanitarianism, the far more crucial concept is the applicability of that clinical trial to its target population, and the beneficial or harmful effects a trial has on that target population. Chippaux states that,

> Only drugs that meet Africa's needs should be tested there. They should satisfy specific criteria determined by their potential use. They should be effective and, in given the inadequacy of local mechanisms to monitor side effects, harmless. They should be accessible, and easy to distribute, prescribe, and administer. They should… encourage the patient adherence to treatment, compensating for weakness in the health system (2005, p. 4).

Therefore, the immoral fault that lays with Pfizer is the African children's deaths contributed by an antibiotic whose optimistic purpose was to save the lives of American children. To quote John le Carre's screenplay, *The Constant Gardener*, there are "only regrettable deaths [in Africa]. And from those deaths we derive the benefits of civilization, benefits we can afford so easily… because those lives were bought so cheaply" (2005).

References

Bollyky, T. (2009, August 27). Potential U.S. Supreme Court Case on Nigerian Drug Trial Presents Mixed Picture for Global Health. *Global Health Policy*. Retrieved from http://blogs.cgdev.org/globalhealth/2009/08/potential-us-supreme-court-case-on-nigerian-drug-trial-presents-mixed-picture-for-global-health.php

Cable News Network. (1999, June 10). FDA Warns Doctors About Antibiotic Trovan. *CNN*. Retrieved from http://www.cnn.com/HEALTH/9906/10/antibiotic.warning/index.html?iref=allsearch

Channing-Williams, S. (Producer), & Meirelles, F. (Director). (2005, August 31). *The Constant Gardener* (Motion Picture). United Kingdom: Focus Features.

Chippaux, J. (2005, August 11). Pharmaceutical Colonialism in Africa. *Le Monde Diplomatique*. Retrieved from http://mondediplo.com/2005/08/11pharma

Hladky, G. (2010, July 27). Lawsuit Alleges that Pfizer Botched Test Involving Hundreds of Nigerian Children. *New Haven Advocate*. Retrieved from http://www.newhavenadvocate.com/featured-news/lawsuit-alleges-that-pfizer-botched-test-involving-hundreds-of-Nigerian-children.

Marshall, P. (2007*). Ethical Challenges in Study Design and Informed Consent for Health Research in Resource-Poor Settings.* Retrieved from www.searo.who.int/LinkFiles/RPC_Ethical_Challenges.pdf

Pfizer. (2007, July). *Summary: Trovan, Kano State Civil Case – Statement Defense*. Retrieved from http://www.pfizer.com/news/press_releases/pfizer_press_statements_archive.jsp

Richey, W. (2009, June 29). Supreme Court Allows Drug Test Case Against Pfizer to Proceed. *The Christian Science Monitor*. Retrieved from http://www.csmonitor.com/layout/set/print/content/view/print/311483

Stephens, J. (2007, August 8). Pfizer Seeks Dismissal of Lawsuit in Nigeria – Company Defends Tests on Children, Says Lives Saved in Epidemic. *Washington Post*. Retrieved from http://infoweb.newsbank.com/iw-search/we/InfoWeb