

Globalization of Clinical Trials: Ethics and Conduct

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Abstract

The underlying motif of the article "Ethical and Scientific Implications of the Globalization of Clinical Research" is that the clinical trials conducted in developing countries are justified; and that the suggested changes for improvement in the ethical standards can safeguard the interests of people in those areas. However, through this response, I contend that the conduction of clinical trials by pharmaceutical companies from the developed world in underdeveloped nations is essentially unethical from a pragmatic ground-level view as well as in the realms of philosophical theory.

Keywords: Clinical trials; Science; Global, Ethics

The pharmaceutical industry as it stands today is one of the most despised segments due to the unethical manner in which it has behaved over the past few decades. All the major pharmaceutical companies (like Pfizer, Roche, Bayer, Lilly, Wyeth, Glaxo, BMS, and many more) have been punished with huge penalties for their misdemeanors in the last decade alone [1]. Pfizer was recently fined USD 2.3 billion for illegal marketing of drugs, the fourth time Pfizer has received such penalty since 2002 [2]. If these companies have the gall to be so blatantly unscrupulous in the ever-vigilant developed world, it is unreasonable to believe that they will act any different in the vulnerable nascent developing countries.

Most of the developing countries do not have regulatory laws or organizations to check for the violations of those laws. In addition to this, the government bureaucracy can be manipulated easily to illegally obtain necessary permits and certifications. The patients, physicians as well as researchers do not completely understand the cutting edge technologies from developed nations; and can be misled into conducting clinical trials and manipulating their results. A survey published in US Journal of Medical Ethics showed that in almost a quarter of clinical trials conducted in developing countries, the pharmaceutical companies did not undertake any ethical reviews [3]. In addition to this, it is manifest that all the suggestions for enforcing ethical standards on these companies might force them to camouflage their actions, but not their wily intentions. Therefore, the conduction of clinical trials in developing countries by big pharmaceutical companies can only be considered as unethical, in accordance with the theory of Virtue Ethics, which states that the focus should not be on the right action but on the character of the person (organization) doing it [4].

After acknowledging the real world problems associated with conduction of such trials, it is important to view the subject from a philosophical perspective. I propose that even if the pharmaceutical companies were to mend their way (which in itself is highly improbable); performing the clinical trials for technology from developed world in developing nations still has to be considered as unethical. It breaches the fundamental principles of equality as well as equalitarianism. Every human life is equally precious; and no matter what, no population should be subjected to increased risks for possible improvement in lives of some other population. The principle of equalitarianism propounds that the benefits and the burdens of the humankind should be equally distributed. It is unethical that poor people living in some sub-Saharan nation should bear all the risks of the clinical trials, when the chances of their benefit through the same medication (when approved) are negligible.

At this point, some people may retort that the sub-Saharan nations are bereft of even the basic medical facilities and the clinical trials provide the only hope for the citizens to access any sort of treatment, especially for life threatening conditions like cancer or AIDS. This argument alludes to the beneficence of the developed world, but it is not difficult to see through the naive defense. In the first place, if the developed world were so empathic towards the doomed patients in the underdeveloped nations; they should offer some medication as an aid; not a research chemical, which they intend to keep for themselves anyways, once the trial is over (or sells at exorbitantly high price, which tantamount to the same thing). Nevertheless, it is essential to note here that only one in five investigational drugs that enter clinical trials are approved for medical use; while the others are rejected due to inefficacy or adverse effects. Now it is easier to see that most of the patients that take part in the clinical trial are not better, but on the contrary worse off than what they were before. They will share the burden of all the adverse effects for the benefit of a few patients and billions of dollars for the pharmaceuticals in the developed countries.

It is futile to discuss the topic in such a negative light and then not espouse any solutions for the problems; especially when there could be many conditions under which such trials could be warranted. Clinical trials for malaria or tuberculosis can be completed much faster, in developing nations due to large patient populations. In such cases, clinical trials should be permitted to be conducted in developing areas; since the diseases are huge national health problems for these nations. But this allowance should be contingent to the agreement on the part of the pharmaceutical company to share a part of its profit with that nation. Furthermore, it should be mandatory for the pharmaceutical companies to market the approved drug that country at a price decided by their government, so that the citizens can reap the benefits of the risks they undertook.

To reprise the argument, the mercenary disposition of the pharmaceutical companies indicates that the clinical trials in developing countries cannot be conducted in ethical manner.

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Philosophical discussions point out towards the unethical nature of conduction of these trials due to the base intentions as well as puerile justifications around them. But these hitches can be overcome by legislations granting the underdeveloped nations some privileges. To conclude, unethical behavior can be thought of as a manifestation of the inability of people to see that despite being divided by gender, color, appearance, country borders, religious inclinations or histories; we are one species of organism and we can never hurt one without hurting ourselves in the long run. And, it is not the elevations in the financial charts that add value to our existence but the lucidity of our convictions that help us live in the chaos of absurdities surrounding us. The presence of under-resourced undeveloped nations itself is an

attestation to the lasciviousness of our times. Hopefully we can get over the quagmire of vain yearnings; the euphemistic term “developing nation” ceases to exist and discussions like this are things of a part of forgotten past.

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