Dear Dr. Alvares:

Ethics is a cornerstone of dental research or for that matter any research involving living things. The principles of ethics like beneficence, autonomy, justice, and confidentiality have been pillars of research since the time of the Nuremberg Declaration. For decades, industrialized countries have been at the forefront of dental research and have been involved in almost all pathbreaking discoveries, whether it involves development of new restorative materials, new drugs, or new treatment regimens. However, as time progressed, the very societies that nurtured such discoveries began to take a more cautious look at medical research. This coincided with the rise of liberal sentiments and concern for the protection of human rights within developed nations. The growing concern for protection of the public from potentially unscrupulous investigators heightened emphasis on the ethical aspects of research. Instances of human rights and animal rights groups waging relentless campaigns against drug companies and research organizations are common knowledge. Although the underlying reasons for conducting these campaigns against patient abuse and inappropriate use of animals in research are justified, it also has to be conceded that most of the current essential drugs and treatments are a result of extensive animal and human trials. In the face of such intense scrutiny in the developed world, drug companies have been forced to look at more hospitable environments for conducting research that relies on animal and human testing.

“Outsourcing” is a term that inspires awe as well as trepidation in developed countries. Many components and functions of corporations are being outsourced on a massive scale to developing countries to cut costs and improve efficiency. Outsourcing is slowly beginning to permeate every aspect of life for people in developed countries. A new aspect of this concept is outsourcing the research process. Drug companies and research organizations under pressure in their own countries to curb questionable product-testing practices are flocking to developing countries like India, China, and Brazil, where the rules and ethical protocols are much more relaxed and where governments welcome the jobs and income that major research companies can provide. Renowned medical institutions in developed nations are now actively engaged in outsourced research as a means of fast-tracking clinical trials, generating additional revenue, enhancing prestige, and providing faculty enrichment.

From the perspective of a university in developed countries looking to cut costs by outsourcing clinical research, India has several advantages. It has a vast pool of treatment-ignorant patients with a high incidence of diseases common to both the developed and developing worlds. As a result, patient recruitment is generally five to ten times faster in India than it is in the United States. There is, however, a flip side to the process of research outsourcing. There are instances in which even basic procedures like informed consent are not provided to subjects enrolled in biomedical research. The “volunteers” for clinical trials of new medications or treatments in developing nations are usually people who live in abject poverty and cannot afford even the most basic forms of medical care. Their sheer helplessness and their families’ pressure caused by poverty force them to accept any treatment offered to them. In cases of death or injury, a marginal compensation is provided, and the matter is closed.

The medical/dental academic community is knowingly or unknowingly a partner in this new research outsourcing strategy and has been willing to participate because this arrangement provides much needed revenue. Instances in which poor patients are pressured or influenced against their will by the researchers to enroll in trials are not uncommon. In recent years, there have been numerous instances in which clinical trials of experimental medications have proceeded without the necessary approvals. In 2003, researchers tested a breast cancer drug called Letrozole on 430 young women to determine its effectiveness as an infertility treatment. Letrozole is known to be embryotoxic and fetotoxic at doses of one-tenth to one-hundredth of the approved human dose in breast cancer. Its side effects include, among other things, ovarian tumors, liver cancer, and atrophy of the reproductive tract. Between November 1999 and February 2000, a researcher, formerly associated with a world famous university, tested an anticancer agent on twenty-six oral cancer patients.
patients at a leading government-run cancer institute in India. After a four-month inquiry, the university concluded that the trials were, in fact, the first human trials. Further, the drug had not undergone adequate preliminary tests in animals. The researcher had not gained authorization from the university’s Institutional Review Board, nor had she secured the consent of the patients before they were included in the experiment. The issue sparked national outrage in India, and the media reported that “the statements made by a few patients . . . showed that most of the patients who signed the consent forms thought the painful injections they received were part of their treatment.”

The drug companies are equally culpable. They encourage research outsourcing by funding trials that are conducted in developing nations, publish the results (every academic has a weakness for publications!), send their researchers on trips to foreign nations to supervise the research, and present papers at international conferences.

This phenomenon is only going to increase, and hence, there is an urgent need to take a closer look at this issue. The drug industry, the research community, and governments have to come together and reach a common minimum standard for protecting patients’ rights in order to maximize the benefits and minimize the risks. The issue of human rights should not be drowned in the din of outsourcing.

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