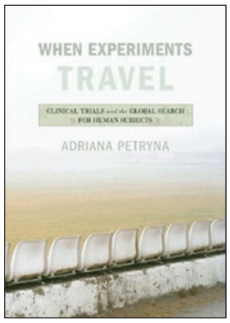
Globalizing pharmaceutical trials



When Experiments Travel: Clinical Trials and the Global Search for Human Subjects

Adriana Petryna

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Reviewed by George J Annas

Transnational pharmaceutical companies want to do more clinical trials, and faster and cheaper. Private contract research organizations (CROs) have rapidly developed to meet this need by indentifying and organizing research sites around the world that offer both qualified researchers and previously untreated research subjects. This global marriage of 'big pharma' and CROs has created both opportunities and perils for local researchers and their subjects.

In *When Experiments Travel*, University of Pennsylvania anthropologist Adriana Petryna explores what happens on the ground when clinical drug trials are globalized. The anthropologist Paul Rabinow, in a blurb for the book, is on target in suggesting that Petryna "casts light on the gray zone where research, medicine, and capitalism merge."

Petryna interviewed leaders of US-based CROs as well as principal investigators and public health experts in Poland and Brazil. Many of her informants are quite candid. A Brazilian public health expert tells her that in his country, "pharmaceuticals are the new gold," with the costs of new pharmaceuticals overwhelming the country's health budget. CRO leaders see themselves as realistic and their corporate clients as "self-servingly delusional" and "out of touch" with realities on the ground, especially with the ability of sick people in developing countries to distinguish between a research trial designed to test a hypothesis and a medical treatment intended to benefit a patient.

Scientific and medical objectives are often at odds with profits, but there are also other conflicts. One is the use of narrow, industry-inspired guidelines, such as the Guideline for Good Clinical Practice issued by the International Conference on Harmonisation. On the surface, Petryna notes, these guidelines seem to provide "assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected," but in reality, as she convincingly observes, they promulgate a "very narrow conception of patient rights and corporate responsibility," an issue in US-based research trials, as well. There is no requirement, for example, for access to trial drugs after the trial is concluded or for any benefit sharing with the research population at all. Another conflict is that research trials (sometimes termed 'phase 4 trials' in the US) are used to simply pay physicians to prescribe 'new' drugs not currently being prescribed and are about marketing, not obtaining new knowledge. For example, international pharmaceutical companies work with local physicians to do research trials in which the drug (previously approved in the US and elsewhere) is provided without cost. Then, when the trials are complete and a constituency for the drugs has been developed, the companies convince the subjects who have become dependent on the drug to organize and insist that the drug be paid for by the government under local right-to-health laws.

The profit-seeking motives of the transnational pharmaceutical companies are clear; the motives of virtually all of the other players are, as Petryna explicates, much more complex. In this regard, the insights provided by her informants are of great value to anyone interested in understanding the globalization of clinical trials, especially anyone interested in the ethics of conducting them. Petryna's in-depth exploration of the conduct of research trials in Poland and Brazil with well-qualified clinical investigators demonstrates the power of anthropology to shed light on what have quickly become everyday practices in drug research and marketing in developing countries. As a proponent of the right to health and its growing importance in international law, I was, for example, stunned to see how agile drug companies have been in converting that right of the people into a profit maximization tool for industry.

However, although I am also a strong supporter of the rights of both patients and research subjects—including the use of the informed consent process to protect the rights of individuals—with regards to consent, I found the anthropologist's methodology of less value. Informed consent is a constant in Petryna's discussions. Nonetheless, she spends an entire chapter on human experimentation in Poland without even mentioning Auschwitz and the infamous medical experiments of the Nazi doctors there—which, among others, led to the Nuremberg Code whose first principle requires the voluntary, competent, informed and understanding consent of the research subject. This is, at best, an unfortunate oversight.

Also, because Petryna's work draws almost exclusively from the experiences of only two countries, it cannot support global conclusions. Nonetheless, some of her conclusions are strongly supported by her research. Firstly, in resource-poor health care settings (like those in Brazil and Poland), local officials see the conduct of clinical trials as attractive, and so do, as the author notes, "desperate patients who would otherwise go without treatment." Secondly, clinical trials can be powerful marketing tools and can distort public health priorities. And, thirdly, continuity of treatment, control of subject data by trial sponsors and the priority of expensive pharmaceuticals in public health programs are pressing issues.

Adriana Petryna informs us that the dysfunctional US system that prioritizes profit maximization over public health and the rights of research subjects has been globalized by the transnational pharmaceutical industry. The pharmaceutical industry deserves praise for developing drugs that treat currently untreatable conditions, but it deserves only criticism for manufacturing demand by marketing expensive and unaffordable drugs to developing countries in the guise of research trials.

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