

Except for all the others



The Professional Guinea Pig: Big Pharma and the Risky World of Human Subjects

Roberto Abadie

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Phase 1 trials are the first tests of newly developed drugs in humans. They are designed not to test for efficacy or for a positive risk-benefit ratio when treating a particular condition but instead for dosage and toxicity. They are ideally conducted on healthy volunteers, whose responses best indicate whether human beings can tolerate the new medication. However, these trials pose myriad ethical challenges. Informed consent may be illusory at best, as it is difficult to extrapolate from animal models the likelihood or degree of adverse events in human beings. Furthermore, the healthy volunteers in these trials are subjected to a drug from which they derive no benefit, only potential harm. Also, questions persist about the subject selection and the willingness of the volunteers. After all, who would volunteer to be among the first to test a new drug in humans?

Roberto Abadie considers one group of phase 1 volunteers in his ethnographic study *The Professional Guinea Pig: Big Pharma and the Risky World of Human Subjects*. Abadie focuses primarily on members of an anarchist community in West Philadelphia. These men—and only a very few women—are enticed into phase 1 trials by the lure of easy money. They see their freelance work as a way of avoiding the exploitation of traditional labor in a capitalist society. Ironically, the contributions of these professional guinea pigs are essential to pharmaceutical companies, some of the largest corporations on the planet.

Until the mid-1970s, phase 1 volunteers were primarily prisoners, but an evolving belief that prisoners were a vulnerable population coerced into the studies ushered in reform. Today's phase 1 subjects are 'paid volunteers,' an oxymoron that Abadie explores in detail. Officially, phase 1 volunteers aren't paid to be exposed to potentially harmful drugs and are instead reimbursed for travel and other costs associated with being in the studies. Abadie refers to their participation as the "mild torture economy," in which people are paid not for what they manufacture or contribute, but for their willingness to undergo the commodification of their bodies while enduring poking, prodding, blood draws, medical tests and extensive boredom. How much reimbursement is enough to make this type of pharmaceutical roulette worth it to professional guinea pigs? Some of the most grueling trials promise as much as \$5,000 over

several weeks. Professional guinea pigs seem to have traded in one type of capitalistic exploitation for another.

Interestingly, some of the regulations designed to protect human subjects promote distrust among phase 1 volunteers. For example, any change to a research protocol must be reported to the institutional review board (IRB). When changes affect the risk-benefit profile of the drug, research participants must be told of these changes, in most cases with a revised consent form. From the perspective of researchers and IRB members, informing subjects of these changes is acting responsibly and ethically. From the point of view of some subjects, doing so breeds the suspicion that they were initially given misleading or incomplete information.

The above example about revised consent forms illustrates the greatest strength of Abadie's work. As the stories in the book make clear, whereas the ethical protections of the Nuremberg Code, the Declaration of Helsinki, the US Belmont Report and the US Common Rule are reasonable guidelines from the point of view of researchers and IRBs, those on the inside, the phase 1 volunteers, may see things differently. *The Professional Guinea Pig* gives voice to volunteers skeptical of the current ethical protections in phase 1 trials, even as they endure the risks of those trials. Abadie concludes the book with a few recommendations to better protect volunteers in phase 1 trials: a national registry of phase 1 volunteers; increased follow-up on those who participate; compensation in keeping with that of other high-risk professions, such as mining; subject-initiated regulations and report cards of research sites; and a restriction on the number of phase 1 trials, enforced by potentially levying taxes on 'me-too' drug trials, to create cost offsets for trials of truly novel drugs.

One unanswered question is the degree to which the professional guinea pigs Abadie profiles reflect phase 1 volunteers at large. If they do, the suggestions Abadie makes to improve subject protections make sense; furthermore, both scientists and IRB members can benefit from an understanding of phase 1 volunteers' perspectives. If not—if Abadie has given us only a small window into a rarified community—then it is unclear whether his suggestions will improve the situation for all phase 1 trials. It is also unclear whether those recruiting phase 1 volunteers from beyond the now-gentrified West Philadelphia area will have learned anything from this book that will help them do their jobs better. Readers will learn something about a fascinating counterculture, but they will be disappointed if they think that Abadie's work will help to promote widespread ethical research.

This all leads to perhaps the greatest challenge faced by readers of *The Professional Guinea Pig*: the changes Abadie recommends are not that extensive or far reaching. Using paid volunteers in phase 1 studies is still the best strategy to avoid the perils of undue coercion when using subjects such as prisoners or of a therapeutic misconception when using persons who are unhealthy. Abadie's recommendations will raise compensation amounts, allow for more open information about competing drug trials and potentially yield information about the long-term side effects of the mild torture economy, but the ironically named paid volunteer will continue on the front lines of medical progress. Perhaps, as has been said of democracy, the current system of using healthy paid volunteers in phase 1 studies is the worst system, except for all the others.

COMPETING FINANCIAL INTERESTS

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