Jennifer S. Hawkins and
Ezekiel J. Emanuel, **eds**.
Exploitation and Developing Countries:
The Ethics of Clinical Research.
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In 1980 the American Food and Drug Administration began accepting data from foreign research trials in its consideration of new drugs for release on the U.S. market. Over a quarter of all applications made to the FDA now include results from research conducted abroad, typically in the developing world. Medical research in developing nations can be conducted faster because of the size of test populations from which to draw, enabling new drugs to gain approval and reach market sooner. Research trials also bring infrastructure, training and equipment to health poor regions of the globe. But despite these apparent advantages, international trials have given rise to concerns about the exploitation of test subjects by first world drug manufacturers. Trials can be run faster in the developing world precisely because there are so many sick people to enlist, people who may be willing to sign up for anything they perceive as treatment when faced with no other health care options, and who may agree to participate without properly understanding the antecedent risks.

These concerns dominate current debates in international research ethics and have been termed the problems of standard of care, informed consent and reasonable availability, respectively. The standard of care worry is that, although the Declaration of Helsinki insists that all trial participants be assured the best prophylactic, diagnostic, or therapeutic care, it is unclear whether this means that subjects are guaranteed best local care, or best care globally understood. Accordingly, it may or may not be justifiable to deny third world subjects first world care on the grounds that they would not have had access to that level of care otherwise. The problem of informed consent is thornier still: due to illness, poverty, lack of alternative health care options, limited education, language barriers, and allegiance to moral codes that do not value autonomy, citizens of developing nations may not be in a position to give the kind of genuinely informed and voluntary consent demanded by the Nuremberg Code. Finally, the risks of participation are typically thought to be offset by the potential benefits that new drugs provide for the community at large. But this positive risk/benefit ratio rests on the assumption that the communities from which participants are drawn will actually have reasonable access to the fruits of the research once the trial is complete. In the developing world this assumption is false, given the absence of effective health care infrastructure for delivering drugs, low per capita health care spending, and low per capita income.

Research ethicists have been arguing with increasing vehemence that standard of care must be globally understood, that trial sponsors must (at the very least) make their products reasonably available post-trial, and that every effort must be made to guarantee that consent is genuinely informed and uncoerced; failing to do these things, they claim, would be to exploit third world vulnerability for first world gain. But what is missing in these discussions, according to Hawkins and Emanuel, is a clear and coherent understanding of the very concept of exploitation. As they rightly point out, 'characterizing the ethical issue at the heart of clinical research as one of exploitation can be both helpful and problematic. It is helpful because it unifies what have often been diffuse, disjointed, and even incoherent concerns about research in developing countries into what seems to be a single clear ethical issue. It is problematic because the appearance of simplicity is deceiving. Exploitation is itself a diffuse and unclear concept. Hence we run the danger of substituting a vague pile of concerns for an equally vague label — giving it the patina of coherence but without any real clarity' (13).

Hawkins and Emanuel thus take it as their task to provide genuine coherence to the concept of exploitation in the context in international clinical research. Two famous case studies are offered early on, which the central papers in the volume are meant to use as a common reference point — as benchmarks against which to test their theories of exploitation. Hawkins and Emanuel are quick to dismiss the original, Marxist understanding of the concept, offering no reason for doing so but presumably accepting the general (and widely undefended) view that trial participation does not constitute a form of labor. The volume goes on to present five essays which offer five (quasi) distinct conceptions of exploitation: transactional, institutional, utilitarian, Kantian and contextual. The editors make it quite obvious, both in the introduction and in their respective contributions at the end of the volume, that they endorse the transactional conception defended by Alan Wertheimer in the first substantive chapter of the book.

According to Wertheimer, exploitation is a matter of how cooperative gains are distributed among co-contractors. For him, morally troubling exploitation occurs if one party walks away better off, and the other worse off, as a result of their transaction. If both parties benefit, even to wildly different degrees, no morally troubling exploitation has occurred (provided both parties consented). Ergo, if developing world communities benefit in any way from hosting or participating in clinical research, there is nothing morally troublesome about the transaction. In the chapter immediately following, respondent Thomas Pogge argues compellingly (although apparently not compellingly enough for the editors) that we shouldn't accept the wildly different starting points of co-contractors in research transactions as normatively acceptable benchmarks against which to judge their distributive entitlements. He goes on to make his usual case for global redistribution: because first world citizens benefit from the vulnerability of the global poor they have obligations to erode the very conditions of that vulnerability. In this particular piece he defends his new preferred strategy: that tax dollars be spent incen-

tivizing pharmaceutical companies to develop and distribute drugs actually needed in the third world.

The next few contributions are less interesting and even a little repetitive. Richard Arneson defends a Wertheimerian account in consequentialist terms, arguing unsurprisingly that when exploitation produces greater overall utility for the worst off it should be tolerated. A hard and fast anti-exploitation principle (rather than a general and flexible utilitarian rule) would produce perverse incentives that would leave everyone worse off. International research may indeed take advantage of developing world subjects, but all told it produces greater benefits than would realistically be achieved without it. Andrew Siegel responds with a nicely nuanced but predictable Kantian version of Pogge's argument, arguing for international duties of beneficence on the grounds of our shared humanity but acknowledging that these belong to all of those in a position to help rather than to researchers and their sponsors alone. Finally, Carse and Little add something new to the debate with their contextualist account, according to which exploitation occurs in the research context when subject vulnerability is taken advantage of for purposes not in accord with research objectives. On their view, international research objectives share much with the objectives of public health, and so international researchers encounter unique obligations because of the emergent public health crises in the developing world. Hawkins and Emanuel close the volume with respective pieces, previously published, in which the former employs Wertheimer's account to assess standard of care requirements in placebo trials, and the latter articulates a post-trial distributive principle alternative to that of reasonable availability.

The volume as a whole is a good one: clear in its central aims, well-organized, and argumentative. Some of the contributions, however, exhibit a failure of consistency when their authors finally get around to discussing the case studies, as though they had already forgotten that they had just presented a reasonably worked out theory of exploitation to which they might appeal. (This is not true of the chapters by Carse and Little, or by Hawkins.) If philosophical accounts of exploitation cannot be coherently applied by their own authors to actual cases, what hope for the clinicians, policy-makers, and research sponsors that philosophers love to belittle for their failures of systematicity? Only the contributions by Carse and Little, and Emanuel offer anything strategic for the clinical community. But to be fair, the target audience here (despite the editors' claim to be casting the net more widely) is philosophers frustrated by the lack of scholarly coherence in bioethical debates on the topic of international research. And as one such philosopher, I am grateful for the volume. The book is bang on in its timeliness, usefulness and central insight: yes, various problems in international research do come down to one large worry about the exploitation of vulnerable populations, and that acknowledgement doesn't settle the debate, it launches it.

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