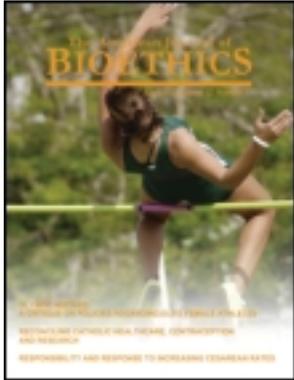


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## The American Journal of Bioethics

Publication details, including instructions for authors and subscription information:

<http://www.tandfonline.com/loi/uajb20>

### The Elephant in the (Board) Room: The Role of Contract Research Organizations in International Clinical Research

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Version of record first published: 16 Oct 2012.

To cite this article: Charles Foster & Aisha Y. Malik (2012): The Elephant in the (Board) Room: The Role of Contract Research Organizations in International Clinical Research, *The American Journal of Bioethics*, 12:11, 49-50

To link to this article: <http://dx.doi.org/10.1080/15265161.2012.719267>

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# The Elephant in the (Board) Room: The Role of Contract Research Organizations in International Clinical Research

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We have no quarrel with the main thesis of Pratt and colleagues (2012). The four theories of justice they discuss are capable of contributing usefully to the conduct of International clinical research (ICR) in low- and middle-income countries (LMICs). The theories have the limitations identified by the authors.

We seek to highlight the role played by contract research organizations (CROs) in ICR. We suggest that each of the four theories of justice would be even more stridently critical of research conducted by CROs than they would be of the same research conducted directly by (for example) pharmaceutical companies.

Many of the activities in LMICs of multinational pharmaceutical and other companies cannot be justified under any of the four theories of justice. The authors' opening statement is: "Redressing the inequities in health experienced by impoverished populations is not the primary function of most international health research" (Pratt et al. 2012, 30). This is a masterly understatement. Most ICR is conducted by commercial organizations ("the companies"). An example: Of the 582 registered trials in India in 2008, 72% were conducted by pharmaceutical companies (Srinivasan 2012). The objective is profit.

The companies therefore seek to reduce their costs (Bailey et al. 2009). One of the ways of doing that is to subcontract the research to CROs (Shuchman 2007). CROs act as middlemen. They go to the relevant country, negotiate the terms of the trial with the local players, supervise the trial, pay the local actors, and return the results to the companies. The CROs want to give the companies a good price; it is a competitive market. Ethical research is likely to be a casualty of competition (Gitanjali 2011). ICRs responsive to the diseases that impact LMICs are a rarity (Nundy and Gulhati 2005). The local context and the health needs of the population in LMICs are frequently ignored (Yadev et al. 2011). The CRO will certainly be slow to recommend that there be investment in diseases that particularly afflict the local population; the CRO is engaged to conduct a particular project, not to suggest what those projects should be. Similarly, social justice is an irrelevant criterion for the CRO

(Srinivasan 2012), except insofar as a squirt of social justice might oil the wheels of the project in hand.

It might be said that the involvement of CROs does not change the way that the theories of justice speak to the companies. This assertion assumes that CROs are simply the hands of the companies. But the assumption is untrue. It underestimates the independence of the CROs.

CROs operate in LMICs in ways that the companies could not themselves operate directly. The difference is mainly a creature of politics. Even taking into account the endemic corruption of many LMICs, and governmental collusion with multinational companies, there are some things it would be politically impossible for multinationals to get away with. Unethical or socially irresponsible conduct might make life difficult for the multinationals at home: they usually pay at least lip service to an ethical code. Unethical behavior in the name of the company might cause embarrassing questions to be asked at the AGM—questions that might well be framed in the language of Rawls, Pogge, Shue, or Ruger. CROs, however, not acting expressly in the name of the sponsoring multinational, are not so inhibited. For CRO X to undertake a piece of research that does not conceivably benefit the local population is often much easier than for multinational Y. It is often the case, too, that the multinational will want to use a particular LMIC repeatedly as a laboratory, and it is sometimes the case that the multinational will seek to sell its products there. It is much more important for the multinational to keep its nose clean than it is for a CRO to whom it subcontracts the research work. One might cynically suggest, indeed, that CROs are sometimes engaged precisely because they can use cheaper and less ethically sanitary practices.

What, then, is the main difference between CROs and the companies as far as the application of the theories of justice is concerned? It's a practical one. The CROs can get away with more. Each of the theories of justice condemns many of the activities of both the companies and the CRO, but political and other realities make it less feasible for any of the theories to call CROs to account. ■

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