

## BOOK REVIEWS

### Outsourcing clinical trials

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**Sonia Shah. *The body hunters*. New York: The New Press; 2006, pp 242, \$24.95, ISBN 978-1-56584-912-9**

"There's a lot of money in this, you know," said the director of a contract research organisation while talking to me about a clinical trial about a year ago. Unwittingly, he had hit the nail on the head and had admitted the real – and the only – reason for his company's interest in clinical research.

That clinical trials and medical research have usually been done on the poor and the oppressed is clear to those of us in the fields of medical ethics and history of medicine. The only thing that is new is the setting: Russia, India and other developing nations. Why is it that drug companies wish to outsource their trials to the developing world?

Shah sets out to get the facts right in this book. She is decidedly anti-pharma and this clouds her view. However, we learn something surprising from the foreword by John Le Carre, author of the chilling book (later made into an equally engrossing movie), *The Constant Gardener*. Le Carre writes that many people who planned to write a book exposing the pharmaceuticals industry, chickened out because they felt it was too risky.

While pro-outsourcing politicians in the West come under a lot of flak from their media, nobody seems to object to clinical trials being done elsewhere. The reason for this is simple. The cost advantage: it's cheaper to do it in India. This is true for call centres as well as for clinical trials – but what is more important is that there is a perception and a reality that it is easier to get away with ethically flawed studies here than it is abroad. (Such a statement would, of course, hold true even for BT cotton trials). Earlier, American physicians often conducted studies on African Americans or on convicts. The Tuskegee experiment, which traced the effects of untreated syphilis in poor African Americans (at a time when treatment was available), is a prime example of such practices. After the civil rights movement in the US, such experiments became impossible, so it was logical to turn to a country with limited resources. Besides, patients in developing countries are more likely to provide "events", to use

the euphemistic term.

The book covers the background to today's situation. Shah documents the growth of the pharmaceutical industry, the Thalidomide incident and the FDA regulations that followed, disease-mongering, direct to consumer marketing, and the marketing blitz that it involves.

The clinical trials that she writes about are splendid examples of man's inhumanity to man. Perhaps prime among them is the Trovan trial done by Pfizer in Nigeria in 1996. *The Washington Post*, on learning of these trials, which were carried out without consent, among other irregularities, carried an expose in 2000 in a series of articles entitled '*The Body Hunters*'; the title of Shah's book is presumably based on this series. Other such trials include the HIV vaccine trials in Africa in 1997 and the brouhaha that followed the editorial in the *New England Journal of Medicine*. I also learnt, to my surprise, that the PDR (physicians desk reference), which I had assumed was an unbiased source of pharmaceutical information, was funded by the pharma industry.

As one would expect, the *Indian Journal of Medical Ethics*, some of its editors, and some of the papers published in it, are quoted. Yet, I am not sure why the author has failed to quote the exact page numbers of articles from this and other journals. At least some of the provocative statements are not referenced and, in some cases, a secondary source of information is quoted rather than the primary source or study. Some statements are inconsistent with the facts, such as the one on pages 113-114 of the book, about the paucity of medical ethics teaching in medical schools in India. Shah states on the same page that a group of progressive physicians fought the elections for the medical council in the late 1980s – as readers of this journal know, this happened in the early 1990s.

Though it has some flaws, I believe that this book should be read by both, lay people and physicians, because it does not seem to have registered with most people, that clinical trials, whether outsourced or otherwise, often involve blatantly unethical medical practice. There are no easy solutions to this problem. But recognition of the existence of the problem is the first step towards correction.

Pai Sanjay A. Outsourcing clinical trials: *The body hunters* by Sonia Shah. *Ind J Med Ethics* 2007; 3: 90.