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Review of Sonia Shah. *The Body Hunters: How the Drug Industry Tests its Products on the World's Poorest Patients*

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Review of Sonia Shah. *The Body Hunters: How the Drug Industry Tests its Products on the World's Poorest Patients*¹

Reviewed by Jennifer S. Bard, TTU School of Law

In *The Body Hunters: How the Drug Industry Tests its Products on the World's Poorest Patients*, investigative journalist Sonia Shah has written a fast-paced and highly readable overview of the pharmaceutical industry's current practice of conducting human subject clinical research trials in developing countries. In the course of ten short chapters, Ms. Shah reports on commercial drug trials conducted in Eastern Europe, Africa, and India under conditions which would not be acceptable in the United States. She asserts that the trials are being undertaken without the individual informed consent that would be required in the United States.

Ms. Shah's emphasis on current events is a good antidote to the usual historical presentation of the development of principles of research ethics which may lead students to believe that ethical violations are a thing of the past. In fact, many of the studies Ms. Shah describes in her book are presently the subjects of lawsuits and ethical reviews. In addition to providing a resource for students, the book may also be well suited to distribution and discussion at Academic Medical Centers' Institutional Review Boards ("IRB's"), even if their institution does not conduct research overseas. Despite its title the book contains quite a bit of information about human subject testing in the U.S., and provides substantial insight into the world of people who make a living by seeking out phase one drug trials.

Although the book is appealing because of Ms. Shah's highly accessible style, extensive original research and generous citation to sources, it very much comes with a point of view. Ms. Shah is highly critical of the pharmaceutical industry, to which she consistently refers as "Big Pharma." Those connected with this industry, and no doubt others, will disagree vigorously with the conclusions she draws. The tone of the book is set in the first sentence of the foreword, which is written by the novelist John Le Carre, author of *The Constant Gardener* which tells the story of a woman living in Africa who is murdered because she uncovers information about pharmaceutical company drug testing. Mr. Le Carre writes: *The Body Hunters* "is an act of courage on the part of its author and its publisher. . . [b]ecause it seeks to lift the veil on the darker side of the world's most profitable trade: the pharmaceutical industry" (vii).

Ms. Shah herself takes some extreme positions. For example, condemning the presence of a placebo arm in a trial of anti-retroviral drugs on HIV-positive pregnant women in Uganda, she writes: "From the Nazi camps to Tuskegee, when investigators needed their test subjects to suffer in order to acquire results, they often assumed the posture of innocent bystander: in the concentration camps, inmates were going to be killed anyway; at Willowbrook, the children would have infected themselves with hepatitis if the scientists hadn't intervened; at Tuskegee, the sharecroppers wouldn't have been able to afford treatment, so what did it matter that investigators didn't provide any?" (77).

While the study to which she refers is almost universally viewed as unethical and misguided it is neither accurate, necessary, nor helpful to compare its investigators to Nazis. Also, by omitting the serious efforts made by international and European oversight bodies such as the Council for International Organizations of Medical Sciences (CIOMS) and the European and Developing Countries Clinical Trials Partnership (EDCTP) to impose regulations on researchers working in countries with few or no legal restraints, the book gives the misleading impression that nothing is being done to counter the unethical practices it documents.

My most serious concern about the book as a resource for the classroom, however, is that in making its points it sometimes blurs the distinctions between various kinds of research. This blurring is not due to ignorance on the author's part but rather is an effect of the book's structure as a series of vignettes rather than an integrated whole. While the subject of the book is pharmaceutical trials, the ethical concerns it raises are not limited to studies funded by pharmaceutical companies. By focusing on the drug industry the book omits a wide variety of other entities which conduct human subject research for purposes such as developing new weapons (Jonathan Moreno, *Mind Wars*), or simply advancing scientific knowledge. Nor is the mere fact that research is conducted overseas sufficient basis to believe that there is unethical behavior. Some trials are better conducted in places other than the U.S. For example, there are many diseases, such as malaria, which are almost nonexistent in the United States and others, like drug resistant tuberculosis, much more prevalent outside the United States than in it.

1. New York, NY, The New Press, \$24.95.

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Finally, there are substantial differences between the ethical issues raised by phase one drug trials, which are conducted with healthy people, and phase two and phase three trials which involve people who are sick with the illness or condition under study. The ethical issues involving placebo use, for example, only arise in later phase trials.

These may not be fair criticisms of a book intended to be descriptive rather than prescriptive, but someone considering this book as an instructional tool must be warned that the result may be to leave the reader with a series of horror stories, rather than a coherent understanding of the underlying ethical issues involved when people trained in science and medicine go to another country not to provide care but

to acquire commercially valuable information. To say that this book sometimes ignores shades of gray in order to tell its stories is not to say that there aren't serious ethical and legal concerns arising from international research. The information presented in this book is interesting and important, and it will provoke lively discussion in any classroom. However, the information is presented with a strong bias against the pharmaceutical industry and thus needs to be balanced both with a more detailed and nuanced study of the ethical pitfalls in all human subject research, and a description of how those pitfalls are magnified when the research is conducted in countries with little or no tradition of protecting subjects of medical research.

Review of Barry Kellman, *Bioviolence: Preventing Biological Terror and Crime*¹

Reviewed by Nicholas B. King, McGill University

Barry Kellman's *Bioviolence: Preventing Biological Terror and Crime* is unique among the growing crop of volumes warning of the threat of biological weapons, in its combination of erudition, sobering analysis, passionate advocacy, and international focus. The richness of this book is partially due to Kellman's decision to address the broad topic of "bioviolence" – "the infliction of harm by the intentional manipulation of living micro-organisms or their natural products for hostile purposes" (1) – rather than limiting his focus to either State-sponsored biological weapons (BW) development, or bioterrorism by non-State actors.

The first section of the book presents the case for why bioviolence should be taken seriously as a paramount threat to global health and security. The introductory chapter argues that BW are distinctive in their resemblance to naturally occurring pathogens, potential for creating self-propagating epidemics with massive death tolls, and ease of manufacture and delivery. The following chapter reviews the agents most likely to be developed into biological weapons, as well as the role of emerging scientific advances in the modification or synthesis of new agents. The final chapter in the section reviews past and current state bioweapons programs, including Japan's Unit 731, South Africa's Project Coast, and American, Soviet, Egyptian, Iraqi, and Israeli programs; as well as current terrorist groups' interest in BW. The latter section focuses primarily on Al Qaeda's attempts to develop or acquire BW, and their rhetorical justifications for such use.

While these chapters offer little new information, they are a succinct and comprehensive compendium of past, cur-

rent, and future threats. Kellman's discussion is balanced throughout, and he is careful to hedge where appropriate. For example, before discussing new developments in molecular biology, synthetic genomics, and nanotechnology, he cautions that "scientific advances certainly thicken the fog of bioviolence prevention, but less certain is whether we should fear Frankensteins lurking in the shadows" (48). Kellman also notes the limitations of relying on open-source information. Unlike many biodefense advocates, he acknowledges that most bioweapons-related information is currently classified, and what is available is often the subject of considerable debate.

Despite these cautions, these initial chapters leave the reader with the overall impression of extreme vulnerability in the face of a considerable threat of bioviolence. States have successfully weaponized pathogens in the past, continue to do so, and will capitalize on scientific advances to produce more dangerous agents in the future. Non-state actors appear increasingly likely to overcome the technological hurdles that prevented successful acquisition or development of BW in the past. Kellman has amassed considerable evidence in support of his contention that "bioweapons are far more available, cheaper, easier to use, undetectable, and could have more widespread and long-lasting effects. If you want to stop modern civilization in its tracks, bioviolence is the way to go" (18).

The second section of the book presents his "Global Strategy for Preventing Bioviolence." In the opening chapter, Kellman surveys the sorry state of current bioviolence

1. New York, Cambridge University Press, 2007, \$28.00.

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