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## [Book Review of] *Human Experimentation: A Guided Step into the Unknown*, by William A. Silverman

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## BOOK REVIEWS

### *Human Experimentation: A Guided Step into the Unknown*

by William A. Silverman

Oxford University Press, 1985. 204 pp.

This slim volume on human experimentation is readable and made especially enjoyable by a number of interspaced anecdotes and historical tidbits. Silverman covers in detail many important pitfalls in the evaluation of clinical studies. He emphasizes the importance of not letting ourselves be biased by our desire for a specific outcome. It is easy, he notes, to allow our legitimate thirst for answers to trap us into accepting unproved conclusions.

As he reviews the history of the development of modern science, Silverman makes an important distinction between Francis Bacon's "accumulation of observations" and Galileo's "experimentation and critical analysis of alternative explanations." That distinction is an important one to keep in mind.

Silverman identifies an important driving force in contemporary medical research as he relates that "doubt is unwelcome at the bedside" and that both the profession as well as society have a "deep seated yearning for magical cures." The author rejects the contention that medical and scientific research can easily bring on a "medical millennium." He advises caution as we seek easy solutions and offers an admonition he judges appropriate for medicine. It is found in fireworks factories:

**"It is better to curse the darkness than to light the wrong candle."**

Silverman is especially provocative when he sets out to examine the "how" of the acquisition of medical knowledge. He suggests that, just as Vesalius and Harvey challenged Galen, and Bacon challenged the natural science of Aristotle, we need to be more questioning of both the method and conclusions of contemporary medical researchers. Just as in the seventeenth century when mystical, religious and philosophical **certainty** were appropriately examined and critiqued, Silverman asks us to question the medical and scientific mystique of today.

Such approach is critical if we are to resolve many of the ethical dilemmas of our time. Certainly in applied ethics as we deal with "hard cases" it is essential that first of all we clarify and understand the facts. There is almost universal agreement among moral philosophers and theologians that, even though the *ultimate* resolution of medical-moral questions will be based on ethical principles, that there must be initially a solid factual foundation. History is full of too many examples of catastrophe when that course was not followed.

Although the book is primarily directed at the critical analysis of clinical studies the final chapter deals with ethical questions in human experimentation. Silverman returns to the "fireworks admonition" and reminds us of the fundamental precept of medicine: "first do no harm." He notes that we are no longer in an era in which most treatments are relatively "harmless palliatives." Silverman includes the notorious Tuskegee syphilis and the Brooklyn live cancer cell studies as unfortunate incidents that are a reminder of the misguided past.

What he does not empathize enough is the contemporary, more subtle data manipulation that pharmaceutical companies utilize, especially in their promotional material. Selective, limited and often poorly controlled studies are often the basis of marketing strategies. We are too quick to accept the claims as valid simply because they appear in print. Although currently under some scrutiny from the FDA, there has been a proliferation of clinical trials funded by drug companies to accomplish market goals. This has become a pattern not only involving academic practice groups but also physicians in private practice. The justification presented to such groups is often an opportunity for income rather than to further scientific inquiry. From my personal experience the requirements of the data collection are so onerous and burdensome that the responsibility must be delegated to either house staff or ancillary personnel. The time required is such that in many instances there is a high probability that the reliability of the data collection (and therefore conclusions) are compromised.

Although Silverman acknowledges that some argue that "there are ethical limits to discovery" he takes the position that "scientific research seems to thrive best when it is completely unrestricted and when it is directed toward a specific practical goal." He argues that "freedom of inquiry in biomedical research is part of a generally accepted system of values in Western societies." He quotes Isidor I. Rabi: "science simply operates on the faith that knowledge is good and ignorance is something to overcome. You cannot really vindicate this faith empirically. It is faith." The implication is that knowledge, no matter how arrived at, is a good in itself. As valuable as the remainder of the book is, the ethical tenets need to be examined carefully.

Silverman does reject a completely unbridled search for knowledge when it involves human experimentation, recognizing the rights of individual patients. He is primarily concerned about the validity of conclusions and it is unclear whether he would put limits on research if competent patients consent. He appears to join Rabi stating "the controversy about the limits of research is irrelevant . . . to the issues that arise at the threshold of the clinical applications . . ." Silverman continues: "we are obliged to develop arguments for policy to justify the conduct of research involving human beings. Collective justifications that point to some overall benefit for the community as a whole, are the minimal requirements in the development of policies; a world view adds even more burdens to be considered." Once patient autonomy has been satisfied the utilitarian calculus appears to rule.

Silverman supports the Helsinki Declaration of 1975 which requires "an objective in proportion to the inherent risks to the subject" and "concern for the subject must prevail over the interest of science and society." It is not clear that he would consider interdicting genetic engineering on moral grounds. Silverman appears to fall back on an argument that seeks to identify *who* would give consent rather than asking the question: are there some things that should not be done (independent of the question of consent)?

Although clinical research should continue and it is critical that data, methods and conclusions should be critically examined, all moral considerations cannot be ignored.

There is important distinction between fundamental needs on the one hand and demands and desires on the other. In medicine our goal should be to seek what is necessary to insure a level of scientific advancement and improvement in health care that will allow all members of society to be born, live and die in a way that recognizes their inherent dignity. That needs to be done without technological entrapment. The basic needs that will allow us to attain that goal are not always easy to identify. What Silverman can help us to do is to recognize that self-serving agendas, whether of researchers or of other vested interest, may manipulate us, knowingly or not, to accept conclusions because they are ones we want hear or simply because they appear in print.

Silverman is to be commended for his important critique of clinical research. His emphasis on the importance of patients' rights and meaningful informed consent and the call for the greater involvement of practicing physicians and the community itself in the design and analysis of clinical trials is appropriate. What is needed in reading this book is the recognition that sound ethical principles may appropriately require a limit on both scientific research and our acquisition of knowledge. This is especially important at a time at which entrepreneurship has reinforced professional and academic ambition as factors influencing clinical research results submitted to federal agencies, institutional review boards and peer review journals. Unfortunately societal