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Book Review of Baruch A. Brody, *Ethical Issues in Drug Testing, Approval, and Pricing*

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Book Reviews

Baruch A. Brody, *Ethical Issues in Drug Testing, Approval, and Pricing* (Oxford University Press 1995). Conclusions, index, introduction, preface. LC 94-4479; ISBN 0-19-508831-X. [268 pp. Cloth \$35.00. 200 Madison Avenue, New York NY 10016.]

Dr. Brody presents an encyclopedic chronology of the clinical trial sequence which led to the approval of thrombolytic agents that dissolve clots in coronary arteries. A member of an Institutional Review Board (IRB) that dealt with streptokinase and tPA thrombolytic agents, he uses this experience to shed light on ethical issues involved in drug development. Readers gain an understanding of how the interdigitating roles of the Food and Drug Administration (FDA), National Institutes of Health, Health Care Finance Administration, pharmaceutical industry, hospitals, physicians, investors and journalists play out against the background of science, the economy, medical ethics and patent law.

Ethical issues regarding streptokinase and tPA are magnified and methodically analyzed. Brody weighs the scientific merit of placebo controlled studies against risks and benefits of the drugs to individual patients. He demonstrates that the risk-benefit ratio continually alters as further information about the drugs' safety and efficacy becomes available and is factored into the equation.

A section on informed consent includes thoughtful discussion of the Nuremberg Code and Declaration of Helsinki. These provide a philosophical basis to remind us of the necessity for a responsible and informed consent. A history of informed consent, its current relevancy and circumstances when it is not needed are included.

Brody's conflict of interest section is refreshing. It acknowledges that double-masked studies using objective criteria, when well controlled and properly executed, dramatically limit the potential for biased results. However, the author does not acknowledge the role of the IRB and the FDA in reviewing study design and execution as further protection of integrity. He feels that stock ownership and consulting agreements by investigators, while creating the perception of

conflicts, are unlikely to lead to biased results. Brody finds investigator grants or per capita reimbursement, the usual means by which investigators are remunerated, as having more potential for fostering conflicts of interest but proposes no satisfactory alternative.

Readers are also encouraged to think about the justice of health resource allocation, and a two tiered system is suggested: One with reasonable basic benefits, the other for those who choose to use their wealth to obtain more expensive, only marginally more efficient, drugs. Brody challenges readers to put a price on life to evaluate whether we should be using very expensive drugs that enhance survival by a small percentage. He relates this to using tPA over streptokinase where tPA is ten times the price.

In this regard it would have been good to have seen some mention of the new field of pharmacoeconomics which attempts to place an objective value on an agent according to benefits derived from its use. Also, while Brody shows that pricing in other countries is directly related to the number of new drugs developed, he advances socializing the pharmaceutical industry without apparent recognition that a free market economy is most likely propulsion behind drug development.

Ethical Issues deals thoughtfully with critical ethical issues in drug development. It is well organized, readable and informative. While there will always be excitement surrounding the prospects of new agents, investigators can never forget that they are dealing with the unknown consequences of new chemicals. Patients have rights; anyone involved in drug development must consider those rights and will find this book a scholarly approach to the subject.

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