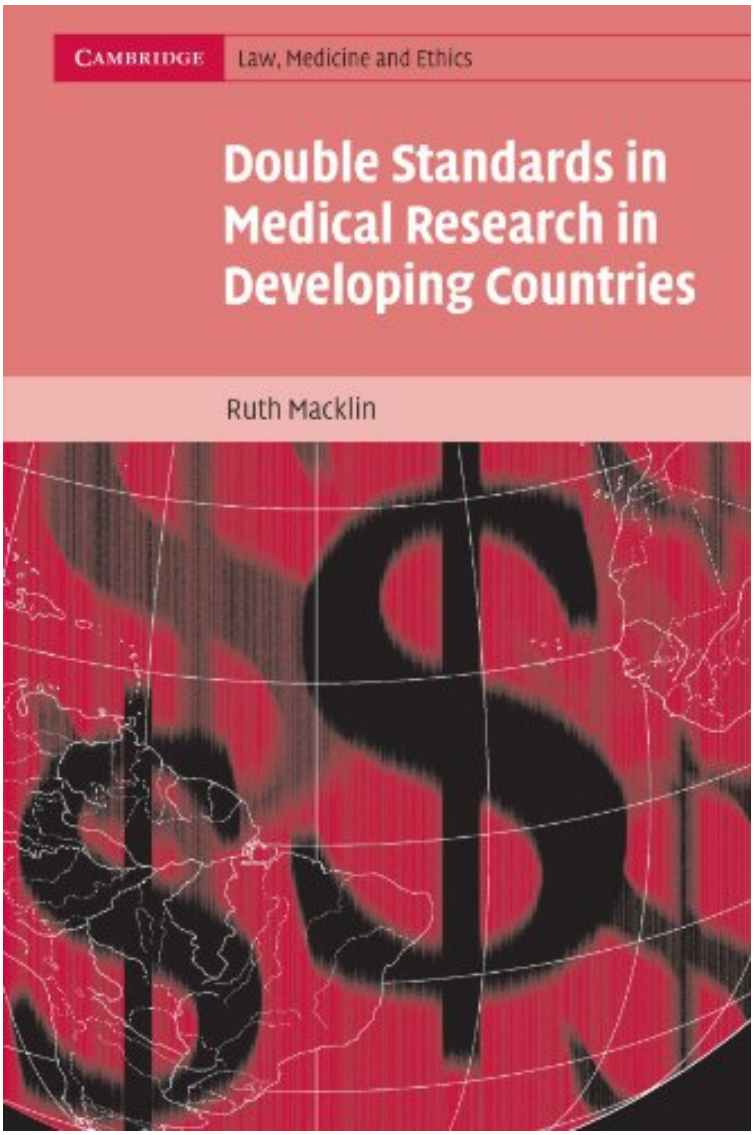
Double Standards in Medical Research in Developing Countries (Cambridge Law, Medicine and Ethics)

Ruth Macklin



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Ruth Macklin : Double Standards in Medical Research in Developing Countries (Cambridge Law, Medicine and Ethics) before purchasing it in order to gage whether or not it would be worth my time, and all praised Double Standards in Medical Research in Developing Countries (Cambridge Law, Medicine and Ethics):

0 of 0 people found the following review helpful. An essential book in BioethicsBy CustomerA documented and

thoughtful analysis of the complex ethical issues involved in research funded from developed countries and performed in developing countries. This book is essential for teaching at graduate and postgraduate level, and for anyone interested in modern bioethics.

This book examines the ethical controversies that have surrounded the design and conduct of international medical research sponsored by industrialized countries or industry, and carried out in developing countries. Is it acceptable to lower the ethical standards adopted in the industrialized world when carrying out research in developing, or resource-poor, countries? Ruth Macklin concludes that double standards in medical research are ethically unacceptable.

From The New England Journal of MedicineThe controversy at the center of this book regarding the use of placebo in trials in developing countries came to light in 1997. The studies in question were evaluating the efficacy of zidovudine in the prevention of perinatal transmission of HIV, even though the drug had already been proved effective. The dispute filled hundreds of articles in medical journals and the lay press, and it led the public to question the existence of ethical guidelines in research and their application in developing countries. As some contenders in the debate provocatively asked, were these studies in Africa or Asia not merely modernized versions of the Tuskegee experiments? Were we not condoning or even promoting double standards in medical research in developing countries? In her book, Ruth Macklin asks equally critical questions: Should clinical trials that would be considered unethical in the United States or Europe be conducted in developing countries? What standard of care should be secured for study participants during the trials? If the tested therapies prove more effective, acceptable, or cost-effective than the current "standard of care," should they be made available to the study participants and others in their community or country and, if so, through which mechanisms? These very questions prompted the landmark revision of the Declaration of Helsinki in 2000 to reaffirm that a new medical method of prevention or treatment should be tested against the best current methods, a point reiterated in the footnotes of the 2004 revision. As one of the world's leading experts in medical ethics, Macklin has taken an active role in virtually all aspects of the controversy in an attempt to help, as she puts it, to overcome the difficulty of crafting ethical guidelines that are "usefully prescriptive without being hopelessly aspirational." In this book, she visits the essential components of the debate, including ethical standards in research, justice, exploitation, informed consent, the affordability of drugs, human rights, and the harmonization of international guidelines. Her writing is accessible; chapters start with a debate surrounding case studies and offer an outline of existing guidelines and a presentation of opposing arguments. One unique feature is that Macklin, as an insider, can effectively depict the parties involved, their constituencies, and their role in the process of revising or confronting guidelines and institutional positions. She helps the reader understand why statements on the same topic from the World Medical Assembly, the Food and Drug Administration, the International Federation of Pharmaceutical Manufacturers and Associations, and the International Conference on Harmonization do not match. Although it is fascinating to visualize the actors developing their arguments, this format is also one of the book's drawbacks, since the conceptual bases of the debate are somewhat sidetracked. The reader then needs to fill in the gaps. Placebo-controlled studies, for example, are often referred to as easier, and therefore cheaper, to implement than are studies with active controls. Although this may often be the case, the basis for this statement is not obvious and deserves more attention. Moreover, these two kinds of trials do not answer the same types of questions. Another issue that deserves more attention is cultural and economic relativism. If the goal is to come up with guidelines that have practical applications, this issue needs to be faced squarely. Yet Macklin succeeds in widening the scope of the debate, particularly in two important chapters on the critical issues of making drugs affordable and protecting human rights. She explores the subject of drug pricing and intellectual property, reminding the reader that the ethical basis of research goes far beyond protecting human subjects from harm or abuse. It also mandates the promotion of access to better health care and to the product of the knowledge acquired through research, especially in developing nations where the needs are immense. Macklin draws on the 1948 Universal Declaration of Human Rights and the 1966 International Convenant on Civil and Political Rights to remind the reader that embedded in these declarations are the right to the means of improving and protecting health and the right to benefit from the advancement of medical science. Although this book will be essential reading for those conducting or participating in research, their views during and after the controversial studies are not examined. Citations are mostly from newspaper articles, guidelines, regulations, and commentaries in interviews but rarely from articles in medical journals. Macklin states that "most of the people who have given any thought to the matter have already formed an opinion and there would be little point in trying to convince them otherwise," but I would argue that some investigators may have changed their opinions and may want to revisit the arguments, precisely because of the points raised in this book -- how the studies' results got translated into public health policy, for example. What seems to be lost here is the fact that much of the debate surrounding the zidovudine trials was not about whether study participants should have received placebo but about what the researchers had known, proven, believed, or hypothesized that allowed them to use placebo. For example, the question of whether an established, effective intervention exists or is likely to be available in the near future is not always straightforward and is certainly central to the debate. I took immense pleasure in reading this book but also

suffered from quite a bit of frustration at times. I believe this is the hallmark of an important book -- the kind you loan to a friend for the pleasure of arguing about it later. Marc Lallemant, M.D. "The strength of the book lies in its breadth of coverage. It moves from deliberations over the wording of guidelines to theoretical considerations of the substantive content of those words, showing why their careful usage is ethically, and practically salient. Macklin's experience on international committees and study teams adds to the depth of her considerations. [S]he has made an important and timely contribution to the thinking of medical and pharmaceutical professionals, policymakers, and ethicists." Jackie Leach Scully, University of Basel, JAMA"[Macklin] has made an important and timely contribution to the thinking of medical and pharmaceutical professionals, poicymakers, and ethicists." JANAAbout the AuthorProfessor of Bioethics, Albert Einstein College of Medicine, New York.