The Progress of Experiment: Science and Therapeutic Reform in the United States, 1900-1990 (Cambridge Studies in the History of Medicine)

Harry M. Marks
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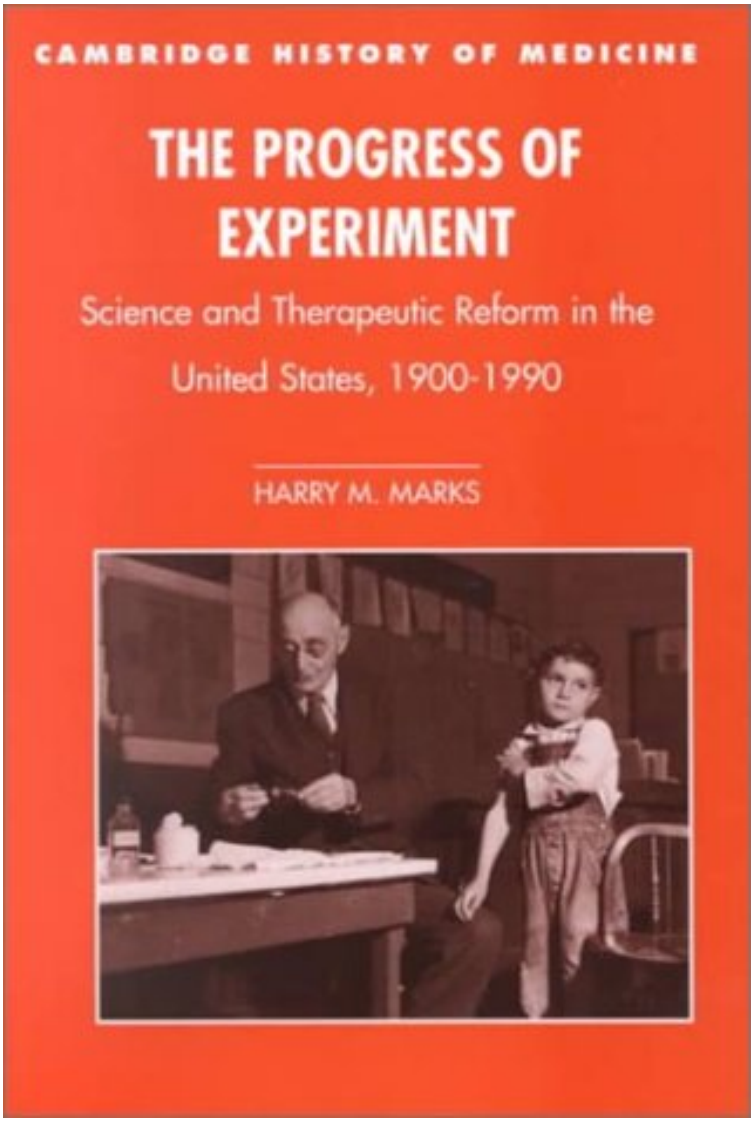

#1519922 in Books Cambridge University Press 2000-10-02Original language:EnglishPDF # 1 8.98 x .63 x 5.98l, .84 #File Name: 0521785618272 pages | File size: 44.Mb

Harry M. Marks : The Progress of Experiment: Science and Therapeutic Reform in the United States, 1900-1990 (Cambridge Studies in the History of Medicine) before purchasing it in order to gage whether or not it would be worth my time, and all praised The Progress of Experiment: Science and Therapeutic Reform in the United States,

1900-1990 (Cambridge Studies in the History of Medicine):

This book explores the origins of our contemporary system of drug regulation and the modern clinical trial. Marks illustrates the symbiotic relationship between the history of modern drug regulation and the history of therapeutic reform. Accompanying this history of public policy is a detailed account of changing experimental ideals and practices. Marks traces the history of therapeutic experimentation, from the "collective investigations" of the past century to the controlled clinical trial that emerged after 1950 as the paradigm of scientific experimentation. The result is the first general history of clinical research in the United States, a book that examines therapeutic experiments in a wide range of diseases, from syphilis and pneumonia to heart disease and diabetes.

From The New England Journal of MedicineWhat kinds of tests should be performed on a drug before its release? What kinds of professional skills are most appropriate for performing such tests, and how safe must a drug be before it is marketed? Harry Marks, a medical historian at Johns Hopkins University, shows that none of these questions are new; issues of authority, risk, and benefit have been raised since early in the 20th century, when the new "wonder drugs" gave hope that diseases would succumb to the weight of laboratory science. The primary focus of the book is on the post-World War II era, when randomized clinical trials became the gold standard of clinical drug research. Historians and clinicians have tended to regard the introduction of powerful new statistical methods as part of the march of science, but Marks shows that this progress was not achieved without resistance. Much of the resistance stemmed from the requirement that large-scale drug tests be conducted according to standardized experimental protocols, a requirement that many physicians saw as compromising the doctor-patient relationship. The point of the new experimental designs was to diminish bias (both "profligate" administration of drugs by physicians and exaggerated claims by drug manufacturers), but many physicians also resented the push for statistical controls, insofar as it diminished their discretion in deciding how to treat their patients. The Veterans Administration's 1947 experiments to test the therapeutic value of streptomycin against advanced tuberculosis, for example, ran up against the concern that the untreated controls would be deprived of the benefits of the drug. Many Veterans Administration physicians were not eager to treat their patients as experimental subjects, and the decision was eventually made to abandon the use of untreated controls. Marks does not mention it, but the timing of the decision (September 1947) suggests that ethical questions raised by the Nuremberg medical trials may have contributed to the decision. The introduction of double-blind experiments shortly thereafter led to new kinds of ethical quandaries. Marks concentrates on two studies that ran into difficulties, for rather different reasons. The ambitious Diet-Heart Study, designed to assess the effects of fats and meats on arteriosclerosis, came to a premature end when it was realized that the people under study might alter their diets as new evidence of health effects came to be publicized. The University Group Diabetes Program ran into a different kind of problem when it turned out that patients receiving one of the study drugs (tolbutamide) were dying of heart disease at higher rates than patients in a control group. Those in charge of the study had to wrestle with an entirely new kind of ethical question in the context of clinical trials -- namely, how much evidence of the harm of a drug is required to halt a study. The book is heavily documented, almost overly so. Footnotes occupy about half the text, giving it something of the flavor of an annotated bibliography or a doctoral thesis. There are also points where one wishes the topic could have been brought up to date. There are many ongoing controversies over the value of "evidence-based" medicine, fraud, and statistical standardization that deserve historical scrutiny. There is some discussion -- though more would have been better -- about efforts by consumer activists (largely inspired by the AIDS epidemic) to "fast-track" the process of drug approval, as well as recent congressional mandates to include women and minorities in clinical trials. Marks's book is slow going at first, but the chapters on the struggles to introduce randomized clinical trials are impressive. The book is sure to change how we regard the origins of clinical trials; it also asks us to broaden our understanding of experimental ethics and to question the political effects of different kinds of disciplinary authority. Marks shows once again that there is no single voice for science, but also that statistical designs can never substitute for political engagement when it comes to the kinds of therapies we decide to bar or allow. There is no better history of the complex weave of science, politics, and ethics in the design of therapeutic research protocols. ed by Robert N. Proctor, Ph.D. "The Progress of Experiment is authoritative and erudite, yet reflective and philosophical. Its insights into the dynamics and processes of the dramatic change in therapeutics in this century are provocative, illuminating, and lucid. This is a thought-provoking book of therapeutic breadth and historical depth that will provide new, and sometimes uncomfortable, insights for clinicians and researchers." Rodney H. Taylor, The Lancet"...this is a challenging historical study, sophisticated in its research and justifiably confident in its analysis. Marks has given us the best study we have of the shifting place and meanings of science in the culture of twentieth-century American clinical medicine." John Harley Warner, Nature"...the chapters on the struggles to introduce randomized clinical trials are impressive. The book is sure

to change how we regard the origins of clinical trials; it also asks us to broaden our understanding of experimental ethics and to question the effects of different kinds of disciplinary authority. Marks shows once again that there is no single voice for science, but also that statistical designs can never substitute for political engagement when it comes to the kinds of therapies we decide to bar or allow. There is no better history of the complex weave of science, politics, and ethics in the design of therapeutic research protocols." Robert N. Proctor, Ph.D., The New England Journal of Medicine"In a deeply researched, superbly structured, and lucidly written account, Harry Marks describes the attitudes and activities of a varied American group he terms 'therapeutic reformers,' who during this century strove 'to use the science of controlled experiments to direct medical practice'...Marks ends with a chapter on contemporary problems...His perspectives of science, politics, and ethics is well worth the attention of all participants in and observers of this complicated and crucial process related to the health of the nation." James Harvey Young, Bulletin of the History of Medicine"This book merits reading by anyone trying to understand the complex and problematic rrelationship between biomedical science and clinical patient care." Marcia Meldrum, Isis"This book merits reading by anyone trying to understand the complex and problematic relationship between biomedical science and clinical patient care." Marcia Meldrum, Isis"Marks has drwan on a wide array of published and unpublished sources in this well-written book. The story that he tells is a complex one that weaves together many threads..." John Parascandola, American Historical "This sociologically-informed historical account enables some of the underbelly of relationships between health-care knowledge and medical policy to be examined. Its depiction of a science relatively weak in its ability to shape health-care policy is worthy of careful consideration amongst the current proponents of health technology assessment and evidence-based medicine." Alex Faulkner, Science and Public Policy"The Progress of Experiment: Science and Therapeutic Reform in the United States: 1900-1990" explains the origins of clinical research in the United States and how it has evolved into an indispensible foundation for medical care. It also explains why the Food Drug Administration controls the marketing and labeling of drugs, but not how physicians prescribe them." - Journal of Clinical Research Best Practices