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978-0-521-39557-1 - Worse than the Disease: Pitfalls of Medical Progress

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Pitfalls of medical progress

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DIANA B. DUTTON

with contributions by

THOMAS A. PRESTON

NANCY E. PFUND



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978-0-521-39557-1 - Worse than the Disease: Pitfalls of Medical Progress

Diana B. Dutton

Frontmatter

[More information](#)

For Hal and Geoffrey, with gratitude and love

Hal, my husband, has been my major source of inspiration for every phase of this book, from the project's initial conception, through the challenges of research, teaching, public outreach, and writing, to the final grueling stages of editing and revision. He gave generously and unstintingly, whether the need was for critical editorial counsel, cooking and shopping so I could write, or all that fell in between. My son Geoffrey's help was less direct but also vital. He allowed me nine uneventful months to work on the book, timing his arrival perfectly a few days after the manuscript was sent off. I am deeply grateful to them both.

Cambridge University Press

978-0-521-39557-1 - Worse than the Disease: Pitfalls of Medical Progress

Diana B. Dutton

Frontmatter

[More information](#)

Contents

<i>List of contributors</i>	page viii
<i>Preface</i>	ix
<i>Acknowledgments</i>	xiii
<i>List of abbreviations</i>	xvi
Part I Overview	1
1 Introduction	3
2 Where are we and how did we get there?	13
Part II Four case studies	29
3 DES and the elusive goal of drug safety	31
4 The artificial heart <i>by Thomas A. Preston</i>	91
5 The swine flu immunization program	127
6 Genetic engineering: science and social responsibility <i>by Diana B. Dutton and Nancy E. Pfund</i>	174
Part III Lessons, questions, and challenges	227
7 Risks and rights	229
8 Compensating the injuries of medical innovation	255
9 What is fair? Medical innovation and justice	285
10 The role of the public	319
11 What is possible? Toward medical progress in the public interest	350
<i>Notes</i>	383
<i>Index</i>	513

Cambridge University Press

978-0-521-39557-1 - Worse than the Disease: Pitfalls of Medical Progress

Diana B. Dutton

Frontmatter

[More information](#)

Contributors

DIANA B. DUTTON, Ph.D., is Senior Research Associate at the Stanford University School of Medicine, where she is Associate Director of the Robert Wood Johnson Clinical Scholar Program, a postgraduate training program in the social sciences for physicians. She holds a Ph.D. in social policy analysis from the Massachusetts Institute of Technology, and has taught health policy and medical sociology at the undergraduate and graduate levels at Stanford and at the University of California at Berkeley School of Public Health. She has published numerous articles on the relation between social class and health, the nature of medical care in different practice settings, and the theory and practice of public participation in science policymaking.

THOMAS A. PRESTON, M.D., is Chief of Cardiology, Pacific Medical Center and Professor of Medicine, University of Washington, Seattle, Washington. He has written widely about the artificial heart, contributing articles to the *Hastings Center Report*, major newspapers, and magazines. In 1983, he won the National Association of Science Writers' Science in Society Journalism Award for his work on the artificial heart. He is also author of *The Clay Pedestal* (Charles Scribners and Sons, 1986).

NANCY E. PFUND, M.A., M.P.P.A., received a masters degree in anthropology from Stanford University, where she studied the culture of modern science, and training in management at Yale University. In the late 1970s, she served as a lobbyist for the Sierra Club on Capitol Hill during the height of the debate over recombinant DNA research regulation. Since then she has written a position paper on genetic engineering for the California State Office of Appropriate Technology and has participated in other state policy activities, and has contributed articles to *Biotechnology News-watch*, a trade journal. She is presently a Senior Analyst for Hambrecht and Quist in San Francisco, where she follows the environmental service industry.

Cambridge University Press

978-0-521-39557-1 - Worse than the Disease: Pitfalls of Medical Progress

Diana B. Dutton

Frontmatter

[More information](#)

Preface

This book explores the social, ethical, and economic dilemmas society faces as a result of medical innovation, and the role of the general public in resolving them. It is the product of a multidisciplinary research project based at the Stanford University School of Medicine and funded by the National Science Foundation's Program in Ethics and Values in Science and Technology, with additional support from the Rockefeller Foundation.

Many aspects of the book and the project that produced it are, by conventional academic standards, rather unusual. First, the book is written for a general audience rather than for specialists, although we hope that specialists will also find in it new ideas and information. Its primary purpose is to communicate the central issues raised by medical and scientific innovation in a manner that is widely accessible, yet also accurate. We have therefore tried to keep specialized terminology to a minimum and to avoid the dry and often obscure style characteristic of much academic writing, without sacrificing scholarly standards of analytic rigor and documentation. We have also tried to bridge the sometimes considerable chasm between abstract intellectual theories and the practical concerns of policymakers and citizens.

Second, the book is broadly interdisciplinary in outlook. At one point or another, the project included faculty, staff, and students from medicine, history, political science, sociology, economics, philosophy, anthropology, education, regional planning, and law. In analyzing the history and implications of the four cases, we have used the varied perspectives of these different disciplines to enrich our understanding of both the problems of medical innovation and their potential solutions. The issues involved are complex and intertwined. By looking at them through multiple "lenses," we have tried to delineate their principal dimensions.

To have restricted our investigation to the vantage point of a single discipline, or to the "testing" of a particular theoretical

model or hypothesis, would, we felt, have imposed unnecessary and arbitrary constraints on our inquiry. For much as one might wish otherwise, the present level of knowledge about medicine's dilemmas and what to do about them is woefully inadequate. Such questions do not respect the traditional boundaries of academic disciplines, nor does any one discipline possess a theoretical framework sufficiently powerful to provide comprehensive hypotheses about expected relationships. The best that can be done under these circumstances is to approach the investigation with an open mind – unfettered by intellectual blinders and cognizant of as many of the potentially relevant theories and facts as possible – and then, putting it all together, try to interpret what has been learned. The merits of the insights gained will be determined not, as in the hard sciences, through replication by independent investigators, but through the test of time and actual experience.

The traditional norm in academe is depth, not breadth. Expertise, as one wag put it, involves knowing more and more about less and less, until one finally knows everything about nothing. Obviously, specialization has allowed enormous efficiencies in the pursuit of knowledge. But, in the process, the “big picture” is often lost. Experts are prepared to expound on one small piece of the puzzle, but not on how the various pieces fit together. In this book we reverse that emphasis. Focusing on innovations in four different areas, we try to show how the present structure and process of biomedical decisionmaking relates to such broad questions as the justice of resource allocation, the nature of judgments about risk, legal and social responsibility for medical injuries, and the governance of science and medicine. We do not pretend to present an exhaustive analysis of any of these issues; readers who wish more extensive or detailed discussions will find a huge volume of literature on each topic. Instead, we have tried to illuminate the central policy questions raised by the cases in light of the major theoretical arguments in the literature, distilling the theory and evidence in each area and leaving to interested readers the task of filling in the details. Such a synthesis, we believe, is essential in attempting to understand the problems confronting medicine and the choices that lie ahead. It is, after all, the broad contours and interrelationships of policy questions rather than their isolated details that must ultimately inform our choices.

Implicit in policy questions, as well as answers, are social values. The values reflected in this book are, generally speaking, egalitarian and humanitarian; they are concerned with respect for in-

Cambridge University Press

978-0-521-39557-1 - Worse than the Disease: Pitfalls of Medical Progress

Diana B. Dutton

Frontmatter

[More information](#)*Preface*

xi

dividual autonomy and with social justice. Whether one agrees that the arguments and recommendations presented would in fact promote these ideals depends not only on values but also on one's assumptions about social, economic, and political dynamics. Some of the dynamics that influence medical innovation are described in the chapters that follow; others are merely hinted at. The important point here is that our analysis is not, and could not be, "value free." Social values, whether acknowledged or not, form the core of all historical interpretation and policy analysis; the decision to report one event and not another, for instance, or to analyze particular policy consequences and not others, involves value choices. Furthermore, value choices are inescapable in interpreting the human meaning of the events described.

Several unusual aspects of the project that produced this book are also worth mentioning. The project was, in a sense, itself an experiment in participatory, collaborative research, melding investigation with teaching and community involvement. Our goal was to gain a better understanding of the advantages and disadvantages of public participation in biomedical policy decisions through direct observation of the role of nonexperts in our own research, and to involve students in our learning process as well. There were two main forms of public participation. Throughout the early stages of the project, we met regularly with a volunteer "Public Advisory Board," consisting of members of local labor, professional, civic, religious, public interest, educational, and environmental groups. In addition, we undertook an active program of outreach to the community, holding discussions with civic, medical, public health, religious, labor and environmental groups as well as with individual government officials, scientists, academics working on related topics, and groups of lay citizens. The Public Advisory Board gave us ongoing feedback from people familiar with the project as a whole, while the outreach discussions offered a fresh perspective on people's reactions to particular cases or issues.

The responses of these predominantly lay audiences were often remarkably perceptive. It was generally understood, for example, that the health care budget cannot be evaluated separately from overall public expenditures, and that many nonmedical programs may yield greater health benefits than some medical innovations. Referring to the artificial heart program, one person commented: "It seems to me that there are many possible projects which could prevent more deaths – deaths of potentially much healthier pop-

Cambridge University Press

978-0-521-39557-1 - Worse than the Disease: Pitfalls of Medical Progress

Diana B. Dutton

Frontmatter

[More information](#)

ulations; for example, highway safety, air traffic control.” Another, stressing the finite volume of health resources, commented that “the government cannot continue to finance every ‘good idea’ that comes along. . . .” One person urged that since the artificial heart program “was done in secret and the cost is astronomical, anything we can do to stop it we should do.” Another asked bluntly, “Why are we just sitting here?”

These experiences gave us a firsthand view of public reactions to the case studies and related policy questions, and certainly influenced our own perspective on policy choices. They confirmed our expectation that broader involvement in the research would enrich and deepen our understanding of the issues we were studying. We were impressed, and heartened, by the extent of interest among lay citizens in the problems posed by medical innovation and the desire of many to help with the search for possible solutions.

Predictably, perhaps, this multidisciplinary, participatory experiment in research and teaching also ran into a number of problems. A subject as large and amorphous as that of this book requires a breadth of knowledge and background that neither I, as project director, nor any of the other investigators had at the outset, and we had trouble providing adequate guidance for students and lay volunteers. While many students felt they had received an unusual and much-appreciated educational experience, the mixture of teaching and investigation was clearly not the most efficient way to conduct research. Even more time-consuming was our experimentation with public participation. Although contacts with diverse community groups yielded valuable insights for the project while also providing useful public education, they inevitably slowed the pace of the research and writing.

We expected that most students and lay volunteers, given their inexperience with research, would need considerable direction in order to take an active part in the investigation. They did. We were less prepared for the converse problems of overspecialization among many of the experts we consulted. Although highly knowledgeable about a given field, many experts had difficulty relating the field’s major theories to the empirical realities of the four cases, and in expressing their ideas in terms comprehensible to nonexperts (including specialists in other areas). There were also some attempts at “disciplinary imperialism,” in which particular experts, convinced of the unique merits of their discipline, sought

Cambridge University Press

978-0-521-39557-1 - Worse than the Disease: Pitfalls of Medical Progress

Diana B. Dutton

Frontmatter

[More information](#)*Preface*

xiii

to extend its sway over the rest of the project. These and other difficulties may be part of the price one must pay for the breadth of vision and cross-fertilization of ideas that can come from interdisciplinary communication and cooperation.

Looking back, many things could perhaps have been done differently. Certainly this was not the most efficient way to write a book. But the book was only one of the project's goals; equally important were our community outreach, teaching, and experimentation with public participation in the study itself. The book is informed by all of these experiences, although in many ways that at this point would be difficult to trace.

Acknowledgments

Because the book emerges from a collaborative research process, it represents the fruits of many people's labor. Students who took affiliated courses, community volunteers, project staff, and expert consultants all helped to develop and interpret much of the necessary information and to formulate some of the basic arguments and ideas. The book could not have been written without their contributions, even though their names may not appear on the final chapters. I am deeply indebted to them, as are the book's other contributors.

A number of individuals deserve special mention. John Bunker, M.D., Professor of Family, Community and Preventive Medicine, helped conceive of and design the original study, served as my co-principal investigator on the National Science Foundation grant, and participated in our many research meetings and teaching activities. He worked on early drafts of the chapters on risks and compensation, and offered valuable help and counsel on many aspects of the book and its completion. Equally instrumental in the original conception of the project was Halsted Holman, M.D.,

Cambridge University Press

978-0-521-39557-1 - Worse than the Disease: Pitfalls of Medical Progress

Diana B. Dutton

Frontmatter

[More information](#)

xiv

Acknowledgments

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Many other people played a major role in the work leading to the final written products. Barton Bernstein, Ph.D., helped with the design and development of the project, attending research meetings, critiquing chapter drafts and conducting extensive research on the artificial heart and swine flu immunization programs. Ralph Silber, M.P.H., served as administrator for the project in its early years, maintaining order among the chaos of its disparate participants and organizing and documenting our public outreach program. Along with Malcolm Goggin, Ph.D., he performed much of the original investigation relating to public participation. Malcolm Goggin, in turn, was actively involved in project teaching, and also conducted the original research on the swine flu program. Richard Gillam, Ph.D., unearthed valuable information on the history of DES and prepared drafts for the project. Lawrence Molton, J.D., furnished the project with his impressive knowledge about legal aspects of the cases, making important contributions to our research on compensation, risks, and DES. Other project participants whose work helped make this book possible include Robin Baker, M.P.H., Randy Bean, Dennis Florig, Ph.D., Seth Foldy, M.D., Jinnet Fowles, Ph.D., Kenneth Freedberg, M.D., Susan Friedland, M.D., Jane Grant, Ph.D., Thomas Grey, J.D., Deborah Lubeck, Ph.D., Carla Lupi, M.D., Becky O'Malley, Linda Schilling, J.D., David Schnell, M.D., Clara Sumpff, and Carol White, Ph.D. We are grateful to Natalie

Cambridge University Press

978-0-521-39557-1 - Worse than the Disease: Pitfalls of Medical Progress

Diana B. Dutton

Frontmatter

[More information](#)*Acknowledgments*

xv

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Cambridge University Press

978-0-521-39557-1 - Worse than the Disease: Pitfalls of Medical Progress

Diana B. Dutton

Frontmatter

[More information](#)

Abbreviations

ACIP	Advisory Committee on Immunization Practices of the Public Health Service (in practice, of CDC)
AIA	American Insurance Association, a trade organization representing casualty insurers
AMA	American Medical Association, a national professional medical organization
CDC	Centers for Disease Control, Atlanta, Georgia, an agency of the Public Health Service
<i>E. coli</i>	<i>Escherichia coli</i> , a common type of bacteria that inhabits the human gut
FDA	Food and Drug Administration, an agency of HHS
GAO	U.S. General Accounting Office, an agency of Congress
HEW	U.S. Department of Health, Education and Welfare (now called HHS)
HHS	U.S. Department of Health and Human Services (formerly called HEW)
HSAs	Health Systems Agencies, regional agencies established by Congress in the mid-1970s to plan local health care services
<i>JAMA</i>	<i>Journal of the American Medical Association</i>
NAS	National Academy of Sciences, an honorary society that advises the government on scientific issues
NIH	National Institutes of Health, an agency of HHS
Ob-Gyn	Obstetrics and Gynecology, as in Ob-Gyn Advisory Committee, an advisory committee to the FDA
OCAW	Oil, Chemical, and Atomic Workers Union
OMB	Office of Management and Budget, a fiscal agency in the Executive Office of the President
OTA	Office of Technology Assessment, an advisory agency to Congress
RAC	Recombinant DNA Molecule Program Advisory Committee, an advisory committee to the NIH
USDA	U.S. Department of Agriculture
WHO	World Health Organization, Geneva, Switzerland