

Appendix G.—Method of the Study and Description of Other Volumes

Method of the Study

The study *Strategies for Medical Technology Assessment* began on July 1, 1980. Immediately thereafter, a planning period was begun, and an advisory panel was selected.

Most of the studies undertaken at OTA rely on the advice and assistance of an advisory panel of experts. The advisory panel for a particular assessment suggests source materials, subject areas, case studies, and perspectives to consider; assists in interpreting information and points of view that are assembled by OTA staff; and suggests possible findings and conclusions based on the accumulation of information produced by the study. The panel members review staff and contract materials for accuracy and validity, discuss policy options of the study, and present arguments for and against the options and conclusions. However, they do not determine the report's final form and are not responsible for its content, direction, or conclusions.

The advisory panel for this assessment consisted of 19 men and women with backgrounds in medicine, public health, sociology, information and library science, economics, law, psychiatry, consumer advocacy, technology assessment, industry, health policy, ethics, and health insurance. The panel was chaired by Lester Breslow of the University of California at Los Angeles. One member of the OTA Health Program Advisory Committee, Kerr White, also served on the panel.

The first panel meeting was held on September 12, 1980, in Washington, D.C. (the site of all three panel meetings). Prior to the meeting, panel members were sent a detailed study plan, including a suggested outline, and several pertinent articles as background for discussion. During the meeting, panel members discussed the overall study plan for the assessment and helped OTA staff refine the goals for the project. The panel examined the project boundaries and definitional issues and was key in sharpening the study's focus. The panel was also helpful in reviewing the primary issue areas to be covered and in providing suggestions of individuals and organizations to contact for information and assistance. The panel was particularly helpful in suggesting modifications in several of the contractors' reports (which were just beginning). Several contractors were present and participated in the meeting.

By the fall of 1980, all of the major contracts for the main report were let. Each contract effort is described below:

- John Williamson (Johns Hopkins University) developed a helpful and imaginative theoretical framework for a strategy for medical technology assessment.
- Kathleen Lohr and Robert Brook (Rand Corp.) were asked to explore the potential role of the Professional Standards Review Organizations (PSROs) in a medical technology assessment system. With the assistance of John Winkler (Rand), they examined how physicians received new medical knowledge, the potential for PSROs to transfer that knowledge, and the ability of PSROs to test technologies for safety and effectiveness. Their work is available from Rand as a published document.
- Paul Wortman (University of Michigan) and Leonard Saxe (Boston University) analyzed the methods of testing medical technologies, synthesizing information and soliciting group opinions. Their paper, reproduced as appendix C, formed the basis for much of chapters 3 and 5 of this report.
- John Reiss (Baker & Hostetler) was asked to write a paper on the role of reimbursement policy in an assessment strategy. His ideas are included in many sections of this report.
- John Bunker collaborated with Jinnet Fowles (both of Stanford) and a number of associates to write a paper on the effects of reimbursement on the innovation process for medical and surgical procedures. They developed the concept for the "Institute for Health Care Evaluation," reproduced as appendix F, and submitted several case studies, two of which are included in appendix E. Their main work is published as a two-part series by the *New England Journal of Medicine* (Mar. 4 & 11, 1982).
- John Wennberg (Dartmouth) submitted an interesting paper on the use of health insurance claims and patient outcome data to evaluate health care technologies after they are generally available.
- Patricia Woolf (Princeton) prepared a paper describing private sector activities in both bibliographic data base production and vending. Appendix B contains a listing of those bibliographic-related resources.

Contractors' reports were reviewed both by OTA staff and by a large number of outside experts. Reviewer's comments were forwarded to the authors, who incorporated them in revising drafts.

In January 1981, a workshop was held in Boston to review the first draft of the Wortman/Saxe paper on the role of various methods for testing medical technologies for safety, efficacy, and effectiveness. Participants included the authors and other scientists from several research disciplines, an advisory panel member, and OTA staff. Wortman and Saxe prepared a second draft of their paper on methods based largely on that workshop.

The second advisory panel meeting was held on January 28, 1981. The discussion of that meeting centered around three main topics: 1) the selection of methods for testing medical technologies, 2) the use of the PSROs in technology assessment, and 3) the Medical Literature Analysis and Retrieval System (MEDLARS) and the National Library of Medicine (NLM). Panel comments were helpful in all three areas of study and were instrumental in determining the role of all three areas in an assessment strategy.

OTA staff produced two staff papers for congressional hearings held by the House Energy and Commerce Committee and the Senate Labor and Human Resources Committee in March 1981. One paper dealt with NLM, the other with the National Center for Health Care Technology (NCHCT). After the hearings, both papers were reviewed widely and were subsequently incorporated in this report and related technical memorandum.

A workshop on reimbursement policies and innovation met in Washington on May 13, 1981. The purpose of this workshop was to review the papers by Reiss and by Bunker and generally to discuss the effects that medical technology assessment and reimbursement policy have on innovation. In addition to the authors and OTA staff, workshop participants included several members from the study advisory panel, an inventor, representatives from industry and researchers and academicians interested in medical technology innovation. The workshop was helpful to Reiss and Bunker in revising their papers and was particularly helpful to OTA in understanding both the innovation process and the effects that an assessment policy may have on that process.

While the main project was proceeding, several sub-components began to take on added significance as separate projects in their own right. Following the March Senate Labor and Human Resources Committee hearing, OTA was asked by Chairman Hatch to prepare a separate technical memorandum by expanding the NLM component of the study to examine the role of both the private and public sectors in producing and vending bibliographic data bases. In addition, a separate volume concerning the postmarketing surveillance of drugs was prepared in draft. Subsequent-

ly, OTA was asked by the House Committee on Energy and Commerce to elevate the postmarketing surveillance effort to full report status (i.e., complete with options). It is being published as volume II of this assessment. And finally, the House Committee on Energy and Commerce also asked OTA to write a separate report on the effects which competitive health care system proposals may have on medical technologies. The Senate Committee on Labor and Human Resources endorsed that request.

Prior to the third panel meeting, held on September 22, 1981, an initial draft of the final report was prepared and sent to panel members. The entire meeting was spent reviewing that draft and focused primarily on the policy analysis and options for Congress.

The draft was then revised by OTA staff on the basis of the suggestions and comments of the advisory panel. The revised draft was then sent for a further round of review by a much broader range of experts in a diversity of settings: Federal agencies, private and non-profit organizations, academic institutions, practicing health professionals, consumer groups, and other selected individuals. Altogether, more than 150 individuals or organizations were asked to comment on drafts of the main volume or other components of this assessment. The main volume, containing policy options, was reviewed by approximately 100. Following revisions by OTA staff, the report was submitted to the Technology Assessment Board.

Description of Other Volumes

This assessment has resulted in seven documents:

1. the main report, of which this index is a part;
2. a brochure that summarizes the main report;
3. a staff paper on NCHCT, issued to Congress in March 1981;
4. a staff paper on NLM, also issued to Congress in March 1981;
5. a monograph published by Rand Corp. entitled *Peer Review and Technology Assessment in Medicine*;
6. a full report, which is volume II of this assessment, entitled *Postmarketing Surveillance of Prescription Drugs*; and
7. a technical memorandum on *MEDLARS and Health Information Policy*.

Brief descriptions of the last two volumes are provided below. Also described below is a volume entitled *Medical Technology Under Proposals To Increase Competition in Health Care*. This report grew out of the *Strategies* assessment but is now being published separately.

Postmarketing Surveillance of Prescription Drugs (Vol. II of *Strategies for Medical Technology Assessment*)

To market a drug, manufacturers must provide evidence of its efficacy and safety to the U.S. Food and Drug Administration (FDA). Once these premarketing requirements are met and a drug is released, FDA can suggest but cannot impose restrictions on the drug's use. However, it can remove the drug from the market for reasons such as new evidence on safety or efficacy, any untrue statement of a material fact, or failure to meet manufacturing standards.

In the premarketing clinical tests, controlled clinical trials with limited numbers of test subjects are used. Observation of limited numbers of patients for a short period of time uncovers minimal information about a drug's potential uses and dangers, and postmarketing activities of various types have been proposed over the past decade. However, postmarketing surveillance has been linked to other policy objectives, such as speeding up the premarketing approval process and using postmarketing information to improve physician prescribing practices.

In OTA's report, the analysis of these issues is framed around the following questions: 1) what aspects of the premarketing requirements might be curtailed to shorten the drug approval process? 2) what additional powers would help strengthen FDA's activities in the postmarketing period? and 3) what possible tradeoffs might there be between curtailing some premarketing requirements and strengthening FDA's role in monitoring drugs once they are released into the marketplace?

MEDLARS and Health Information Policy

This technical memorandum examines the role of NLM's computerized bibliographic retrieval and tech-

nical processing system, MEDLARS, with respect to the role of private sector information systems in the creation and distribution of computerized bibliographic health-related information.

The study examines two specific sets of issues: the range of NLM's computerized products and services, and NLM's pricing structure for leasing data base tapes and for online access to the data bases. It focuses on the domestic and international implications of these issues and stresses the importance of new and emerging computer and communications technologies on biomedical information policy.

The issues are considered within a general framework of the Government's role in the allocation of resources to information development and distribution, the effect of the Government's involvement in allocative activities on certain segments of the private information sector and the health community, and the historic role of the Government in health information activities.

Medical Technology Under Proposals To Increase Competition in Health Care

Proposals to stimulate competition in medical care tend to fall into three categories: 1) increased cost sharing by patients for services, 2) increased competition and hence greater pressure for efficiency among health plans or providers, and 3) increased antitrust activities. OTA's study considers only the first two.

The study focuses on the effects and policy implications of the different proposals in three major areas of medical care: 1) consumer information, 2) quality of care, and 3) technology innovation and use. In each of these areas, the study examines the situation that would pertain under each type of proposal and any differences from the present situation, effects that could be expected, any problems that would arise, and methods of addressing these problems.