# Appendix B

# METHOD OF THE STUDY

Studies in the Office of Technology Assessment (OTA) are frequently done with the assistance of an advisory panel of experts. Panel members suggest source materials and subject areas, assist in data collection and interpretation, review staff drafts for accuracy and validity, suggest conclusions based on the facts, discuss alternatives for the consideration of Congress, and give arguments for and against specific alternatives. The panel, however, does not determine the content of the report and is not responsible for the conclusions and options,

An advisory panel of experts was formed for the study of efficacy and safety of medical technology. Dr. Lester Breslow was named panel chairman, With the help of Dr. Breslow, other panel members then were selected to represent a wide range of disciplines, viewpoints, and expertise. Two members of the OTA Health Advisory Committee, who had expressed particular interest in this study, were named to the panel.

The first meeting of the panel was held in Washington, D. C., on October **26, 1976.** At this meeting, the panel considered the work plan prepared by the staff. The panel endorsed the use of specific case studies of medical technologies to illustrate the benefits and problems involved in assessing the efficacy and safety of medical technologies. The panel also discussed the concepts of efficacy and safety.

After the October meeting, all panel members submitted lists of technologies for the proposed cases. Staff developed criteria for selection of the final list of cases. These criteria were designed to include:

1. Examples of types of technology by function (preventive, diagnostic, and therapeutic and rehabilitative);
2. Examples of different stages of development and diffusion (not yet diffused, experimental or pilot, established in medical care, abandoned);
3. Examples from different areas of medicine (such as general medical practice, pediatrics, obstetrics, and surgery);
4. Examples addressing medical problems that are important because of their high frequency or significant impacts;
5. Examples with associated high costs;
6. Examples of technologies in widespread use; and
7. Examples with sufficient evaluable literature.

Based on the chosen criteria and panel suggestions, *16* cases were selected, and the literature on each was reviewed. (Case 17 was added during 1978. )

The second meeting of the panel was held in Washington, D, C., on December **10, 1976.** At this meeting, the panel reviewed a brief precis on each of the suggested cases. The panel made several suggestions concerning selection of cases, corrected mistakes of fact and interpretation in the case descriptions and suggested additional references. Fur-

ther, the panel reviewed a staff paper on methods for evaluating the efficacy and safety of medical technologies, which was the basis for chapter 4 of this report. Two panel members agreed to develop cases for the final report, and one panel member agreed to develop a brief paper on private sector activities,

After the second meeting of the panel, data collection activities were intensified. In addition to review of the scientific literature, the staff read many Government and private sector reports. All Government agencies and departments listed by the Office of Management and Budget (OMB) as having health activities were sent a survey asking them to summarize their involvement in efficacy and safety issues. Almost 100 private sector organizations also were sent a survey requesting information about their activities in the areas of efficacy and safety of medical technologies. Finally, officials of a large number of public and private agencies and organizations were interviewed, either in person or by telephone.

The third meeting of the panel was held in Washington, D. C., on February 11, 1977. At this meeting, four guests made comments and answered questions from staff and panel: Dr. Seymour Perry, Special Assistant to the Director, National Institutes of Health (NIH); Dr. Mark Novitch, Deputy Associate Commissioner for Medical Affairs, Food and Drug Administration (FDA); Dr. Michael Goran, Director, Bureau of Quality Assurance; and Dr. Clifton Gaus, Director of Health Insurance Studies, Social Security Administration (SSA). These witnesses also commented on a staff draft concerning the involvement of their agencies in efficacy and safety assessment. During the remainder of the meeting, the panel discussed a staff draft that was the basis for chapter 5 of this report and suggested conclusions and policy alternatives that might result from the study.

From February 11 to March 11, 1977, OTA staff wrote a first complete draft of the report. NIH was particularly helpful in this effort, submitting material on almost all of the selected case studies. The responses to the survey of Government agencies and departments were incorporated in chapter 5.

The final meeting of the panel was held, again in Washington, D. C., on March 11, 1977. The panel reviewed the first draft and offered comments and criticisms.

After the meeting, revised cases were sent to NIH for substantive review and to all agencies of the Department of Health, Education, and Welfare (HEW) for confirmation of their roles as described in the cases. Each case was also reviewed by experts in the private sector.

A second draft of the report was then prepared, and in May *1977* was sent *to* the study advisory panel, to the Health Advisory Committee, to the OTA Technology Assessment Advisory Council, and to approximately 100 individuals both within and outside the Federal Government, including officials of Government agencies described in the report.

Changes in staff and time devoted to preparation of other OTA reports, particularly, Policy *Implications of CT Scanners,* delayed work on the third draft of this report, except for the incorporation of comments on the second draft.

The third, and final, draft was prepared during spring of 1978. This draft was reviewed by the study advisory panel, the Health Advisory Committee, and by approximately 80 additional individuals and organizations from both within and outside of Government. Also, several of the cases were revised by contract. All cases were again reviewed by specialists in the particular subject areas. The Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA); the National Center for Health Services Re-

search (NCHSR); and, again, the NIH were particularly helpful in their reviews of substantive material. The final report was written in accordance with the comments and suggestions provided.