Appendixes

Appendix A.— Method of the Study

On June 17, 1982, OTA's Technology Assessment Board approved the assessment entitled "Federal Policies and the Medical Devices Industry, " to begin September 1, 1982. The proposal stated that the study would address gaps in basic information about the medical devices industry and would examine present and proposed Federal policies that influence the sector.

During the planning period that preceded the study, OTA staff consulted with industry trade associations, consumer groups, and Federal agencies for two purposes: to seek suggestions for members of the study's advisory panel and to identify issues in the field. An advisory panel guides OTA staff in selecting material and issues to consider and reviews written work, but the panel is not responsible for the content of the final report.

The advisory panel selected for this assessment consisted of members from different segments of the industry—large and small companies, medicine, nursing, hospital administration, economics, policy analysis, law, and consumer advocacy. Richard R. Nelson of Yale University chaired the panel, and two other members, Joyce Lashof and Rosemary Stevens, served concurrently on the standing Health Program Advisory Committee. At the beginning of the study, the staff compiled a bibliography and gained familiarity with major issues and with sources of data on companies that make up the industry. This effort was aided by a background paper prepared by Anthony A. Romeo and by a September meeting with company executives arranged by the Health Industry Manufacturers Association. The study was also considered at the September meeting of the Health Program Advisory Committee, which advised that the perspectives of consumers and of different segments of the industry be sought.

At the first panel meeting, on October 7, 1982, discussion centered on the overall study plan and on major policy areas, especially payment for the use of medical devices and premarket regulation by the Food and Drug Administration (FDA). In order to illuminate certain policies and to gain greater insight into certain segments of the industry, it was decided to select specific medical devices for more detailed case study. The panel discussed criteria for selecting the case studies, including the importance of certain policies. Also raised was interest in the process by which devices are developed and brought to market.

Following the panel meeting, OTA staff selected six case studies: the Boston elbow, contact lenses, hemodialysis equipment, nuclear magnetic resonance imaging, technologies for urinary incontinence, and wheelchairs. It was also decided to produce a separate technical memorandum on the policies of the Veterans Administration (VA) concerning medical devices, since the relevant policies of this health care delivery system are both extensive and separate from others. The technical memorandum was to be prepared by OTA staff, and the case studies and other background papers by contractors outside of OTA.

On the basis of advice from the Health Program Advisory Committee and the advisory panel for this assessment, two workshops were held at OTA in December 1982: one on December 7 on the purchase and use of medical devices and the other on December 1.5 on research, development, and marketing of medical devices. Suggestions for organizations and individuals to participate were solicited from a wide range of interested parties.

The first workshop, which was chaired by Louise Russell from the advisory panel, consisted of people involved in different facets of the purchase and use of devices, including multihospital organizations, municipal hospital administration, hospital administration in the VA, hospital bioengineering, handicapped people, and physicians of different specialties (see app. B). Although their interests varied, the participants shared the need for better evaluative information on devices, concern about postmarketing surveillance of device problems and standard setting for devices by FDA, and interest in devices that meet a clinical need instead of overly sophisticated ones.

The participants at the second workshop, chaired by Richard Nelson of the advisory panel, were involved in the invention, development, and marketing of devices as individual inventors, managers in large companies, university researchers, or marketing representatives (see app. B). Discussion in this workshop centered on problems in commercializing devices, especially in securing funding to develop prototype devices; the role of Federal regulation, including FDA, VA, and the Patent Office; the role in the development process of different actors, such as individual inventors, small firms, and large firms. On the basis of this discussion, the OTA staff decided to compile vignettes on the development process from inventors of different devices and from different organizations.

The staff next prepared a draft status report, which presented information gained up to that point in the study on the industry and on Federal policies regarding payment, FDA regulation, the VA, research and development, patents, and international trade. The status report was the major topic of the second panel meeting held at OTA on March 3, 1983. The discussion pointed out the advisability of focusing the final report of the assessment on policies specific to medi-

cal care and, within those policies, on matters related to medical devices.

Considerable discussion at the panel meeting also surrounded FDA regulation of medical devices. Because of the importance of this policy area, a workshop on regulation under the 1976 Medical Device Amendments was held at OTA on May 19, 1983. Participants included attorneys and other policymakers from Federal agencies, consumer groups, and private firms who had been involved in drafting and implementing the legislation (see app. B). The workshop discussed the intentions of the framers of the law, the evolution of the bill as it went through the legislative process, and its implementation as practical problems were faced by FDA.

At its third meeting, on August 4, 1983, the advisory panel discussed the revised draft of the status report as well as drafts of a case study and background paper that had been received. The panel noted that the report would have to take into account the changes in payment occasioned by Medicare's forthcoming use of diagnosis related groups. The final draft of the status report was sent to the requesting congressional committees in order to inform them of the progress and components of the study.

During the fall and earl$_y$ winter, drafts of the remaining case studies and background papers were received, sent to the advisor$_y$ panel and other experts for review, and revised by contractors. The material was therefore available to OTA staff as they were preparing the first draft of the final report. In March 1984, that draft was sent to the advisory panel, the Health Program Advisory Committee, and 75 other reviewers who are experts in fields related to different aspects of the study.

The draft report was discussed at the March 31 meeting of the Health Program Advisory Committee and at the fourth and final meeting of the advisory panel on April 3. The committee advised that more note be taken of devices for which adoption and use have been insufficient. The advisory panel concentrated on the summary chapter, FDA regulation, and policy options. After the meeting, OTA staff revised the final report based on comments received from the panel and other reviewers and in early May sent the revised summary chapter to the advisor$_y$ panel and the Health Program Advisory Committee. The revised report was reviewed within OTA and in mid-May was submitted for approval to the Technology Assessment Board.

Several documents are being published in connection with the assessment: the main report (of which this appendix is a part), a booklet summarizing the main report, a technical memorandum on policies of the VA, a background paper of inventors' vignettes, and six case studies. In addition to this report and the summary, the following publications will be available through the U.S. Government Printing Office:

- *Inventors' Vignettes of the Development of Medical Devices,* edited by OTA staff.
- *Medical Devices and the Veterans Administration,* by OTA staff.
- *Technologies for Managing* ***Urinary Incontinence,*** by Joseph Ouslander and Robert L. Kane, University of California, Los Angeles.
- ***The Boston Elbow,*** by Sandra J. Tanenbaum, Massachusetts Institute of Technology.
- ***The Contact Lens Industry: Structure, Competition and Public Policy,*** by Leonard G. Schifrin, College of William and Mary.
- ***Nuclear Magnetic Resonance Imaging Technology: A Clinical, Industrial, and Policy Analysis,*** by Earl P. Steinberg and Alan B. Cohen, Johns Hopkins Medical Institutions.
- ***The Hemodialysis Equipment and Disposable Industry,*** by Anthony A. Romeo, University of Connecticut.
- ***The Market for Wheelchairs: Innovations and Federal Policy,*** by Donald S. Shepard and Sarita L. Karen, Harvard School of Public Health.

In addition, papers were prepared on contract to OTA to provide background information for the main report and are available through OTA in limited quantities:

- "Capital Markets, Government Regulation, Tax Policy, and the Financing of Medical Device Innovations," by James R. Barth and Joseph J. Cordes, with Michael Bradley, George Washington University.
- "Governmental Barriers to International Trade in Medical Devices in the United States, United Kingdom, France, the Federal Republic of Germany, Canada, Japan, and Mexico, " by Kaye, Scholer, Fierman, Hays & Handler, Washington, DC.
- "Innovative Activity in the Medical Devices Industry," by Anthony A. Romeo, University of Connecticut.
- "Medical Device Standards and International Trade, " by Kornmeier, McCarthy, Lepon & Harris, Washington, DC.
- "The Impact of Federal and State Regulatory Programs on the Ambulatory Laboratory Testing Industry and the Demand for Instrumentation," by Hope S. Foster, O'Connor & Hannan, Washington, DC.
- "The Relationship of FDA, PHS, and HCFA Regarding Medical Device and Organ Transplant

Technologies," by Dennis J. Cotter, Georgetown University.

- "The Role of the Government in the Research, Development, and Commercialization of Computed Tomography (CT) Scanning and Nuclear Magnetic Resonance (NMR) in the United Kingdom," by John Hutton, University of York, England.
- "Veterans Administration Procurement and the Market for Medical Equipment," by Ralph M. Bradburd, Williams College.