

*Federal Policies and the Medical Devices  
Industry*

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**FEDERAL POLICIES  
AND THE  
MEDICAL DEVICES  
INDUSTRY**

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# Foreword

In recent decades, both the range of medical devices and the industry that manufactures them have greatly expanded. At the same time, there has been growing Federal involvement in the U.S. health care system. The Medicare and Medicaid programs established in the 1960s have increased the market for medical technologies and have greatly influenced patterns of payment and use. The Federal Government instituted a premarketing approval process for medical devices in 1976. Other activities, such as funding research and development, regulating the providers of medical devices, and providing medical care for veterans, have involved the Government in the development and purchase of medical devices.

Since the late 1970s, congressional committees have been interested in the effects of such Federal policies on the companies that manufacture medical devices. In early 1982, this interest resulted in a request from the Senate Labor and Human Resources Committee to the Office of Technology Assessment (OTA) for an assessment of Federal policies and their effect on the medical devices industry. The Senate Veterans' Affairs Committee endorsed the request and expressed particular interest in the activities of the Veterans Administration regarding device development and procurement.

In preparing this report, OTA staff drew upon the expertise of members of the advisory panel for the study, members of the OTA Health Program Advisory Committee, and experts in health policy, industry, research and development, economics, health administration, and medicine. Drafts of the final report were reviewed by the advisory panel, chaired by Dr. Richard R. Nelson; OTA's Health Program Advisory Committee, chaired by Dr. Sidney S. Lee; and other individuals and groups with expertise in the area. We are grateful for their assistance. Key OTA staff involved in the preparation of the document were Jane E. Sisk, Cynthia P. King, John C. Langenbrunner, Katherine E. Locke, Lawrence H. Miike, and Judith L. Wagner.



U JOHN H. GIBBONS

*Director*

# Advisory Panel for Federal Policies and The Medical Devices Industry

Richard R. Nelson, *Chair*  
Institute for Social and Policy Studies, Yale University  
New Haven, CT

William F. Ballhaus  
International Numatics, Inc.  
Beverly Hills, CA

Ruth Farrissey  
Massachusetts General Hospital  
Boston, MA

Peter Barton Hutt  
Covington & Burling  
Washington, DC

Alan R. Kahn  
Consultant  
Cincinnati, OH

Grace Kraft  
Kidney Foundation of the Upper Midwest  
Cannon Falls, MN

Joyce Lashof  
School of Public Health  
University of California  
Berkeley, CA

Penn Lupovich  
Group Health Association  
Washington, DC

Victor McCoy  
Paralyzed Veterans of America  
Washington, DC

Robert M. Moliter  
Medical Systems Division  
General Electric  
Washington, DC

Louise B. Russell  
The Brookings Institution  
Washington, DC

Earl J. Saltzgeber  
Foremost Contact Lens Service, Inc.  
Salt Lake City, UT

Rosemary Stevens  
Department of History and Sociology of Science  
University of Pennsylvania  
Philadelphia, PA

Allan R. Thieme  
Amigo Sales, Inc.  
Albuquerque, NM

Eric von Hippel  
Sloan School  
Massachusetts Institute of Technology  
Cambridge, MA

Edwin C. Whitehead  
Technicon Corp.  
Tarrytown, NY

# OTA Project Staff—Federal Policies and the Medical Devices Industry

Jane E. Sisk, *Project Director*

Cynthia P. King, *Analyst*

John C. Langenbrunner, *Analyst*<sup>1</sup>

Katherine E. Locke, *Research Assistant*

Lawrence H. Miike, *Senior Associate*

Elaine J. Power, *Intern*<sup>2</sup>

Judith L. Wagner, *Senior Analyst*

Kerry Britten Kemp, *Health and Life Sciences Division Editor*

Virginia Cwalina, *Administrative Assistant*

Rebecca I. Erickson, *Secretary/Word Processing Specialist*

Brenda B. Miller, *Word Processor/P. C. Specialist*

Clyde J. Behney, *Health Program Manager*

Roger C. Herdman<sup>3</sup> and H. David Banta,<sup>4</sup> *Assistant Director, OTA  
Health and Life Sciences Division*

## Contractors

James R. Barth and Joseph J. Cordes, George Washington University

Dennis J. Cotter, Georgetown University Health Policy Center

Pony M. Ehrenhaft, Washington, DC

Hope S. Foster, O'Connor & Hannan, Washington, DC

John Hutton, University of York, England

IMS America Ltd., Rockville, MD

Kaye, Scholer, Fierman, Hays & Handler, Washington, DC

Kornmeier, McCarthy, Lepon & Harris, Washington, DC

Anthony A. Romeo, University of Connecticut

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<sup>1</sup>Until November 1983.

<sup>2</sup>Summer 1983.

<sup>3</sup>From December 1983.

<sup>4</sup>Until August 1983.