

References

References

1. Abelson, D. S., Director, Technical Trade Barriers, Office of the U.S. Trade Representative, Washington, DC, personal communication, Nov. 29, 1983.
2. Adams, W., Surgilite International, Inc., comments made at OTA workshop, December 1982.
3. Agress, P., "Problems Encountered in Marketing U.S. Medical Devices in Japan: Discussions Between the Two Governments Aimed at Easing Difficulties," *Food Drug Cosmetic Law J.* 38:43, 1983.
4. American Association for Respiratory Therapists, "Guidelines for the Use of Intermittent Positive Pressure Breathing," Dallas, TX, April 1979.
5. American Health Planning Association, *Report of the Commission on Capital Policy*, Washington, DC, March 1984.
6. American Hospital Association, Division of Health Financing Policy, Office of Public Policy Analysis, **Hospital-Blue Cross Contract Provisions, July 1, 1981**, AHA catalog No. 073200, Chicago, IL, February 1982.
7. American Hospital Association, **Hospital Regulation**, Report of the Special Committee on the Regulatory Process, Chicago, IL, 1977.
8. American Hospital Association, Office of Public Policy Analysis, "Incorporating Capital Costs into Medicare Prospective Prices," unpublished draft, Chicago, IL, July 1983.
9. American National Standards Institute, **Directory of International and Regional Standards Organizations (New York: ANSI, 1982)**.
10. American Society for Parenteral and Enteral Nutrition, "Parenteral and Enteral Nutrition," unpublished briefing paper, Washington, DC, Nov. 18, 1982.
11. American Society for Parenteral and Enteral Nutrition, **Public and Private Insurance Coverage of Parenteral and Enteral Nutrition Services**, background paper prepared by Memel, Jacobs, Pierre & Gersh, Washington, DC, March 1983.
12. *AMP, Inc. v. Gardner*, 389 F. 2d 825 (1968); cert. **denied** 393 U.S. 825 (1968).
13. Anbar, M., "University-Based R&D: A New Development in National Economy," **Medical Device & Diagnostic Industry** 5(12):26-29, December 1983.
14. Anderson, G., and Ginsburg, P. B., "Prospective Capital Payments to Hospitals," **Health Affairs** 2(3):52-63, fall 1983.
15. Arakaki, E., U.S. Department of Commerce, Washington, DC, personal communications, February and August 1984.
16. Arizona Board of Regents, "Patent Policy of the Arizona Board of Regents," adopted Apr. 16, 1977.
17. Arthur D. Little, Inc., **Cost of Compliance With Good Manufacturing Practices Regulations by the Medical Device Industry**, prepared for the Food and Drug Administration, Department of Health and Human Services, contract No. 223-79-8052 (Springfield, VA: National Technical Information Service, Department of Commerce, March 1982).
18. Arthur Young & Co. and The Emergency Care Research Institute, **A Profile of the Medical Technology Industry and Governmental Policies**, final report, vol. 1, contract No. 233-79-3011, report to the National Center for Health Services Research, U.S. Department of Health and Human Services, Hyattsville, MD, June 30, 1981.
19. Axelson, P., U.S. Veterans Administration Rehabilitation Research and Development Center, Palo Alto, CA, personal communication, July 1983.
20. Ayres, S. M., "Magnitude of Use and Costs of In-Hospital Respiratory Therapy," **Am. Rev. Resp. Dis.** 122(5):11-13 (pt. 2), November 1980.
21. Baker, D. F., speech presented at the Ninth Annual AAMI/FDA Conference on Medical Device Regulation, Arlington, VA, Nov. 10, 1982.
22. Bandy, W. C., U.S. Department of Commerce, Bureau of Industrial Economics, Washington, DC, personal communication, January 1983.
23. Banta, H. D., "Computed Tomography: Cost Containment Misdirected" (editorial), **Am. J. Public Health** 70:215, 1980.
24. Banta, H. D., Ruby, G., and Burns, A. K., "Using Coverage Policy to Contain Medicare Costs," in U.S. Congress, House Committee on Ways and Means, Subcommittee on Health, **Proceedings of the Conference on the Future of Medicare**, Committee Print No. 23 (Washington, DC: U.S. Government Printing Office, 1984).
25. Barach, A. L., and Segal, M. S., "The Indiscriminate Use of IPPB," **JAMA** 231(11):1141-1142, Mar. 17, 197s.
26. Barth, J. R., and Cordes, J. J., "Capital Markets, Government Regulation, Tax Policy and

- the Financing of Medical Device Innovations," contract report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, February 1984.
27. Barth, J. R., Cordes, J. J., and Tasse, G., "The Impact of Recent Changes in Tax Policy on Innovation and R&D," in *Strategic Management of Industrial R&D: Interdisciplinary Perspectives*, B. Bozeman, M. Crow, and A. Link (eds.) (Lexington, MA: Lexington Books/D.C. Heath & Co., 1984).
 28. Batres, Valdes, Wygard y Asociados, S. C., "Market Survey of Medical Equipment (Mexico)," prepared for U.S. Trade Center, April 1982.
 29. Beck, R. H., "The Effects of Copayment on the Poor," *J. Hum. Resour.* (1):129, 1974.
 30. *Becton, Dickinson & Co. v. Food and Drug Administration; United States v. Becton, Dickinson & Co.*; and *In the Matter of the Establishment Inspection of Bard-Parker, Division of Becton-Dickinson Co.*; 589 F.2d 1175 (2d Cir. 1978).
 31. Berenson, R., Washington, DC, personal communication, January 1984.
 32. Bialys, S., U.S. Veterans Administration, Hines, IL, personal communication, May 1983.
 33. Biles, B., Schramm, C. J., and Atkinson, J. G., "Hospital Cost Inflation Under State Rate-Setting Programs," *N. Engl. J. Med.* 303(12):664, Sept. 18, 1980.
 34. *Biomedical Business International*, "Medical Nutritionals: Markets, Trends, Outpatient Services and Synergies," VII(3):18-19, Feb. 8, 1984.
 35. *Biomedical Business International*, "Trends in Clinical Testing," VI(14):124-126, Aug. 10, 1983.
 36. Blue Cross and Blue Shield Association, "Medical Necessity Guidelines on Respiratory Care (Inpatient)," Chicago, IL, Oct. 20, 1982.
 37. *The Blue Sheet*, "Health Planning Will Get Funding If Legislation Clears," 27(5):14-15, Feb. 1, 1984.
 38. *The Blue Sheet*, "New York Certificate-of-Need Review to Focus on New Projects' Operating Costs," 26(25):12-13, June 22, 1983.
 39. Booker, H., U.S. Veterans Administration, Washington, DC, personal communications, November 1982 and April 1984.
 40. Bovbjerg, R. R., Diamond, L. H., Held, P. J., et al., "Continuous Ambulatory Peritoneal Dialysis: Preliminary Evidence in the Debate Over Efficacy and Cost," *Health Affairs* 2(2):96-102, summer 1983.
 41. Bozeman, B., Crow, M., and Link, A. (eds.), *Strategic Management of Industrial R&D: Interdisciplinary Perspectives* (Lexington, MA: Lexington Books/D.C. Heath & Co., 1984).
 42. Bradburd, R. M., "Veterans Administration Procurement and the Market for Medical Equipment," contract report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, Oct. 19, 1983 (draft).
 43. Braun, S. R., Smith, F. R., McCarthy, T. M., et al., "Evaluating the Changing Role of Respiratory Therapy Services at Two Hospitals," *JAMA* 245(20):2033-2037, May 22-27, 1981.
 44. Brennan, M. F., "Total Parenteral Nutrition in the Cancer Patient," *New Engl. J. Med.* 30s(7):375-382, Aug. 13, 1981.
 45. Breslar, J., U.S. Veterans Administration, Washington, DC, personal communications, May and June 1983.
 46. Bridgman, E., "The Impact of the GATT Standards Code and United States Trade Agreement Act on Private Sector Standards Development," presented at the Ninth Annual AAMI/FDA Conference on Medical Device Regulation, Arlington, VA, Nov. 10, 1982.
 47. Britain, R., U.S. Department of Health and Human Services, Food and Drug Administration, comments made at OTA Workshop on the Medical Device Amendments of 1976, Washington, DC, May 19, 1983.
 48. Britain, R., U.S. Department of Health and Human Services, Food and Drug Administration, Silver Spring, MD, personal communication, August 1983.
 49. Britt, M. R., Child, S. R., and Grantham, M. L., *Reduction of Intermittent Positive Pressure Breathing (IPPB) Usage in Surgical Patients by a PSRO*, Utah PSRO, Salt Lake City, UT, n.d.
 50. Brook, R. H., Williams, K. N., and Rolph, J. E., "Controlling the Use and Cost of Medical Services: The New Mexico Experimental Medical Care Review Organization—A Four-Year Case Study," *Medical Care* 16(9) (Suppl.), September 1978.
 51. Bunker, J. P., Fowles, J., and Schaffarzick, R., "Evaluation of Medical Technology Strategies: Evaluation of Coverage and Reimbursement," *N. Engl. J. Med.* 306(10):620, Mar. 11, 1982.
 52. Business Management Consultants, Ltd., "Survey of the United Kingdom Market for Medical Equipment," report prepared for the U.S. Department of Commerce, International Trade Administration, Office of Trade Information Services, Aldershot, Hampshire, U. K., June 15, 1983.
 53. Campbell, J., "The 1976 Medical Device Amend-

- ments and the 510(k) Process," presented to the Food and Drug Law Institute, Washington, DC, May 1, 1983.
54. Carney, T. P., President, Metatech Corp., paper prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1983.
 55. Carroll, M. S., and Arnett, R. H., III, "Private Health Insurance Plans in 1977: Coverage, Enrollment, and Financial Experience," *Health Care Finan. Rev.* 1(2):3, fall 1979.
 56. Carter, C., "Conditions for the Successful Use of Science," *Science* 219(4590):1295-1298, Mar. 18, 1983.
 57. Chassin, M., "Chapter IV, Certificate of Need," *Medical Care* 16(10) (Suppl.):21-26, October 1978.
 58. Cherniak, et al., "Home Care of Chronic Respiratory Disease," *JAMA* 208:821, 1969.
 59. Chrysomilides, S. A., and Kaminski, M. V., "Home Enteral and Parenteral Nutritional Support: A Comparison," *Am. J. Clin. Nutr.* 34(10):2271-2275, October 1981.
 60. Coelen, C., and Sullivan D., "An Analysis of the Effects of Prospective Reimbursement Programs on Hospital Expenditures," *Health Care Finan. Rev.* 2(3):1, winter 1981.
 61. Cohen, A. B., and Cohodes, D. R., "Certificate of Need and Low Capital-Cost Medical Technology," *Milbank Mere. Fund Q.* 60(2):307-28, spring 1982.
 62. Cohen, J. S., Research Chemist, National Institute of Child Health and Human Development, National Institutes of Health, Bethesda, MD, personal communication, Aug. 1, 1983.
 63. Cohodes, D. R., "The State Experience With Capital Management and Capital Expenditure Review Programs," article cited in "Health Capital Issues," papers presented at the Health Capital Conference sponsored by the Bureau of Health Facilities, Feb. 19-20, 1980.
 64. Cohodes, D. R., "Which Will Survive? The \$150 Billion Capital Question," *Inquiry* 20:5-11, spring 1983.
 65. Collins, E., "Tax Incentives for Industrial R&D: Effects of the New Provisions and Proposals for Further Action," mimeo, National Science Foundation, Washington, DC, 1983.
 66. Comanor, W. S., "Market Structure, Product Differentiation, and Industrial Research," *Q. J. Econ.* 85:639-657, November 1967.
 67. Committee for Economic Development, Research and Policy Committee, *Stimulating 7ech-*
nological Progress (New York: The Heffernan Press, Inc., 1980).
 68. Cook, C., U.S. Veterans Administration, Washington, DC, personal communication, December 1982.
 69. Coombs, F., U.S. Veterans Administration, Washington, DC, personal communication, January 1983.
 70. Cordes, J. J., "The Impact of Tax and Financial Regulatory Policies on Industrial Innovation," report of a workshop sponsored by the National Research Council and the National Academy of Engineering, July 20, 1978 (Washington, DC: National Academy of Sciences, 1980).
 71. Cromwell, J., Ginsburg, P., Hamilton, D., et al., *Incentives and Decisions Underlying Hospitals' Adoption and Utilization of Major Capital Equipment* (Cambridge, MA: Abt Associates, 1975), as cited in (351).
 72. Cromwell, J., and Kanak, J., "The Effects of Prospective Reimbursement Programs on Hospital Adoption and Service Sharing," *Health Care Finan. Rev.* 4(2):67, December 1982.
 73. Cutler, I. R., "The European Scene With Respect to Standards and National Regulatory Requirements for Medical Devices and Equipment," paper presented at the Ninth Annual AAMI/FDA Conference on Medical Device Regulation, Arlington, VA, Nov. 9-10, 1982.
 74. Cutler, S., Health Care Financing Administration, Baltimore, MD, personal communication, Aug. 17, 1983.
 75. Damadian, R., Minkoff, L., Goldsmith, M., et al., "Tumor Imaging in a Live Animal by Field Focusing NMR (Fonar)," *Physiol. Chem. & Phys.* 8:61-65, 1976.
 76. Damadian, R., Zaner, K., and Her, D., "Human Tumors by NMR," *Physiol. Chem. & Phys.* 5:381-402, 1973.
 77. Damadian, R., Zaner, K., Her, D., et al., "Human Tumors Detected by Nuclear Magnetic Resonance," *Proc. Nat. Acad. Sci. USA* 71(4):1471-1473, 1974.
 78. Davis, C., Health Care Financing Administration, testimony at hearing on *Proposed Prospective Reimbursement Rates for the End-Stage Renal Disease Program*, before the Subcommittee on Health, Committee on Finance, U.S. Senate, Mar. 15, 1982 (Washington, DC: U.S. Government Printing Office, 1982).
 79. Demlo, L. K., Hammons, G. T., Kuder, J. M., et al., "Report of a Study on Decisionmaking by Medicare Contractors for Coverage of Med-

- ical Technologies," College of Medicine and Graduate College of University of Iowa Hospitals and Clinics, contract report prepared for the Office of Technology Assessment, U.S. Congress, October 1983 (draft).
80. **Devices and Diagnostics Letter**, "FDA Denies Petition To Simplify 510(k) Procedures," 10(33), Aug. 19, 1983.
 81. **Devices and Diagnostics Letter**, "FDA Limits Number of YAG Laser Investigations," 10(50), Dec. 16, 1983.
 82. **Devices and Diagnostics Letter**, "Firms Line Up Behind Petition To Revamp 510(k) Rule," 10(1), Jan. 7, 1983.
 83. **Devices and Diagnostics Letter**, "HRG Takes Neuro Device Submission Argument to Dingell," 9(50), Dec. 10, 1982.
 84. **Devices and Diagnostics Letter**, "Investigational Devices Need Not Be Loss-Leaders," 9(51):2, Dec. 17, 1982.
 85. **Devices and Diagnostics Letter**, "Naderites Spurned On Effort To Force Device Standards," 9(49), Dec. 3, 1982.
 86. **Devices and Diagnostics Letter**, "PMA Requirements May Stifle Cerebella Stimulator," 11(2), Jan. 13, 1984.
 87. **Devices and Diagnostics Letter**, "Progress Toward Revising Class II Standards Starts," 10(48), Dec. 2, 1983.
 88. **Devices and Diagnostics Letter**, "YAG Laser Studies Limited to 500 Patients, 6 Months," 10(41):1, Oct. 14, 1983.
 89. diMonda, R., "How Hospitals Perceive Standards," *Medical Instrumentation* 13(4):200-3, July-August 1979.
 90. Dolan, A. M., "The Development of Consensus Standards for Medical Devices in Canada," *Medical Progress Through Technology* 6(3):137-40, June 1979.
 91. Donaldson, J. L., Deputy Director, Office of Products Standards Policy, Office of the Director, National Bureau of Standards, Washington, DC, personal communication, Nov. 29, 1983.
 92. Dowdal, T. G., U.S. General Accounting Office, letter to Carolyn K. Davis, Administrator, Health Care Financing Administration, re: Analysis of Medicare Durable Medical Equipment Claims in Georgia, Idaho, and Southern California (GAO/HRD-84-40), Feb. 13, 1984.
 93. Downs, F., U.S. Veterans Administration, Washington, DC, personal communications, November 1982 and June 1983.
 94. Drug Reform Law (Law on the Reform of Drug Legislation), Federal Republic of Germany, Aug. 24, 1976, Bundesgesetzblatt [BGB1].
 95. Dun & Bradstreet, Dun's Financial Profiles, 1981 *Industry Norms, Three Years*, vols. I and II, New York, November 1981.
 96. Dunkelberg, J. S., Furst, R. W., and Roenfeldt, R. L., "State Rate Review and the Relationship Between Capital Expenditures and Operating Costs," *Inquiry* 20:240-247, fall 1983.
 97. Eads, G. C., "Regulation and Technical Change: Some Largely Unexplored Influences," *Am. Econ. Rev.* 70(2):50, May 1980.
 98. Eggers, P. W., Office of Research, Health Care Financing Administration, Baltimore, MD, personal communication, February 1984, as cited in (260).
 - 98a. Eisner, R., Albert, S. H., and Sullivan, M. A., "Tax Incentives and R&D Expenditures," presented at the 16th CIRET Conference, Washington, DC, September 1983.
 99. Eli Lilly & Co., "Lilly Hospital Pharmacy Survey, '82," Indianapolis, IN, 1982.
 100. Emergency Care Research Institute, "NMR: Still Too Early for Answers to Many Questions," *Issues in Health Care Technology*, November 1983.
 101. Engelberg, A. B., "Patent Term Extension: An Overreaching Solution to a Nonexistent Problem," *Health Affairs* 2:34-45, spring 1982.
 102. EUROTASC (European Regulatory-Technical Affairs Study Committee), Six-Volume Report, September 1981.
 103. Evans, C. C., U.S. Veterans Administration, Washington, DC, personal communication, Mar. 5, 1984.
 104. Evans, C. C., Holden, F., and Speight, J., "A DRG Based Resource Allocation System for the Veterans Administration," Allocation Development Service, U.S. Veterans Administration, unpublished paper, 1983.
 105. *Exporters' Encyclopedia*, 2:481-482, 1405-1428.
 106. Farrow, S. C., Kaluzny, A. D., and Ricketts, -r., "Proceedings of a Conference on Health Services Research Issues in the Veterans Administration," *J. Med. Systems* 5(1/2):1-16, 1981.
 107. Feder, J., *Medicare: The Politics of Federal Hospital Insurance* (Lexington, MA: Lexington Books, 1977).
 108. Feder, J., Hadley, J., and Mullner, R., "Poor People and Poor Hospitals: Implications for Public Policy," *J. Health Polit. Policy Law*, forthcoming.
 109. Feil, C., Associate Manager of Public Information, Underwriters Laboratory, Northbrook, IL, personal communication, September 1983.
 110. Feldstein, M. S., and Taylor, A. K., *The Rapid Rise of Hospital Costs*, a report to the President's

- Council on Wage and Price Stability (Washington, DC: U.S. Government Printing Office, 1977).
111. Feldstein, P. J., "Relying on Regulation To Improve Hospital Performance," *Health Care Economics* (New York: John Wiley & Sons, 1979).
 112. Fellner, W., "The Influence of Market Structure on Technological Progress," *Quality J. Econ.* 65:560, November 1951, as cited in (274).
 113. Ferry, T. P., Gornick, M., Newton, M., et al., "Physicians' Charges Under Medicare: Assignment Rates and Beneficiary Liability," *Health Care Finan. Rev.* 2:49-73, winter 1980,
 114. Fineberg, H. V., "Gastric Freezing—A Study of Diffusion of a Medical Innovation," in Institute of Medicine and National Research Council, *Medical Technology and the Health Care System: A Study of Equipment-Embodied Technology* (Washington, DC: National Academy of Sciences, 1979).
 115. Finkel, M. J., "The Development of Orphan Products," *N. Engl. J. Med.* 307(15):963-964, Oct. 7, 1982.
 116. Finkel, M. J., Director, Office of Orphan Products Development, Food and Drug Administration, Rockville, MD, personal communications, Jan. 25 and Apr. 15, 1984.
 117. Flaherty, R., Director, Diagnostic Standards and Scientific Affairs, Health Industry Manufacturers Association, Washington, DC, personal communication, July 29, 1983.
 118. Flink, R. C., "Standards: A Benefit or Burden to Industry?" *Medical Instrumentation* 13(4): 197-8, July-August 1979.
 119. Foster, H. S., Attorney at Law, O'Conner and Hannan, Washington, DC, personal communication, April 1984.
 120. Foster, H. S., "The Impact of Federal and State Regulatory Programs on the Ambulatory Laboratory Testing Industry and the Demand for Instrumentation," contract report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, January 1984 (revised draft).
 121. Foster, M. E., "Sweeping Amendments to Standards and Certification System Adopted," *East Asian Exec. Rep.* 5(7):9,13-14, July 15, 1983.
 122. Fuji National City Consulting Ltd., "Survey of Japanese Markets for Medical and Dental Equipment," vol. 2, prepared for the U.S. Embassy, May 1983.
 123. The Futures Group, "Characterization of Innovations Introduced on the U.S. Market in 1982," contract report prepared for the U.S. Small Business Administration, contract #SBA-6050-OA-82, Glastonbury, CT, March 1984.
 124. Gellman Research Associates, Inc., *The Relationship Between Industrial Concentration, Firm Size, and Technological Innovation*, report prepared for the Office of Economic Research, Office of Advocacy, U.S. Small Business Administration, Washington, DC, May 11, 1982.
 125. Giannini, M., U.S. Veterans Administration, Washington, DC, personal communication, November 1982.
 126. Gibson, R. M., "National Health Expenditures, 1978," *Health Care Finan. Rev.* 1:1-36, summer 1979.
 127. Gibson, R. M., and Waldo, D. R., "National Health Expenditures, 1981," *Health Care Finan. Rev.* 4(1):1-35, September 1982.
 128. Gibson, R. M., Waldo, D. R., and Levit, K. R., "National Health Expenditures, 1982," *Health Care Finan. Rev.* 5(1):1-31, fall 1983.
 129. Gold, J., Office of Health Planning, U.S. Department of Health and Human Services, Public Health Service, Health Resources and Services Administration, Washington, DC, personal communication, Apr. 12, 1984.
 130. Goldschmidt, P. G., U.S. Veterans Administration, Washington, DC, personal communication, January 1983.
 131. Grace Commission, *President's Private Sector Survey on Cost Control: Task Force Report on the Veterans Administration*, draft, Washington, DC, May 1983.
 132. *Graham, et al. v. John Deere Co. of Kansas City, et al.*, 383 U.S. 1 (1966).
 - 132a. Grayson, R. T., "Effects of Regulatory Controls on the Accuracy of Clinical Laboratory Tests," *J. Medical Technology* (forthcoming).
 133. Greenfield, W. M., "New Approaches To Using the Determination-of-Need Process To Contain Hospital Costs," *N. Engl. J. Med.* 309(6):372-375, Aug. 11, 1983.
 134. Greer, D. F., and Rhoades, S. A., "Concentration and Productivity Changes in the Long and Short Run," *South. Econ. J.* 43:1031, October 1976, as cited in (274).
 135. Griessbach, L., German American Chamber of Commerce, personal communication, Nov. 29, 1983.
 136. Hadley, D., Health Care Financing Administration, Baltimore, MD, personal communication, Aug. 11, 1983.
 137. Hadley, J., "Critique of Peter Fox's 'Physician Reimbursement Under Medicare: An Overview and a Proposal for Area-Wide Physician Incentives,'" in U.S. Congress, House Committee on Ways and Means, Subcommittee on Health, *Proceedings of the Conference on the Future of Medicare*, Committee Print No. 23 (Washing-

- ton, DC: U.S. Government Printing Office, 1984).
138. Hadley, J., and Feder, J., "Hospital Cost Shifting," Urban Institute working paper #3179-07 (Washington, DC: The Urban Institute, 1984).
 139. Hadley, J., Holahan, J., and Scanlon, W., "Can Fee-for-Service Reimbursement Coexist With Demand Creation?" *Inquiry* 16(3):247, fall 1979.
 140. Hadley, J., Juba, D., Swartz, K., et al., *Alternative Methods of Developing a Relative Value Scale of Physicians' Services* (Washington, DC: The Urban Institute, February 1983).
 141. Hamilton, R., "Certificate of Need: Scope of Coverage," paper presented at the American Health Planning Association and the National Health Lawyers Association, Washington, DC, Dec. 7, 1983.
 142. Harnnan, A. J., "Industrial Innovation and Governmental Policy: A Review and Proposal Based on Observation of the U.S. Electronics Sector," *Tech. Forecast. Soc. Change* 18:15, 1980.
 143. Hayes, A. H., Jr., Statement of the Commissioner, Food and Drug Administration at Hearings on *FDA Oversight: Medical Devices*, U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, July 16, 1982, serial No. 97-144 (Washington, DC: U.S. Government Printing Office, 1982).
 144. Hazelwood, C. F., Cleveland, G., Medina, D., "Relationship Between Hydration and Proton Nuclear Magnetic Resonance Relaxation Times in Tissue of Tumor-Bearing and Non-tumor Bearing Mice: Implications for Cancer Detection," *J. Natl. Cancer Inst.* 52:1849-1853, 1974.
 145. Health Industry Manufacturers Association, *Guidelines for the Development of Voluntary Device Law Standards*, HIMA Report No. 79-6, Washington, DC, October 1979.
 146. Health Industry Manufacturers Association, *International Activities Survey*, HIMA Document 10, vol. 2, Washington, DC, July 1980.
 147. Heimbürger, H. C., "Home Parenteral Nutrition," *Ala. J. Med. Sci.* 19(4):377-380, October 1982.
 148. Hellinger, F. J., "The Effect of Certificate-of-Need Legislation on Hospital Investment," *Inquiry* 13:187-193, June 1976.
 149. Higson, G. R., "The UK Department of Health and Social Security's Scientific and Technical Services Branch," *J. Medical Engineering and Technology* 7(3):130-35, May/June 1983.
 150. Holder, J., U.S. Veterans Administration, Washington, DC, personal communication, June 1983.
 151. Holland, D., "The Effect of Taxation on Effort: Some Results for Business Executives," *National Tax Association—Proceedings of the 62nd Annual Conference*, September 1969.
 152. Hollis, D. P., Saryan, L. A., Eggleston, J. C., et al., "Nuclear Magnetic Resonance Studies of Cancer," *J. Natl. Cancer Inst.* 54:1469-1472, 1975.
 153. *Home Health Line*, "A Big Chill Settles Over Part A Home Hyperalimentation," IX:22-24, Jan. 30, 1984.
 154. *Home Health Line*, "Atlanta Home Care Seminar—National Medical Enterprises V. P. Livingston Says Home Care Low Priority for Hospitals; Manufacturers Expand Into Home Care Centers," VIII:212-214, Nov. 21, 1983.
 155. *Home Health Line*, "Changing Face of Medicare Home Health" (table), VIII:28, Feb. 4, 1983.
 156. *Home Health Line*, "DME Under \$120 Should Be Purchased, GAO Report Says," VIII:126, July 18, 1983.
 157. *Home Health Line*, "GAO Again Finds DME Excess Rental—This Time in 'High-Cost' Oxygen Concentrators," IX:53, Feb. 27, 1984.
 158. *Home Health Line*, "GAO Finds Only \$18 Million in HHA DME Expenditures," IX:85, Apr. 9, 1984.
 159. *Home Health Line*, "Medicare Home Health Outlays Up 1,000% From 1974 (table)," VIII:136, July 25 and Aug. 1, 1983 (combined issue).
 160. *Home Health Line*, "Medicare Home Health Yearly Outlays to Break \$3 Billion by End of Decade, Total Hospice Outlays Equal \$815 Million Before Sunset," IX:43, Feb. 13, 1984.
 161. *Home Health Line*, "NAMES Presses 'Freedom of Choice' in Hospital DME Referrals," IX:49, Feb. 20, 1984.
 162. *Home Health Line*, "Region V Flattens Daily Care After Consulting HCFA; Says Patient Should Be in Skilled Nursing Facility If Cheaper," VIII:167-168, Sept. 12, 1983.
 163. Howard, A. J., "European Medical Device Regulations: An Update," *Medical Device and Diagnostic Industry* 5(9):46-50, September 1983.
 164. Hulse, J. W., "The Impact of Foreign Regulation on International Trade: Potential Barriers to U.S. Products," paper presented at the Ninth Annual AAMI/FDA Conference on Medical Device Regulation, Arlington, VA, Nov. 10, 1982.
 165. Iglehart, J., "Health Report/Federal Regulation of Medical Devices Gets Serious Attention in Congress," *National Journal Reports*, pp. 1184-1188, Aug. 11, 1973.
 166. IMS America, Ltd., Rockville, MD, unpublished

- data provided to the Office of Technology Assessment, U.S. Congress, under contract, December 1983.
167. IMS America, Ltd., *Veterans Administration Price Analysis of Hospital Supply and Pharmaceutical Products*, Order No. TE-Q1-83, Rockville, MD, May 1983.
 168. Institute of Medicine and National Research Council, *Medical Technology and the Health Care System: A Study of Equipment-Embodied Technology* (Washington, DC: National Academy of Sciences, 1979).
 169. International Organization for Standardization, *MEMENTO 1978 and 1983* (Geneva, Switzerland: ISO, 1978 and 1983).
 170. InterStudy, "The December 1983 HMO Enrollment in the U. S.: A Mid-Year Census" (Excelsior, MN: InterStudy, 1984).
 171. *In the Matter of the Establishment Inspection of Portex, Inc., Food and Drug Administration, Appellant*, 595 F. 2d 84 (1st Cir. 1979).
 172. Janssen, T. J., and Saffran, G. T., "Reimbursement for Durable Medical Equipment," *Health Care Finan. Rev.* 2(3): 94, winter 1981.
 173. Japan Ministry of Health and Welfare, "Measures Taken by the Japanese Ministry of Health and Welfare (MHW) for Further Opening the Japanese Market Regarding Pharmaceuticals, Food, Etc.," April 1983.
 174. Jarvis, A. E., "A Detailed Review of the Medical Device Regulations of Major Importers of U.S. Products," paper presented at the Ninth Annual AAMI/FDA Conference on Medical Device Regulation, Arlington, VA, Nov. 10, 1982.
 175. Jewkes, J., Sawers, D., and Stillerman, R., *The Sources of Invention*, 2d ed. (New York: Norton, 1969).
 176. Joint Commission on Accreditation of Hospitals, *Accreditation Manual for Hospitals 1983*, Chicago, IL, 1982.
 177. Joskow, P. L., *Controlling Hospital Costs: The Role of Government Regulation* (Cambridge, MA: The Massachusetts Institute of Technology Press, 1981).
 178. Kamien, M. I., and Schwartz, N. L., "On the Degree of Rivalry for Maximum Innovative Activity," *Q. J. Econ.* 90(2):245-260, May 1976.
 179. Kamien, M. I., and Schwartz, N. L., *Market Structure and Innovation* (Cambridge, MA: Cambridge University Press, 1982).
 180. Kasper, J. A., *Prescribed Medicines: Use, Expenditures, and Sources of Payment*, Data Preview 9, DHHS publication No. (PHS) 82-3320, National Health Care Expenditures Study, National Center for Health Services Research, U.S. Department of Health and Human Services, Hyattsville, MD, April 1982.
 181. Kaye, Scholer, Fierrnan, Hays, & Handler, "Governmental Barriers to International Trade in Medical Devices in the United States, United Kingdom, France, The Federal Republic of Germany, Canada, Japan, and Mexico," contract report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, February 1984.
 182. Kelly, P., and Kranzberg, M. (eds.), *Technological Innovation: A Critical Review of Current Knowledge* (San Francisco: San Francisco Press, 1978).
 183. Kenney, M., independent consultant, Berkeley, CA, personal communication, Apr. 19, 1984.
 184. Kessler, P., "You: Putting Teeth Into Bonding," *The Washington Post*, C5 (col. 2), July 5, 1983.
 185. Kettering, V., U.S. Department of Commerce, Bureau of Industrial Economics, Washington, DC, personal communication, February 1984.
 186. Kidder, Peabody & Co., *Baxter Travenol Laboratories, Inc.: 1983 Review and Outlook, Company Follow-up*, May 13, 1983.
 187. Kimberly, J. R., "Hospital Adoption of Innovations in Medical and Managerial Technology: Individual, Organizational and Contextual/Environmental Effects," Executive Summary, National Science Foundation Grant No. PRA 76-23080, March 1978.
 188. Kindel, K., "Survey of the Market for Medical Equipment in Germany," prepared for the U.S. Department of Commerce, Berlin, March 1981.
 189. Kleinfield, N. R., "The Home Health Care Boom," *The New York Times*, sec. D1, June 30, 1983.
 190. L. W. Bergman & Co., "Financial Issues in Biotechnology," contract report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, March 1983.
 191. Lauterbur, P. C., "Image Formation by Induced Local Interactions: Examples Employing Nuclear Magnetic Resonance," *Nature* 242:190-191, 1973.
 192. Law on Technical Equipment and Devices, Federal Republic of Germany, June 24, 1968, as amended Aug. 13, 1979, Bundesgesetzblatt [BGB1], p. 1432.
 193. Lepon, J., and Gawron, E., Kornmeier, McCarthy, Lepon, and Harris, "Medical Device Standards and International Trade," contract report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1983.
 194. Lewis, P., "U.S. and Third World At Odds Over

- Patents," *The New York Times*, D1 (col. 1), Oct. 5, 1982.
195. Liaison and Coordination Headquarters on Standards and Certification Systems, "Improvement of Japan's Standards and Certification Systems, Etc.," Mar. 26, 1983.
 196. Liefer, L., U.S. Veterans Administration Rehabilitation Research and Development Center, Palo Alto, CA, personal communication, July 1983.
 197. Louis Harris & Associates, Inc., *A Survey of Medical Device Manufacturers*, study No. 802005, report submitted to the Bureau of Medical Devices, Food and Drug Administration, U.S. Department of Health and Human Services, July 1982.
 198. Luft, H. S., *Health Maintenance organizations: Dimensions of Performance* (New York: John Wiley & Sons, Inc., 1981).
 199. Lupovich, P., "Changes in the Clinical Laboratory," paper prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, February 1984.
 200. Mansfield, E., *Industrial Research and Technological Innovation* (New York: W. W. Norton & Co., 1968).
 201. Mansfield, E., and Wagner, S., "Organizational and Strategic Factors Associated With Probabilities of Success in Industrial R and D," *J. Business* 48:179-98, April 1975, as cited in (274).
 202. Marcus, P., U.S. Department of Commerce, Washington, DC, personal communication, January 1984.
 203. Markham, J. W., "Market Structure, Business Conduct, and Innovation," *Am. Econ. Rev.* 60:323, 1965, as cited in (182).
 204. Martin, D. R., Director, International Investigations Staff, Executive Directorate for Regional Operations, Food and Drug Administration, Rockville, MD, personal communication, Dec. 16, 1983.
 205. *Medical Devices, Diagnostics and Instrumentation Reports* (The Gray Sheet), "Abbott's Alpha-Fetoprotein Diagnostic Kit for Testicular Cancer," 10(8):9-10, Feb. 20, 1984.
 206. *Medical Devices, Diagnostics and Instrumentation Reports* (The Gray Sheet), "Annual Registration of Medical Device Firms Temporarily Delayed," 10(3), Jan. 16, 1984.
 207. *Medical Devices, Diagnostics and Instrumentation Reports* (The Gray Sheet), "Contact Lens Guidelines: FDA Is Establishing Working Group," 9(48), Nov. 28, 1983.
 208. *Medical Devices, Diagnostics and Instrumentation Reports* (The Gray Sheet), "NMR Purchases in New York Limited to 13 Sites Under Health Planning Commission Proposal; Wisconsin, Oregon, North Carolina Also Move To Restrict Purchases," pp. 9-10, Feb. 27, 1984.
 209. *Medical Devices, Diagnostics and Instrumentation Reports* (The Gray Sheet), reporting on testimony of NIH Director James Wyngaarden to two subcommittees of the House Science and Technology Committee, 8(40), Oct. 4, 1982.
 210. *Medical Devices, Diagnostics and Instrumentation Reports* (The Gray Sheet), "Sealants Are 'Highly Effective' and 'Safe'," 9(50):12-13, Dec. 12, 1983.
 211. *Medical Device and Diagnostic Industry*, "The Effect of DRGs on Devices and Diagnostics," 6(2):31-36, February 1984.
 212. *Medical World News*, "Physician-Office Lab Results Less Accurate Than Those of Licensed Labs, Study Shows," 25(3):46-47, Apr. 9, 1984.
 213. Medsger, B., "The Most Captive Consumers: At the Mercy of the Wheelchair Barons," *The Progressive*, pp. 34-39, March 1979.
 214. Mixon, A. M., III, President, Invacare Corp., personal communication, Aug. 16, 1983.
 215. Miyamo, H., Japan Ministry of International Trade and Industry, personal communication, Nov. 16, 1983.
 216. Moliter, R. M., General Electric Co., Washington, DC, personal communication, Nov. 18, 1983.
 217. "More Patents Bear the Label 'Made in Japan'," *National Journal* 14:1069, June 12, 1982.
 218. Morrone, F., U.S. Veterans Administration, Washington, DC, personal communication, June 1983.
 219. Mosley, M., "Talking Points on U.S. Exports of Medical Instruments," paper presented at the meeting of the Association for the Advancement of Medical Instrumentation, Arlington, VA, Oct. 10, 1982.
 220. Mossinghoff, G. J., Patent and Trademark Commissioner, commenting on the 1983 legislative proposals, *Chemical & Engineering News* 60(33): Aug. 16, 1982.
 221. Motley, H. L., Werko, L., Cournard, A., et al., "Observations on the Clinical Use of Intermittent Positive Pressure," *J. Aviation Med.* 18:417-435, October 1947.
 222. Mullin, P., Joint Commission on Accreditation of Hospitals, Chicago, IL, personal communication, Apr. 17, 1984.
 223. Myers, S., and Marquis, R. G., *Successful Industrial Innovations*, NSF-No. 69-17 (Washington, DC: U.S. Government Printing Office, 1969).

224. National Academy of Sciences, *Health Care for American Veterans*, prepared for the Committee on Veterans Affairs, U.S. House of Representatives, Committee Print No. 36 (Washington, DC: U.S. Government Printing Office, 1977).
225. National Academy of Sciences, Assembly of Life Sciences, *Final Report of the Committee on Prosthetics Research in the Veterans Administration*, 1976.
226. "National Survey of Hospital and Non-Hospital Clinical Laboratories," *Laboratory Mgt.* 17(3): 33-48, March 1979.
227. Needleman, J., and Lewin, L. S., "The Impact of State Regulation on the Adoption and Diffusion of New Medical Technology," Appendix F in Institute of Medicine and National Research Council, *Medical Technology and the Health Care System: A Study of Equipment-Embodied Technology* (Washington, DC: National Academy of Sciences, 1979).
228. Nelson, R. R. (cd.), *Government and Technical Progress: A Cross-Industry Analysis* (New York: Pergamon Press, 1982).
229. Nelson, R. R., "Government Stimulus of Technological Progress: Lessons From American History," in *Government and Technical Progress: A Cross-Industry Analysis*, R. R. Nelson (cd.).
230. Nelson, R. R., "The Simple Economics of Basic Scientific Research," *J. Political Economy* 67: 297-306, June 1959.
231. Nelson, R. R., and Langlois, R. N., "Industrial Innovation Policy: Lessons From American History," *Science* 219:814-818, Feb. 18, 1983.
232. Nelson, R. R., and Winter, S. G., "In Search of a Useful Theory of Innovation," *Research Policy* 6:36-76, 1977.
233. Newhouse, J. P., Manning, W. G., Morris, C. N., et al., "Some Interim Results From a Controlled Trial of Cost Sharing in Health Insurance," *N. Engl. J. Med.* 305:1501, 1981.
234. Obermayer, J., *The Role of Patents in the Commercialization of New Technology for Small Innovative Companies* (Cambridge, MA: Research & Planning Inc., 1981).
235. Olsson, J., Manager, Safety and Regulatory Engineering, General Electric Co., Medical Systems Operation, Milwaukee, WI, personal communication, Aug. 15, 1983.
236. Organization for Economic Cooperation and Development, *Innovation in Small and Medium Firms* (Paris: Organization for Economic Cooperation and Development, 1982).
237. Over, A. M., Jr., Bradburd, R. M., Williams, R. C., Jr., et al., *Determinants of Current and Future Expenditures on Durable Medical Equipment by Medicare and Its Program Beneficiaries*, contract report submitted to the Health Care Financing Administration, U.S. Department of Health and Human Services, Baltimore, MD, April 1983.
238. Palmer, F., U.S. Veterans Administration Marketing Center, Hines, IL, personal communication, May 1983.
239. Pauly, M., *Doctors and Their Workshops: Economic Models of Physician Behavior* (Chicago: University of Chicago Press, 1980).
240. Pavliscak, M., U.S. Department of Commerce, Washington, DC, personal communication, June 1984.
241. Peter Barnard Associates, "International Market Research Survey of the Canadian Market for Medical Equipment," prepared for the U.S. Department of Commerce, July 1983.
242. Pharmaceutical Affairs Law, Aug. 10, 1950, as amended.
243. Pharmaceutical Affairs Law, No. 145, 1960.
244. Pharmaceutical Manufacturers Association, *Medical Devices and Diagnostic Products Industry: A Profile*, Washington, DC: March 1982.
245. Phillips, L., National Research Director, Paralyzed Veterans of America, Washington, DC, personal communication, June 1983.
246. Pierce, A. K., "Scientific Basis of In-Hospital Respiratory Therapy," *Am. Rev. Resp. Dis.* 122(5):1-2 (pt. 2), November 1980.
247. Policy Analysis, Inc., "Evaluation of the Effects of Certificate of Need Programs," Volume III: Analytic Reports, contract report prepared for the Bureau of Health Planning and Resources Development, Health Resources Administration, Department of Health and Human Services, contract No. 231-77-0114 (Brookline, MA: Policy Analysis, Inc., August 1980.)
248. Pontoppidan, H., "Mechanical Aids to Lung Expansion in Non-intubated Surgical Patients," *Am. Rev. Resp. Dis.* 122(5): 11-13 (pt. 2), November 1980.
249. Porges, A., Assistant General Counsel, Office of the U.S. Trade Representative, personal communication, Dec. 14, 1983.
250. Powell, R. S., Program Director, Diagnostic Imaging Research Branch, National Cancer Institute, National Institutes of Health, Bethesda, MD, personal communication, July 29, 1983.
251. *Predicasts Forecasts, No. 91*, Apr. 22, 1983.

252. Public Citizen Health Research Group, "Comments of Public Citizen Health Research Group on FDA's Proposed Classification of General and Plastic Surgery Medical Devices," Washington, DC, June 21, 1982.
253. Public Citizen Health Research Group, petition to the National Center For Devices and Radiological Health, Food and Drug Administration, to call for safety and effectiveness data on 16 devices used in obstetrics and gynecology, Washington, DC, Mar. 2, 1983.
254. Radiation Emitting Devices Act and Regulations, as amended, Nov. 8, 1977.
255. "Regulations Respecting Medical Devices," P.C. 1975-2031, Aug. 27, 1975, as amended.
256. Rettig, R. A., "End-Stage Renal Disease and the 'Cost' of Medical Technology," in *Medical Technology: The Culprit Behind Health Care Costs?* S. Altman and R. Blendon (eds.) (Washington, DC: U.S. Department of Health, Education, and Welfare, 1979).
257. Reynolds, C., U.S. Department of Health and Human Services, Food and Drug Administration, Silver Spring, MD, personal communication, February 1984.
258. Robb, W. L., Vice-President and General Manager, General Electric Co., Medical Systems Operations, Milwaukee, WI, personal communication, October 1982.
259. Roberts, E. B., et al. (eds.), *Biomedical Innovation* (Cambridge, MA: The Massachusetts Institute of Technology Press, 1981).
260. Romeo, A. A., "The Hemodialysis Equipment and Disposable Industry," contract report prepared for the Office of Technology Assessment, U.S. Congress, February 1984 (revised draft).
261. Romeo, A. A., "Interindustry and Interfirm Differences in the Rate of Diffusion of an Innovation," *Rev. Econ. Stat.* 57:311, August 1975, as cited in (274).
262. Rosenbloom, R. S., "Technological Innovation in Firms and Industries: An Assessment of the State of the Art," in *Technological Innovation: A Critical Review of Current Knowledge*, P. Kelly and M. Kranzberg (eds.) (San Francisco: San Francisco Press, 1978).
263. Rothwell, R., "Marketing a Success Factor in Industrial Innovation," *Mgt. Decision* 14(1):43, 1976.
264. Rothwell, R., "Some Indirect Impacts of Government Regulation on Industrial Innovation in the United States," *Technological Forecasting and Social Change*, Elsevier North Holland, Inc., 19:57-80, 1981.
265. Russell, L. B., "The Diffusion of Hospital Technologies: Some Econometric Evidence," *J. Human Resources* 12:482-502, fall 1977.
266. Russell, L. B., *Technology in Hospitals: Medical Advances and Their Diffusion* (Washington, DC: The Brookings Institution, 1979).
267. Safir, A., "How Ophthalmology Changed During My Career," paper prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1983.
268. Sahal, D., *Patterns of Technological Innovation* (Reading, MA: Addison-Wesley, 1981).
269. Salans, L. B., Acting Director, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, National Institutes of Health, testimony at hearing, *The End Stage Renal Disease Program (Part 2-Treatment Standards and Methods)*, before the Subcommittee on Government Operations, House of Representatives, Apr. 28, 1982 (Washington, DC: U.S. Government Printing Office, 1982).
270. Salkever, D. S., and Bice, T. W., "The Impact of Certificate-of-Need Controls on Hospital Investment," *Milbank Mere. Fund Q.* 54(2):185-214, spring 1976.
271. Sanford C. Bernstein & Co., Inc., *The Kidney Dialysis Industry*, New York, February 1981.
272. Scheffler, R. M., and Delaney, M., "Assessing Selected Respiratory Therapy Modalities: Trends and Relative Costs in the Washington, DC Area," in *The Implications of Cost-Effectiveness Analysis of Medical Technology/Background Paper #12: Case Studies of Medical Technologies*, prepared for the Office of Technology Assessment, U.S. Congress (Washington, DC: U.S. Government Printing Office, April 1981).
273. Scherer, F. M., "Demand-Pull and Technological Invention—Schmookler Revisited," *J. Industrial Econ.* 30(3):225-237, March 1982.
274. Scherer, F. M., *Industrial Market Structure and Economic Performance*, 2d ed. (Chicago: Rand McNally College Publishing Co., 1980).
275. Schiffrin, L. G., and Rich, W. J., "The Contact Lens Industry: Structure, Competition, and Public Policy," contract report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1983 (draft).
276. Schmookler, J., *Invention and Economic Growth* (Cambridge, MA: Harvard University Press, 1966).
277. Schroeder, S., and Showstack, J. A., "Financial Incentives to Perform Medical Procedures and Laboratory Tests: Illustrative Models of Office Practice," *Medical Care* 16(4):289-298, April 1978.
278. Schwartz, S., American College of Physicians,

- Philadelphia, PA, personal communication, July 18, 1983.
279. Scitovsky, A. A., and McCall, N., "Coinsurance and the Demand for Physician Services Four Years Later," *Soc. Sec. Bull.* 40:19, May 1977.
280. Shapley, W. H., Teich, A. H., and Weinberg, J. P., **AAAS Report VIII: Research and Development, FY 1984**, a report prepared for the Executive Officer and the AAAS Committee on Science, Engineering, and Public Policy (Washington, DC: American Association for the Advancement of Science, 1983).
281. Shepard, D. S., Associate Professor, Harvard School of Public Health, Center for the Analysis of Health Practices, Boston, MA, personal communication, Apr. 30, 1984.
282. Shepard, D. S., and Karen, S. L., **The Market for Wheelchairs: Innovations and Federal Policy**, contract report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1984 (forthcoming).
283. Shils, M. E., "Registry of Patients on HPN," in **Home Parenteral Nutrition** (symposium proceedings, American Society for Parenteral and Enteral Nutrition), pp. 42-44, Washington, DC, 1980.
284. Sholer, J., Abbott Laboratories, Chicago, IL, personal communication, Oct. 6, 1983.
285. Showstack, J. A., Blumberg, B. D., Schwartz, J., et al., "Fee-for-Service Physician Payment: Analysis of Current Methods and Their Development," **Inquiry** 16(3):230, fall 1979.
286. Sira Institute Ltd., "Report on Medical Equipment Study—France," vol. 2, prepared for the U.S. Embassy, Kent, England, Mar. 31, 1981.
287. Skalnik, B., "IPPB: A Question of Quality," **Resp. Ther.** 6:81-83, November-December 1976.
288. Sommer, J., Deputy Director, The American Legion, Washington, DC, personal communication, July 1983.
289. Stanford University, "Policy on Tangible Research Property," memo from the Vice Provost and Dean of Graduate Studies and Research to members of the Academic Council and members of the Academic Staff-Research, Mar. 16, 1982.
290. Steiger, E., The Cleveland Clinic, Cleveland, OH, personal communication, April 1984.
291. Steinberg, E. P., and Cohen, A. B., "Nuclear Magnetic Resonance Imaging Technology: A Clinical, Industrial and Policy Analysis," contract report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1984.
292. Stevenson, G. L., "FEC Acceptance, Growth, Cost Benefits Confirmed," *Emergence*, June 1983 (special issue).
293. Stewardson, J. D., Regulatory Standards Administrator, Cobe Laboratories, Inc., Lakewood, CO, personal communications, Dec. 6 and 13, 1983.
294. *Sugar-man v. Forbragd*, 405 F. 2d 1189 (9th Cir. 1968).
295. Swartz, K., Senior Analyst, The Urban Institute, Washington, DC, personal communication, April 1984.
- 295a Swartz, K., The Urban Institute, "The Changing Face of the Uninsured," paper prepared for presentation at the First Annual Meeting of the Association for Health Services Researchers, Panel on "Health Care for the Poor in an Era of Retrenchment," Washington, DC, June 11, 1984.
296. Swartz, K., "Who Has Been Without Health Insurance? Changes Between 1963 and 1979," Urban Institute working paper (Washington, DC: The Urban Institute, April 1984).
297. Swift, C., National Cancer Institute, Bethesda, MD, personal communication, Apr. 12, 1984.
298. Thompson, F., **Health Policy and the Bureaucracy: Politics and Implementation** (Cambridge, MA: The Massachusetts Institute of Technology Press, 1983).
299. Traub, J., National Institute for Handicapped Research, Washington, DC, personal communication, February 1984.
300. Travers, P., U.S. Congress, General Accounting Office, Washington, DC, personal communication, April 1984.
301. Turner, R., Mexico Desk Officer, Office of Trade Administration, U.S. Department of Commerce, Washington, DC, personal communication, Aug. 30, 1983.
302. **United States v. An Article of Drug . . . Bactunidisk**, 394 U.S. 784 (1969).
303. U. S., **Federal Register** 41:22620, June 4, 1976.
304. U. S., **Federal Register** 44:53577, Sept. 14, 1979.
305. U. S., **Federal Register** 45:65619, Oct. 3, 1980.
306. U. S., **Federal Register** 45:69678, Oct. 21, 1980.
307. U. S., **Federal Register** 45:76183, Nov. 18, 1980.
308. U. S., **Federal Register** 45:81769, Dec. 12, 1980.
309. U. S., **Federal Register** 46:57568-69, Nov. 24, 1981.
310. U. S., **Federal Register** 47(189):42906, Sept. 29, 1982.
311. U. S., **Federal Register** 47:2810, Jan. 19, 1982.
312. U. S., **Federal Register** 47:24332, June 3, 1982 (Initiation of Investigation pursuant to 19 U.S.C. §337).
313. U. S., **Federal Register** 47:53402, Nov. 26, 1982.

314. U.S., *Federal Register* 47:54990, Dec. 7, 1982.
315. U.S., *Federal Register* 48(2):299-315, Jan. 4, 1983.
316. U.S., *Federal Register* 48(92), Mar. 11, 1983, Final Rule, Department of Health and Human Services, Health Care Financing Administration, 42 CFR, Part 405.
317. U.S., *Federal Register* 48:13020, Mar. 29, 1983.
318. U.S., *Federal Register* 48:24014, May 27, 1983.
319. U.S., *Federal Register* 48:25126, June 3, 1983.
320. U.S., *Federal Register* 48:27723, June 17, 1983.
321. U.S., *Federal Register* 48:40272, Sept. 6, 1983.
322. U.S., *Federal Register* 48:40960, Sept. 12, 1983 (Institution of Investigation pursuant to 19 U.S.C. §337).
323. U.S., *Federal Register* 48:56778, Dec. 23, 1983.
324. U.S., *Federal Register* 49:1177, Jan. 10, 1984.
325. U.S. Congress, Congressional Budget Office, *The Effect of PSROs on Health Care Costs: Current Findings and Future Evaluations* (Washington, DC: U.S. Government Printing Office, June 1979).
326. U.S. Congress, Congressional Budget Office, *The Impact of PSROs on Health Care Costs: Update of CBO's 1979 Evaluation* (Washington, DC: U.S. Government Printing Office, January 1981).
327. U.S. Congress, Congressional Budget Office, *Veterans Administration Health Care: Planning for 1990*, Washington, DC, February 1983.
328. U.S. Congress, Congressional Research Service, *Medical Devices: A Brief Review of Legislation and Issues Related to Regulation* (Washington, DC: U.S. Government Printing Office, 1974).
329. U.S. Congress, General Accounting Office, "Centers for Disease Control Should Discontinue Certain Diagnostic Tests and Charge for Others," report No. 83-37, Washington, DC, Apr. 16, 1983.
330. U.S. Congress, General Accounting Office, *Computed Tomographic Scanners: Opportunity for Coordinated Federal Planning Before Substantial Acquisitions*, Report No. HRD-78-41, Washington, DC, January 1978.
331. U.S. Congress, General Accounting Office, *Federal Regulation of Medical Devices—Problems Still To Be Overcome*, GAO/HRD-83-53 (Gaithersburg, MD: General Accounting Office, September 1983).
332. U.S. Congress, General Accounting Office, Human Resources Division, "VA Needs To Improve Its Quality Assurance Program for Medical Supply and Equipment Items" (PLRD-82-44) unpublished memorandum report, Washington, DC, February 1982.
333. U.S. Congress, General Accounting Office, *Medicare Payments for Durable Medical Equipment Are Higher Than Necessary*, Comptroller General's Report to the Congress, GAO/HRD-82-61, Washington, DC, July 1982.
334. U.S. Congress, General Accounting Office, *Problems With Evaluating the Cost Effectiveness of Professional Standards Review Organization* (Washington, DC: U.S. Government Printing Office, July 19, 1979).
335. U.S. Congress, General Accounting Office, *VA Needs Better Visibility Over Medical Center Purchases*, report No. PSAD 81-16, Washington, DC, December 1980.
336. U.S. Congress, House Committee on Energy and Commerce, *FDA Oversight: Medical Devices*, hearings before the Subcommittee on Oversight and Investigations, July 16, 1982, serial No. 97-144 (Washington, DC: U.S. Government Printing Office, 1982).
338. U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Health and the Environment, "Oversight Hearing on the Medical Device Amendments of 1976," Washington, DC, Feb. 24, 1984.
338. U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, *Medical Device Regulation; The FDA's Neglected Child*, An Oversight Report on FDA Implementation of the Medical Device Amendments of 1976, Committee Print 98-F (Washington, DC: U.S. Government Printing Office, May 1983).
339. U.S. Congress, House Committee on Interstate and Foreign Commerce, *Medical Devices*, hearings before the Subcommittee on Public Health and the Environment, Oct. 23-24, 1973, serial No. 93-61 (Washington, DC: U.S. Government Printing Office, 1973).
340. U.S. Congress, House of Representatives, *The Medical Device Amendments of 1976*, 94th Cong., 2d sess., 1976, House Report No. 94-853 (Washington, DC: U.S. Government Printing Office, 1976).
341. [J. S. Congress, Office of Technology Assessment, *Diagnosis Related Groups (DRGs) and Medicare Program: Implications for Medical Technology—A Technical Memorandum*, GPO stock No. 052-003-00919-6 (Washington, DC: U.S. Government Printing Office, July 1983).
342. U.S. Congress, Office of Technology Assess-

- ment, *The Impact of Randomized Clinical Trials on Health Policy and Medical Practice—Background Paper*, GPO stock No. 052-003-00924-2 (Washington, DC: U.S. Government Printing Office, 1983).
343. U.S. Congress, Office of Technology Assessment, *The Implications of Cost-Effectiveness Analysis of Medical Technology*, GPO stock No. 052-003-00765-7 (Washington, DC: U.S. Government Printing Office, August 1980).
344. U.S. Congress, Office of Technology Assessment, *Medical Devices and the Veterans Administration—A Technical Memorandum*, Washington, DC, in press, n.d.
345. U.S. Congress, Office of Technology Assessment, *Medical Technology and Costs of the Medicare Program*, GPO stock No. 052-003-00957-9 (Washington, DC: U.S. Government Printing Office, July 1984).
346. U.S. Congress, Office of Technology Assessment, *Medical Technology Under Proposals To increase Competition in Health Care*, GPO stock No. 052-003-00892-1 (Washington, DC: U.S. Government Printing Office, 1982).
347. U.S. Congress, Office of Technology Assessment, *Patents and the Commercialization of New Technology* (Washington, DC: U.S. Government Printing office, 1984 (in press)).
348. U.S. Congress, Office of Technology Assessment, *Policy Implications of the Computed Tomography (CT) Scanner*, GPO stock No. 052-003-00565-4, (Washington, DC: U.S. Government Printing Office, August 1978).
349. U.S. Congress, Office of Technology Assessment, *Policy Implications of the Computed Tomography (CT) Scanner: An Update*, GPO stock No. 052-003-00793-2 (Washington, DC: U.S. Government Printing Office, January 1981).
350. U.S. Congress, Office of Technology Assessment, *The Safety, Efficacy, and Cost Effectiveness of Therapeutic Apheresis*, GPO stock No. 003-052-00918-8 (Washington, DC: U.S. Government Printing Office, 1983).
351. U.S. Congress, Office of Technology Assessment, *Strategies for Medical Technology Assessment*, GPO stock No. 052-003-00887-4 (Washington, DC: U.S. Government Printing Office, 1982).
352. U.S. Congress, Office of Technology Assessment, *Technology and Handicapped People*, GPO stock No. 052-003-00874-2 (Washington, DC: U.S. Government Printing Office, 1982).
353. U.S. Congress, Office of Technology Assessment, *Technology, Innovation, and Regional Economic Development: Census of State Government Initiatives for High-Technology Industrial Development—Background Paper*, GPO stock No. 052-003-00912-9 (Washington, DC: U.S. Government Printing Office, May 1983).
354. U.S. Congress, Office of Technology Assessment, *Technology, Innovation, and Regional Economic Development: Encouraging High-Technology Development—Background Paper #2*, GPO stock No. 052-003-00942-1 (Washington, DC: U.S. Government Printing Office, February 1984).
355. U.S. Congress, Senate, *Clinical Laboratory Improvement Act of 1977*, S. Report No. 95-360, 95th Cong., 1st sess. (Washington, DC: U.S. Government Printing Office, 1977).
356. U.S. Congress, Senate Committee on Finance, *End-Stage Renal Disease (ESRD) Program Under Medicare*, Committee Print 97-9, September 1981 (Washington, DC: U.S. Government Printing Office, 1982).
357. U.S. Constitution, Article 1, Section 8, Clause 8 (the patent clause of the Constitution).
358. U.S. Council of Economic Advisers, *Economic Report of the President and the Annual Report of the Council of Economic Advisers* (Washington, DC: U.S. Government Printing Office, February 1983).
359. U.S. Department of Agriculture, Department of Commerce, Department of State, and Office of the U.S. Trade Representative, *Report to the United States Congress on the Agreement on Technical Barriers to Trade—"Standards Code"* (Washington, DC: U.S. Government Printing Office, 1983).
360. U.S. Department of Commerce, Bureau of the Census, 1963 *Census of Manufactures*, Industry Series, MC63-I-36E and MC63-I-38A (Washington, DC: U.S. Government Printing Office, 1966).
361. U.S. Department of Commerce, Bureau of the Census, 1972 *Census of Manufactures*, Industry Series, MC72-I-36E and MC72-I-38B (Washington, DC: U.S. Government Printing Office, 1976).
362. U.S. Department of Commerce, Bureau of the Census, 1977 *Census of Manufactures*, Industry Series, MC77-I-38B and MC77-I-36F (Washington, DC: U.S. Government Printing Office, June 1980).
363. U.S. Department of Commerce, Bureau of the Census, 1977 *Census of Manufactures*, General Summary, Subject Series, MC77-SR-1 (Washington, DC: U.S. Government Printing Office, April 1981).

364. U.S. Department of Commerce, Bureau of the Census, **1982 Census of Manufactures**, Preliminary Report Industry Series, MC82-I-36F-3(P), MC82-I-38B-1(P), MC82-I-38B-2(P), MC82-I-38B-3(P), MC82-I-38B-4(P) (Washington, DC: U.S. Government Printing Office, 1984).
365. U.S. Department of Commerce, Bureau of the Census, **1979 Annual Survey of Manufactures**, Value of Product Shipments, M79(AS)-2 (Washington, DC: U.S. Government Printing Office, October 1981).
366. U.S. Department of Commerce, Bureau of the Census, **Annual Survey of Manufactures**, Statistics for Industry Groups and Industries, for years 1958, 1963, 1972, 1977 and 1981.
367. U.S. Department of Commerce, Bureau of the Census, **Statistical Abstract of the United States: 1982-83** (103d ed.) Washington, DC, 1982.
368. U.S. Department of Commerce, Bureau of Industrial Economics, **1983 U.S. Industrial Outlook** (Washington, DC: U.S. Government Printing Office, January 1983).
369. U.S. Department of Commerce, Bureau of Industrial Economics, **1984 U.S. Industrial Outlook** (Washington, DC: U.S. Government Printing Office, January 1984).
370. U.S. Department of Commerce, Bureau of Industrial Economics, Capital, Energy, and Productivity Studies Division, Washington, DC, unpublished data, January 1984.
371. U.S. Department of Commerce, Bureau of Industrial Economics, Office of Producer Goods, Science and Electronics Division, "United States Exports of Selected Commodities by Country, January-December 1981," unpublished, Washington, DC, Mar. 5, 1982.
372. U.S. Department of Commerce, Bureau of Industrial Economics, Office of Producer Goods, Science and Electronics Division, "United States Exports of Selected Commodities by Country, January-September 1982," unpublished, Washington, DC, Nov. 23, 1982.
373. U.S. Department of Commerce, Bureau of Industrial Economics, Office of Producer Goods, Science and Electronics Division, "United States Imports of Selected Commodities by Country, January-December 1981," unpublished, Washington, DC, Mar. 5, 1982.
374. U.S. Department of Commerce, Bureau of Industrial Economics, Office of Producer Goods, Science and Electronics Division, "United States Imports of Selected Commodities by Country, January-September 1982," unpublished, Washington, DC, Nov. 26, 1982.
375. U.S. Department of Commerce, Bureau of Industrial Economics, Office of Research, Analysis, and Statistics, Washington, DC, unpublished data, 1984.
376. U.S. Department of Commerce, International Trade Administration, **Countryman.et Survey: Medical Equipment France**, CMS 78-010, Washington, DC, June 1978.
377. U.S. Department of Commerce, International Trade Administration, **Country Market Survey: Medical Equipment Germany**, CMS 82-516, Washington, DC, February 1982.
378. U.S. Department of Commerce, International Trade Administration, **Country Market Survey: Medical Equipment Mexico**, CMS 79-004, Washington, DC, February 1979.
379. U.S. Department of Commerce, International Trade Administration, **Technical Barriers to Trade**, vol. 4 (Washington, DC: U.S. Government Printing Office, 1981).
380. U.S. Department of Commerce, International Trade Administration, **The Tokyo Round Trade Agreements Technical Barriers to Trade**, vol. 4 (Washington, DC: U.S. Government Printing Office, September 1981).
381. U.S. Department of Commerce, Patent and Trademark Office, Office of Patent Program and Documentation Control, unpublished data, Washington, DC, February 1984.
382. U.S. Department of Commerce, Patent and Trademark Office, Office of Technology Assessment and Forecast, "OTAF Custom Report, All Technologies Report, January 1963-June 1983" (mimeo), Washington, DC, 1983.
383. U.S. Department of Commerce, Patent and Trademark Office, Washington, DC, unpublished data, 1984.
384. U.S. Department of Health and Human Services, Food and Drug Administration, **FDA Compliance Policy Guide No. 7155g.03**, Silver Spring, MD, Oct. 1, 1980.
385. U.S. Department of Health and Human Services, Food and Drug Administration, unpublished data, Silver Spring, MD, 1983.
386. U.S. Department of Health and Human Services, **Bureau of Medical Devices Standards Survey 1982, International Edition** (Washington, DC: U.S. Government Printing Office, 1982).
387. U.S. Department of Health and Human Services, Food and Drug Administration, Bureau of Medical Devices, "Policy for Class II Medical Devices," unpublished internal draft, Silver Spring, MD, August 1982.
388. U.S. Department of Health and Human Serv-

- ices, Food and Drug Administration, Bureau of Medical Devices, **Product Development Protocol Guideline**, Silver Spring, MD, 1980.
389. U.S. Department of Health and Human Services, Food and Drug Administration, Bureau of Medical Devices, **Regulatory Requirements for Marketing a Device** (Washington, DC: U.S. Government Printing Office, 1982).
390. U.S. Department of Health and Human Services, Food and Drug Administration, Office of Economic Analysis, compilation of unpublished data from the U.S. Patent and Trademark Office, Washington, DC, December 1983.
391. U.S. Department of Health and Human Services, Food and Drug Administration, Office of Planning and Evaluation, **Baseline Data on the Availability of Medical Devices and In-Vitro Diagnostic Products**, OPE Study 54 (Rockville, MD: Food and Drug Administration, Office of Planning and Evaluation, July 1980).
392. U.S. Department of Health and Human Services, Food and Drug Administration, Office of Planning and Evaluation, **Baseline Data On Medical Device Establishments**, OPE Study 59 (Rockville, MD: Food and Drug Administration, Office of Planning and Evaluation, September 1981).
393. U.S. Department of Health and Human Services, Food and Drug Administration, Office of Planning and Evaluation, **Baseline Data on Medical Device Industries in the Census of Manufactures**, OPE Study 53 (Rockville, MD: Food and Drug Administration, Office of Planning and Evaluation, July 1980).
394. U.S. Department of Health and Human Services, Food and Drug Administration, Office of Planning and Evaluation, Rockville, MD, unpublished data, 1983.
395. U.S. Department of Health and Human Services, Health Care Financing Administration, **1979 PSRO Program Evaluation** (Washington, DC: U.S. Government Printing Office, 1980).
396. U.S. Department of Health and Human Services, Health Care Financing Administration, **1981 End-Stage Renal Disease Annual Report to Congress** (Washington, DC: U.S. Government Printing Office, 1981.)
397. U.S. Department of Health and Human Services, Health Care Financing Administration, "Annual Report to the Congress from the Secretary of Health and Human Services on the Professional Standards Review Organizations Program Fiscal Year 1980," mimeo, February 1981.
398. U.S. Department of Health and Human Services, Health Care Financing Administration, "Draft Report of HCFA Task Force on Independent Laboratories," Aug. 17, 1983, as cited in Foster, 1984.
399. U.S. Department of Health and Human Services, Health Care Financing Administration, Office of Research and Demonstrations, **Medicare: Use of Home Health Services, 1980**, prepared by Kathryn D. Barrett, Baltimore, MD, July 1983 (draft).
400. U.S. Department of Health and Human Services, Health Care Financing Administration, "PSRO Evaluation," **Health Care Financing: Research and Demonstrations in Health Care Financing** 1980-1981, HCFA publication No. 03144, Rockville, MD, 1982.
401. U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, unpublished data supplied by G. Wilson, Bethesda, MD, December 1983.
402. U.S. Department of Health and Human Services, National Institutes of Health, National Heart, Lung, and Blood Institute, **Task Force Report on Pulmonary Technology**, NIH publication No. 81-2110, Bethesda, MD, July 1981.
403. U.S. Department of Health and Human Services, National Institutes of Health, National Institute for Neurological and Communicable Disease and Stroke, Request for Proposals, "Orphan Products Development Studies" (RFP #NIH-NINCDS-8407), Bethesda, MD, Jan. 23, 1984.
404. U.S. Department of Health and Human Services, National Institutes of Health, Office of Program Planning and Evaluation and the Division of Research Grants, **NIH Data Book** 1983, Washington, DC, June 1983.
405. U.S. Department of Health and Human Services, Public Health Service, **Annual Report: Activities of the Orphan Products Board**, March 1982-May 1983, Washington, DC, 1983.
406. U.S. Department of Health and Human Services, Public Health Service, Bureau of Health Maintenance Organizations and Resources Development, Office of Health Planning, **Status Report on State Certificate of Need Programs**, Rockville, MD, March 1983.
407. U.S. Department of Health and Human Services, Request for Proposal No. HCFA-84-015, **Operation of Utilization and Quality Control Peer Review Organizations**, Feb. 28, 1984.
408. U.S. Department of Health and Human Services, unpublished statistical data, 1983.
409. U.S. Department of Health, Education, and

- Welfare, Health Care Financing Administration, Professional Standards Review Organization 1978 Program Evaluation, HEW publication No. HCFA-03000, Washington, DC, January 1979.
410. U.S. Department of Health, Education, and Welfare, National Institutes of Health, *Antenatal Diagnosis*, NIH publication No. 79-1973, Bethesda, MD, April 1979.
411. U.S. Department of Health, Education, and Welfare, Public Health Service, *PSRO: An Initial Evaluation of the Professional Standards Review Organization*, "Vol. 1: Executive Summary," Washington, DC, February 1978.
412. U.S. Department of Health, Education and Welfare, et al., *Rehabilitation Engineering: A Plan for Continued Progress* (Charlottesville, VA: Rehabilitation Engineering Center, University of Virginia, 1978).
413. U.S. Department of Health, Education, and Welfare, Public Health Service, *Report of the President's Biomedical Research Panel*, "Appendix A: The Place of Biomedical Science in Medicine and the State of Science," DHEW publication No. (OS) 76-501, Washington, DC, Apr. 30, 1976.
414. U.S. Department of the Treasury, Internal Revenue Service, *A General Description of the Corporation Sourcebook*, publication 647 (Washington, DC, U.S. Government Printing Office, revised June 1983).
415. U.S. Department of the Treasury, Internal Revenue Service, *Corporation Income Tax Returns, Statistics of Income*, for years 1963, 1967, 1972, 1977 and 1980, Washington, DC, U.S. Government Printing Office.
416. U.S. Department of the Treasury, Internal Revenue Service, *Sourcebook of Statistics of Income*, for years 1963, 1967, 1977, and 1980, Washington, DC, U.S. Government Printing Office.
417. U.S. Department of the Treasury, Internal Revenue Service, *Sourcebook of Statistics of Income*, for years 1976-80, as cited in (26).
418. U.S. Department of the Treasury, Office of Tax Analysis, unpublished data, Washington, DC, 1983.
419. U.S. Executive Office of the President, Office of the U.S. Trade Representative, *A Preface to Trade* (Washington, DC: U.S. Government Printing Office, 1982).
420. U.S. Executive Office of the President, Office of the U.S. Trade Representative, "Status of Tokyo Round MTN Agreement Signatures and Acceptances," Nov. 1, 1983.
421. U.S. National Science Foundation, **Federal Funds for Research and Development: Fiscal Years 1980, 1981, and 1982**, NSF 81-325 (Washington, DC: NSF, 1981).
422. U.S. National Science Foundation, **National Patterns of Science and Technology Resources, 1982**, NSF 82-319, Washington, DC, 1982.
423. U.S. National Science Foundation, **Research and Development in Industry, 1979**, detailed statistical tables, NSF 81-324, Washington, DC, 1981.
424. U.S. National Science Foundation, "Survey of Industrial Research and Development," conducted by the U.S. Bureau of the Census, Washington, DC, 1982.
425. U.S. Small Business Administration, **The State of Small Business: A Report to the President** (Washington, DC: U.S. Government Printing Office, 1984).
426. U.S. Veterans Administration, **1982 Annual Report**, Washington, DC, 1983.
427. U.S. Veterans Administration, Assistant Inspector General for Auditing, "Report of Audit: Procurement and Monitoring of Pacemakers," Project No. 101A-79-42, Washington, DC, Feb. 13, 1980.
428. U.S. Veterans Administration, **Brief of Office of Procurement and Supply**, unpublished, Washington, DC, December 1982.
429. U.S. Veterans Administration, Department of Medicine and Surgery, "Chief Medical Director's Preface to Strategic Outlook," draft 5, version 2, Washington, DC, May 1983.
430. U.S. Veterans Administration, Department of Medicine and Surgery, letter to Honorable Alan K. Simpson, Chairman, Senate Committee on Veterans Affairs, concerning the VA Rehabilitation Engineering Center (VAREC), Washington, DC, May 12, 1983.
431. U.S. Veterans Administration, Department of Medicine and Surgery, **Veterans Administration Prosthetic and Sensory Aids Program Since World War II** (Washington, DC: U.S. Government Printing Office, 1977).
432. U.S. Veterans Administration, **Medical District Initiated Program Planning: Guidance for the Preparation of Medical District Plans**, vol. 1, Washington, DC, June 1983.
433. U.S. Veterans Administration, Office of Planning and Program Evaluation, **Rehabilitative Engineering Research and Development Program Evaluation**, Washington, DC, August 1981.
434. U.S. Veterans Administration, Office Of Procurement and Supply, "Evaluation of New Products," Washington, DC, January 1983.
435. U.S. Veterans Administration, Rehabilitation

- Research and Development Service, "Development and Evaluation Program," Washington, DC, 1983.
436. Urban Systems Research and Engineering, and Policy Analysis, Inc., ***Certificate of Need Programs: A Review, Analysis, and Annotated Bibliography of the Research Literature***, prepared under contract No. HRA-231-77-0114 for the Department of Health, Education, and Welfare, publication No. (HRA) 79-14006 (Washington, DC: U.S. Government Printing Office, November 1978).
437. Utterback, J. M., "Innovation in Industry and the Diffusion of Technology," *Science* 183:620-626, Feb. 15, 1974.
438. Utterback, J. M., and Abernathy, W. J., "A Dynamic Model of Process and Product Innovation," *Omega* 3:639-656, 1975, as cited in (259).
439. "VA Prosthetics . . . Some Recommendations," *DAV Magazine* 24(8):8-9, August 1982.
440. Venture Capital Journal, "Capital Transfusion 1982," 23(1):6, January 1983.
441. Venture Capital Journal, "Evolution of an Industry: Venture Capital Redefined for the 1980's," January 1980.
442. Venture Capital Journal, "Venture Capital Disbursements 1981: A Statistical Overview," 22(6):7, June 1982.
443. Venture Economics, Wellesley Hills, MA, "Venture Capital Investment in the Medical Health Care Field," contract report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, August 1983.
444. Vlassembrouck, J. M., Surgical Products Division, 3M, Minneapolis, MN, personal communication, Dec. 21, 1983.
445. Von Hippel, E., "Appropriability of Innovation Benefit as a Predictor of Functional Locus of Innovation," unpublished, MIT Sloan School of Management, Cambridge, MA, 1979, as cited in (259).
446. Von Hippel, E., "A Review of Data Bearing on the User's Role in Industrial Innovation," unpublished, MIT Sloan School of Management, Cambridge, MA, 1978, as cited in (259).
447. Wagner, J., "The Economic Evaluation of Medicine: A Review of the Literature," prepared for the Pharmaceutical Manufacturers of America, mimeo, Oct. 1, 1982.
448. Wagner, J. L., et al., ***Final Report: A Study of the Impact of Reimbursement Strategies on the Diffusion of Medical Technologies***, Vol. II: Appendices, report submitted to the Health Care Financing Administration, HCFA/HHS grant # 18-p-97113/3-01 (Washington, DC: The Urban Institute, 1982).
449. Wagner, L., Program Analyst, Office of the Director, National Institutes of Health, Bethesda, MD, personal communication, Dec. 30, 1983.
450. Warner, K. E., "Effects of Hospital Cost Containment on the Development and Use of Medical Technology," *Milbank Mere. Fund Q.* 56(2):187-211, 1978.
451. ***Washington Report on Medicine and Health*** 37(39):4, Oct. 3, 1983.
452. *Washington Report on Medicine and Health* 38(9):1, Feb. 27, 1984.
453. *Washington Report on Medicine and Health*, "Perspectives: Health Planning Looks to the Future," 37(48), Dec. 5, 1983.
454. Weinstein, M. C., and Stason, W. B., "Cost-Effectiveness of Coronary Artery Bypass Surgery," *Circulation* 66(5) Part II, AHA Monograph No. 92, ***Technology Assessment Forum on Coronary Artery Bypass Surgery: Economic, Ethical and Social Issues***, November 1982.
455. Westphal, M., Frazier, E., and Miller, M. C., "Changes in Average Length of Stay and Average Charges Generated Following Institution of PSRO Review," *Health Services Research* 14(4): 253-265, winter 1979.
456. Williams, K., Health Insurance Association of America, Washington, DC, personal communication, December 1982.
457. Willingmyre, G. T., ***Reuse of Single-Use Hemodialyzers*** (Washington, DC: Health Industry Manufacturers Association, 1979).
458. Willingmyre, G. T., Vice President for Technical Affairs, Health Industry Manufacturers Association, comments made at meeting, Nov. 28, 1983.
459. Wilson, et al., "Intermittent Positive Pressure Breathing," *Calif. Med.* 87:161, 1957.
460. Wilson, G. H., Special Assistant for Diagnostic Imaging Research, National Cancer Institute, National Institutes of Health, Bethesda, MD, personal communications, June 24, 1983 and September 1983.
461. Wineman, R., memorandum to file, re summary of meeting concerning end-stage renal disease issue, Jan. 21, 1980, reprinted in ***The End Stage Renal Disease Program (Part 2-Treatment Standards and Methods)***, Hearing before Subcommittee of the Committee on Government Operations, House of Representatives, Apr. 28, 1980 (Washington, DC: U.S. Government Printing Office, 1982).
462. Wisconsin Hospital Association, ***Report on***

- WHA'S Evaluation of the Wisconsin Certificate of Need Program**, July 23, 1982 (working draft).
463. Wishinsky, H., Vice President, Scientific and Regulatory Affairs, Professional Products Group, Miles Laboratories, Inc., Elkhart, IN, personal communication, Dec. 14, 1983.
464. Witt, A., U.S. Department of Health and Human Services, Food and Drug Administration, Office of General Counsel, Food and Drug Division, personal communication, April 1984.
465. Wright, D., U.S. Veterans Administration, Rehabilitation Engineering Center, New York, NY, personal communication, June 1983.
466. Zakupowsky, A., and Sunley, E., "An Early Assessment of the Capital Cost Recovery System for R&D Equipment Provided by the Economic Recovery Tax Act of 1981," working paper prepared for the National Science Foundation, Washington, DC, September 1982.
467. Ziment, I., "Intermittent Positive Pressure Breathing," *Respiratory Care*, G. Burton, G. Gee, and J. Hodgkin (eds.) (Philadelphia: J. B. Lippincott, 1977).