References

References

1. Armed Forces Institute of Pathology, Hepatic Branch, and the Centers for Disease Control, Bureau of Epidemiology, Family Planning Evaluation Division, "Increased Risk of Hepatocellular Adenoma in Women With Long-Term Use of Oral Contraceptives," *Morbidity and Mortality Weekly Report* 26:293, *1977.*
2. Beta-Blocker Heart Attack Study Group, "The Beta-Blocker Heart Attack Trial," *./. A.M.A. 246: 2073, 1981.*
3. Boman, G., "The Nordic Countries," in *Monitoring for Drug Safety,* W. H. W. Inman (cd.) (Philadelphia: J. B. Lippincott Co., 1980).
4. Borden, E, K., The Upjohn Co., personal communication with the Office of Technology Assessment, February 1982.
5. Borden, E. K., The Upjohn Co., "Postmarketing Surveillance of Outpatient Drugs Using a Pharmacy-Based Registry System—Report of Two Studies" presented at the Drug Information Association Workshop, Williamsburg, Va., December **1981.**
6. **Boston Collaborative** Drug Surveillance Program, "Oral Contraceptives and Venous Thromboembolic Disease, Surgically Confirmed Gallbladder Disease and Breast Tumors," *Lancet* 1:1399, **1973.**
7. Boston Collaborative Drug Surveillance Program, "Surgically Confirmed Gallbladder Disease, Venous Thromboembolism and Breast Tumors in Relation to Post Menopausal Estrogen Therapy," N. *Eng. J. Med.* 290:15,1974.
8. British Medical Journal, "Oral Contraceptives and Breast Neoplasia" (leading article), *Br. Meal, J.* 1:545, **1976.**
9. **Chalmers, T. C., "Who** Will Fund Clinical Trials?" *The Sciences* 22:6, *1982.*
10. Clarren, S. N., Director, The Regulatory Center, Performance Development Institute, Washington, D. C., personal communication with the Office of Technology Assessment, **1982.**
11. Clarren, S. N., and Jones, J., "Using Post-Marketing Experience To Improve the Drug Review and Approval Process," presented at the Annual Meeting of the American Association for the Advancement of Science, session on "Regulatory Reform as It Affects Science and Technology," Washington, D. C., January 1982.
12. Clarren, *S. N.,* **et al.,** *The Evaluability Assessment of the Developing Experiment in Post-Marketing Surveillance of Prescription Drugs,* prepared for the Experimental Technology Incentives Program, National Bureau of Standards (contract No. NBS-GCR-ETIP-81-96) (Washington, D. C.: Performance Development Institute, 1981).
13. Cohen, J., *Statistical Power Analysis for the Behavioral Sciences (New* York: Academic Press, 1967).
14. Cohen, L., et al., "Pregnancy Oral Contraceptives and Chronic Familial Jaundice With Predominantly Conjugated Hyperbilirubinemia (Dubin-Johnson Syndrome)," *Gastroenterology* 62:1182, 1972.
15. Collaborative Group for the Study of Stroke in Young Women, "Oral Contraceptives and Stroke in Young Women," *J. A.M.A.* 231:718, **1975.**
16. Department of Health, Education, and Welfare, *Review Panel on New Drug Regulation, Final Report* (Washington, D. C.: U.S. Government Printing Office, *1977).*
17 Dollery, C. T., and Rawlins, M. D., "Monitoring Adverse Reactions to Drugs," *Br. Med. J.* 1:96, 1977.
18. Dorsen, M., and Miller, J. M., "The Drug Regulation Process and the Challenge of Regulatory Reform," *Ann. intern. Med.* 91:908, *1979.*
19. Elder, J. B., et al., "Cimetidine and Gastric Cancer," *Lancet* 1:1005, 1979.
20. European Workshop (Report of), "Towards a More Rational Regulation of the Development of New Medicines," *Europ. J. Clin. Pharmacol.* 11:233, **1977.**
21. F-D-C Reports ("The Pink Sheet"), "'Substantial Evidence' Requirement Should Be Reduced by FDA Through Regs, McMahon Commission Urges in Draft of Report," *F-D-C 'Reports* 44(10):3, *1982.*
22. Finkel, M. J., "FDA's Criteria for Safety and Effectiveness of Drugs," presented at the First Workshop on Drug Control in the Region of the Americas, Pan American Health Organization, Washington, D. C., May 1, **1979.**
23. Finney, D. J., "Statistical Logic in the Monitoring of Reactions to Therapeutic Drugs," in *Monitoring for Drug Safety,* W. H. W. Inman (cd.) (Philadelphia: J, P. Lippincott Co., **1980).**
24. Food and Drug Administration, "General Considerations for the Clinical Evaluation of Drugs," HEW(FDA)77-3040 (Washington, D. C.: U.S. Government Printing Office, 1977).
25. Food and Drug Administration, "Supplementar, Report to Contracts and Grants Committee on Medicaid," from the Division of Drug Experience, Bureau of Drugs (mimeo.), **1982.**
26. Food Drug Cosmetics Law Reports, "Timolol Ap-

proved as First Drug for Prevention of Death After Heart Attack," *HHS News*, dated Nov. 25, 1981, sec. 41,560.
27. Friedman, G. D., et al., "Experience in Monitoring Drug Reactions in Outpatients," *J. A.M. A.* 217:567, 1971.
28. Frommer, P. L., Acting Director, National Heart, Lung, and Blood Institute, personal communication with the Office of Technology Assessment, 1982.
29. General Accounting Office, U.S. Congress, *FDA Can Further Improve Its Adverse Drug Reaction Reporting System* (Washington, D. C.: GAO, 1982).
30, General Accounting Office, U.S. Congress, *FDA Drug Approval: A Lengthy Process That Delays the Availability of Important New Drugs* (Washington, D. C.: GAO, 1980).
31. Gifford, L. M., et al., "Cimetidine Postmarked Outpatient Surveillance Program," *J.A.M.A.* 243:1532, *1980.*
32. Gillie, O., "The Journalist," in *Monitoring for Drug Safety*, W, H, W. Inman (cd,) (Philadelphia: J. B. Lippincott Co., 1980).
33. Gross, F. H., and Inman, W. H. W. (eds.), *Drug Monitoring*, proceedings of an International Workshop held in Honolulu, January 1977 (London: Academic Press, 1977).
34. Hawker, P, C., et al., "Gastric Cancer After Cimetidine in Patient With Two Negative Pretreatment Biopsies," *Lancet* 1:709, 1980.
35 Inman, W. H. W. (cd.), *Monitoring for Drug Safety* (Philadelphia: J. B. Lippincott Co., 1980).
36 Inman, W. H. W., "Recorded Release," in *Drug Monitoring*, F. H. Gross and W. H. W. Inman (eds.), Proceedings of an International Workshop held in Honolulu, January 1977 (London: Academic Press, 1977).
37 Inman, W. H. W., "The United Kingdom," in *Monitoring for Drug Safety*, W. H. W. Inman (cd.) (Philadelphia: J. B. Lippincott Co., 1980).
38 Inman, W. H. W., and Vessey, M. P., "Investigation of Deaths From Pulmonary, Coronary and Cerebral Thrombosis and Embolism in Women of Child-Bearing Age," *Br. Med. J.* 2:193, 1968.
39. Inman, W. H. W., et al., "Thromboembolic Disease and the Steroidal Content of Oral Contraceptives," *Br. Med. J.* 2:203, *1970.*
40, Jick, H., Boston Collaborative Drug Surveillance Program, Boston University Medical Center, personal communication with the Office of Technology Assessment, 1981.
41, Jick, H., Boston Collaborative Drug Surveillance Program, Boston University Medical Center, personal communication with the Office of Technology Assessment, 1982.
42. Joint Commission on Prescription Drug Use, *Report of the Joint Commission on Prescription Drug Use, Final Report* (Rockville, Md.: Joint Commission on Prescription Drug Use, Inc., 1980).
43 Lasagna, L., Professor of Pharmacology and Toxicology and Professor of Medicine, University of Rochester School of Medicine, personal communication with the Office of Technology Assessment, 1982.
44. Lawson, D. H., "Intensive Monitoring in Hospitals—l: Boston Collaborative Drug Surveillance Program (BCDSP)," in *Monitoring for Drug Safety*, W. H, W. Inman (cd.) (Philadelphia: J. B. Lippincott Co., **1980).**
45. Lawson, D. H., and Henry, D. A., "Monitoring Adverse Reactions to New Drugs: 'Restricted Release' or 'Monitored Release'," *Br. Med. J.* 1:691, *1977.*
46. Levy, R., and Sondik, E., "Decision-Making in Planning Large-Scale Comparative Studies," *Ann. N. Y. Acad. Sci.* 304:441, *1978.*
47. Lewis, J, A., "Post-Marketing Surveillance: How Many," *Trends in Pharmacological Sciences* 2:93, **1981.**
48. Lindsjö, A., "Down's Syndrome in Sweden," *Acta Paediatr. Scand.* 63:571, 1974.
49, MacMahon, B., et al., *Epidemiologic Methods* (Boston: Little, Brown, 1960),
50. Mann, J. I., "Principles and Pitfalls in Drug Epidemiology," in *Monitoring for Drug Safety,* W. H. W. Inman (cd.) (Philadelphia: J.B. Lippincott Co., 1980),
51. Mann, J. I., and Inman, W. H. W., "Oral Contraceptives and Death From Myocardial Infarction in Young Women," *Br. Med. J.* 2:245, **1975.**
52. Mann, J. I., et al., "Myocardial Infarction in Young Women With Special Reference to **Oral** Contraceptive Practice," *Br. Med. J.* 2:241, 1975.
53. Medico-Pharmaceutical Forum, *Post-Marketing Surveillance of Adverse Reactions to New Medicines*, publication No. 7 (London: Medico-Pharmaceutical Forum, 1977).
54. Meyboom, R. H. B., "Drug Interactions With the 'Pill'," in Drug *Interactions*, D. G. Grahame-Smith (cd,) (London: MacMillan, 1977).
55. Mosteller, F., Chairman, Department of Health Policy and Management, School of Public Health, Harvard University, personal communication with the Office of Technology Assessment, 1982.
56. Nicholls, J. T., "The Practolol Syndrome—A Retrospective Analysis," in *Postmarketing Surveillance of Adverse Reactions to New Medicines,*

publication No. 7 (London: Medico-Pharmaceutical Forum, 1978).
57. Norwegian Multicenter Study Group, "Timolol-Induced Reduction in Mortality and Reinfarction in Patients Surviving Acute Myocardial Infarction," N. *Eng. J. Med.* 304:801, 1981.
58. Ory, H., "Function of Ovarian Cysts and Oral Contraceptives," *J. A.M.A.* 228:68, *1974.*
59. Reed, P. I., et al., "Effect of Cimetidine on Gastric Juice N-Nitrosamine Concentration," *Lancet* 2:553, **1981.**
60. Reed, P. I., et al., "Gastric Cancer in Patients Who Have Taken Cimetidine," *Lancet* 1:1234, 1979.
61. Remington, R. D., "Post-Marketing Drug Surveillance: A Comparison of Methods," *Amer. J. Pharmacy* 150:72, 1978.
62. Royal College of General Practitioners' Oral Contraception Study, "Mortality Among Oral-Contraceptive Users," *Lancet* 2:727, *1977.*
63 Ruskin, A., and Anello, C , "The United States of America," in *Monitoring for Drug Safety,* W. H. W. Inman (cd.) (Philadelphia: J. B. Lippincott Co., 1980).
64. Sackett, D. L., et al., "Compliance," in *Monitoring for Drug Safety,* W. H. W. Inman (cd.) (Philadelphia: J. B. Lippincott Co., 1980).
65. Sartwell, P. E., "Retrospective Studies: A Review for the Clinicianr " *Ann. Intern. Med.* 81:381, *1974.*
66. Schor, S., Executive Director, Clinical Biostatistics and Research Data Systems, Merck Sharp & Dohme Research Laboratories, personal communication with the Office of Technology Assessment, **1982.**
67. Sherrid, P., "Drugs," *Forbes* magazine, Jan. 4, 1982, p. 214.
68. Shimomura, T., "Compensation for Drug-Induced Illness in Japan," in *Monitoring for Drug Safety,* W. H. W. Inman (cd.) (Philadelphia: J. B. Lippincott co., 1980).
69. Strom, B., Clinical Epidemiology Unit, School of Medicine, University of Pennsylvania, personal communication with the Office of Technology Assessment, 1982.
70. Taylor, T. V., et al., "Gastric Cancer and Cimetidine," *J. Royal Coll. Surg. Edinburgh* 26:34, *1981.*
71. Thayer, C. F., "Results of Postmarketing Surveillance Program on Streptokinase, 'f *Current Therapeutic Research* 20:129, *1981.*
72. U.S. Senate, Committee on the Judiciary, report on *The Patent Term Restoration Act of 1981,* report No, 97-138 (Washington, D. C.: U.S. Government Printing Office, 1981).
73. Vessey, M. P., and Doll, R., "Investigation of Relation Between Use of Oral Contraception and Thromboembolic Disease, " *Br. Med. J.* 2:199, *1968.*
74. Vessey, M. P., et al., "Postoperative Thromboembolism and the Use of Oral Contraceptives, " *Br. Med. J.* 3:123, **1970.**
75. Walden, R. J., and Prichard, B. N. C., "Post-Marketing Drug Surveillance, " *Br. J. Clin. Pharmace].* 6:191, **1978.**
76. Walker, A. M., Sidney Farber Cancer Institute, School of Public Health, Harvard University, personal communication with the Office of Technology Assessment, 1982.
77. Wardell, W. M., et al., "Postmarketing Surveillance of New Drugs: I. Review of Objectives and Methodology, " *J. Clin. Pharmacol.* 19:85, **1979.**
78. Wardell, W. M., et al., "Postmarketing Surveillance of New Drugs: II. Case Studies, " *J. Clin. Pharmacol.* 19:169, 1979.
79. Wilson, A. B., "Post-Marketing Surveillance of Adverse Reactions to New Medicines, " *Br. Med. J.* 2:1001, 1977.
80. Wolfe, S., Director, Health Research Group, Washington, D. C., personal communication with the Office of Technology Assessment, 1982.