

1. Record Nr.	UNINA9910970045603321
Titolo	Food and Drug Administration advisory committees // Committee to Study the Use of Advisory Committees by the Food and Drug Administration ; Richard A. Rettig, Laurence E. Earley, Richard A. Merrill, editors
Pubbl/distr/stampa	Washington, D.C., : National Academy Press, 1992
ISBN	9786610246861 9781280246869 1280246863 9780309585200 0309585201 9780585085500 0585085501
Edizione	[1st ed.]
Descrizione fisica	xii, 226 p. : ill
Altri autori (Persone)	RettigRichard A EarleyLaurence E MerrillRichard A
Disciplina	353.0077/8
Soggetti	Public health advisory groups - United States - Evaluation
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	"Division of Health Care [sic] Policy, Institute of Medicine."
Nota di bibliografia	Includes bibliographical references.
Nota di contenuto	Food and Drug Administration Advisory Committees -- Copyright -- Preface -- NOTES -- Acknowledgments -- Contents -- List of Abbreviations -- Summary -- The Roles of FDA Advisory Committees -- Practical Limits on Advisory Committees -- COMMITTEE MEMBERSHIP -- Nomination Criteria -- Recruitment Procedures -- Consumer Members -- Appointment Authority -- Administrative Responsibility for Appointments -- COMMITTEE INTEGRITY -- Options Requiring Legislation -- Options Available within Existing Authority -- COMMITTEE OPERATIONS -- Scheduling Meetings -- Meeting Preparation -- General Criteria for Setting the Agenda -- Setting Specific Agendas -- Timely Distribution of Materials -- Summaries of Materials Sent to Advisory Committees -- Use of Primary Reviewers -- Communications Issues -- Conducting an Advisory Committee Meeting

-- Allocation and Control of Agenda Time -- Electronic Coverage of Meetings -- Voting -- Agency Neutrality -- Custom Tailoring of Committee Membership -- Meeting Follow-up -- ORGANIZATION AND MANAGEMENT -- System Management -- Compensation -- Orientation and Training -- AGENCY MANAGEMENT AND ACCOUNTABILITY -- Agency Management -- Agency Accountability -- A CONCLUDING RECOMMENDATION -- NOTES -- 1 Introduction -- ORIGINS OF THE STUDY -- STUDY OBJECTIVES -- SCOPE OF THE STUDY -- THE ROLES OF FDA ADVISORY COMMITTEES -- PRACTICAL LIMITS ON THE USE OF ADVISORY COMMITTEES -- THE FEDERAL ADVISORY COMMITTEE ACT -- STUDY METHODS -- REPORT ORGANIZATION -- A NOTE ON CROSS-NATIONAL COMPARISONS -- APPENDIX -- NOTE -- 2 Historical Evolution of FDA Advisory Committees -- DRUGS -- Drug Efficacy Study -- Over-the-Counter Drugs -- Prescription Drug Review -- Summary -- BIOLOGICS -- MEDICAL DEVICES -- The Cooper Report -- The Medical Device Amendments of 1976 -- NIH STUDY SECTIONS -- SUMMARY -- NOTES -- 3 The FDA Advisory Committee System. THE PRODUCT EVALUATION PROCESS -- The Drug Evaluation Process -- The Biologics Approval Process -- The Device Approval Process -- AGENCY WORKLOAD AND ADVISORY COMMITTEES -- OFFICIAL PURPOSES OF ADVISORY COMMITTEES -- The FDA Regulations -- The NDA Rewrite -- Medical Device Statutes -- FDA Advisory Committee Charters -- THE USES OF ADVISORY COMMITTEES -- Variations Among Centers -- Center Workload and Stage of Advisory Committee Use -- Other Means of Seeking Advice -- SUMMARY -- NOTES -- 4 Recurring Issues -- MAJOR PRIOR REPORTS -- The Fountain Committee Report (1976) -- The Dorsen Committee Report (1977) -- The McMahon Commission Report (1982) -- The Lasagna Committee Report (1990) -- Other Reports -- THE GOLDFISH BOWL -- Congressional Oversight -- Media Coverage -- The Financial Community -- CONCLUSIONS -- NOTES -- 5 Committee Membership -- NOMINATION CRITERIA -- General and Specific Criteria -- Diversity Objectives -- Balance -- Implications -- RECRUITMENT PROCEDURES -- CONSUMER MEMBERS -- APPOINTMENT AUTHORITY -- ADMINISTRATIVE RESPONSIBILITY FOR APPOINTMENTS -- 6 Ensuring Committee Integrity -- FINANCIAL CONFLICT OF INTEREST -- THE STATUTORY FRAMEWORK -- Subsection 208(b)(1) -- Subsection 208(b)(2) -- Subsection 208(b)(3) -- FDA'S ADMINISTRATION OF CONFLICT-OF-INTEREST RESTRICTIONS -- Screening Potential Committee Members -- Identification of Conflict and Decision to Seek a Waiver -- A RAPIDLY CHANGING SYSTEM -- Notable Controversies -- Psychopharmaceutical Drugs Advisory Committee: Meeting of September 20, 1991 -- General and Plastic Surgery Devices Advisory Panel: Meeting of November 12-13, 1991 -- Arthritis Drugs Advisory Committee: Meeting of December 6, 1991 -- Blood Products Advisory Committee Meeting: December 12-13, 1991 -- Biologics Response Modifiers Advisory Committee: Meeting of January 16-17, 1992. Dermatologic Drugs Advisory Committee: Meeting of April 10, 1992 -- Circulatory Systems Devices Panel: Meeting of May 11, 1992 -- Analysis of Waiver Processing -- Interpretation -- Glimmers of Progress -- Workload -- Waiver Preparation and Review -- Schedule for Review of Waivers -- Waiver Form -- RECOMMENDATIONS ON FINANCIAL CONFLICT OF INTEREST -- Options Requiring Legislation -- Options Available Within Existing Authority -- INTELLECTUAL BIAS -- Remedies -- Screening -- NOTES -- APPENDIX -- A Suggested Approach to the Codification of Section 208(b)(3) Waiver Criteria -- 7 Committee Operations -- SCHEDULING ADVISORY COMMITTEE MEETINGS -- MEETING PREPARATION -- General Criteria for Setting the Agenda --

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