

1. Record Nr.	UNINA9910827560703321
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	1-280-24686-3 9786610246861 0-309-58520-1 0-585-08550-1
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 -- Product Evaluation and Guidelines Development at CDER -- Program Management at CDER -- Setting the Agenda -- Content of the Agenda Questions -- Timely Distribution of Materials -- Summaries of

Materials Sent to the Committee -- Use of Primary Reviewers --  
Communications Issues Before an Advisory Committee Meeting -- FDA  
Communication to Advisory Committee Members -- Communication  
Among Advisory Committee Members -- Communication Between  
Sponsors and Advisory Committee Members -- Agency Communication  
to Sponsors -- Communication Between the FDA and the Public --  
CONDUCTING AN ADVISORY COMMITTEE MEETING -- Roles of the  
Principal Participants -- Allocation and Control of Agenda Time --  
Electronic Coverage of Meetings -- Voting -- Agency Neutrality --  
Agency Presentations -- FDA-Committee Interaction -- Seating  
Arrangements -- Closed Deliberations -- CUSTOM TAILORING OF  
COMMITTEE MEMBERSHIP -- MEETING FOLLOW-UP -- NOTES -- 8  
Organization and Management -- SYSTEM MANAGEMENT -- The  
Commissioner and His Office -- Center Directors -- Office and Division  
Directors -- Executive Secretaries -- COMPENSATION -- ORIENTATION  
AND TRAINING.  
TYPES OF ADVISORY COMMITTEES -- Policy Advisory Committee --  
Other Issues -- AGENCY MANAGEMENT AND ACCOUNTABILITY --  
Agency Management -- Agency Accountability -- A CONCLUDING  
RECOMMENDATION -- NOTES -- Appendix A Resource Implications --  
CURRENT SYSTEM COSTS UNDERESTIMATED -- RECOMMENDATIONS  
THAT WILL HAVE RESOURCE IMPLICATIONS -- Appendix B Glossary.

---