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Nota di contenuto	Blood Banking and Regulation: Procedures, Problems, and Alternatives -- Copyright -- Foreword -- Preface -- Contents -- I Overview of Regulatory and Policy-Making Procedures in Blood Banking -- FDA Policy and Regulation -- THE REGULATORY MANDATE -- REGULATORY MECHANISMS -- LEGAL AUTHORITIES -- REGULATION AND ENFORCEMENT AT FDA -- ENSURING BLOOD SAFETY AND AVAILABILITY IN THE FUTURE -- CDC Recommendations -- CDC'S MISSION -- EFFECTIVENESS OF CDC -- RESEARCH ON HIV -- HOW CDC AFFECTS POLICY -- FORMAL RECOMMENDATIONS -- Blood Banking's Policy Groups and Procedures -- THE TRADITION OF SELF-REGULATION --

STANDARD-SETTING ORGANIZATIONS -- AMERICAN ASSOCIATION OF BLOOD BANKS -- JOINT EFFORTS -- OTHER STANDARDS AND GUIDELINES -- Opportunities and Venues for Dialogue -- THE CHANGING CLIMATE IN BLOOD BANKING -- VENUES FOR DIALOGUE -- THE BLOOD PRODUCTS ADVISORY COMMITTEE -- OTHER VENUES FOR DIALOGUE -- THE VOICE OF BLOOD PRODUCT CONSUMERS -- ATTENDING TO THE DONOR -- REGULATORY DIFFICULTIES -- Discussion -- II Regulatory Enforcement And Compliance -- CBER Compliance Activity -- COORDINATION BETWEEN THE CENTERS AND THE FIELD -- OFFICE OF REGULATORY AFFAIRS -- INSPECTION CONSISTENCY -- INSPECTIONS AND ENFORCEMENT -- FDA Practice in the Field -- TRAINING FOR THE FIELD -- SOURCES OF CONSISTENCY -- Challenges and Questions About Compliance -- IMPROVEMENTS IN SAFETY -- QUESTIONS ABOUT ENFORCEMENT -- Evidence That Compliance Works -- Indirect Effects: "Bulletproofing -- Is Compliance Improving? -- REGULATION AND OTHER FORCES -- Discussion -- III Innovations and Alternatives in Regulation -- Regulatory Alternatives -- REGULATORY DIAGNOSIS AND MISMATCH -- MAXIMIZING EFFECTIVENESS AND EFFICIENCY -- PROPOSED ALTERNATIVES TO COMMAND-AND-CONTROL -- Specific Techniques -- ACUS STUDY AND RECOMMENDATIONS -- THE ADMINISTRATIVE PROCEDURE ACT -- THE ALTERNATIVE: NEGOTIATION. RECENT DEVELOPMENTS AND THE FEDERAL ADVISORY COMMITTEE ACT (FACA) -- AUDITED SELF-REGULATION -- Negotiated Rule-Making -- REG-NEG"-DOES IT WORK? -- THE PUBLIC AT THE NEGOTIATION TABLE -- CONSENSUS -- DECISION-MAKING DYNAMICS -- BENEFITS OF COLLABORATION -- POLITICAL CONSENSUS -- REG-NEG OUTCOMES -- GETTING REG-NEG STARTED -- CHOOSING THE PROBLEM -- OTHER REQUISITES -- CONSTITUENCY PRESSURES -- ACCOUNTABILITY -- REG-NEG PROCESS -- QUESTIONS ABOUT REG-NEG -- Panel Discussion on Applications of Negotiated Rule-Making to Issues in Blood Banking -- Kathryn C. Zoon -- REGULATORY INITIATIVES AT FDA -- FDA IN THE FUTURE -- INITIATIVES AT CBER -- WILLINGNESS TO EXPLORE PILOTS -- Jay Epstein -- INITIATIVES IN BLOOD REGULATION -- PARTICIPATORY DECISION-MAKING -- PUBLIC MEETINGS -- NATIONAL PERFORMANCE REVIEW -- EXPERIMENTS IN REGULATION -- THE FORCES OF CHANGE -- THE ROLE OF THE RULE-MAKING PROCESS -- Toby Simon -- COMMENTS AND QUESTIONS -- General Discussion of Issues for Negotiated Rule-Making -- CRITERIA FOR SELECTING ISSUES -- CANDIDATES FOR REG-NEG -- IV Congressional Oversight and Regulatory Initiatives -- Congressional Oversight of Blood Safety Issues -- THE WORK OF THE SUBCOMMITTEE -- THE QUESTION OF COSTS -- DHHS Task Force on HIV and the Blood Supply -- THE TASK FORCE CHARGE -- BLOOD PRODUCTS ADVISORY COMMITTEE -- DECISION-MAKING -- COST AS A FACTOR -- THE PUBLIC VIEW -- V Postscript -- Investing in Regulatory Quality -- REQUISITES OF REGULATORY PROCEDURES -- PUBLIC PERCEPTIONS -- Appendixes -- A Negotiated Rule-Making Procedure -- Preamble -- 561. Purpose -- 562. Definitions -- 563. Determination of need for negotiated rulemaking committee -- 564. Publication of notice -- applications for membership on committees -- 565. Establishment of committee -- 566. Conduct of committee activity -- 567. Termination of committee. 568. Services, facilities, and payment of committee member expenses -- 569. Role of the Administrative Conference of the United States and other entities -- 570. Judicial review -- B Workshop Participants -- WORKSHOP ON RISK AND REGULATION -- WORKSHOP ON MANAGING THREATS TO THE BLOOD SUPPLY -- C Acronyms.

blood banking, regulatory enforcement and compliance, innovations and alternatives in regulation, congressional oversight and regulatory initiatives, and investment in regulatory quality.
