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Nota di contenuto	Orphans and Incentives: Developing Technologies to Address Emerging Infections -- Copyright -- Preface -- THE FORUM -- THE TOPIC -- THE REPORT AND ITS ORGANIZATION -- ACKNOWLEDGMENTS -- NOTES -- Contents -- Summary -- LESSONS -- Introduction -- BACKGROUND -- THE WORKSHOP -- Workshop Summary -- THE CHILDREN'S VACCINE INITIATIVE* -- A Brief History -- Defining and Implementing Cross-Sectoral Collaboration -- Defining, Creating, and Stabilizing the Market -- Situation Analysis -- Market Segmentation -- Centralized Procurement -- Tiered Pricing -- Intellectual Property and Its Protection

-- Technology Transfer -- Individual Product Experiences -- A More Heat-Stable Polio Vaccine -- The Hepatitis B Vaccine -- OTHER MODELS* -- The Malaria Vaccine Development Board -- The International AIDS Vaccine Initiative (IAVI) -- AN INDUSTRY PERSPECTIVE ON THE EMERGING INFECTIONS AGENDA* -- Industry's Response to HIV/AIDS -- The Emerging Infections Scenario and HIV/AIDS -- Barriers -- LEGAL AND REGULATORY ISSUES* -- Accelerated Approval and Development of Drugs for Serious and Life-Threatening Illnesses -- Clinical Studies -- Surrogate Endpoints -- Restricted Distribution and the Matter of Antimicrobial Resistance -- Product Labeling -- Product Availability -- International Harmonization of Technical Requirements to Register Pharmaceuticals -- Intellectual Property Rights Revisited -- Orphan Drug Legislation -- PUBLIC-SECTOR AGENDAS AND PRIORITIES* -- LESSONS LEARNED AND ISSUES FOR RESOLUTION -- Lessons from the Children's Vaccine Initiative -- Divergent Sectoral Mandates and Notions of Risk -- The Product Life Cycle and the Role of Market Analysis -- Authentic Collaboration -- The Pivotal Roles of Advocacy and Public Information -- Issues for Resolution -- Agendas and Priorities -- Funding -- Multi-Tiered Pricing -- Restricted Distribution -- Surrogate Endpoints. Patent Extensions -- Technology Transfer and Local Production -- Orphan Drug Designation -- Other Topics -- A Final Observation -- NOTES -- APPENDIX A Emerging Infectious Diseases Research and Development Agendas: Principal Public-Sector In ... -- CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) -- R& D Priorities -- Implementation -- Collaborations -- Budget Allocations -- Future Challenges/Concerns/Issues -- DEFENSE ADVANCED RESEARCH PROJECTS AGENCY (DARPA) -- R& D Priorities -- Implementation -- Collaborations -- Budget Allocations -- Future Challenges/Concerns/Issues -- NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID) -- R& D Priorities -- Implementation -- Collaborations -- Budget Allocations -- Future Challenges/Concerns/Issues -- UNITED STATES DEPARTMENT OF STATE (DOS) -- R& D Priorities -- Implementation -- Collaborations -- Budget Allocations -- Future Challenges/Concerns/Issues -- DEPARTMENT OF VETERANS AFFAIRS (VA) -- R& D Priorities -- Implementation -- Collaborations -- Budget Allocations -- Future Challenges/Concerns/Issues -- WORLD BANK -- R& D Priorities -- Implementation -- Collaborations -- Budget Allocations -- Future Challenges/Concerns/Issues -- APPENDIX B Workshop Agenda -- APPENDIX C Public-/Private-Sector Collaboration in Pharmaceutical Research and Development: Inventor ... -- LEGISLATIVE AND REGULATORY MECHANISMS -- Bayh-Dole Act -- Background -- Outcomes -- Issues -- References -- Orphan Drug Act -- Background -- Outcomes -- Issues -- References -- National Vaccine Injury Compensation Program -- Background -- Outcomes -- Issues -- References -- Cooperative Research and Development Agreements -- Background -- Outcomes -- Issues -- References -- Small Business Innovation Research Program -- Background -- Outcomes -- Issues -- References -- Small Business Technology Transfer. Background -- Outcomes -- References -- Intellectual Property Rights/Patent Protection -- Background -- Outcomes -- Issues -- References -- Product Liability Protection -- Background -- Outcomes -- Issues -- References -- NIH Legislative Proposal for Product Liability Exemption for Public Health Service IND and IDE Research -- Background -- Issues -- References -- Prescription Drug User Fee Act -- Background -- Outcomes -- References -- Drug Approval Process

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Sommario/riassunto

Infectious diseases remain a leading cause of prolonged illness, premature mortality, and soaring health costs. In the United States in 1995, infectious diseases were the third leading cause of death, right behind heart disease and cancer. Mortality is mounting over time, owing to HIV/AIDS, pneumonia, and septicemia, with drug resistance playing an ever-increasing role in each of these disease categories. This book, a report from a Forum on Emerging Infections workshop, focuses on product areas where returns from the market might be perceived as being too small or too complicated by other factors to compete in industrial portfolios with other demands for investment. Vaccines are quintessential examples of such products. The lessons learned fall into four areas, including what makes intersectoral collaboration a reality, the notion of a product life cycle, the implications of divergent sectoral mandates and concepts of risk, and the roles of advocacy and public education. The summary contains an examination of the Children's Vaccine Initiative and other models, an industry perspective on the emerging infections agenda, and legal and regulatory issues.
