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Nota di contenuto	Clinical Trials in Psychopharmacology; Contents; Acknowledgments; Introduction; List of Contributors; SECTION I: The Health Care Environment and Medications; 1. FDA Reform: D'ej`a vu Encore; 1.1 Introduction; 1.2 The 1992 prescription drug user fee act adds funds and changes FDA's focus; 1.3 PDUFA shortens drug review times and eliminates the drug lag; 1.4 PDUFA timetables feed safety concerns; 1.5 FDA responds to safety concerns; 1.6 The pipeline problem; 1.7 The 2007 FDA Science Board's Subcommittee on Science and Technology report 1.8 The FDAAA of 2007 reauthorize PDUFA and provide new authority to address safety and the critical path initiative1.9 The impact of PDFUA on FDA; 1.10 Comparative medical benefits, comparative effectiveness and FDA; 1.11 FDA and non-inferiority trials; 1.12 FDA and CMS decisions on Medicare coverage; 1.13 Preemption: FDA's role in relation to liability litigation in state courts; 1.14 FDA's exclusivity in allowing access to experimental drugs; 1.15 Conclusions; 2. Do Antidepressants Cause Suicide?; 2.1 Some definitional problems

2.2 A brief history of the concerns of suicidality caused by antidepressants; 2.3 Politics rears its ugly head; 2.4 The FDA responds; 2.5 What changes in public policy wrought; 2.6 A funny thing happened on the way to the forum; 2.7 Meanwhile back at the ranch; 2.8 Moral (maybe); 3. The Genome, Genes and Brain - Tailored Drugs; 3.1 Introduction; 3.2 Issues in new drug development; 3.3 Early development of psychiatric pharmaceutical entities; 3.4 Advances in research technology; 3.5 Review of genetics; 3.6 Activation of genes by signal transduction cascades; 3.7 The human genome; 3.8 The sequencing of the genome; 3.9 DNA variation; 3.10 Genes and illness; 3.11 Genomic findings, potential targets and new drug development; 3.12 Conclusion; 4. Patenting and Licensing Concerns in Psychiatric Genetics; 4.1 Genetic diagnoses in psychiatry; 4.2 The evolving patent landscape in psychiatry; 4.3 Approaches to solving potential problems; 4.4 Conclusions; 5. Women's Issues in Clinical Trials; 5.1 History; 5.2 Perceived advantages of excluding women; 5.3 Change in perspective; 5.4 Have things changed?; 5.5 Progress since 1993; 5.6 Reported current difficulties in including women; 5.7 Contraception in clinical trials; 5.8 Drugs in lactating women; 5.9 How often do women take drugs during pregnancy?; 5.10 Ethical issues: risk/benefit analysis; 5.11 Adequate information; 5.12 Adolescent women; 5.13 Recruitment and retention of women; SECTION II: Clinical Trials and Mood Disorders; 6. Issues and Clues in the Pharmacological Treatment of Mood Disorders; 6.1 What do we know about mood disorders that may be relevant for their pharmacological treatment?; 6.2 Are there clues for the pharmacological treatment of mood disorders?; 6.3 Perspectives; 7. Bipolar Disorder; 7.1 Introduction

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Sommario/riassunto

Although clinical trials were virtually unheard of in psychiatry for many years, they are now the gold standard for judging whether drugs are safe and useful. But should they be? What is the true status of clinical trials? Even when they ostensibly demonstrate a benefit of a certain treatment, the strict patient selection criteria, poor compliance and high drop-out rate leave the conclusions open to question. Are the new treatments really better or more cost-effective than the old? Do they have fewer side effects? In this book the authors take a critical look at recent developments and prese

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