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KEY=INDUSTRY - ELIANNA OSBORNE

CONSUMER GUIDE TO GENERIC DRUGS

GUIDE TO INTERCHANGEABLE DRUGS

GENERIC DRUGS

A CONSUMER'S SELF-DEFENSE GUIDE

iUniverse *When you purchase drug products, you don't expect them to be contaminated with antifreeze, industrial chemicals, glass, or dangerous bacteria. But this happens every day when uninformed consumers buy prescription or over-the- counter and behind-the-counter drug products. Armed with the right knowledge, you can avoid the dangers and risks of these drugs and protect yourself and your family. This layperson's guide, written by a drug industry insider, will tell you how the U.S. drug industry works, how drugs are made, where the ingredients come from, and how to identify which drug companies are good and which to avoid. Topics covered include: how generic drugs are approved versus brand name drugs; real stories about how bad drugs have destroyed lives; questionable manufacturing practices; dangers of active ingredients. You don't have to put yourself and your family at risk every time you buy a drug at the store. Make smart buying decisions and take charge of your life withGeneric Drugs: A Consumer's Self-Defense Guide.*

NEW DRUGS

AN INSIDER'S GUIDE TO THE FDA'S NEW DRUG APPROVAL PROCESS, FOR SCIENTISTS, INVESTORS, AND PATIENTS

Booksurge Publishing *Drug development, the processes by which a chemical compound becomes a “drug” and is approved for sale by the FDA and European and Asian regulators, is not for the faint-of-heart or the shortsighted. Designing and monitoring studies, obtaining and analyzing scientific data, and reconciling clinical results against the ethical constraints and regulatory guidelines of government agencies, requires a complex interaction of in-house specialists and academic and commercial consultants worldwide. Scientific, technical, and tactical considerations play out in an environment where a balance must be struck between the often-competing interests of the corporation, its investors, government regulators, and the safety and well being of intended patients. All the while, dwindling patent protections impose an ever-contracting timeframe for success.Written to be accessible to a wide audience, NEW DRUGS provides a thorough, succinct, and practical understanding of these drug-development processes. If you're involved in the pharmaceutical industry, NEW DRUGS will provide scientific and management tools to increase the likelihood of regulatory approval at each phase of your compound's development. If you're a patient or consumer, NEW DRUGS will enable you to intelligently discuss medications with your health-care provider and empower you to make informed decisions at the pharmacy. If your portfolio, rather than your health, makes you an interested observer of the fortunes of this critical sector of the US economy, NEW DRUGS will help you to decode press releases and annual reports, so that you can recognize and invest in well-run companies with promising products.*

HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY

U.S. Government Printing Office

GENERIC DRUG PRODUCT DEVELOPMENT

SOLID ORAL DOSAGE FORMS, SECOND EDITION

CRC Press *In this era of increased pharmaceutical industry competition, success for generic drug companies is dependent on their ability to manufacture therapeutic-equivalent drug products in an economical and timely manner, while also being cognizant of patent infringement and other legal and regulatory concerns. Generic Drug Product Development: Solid Oral Dosage Forms, Second Edition presents in-depth discussions from more than 30 noted specialists describing the development of generic drug products—from the raw materials to the development of a therapeutic-equivalent drug product to regulatory approval. Major topics discussed include: Active pharmaceutical ingredients Experimental formulation development, including a new section on Quality by Design (QbD) Scale-up Commercial product formulation Quality control and bioequivalence Drug product performance ANDA regulatory process Post-approval changes Post-marketing surveillance Legislative and patent challenges This second edition also contains a new chapter on the relationship between the FDA and the United States Pharmacopeia and in Chapter 4, using specific examples, the application of Quality by Design (QbD) during formulation development is examined.The book is a thorough guide to the development of solid oral generic dosage formulations. This textbook is ideal for the pharmaceutical industry, graduate programs in pharmaceutical sciences, and health professionals working in the area of generic drug development.*

GENERIC ALTERNATIVES TO PRESCRIPTION DRUGS

Basic Health Publications, Inc. *A licensed pharmacist and pharmaceutical industry veteran explains how consumers can save money by asking their physicians or pharmacists to substitute generic equivalents for many well-known prescription drugs.*

DRUGS AND MEDICINES

A CONSUMERS' GUIDE

Oxford University Press, USA *This comprehensive volume provides valuable information on the nature of a wide variety of prescription drugs for lay readers. It describes the treatment of common illnesses, and how the drugs used to remedy these illnesses act, as well as their side effects. Emphasis is placed on the testing of pharmaceuticals and the role of the drug industry. An informative listing of almost 5000 prescription and over-the-counter medications is included, with categorization by generic and trade name. Brief commentary is provided to steer the reader to the appropriate chapter for further information.*

GENERIC

THE UNBRANDING OF MODERN MEDICINE

Johns Hopkins University Press *Greene's history sheds light on the controversies shadowing the success of generics: problems with the generalizability of medical knowledge, the fragile role of science in public policy, and the increasing role of industry, marketing, and consumer logics in late-twentieth-century and early twenty-first century health care.*

OTC POCKET GUIDE

OTC POCKET GUIDE: QUICK NONPRESCRIPTION DRUG REFERENCE

The OTC Pocket Guide was made to give you the most vital information without excess nonsense. 52 full color pages covering all OTC topics you would face in the healthcare industry. This is a Over-the-Counter Medication reference guide covers all potential self care treatments from allergies to infections to vitamins and supplements. The guide was created by a Pharmacy student geared toward other healthcare professionals to use as a quick reference. The book is organized by chief complaint and includes the medications available (brand/generic), dosing, drug-drug interactions, contraindications, counseling points, and more, specifically for each topic. All information is from accredited medical sources not opinion.

PILLS & THE PUBLIC PURSE

THE ROUTES TO NATIONAL DRUG INSURANCE

Univ of California Press *Examines controversial issues in the drug industry, including generic drugs, new drug licensing, and the changes national health insurance may promote*

PHARMACEUTICALS IN THE ENVIRONMENT

CURRENT KNOWLEDGE AND NEED ASSESSMENT TO REDUCE PRESENCE AND IMPACT

IWA Publishing *Pharmaceuticals in the Environment: current knowle*

BIOSIMILARS OF MONOCLONAL ANTIBODIES

A PRACTICAL GUIDE TO MANUFACTURING, PRECLINICAL, AND CLINICAL DEVELOPMENT

John Wiley & Sons *Addressing a significant need by describing the science and process involved to develop biosimilars of monoclonal antibody (mAb) drugs, this book covers all aspects of biosimilar development: preclinical, clinical, regulatory, manufacturing. • Guides readers through the complex landscape involved with developing biosimilar versions of monoclonal antibody (mAb) drugs • Features flow charts, tables, and figures that clearly illustrate processes and makes the book comprehensible and accessible • Includes a review of FDA-approved mAb drugs as a quick reference to facts and useful information • Examines new technologies and strategies for improving biosimilar mAbs*

THE GENERIC CHALLENGE

UNDERSTANDING PATENTS, FDA AND PHARMACEUTICAL LIFE-CYCLE MANAGEMENT (THIRD EDITION)

Brown Walker Press *The Generic Challenge is a must-read for pharmaceutical executives and managers, and regulatory, legal, business development, R&D and strategic marketing professionals and anyone who has an interest in the future of the leading American pharmaceutical and biotechnology industries and the high value jobs they provide. It explains clearly and understandably the role of patents, FDA regulation of generic drugs and the Hatch Waxman Act on drug development today and how improvements in innovative drug products provide enhanced benefits to patients while extending the commercial lives of the drugs.There is simply no other book of its kind available on this important subject. REVIEWS "I read The Generic Challenge in one evening. It is easy to read, anecdotal and short. It is hard to believe that so much information and seasoned advice is packed into this little book. Patents and FDA Exclusivity form the bedrock foundation of today's pharmaceutical and biotechnology industries. I would recommend this book to virtually everyone working in those industries -- from the CEO down to the drug reps and lab techs -- regardless of whether they will deal directly with patents." Dennis Crouch, Associate Professor of Law, University of Missouri, Editor of Patently-O.com "An extraordinary book full of practical, strategic information on the interaction of drug creation, law and regulatory approval. Provides a perceptive and insightful analysis of patent and regulatory laws affecting drug development. A must-read for anyone associated with a pharmaceutical company, from mangers and CEOs to CFOs and regulatory professionals, The Generic Challenge will guide readers through the many legal and business pitfalls that arise at every stage of their business." Stephen R. Albainy-Jenei, Attorney at Law, Editor of PatentBaristas.com*

BOTTLE OF LIES

THE INSIDE STORY OF THE GENERIC DRUG BOOM

HarperCollins *A NEW YORK TIMES BESTSELLER New York Times 100 Notable Books of 2019 New York Public Library Best Books of 2019 Kirkus Reviews Best Health and Science Books of 2019 Science Friday Best Books of 2019 New postscript by the author From an award-winning journalist, an explosive narrative investigation of the generic drug boom that reveals fraud and life-threatening dangers on a global scale—The Jungle for pharmaceuticals Many have hailed the widespread use of generic drugs as one of the most important public-health developments of the twenty-first century. Today, almost 90 percent of our pharmaceutical market is comprised of generics, the majority of which are manufactured overseas. We have been reassured by our doctors, our pharmacists and our regulators that generic drugs are identical to their brand-name counterparts, just less expensive. But is this really true? Katherine Eban's Bottle of Lies exposes the deceit behind generic-drug manufacturing—and the attendant risks for global health. Drawing on exclusive accounts from whistleblowers and regulators, as well as thousands of pages of confidential FDA documents, Eban reveals an industry where fraud is rampant, companies routinely falsify data, and executives circumvent almost every principle of safe manufacturing to minimize cost and maximize profit, confident in their ability to fool inspectors. Meanwhile, patients unwittingly consume medicine with unpredictable and dangerous effects. The story of generic drugs is truly global. It connects middle America to China, India, sub-Saharan Africa and Brazil, and represents the ultimate litmus test of globalization: what are the risks of moving drug manufacturing offshore, and are they worth the savings? A decade-long investigation with international sweep, high-stakes brinkmanship and big money at its core, Bottle of Lies reveals how the world's greatest public-health innovation has become one of its most astonishing swindles.*

REAL PLACES

AN UNCONVENTIONAL GUIDE TO AMERICA'S GENERIC LANDSCAPE

University of Chicago Press *An urban affairs specialist examines how ordinary American places come to be, and come to be labeled as, good and bad neighborhoods, drug scenes, ghost towns, "the boondocks," and growth areas, with the help of scores of photographs. UP.*

GENERICHANDBOOK 2006

A GUIDE TO US GENERIC REGULATIONS, MARKETS AND COMPANIES

*GENERICHANDBOOK® - Industry Research & Reference Publications The first edition of GenericHandbook (published September, 2005) - provides industry executives with up-to-date information and analysis needed to make complex decisions concerning the generic pharmaceuticals - industry in the United States. Editorial coverage of the regulatory issues, the market conditions and the major companies involved. REGULATORY SECTION: * FDA structure, policies and procedures * Administrative actions and trends * Hatch-Waxman - Case law developments * Paragraph IV challenges and success rates * Biogenerics * Authorized deals with branded companies * Impact of Medicare Modernization Act MARKET SECTION: * Sales and growth rates for Top 200 products * Percent generic-share within category * Share by company within multi-source segment of top 20 categories * Share within therapeutic categories * Highlights of recent news and upcoming events * Opportunity assessment: products losing patent protection (2005-2010) * Listed patents on Top 100 brands * Emerging providers in India and China COMPANIES: The following information is included for companies selling generic drugs in the United States: * Senior Executives and contact information * Company description (history, areas of therapeutic focus, etc.) * Number/Type of Drug Master Files (DMFs) * Ownership structure - public or private * Sales figures * Summary of company strategy * Financial data ((for publicly traded companies).*

IMPROVING AND ACCELERATING THERAPEUTIC DEVELOPMENT FOR NERVOUS SYSTEM DISORDERS

WORKSHOP SUMMARY

National Academies Press *Improving and Accelerating Therapeutic Development for Nervous System Disorders is the summary of a workshop convened by the IOM Forum on Neuroscience and Nervous System Disorders to examine opportunities to accelerate early phases of drug development for nervous system drug discovery. Workshop participants discussed challenges in neuroscience research for enabling faster entry of potential treatments into first-in-human trials, explored how new and emerging tools and technologies may improve the efficiency of research, and considered mechanisms to facilitate a more effective and efficient development pipeline. There are several challenges to the current drug development pipeline for nervous system disorders. The fundamental etiology and pathophysiology of many nervous system disorders are unknown and the brain is inaccessible to study, making it difficult to develop accurate models. Patient heterogeneity is high, disease pathology can occur years to decades before becoming clinically apparent, and diagnostic and treatment biomarkers are lacking. In addition, the lack of validated targets, limitations related to the predictive validity of animal models - the extent to which the model predicts clinical efficacy - and regulatory barriers can also impede translation and drug development for nervous system disorders. Improving and Accelerating Therapeutic Development for Nervous System Disorders identifies avenues for moving directly from cellular models to human trials, minimizing the need for animal models to test efficacy, and discusses the potential benefits and risks of such an approach. This report is a timely discussion of opportunities to improve early drug development with a focus toward preclinical trials.*

BAD PHARMA

HOW DRUG COMPANIES MISLEAD DOCTORS AND HARM PATIENTS

Macmillan *Argues that doctors are deliberately misinformed by profit-seeking pharmaceutical companies that casually withhold information about drug efficacy and side effects, explaining the process of pharmaceutical data manipulation and its global consequences. By the best-selling author of Bad Science.*

GUIDE TO BUYING VIAGRA ONLINE AND OFFLINE

ALL YOU NEED TO KNOW ABOUT THE DOSAGE, SIDE-EFFECTS, ERECTILE DYSFUNCTION, GENERIC VIAGRA AND HOW TO BUY VIAGRA WITH OR WITHOUT PRESCRIPTION ONLINE

Createspace Independent Publishing Platform *No Spam! No Scams! Find out where you can REALLY buy Viagra online! Discover the SAFE and LEGAL ways you can purchase erectile dysfunction medication online, with OR without a prescription, Icluding top and secured site to purchase viagra at a cheap rate Well, acclaimed men's lifestyle expert john leggette m.d is here to help. The author of the best seling book alternative to "Viagra" Cure Erectile Dysfunction Without Prescription Drugs is here with a book aimed at men for whom the natural route isn't an option: A guide to the different ways you can safely and legally get your hands on prescription medication like Viagra or Cialis, whether or not you have a prescription. In this book, you'll discover: What erectile dysfunction medications exist- and which one is right for you. The medical industry quagmire- and why pharma companies are gouging their customers through traditional sales channels. The five routes to obtaining erectile dysfunction medication - and the pros and cons of each of them. Fast-paced and informative, this book could change your life - and help you tackle your erectile dysfunction safely, legally and effectively*

A COMPREHENSIVE GUIDE TO THE THREE BIOSIMILAR MARKETS (EUROPE, US, JAPAN) AND THE REGULATORY PATHWAYS

Generics in the pharmaceutical industry have been instrumental in reducing overall healthcare cost and allowing for greater dispersal of life saving drugs to the general population. The Hatch-Waxman Act of 1984 played a critical role in changing the landscape of the pharmaceutical industry and providing legislation for an abbreviated regulatory pathway for generic drugs. The conversation has shifted to the need to implement similar regulatory paths for generics of biologics. First generation biologic patents have or are geared to expire within the next five years, providing a great opportunity for generic companies in this space to enter. Biologic generics, termed biosimilars or follow-on biologics, are more difficult to evaluate due to the complex nature of the molecule and the variables involved in the development and manufacturing process. This research seeks to understand the current debate in the biosimilar conversation, and examine whether there is a clear regulatory path to market for biosimilars using epoetin as a case example across the three main markets; US, Europe and Japan.

COUNTERING THE PROBLEM OF FALSIFIED AND SUBSTANDARD DRUGS

National Academies Press *The adulteration and fraudulent manufacture of medicines is an old problem, vastly aggravated by modern manufacturing and trade. In the last decade, impotent antimicrobial drugs have compromised the treatment of many deadly diseases in poor countries. More recently, negligent production at a Massachusetts compounding pharmacy sickened hundreds of Americans. While the national drugs regulatory authority (hereafter, the regulatory authority) is responsible for the safety of a country's drug supply, no single country can entirely guarantee this today. The once common use of the term counterfeit to describe any drug that is not what it claims to be is at the heart of the argument. In a narrow, legal sense a counterfeit drug is one that infringes on a registered trademark. The lay meaning is much broader, including any drug made with intentional deceit. Some generic drug companies and civil society groups object to calling bad medicines counterfeit, seeing it as the deliberate conflation of public health and intellectual property concerns. Countering the Problem of Falsified and Substandard Drugs accepts the narrow meaning of counterfeit, and, because the nuances of trademark infringement must be dealt with by courts, case by case, the report does not discuss the problem of counterfeit medicines.*

FORENSIC CHEMISTRY OF SUBSTANCE MISUSE

A GUIDE TO DRUG CONTROL

Royal Society of Chemistry *This book builds on an earlier publication by the same author: The Misuse of Drugs Act: A Guide for Forensic Scientists. It provides a chemical background to the domestic and international controls on drugs of abuse and related substances, and includes coverage of 'designer drugs' and generic/analogue controls from UK, USA and New Zealand perspectives. More general chapters cover recent history of the drug classification debate, and a proposal for consolidating a wide range of legal controls on chemical substances. This unique book will be appeal to a general readership. Forensic scientists, researchers, teachers, postgraduate and graduate students will all find this book an exceptional point of reference.*

APPROVED PRESCRIPTION DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

Accompanied by supplements.

THE PILL BOOK

Bantam *The new seventh edition of The Pill Book is bigger than ever and contains more profiles of commonly prescribed drugs than any other consumer reference. Compiled by a team of eminent pharmacologists, it is based on official, FDA-approved information usually available only to doctors and pharmacists, plus the latest information gathered from computer databases and professional on-line resources. It synthesizes the most important facts about each drug into a concise, readable, easy-to-understand entry. Here are complete profiles of more than 1,500 of the most commonly prescribed drugs, including: Generic and brand names What the drug is for and how it works Usual dosages, and what to do if a dose is skipped Side effects and possible adverse reactions, highlighted for quick reference Interactions with other drugs and foods Overdose and addiction potential Alcohol-free and sugar-free medications Information for seniors, pregnant and breast-feeding women, and others with special needs Cautions and warnings, and when to call your doctor*

REGISTRIES FOR EVALUATING PATIENT OUTCOMES

A USER'S GUIDE

Government Printing Office *This User's Guide is intended to support the design, implementation, analysis, interpretation, and quality evaluation of registries created to increase understanding of patient outcomes. For the purposes of this guide, a patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes. A registry database is a file (or files) derived from the registry. Although registries can serve many purposes, this guide focuses on registries created for one or more of the following purposes: to describe the natural history of disease, to determine clinical effectiveness or cost-effectiveness of health care products and services, to measure or monitor safety and harm, and/or to measure quality of care. Registries are classified according to how their populations are defined. For example, product registries include patients who have been exposed to biopharmaceutical products or medical devices. Health services registries consist of patients who have had a common procedure, clinical encounter, or hospitalization. Disease or condition registries are defined by patients having the same diagnosis, such as cystic fibrosis or heart failure. The User's Guide was created by researchers affiliated with AHRQ's Effective Health Care Program, particularly those who participated in AHRQ's DEcIDE (Developing Evidence to Inform Decisions About Effectiveness) program. Chapters were subject to multiple internal and external independent reviews.*

GENERIC DRUG PRODUCT DEVELOPMENT

SOLID ORAL DOSAGE FORMS

CRC Press *Keeping pace with the latest technologies in the field, this guide describes the development of solid oral generic drug products from project initiation to market approval. Focusing on immediate-release and modified-release dosage forms, the book collects in-depth discussions from more than 30 noted specialists on topics such as quality control, experimental formulation, pharmaceutical ingredients, and bioequivalence, and considers key elements in the formulation of generic drug products including the availability of raw materials, chemical purity. It also highlights constraints in generic drug development that differ from the formulation design of a brand name pharmaceutical product.*

FDA NUTRITION LABELING MANUAL

A GUIDE FOR DEVELOPING AND USING DATABASES

Gives generic instructions for developing and preparing an acceptable data base when valid estimates of nutrient content and variation are not available for the food (single or mixed products) to be labeled. The purpose of the manual is to advise the food industry in developing nutrition labels for food products that must comply with the regulations and to assist health professionals in interpreting nutrition labels on food products.

GENERIC DRUG PRODUCT DEVELOPMENT

SPECIALTY DOSAGE FORMS

CRC Press *Generic Drug Product Development: Specialty Dosage Forms explores the issues related to providing evidence of pharmaceutical equivalence and bioequivalence for specialty drug products. It describes various scientific approaches and regulatory requirements for manufacturers who need to demonstrate the therapeutic equivalence of generic specialty drug products to brand name alternatives. The contributors discuss measurement of drug product quality and performance, as well as the regulatory and scientific requirements of topical, nasal and inhalation, and transdermal drug delivery products, along with generic biologics and modified release parenteral drug products. The book is essential reading for specialists and researchers in pharmaceutical drug development, regulation, manufacturing, and others in the pharmaceutical sciences.*

GENERIC DRUG PRODUCT DEVELOPMENT

INTERNATIONAL REGULATORY REQUIREMENTS FOR BIOEQUIVALENCE

CRC Press *Due to a worldwide need for lower cost drug therapy, use of generic and multi-source drug products have been increasing. To meet international patent and trade agreements, the development and sale of these products must conform to national and international laws, and generic products must prove that they are of the same quality and are therapeutically equivalent to the brand name alternative. However, many countries have limited resources to inspect and verify the quality of all drug products for sale in their country. This title discusses the worldwide legislative and regulatory requirements for the registration of generic and multi-source drug products.*

COMMUNICATING RISKS AND BENEFITS

AN EVIDENCE BASED USER'S GUIDE

Government Printing Office *Effective risk communication is essential to the well-being of any organization and those people who depend on it. Ineffective communication can cost lives, money and reputations. Communicating Risks and Benefits: An Evidence-Based User's Guide provides the scientific foundations for effective communications. The book authoritatively summarizes the relevant research, draws out its implications for communication design, and provides practical ways to evaluate and improve communications for any decision involving risks and benefits. Topics include the communication of quantitative information and warnings, the roles of emotion and the news media, the effects of age and literacy, and tests of how well communications meet the organization's goals. The guide will help users in any organization, with any budget, to make the science of their communications as sound as the science that they are communicating.*

PATENT SETTLEMENTS IN THE PHARMACEUTICAL INDUSTRY UNDER US ANTITRUST AND EU COMPETITION LAW

Kluwer Law International B.V. *Reverse payment settlements or "pay-for-delay agreements" between originators and generic drug manufacturers create heated debates regarding the balance between competition and intellectual property law. These settlements touch upon sensitive issues such as timely generic entry and access to affordable pharmaceuticals and also the need to preserve innovation incentives for originators and to strengthen the pipeline of life-saving pharmaceuticals. This book is one of the first to critically and comparatively analyse how such patent settlements and various other strategies employed by the pharmaceutical industry are scrutinised by both United States (US) and European courts and enforcement authorities, and to discuss the applicable legal tests and the main criteria used for their assessment. The book's ultimate objective is to provide guidance to the pharmaceutical industry regarding the types of patent settlements, strategies and conduct which may be problematic from US antitrust and European Union (EU) competition law perspectives and to assist practitioners in structuring settlements which are both efficient and compliant. To this end, an exhaustive legal analysis of some of the most controversial issues regarding pharmaceutical patent settlements is provided, including: – the lengthy split among US Circuit Courts on the issue of pay-for-delay settlements, its resolution by the US Supreme Court in FTC v. Actavisand subsequent*

jurisprudence; – the decision of Lundbeck v. Commissionby the European General Court and the Servier decision of the European Commission; – the Roche/Novartisdecision of the European Court of Justice and the most important decisions by National Competition Authorities on pharma patent settlements in the EU; – an overview of other types of strategies such as product-hopping and product reformulations, no-authorised generic commitments, problematic side-deals, mechanisms affecting generic substitution; – the rejection of the "scope of the patent" test in both the US and the EU and the balancing of patent law and antitrust law considerations in the prevailing applicable tests; – the benefits of settlements and the main criteria for assessing their legitimacy under US antitrust and EU competition law. The analysis provides concrete examples of both illegitimate and legitimate settlements and strategies, emphasising on conduct that falls within a grey zone and on the circumstances and criteria under which such conduct could be deemed problematic from an antitrust perspective. This book will serve as a valuable guide for pharmaceutical companies wishing to minimise the risk of engaging in conduct that could potentially infringe US antitrust and EU competition law. It further aims to save courts and enforcement agencies and also practitioners and academics considerable time and resources by providing an exhaustive analysis of the relevant caselaw, with the ultimate goal to increase legal certainty on the most controversial aspects of patent settlements in the pharmaceutical industry.

THE TRUTH ABOUT THE DRUG COMPANIES

HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT

Random House *During her two decades at The New England Journal of Medicine, Dr. Marcia Angell had a front-row seat on the appalling spectacle of the pharmaceutical industry. She watched drug companies stray from their original mission of discovering and manufacturing useful drugs and instead become vast marketing machines with unprecedented control over their own fortunes. She saw them gain nearly limitless influence over medical research, education, and how doctors do their jobs. She sympathized as the American public, particularly the elderly, struggled and increasingly failed to meet spiraling prescription drug prices. Now, in this bold, hard-hitting new book, Dr. Angell exposes the shocking truth of what the pharmaceutical industry has become–and argues for essential, long-overdue change. Currently Americans spend a staggering $200 billion each year on prescription drugs. As Dr. Angell powerfully demonstrates, claims that high drug prices are necessary to fund research and development are unfounded: The truth is that drug companies funnel the bulk of their resources into the marketing of products of dubious benefit. Meanwhile, as profits soar, the companies brazenly use their wealth and power to push their agenda through Congress, the FDA, and academic medical centers. Zeroing in on hugely successful drugs like AZT (the first drug to treat HIV/AIDS), Taxol (the best-selling cancer drug in history), and the blockbuster allergy drug Claritin, Dr. Angell demonstrates exactly how new products are brought to market. Drug companies, she shows, routinely rely on publicly funded institutions for their basic research; they rig clinical trials to make their products look better than they are; and they use their legions of lawyers to stretch out government-granted exclusive marketing rights for years. They also flood the market with copycat drugs that cost a lot more than the drugs they mimic but are no more effective. The American pharmaceutical industry needs to be saved, mainly from itself, and Dr. Angell proposes a program of vital reforms, which includes restoring impartiality to clinical research and severing the ties between drug companies and medical education. Written with fierce passion and substantiated with in-depth research, The Truth About the Drug Companies is a searing indictment of an industry that has spun out of control.*

THE PILL BOOK

Bantam *This new 9th edition of The Pill Book contains more profiles of commonly prescribed drugs than any other consumer reference. Compiled by a team of eminent pharmacologists, it is based on official, FDA-approved information usually available only to doctors and pharmacists, plus the latest information gathered from computer databases and on-line resources. It synthesizes the most important facts about each drug in a concise, readable, easy-to-understand entry. No home should be without this book! For nearly two decades, millions of consumers have trusted The Pill Book to provide official, FDA-approved drug information plus guidelines from leading pharmacists. Each drug is profiled in a concise, readable, and easy-to-understand entry, making The Pill Book the perfect reference when you have questions about the medications your doctor prescribes. The consumer's guide to pills--more than 35 important new drugs approved for sale in 2000 and dozens of new brand names in this completely revised 9th edition. With more than 11 million copies in print, The Pill Book is the best-selling consumer drug reference ever, offering the most up-to-date, comprehensive information, in a format designed for ease of use. The most up-to-date information about the 1,500 most commonly prescribed drugs in the United States: Generic and brand-name listings that can help you save money What the drug is for, and how it works Usual dosages, and what to do if a dose is skipped Side effects and possible adverse reactions, highlighted for quick reference Interactions with other drugs and food Overdose and addiction potential Alcohol-free and sugar-free medications Information for seniors, pregnant and breast-feeding women, children, and others with special needs Cautions and warnings, and when to call your doctor PLUS 32 pages of actual-size color photographs of most prescription pills*

RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY (A CBO STUDY)

Lulu.com *Perceptions that the pace of new-drug development has slowed and that the pharmaceutical industry is highly profitable have sparked concerns that significant problems loom for future drug development. This Congressional Budget Office (CBO) study-prepared at the request of the Senate Majority Leader-reviews basic facts about the drug industry's recent spending on research and development (R&D) and its output of new drugs. The study also examines issues relating to the costs of R&D, the federal government's role in pharmaceutical research, the performance of the pharmaceutical industry in developing innovative drugs, and the role of expected profits in private firms' decisions about investing in drug R&D. In keeping with CBO's mandate to provide objective, impartial analysis, the study makes no recommendations. David H. Austin prepared this report under the supervision of Joseph Kile and David Moore. Colin Baker provided valuable consultation...*

THE PRESCRIBER'S GUIDE

Cambridge University Press *This completely revised and updated edition of Stephen M. Stahl's much-acclaimed Prescriber's Guide is the latest addition to the Essential Psychopharmacology range. Seven new drugs have been added, and every drug has been revised and updated to take into account new regulations and uses. In full color throughout, and with four or more pages for each of the more than 100 psychotropic drugs, Stephen M. Stahl distills his great expertise into a pragmatic formulary that gives all the information a prescriber needs to treat patients effectively. Each drug is covered in five categories: general therapeutics, dosing and use, side effects, special populations, and pearls. Target icons appear next to key categories for each drug so the prescriber can go easily and instantly to the information needed. Several indices are included, listing drugs by name (generic and international), use, and class. In addition, Dr. Stahl indicates which drugs have FDA approval and also gives the FDA Use-in-Pregnancy Ratings.*

99 JUMPSTARTS TO RESEARCH: TOPIC GUIDES FOR FINDING INFORMATION ON CURRENT ISSUES, 2ND EDITION

ABC-CLIO *This book provides research assistance for 99 current and provocative issues students can use to write a brief argumentative paper. • Each jumpstart topic contains a photograph, chart, or drawing • Bibliography collects all book and audio-video selections used in the jumpstarts, and can be used for library collections*

FEDERAL REGULATORY GUIDE

CQ Press *The Federal Regulatory Directory, Eighteenth Edition continues to offer a clear path through the maze of complex federal agencies and regulations, providing to-the-point analysis of regulations. Information-packed profiles of more than 100 federal agencies and departments detail the history, structure, purpose, actions, and key contacts for every regulatory agency in the U.S. government. Now updated with an improved searching structure, the Federal Regulatory Directory continues to be the leading reference for understanding federal regulations, providing a richer, more targeted exploration than is possible by cobbling together electronic and print sources.*

FEDERAL REGISTER

PHARMAHANDBOOK 2006

A GUIDE TO THE INTERNATIONAL PHARMACEUTICAL INDUSTRY

*PharmaHandbook® - Industry Research & Reference Publications The fourth edition of PharmaHandbook (2006) - provides pharmaceutical and healthcare industry decision-makers with a single source of accurate, up-to-date statistics, information and analysis on prescription drug business and regulatory environments throughout the world. Coverage of 39 individual countries (cumulatively representing more than 99% of global sales) and a summary section on the EU are included. Company executives, consultants, marketing and licensing partners, policy makers, researchers, investors, reporters and others who work with the pharmaceutical industry will benefit from PharmaHandbook.® Editorial Coverage Regulatory Bodies * Approval Procedures * Pricing Regulations * Expanded Contact Information * Payment Patterns * Population & Prescriber Characteristics * Sales Channels * Sales*

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