Ways Of Regulating Drugs In The 19th And 20th Cent

An Introduction to FDA Drug Regulation
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Law and the Regulation of Medicines
Regulating Pharmaceuticals In Europe: Striving For Efficiency, Equity And Quality
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The Drug Solution
The Law and Ethics of the Pharmaceutical Industry
Science, Politics, and the Pharmaceutical Industry
How to Develop and Implement a National Drug Policy
Review Panel on New Drug Regulation
Prohibition, Religious Freedom, and Human Rights: Regulating Traditional Drug Use
The Real Dope
Strange Trips

JOHN BRONSON

An

Introduction to FDA Drug Regulation University of Toronto Press Japan is suffering from a "device gap." Compared to its American and European counterparts, Japan lags in adopting innovative medical devices and making new treatments and procedures available to its patients. Many blame its government and bureaucracy for Japan's delayed access to modern medicine and new medical devices. Christa Altenstetter examines the contextual social, historical, and political conditions of Japan's medical field to make sense of the state of the country's medical profession and its regulatory framework. She explores the development of regulatory frameworks and considers possibilities for eventual reform and modernization . More specifically, Altenstetter looks into how physicians and device companies connect to the government and bureaucracy, the relationships connecting Japanese patients to their medical system and governmental bureaucracy, and how the relationships between policymakers and the medical profession are changing. The issues addressed here are becoming increasingly relevant as

numerous countries in Asia, Latin America, and Central and Eastern Europe are only now beginning to regulate medical technology, following the lead of the US and the European Union. Those interested in global medicine and Asian studies will find this book both informative and compelling.

Effective Drug Regulation

Routledge

Drug disasters from Thalidomide to Opren, and other less dramatic cases of drug injury, raise questions about whether the testing and control of medicines provides satisfactory protection for the public. In this revealing study, John Abrahan develops a theoretically challenging realist approach, in order to probe deeply into the work of scientists in the pharmaceutical industry and governmental drug regulatory authorities on both sides of the Atlantic. Through the examination of contemporary controversial case studies, he exposes how the commercial interest of drug manufacturers are consistently given the benefit of the scientific doubts about medicine safety and effectiveness, over and above the best interests of patients.; A highly original combination

of philosophical rigour, historical sensitivity and empirical depth enables the "black box" of industrial and government science to be opened up to critical scrutiny much more than in previous social scientific study. All major aspects of drug testing and regulation are considered, including pre-clinical animal tests, clinical trials and postmarketing surveillance of adverse drug reactions. The author argues that drug regulators are too dependent on pharmaceutical industry resources and expertise, and too divorced from public accountability. The problem of corporate bias is particularly severe in the UK, where regulatory decisions about medicine safety are shrouded in greater secrecy than in the US.; Since the purpose of drug regulation should be to maximize the safety and effectiveness of medicines for patients, the public needs and deserves policies to counteract corporate bias in drug testing and evaluation. John Abraham's realist analysis provides a robust basis for policy interventions at the institutional and legislative levels. He proposes that corporate bias could be reduced by more

extensive freedom of information, greater autonomy of government scientists from pharmaceutical industry, the development of independent drug testing by the regulatory authority, increased patient representation on regulatory committees, and more frequent and thorough oversight of regulatory performance by the legislature. This book should be of interest to anyone who cares about how medicines should be controlled in modern society. It should prove particularly rewarding for students and researchers in the sociology of science and technology, science and medicines policy, medical sociologists, the medical and pharmaceutical professions, and consumer organizations.

Countering the Problem of Falsified and Substandard Drugs McGraw-Hill Education (UK)

This is the first book to examine how effectively American and supranational EU governments have regulated innovative pharmaceuticals during the last 30 years regarding public health. It explains why pharmaceutical regulation has been misdirected by commercial interests and misconceived ideologies.

Regulation of the

Pharmaceutical Industry Routledge Second in a series of publications from the Institute of Medicine's Quality of Health Care in America project Today's health care providers have more research findings and more technology available to them than ever before. Yet recent reports have raised serious doubts about the quality of health care in America. Crossing the Quality Chasm makes an urgent call for fundamental change to close the quality gap. This book recommends a sweeping redesign of the American health care system and provides overarching principles for specific direction for policymakers, health care leaders, clinicians, regulators, purchasers, and others. In this comprehensive volume the committee offers: A set of performance expectations for the 21st century health care system. A set of 10 new rules to guide patient-clinician relationships. A suggested organizing framework to better align the incentives inherent in payment and accountability with improvements in quality. Key steps to promote evidence-based practice and strengthen clinical information systems. Analyzing health care organizations as complex

systems, Crossing the Quality Chasm also documents the causes of the quality gap, identifies current practices that impede quality care, and explores how systems approaches can be used to implement change.

Final Report

Oxford University Press, USA

This provocative volume makes a valuable contribution to debates on drug legislation. It is the only book that analyses and assesses all regulatory alternatives to drug prohibition. The author brings together research from the scientific, medical, ethical and legal fields to criticize drug laws and enforcement policies of many countries, including the U.S. and Canada.

How the Food and Drug Administration (FDA) Approves Drugs and Regulates Their Safety and Effectiveness

Aarhus Universitetsforlag

This collection takes the perspective that the historiography of science, technology, and medicine needs a broader approach toward regulation. The authors explore the distinct social worlds involved in regulation, the forms of evidence and expertise mobilized, and means of intervention chosen to tame drugs in factories,

consulting rooms and courts.

Regulating Medicines in a Globalized World Yale University Press

This book traces the history of the London ‘white drugs’ (opiate and cocaine) subculture from the First World War to the end of the classic ‘British System’ of drug prescribing in the 1960s. It also examines the regulatory forces that tried to suppress non-medical drug use, in both their medical and juridical forms. Drugs subcultures were previously thought to have begun as part of the post-war youth culture, but in fact they existed from at least the 1930s. In this book, two networks of drug users are explored, one emerging from the disaffected youth of the aristocracy, the other from the night-time economy of London’s West End. Their drug use was caught up in a kind of dance whose steps represented cultural conflicts over identity and the modernism and Victorianism that coexisted in interwar Britain.

How FDA Approves Drugs and Regulates Their Safety and Effectiveness Springer

Seven independent variables were used including the five financing instruments, the firm's ordinary debt, and the firm's operating risk.

Science, Politics And

The Pharmaceutical Industry Springer Examining the boundaries between recreational and medicinal drugs in the eyes of the public and the law. **Unhealthy Pharmaceutical Regulation** Springer In the context of global efforts to control the production, distribution and use of narcotic drugs, China's treatment of the problem provides an important means of understanding the social, political, and economic limits of national and international policies to regulate drug practices. In the nineteenth and early twentieth centuries, China was known for its national addiction to opium, but its drug-eradication campaigns from the 1950s to the 1970s achieved unprecedented success that ultimately transformed China into a "drug-free" society. However, since the economic reforms and open-door policy of the late twentieth century, China is now facing a re-emergence of the production, use and trafficking of narcotic drugs. Employing case studies and a comparative historical approach, and drawing on a variety of data sources including historical records, official crime data only

recently made available, and news reports, this book is the first English-language publication to provide such a comprehensive documentation and analysis of the nature of China's legal regulation of controlled substances. The authors also offer theoretical approaches for studying drug regulation, aspects of drug consumption cultures, the socio-political treatment of drugs during various historical periods and ongoing efforts to legislate drug trade, criminalize drug use and manage the drug addict population within national and international contexts.

Review Panel on New Drug Regulation

World Health Organization Public concerns about the regulation of the pharmaceutical industry have intensified in recent years. Paradoxically, these concerns center on the over-consumption of medicines of dubious benefit in Western societies and lack of access to essential medicines in the Global South. By demonstrating how the analysis of pharmaceutical drug regulation can provide rich insights into the operation of power and politics in contemporary society, the contributors challenge the

prevailing construction of drug regulation as a sphere of "policy without politics" and suggest alternative ways of regulating medicines.
Power, Politics and Pharmaceuticals
Bloomsbury Publishing
The Food and Drug Admin. (FDA) is a regulatory agency within the Dept. of Health and Human Services (HHS). A key responsibility is to regulate the safety and effectiveness of drugs sold in the U.S. FDA divides that responsibility into two phases: preapproval (premarket) and postapproval (postmarket). FDA reviews manufacturers ' applications to market drugs in the U.S.; a drug may not be sold unless it has FDA approval. The agency continues its oversight of drug safety and effectiveness as long as the drug is on the market. Beginning with the Food and Drugs Act of 1906, Congress has incrementally refined and expanded FDA's responsibilities regarding drug approval and regulation. Contents of this report: Legislative History of Drug Regulation; How FDA Approves New Drugs; How FDA Regulates Approved Drugs. Figures and tables. This is a print on demand report.
How FDA Approves

Drugs and Regulates Their Safety and Effectiveness Routledge "This thoughtful and comprehensive book represents the best work I have seen on the current situation concerning medication policies in the EU. It is not just that this is a very up-to-date compendium of facts and data across a wide variety of domains that impact on pharmaceutical regulation. The book is also strong on analysis of those facts as well." Jerry Avorn, Harvard Medical School. "This book offers a comprehensive examination of approaches to manage pharmaceutical expenditures in Europe. It is a must-read for those who seek to understand and navigate the changing regulatory environment for medicines in the European Union." Bernie O'Brien, McMaster University, Canada. The rising cost of pharmaceutical expenditures in many European countries is of concern to governments required to make effective use of health care budgets. Taking a broad perspective that encompasses institutional, political and supranational aspects of pharmaceutical regulation, this book examines approaches used to manage pharmaceutical expenditure across Europe

and what impact these strategies have had on efficiency, quality, equity and cost of pharmaceutical care.Regulating Pharmaceuticals in Europe is an important book for students of health policy, regulation and management, and for health managers and policy makers. The editors: Elias Mossialos is Brian Abel-Smith Professor of Health Policy at the London School of Economics and Political Science and a Research Director of the European Observatory on Health Systems and Policies. Monique Mrazek is a Health Economist (Europe and Central Asia region) for the World Bank and formerly a Research Officer in Health Economics for the European Observatory on Health Systems and Policies. Tom Walley is Professor of Clinical Pharmacology at the University of Liverpool and Director of the UK National Health Technology Assessment Programme. Contributors:Julia Abelson, Christa Altenstetter, Vittorio Berteleâ€™, Christine Bond, Marcel L. Bouvy, Colin Bradley, Steve Chapman, Anna Dixon, Michael Drummond, Pierre Durieux, Edzard Ernst, Armin Fidler, Eric Fortess, Richard Frank, Silvio Garattini, Leigh

Hancher, Ebba Holme Hansen, Steve Hudson, Kees de Jonchere, Panos Kanavos, Sjoerd Kooiker, Jean-Marc Leder, Graham Lewis, Donald W. Light, Alistair McGuire, Elias Mossialos, Monique Mrazek, Maria Pia Orru', Govin Permanand, Guenka Petrova, Munir Pirmohamed, Dennis Ross-Degnan, Frans Rutten, Steven Soummerai, David Taylor, Sarah Thomson, Tom Walley.

National Academies Press
This Book explains and investigates how medicines are controlled in Europe, especially the EU. Based on penetrating documentary and interview research with the pharmaceutical industry, regulators and consumer organisations,it provides the first major critical examination of the new Europeanised systems of medicine regulation. The authors argue that the drive to produce and approve more drugs more quickly for a single European market dominates other considerations, such as improvements in democratic accountability, the independence of regulators and scientific expertise from commercial interests, and drug safety testing and surveillance.

The Effects of Drug Regulation

Createspace Independent Publishing

Platform 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. *Ways of Regulating Drugs in the 19th and 20th Centuries* Routledge Drug disasters from Thalidomide to Opren, and other less dramatic cases of drug injury, raise questions about whether the testing and control of medicines provides satisfactory protection for the public. In this revealing study, John Abrahan develops a theoretically challenging realist approach, in order to probe deeply into the work of scientists in the pharmaceutical industry and governmental drug regulatory authorities on both sides of the Atlantic. Through the examination of contemporary controversial case studies, he exposes how the commercial interest of drug manufacturers are consistently given the benefit of the scientific doubts about medicine safety and effectiveness, over and above the best interests of patients.; A highly original combination of philosophical rigour, historical sensitivity and empirical depth enables

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Crossing the Quality Chasm

Columbia University Press

A drug policy is a crucial ingredient in every country's national health strategy as it provides a strategic framework to identify goals and commitments. This publication discusses the key components of such a policy. Issues covered include: the selection of essential drugs, affordability; finance and supply; regulation and quality assurance; rational use; research; human resources; monitoring

and evaluation. *Regulating Medicines in Europe* McGill-Queen's Press - MQUP 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.

Comparison of Bills to Regulate Controlled Dangerous Substances and to Amend the Narcotic and Drug Laws Springer Science & Business Media

Drug-related morbidity and mortality is rampant in contemporary industrial society, despite or perhaps because, government has assumed a critical role in the process by which drugs are developed and approved. Parrish asserts that, as a

people, Americans need to understand how it is that government became the arbiter of pharmaceutical fact. The consequences of our failure to understand, he argues, may threaten individual choice and forestall the development of responsible therapeutics. Moreover, if current standards and control continues unabated, the next therapeutic reformation might well make possible the sanctioned commercial exploitation of patients. In Defining Drugs, Parrish argues that the federal government became arbiter of pharmaceutical fact because the professions of pharmacy and medicine, as well as the pharmaceutical industry, could enforce these definitions and standards only through police powers reserved to government. Parrish begins his provocative study by examining the development of the social system for regulating drug therapy in the United States. He reviews the standards that were negotiated, and the tensions of the period between Progressivism and the New Deal that gave cultural context and historical meaning to drug use in American society. Parrish describes issues related to the development of narcotics

policy through education and legislation facilitated by James Beal and Edward Kremers, and documents the federal government's evolving role as arbiter of market tensions between pharmaceutical producers, government officials, and private citizens in professional groups, illustrating the influence of government in writing enforceable standards for pharmaceutical therapies. He shows how the expansion of political rights for practitioners and producers has shifted responsibility for therapeutic consequences from individual practitioners and patients to government. This timely and controversial volume is written for the scholar and the compassionate practitioner alike, and a general public concerned with pharmacy regulation in a free society.

China's Drug Practices and Policies McGill-Queen's Press - MQUP

Most national governments have created agencies with the responsibility for deciding which medicinal drugs should be imported or manufactured and made available through their health systems. Many of these agencies were set up some twenty years ago in the wake of the thalidomide disaster. Since that time they

have developed in quite different ways in response to national, cultural and economic influences. Their direct cost is very small in comparison to overall health budgets but their indirect effects, both in terms of health and the economy, can be substantial. In 1980 the World Health Organization (WHO) Regional Office for Europe set up a series of studies of drug evaluation in the European region aimed at determining the effects of the work of regulatory agencies on the availability of drugs, on the pharmaceutical industry, and on the health of individuals in the countries concerned. This book sets that work in a historical context and describes the sources of the data used by the project team and the methods used by WHO and others in assessing the work of these agencies and its repercussions for the community. Finally, it presents an analysis of current knowledge and the plans and prospects for future research. The first draft of this book was presented to a meeting of experts in the field of drug regulation at Oslo in March 1984, and the present text embodies the views and conclusions of that meeting.