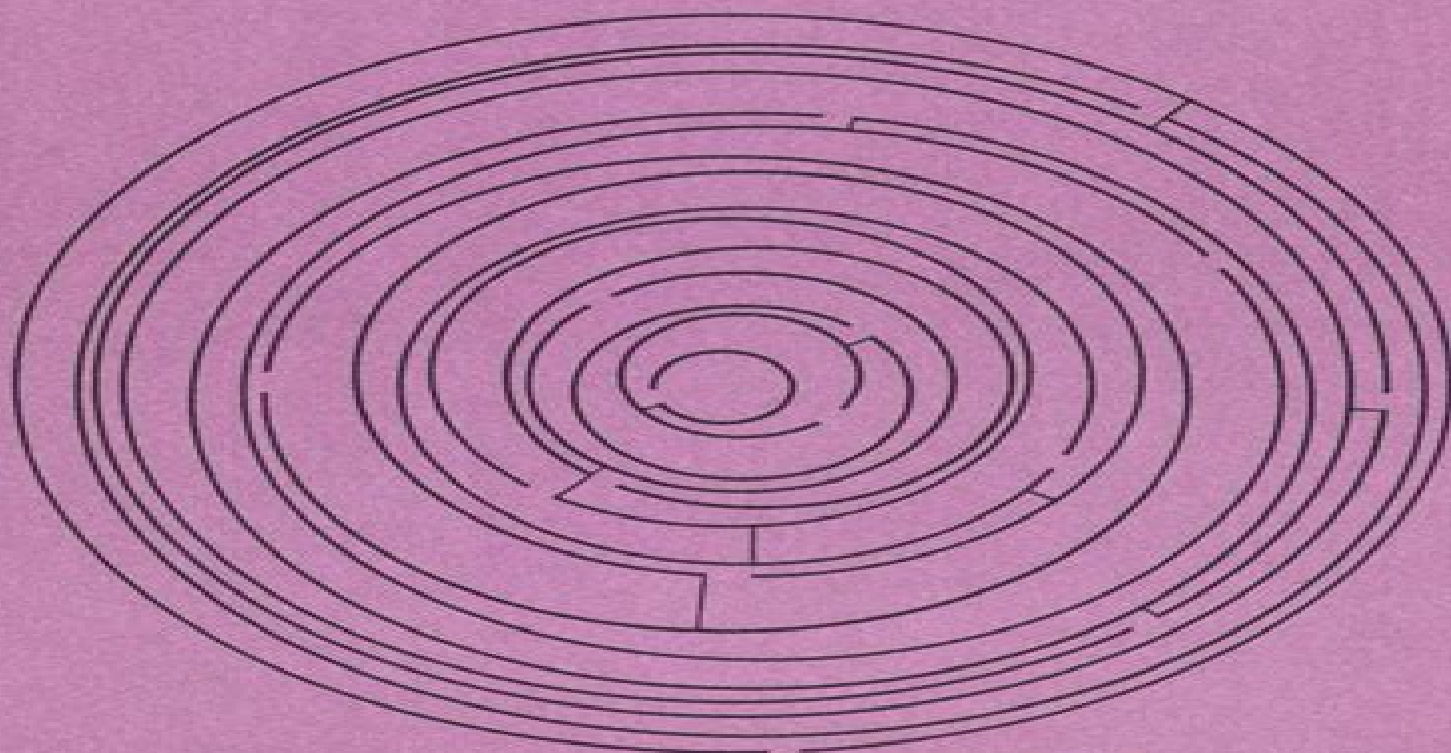


Evaluative Studies

DRUG REGULATION AND INNOVATION

Empirical evidence and policy options

Henry G. Grabowski



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Drug Regulation And Innovation Empirical Evidence And Policy Options

J. Kiffin Penry



Drug Regulation And Innovation Empirical Evidence And Policy Options:

Drug Regulation and Innovation Henry G. Grabowski, 1976 *The Effects of Drug Regulation* Graham Dukes, 2012-12-06 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 *Review Panel on New Drug Regulation* United States. Department of Health, Education, and Welfare. Review Panel on New Drug Regulation, 1977

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Acceptable Risks C. F. Larry Heimann, 2010-03-10 Complex and risky technologies technologies such as new drugs for the treatment of AIDS that promise great benefits to our society but carry significant risks pose many problems for political leaders and the policy makers responsible for overseeing them Public agencies such as the Food and Drug Administration are told by political superiors not to inhibit important technological advances and may even be charged with promoting such development but must also make sure that no major accidents occur under their watch Given the large costs associated with catastrophic accidents the general public and elected officials often demand reliable or failure free management of these technologies and have little tolerance for the error Research in this area has lead to a schism between those who argue that it is possible to have reliable management techniques and safely manage complex technologies and others who contend that such control is difficult at best In this book C F Larry Heimann advances an important solution to this problem by developing a general theory of organizational reliability and agency decision making The book looks at both external and internal influences on reliability in agency decision making It then tests theoretical propositions developed in a comparative case study of two agencies involved with the handling of risky technologies NASA and the manned space flight program and the FDA s handling of pharmaceuticals particularly new AIDS therapies Drawing on concepts from engineering organizational theory political science and decision theory this book will be of interest to those interested in science and technology policy

bureaucratic management and reform as well as those interested in health and space policy C F Larry Heimann is Assistant Professor of Political Science Michigan State University International Health Planning Reference Series ,1979

Regulatory Reform Seminar ,1978 **The Risks of Prescription Drugs** Donald W. Light,2010-10-14 Few people realize that prescription drugs have become a leading cause of death disease and disability Adverse reactions to widely used drugs such as psychotropics and birth control pills as well as biologicals result in FDA warnings against adverse reactions The Risks of Prescription Drugs describes how most drugs approved by the FDA are under tested for adverse drug reactions yet offer few new benefits Drugs cause more than 2 2 million hospitalizations and 110 000 hospital based deaths a year Serious drug reactions at home or in nursing homes would significantly raise the total Women older people and people with disabilities are least used in clinical trials and most affected Health policy experts Donald Light Howard Brody Peter Conrad Allan Horwitz and Cheryl Stults describe how current regulations reward drug companies to expand clinical risks and create new diseases so millions of patients are exposed to unnecessary risks especially women and the elderly They reward developing marginally better drugs rather than discovering breakthrough life saving drugs The Risks of Prescription Drugs tackles critical questions about the pharmaceutical industry and the privatization of risk To what extent does the FDA protect the public from serious side effects and disasters What is the effect of giving the private sector and markets a greater role and reducing public oversight This volume considers whether current rules and incentives put patients health at greater risk the effect of the expansion of disease categories the industry s justification of high U S prices and the underlying shifts in the burden of risk borne by individuals in the world of pharmaceuticals Chapters cover risks of statins for high cholesterol SSRI drugs for depression and anxiety and hormone replacement therapy for menopause A final chapter outlines six changes to make drugs safer and more effective Suitable for courses on health and aging gender disability and minority studies this book identifies the Risk Proliferation Syndrome that maximizes the number of people exposed to these risks Additional Columbia SSRC books on the privatization of risk and its implications for Americans Bailouts Public Money Private Profit Edited by Robert E Wright Disaster and the Politics of Intervention Edited by Andrew Lakoff Health at Risk America s Ailing Health System and How to Heal It Edited by Jacob S Hacker Laid Off Laid Low Political and Economic Consequences of Employment Insecurity Edited by Katherine S Newman Pensions Social Security and the Privatization of Risk Edited by Mitchell A Orenstein **State Intervention in Medical Care** J. Rogers Hollingsworth, Jerald Hage, Robert Hanneman, 2019-05-15 State Intervention in Medical Care is a substantial and unique contribution to the ongoing debate about government participation in the delivery of medical care It offers historical cross national comparisons of the performance of medical systems in Britain France Sweden and the United States over most of the last century J Rogers Hollingsworth Jerald Hage and Robert A Hanneman examine the impact of state intervention on a number of characteristics mortality rates the per capita cost of medical care the social efficiency of the delivery of services the introduction and diffusion of innovations and

the equality of the system including not only regional or spatial equality but also equality in access to medical resources and equality in levels of health across social classes and income groups Science Policy Implications of DNA Recombinant Molecule Research United States. Congress. House. Committee on Science and Technology. Subcommittee on Science, Research, and Technology, 1977 **Indexes to the Epilepsy Accessions of the Epilepsy Information System** J. Kiffin Penry, 1978 **Science, Politics And The Pharmaceutical Industry** John Abraham, 0 John Abraham University of Reading., 2023-05-31 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 Abraham 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 **Private Markets and Public Intervention** Harvey Averch, 2010-11-23 Averch describes and analyzes common strategies for solving problems in public policy The strategies discussed include the use of markets bureaus regulation planning and budgeting benefit cost systems analysis and evaluation He examines the historical development of each strategy describes how each strategy would ideally work explains the necessary or sufficient conditions that permit each strategy to work lists the

potential failures of each strategy and provides a judgment or appraisal of each strategy

Act of 1981--S. 255 United States. Congress. Senate. Committee on the Judiciary,1981

Ceccoli,2004 Criticism that the FDA s approach failed to meet public need and impeded commerce led to a political compromise regarding its mission The author of this study attempts to show that the drug approval process whilst redressing complaints also creates new more complex problems

Proceedings and Background Papers ,1979 *Developing a Regulatory Bureaucracy* Neal Shover,1983

The Oxford Handbook of Health Economics Sherry Glied,Peter C.

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Pharmaceutical Innovation Ralph Landau,Basil Achilladelis,Alexander Scriabine,1999 Documents how science has provided an astonishing array of medicines for coping with human ailments This volume addresses industry leaders economic influences and the development of individual products It is suitable for policy makers economists corporate executives research managers and historians of science technology and medicine

Health Care Financing Review ,1982

The Patent Term Restoration Pill Politics Stephen J.

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