

Federal Regulation and Chemical Innovation



Federal Regulation and Chemical Innovation

Christopher T. Hill, EDITOR
Massachusetts Institute of Technology

Based on a symposium
sponsored by the Division of
Industrial and Engineering Chemistry
at the 176th Meeting of the
American Chemical Society,
Miami Beach, Florida,
September 14, 1978.

A C S S Y M P O S I U M S E R I E S **109**

AMERICAN CHEMICAL SOCIETY
WASHINGTON, D. C. 1979



Library of Congress CIE Data

Federal regulation and chemical innovation.
(ACS symposium series; 109 ISSN 0097-6156)

Includes bibliographies and index.

1. Chemical research—United States—Congresses. 2.
Science and state—United States—Congresses.

I. Hill, Christopher T. II. American Chemical Society.
Division of Industrial and Engineering Chemistry. III.
Series: American Chemical Society. ACS symposium
series; 109.

QD47.F4 540'.973 79-15407
ISBN 0-8412-0511-6 ASCMC 8 109 1-200 1979

Copyright © 1979

American Chemical Society

All Rights Reserved. The appearance of the code at the bottom of the first page of each article in this volume indicates the copyright owner's consent that reprographic copies of the article may be made for personal or internal use or for the personal or internal use of specific clients. This consent is given on the condition, however, that the copier pay the stated per copy fee through the Copyright Clearance Center, Inc. for copying beyond that permitted by Sections 107 or 108 of the U.S. Copyright Law. This consent does not extend to copying or transmission by any means—graphic or electronic—for any other purpose, such as for general distribution, for advertising or promotional purposes, for creating new collective works, for resale, or for information storage and retrieval systems.

The citation of trade names and/or names of manufacturers in this publication is not to be construed as an endorsement or as approval by ACS of the commercial products or services referenced herein; nor should the mere reference herein to any drawing, specification, chemical process, or other data be regarded as a license or as a conveyance of any right or permission, to the holder, reader, or any other person or corporation, to manufacture, reproduce, use, or sell any patented invention or copyrighted work that may in any way be related thereto.

PRINTED IN THE UNITED STATES OF AMERICA

Federal Regulation and Chemical Innovation

ACS Symposium Series

M. Joan Comstock, *Series Editor*

Advisory Board

Kenneth B. Bischoff

Donald G. Crosby

Robert E. Feeney

Jeremiah P. Freeman

E. Desmond Goddard

Jack Halpern

Robert A. Hofstader

James D. Idol, Jr.

James P. Lodge

John L. Margrave

Leon Petrakis

F. Sherwood Rowland

Alan C. Sartorelli

Raymond B. Seymour

Aaron Wold

Gunter Zweig

FOREWORD

The ACS SYMPOSIUM SERIES was founded in 1974 to provide a medium for publishing symposia quickly in book form. The format of the Series parallels that of the continuing ADVANCES IN CHEMISTRY SERIES except that in order to save time the papers are not typeset but are reproduced as they are submitted by the authors in camera-ready form. Papers are reviewed under the supervision of the Editors with the assistance of the Series Advisory Board and are selected to maintain the integrity of the symposia; however, verbatim reproductions of previously published papers are not accepted. Both reviews and reports of research are acceptable since symposia may embrace both types of presentation.

PREFACE

The past two decades have witnessed rapid growth in government regulation of the environmental, health, and safety aspects of industrial processes and products. The chemical process industries and the products they make are a major focus of the regulations administered by EPA, OSHA, FDA, and CPSC, and by their state-level counterparts. It is not surprising that these industries have received considerable attention from government regulators. The synthetic organic chemical, petroleum refining, and primary metals industries as well as such products as pesticides, pharmaceuticals, chlorinated hydrocarbons, and heavy metals can pose significant risks to human health, safety, and the environment.

The economic regulation passed in an earlier age is concerned with markets, prices, and preservation of competition. By contrast, a major objective of much of the "new regulation" is to stimulate firms to redesign or to change the processes they use and the products they sell. The chemical industries depend heavily on a continual flow of new processes and products to meet consumer needs; to control production costs in the face of higher prices for raw materials, labor, and equipment and to meet the challenge of foreign competition. Furthermore, technological innovation is often the means by which new firms enter the chemical industries and by which existing firms adapt and grow. It is also not surprising, then, that concern has arisen for the effects that environmental, health, and safety regulations have on the rate and nature of technological innovation in the chemical industries.

The importance of chemical innovation is not confined to chemical firms. It is equally important to the economy and to society as a whole. New technology provides the major improvements in productivity that help control inflation and that contribute to the nation's economic growth. At the same time, society needs new chemical technology to help solve many of the pressing problems of our time such as energy conservation and supply, production of food, preservation of environmental quality, and control of population growth.

Most of the papers in this volume were presented at an ACS symposium in September 1978. Perhaps a no more diverse and comprehensive set of papers on the effects of regulation on chemical innovation has ever before been assembled. They present a cross section of research

results from most of the major schools of thought as well as the practical experiences and observations of people from industry and government. The disciplines represented by the authors include chemistry, chemical engineering, medicine, law, economics, business administration, and psychology.

The papers are arranged to provide (1) an introduction to the issues, (2) conceptual and analytical models and empirical results, and (3) policy implications and prescriptions for change. The first three papers provide a broad introduction to the issues. Eads covers the origins of the "new regulation," contrasts it with older economic regulation, and discusses how such regulation affects corporate decision making. Newburger discusses five real dilemmas society faces in regulating the conduct of firms and points out that regulation can be neither entirely just nor entirely positive in its effects. Leenhouts reviews and assesses the empirical evidence on the effects of regulation on innovation from the perspective of a chemical engineer in industry.

The next six papers present conceptual frameworks, theoretical models and empirical evidence, on the effects of regulation on chemical innovation. Ashford and Heaton and Iverstine and Kinard present evidence from surveys of firm-level responses to regulation. Both papers note regulation-induced changes in the level and nature of research and development, in the processes of decision making in technology areas in firms, and in the kinds of products and processes that are commercially successful. Cohen and Bennett provide first-person confirmation of the fact that government regulation creates new business opportunities to develop and sell new control technologies. Both Greenberg and Thompson present analytical models that are useful in examining responses of process technology to regulation. These studies are rooted in models developed by economists to study dynamic responses to price changes. DiRaddo and Wardell review past work and present new data on the effects of pharmaceutical regulation on the development of new drugs. Generally, more is known about the drug part of the regulation/innovation interface than about any other, since the regulations are older and the FDA new drug approval process automatically generates measures of innovation.

The final four papers move from theoretical concepts and research results to policy and prescription. Updegraff assesses the potential impact on innovation of the proposed Drug Regulation Reform Act. This Act originated, in part, from the recognition of the kinds of problems raised in the DiRaddo and Wardell paper. DeKany and Malkenson of EPA describe how EPA is implementing the Toxic Substances Control Act in light of the Congressional statement of policy that it not unduly impede technological innovation. Gerstenfeld and Nason find that regu-

lation inhibits innovation, and to address this problem, present an 11-point program of government actions designed to improve the formal and informal processes by which regulations are developed. Schweitzer agrees that regulation is a problem for innovation, especially in the long term. Among other proposals, he recommends legislated changes in the Toxic Substances Control Act and formation of a national commission that would present recommendations for amending it. The commission would also evaluate the impact of regulation on society, including the chemical industry.

After digesting all the ideas in this book, however, the reader looking for a definitive understanding must continue to search. Despite the importance of both regulation and innovation to industry and society, and despite the hours that have been devoted to discussion of their interactions, there is still much to learn. Problems of description, definition, and measurement plague serious research in the field. Reasonable arguments can be made on theoretical grounds that regulation would inhibit or stimulate innovation, and empirical confirmation is available to support both sides. Furthermore, some participants in the debate confuse the impacts of regulation on innovation with the larger question of whether regulation's costs are worth the benefits.

Thus, there is still a great need for good empirical research on the effects of government regulation on chemical innovation. The papers in this volume provide an array of ideas that can be examined, expanded, and integrated to help improve our understanding of this interaction. With a better understanding, Congress and the agencies can better design regulations to meet important social goals, including the development of needed technologies for regulatory compliance, while maintaining the ability of the chemical industries to remain viable and grow.

I would like to thank David Gushee, former chairman of the ACS Industrial and Engineering Chemistry Division, for suggesting this symposium. I would also like to thank the authors and the reviewers for participating, and the Congressional Office of Technology Assessment and the MIT Center for Policy Alternatives for assistance in preparing the symposium and this volume. Betsi Wasserman helped immensely with the tasks involved in putting this work together. Finally, I would like to acknowledge the Division of Policy Research and Analysis of the National Science Foundation, which has funded or otherwise supported most of the research that appears in this volume.

Massachusetts Institute of Technology
Cambridge, Massachusetts 02139
March 30, 1979

CHRISTOPHER T. HILL

CONTRIBUTING AUTHORS

NICHOLAS A. ASHFORD (Chemistry, Law) is Assistant Director of the MIT Center for Policy Alternatives. He has worked at the ITT Research Institute, serves as the Chairman of the National Advisory Committee on Occupational Safety and Health, and is a consultant to several regulatory agencies.

ROBERT P. BENNETT (Chemistry) is Vice President and Technical Director at Apollo Chemical Corporation. He was formerly Director of R&D at Apollo, and has worked for American Cyanamid.

MURRAY S. COHEN (Chemistry) is Director of New Business Development at Apollo Chemical Corporation. He was formerly Technical Director for Borg Warner Chemicals and prior to that, Laboratory Director for Exxon Research and Development, Paramins Laboratory.

JOHN DEKANY (Chemical Engineering) is Deputy Assistant Administrator for Chemical Control in the EPA Office of Toxic Substances. He was formerly Director of Emission Control Technology at the EPA Mobile Source Air Pollution Control Program and has worked for Westinghouse Electric and Gulf Oil.

JEAN DIRADDIO (Psychology, Neurochemistry) is Center Projects Manager at the Center for the Study of Drug Development at the University of Rochester's School of Medicine.

GEORGE C. EADS (Economics) is a Member of the President's Council of Economic Advisers and was the Director of the Regulatory Policies and Institutions Program at the RAND Corporation.

ARTHUR GERSTENFELD (Industrial Management) is Professor and Head of the Department of Management at Worcester Polytechnic Institute.

EDWARD GREENBERG (Economics) is Professor of Economics at Washington University in St. Louis.

GEORGE HEATON (Law) is a Research Associate at the MIT Center for Policy Alternatives.

CHRISTOPHER T. HILL (Chemical Engineering) is a Senior Research Associate at the MIT Center for Policy Alternatives. He has worked for the Congressional Office of Technology Assessment, Washington University in St. Louis, and Uniroyal, Inc.

JOE C. IVERSTINE (Chemical Engineering, Business Administration) is Professor of Business Administration at Southeastern Louisiana University at Hammond, Louisiana. He has worked for Allied Chemical Company.

JERRY L. KINARD (Business) is Professor and Head of the Department of Business Administration at Southeastern Louisiana University at Hammond, Louisiana.

JAMES. W. LEENHOUTS (Chemistry) is Manager of Business Development in R&D and is the Toxic Substances Coordinator for the Michigan Division at Dow Chemical U.S.A.

STEVEN MALKENSON (Economics) is currently at Blythe, Eastman, and Dillon. He was formerly in the Economic Analysis Division at EPA.

HOWARD K. NASON (Business, Chemistry) is President of the Industrial Research Institute, Research Corporation. He was formerly President of Monsanto Research Corporation and Vice President of the Research and Engineering Division at Monsanto.

DAVID J. NEWBURGER (Law) is Assistant Professor of Law at Washington University in St. Louis and is an attorney in private practice. He has worked for the State of Ohio, the Department of Commerce, and the firm of Arnold and Porter.

GLENN E. SCHWEITZER (Engineering) is Senior Research Associate at Cornell University and Associate Executive Director of the Council on Science and Technology for Development in Washington, D.C. He was formerly Director of the EPA Office of Toxic Substances.

RUSSELL G. THOMPSON (Economics) is Professor of Quantitative Management Science and Director of Industry Studies in the College of Business Administration at the University of Houston. He is also President of Research for Growth and Transfer, Inc.

GAIL UPDEGRAFF (Economics) is Senior Economist at JRB Associates in McLean, Virginia. He was formerly Chief of the Economic Analysis Group at the Food and Drug Administration.

WILLIAM M. WARDELL (Clinical Pharmacology, Medicine) is Associate Professor of Pharmacology and Toxicology and Director of the Center for the Study of Drug Development at the University of Rochester.

CONTENTS

Preface	ix
Contributing Authors	xiii
1. Chemicals as a Regulated Industry: Implications for Research and Product Development	I
George C. Eads	
2. A Reasoned Approach to Government Regulation: How Can We Separate the Good from the Bad?	21
David J. Newburger	
3. What Do We Really Know About the Impact of Regulation on Innovation?	29
James W. Leenhouts	
4. The Effects of Health and Environmental Regulation on Technological Change in the Chemical Industry: Theory and Evidence	45
Nicholas A. Ashford and George R. Heaton	
5. The Impact of Environmental Protection Regulations on Research and Development in the Industrial Chemical Industry	67
Joe C. Iverstine and Jerry L. Kinard	
6. Case Studies on Chemical Flue Gas Treatment as a Means of Meeting Particulate Emission Regulations	77
Murray S. Cohen and Robert P. Bennett	
7. A Framework for Examination of the Impacts of Government Regulation and Input Prices on Process Innovation	103
Edward Greenberg	
8. Economic Trends, Resource Scarcity, and Policymaking	117
Russell G. Thompson	
9. Methodology for Measuring the Effects of Regulation on Pharmaceutical Innovation: Regulatory Disposition and National Origin of New Chemical Entities in the United States	127
Jean DiRaddo and William M. Wardell	
10. Innovation in the Pharmaceutical Industry: Possible Effects of the Proposed Drug Regulation Reform Act of 1978	151
Gail Updegraff	
11. Meeting the Challenge of the Toxic Substances Control Act with Technological Innovation	167
John DeKany and Steven Malkenson	

12. The Effect of Government Regulation on Innovation in the
Chemical Industry 173
Arthur Gerstenfeld and Howard K. Nason

13. Regulation and Innovation: Short-Term Adjustments and
Long-Term Impacts 179
Glenn E. Schweitzer

Index 195

Chemicals as a Regulated Industry: Implications for Research and Product Development

GEORGE C. EADS

Regulatory Policies and Institutions Program, The Rand Corporation,
Santa Monica, CA 90406

Governmentally imposed restrictions on private enterprise are not a new phenomenon. For about 100 years, certain industries, such as the railroads and the electric utilities, have operated under detailed regulation, and even the so-called "unregulated" industries have been subject to antitrust, securities, tax, and labor laws. It is now widely recognized, however, that government regulation has entered a new era. This era began in the mid-1960s with the passage of a series of laws aimed at, among other things, protecting the environment, insuring worker health and safety, and assuring the safety and performance of consumer products. This "new regulation" applies to all private enterprise, and is administered by a multiplicity of agencies, each interested only in specialized segments of a firm's operations. In further contrast with traditional regulation agencies, the regulators in these new agencies have no specific mandate to promote the industries they regulate or even to assure the continued existence of these industries.

A number of observers, both within and outside government, have expressed concern that this new use of regulation is fundamentally altering the behavior and performance of U.S. private enterprise, with potential repercussions far beyond the intended scope of regulatory activity. One reason for concern is the fact that the increase in regulatory activity requires that a larger share of U.S. economic and social resources be devoted to supporting the regulatory bureaucracy, to assuring effective and appropriate representation of firms' interests before regulatory bodies, to gathering and processing numerous data requests made by government agencies and their contractors and, finally but certainly not least important, to complying with regulations once they are promulgated. Estimates of these costs vary widely, but some notion of their potential consequence is given by a recently published study by Denison (1) in which he estimates that compliance with environmental constraints introduced since 1967 diverted nearly one percent of 1975 nonresidential business resources away from final output, with another 0.42 percent diverted as a result of compliance with regulations to improve

worker health and safety. This may seem like a small figure, but it is not. Denison estimates that by 1975, this reduction was equivalent to knocking 1/2 of one percentage point off the economy's annual growth rate. This, in turn, represents fully a 25 percent reduction in the economy's long-term rate of improvement in output per unit of input. Moreover, Denison reports that the share of resources being diverted has been steadily rising.

But the diversion of economic and social resources away from final production may not be the only, or even the most important, cost of the "new regulation." Virtually every aspect of the firm's strategic environment is likely to be affected. Of special concern is that the pace and direction of technological advance is likely to be altered in ways that are not presently predictable.

Historically, technological innovation has been a prime force in economic development. New processes and products have been credited with such diverse benefits as increased employment, increased labor productivity, new opportunities for preventing and curing disease, greater consumer comfort, and improvements in the balance of trade.

Of course, it is also argued that technological development is at least partly responsible for precisely the environmental, health, and safety hazards to which the bulk of the "new regulation" is addressed. Therefore, some of the changes that regulation may induce may be all to the good. But we need not deny the existence of technology created hazards in order to be concerned about the possible negative effects of this regulation on the rate of technological advance. The issue is not whether some regulation is justified, but what trade-offs our society is willing to make between the social and economic benefits from further high rates of technological advance and the losses associated with actual and potential new product and process hazards.

We are in the very early stages of research aimed at exploring just such questions as these. This paper is intended to describe some of our preliminary hypotheses and to expose our general approach to comment and criticism.

The target industry for our research is chemicals. This choice has merit for several reasons. Chemicals has long been considered a prime example of an industry whose success has been based on a continued high rate of technological innovation. Traditionally grouped among the "research intensive" industries, chemicals has been particularly noteworthy for the extremely low proportion of its R&D funds that have been federally supplied. Thus it is little wonder that researchers seeking to understand the process of industrial innovation have been attracted to the chemicals industry and, in particular, to its technologically most advanced firms.

But chemicals is distinctive in another way. The industry has been a prime target of the "new regulation." Indeed, with

the possible exceptions of autos and steel, no previously "unregulated" industry has been subjected to a wider variety of regulations. Certainly among the high technology industries, it ranks first.

The chemicals industry also contains a sufficiently large number of firms so that a diversity of behavior likely can be observed. But more importantly, the chemicals industry, being highly dynamic, has always been in the forefront of managerial innovations. As Chandler has noted, a chemicals firm, Du Pont, pioneered the multidivisional form of corporate organization.⁽²⁾ Chemicals firms were among the first to establish organized corporate research activities. And, as we have observed during our research, certain of the firms in the chemicals industry are taking steps to become active participants in the regulatory process. Therefore, if U. S. industry is indeed undergoing significant changes as it attempts to deal with the "new regulation," these changes should readily be observable in chemicals.

Maintaining this particular industry's past excellent performance is of obvious importance to the economy. We have already referred to the industry's high rate of technological advance. The new and improved products it has developed have, in turn, fueled productivity improvements throughout the economy. And, although more high-level policy attention is usually given to the problem and performance of such industries as steel, chemicals long ago surpassed most of these sectors in contributions to the gross national product. Furthermore, chemicals, stimulated no doubt by its enviable performance in developing new products, has continued to make a strong positive contribution to our balance of payments.

One element of the chemicals industry--pharmaceuticals--has already been the subject of intense study. Considerable attention has been given to the role that FDA regulation may or may not have played in an observed slowdown in the rate of development and commercialization of new ethical drugs.

This interest in pharmaceuticals has tended to draw research attention away from the effects that have been felt by the other segments of the chemicals industry. This is unfortunate for, whatever its importance, the effects of FDA regulation on innovation and product development in pharmaceuticals is likely to be quite different from the impact generated by the type regulation to which the nonpharmaceuticals portion of the chemicals industry has become subject. As we shall argue in more detail below, dealing with such regulations and with the entities that promulgate and promote them creates a fundamentally different planning problem for a firm than does coping with regulations administered by an agency which has a scope of interest and responsibility roughly corresponding to the boundaries of the industry being regulated.

In the next section of this paper, we discuss some of the characteristics of the "new regulation" that help to differen-