

## PHARMACEUTICAL ECONOMICS AND POLICY

Second Edition

Stuart O. Schweitzer



## **Contents**

Introduction

The Supply of Pharmaceuticals

	The Demand for Pharmaceuticals Pharmaceutical Prices	7
	The Multinational Pharmaceutical Industry	8 11
	International Price Comparisons	12
	Timing of Pharmaceutical Approvals	12
	Government Intervention in the Pharmaceutical Sector	13
Par	t I. The Industry	
1	The Pharmaceutical Industry	21
	Pharmaceutical Research and Development	22
	The Competitive Structure of the Pharmaceutical Industry	23
	Pharmaceutical Research and Development and Prices	27
	The Pharmaceutical Research Process	29
	Product Liability	38
	Conclusions	40
2	The Biotechnology Industry	44
	Background	44
	Product Development in the Biotechnology Industry	47
	The Natural History of Biotechnology Firms	48
	Case Studies of Alliances	53
	Regulation	55
	Case Studies of Biotechnology Firm Growth	57
	Conclusions	60

3 5 7

## xii Contents

Generic Drugs and Their Manufacturers Outsourcing Firms Conclusions	63
Conclusions	
	68
A. Madavina Diagram	78
4 Marketing Pharmaceuticals	82
Size of Marketing Effort	85
Does It Work?	85
Types of Promotion	87
Disguising Marketing as Research	93
Marketing in an Era of Managed Care	94
Pharmacy Benefit Managers	95
Direct-to-Consumer Advertising	97
Over-the-Counter Drugs	100
Joint Marketing	103
Disease Management	103
Roles of the U.S. Food and Drug Administration in M	
False and Misleading Claims	105
	,
Part II. The Consumer	
5 The Demand for Pharmaceuticals	115
How Is Demand Determined?	116
The Changing Structure of the Pharmaceutical Mark	et 117
Conclusions	131
Part III. The Market	
6 Pharmaceutical Prices	137
6 Pharmaceutical Prices The Problem of Pharmaceutical Prices	138
6 Pharmaceutical Prices The Problem of Pharmaceutical Prices Pharmaceutical Prices over Time	138 139
6 Pharmaceutical Prices The Problem of Pharmaceutical Prices Pharmaceutical Prices over Time Measuring Drug Prices	138 139 141
6 Pharmaceutical Prices The Problem of Pharmaceutical Prices Pharmaceutical Prices over Time Measuring Drug Prices How Are Drug Prices Determined?	138 139 141 143
6 Pharmaceutical Prices The Problem of Pharmaceutical Prices Pharmaceutical Prices over Time Measuring Drug Prices How Are Drug Prices Determined? Cost Structure of Pharmaceutical Firms	138 139 141 143 144
6 Pharmaceutical Prices The Problem of Pharmaceutical Prices Pharmaceutical Prices over Time Measuring Drug Prices How Are Drug Prices Determined? Cost Structure of Pharmaceutical Firms Is the Pharmaceutical Industry Monopolistic?	138 139 141 143 144 149
6 Pharmaceutical Prices The Problem of Pharmaceutical Prices Pharmaceutical Prices over Time Measuring Drug Prices How Are Drug Prices Determined? Cost Structure of Pharmaceutical Firms	138 139 141 143 144
6 Pharmaceutical Prices The Problem of Pharmaceutical Prices Pharmaceutical Prices over Time Measuring Drug Prices How Are Drug Prices Determined? Cost Structure of Pharmaceutical Firms Is the Pharmaceutical Industry Monopolistic? How Drug Quality Influences Price	138 139 141 143 144 149 153
6 Pharmaceutical Prices The Problem of Pharmaceutical Prices Pharmaceutical Prices over Time Measuring Drug Prices How Are Drug Prices Determined? Cost Structure of Pharmaceutical Firms Is the Pharmaceutical Industry Monopolistic? How Drug Quality Influences Price  7 The Worldwide Market for Pharmaceuticals	138 139 141 143 144 149 153
6 Pharmaceutical Prices The Problem of Pharmaceutical Prices Pharmaceutical Prices over Time Measuring Drug Prices How Are Drug Prices Determined? Cost Structure of Pharmaceutical Firms Is the Pharmaceutical Industry Monopolistic? How Drug Quality Influences Price  7 The Worldwide Market for Pharmaceuticals Geographic Patterns of Pharmaceutical Production of	138 139 141 143 144 149 153 157 and Sales 158
6 Pharmaceutical Prices The Problem of Pharmaceutical Prices Pharmaceutical Prices over Time Measuring Drug Prices How Are Drug Prices Determined? Cost Structure of Pharmaceutical Firms Is the Pharmaceutical Industry Monopolistic? How Drug Quality Influences Price  7 The Worldwide Market for Pharmaceuticals Geographic Patterns of Pharmaceutical Production of Pharmaceutical Research and Development: An Inter	138 139 141 143 144 149 153 157 and Sales 158 rnational View 159
6 Pharmaceutical Prices The Problem of Pharmaceutical Prices Pharmaceutical Prices over Time Measuring Drug Prices How Are Drug Prices Determined? Cost Structure of Pharmaceutical Firms Is the Pharmaceutical Industry Monopolistic? How Drug Quality Influences Price  7 The Worldwide Market for Pharmaceuticals Geographic Patterns of Pharmaceutical Production of Pharmaceutical Research and Development: An Inter Does Government Drug Price Setting Influence R&D	138 139 141 143 144 149 153 157 and Sales 158 rnational View 159 ? 166
6 Pharmaceutical Prices The Problem of Pharmaceutical Prices Pharmaceutical Prices over Time Measuring Drug Prices How Are Drug Prices Determined? Cost Structure of Pharmaceutical Firms Is the Pharmaceutical Industry Monopolistic? How Drug Quality Influences Price  7 The Worldwide Market for Pharmaceuticals Geographic Patterns of Pharmaceutical Production of Pharmaceutical Research and Development: An Inter Does Government Drug Price Setting Influence R&D Worldwide Manufacturing and Sales	138 139 141 143 144 149 153 157 and Sales 158 rnational View 159 ? 166 167
6 Pharmaceutical Prices The Problem of Pharmaceutical Prices Pharmaceutical Prices over Time Measuring Drug Prices How Are Drug Prices Determined? Cost Structure of Pharmaceutical Firms Is the Pharmaceutical Industry Monopolistic? How Drug Quality Influences Price  7 The Worldwide Market for Pharmaceuticals Geographic Patterns of Pharmaceutical Production of Pharmaceutical Research and Development: An Inter Does Government Drug Price Setting Influence R&D	138 139 141 143 144 149 153 157 and Sales 158 rnational View 159 ? 166 167
6 Pharmaceutical Prices The Problem of Pharmaceutical Prices Pharmaceutical Prices over Time Measuring Drug Prices How Are Drug Prices Determined? Cost Structure of Pharmaceutical Firms Is the Pharmaceutical Industry Monopolistic? How Drug Quality Influences Price  7 The Worldwide Market for Pharmaceuticals Geographic Patterns of Pharmaceutical Production of Pharmaceutical Research and Development: An Inter Does Government Drug Price Setting Influence R&D Worldwide Manufacturing and Sales Access to Appropriate Drugs in Developing Countrie	138 139 141 143 144 149 153 157 and Sales 158 rnational View 159 ? 166 167 s 170
6 Pharmaceutical Prices The Problem of Pharmaceutical Prices Pharmaceutical Prices over Time Measuring Drug Prices How Are Drug Prices Determined? Cost Structure of Pharmaceutical Firms Is the Pharmaceutical Industry Monopolistic? How Drug Quality Influences Price  7 The Worldwide Market for Pharmaceuticals Geographic Patterns of Pharmaceutical Production of Pharmaceutical Research and Development: An Inter Does Government Drug Price Setting Influence R&D Worldwide Manufacturing and Sales Access to Appropriate Drugs in Developing Countrie Effect of the World Trade Organization Treaty	138 139 141 143 144 149 153 157 and Sales 158 rnational View 159 2 166 5 170 173
6 Pharmaceutical Prices The Problem of Pharmaceutical Prices Pharmaceutical Prices over Time Measuring Drug Prices How Are Drug Prices Determined? Cost Structure of Pharmaceutical Firms Is the Pharmaceutical Industry Monopolistic? How Drug Quality Influences Price  7 The Worldwide Market for Pharmaceuticals Geographic Patterns of Pharmaceutical Production of Pharmaceutical Research and Development: An Inter Does Government Drug Price Setting Influence R&D Worldwide Manufacturing and Sales Access to Appropriate Drugs in Developing Countrie Effect of the World Trade Organization Treaty  8 Pricing Pharmaceuticals in a World Environm Why Do Drug Prices Vary Across Country?	138 139 141 143 144 149 153 157 and Sales 158 rnational View 2 166 5 170 173 ent 177
6 Pharmaceutical Prices The Problem of Pharmaceutical Prices Pharmaceutical Prices over Time Measuring Drug Prices How Are Drug Prices Determined? Cost Structure of Pharmaceutical Firms Is the Pharmaceutical Industry Monopolistic? How Drug Quality Influences Price  7 The Worldwide Market for Pharmaceuticals Geographic Patterns of Pharmaceutical Production of Pharmaceutical Research and Development: An Inter Does Government Drug Price Setting Influence R&D Worldwide Manufacturing and Sales Access to Appropriate Drugs in Developing Countrie Effect of the World Trade Organization Treaty	138 139 141 143 144 149 153 157 and Sales 158 rnational View 2 166 167 s 177 178 186

	Co	ontents	xiii
	Why Drug Price Differences Persist Policy Implications		186 186
9	The Timing of Drug Approvals in the United States and Abroac The Timing of Pharmaceutical Approvals and Health Policy The Drug Approval Process in the United States	i	191 192 193
	Recent Initiatives to Expedite Drug Approvals Is There a U.S. Drug Lag?		198 199
Part	t IV. Intervention in the Pharmaceutical Market: Public and Private		
10	Pharmaceutical Regulation and Cost Containment		
	by the Public Sector		209
	Evolution of the U.S. Food and Drug Administration		210
	Medicaid		211
	State Cost-Containment Efforts		213
	Medicare		214
11	Regulation by the Private Sector		222
	Cost-Containment Mechanisms		222
	Cost Containment in Managed Care		230
12	Pharmaceutical Regulation in Europe		238
	The Pharmaceutical Industry in Europe		238
	History of Regulation in Europe		239
	Move Toward a Single Market		240
	Structure and Role of the European Medicines Evaluation Agency		240
	Drug Review under the European Medicines Evaluation Agency		241
	Current Regulatory Structure		242
	The Centralized Procedure for Marketing Authorization		243
	The Mutual-Recognition Procedure		245
	Performance of Europe's Centralized Drug Approval		246
	Rules on Labeling of Medicinal Products		247
	Advertising Regulations		248
	Pharmacovigilance Generic Drugs		248 249
10	Detect Protect's		252
13	Patent Protection		252
	Patent Law		253
	Patentability and Patent Categories		254
	How Are Patents Obtained?		255
	What Protection Does a Patent Confer?		256
	Duration of Patent Protection		256
	Infringement of Patents		258
	International Patent Treaties Patent Procedures under International Conventions		258 260
			260
	Shortcomings of the Patent System Patents and Societal Choice		261
	Social Benefits of the Patent System		261
	DOGINI DENEJIID OJ INC I NICIN DYSICIII		~UI

Social Benefits of the Patent System

## xiv Contents

14	Evaluating New Drugs	263
	Optimizing Production of Health	263
	Cost-Benefit Analysis	266
	Cost–Effectiveness Analysis	270
	Cost-Utility Analysis	272
	Policy Applications	274
	Interpretation and Misinterpretation of Cost-Effectiveness Studies	277
15	Complementary and Alternative Medicines	280
	Who Uses Complementary and Alternative Medicines?	282
	Manufacturers and Distributors of Complementary and Alternative Medicines	282
	Dietary Supplements	283
	Food Additives	293
	Medical Foods	296
	Concluding Remarks on Complementary and Alternative Medicines	300
16	Pharmaceuticals and Health Policy: A Look Ahead	304
	Structure of the Pharmaceutical Industry	304
	Health System Reform	306
	Drug Prices	308
	Drug Imports	308
	Patent Protection	309
	Drug Approvals	310
	Managed Care and Restricted Access to Pharmaceuticals	311
	The U.S. Food and Drug Administration	313
	Genetically Targeted Drugs	314
	Conclusions	315
Inde	ex	317