



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

JULY 1998

The Congress of the United States
Congressional Budget Office

NOTES

The numbers in the text and tables of this study may not add up to totals because of rounding.

Cover photo ©The Stock Market/Dennis Meyler.

Preface

In 1984, the Drug Price Competition and Patent Term Restoration Act (also known as the Hatch-Waxman Act) created an abbreviated approval process for generic prescription drugs and at the same time extended patent terms for innovator drugs. This Congressional Budget Office (CBO) study examines the extent to which competition from generic drugs has increased since the act. It also analyzes how that competition has affected the returns from developing a drug. The analysis was conducted at the request of the Chairman of the Senate Committee on the Budget.

Anna Cook of CBO's Natural Resources and Commerce Division wrote the study under the supervision of Jan Paul Acton and Elliot Schwartz. The analysis would not have been possible without data and information provided by the Food and Drug Administration (FDA), the Patent and Trademark Office (PTO), the Health Care Financing Administration, and Henry Grabowski of Duke University. A variety of industry experts provided information and insights, including Philip Chao and Donald Hare of the FDA, Karin Tyson of the PTO, Joel Hamilton of the General Accounting Office, David Reiffen of the Federal Trade Commission, Paul Wilson of IMS America, and Gary Persinger of the Pharmaceutical Research and Manufacturers of America (now of the National Pharmaceutical Council). Other outside reviewers included the following economics professors: Ernst Berndt and Scott Stern of MIT, Fiona Scott Morton of Stanford, David Salkever of Johns Hopkins, and F.M. Scherer of Harvard. Within CBO, John Peterson, Linda Bilheimer, Judith Wagner, Patrice Gordon, and Anne Cappabianca (now at Hoffman-La Roche) made extensive and valuable comments. Aaron Zeisler and Carl Muehlmann provided research assistance.

Christian Spoor edited the manuscript, and Melissa Burman proofread it. Angela McCollough typed the many drafts. Kathryn Quattrone prepared the study for publication, and Laurie Brown prepared the electronic version for CBO's World Wide Web site.

June E. O'Neill
Director

July 1998

This study and other CBO publications
are available at CBO's Web site:
<http://www.cbo.gov/>

Contents

	SUMMARY	ix
ONE	INTRODUCTION	1
	The Basis for Competition Among Drug Companies	2
	Changes Made by the Hatch-Waxman Act	3
	Data Used in This Analysis	4
TWO	THE EFFECT OF MANAGED CARE ON THE PHARMACEUTICAL MARKET	5
	The Rise of Managed Care	5
	How PBMs Help Hold Down Drug Expenditures	6
	How Managed Care Affects the Demand for Prescription Drugs	10
	Conclusions	11
THREE	PRICING AND COMPETITION IN THE PHARMACEUTICAL MARKET	13
	Competition Among Brand-Name Drugs	14
	Factors That Determine Discounts on Brand- Name Drugs	23
	Competition Between Brand-Name and Generic Drugs	27
	Competition Among Generic Drugs	32
	Conclusions	34
FOUR	THE EFFECTS OF THE HATCH-WAXMAN ACT ON THE RETURNS FROM INNOVATION	37
	Changes to the Length of Patents for Brand- Name Drugs	38
	Changes to the Approval Process for Generic Drugs	43
	Effects on the Returns from Marketing a Drug	45
	Effects of Proposed Changes to the Hatch- Waxman Act	49
	Conclusions	50

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.