

A
CBO
STUDY

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

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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.

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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

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