



**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

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## **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.

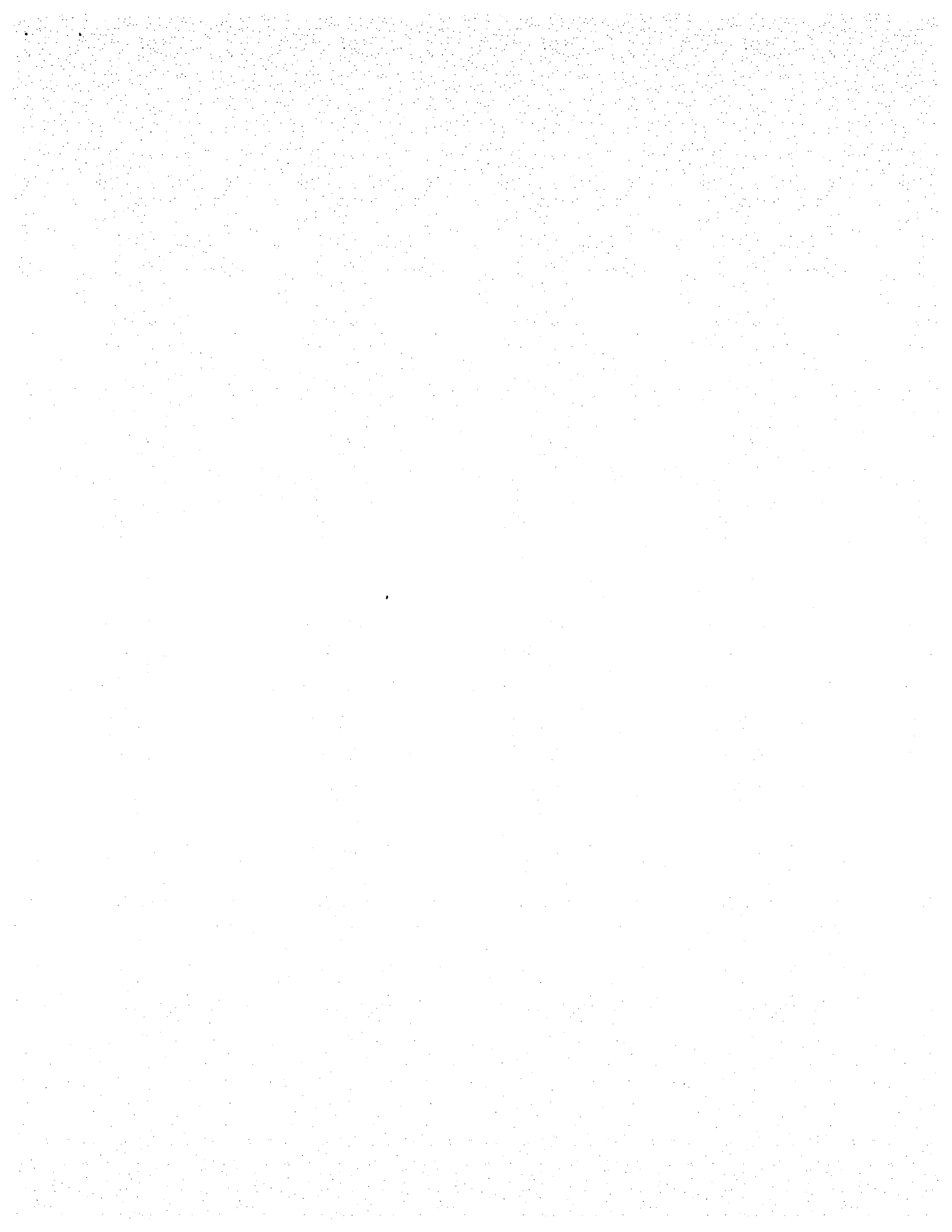
Christian Spoor edited the manuscript, and Melissa Burman proofread it. Angela McCollough typed the many drafts. Kathryn Quattrone prepared the study for publication, and Laurie Brown prepared the electronic version for CBO's World Wide Web site.

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## Summary

The pharmaceutical market has become increasingly competitive since the early 1980s, in part because of the dramatic growth of the generic drug industry. In 1996, 43 percent of the prescription drugs sold in the United States (as measured in total countable units, such as tablets and capsules) were generic. Twelve years earlier, the figure was just 19 percent. Generic drugs cost less than their brand-name, or "innovator," counterparts. Thus, they have played an important role in holding down national spending on prescription drugs from what it would otherwise have been. Considering only sales through pharmacies, the Congressional Budget Office (CBO) estimates that by substituting generic for brand-name drugs, purchasers saved roughly \$8 billion to \$10 billion in 1994 (at retail prices).

Three factors are behind the dramatic rise in sales of generic drugs that has made those savings possible. First, the Drug Price Competition and Patent Term Restoration Act of 1984—commonly known as the Hatch-Waxman Act—made it easier and less costly for manufacturers to enter the market for generic, nonantibiotic drugs. Second, by 1980, most states had passed drug-product substitution laws that allowed pharmacists to dispense a generic drug even when the prescription called for a brand-name drug. And third, some government health programs, such as Medicaid, and many private health insurance plans have actively promoted such generic substitution.

Greater sales of generic drugs reduce the returns that pharmaceutical companies earn from developing brand-name drugs. The Hatch-Waxman Act aimed to

limit that effect by extending the length of time that a new drug is under patent—and thus protected from generic competitors. Those extensions compensate for the fact that part of the time a drug is under patent it is being reviewed by the Food and Drug Administration (FDA) rather than being sold. The act tried to balance two competing objectives: encouraging competition from generic drugs while maintaining the incentive to invest in developing innovative drugs. It fell somewhat short of achieving that balance, however, in part because the act shortened the average time between the expiration of a brand-name drug's patent and the arrival of generic copies on the market (so-called generic entry) from more than three years to less than three months. More important, it also greatly increased the number of drugs that experience generic competition and, thus, contributed to an increase in the supply of generic drugs. In the end, the cost to producers of brand-name drugs from faster generic entry has roughly offset the benefit they receive from extended patent terms. Meanwhile, the greater competition from generic drugs has somewhat eroded their expected returns from research and development.

CBO estimates that those factors have lowered the average returns from marketing a new drug by roughly 12 percent (or \$27 million in 1990 dollars). In this study, "returns from marketing a new drug" refers to the present discounted value of the total stream of future profits expected from an average brand-name drug. Previous studies estimate that those profits had an average present discounted value of \$210 million to \$230 million (in 1990 dollars) for drugs introduced in the early 1980s. Those returns are

valued at the date of market introduction, after subtracting production costs but not the costs of research and development. Also, because the drugs in those studies were not eligible for the patent-term extensions provided by the Hatch-Waxman Act, those estimates do not account for the benefits of the extensions now available under the act. Thus, those figures can be considered a minimum estimate of the returns from marketing. Only part of the estimated decline in returns can be attributed to the Hatch-Waxman Act; the other factors that have boosted sales of generic drugs have played a role as well.

This study relies on a variety of data to produce its estimates, including a data set that represents about 70 percent of prescription drug sales through retail pharmacies in the United States. The various sets of data all have strengths and weaknesses, which are discussed along with the estimates they generate. In general, the empirical estimates in this study are rough rather than precise measures. They help characterize the increase in competition in the pharmaceutical market and its effects on the profits of drug manufacturers and the prices paid for prescription drugs.

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## The Effects of Managed Care on the Pharmaceutical Market

At the same time that the Hatch-Waxman Act has helped increase the supply of generic drugs, changes in the demand for pharmaceuticals have affected the frequency with which generic and brand-name drugs are prescribed and the prices paid for them. Those changes in demand were brought on by newer forms of health care delivery and financing. In particular, because of competitive pressure in the health insurance market, more private-sector health plans have adopted managed care techniques in an effort to hold down overall health spending. The net effect of those techniques on spending for prescription drugs, however, is unclear.

On the one hand, many health plans (including traditional fee-for-service plans) hold down drug costs by "managing" their outpatient prescription drug benefits—either themselves or through organizations called pharmaceutical benefit management companies

(PBMs). Those plans and PBMs use computer networks at pharmacies and electronic card systems for enrollees that allow pharmacists, before filling an enrollee's prescription, to consult a list (or formulary) of the plan's suggested drugs. Formularies typically encourage substituting brand-name drugs with generic versions, or sometimes with other, less expensive brand-name drugs. Savings result not only because of that substitution but also because many manufacturers of brand-name drugs offer discounts to health plans or PBMs in exchange for being included on their formulary. In addition, because they represent a large pool of customers, PBMs can negotiate with pharmacies over the retail prices charged for prescriptions. Since the late 1980s, those various techniques have been putting downward pressure on the prices that PBMs and health plans pay for prescription drugs sold through pharmacies.

On the other hand, health maintenance organizations (HMOs) and some other managed care plans frequently charge lower copayments for health care services—including physician visits and prescription drugs—than traditional fee-for-service plans do. Those lower copayments may lead to greater use of prescription drugs by beneficiaries. The treatment practices of HMOs may also favor more intensive use of prescription drugs, perhaps as an alternative to costlier forms of treatment. As a result, the increasing prevalence of managed care plans may have helped boost the quantity of prescription drugs sold in the United States.

For brand-name drugs still under patent (which do not yet have generic competitors), managed care techniques may have only a small effect on profits, assuming that greater use offsets the downward pressure on prices. For brand-name drugs whose patents have expired, however, profits are probably lower than they would have been without the generic substitution promoted in part by managed care plans and PBMs; that substitution has cut dramatically into the market share of those drugs. (CBO's calculation of the change in returns accounts for the full increase in generic market share since 1984, part of which is attributable to the rise in managed care techniques, but it does not measure managed care's effect on profitability through other variables, such as increases in prescription drug use and changes in pricing.)

## Pricing and Competition in the Pharmaceutical Market

Competition in the pharmaceutical market takes three forms: among brand-name drugs that are therapeutically similar, between brand-name drugs and generic substitutes, and among generic versions of the same drug. Manufacturers of brand-name drugs compete for market share primarily through advertising and the quality of their products (including efficacy and side effects), as well as through pricing. Manufacturers of generic drugs increase their market share mainly by lowering prices. (In general, companies produce either generic or brand-name drugs, not both, although some generic manufacturers are subsidiaries of brand-name manufacturers.)

### Competition Among Brand-Name Drugs

Patents do not grant complete monopoly power in the pharmaceutical industry. The reason is that companies can frequently discover and patent several different drugs that use the same basic mechanism to treat an illness. The first drug using the new mechanism to treat that illness—the breakthrough drug—usually has between one and six years on the market before a therapeutically similar patented drug (sometimes called a "me-too" drug) is introduced. Economic theory and various studies suggest that the presence of several therapeutically similar drugs limits manufacturers' ability to raise prices as much as would otherwise be the case. In addition, brand-name manufacturers are more likely to agree to give purchasers a discount if those purchasers have the option of switching to a generic or me-too competitor.

The factors that limit the number of similar but slightly differentiated brand-name drugs on the market are unclear. In some cases, perhaps, only a limited number of slightly different chemicals that target a given enzyme can be developed into drugs. Or, as one economist has suggested, the high cost of developing a drug may limit the number of similar brand-name drugs that are eventually brought to market. Companies will undertake such investment only if they be-

lieve the market is not already saturated or their drug has some quality advantage that could enable it to compete effectively and earn an adequate return. For that reason, competition among patented brand-name drugs probably results in companies' earning roughly a normal rate of return on their investment in research and development (R&D), on average.

Overall, the pharmaceutical market is not highly concentrated, but when that market is divided into narrowly defined therapeutic classes, it becomes quite concentrated. The top manufacturers of brand-name drugs, ranked by pharmaceutical sales, each account for no more than 7 percent of the entire market for prescription drugs (which totaled \$60.7 billion in 1995 at manufacturer prices). Within each therapeutic class, however, higher levels of concentration appear. In 35 of the 66 therapeutic classes that CBO examined in this study, the top three innovator drugs together constituted at least 80 percent of retail pharmacy sales in their class.

Studies of the average prices paid by pharmacies and hospitals have shown that manufacturers of brand-name drugs do compete with each other through pricing. The markups they charge over the marginal cost of producing a drug are consistent with economic models of price competition in which entry by manufacturers is limited (such as by patents). Offering discounts to some buyers may also be an important dimension of price competition for brand-name drugs. But its extent is difficult to measure because of lack of data.

### Discounts on Brand-Name Drugs

Different buyers pay different prices for brand-name prescription drugs. In theory, when companies are permitted to charge different types of purchasers different prices, those purchasers least sensitive to price will pay the most. In today's market for outpatient drugs, purchasers that have no insurance coverage for drugs, or third-party payers that do not use a formulary to manage their outpatient drug benefits, pay the highest prices for brand-name drugs.

Manufacturers offer discounts on brand-name drugs based not only on the volume purchased but also

on the buyer's ability to affect the drug's market share by using a formulary to systematically favor one brand-name drug over another for a large number of patients. Pharmacies themselves do not generally promote substitution between brand-name drugs, so they do not generally receive large discounts or rebates from manufacturers. Rather, it is the PBMs and insurers who manage benefits for drugs sold through pharmacies that promote brand-name substitution and receive discounts.

Such price discrimination, or discounting, may be an important mechanism for facilitating price competition in the pharmaceutical market. It rewards institutional purchasers that organize their patient base through formularies so as to encourage the use of less costly drugs. Prohibiting discounts, as some policymakers have called for, could decrease price competition.

Drug companies usually do not make their discounts public, but CBO was able to obtain limited information on the prices paid by different types of purchasers for prescription drugs. The prices that pharmacies pay can be seen as a proxy for the final price paid by customers who do not have a managed drug benefit or PBM to negotiate rebates from manufacturers. Based on the average invoice prices for top-selling drugs sold primarily to retail pharmacies, hospitals and clinics pay 9 percent less than retail pharmacies, on average, and HMOs pay 18 percent less. Federal facilities, such as veterans' hospitals, get an even more substantial discount—over 40 percent, on average, compared with the price paid by retail pharmacies. (Those comparisons are based only on invoice prices, so they do not account for rebates and other types of discounts that do not appear on invoices.)

Statistical analysis shows that manufacturers' discounts on brand-name drugs tend to be higher when more generic and me-too drugs are available. That analysis is based on the difference between the average price paid by pharmacies and the lowest price paid by any private purchaser in the United States (the best-price discount), as reported under the Medicaid drug rebate program. CBO found that the best-price discount for a brand-name drug was 10 to 14 percentage points greater when a generic version was available from four or more manufacturers. That analysis also

showed that as the number of brand-name manufacturers in a therapeutic class increases from one to five, the best-price discount grows by 10 percentage points. Those statistical results imply that discounts are at least partly a response to competitive market conditions and may be a sign of greater price competition in some segments of the pharmaceutical market.

## Competition Between Brand-Name and Generic Drugs

The Hatch-Waxman Act eliminated the duplicative tests that had been required for a generic drug to obtain approval from the FDA. (That change applied only to nonantibiotic drugs, since antibiotics already had an abbreviated approval process.) Before 1984, manufacturers of generic drugs were required to independently prove the safety and efficacy of their products. They were prohibited from using the unpublished test results of the original innovator drug, which were considered trade secrets of its manufacturer.<sup>1</sup> The Hatch-Waxman Act streamlined the process for approving generic drugs by requiring only that manufacturers demonstrate "bioequivalence" to an already-approved innovator drug. (Bioequivalence means that the active ingredient is absorbed at the same rate and to the same extent for the generic drug as for the innovator drug.) The tests necessary to prove bioequivalence are much less costly than those required to prove safety and efficacy.

By accelerating the approval process for a generic drug and also allowing its producer to begin clinical tests before the patent on the innovator drug had expired, the Hatch-Waxman Act reduced the average delay between patent expiration and generic entry from more than three years to less than three months for top-selling drugs. Even more important, the act increased the proportion of brand-name drugs that face generic competition once their patents expire. In 1983, only 35 percent of the top-selling drugs with expired patents (excluding antibiotics and drugs approved before 1962) had generic versions available. Today, nearly all do.

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1. This study uses the terms "brand-name" and "innovator" interchangeably.

After a drug's patent expires, generic copies quickly gain a large share of its market. CBO examined 21 brand-name prescription drugs in its retail pharmacy data set that first saw generic competition between 1991 and 1993. Within their first full calendar year after patent expiration, those drugs lost an average of 44 percent of their market (as measured by the quantity of prescriptions sold through pharmacies) to generic drugs. And the generic versions cost an average of 25 percent less than the original brand-name drugs at retail prices. That rapid growth in generic market share after patent expiration is a substantial change from the situation before the 1984 Hatch-Waxman Act. In 1983, for example, generic market share averaged just 13 percent for nonantibiotic drugs.

Various studies have found that generic entry has little effect on the prices of brand-name drugs, which continue to increase faster than inflation. CBO's analysis of the average prices that manufacturers charge for drugs distributed to retail pharmacies is consistent with that result. However, CBO's analysis of discounting shows that certain purchasers other than retail pharmacies receive steeper discounts on brand-name drugs once generic alternatives are available. Taken together, those results imply that the impact of generic entry on brand-name prices may vary considerably among different types of purchasers.

Even if brand-name prices frequently do not respond to generic competition, such competition can effectively save money because price-sensitive buyers may switch to lower-priced generic drugs. CBO estimates that in 1994, purchasers saved a total of \$8 billion to \$10 billion on prescriptions at retail pharmacies by substituting generic drugs for their brand-name counterparts. (That estimate assumes that all of the generic prescriptions dispensed in 1994 would have been filled with a higher-priced brand-name drug if a generic drug was not available.)

### **Competition Among Generic Drugs**

By making generic entry easier and less costly, the Hatch-Waxman Act helped increase the number of generic manufacturers producing the same drug. As the number of manufacturers rises, the average prescription price of a generic drug falls. CBO's analysis

shows that when one to 10 firms are manufacturing and distributing generic forms of a particular drug, the generic retail price of that drug averages about 60 percent of the brand-name price. When more than 10 manufacturers have entered the market, the average generic prescription price falls to less than half of the brand-name price.

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## **The Effects of the Hatch-Waxman Act on the Returns from Innovation**

The patent provisions in the Hatch-Waxman Act have not completely protected drug companies' profits from the dramatic rise in generic competition since 1984. Manufacturers of brand-name drugs invest an average of about \$200 million (in 1990 dollars) to bring a new drug to market, when the cost of capital and the cost of failures (investment in drugs that never make it to market) are included. Patent protection enables manufacturers to earn an adequate return on that investment. By itself, generic entry increases the rate at which sales erode after patent expiration, thus reducing the returns from marketing a new drug. Two studies have estimated that drugs introduced in the early 1980s earned returns that exceeded their capitalized costs of development by \$22 million to \$36 million, on average. (Those figures represent the present discounted value in 1990 dollars.) CBO concludes that since 1984, the expected returns from marketing a new drug have declined by about 12 percent, or \$27 million in 1990 dollars. That decline has probably not made drug development unprofitable on average, but it may have made some specific projects unprofitable.

### **Changes to the Length of Patents for Brand-Name Drugs**

Under the Hatch-Waxman Act, drugs that contain a new chemical entity never before approved by the FDA can qualify for an extension of their patent term. Those extensions, granted after the drug is approved, equal half of the time the drug spent in clinical testing (usually a total of six to eight years) plus all of the

time it spent having the FDA review its new drug application (usually about two years). Two key limitations apply. First, the extension cannot be longer than five years, and second, it cannot grant a total period of patent protection that exceeds 14 years after the drug is approved.

The 14-year limit is the main reason that Hatch-Waxman extensions now average about three years in length. Fifty-one drugs approved between 1992 and 1995 received an extension. Excluding the eight drugs that were subject to a transitional two-year cap (which applied to products already in testing when the act took effect), half of the drugs had their extensions limited by the 14-year cap.

Not all of the new drugs that are approved obtain an extension. Out of 101 drugs approved between 1992 and 1995, 38 did not apply for a Hatch-Waxman extension. Nineteen of those drugs had no patent to extend, and 15 others already had 14 years of patent protection left after obtaining FDA approval.

Besides patent-term extensions, the Hatch-Waxman Act contains other provisions that postpone generic competition. One key provision is the requirement that manufacturers wait five years after an innovator drug is approved before filing an application to sell a generic copy. That requirement benefits drugs that have no patent, or that have very little time left under patent, when they are approved. That exclusivity provision, together with the patent-term extensions, postpones generic entry by an average of 2.8 years for all drugs approved that contain a new chemical entity. Another exclusivity provision delays generic entry for three years when a new application is approved that requires clinical tests (such as for a new dosage form or over-the-counter version of an already-approved drug).

Ten years after the Hatch-Waxman Act, another piece of federal legislation—the Uruguay Round Agreements Act of 1994 (URAA)—further changed the patent terms of prescription drugs. That act altered the length of a patent for all types of inventions to 20 years from the date the application is filed rather than 17 years from the date the patent is granted. That change should have little effect on the average amount of time between market introduction and patent expiration for brand-name drugs patented after

June 8, 1995 (most of which have yet to be introduced on the market). However, many products that were already under patent by that date have benefited from the URAA, since their manufacturers can choose between the 17-year and 20-year patent terms and still be eligible for a Hatch-Waxman extension.

## The Change in Returns from Innovation

As noted earlier, the Hatch-Waxman Act greatly increased the probability that a generic copy would become available once the patent on a brand-name drug expired. It also contributed to a dramatic rise in generic market share. In addition, the act reduced the delay between patent expiration and generic entry, but that acceleration was roughly offset by patent-term extensions and exclusivity provisions that postpone generic entry.

CBO estimates that the increase in the size of the generic market since 1984—part of which is attributable to the act—has reduced the expected level of returns from marketing a brand-name drug by an average of \$27 million in 1990 dollars. That amount is roughly 12 percent of the total discounted returns from selling a brand-name drug, which previous studies have estimated at \$210 million to \$230 million in 1990 dollars for drugs introduced in the early 1980s. (Those figures represent the present discounted value of the total stream of profits from those drugs discounted to the date of market introduction, deducting manufacturing costs but not R&D costs.) That 12 percent decline does not change significantly under reasonable variations in CBO's underlying assumptions.

Other factors besides the Hatch-Waxman Act have played a role in increasing the frequency of generic competition and the average size of generic market share. For example, changes in state laws have given pharmacists more leeway to substitute generic drugs for brand-name ones. And for reasons of cost, many purchasers have put increasing emphasis on generic substitution.

Total returns from selling a brand-name prescription drug vary significantly among different drugs. As noted above, the average cost of developing

such drugs, including failures, is around \$200 million in 1990 dollars. But on average only three in 10 drugs earn that much in discounted returns (after deducting manufacturing, advertising, distribution, and other non-R&D-related costs). For most drugs, the returns from marketing do not exceed the average capitalized costs of development. As a result, for a company's average returns to exceed its average development costs, the company must discover and market a highly profitable drug from time to time.

For all drugs, on average, the increase in generic sales since 1984 has probably not reduced expected returns below the average capitalized costs of R&D. On the margin, however, it is possible that a few drugs that were barely profitable to develop before may no longer be so now.

CBO's calculation of the change in average returns since 1984 considers only increased generic entry and longer patent terms. It does not include many other changes that could either increase or decrease those returns—such as any rise in the volume of prescription drugs sold that might result as HMOs substitute drugs for more expensive forms of treatment and frequently charge lower copayments for prescription drugs and physicians' services. In addition, managed care plans and PBMs are putting downward pressure on the prices of brand-name drugs, which would tend to reduce the returns from selling them.

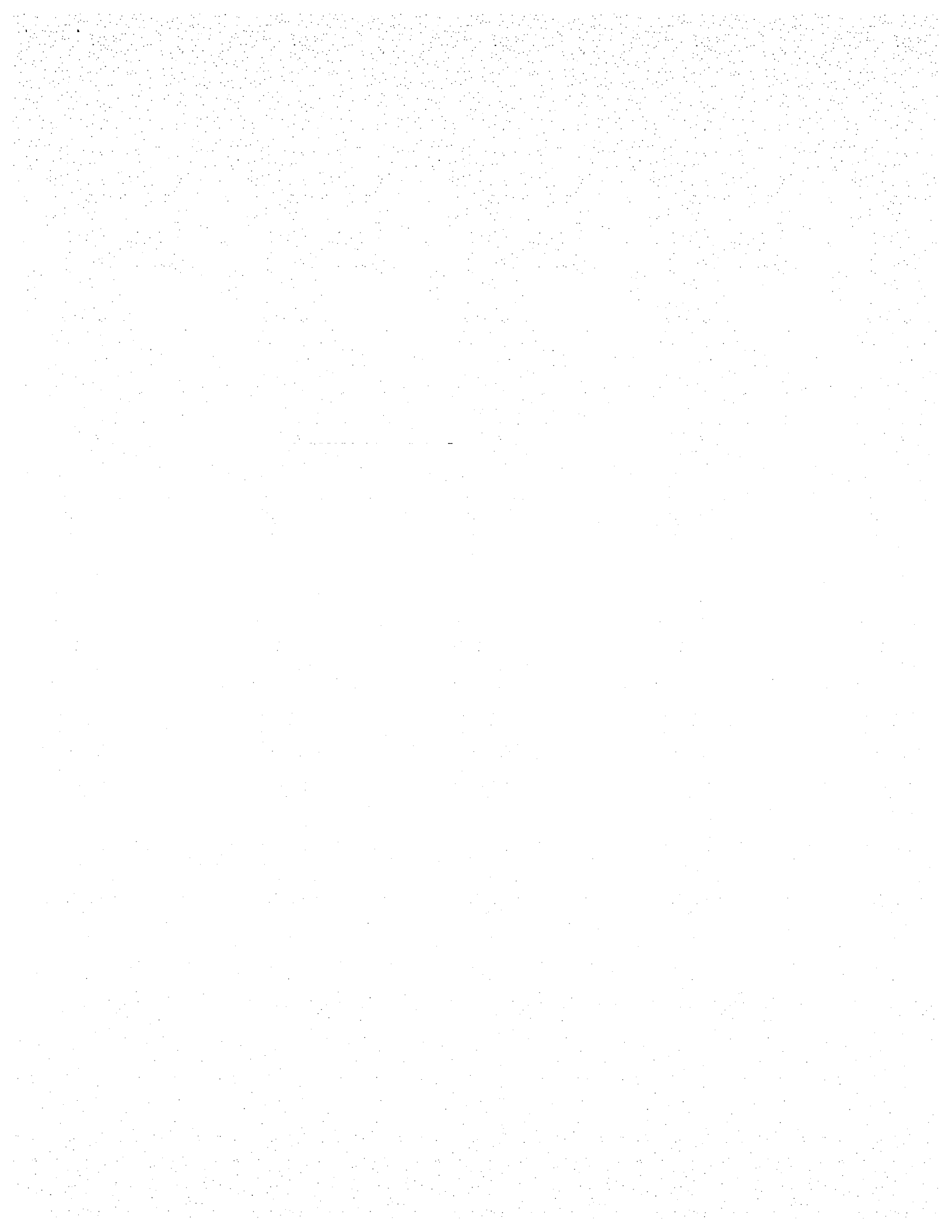
On the other side, returns could increase because drug companies' development projects may be improving as breakthroughs in the basic science of genetics are converted into ideas for new drugs. Moreover, foreign markets for prescription drugs should keep growing as the drug-approval process becomes

streamlined in Europe, and many other countries continue to strengthen patent-protection rights.

Between 1983 and 1995, investment in R&D as a percentage of pharmaceutical sales by brand-name drug companies increased from 14.7 percent to 19.4 percent. Over the same period, U.S. pharmaceutical sales by those companies rose from \$17 billion to \$57 billion (in current dollars). Overall, then, the changes that have occurred since 1984 appear to be favoring investment in drug development.

### **Effects of Changing the Hatch-Waxman Act**

Some representatives of the pharmaceutical industry have called for amending the Hatch-Waxman Act to lengthen patent-term extensions. However, doing that would not encourage innovation as much as accelerating the FDA approval process by the same amount would. The reason is that lengthening patent terms increases profits today for drugs whose patents are about to expire, but it does not have as great an impact on the incentive to invest in R&D—that is, on the expected average value of the profits from marketing a drug. CBO calculates that increasing the average patent term by one year would raise the expected value of those profits by about \$12 million in 1990 dollars. Accelerating the FDA review period by one year would boost returns by much more—about \$22 million in 1990 dollars. Thus, policies that speed up the FDA approval process without sacrificing the safety and efficacy of drugs are much more beneficial to both the pharmaceutical industry and consumers than is lengthening the patent-protection period.





# Introduction

Competition in the pharmaceutical market has changed significantly. During the past decade, many health insurance companies have contracted out the management of their prescription drug benefits to specialized pharmaceutical benefit management companies (PBMs), and enrollment in managed care health plans has increased. In the previous decade, many states repealed ant substitution laws that had prohibited pharmacists from dispensing generic drugs in place of brand-name ones, and changes in federal law sped up the approval process for generic drugs. All of those factors have contributed to a dramatic rise in sales of generic prescription drugs. Generic drugs contain the same active ingredient as a brand-name drug and enter the market after the patent on the brand-name drug has expired. Higher sales of generic drugs in turn have led to lower average prices for prescription drugs in general and a decline in returns from marketing new drugs.

The prices of brand-name prescription drugs are also facing downward pressure as many more purchasers try to negotiate discounts from manufacturers. In particular, PBMs and health maintenance organizations (HMOs) compile lists of suggested drugs (known as formularies) for their enrollees that encourage the use of generic drugs and less expensive brand-name drugs. The lure of being included on a large health plan's formulary allows those plans to leverage discounts on some brand-name drugs. According to the statistical analysis in this study, the discounts and rebates that some purchasers receive on brand-name drugs tend to be larger when more therapeutically similar brand-name drugs are available from different

manufacturers and when generic copies are available. Such discounting may be an important source of price competition among brand-name drugs. However, assessing the amount of drugs sold at a significant discount is difficult, because sufficient data do not exist.

Market competition and federal policies have affected not only drug prices but also the incentives for companies to research and develop new drugs (in other words, to innovate). This study assesses the extent to which longer patents for innovative drugs—the result of 1984 legislation—have offset the effects of increased generic competition on the returns from marketing new drugs. The Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act) established provisions for extending patent terms for innovative drugs. At the same time, it reduced the testing requirements for approval of generic drugs, allowing them to enter the market—and thus cut into the sales of brand-name drugs—more quickly.

Many other changes have occurred on both the demand and supply side of the pharmaceutical market that affect the returns from innovation. This study examines many of those changes, but it does not attempt to explicitly measure their impact. On the supply side, recent breakthroughs in genetics and biomedical research have increased the technological opportunities for developing new drugs. On the demand side, the increase in HMO enrollment and the spread of managed care techniques to all forms of health insurance have made many purchasers more sensitive to drug prices and helped hold down those prices. At the

same time, under some forms of managed care, the demand for prescription drugs may grow. Because of those diverging trends of lower prices and higher demand, it is difficult to assess the net impact of the rise in managed care on profits in the pharmaceutical industry.

## The Basis for Competition Among Drug Companies

Prescription drugs can be divided into two categories: innovator drugs and generic drugs. (See Box 1 for a glossary of various terms for prescription drugs.) Innovator drugs (which this study also refers to as brand-name drugs) generally have a patent on their chemical formulation or on their process of manufacture.<sup>1</sup> They have been approved by the Food and Drug Administration (FDA), after extensive clinical testing, under an original "new drug application" (NDA). Patented brand-name drugs that are therapeutically similar may exist, but each has a different chemical formulation. While they are still under patent protection, innovator drugs are called single-source drugs, because only the company that holds the patent produces them. After the patent has expired, generic copies of the exact chemical formulation usually become available. Then such drugs are referred to as multiple-source drugs.

Generic drugs obtain FDA approval under a shorter process than innovator drugs. They are required only to demonstrate "bioequivalence" to an innovator drug—in other words, to show that the active ingredient is released and absorbed at the same rate for the generic drug as for the corresponding innovator drug. Because they are copies rather than original formulations, generic drugs are not patentable.

Manufacturers of prescription drugs can be divided along similar lines: companies that primarily produce innovator drugs, and companies that focus on

1. In a very small number of cases, generic drugs go by a brand name rather than the drug's chemical name. Those types of drugs are an exception and represent less than 2 percent of total retail pharmacy sales (based on tabulations of the Congressional Budget Office's data set on retail pharmacy sales). In this study, "brand-name drug" means an innovator drug.

### Box 1.

#### Types of Prescription Drugs

**innovator drug:** a drug that receives a patent on its chemical formulation or manufacturing process, obtains approval from the Food and Drug Administration (FDA) after extensive testing, and is sold under a brand name.

**brand-name drug:** as used in this study, an innovator drug.

**generic drug:** a copy of an innovator drug, containing the same active ingredients, that the FDA judges to be comparable in terms of such factors as strength, quality, and therapeutic effectiveness. Generic copies may be sold after the patent on a brand-name drug has expired. Generic drugs are generally sold under their chemical name rather than under a brand name.

**breakthrough drug:** the first brand-name drug to use a particular therapeutic mechanism—that is, to use a particular method of treating a given disease.

**me-too drug:** a brand-name drug that uses the same therapeutic mechanism as a breakthrough drug and therefore competes with it directly.

**single-source drug:** a brand-name drug that is still under patent and thus is usually available from only one manufacturer.

**multiple-source drug:** a drug available in both brand-name and generic versions from a variety of manufacturers.

generic drugs. The two types of manufacturers compete very differently in the market. Producers of innovator drugs invest heavily in research and development (R&D), hoping to recoup that investment in profits from future sales while a drug is under patent and they have a monopoly on its manufacture. Producers of generic drugs do not need to duplicate the research effort of the innovator firm or invest nearly as much in getting FDA approval for their drugs. However, since those producers have neither patents nor a costly approval process to deter potential competitors, they quickly face competition from other companies pro-

ducing identical drugs. That intense competition forces generic manufacturers to charge much lower prices than the innovator firm—which, even after its patent expires, typically enjoys a market advantage based on its reputation for producing a high-quality product.

Although companies invest in research and development because they expect high returns from the future sales of their discoveries, those returns are considerably skewed. Some drugs have billion-dollar sales, whereas others bring in less than \$25 million a year. For drug manufacturers to be successful, the present value of their future profits from the sale of new products (discounted to the date the products were introduced) must exceed the capitalized cost of their original R&D investment (capitalized to the date of market introduction), including investment in drugs that never make it to the market. Patents increase the rewards for innovation by giving companies a temporary monopoly over marketing their discoveries. Although that monopoly status rewards the company with high profits, consumers pay a higher price and get less output than would be the case under competition. But that temporary monopoly status is often necessary to provide sufficient incentives for drug companies to invent the new products that benefit consumers. Without patents, many new drugs could be easily and quickly duplicated by other manufacturers, preventing the innovator firm from obtaining enough reward to justify its investment.

Patents do not grant total monopoly power to companies in the pharmaceutical industry. In many cases, several chemicals can be developed that use the same basic mechanisms to treat a disease. Since a patent applies to a specific chemical or production process, different firms can end up patenting similar, competing drugs based on the same innovative principle. In addition, drug therapies often compete with nondrug therapies. Rather than having a pure monopoly, frequently drug companies produce slightly different products—leading to a form of imperfect competition that allows an innovator firm to earn higher profits than it could in a perfectly competitive market but less than it would with a pure monopoly.

## Changes Made by the Hatch-Waxman Act

In passing the 1984 Hatch-Waxman Act, the Congress attempted to balance the interests of the generic drug industry against those of manufacturers of innovator drugs. That act contained two sets of changes. First, it eliminated the duplicative testing requirements necessary to obtain approval for a generic copy of a previously approved innovator drug. Specifically:

- o It created an abbreviated approval process for generic copies of innovator drugs. A similar abbreviated process already existed under FDA regulations for generic copies of antibiotics and of innovator drugs approved before 1962.
- o It allowed manufacturers of generic drugs to file an abbreviated new drug application and conduct clinical tests demonstrating bioequivalence with a brand-name drug before that drug's patent expires. As a result, the FDA can approve many of those applications immediately after patent expiration. That provision overturned a 1984 decision by the Court of Appeals for the Federal Circuit that clinical tests conducted by generic manufacturers before patent expiration constitute patent infringement.<sup>2</sup>
- o It also established a process to handle patent disputes between generic manufacturers and innovator firms.

Those provisions helped to increase the availability of generic drugs following patent expiration.

Second, the act established patent-term extensions for innovator drugs. Because such drugs receive patents from the Patent and Trademark Office before they receive approval from the FDA, part of their time under patent is spent in the clinical trials necessary for

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2. The case was *Roche Products, Inc. v. Bolar Pharmaceutical Company, Inc.* (733 F. 2d 858 Federal Circuit 1984). See also Alan D. Lourie, "Patent Term Restoration," *Journal of the Patent Office Society*, vol. 66, no. 10 (October 1984), pp. 526-550; and Donald O. Beers, *Generic and Innovator Drugs: A Guide to FDA Approval Requirements*, 11th ed. (Englewood Cliffs, N.J.: Aspen Publishers, 1995), pp. 4-75 to 4-77.

FDA approval. The patent extensions were intended to offset part of the patent term used up during the approval process.<sup>3</sup> Under the new procedures:

- o Manufacturers of a newly approved innovator drug that contains an active ingredient never before approved by the FDA can apply for a patent-term extension that equals the sum of all the time spent in the NDA review process plus half of the time spent in the clinical testing phase. Two limitations exist. A patent-term extension cannot exceed five years, nor can it allow the period between product approval and patent expiration to exceed 14 years. The average length of patent-term extensions granted under this provision is three years.
- o If an innovator drug is not protected by a patent, it may still benefit from certain exclusivity provisions that delay the approval or filing of an abbreviated new drug application in some cases.

By extending patents on brand-name drugs while making it easier for generic drugs to enter the market after patents expire, the Hatch-Waxman Act aimed to benefit consumers by increasing the supply of generic drugs while preserving drug companies' incentive to invest in research and development.<sup>4</sup>

Since the act took effect, pharmaceutical sales in the United States have risen dramatically. Between 1985 and 1995, sales of all prescription drugs by manufacturers grew faster than total health care spending. Valued at manufacturer prices, those sales increased from \$21.6 billion to \$60.7 billion—or from 5.7 percent to 6.9 percent of total health care expenditures in the United States.<sup>5</sup> Over the same period, spending on

drug research and development rose even faster, growing from 15.1 percent to 19.4 percent of brand-name drug sales.<sup>6</sup> Although increased competition from generic drugs by itself reduces the returns from innovation, the rise in R&D spending indicates that, all factors taken together, a strong environment still exists for investing in drug development.

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## Data Used in This Analysis

This study contains a variety of empirical estimates that help to characterize competition in the pharmaceutical market and its impact on consumers and the returns from marketing new drugs. To produce those estimates, the study draws on several data sets. The largest is a set of data on retail sales by pharmacies; it represents about 70 percent of all sales of prescription drugs through pharmacies at retail prices and covers 66 therapeutic classes of drugs. Most of the estimates in Chapter 3—which include market shares and prices of brand-name and generic drugs and an attempt to approximate the savings obtained from generic substitution—rely on that data set. The statistical analysis of discounting in the pharmaceutical industry discussed in Chapter 3 also relies on that data set, as well as on price information made available through Medicaid's drug rebate program.

The calculation in Chapter 4 of changes in the returns from marketing innovator drugs relies on another set of data: figures on the U.S. sales of 67 drugs (introduced between 1980 and 1984) during their first eight to 12 years on the market. That calculation also uses the retail pharmacy data set to estimate the market share of generic drugs immediately after the patent expiration of a brand-name drug.

Each of those data sets has its own strengths and weaknesses, which are discussed along with the empirical results. A summary of the estimates made in this study, together with the methods and data sets that were used, appears in Appendix A.

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3. See 35 U.S.C. 156(c), 98 Stat. 1598.

4. See, for example, the opening statement by Senator Orrin Hatch before the Senate Committee on Labor and Human Resources, June 28, 1984.

5. Data on total sales of prescription drugs, net of discounts and rebates and valued at the prices obtained by manufacturers, were provided by the Pharmaceutical Research and Manufacturers of America on April 28, 1997. If prescription drug sales had been valued at retail prices—the prices used for measuring national health expenditures—they would represent a higher percentage of such expenditures. Health care expenditures in the United States totaled \$376.4 billion in 1985 and \$878.8 billion in 1995; see Katherine R. Levit and others, "National Health Expenditures, 1995," *Health Care Financing Review*, vol. 18, no. 1 (Fall 1996), p. 179.

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6. Pharmaceutical Research and Manufacturers of America, *1997 Industry Profile* (Washington, D.C.: PhRMA, March 1997), p. 57.