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Report to Congressional Requesters

December 2009

BRAND-NAME PRESCRIPTION DRUG PRICING

Lack of Therapeutically Equivalent Drugs and Limited Competition May Contribute to Extraordinary Price Increases

GAO-10-201

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Highlights

Highlights of GAO-10-201, a report to congressional requesters

Why GAO Did This Study

The growing cost of brand-name prescription drugs—FDA-approved drug products that typically have patent protection—is a concern for patients, payers, and providers of health care—particularly when price increases are large and occur suddenly. A 2008 congressional hearing by the Joint Economic Committee drew attention to some small market prescription drugs that had an extraordinary price increase—a price increase of 100 percent or more at a single point in time.

GAO was asked to examine extraordinary price increases for brand-name prescription drugs. Specifically, GAO examined the: (1) frequency of extraordinary price increases for brand-name prescription drugs from 2000 to 2008, (2) characteristics of the brand-name prescription drugs that had extraordinary price increases, and (3) factors that contributed to the extraordinary price increases experienced by these brand-name prescription drugs. To determine the frequency and characteristics of the brand-name prescription drugs that experienced an extraordinary price increase, GAO reviewed drug pricing and other data from a pharmaceutical industry compendium. To illustrate the factors that may contribute to extraordinary price increases, GAO developed case studies of six brand-name prescription drugs identified from the analysis of drug pricing data. These brand-name prescription drugs were selected based on factors including price, and the percentage and number of price increases.

View GAO-10-201 or key components.
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What GAO Found

From 2000 to 2008, 416 brand-name drug products—different drug strengths and dosage forms of the same drug brands—had extraordinary price increases. These 416 brand-name drug products represented 321 different drug brands. The number of brand-name drug products that had these extraordinary price increases represents half of 1 percent of all brand-name drug products. The number of extraordinary price increases each year more than doubled from 2000 to 2008 and most of the extraordinary price increases ranged between 100 percent and 499 percent. Almost 90 percent of all brand-name drug products that had an extraordinary price increase sustained the new higher price—by either having another increase in price or remaining at the increased price.

More than half of the brand-name drug products that had extraordinary price increases were in just three therapeutic classes—central nervous system, anti-infective, and cardiovascular. These therapeutic classes include drugs used to treat conditions such as fungal or viral infections, and heart disease. About half of the extraordinary price increases were for brand-name drug products that were purchased from drug manufacturers or wholesalers, repackaged, and resold in smaller packages to health care providers such as hospitals or physicians. However, some drug repackagers serve a niche in the drug market, and therefore may have a small share of the market in a therapeutic class. The majority of all extraordinary price increases were for drugs priced less than $25 per unit; however, a full course of treatment for some of these drugs could total several thousand dollars.

Based on interviews with experts and industry representatives, a lack of therapeutically equivalent drugs—both generics and other brand-name drugs used to treat the same condition—and limited competition may contribute to extraordinary price increases. The limited availability of therapeutically equivalent drugs may result from patent protection and market exclusivity, and the size of the market for a given drug. Patent protection and market exclusivity temporarily limit competition and thereby allow a drug company to recoup research and development costs and earn a return on its financial investment. Two of six case study drugs that had extraordinary price increases were patented at the time of the extraordinary price increase. The transfer of the rights to a drug and corporate consolidations among drug companies may result in fewer drug options and contribute to extraordinary price increases, according to experts. For example, the rights to four of the case-study drugs were obtained by a new drug company, and two of these drugs had an extraordinary price increase shortly after the rights to the drugs were purchased. Finally, experts and industry representatives noted that unusual events—such as disruptions in production due to shortages of raw materials—and other factors, including manufacturing issues, may also contribute to some extraordinary price increases.

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Abbreviations

AWP	average wholesale price
DOJ	Department of Justice
FDA	Food and Drug Administration
FTC	Federal Trade Commission
NDC	national drug code

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United States Government Accountability Office
Washington, DC 20548

December 22, 2009

The Honorable Charles E. Schumer
Vice Chairman
Joint Economic Committee
United States Congress

The Honorable Amy Klobuchar
United States Senate

The growing cost of brand-name prescription drugs can be a burden on patients, payers, and providers of health care—particularly when price increases are large and occur suddenly. Controlling rising prescription drug prices helps to ensure that patients can afford medically necessary and sometimes life-saving medications, and to moderate costs for hospitals and third-party payers such as insurance plans and state and federal governments. However, a hearing held in July 2008 by the Joint Economic Committee drew attention to certain prescription drugs that recently had an extraordinary price increase—a price increase equal to 100 percent or more at a single point in time.

Drug manufacturers may consider several factors when setting prices for brand-name prescription drugs, including a drug's patent status and market exclusivity. Patents and market exclusivity may provide a limited period of protection from competition, thereby allowing a drug company to recoup research and development costs and earn a return on its financial investment. Drug manufacturers may obtain patents or patent extensions from the U.S. Patent and Trademark Office. In addition, independent of a drug product's patent status, the Federal Food, Drug, and Cosmetic Act authorizes various periods of market exclusivity for drug products.

In this report, GAO studied extraordinary price increases for brand-name prescription drugs. Specifically, we examined (1) the frequency of extraordinary price increases for brand-name prescription drugs from 2000 to 2008, (2) the characteristics of the brand-name prescription drugs that had extraordinary price increases, and (3) the factors that contributed to the extraordinary price increases experienced by these brand-name prescription drugs.

To determine the frequency of extraordinary price increases, we reviewed the average wholesale price (AWP)[1] for all brand-name prescription drugs in Thomson Reuters' Red Book,[2] and identified all extraordinary price increases—a unit price[3] increase of 100 percent or more at a single point in time—from 2000 to 2008. Red Book includes drug prices for each package size (for example, 30, 60, or 100 tablets) and dosage form (for example, tablet or injection) of a brand-name drug.[4] We report the frequency of extraordinary price increases in two ways—by drug brand (or drug label name as recorded in Red Book) and by brand-name drug product. For the drug brand frequencies, we counted an extraordinary price increase if the price of any version of a brand-name drug increased by 100 percent or more at a single point in time. For brand-name drug products, we counted each extraordinary price increase for each version—drug strength and dosage form—of the brand-name drug separately. For example, if both the 1mg and 5mg tablet versions of a drug had extraordinary price increases, we categorized this as one drug brand increase, and as two brand-name drug product increases (one for each version of the brand-name drug). The frequencies of extraordinary price increases reported include brand-name drug products that were repackaged for resale to health care providers such as hospitals or physicians.[5] To identify the characteristics of brand-

[1]In this report, drug prices are measured by the AWP, a drug pricing benchmark that is commonly used in the pharmaceutical industry. AWP is in most cases the manufacturer's suggested list price and does not necessarily reflect the actual price charged by a wholesaler.

[2]Red Book is a drug pricing compendium with information about prices and other characteristics of drug products, published by Thomson Reuters.

[3]A unit price is the (1) price per gram; (2) price per milliliter; or (3) price for each piece, such as for products sold in tablets. The unit price and other characteristics of the brand-name drugs cited in this report were those recorded in the Red Book as of December 31, 2008.

[4]The name of a drug and its manufacturer, the strength of the drug, and the package size or number of units (such as tablets) in the package are represented by a 11-digit national drug code (NDC-11).

[5]Prescription drugs may be repackaged from bulk drug purchases into smaller packages and identified by the repackaging company's unique NDC. Repackaged drugs are typically sold to health care providers, who then resell them to patients.

name drug products that had an extraordinary price increase, we used Red Book data on therapeutic class[6] and price.

To identify the factors that may contribute to extraordinary price increases, we interviewed drug policy experts; academic researchers; state and federal government officials; consumer advocates; insurance company representatives; and representatives from hospital, health insurance, and retail pharmacy associations. To illustrate the factors that may contribute to extraordinary price increases, we developed case studies of six different brand-name drugs from different drug companies identified from our analysis of Red Book data. Each brand-name drug that was active in the market as of December 31, 2008 and that had an extraordinary price increase was eligible for selection for the case study. To achieve variability in the characteristics of the brand-name drugs reviewed for the case study, our selection was based on several factors, including a drug's price, the level of the percentage increase, whether the drug had more than one extraordinary price increase between 2000 and 2008, availability of the drug from multiple sources, and permanence of the price increase. To gain an understanding of the market and other dynamics leading to the extraordinary price increase experienced by each brand-name drug in our case studies, we interviewed representatives of the companies that manufacture and distribute these brand-name drugs,[7] and obtained information about each drug company's business strategy from the companies' Web sites, annual and quarterly reports, and other resources. (See app. I for a detailed description of our scope and methodology.)

We reviewed the Red Book data file to assess its reliability. This review involved an assessment of the variables in Red Book to identify incorrect and erroneous entries or extreme outliers. We compared a random sample of the pricing data reported in Red Book with pricing data in another drug pricing compendium. Based on this review, we determined that the data used in this report were adequate for our purposes.

[6]Drugs that possess a similar chemical structure and similar therapeutic effects are grouped into therapeutic classes. Most drugs within a therapeutic class produce similar benefits, side effects, adverse reactions, and interactions with other drugs and substances.

[7]For this report, companies that manufacture and/or sell brand-name drugs are referred to as drug companies.

We conducted our work from October 2008 through December 2009 in accordance with all sections of GAO's Quality Assurance Framework that are relevant to our objectives. The framework requires that we plan and perform our engagement to obtain sufficient and appropriate evidence to meet our stated objectives and to discuss any limitations in our work. We believe that the information and data obtained, and the analysis conducted, provide a reasonable basis for any findings and conclusions in this product.

Background

Extraordinary price increases for brand-name drugs can lead to substantially higher drug spending for public and private insurance plans, hospitals, and other providers that cover prescription drugs. Patients may also face higher out-of-pocket costs and reduced access to medically necessary and sometimes life-saving drugs. In addition, extraordinary price increases for brand-name drugs may contribute to overall drug spending, which has increased an average of about 10 percent a year since 2000.[8] As reported during the Joint Economic Committee hearing, a small but growing subset of drugs have had very large and sudden price increases since 2000, raising questions about the competitiveness of the prescription drug marketplace.

Overview of Brand-name Drugs

Brand-name drugs are drug products that have received FDA approval and typically have patent protection.[9] After the patent and any applicable period of market exclusivity expires, these drugs are still considered brand-name drugs, but other drug companies may develop a generic equivalent—a similar drug that contains the same active ingredient,

[8]While prescription drug spending and prices continue to rise, the rate of growth in spending and prices for prescription drugs declined in 2007. In 2000, national spending for retail prescription drugs was $120.6 billion, compared to $227.5 billion in 2007—an average increase of 10 percent a year. In 2007, retail prescription drug spending grew 4.9 percent, and prescription drug prices increased 1.4 percent. M. Hartman, A. Martin, P. McDonnell, A. Catlin, and the National Health Expenditure Accounts Team, "National Health Spending in 2007: Slower Drug Spending Contributes to Lowest Rate of Overall Growth Since 1998," *Health Affairs*, vol. 28, no. 1 (2009). However, there is preliminary indication of higher drug price increases from 2008 to 2009.

[9]To obtain FDA approval for a drug, a drug company must conduct clinical studies showing that the drug is safe and effective for its intended use, or indication.

strength, dosage form, route of administration, and intended use.[10] The FDA reviews and approves both brand-name and generic prescription drugs.

Brand-name drugs may be supplied to health care providers from companies other than a drug's manufacturer. For example, brand-name drugs may be repackaged from large drug inventories into smaller packages, and sold by a repackaging company using a unique national drug code (NDC). Repackagers include health maintenance organizations, pharmacies, and private companies. Repackagers are required to follow FDA guidelines, such as registering annually with the FDA and labeling drugs under the same brand name. Repackagers may obtain prescription drugs from wholesalers, and sell the repackaged drugs to health care providers such as hospitals or physicians who then dispense them to patients. Proponents of repackaged drugs believe that they offer convenience to patients and may reduce medication errors.[11] However, some experts suggest that repackaging drugs may unnecessarily increase drug prices and profits. Repackagers may assign AWPs for repackaged drugs that differ from the AWP suggested by the drug's manufacturer.

Patents, Market Exclusivity, and Orphan Drugs

Patents and market exclusivity protect prescription drugs by limiting competition for a set period of time. A drug manufacturer may seek a 20-year patent on various aspects of its new chemical entity from the U.S. Patent and Trademark Office.[12] Once a patent is granted, other drug manufacturers are excluded from making, using, or selling the patented formula during the life of the patent. Companies that develop new brand-name drugs generally obtain a patent on the active ingredient used in the drug. Patents may be granted for other properties of a brand-name drug,

[10]While a brand-name drug is patented, therapeutically similar brand-name drugs not containing the same active chemical ingredient, also known as "me-too" drugs, may be developed and marketed by a drug company. Also, the FDA may not approve generic therapeutic equivalents to a brand-name drug prior to the expiration of the drug's patent unless the applicant certifies that the patent is invalid or that the generic drug does not infringe the patent.

[11]Drugs obtained directly from health care providers may eliminate travel to a pharmacy to obtain a prescribed drug. In addition, the availability of repackaged drugs from the health care provider may reduce medication errors caused by poor handwriting—such as administering the wrong medication or an incorrect dosing.

[12]*See* 35 U.S.C. §§ 111, 154.

such as its formulation and composition, and/or method of use.[13] After receiving a patent on a brand-name drug, drug companies typically seek approval from the FDA for use of the drug to treat certain indications.

Market exclusivity may be granted for approved drugs and is independent of the rights granted by a patent. The Federal Food, Drug, and Cosmetics Act authorizes various periods of market exclusivity for drug products. Generally, market exclusivities prevent the FDA from approving any application for a competing drug compound for a stated period of time. These exclusivities may relate to new chemical entities (5 years),[14] previously approved drugs with a new application that is based on new clinical studies (3 years),[15] generic drugs (180 days),[16] drugs tested for use in children (6 months),[17] and orphan drugs (7 years).[18] Market exclusivity and patent protection may run concurrently.

The Joint Economic Committee hearing in July 2008 identified certain brand-name drugs which treat rare diseases that experienced extraordinary price increases. Incentives are available for drug companies to develop innovative drugs for rare diseases (orphan drugs). In addition to the 7-year market exclusivity status, these incentives may include tax incentives of up to 50 percent of the cost of clinical research, and a waiver of FDA fees.[19] Research grants are also available through the FDA for the development of drugs used to treat rare diseases or conditions.

[13]Patents may be granted for several properties of a drug. For example, a drug company may obtain a patent on the active ingredient used in the drug. Companies may also obtain patents on the use of a drug, and a drug's formula and composition. Although a patent may be granted for a drug product long before its approval for marketing by the FDA, a company may obtain a patent term extension in certain circumstances.

[14]21 U.S.C. § 355(c)(3)(D)(ii).

[15]21 U.S.C. § 355(c)(3)(D)(iii).

[16]21 U.S.C. § 355(j)(2)(D)(iv). Exclusivity pertains to the first applicant of an abbreviated new drug application based on a previously approved brand-name drug.

[17]21 U.S.C. § 355a.

[18]21 U.S.C. § 360cc. An orphan drug is a drug that treats a rare disease or condition which is generally defined as affecting fewer than 200,000 people in the United States.

[19]The FDA is responsible for designating drugs as orphan drugs.

Drug Market Trends

According to experts, the drug industry's traditional business model is changing. In the past, large drug companies conducted research and development on several drugs, with the goal of releasing one or more "blockbuster" drugs that treat a large population and can earn billions of dollars. Recently, drug companies have increasingly focused on specialty drugs that target niche markets, or a smaller population of people with a narrow indication or medical condition. According to experts and industry representatives, the pace of consolidation among drug companies through mergers and acquisitions and transfers of drug ownership rights has increased. Fewer companies producing and marketing drugs can lead to greater market domination among certain companies and less competition. In addition, large drug companies have purchased other drug companies that specialize in manufacturing drugs targeting niche populations or drugs in similar therapeutic classes.

Setting Prescription Drug Prices

According to some economists, the usual mechanisms that enforce market discipline may not work in the same manner in the health care market. In most markets—automobiles, for example—consumers are expected to be conscious of the price of goods. If a company raises the price of its goods, consumers would likely purchase fewer goods, causing the company's revenues to decline. However, health care providers influence demand because they typically act on behalf of patients, who may remain unaware of drug costs. If the patient is insured and their medical bills are paid by a third-party payer, then demand may not be significantly influenced by changes in price to the extent that it might be in other markets. Some price restraint may be provided by pharmacy benefit managers and health plans that use drug formularies to negotiate price rebates on brand name prescription drugs.

According to industry representatives and experts, drug companies may consider several issues when setting the price of a drug. These include: (1) the perceived value of a drug relative to its competitors, such as its ease of use; (2) the unique characteristics of a drug, such as its novelty, the frequency of administration, and safety; (3) the cost of therapeutically alternative drugs and alternative therapies, such as surgery, medical devices, and existing drugs; (4) the disease treated; (5) the size and characteristics of the patient market; (6) research and development, manufacturing, and marketing costs; (7) the willingness of customers to pay for the drug; and (8) the amount of reimbursement for the drug from

third-party payers. To mitigate high drug prices some companies subsidize the price of some of their brand-name drugs through a patient assistance program to low-income uninsured or underinsured patients.[20]

Federal Oversight

While prescription drug pricing in the private sector is not subject to federal regulation, drug companies are subject to antitrust enforcement. The Federal Trade Commission (FTC) and the U.S. Department of Justice (DOJ) enforce federal antitrust laws that prohibit activities such as mergers and acquisitions that may substantially reduce competition or create a monopoly.[21] Companies are required to notify the FTC and DOJ of certain pending mergers, also known as the pre-merger notification program.[22] In addition, the FTC has authority to investigate and take action against unfair methods of competition affecting commerce, including in the drug industry.[23] Price fixing agreements between businesses, certain monopolies, and other anticompetitive conduct are subject to review and enforcement action. FTC officials indicated that the FTC has not brought a case against a drug company for charging extraordinarily high prices because such activity is not expressly prohibited by federal law, and because high drug prices in the absence of anticompetitive behavior are not per se illegal. The FTC has challenged anticompetitive patent settlements between brand-name and generic drug manufacturers. For example, FTC officials indicated that the agency has filed cases challenging "pay-to-delay" settlements in which a brand-name manufacturer shares a portion of its future profits with a potential generic competitor in exchange for an agreement to delay marketing the generic prescription drug.

[20]Underinsured patients typically face limited covered benefits and high out-of-pocket costs such as deductibles, coinsurance, or copayments.

[21]*See* 15 U.S.C. §§ 18, 1. In addition, states investigate and litigate potential violations of state as well as federal antitrust law. *See* 15 U.S.C. § 15c.

[22]15 U.S.C. § 18a. Companies involved in transactions that do not meet certain criteria are not required to notify the FTC and DOJ. The FTC and DOJ may seek an injunction to halt the acquisition or require that companies divest certain drugs if they determine that the merger is likely to be anticompetitive.

[23]*See* 15 U.S.C. § 45 (prohibiting unfair methods of competition).

Finally, drugs must be manufactured in accordance with FDA regulations called good manufacturing practices, and the FDA inspects manufacturing facilities before a drug can be approved.[24] Good manufacturing practices are designed to ensure the safety and quality of drug products and lay out minimum standards for the facilities and equipment used in manufacturing drug products. All drug manufacturers—including companies that acquire the rights to a drug from another manufacturer—are required to comply with good manufacturing practices.

More Than 400 Extraordinary Price Increases Occurred for Over 300 Drug Brands from 2000 to 2008

Between 2000 and 2008, 416 brand-name drug products representing 321 drug brands had extraordinary price increases. Most often, these extraordinary price increases ranged from 100 percent to 499 percent, but in a few cases were 1,000 percent or more.

From 2000 to 2008, 416 Extraordinary Price Increases Occurred for 321 Different Drug Brands

From 2000 to 2008, 416 brand-name drug products representing 321 drug brands had an extraordinary price increase. A number of these 321 drug brands had two or more extraordinary price increases between 2000 and 2008. The number of brand-name drug products that had these extraordinary price increases each year trended upwards, more than doubling from 2000 to 2008; however, they represent about half of 1 percent of all brand-name drug products. (See table 1 for the frequency of extraordinary price increases.) Most brand-name drug products that had an extraordinary price increase sustained the new price after the extraordinary price increase occurred.[25] For example, following the extraordinary price increase, about 87 percent of the brand-name drug

[24]*See* 21 C.F.R. part 211 (2009).

[25]About 90 percent of the extraordinary price increases—380 brand-name drug products—remained at the increased price for more than 90 days after experiencing the price increase, and more than four-fifths remained at the increased price for 180 days or more.

products remained at the increased price, or had another increase in price, and only 13 percent had a decrease in price.[26]

Table 1: Annual Frequency of Extraordinary Price Increases for Brand-name Drugs, 2000 to 2008

Category	2000	2001	2002	2003	2004	2005	2006	2007	2008	Total
Drug brands[a]										
Number of extraordinary price increases for drug brands	24	21	23	38	38	33	38	52	54	**321**
Brand-name drug products[b]										
Number of extraordinary price increases for brand-name drug products	28	27	31	48	51	39	47	74	71	**416**
Total number of all brand-name drug products on the market[c]	**11,503**	**11,503**	**11,106**	**11,413**	**11,436**	**11,979**	**12,798**	**12,895**	**13,193**	**N/A**[d]

Source: GAO analysis of average wholesale price from Red Book.

Note: Drug prices are identified and reported by a unique national drug code (NDC).

[a]A drug brand is the drug label name as recorded in Red Book.

[b]A brand-name drug product includes the same drug brand with different strengths and dosage forms. The frequencies for brand-name drug products are reported using NDC-9s.

[c]Total number of brand-name drugs recorded in the Red Book for each calendar year. As of December 31, 2008, some of these drugs were no longer active on the market.

[d]Totals for the period are not provided. Drugs that were recorded in Red Book may appear in multiple years.

A number of these brand-name drug products had more than one extraordinary price increase. For example, 21 of the 416 brand-name drug products had more than one extraordinary price increase between 2000 and 2008, and 9 of those 21 brand-name drug products had more than one extraordinary price increase in the same year. The 416 brand-name drug products were sold by 91 drug companies, and 12 of these 91 drug companies sold brand-name drug products that had more than one extraordinary price increase between 2000 and 2008. Furthermore, 4 of these 91 drug companies sold brand-name drug products that had more than one extraordinary price increase within the same year. (See app. II for a list of brand-name drugs that had an extraordinary price increase.)

[26]We compared the price of the drug immediately after the extraordinary price increase to the last recorded price of the drug as of December 31, 2008. For 361 drugs that had extraordinary price increases, the final price recorded for these drugs was the same price or higher than the price immediately after the extraordinary price increase.

While Most Extraordinary Price Increases Were Less Than 500 Percent, Some Increases Were 1,000 Percent or More

Most extraordinary price increases—for 357 of the 416 brand-name drug products with extraordinary price increases—ranged from 100 percent to 499 percent.[27] Overall, the median increase for brand name drug products was about 158 percent. However, some brand-name drug products had very large extraordinary price increases. For example, 26 brand-name drug products had extraordinary price increases greater than 1,000 percent—a tenfold increase. The largest extraordinary price increase for brand-name drug products was about 4,200 percent. (See table 2 for the frequency of extraordinary price increases by percent increase.) In addition, 7 brand-name drug products had extraordinary price increases of 500 percent or more multiple times from 2000 to 2008.

Table 2: Annual Frequency of Extraordinary Price Increases for Brand-name Drug Products by Percentage Increase in Price, 2000 to 2008

Category	2000	2001	2002	2003	2004	2005	2006	2007	2008	Total
Brand-name drug products[a]										
Total brand-name drug products with extraordinary increase in price	**28**	**27**	**31**	**48**	**51**	**39**	**47**	**74**	**71**	**416**
100-499 percent	22	15	23	43	43	37	43	64	67	**357**
500-999 percent	3	3	6	5	6	2	2	3	3	**33**
1,000-1,499 percent	0	4	0	0	2	0	1	2	1	**10**
1,500-1,999 percent	1	3	0	0	0	0	0	3	0	**7**
More than 2,000 percent	2	2	2	0	0	0	1	2	0	**9**

Source: GAO analysis of average wholesale price from Red Book.

Note: Drug prices are identified and reported by a unique NDC.

[a]A brand-name drug product includes the same drug brand with different strengths and dosage forms. The frequencies for brand-name drug products are reported using NDC-9s.

[27]The NDC-9 code represents the name of the drug and its manufacturer, and strength of the drug. The price increases for brand-name drug products that had an extraordinary price increase were reported using unit price data recorded at the NDC-9 level.

Most Brand-name Drug Products with Extraordinary Price Increases Were in Three Therapeutic Classes, Cost Less Than $25 Per Unit, or Were Repackaged

Brand-name drug products that had extraordinary price increases shared similar characteristics including therapeutic class, cost, or packaging. While extraordinary price increases occurred in 20 therapeutic classes, more than half of the increases fell into 3 therapeutic classes—central nervous system agents, anti-infective agents, and cardiovascular agents. Most extraordinary price increases were for brand-name drug products costing less than $25 per unit. Depending on the condition treated and length of treatment, the full cost of treatment for a drug could total several thousand dollars. More than half of all extraordinary price increases were for repackaged brand-name drug products.

Three Therapeutic Classes Accounted for More Than Half of the Extraordinary Price Increases

While extraordinary price increases for brand-name drug products occurred in 20 therapeutic classes, the majority of the drugs—52 percent—that had extraordinary price increases fell into 3 therapeutic classes—central nervous system, anti-infective, and cardiovascular drugs.[28]

- Central nervous system—126 brand-name drug products had extraordinary price increases. Central nervous system drugs include sedatives and antidepressants, and are typically used to treat depression or anxiety.
- Anti-infective—55 brand-name drug products had extraordinary price increases. Anti-infective drugs are used to treat infections caused by fungi, bacteria, or viruses.
- Cardiovascular drugs—35 brand-name drug products had extraordinary price increases. Cardiovascular drugs such as anti-arrhythmia agents are used to treat the heart.

The remaining 17 therapeutic classes comprised 192 brand-name drug products that had extraordinary price increases. (See table 3 for frequency of extraordinary price increases by therapeutic class.)

[28]These three therapeutic classes represented 40 percent of all brand-name drugs recorded in Red Book.

Table 3: Therapeutic Classes of Brand-name Drug Products That Had Extraordinary Price Increases, 2000 to 2008

Therapeutic class	2000	2001	2002	2003	2004	2005	2006	2007	2008	Total
Brand-name drug products[a]										
Central nervous system agents	9	6	6	16	12	13	20	24	20	**126**
Anti-infective agents	9	2	9	8	8	6	6	2	5	**55**
Cardiovascular agents	3	2	1	0	4	4	5	5	11	**35**
Other therapeutic classes	7	15	15	23	27	16	16	42	31	**192**
Total brand-name drug products that increased in price[b]	**28**	**27**	**31**	**48**	**51**	**39**	**47**	**74**	**71**	**416**

Source: GAO analysis of average wholesale price from Red Book.

Note: Drug prices are identified and reported by a unique NDC.

[a]A brand-name drug product includes the same drug brand with different strengths and dosage forms. The frequencies for brand-name drug products are reported using NDC-9s.

[b]Columns do not add up to total because eight records were not classified into a therapeutic class in Red Book.

Brand-name Drug Products Priced Less Than $25 Per Unit Accounted for Most of the Extraordinary Price Increases

Ninety-six percent of brand-name drug products that had extraordinary price increases cost less than $25 per unit prior to the price increase.[29,30] Overall, brand-name drug products that had an extraordinary price increase ranged in price from $0.01 per unit to $5,400 per unit prior to the price increase. The median price of the brand-name drug products that had an extraordinary price increase rose from $1.66 per unit before the increase to $4.70 per unit after the increase.[31] (See table 4 for the frequency of extraordinary price increases by price level.)

[29]The unit price for brand-name drug products that had an extraordinary price increase were reported using unit price data at the NDC-9 level. We report the unit price of a drug prior to the extraordinary price increase. A unit price is denoted by Thompson Reuters in Red Book as (1) price per gram; (2) price per milliliter; and (3) price for each piece, such as products sold by the item, such as tablets or capsules.

[30]Of the brand-name drug products priced less than $25 per unit prior to the extraordinary price increase, 40 percent were priced less than a dollar, 54 percent between $1 and $9.99, and 6 percent between $10 and $24.99. After the extraordinary price increase, 18 percent of these drugs were priced less than a dollar, 63 percent between $1 and $9.99, and 19 percent between $10 and $24.99.

[31]The median price after the increase is calculated using the price recorded in Red Book as of December 31, 2008, because the price of these drugs may have increased or decreased following the extraordinary price increase.

Table 4: Frequency of Extraordinary Price Increase by Price Level, by Brand-name Drug Products, 2000 to 2008

Price prior to increase	100-499 percent	500-999 percent	1,000-1,499 percent	1,500-1,999 percent	2,000 percent or more	Total
Brand-name drug products[a]						
Less than $25.00 per unit	344	31	8	7	9	**399**
$25.00 to $49.99 per unit	4	0	1	0	0	**5**
$50.00 or more per unit	9	2	1	0	0	**12**
Total number of brand-name drug products that increased in price	**357**	**33**	**10**	**7**	**9**	**416**

Source: GAO analysis of average wholesale price from Red Book.

Note: Drug prices are identified and reported by a unique NDC.

[a]A brand-name drug product includes the same drug brand with different strengths and dosage forms. The frequencies for brand-name drug products are reported using NDC-9s.

It is important to note that the unit price of a drug is only one factor in determining the cost of a full course of treatment for a medical condition. Other factors affecting cost include the total number of units prescribed and the duration of the treatment. For example, the full cost of treatment for a drug that is priced less than $25 per unit could total several thousand dollars or more. One of the drugs we reviewed that is used to treat a rare cancer cost $390 for a full course of treatment prior to the extraordinary price increase.[32] After two extraordinary price increases, the full cost of a course of treatment rose to more than $3,000.

Repackaged Drugs Accounted for More Than Half of the Extraordinary Price Increases for Brand-name Drug Products

More than half of the brand-name drug products that had extraordinary price increases were repackaged—that is, purchased from drug manufacturers or wholesalers and resold in smaller packages to health care providers such as hospitals or physicians.[33] (See table 5 for frequency of extraordinary price increases for repackaged and nonrepackaged drugs.) Almost all the extraordinary price increases for repackaged drugs appear to have originated from the company that repackaged the drug

[32]The calculation of treatment cost is based on two courses of treatment lasting up to 28 days. In some cases, patients on this drug may receive only one course of treatment. The out-of-pocket cost for a patient varies depending on insurance coverage.

[33]The price increases for drugs that had an extraordinary price increase are reported using unit price data recorded at the NDC-9 level. Less than half of all brand-name drug products recorded in Red Book were repackaged drugs.

rather than from the company that manufactured the drug.[34] Specifically, 95 percent of repackaged drugs had an extraordinary price increase without a corresponding extraordinary price increase by the drug's manufacturer for the identical nonrepackaged drug. However, some drug repackagers serve a niche in the drug market and therefore may have a small share of the market in a therapeutic class.

Table 5: Annual Frequency of Extraordinary Price Increases for Repackaged and Nonrepackaged Brand-name Drug Products, 2000 to 2008

Category	2000	2001	2002	2003	2004	2005	2006	2007	2008	Total
Brand-name drug products[a]										
Repackaged drugs that increased in price	18	10	15	27	19	29	33	31	29	**211**
Nonrepackaged drugs that increased in price	10	17	16	21	32	10	14	43	42	**205**
Total brand-name drugs that increased in price	28	27	31	48	51	39	47	74	71	**416**
Total number of all repackaged brand-name drug products on the market[b]	**3,162**	**3,496**	**3,307**	**3,648**	**3,743**	**4,333**	**5,078**	**5,423**	**5,690**	**N/A**[c]

Source: GAO analysis of average wholesale price from Red Book.

Note: Drug prices are identified and reported by a unique NDC.

[a]A brand-name drug product includes the same drug brand with different strengths and dosage forms. The frequencies for brand-name drug products are reported using NDC-9s.

[b]Total number of brand-name drugs recorded in Red Book for each calendar year. As of December 31, 2008, some of these drugs were no longer active on the market.

[c]Totals for the period are not provided. Drugs that were recorded in Red Book may appear in multiple years.

Almost one-fifth of the 91 companies that sold brand-name drug products that had extraordinary price increases were repackagers. The four companies with the greatest number of brand-name drug products that had an extraordinary price increase were repackagers—ranging from 26 to 51 brand-name drug products per repackaging company.[35] About 99

[34]To determine whether an extraordinary price increase was initiated by a drug's manufacturer or by the repackager of the drug, we matched all repackaged drugs that had an extraordinary price increase to the nonrepackaged equivalent drug brand sold by the manufacturer. To account for increases initiated by manufacturers of nonrepackaged drugs that had an increase of less than 100 percent and therefore were not captured from Red Book, we counted only repackaged drugs that had an increase of at least 200 percent for this analysis.

[35]These four repackaging companies accounted for about three quarters of all repackaged drugs that had an extraordinary price increase.

percent of repackaged drugs cost less than $25 per unit.[36] The median price of repackaged drugs that had extraordinary price increases rose from $2.14 per unit to $5.39 per unit after the increase.[37]

Lack of Therapeutically Equivalent Drugs and Limited Competition May Contribute to Extraordinary Price Increases for Brand-name Drugs

Based on interviews with experts and industry representatives, we found that a lack of therapeutically equivalent drugs—generics and other brand-name drugs used to treat the same condition—and limited competition may contribute to extraordinary price increases. According to these experts and industry representatives, the availability of few therapeutically equivalent drugs may result from patent protection and market exclusivity, and the limited size of the market for a given drug. Experts noted that the transfer of drug rights and corporate consolidations may limit competition among drug companies, resulting in few drug options. The experts and industry representatives also noted that unusual events—such as disruptions in production due to shortages of raw materials—and other factors may also contribute to some extraordinary price increases.

Limited Availability of Therapeutic Equivalents: Experts we interviewed said that drugs without therapeutic equivalents—in some cases due to patents or a limited market size—may be more likely to have an extraordinary price increase.[38] Experts and industry representatives also reported that competition within a therapeutic class of drugs may be limited by (1) patents for a new drug, such as patents for the active ingredient; (2) patents for existing drugs that have been modified by, for example, changing a drug's active ingredient, strength, or delivery mechanism;[39] and (3) market exclusivity protections. Patents and market exclusivity may limit the entry of other prescription drugs into the market. An expert also noted that no single factor leads to extraordinary price

[36]As discussed earlier, the price of a course of treatment depends on the nature of the condition treated, how long the condition should be treated, and the number of units of a drug used to treat the condition.

[37]The median price after the increase is calculated using the price recorded in Red Book as of December 31, 2008, because the price of these drugs may have increased or decreased following the extraordinary price increase.

[38]For this report, we use the term therapeutically equivalent drugs to include both generic versions of a brand-name drug and other brand-name drugs used to treat the same condition. Generally, according to the FDA a therapeutically equivalent drug refers only to the generic version of a brand-name drug.

[39]Drug companies may also receive a patent for minor alterations to the formulation of a drug such as reversing only the structure of the chemical used in the active ingredient.

increases, rather a combination of several factors likely contributes to these extraordinary price increases.

Two of our six case study drugs[40] had patent protection at the time of the extraordinary price increase. (See app. III for a summary of the characteristics of the case study drugs.) One drug had a method-of-use patent and was the only FDA-approved drug available to treat an acute illness affecting infants and young children. The other drug was under patent at the time of its extraordinary price increase, and was sold by a licensed repackager that purchased the drug from wholesalers.

In addition, experts and industry representatives we interviewed reported that small market drugs, such as orphan drugs or drugs for rare diseases, may lack therapeutically equivalent drugs, and thus may be prone to extraordinary price increases. When the target patient population or market for a drug is relatively small, there may be little financial incentive for potential competitors to enter the market and offer competing drugs. Two of the drugs we examined in our case studies treat rare diseases. These drugs did not have generic equivalents at the time of their extraordinary price increases; however, the drug companies reported the availability of other drugs that treat similar conditions. Both drugs had more than one extraordinary price increase—one of the drugs had two price increases that were each more than 1,000 percent, and the other had extraordinary price increases in 2 consecutive years.

Representatives of the manufacturer for one of these drugs reported that their company's business model is based almost solely on sales from the drug that had the extraordinary price increases. This drug is currently approved for several dozen indications, and the company is funding research on other uses for the drug. The second company reported that its business model is structured around facilitating the development of drug products for rare diseases. The company provides financial support to researchers developing new drugs for rare diseases and obtains the rights to the drugs created by these researchers. The company considered their financial support for developing other rare disease drugs when determining the price of their drug. Furthermore, a representative of this company stated that it had obtained other drugs that were discontinued by a prior owner and then reintroduced the drugs onto the market. Both of these drug companies market specialized drugs that treat rare diseases.

[40]See Apps. I and III for more details on the case study drugs.

Transfer of Drug Rights, Corporate Consolidations, Mergers, and Acquisitions: Experts and industry representatives we interviewed reported that transfers of drug ownership rights and consolidations among drug companies have increased.[41] These transfers and consolidations may limit competition as companies that may offer competing prescription drugs in a therapeutic class merge or sell their rights to a drug, potentially leading to extraordinary price increases for drugs. Fewer drug companies competing in a therapeutic class may lead to fewer prescription drugs being developed and sold within that class. Industry representatives and experts reported that larger drug companies are acquiring drugs from smaller drug companies that conduct drug research. Notwithstanding potential FTC or DOJ review, drug companies may still acquire competitors that offer similar drugs, potentially leading to market domination in a therapeutic class.[42] The rights to four of our case study drugs were obtained by a new drug company, and two of these drugs had an extraordinary price increase shortly after the rights to the drugs were purchased.

Unusual Events: Extraordinary price increases were also attributed by industry representatives and experts to the occurrence of unusual events, such as disruptions in the production of a drug due to shortages of necessary raw materials or the added costs to renovate outdated drug production plants. For example, a drug in our case study was purchased from a drug company that was suspending production of the drug. The company that purchased this drug reported investing millions of dollars transferring and upgrading the manufacturing equipment, processes, and testing methods required to make the drug. The drug's manufacturer attributed the first of two extraordinary price increases to compensating for the drug's production expenses and other costs. Prior to the company's purchase of the drug, it was sold only in limited quantities through a patient advocacy group.[43] Another drug from our case study was purchased by a company that spent several years trying to identify a technical partner capable of processing the drug's active ingredient, which was difficult to manufacture because of its cytotoxic nature and the

[41]A drug's patent(s) may be acquired through grant, sale, or other type of transfer.

[42]Two companies in our case studies have acquired another drug company and its drug products. Also, some of the companies in our case studies have acquired the rights to drugs manufactured by other companies.

[43]According to the company, the previous owner sold the rights to the drug because of difficulty manufacturing the drug and its financial losses from low sales of the drug.

limited quantity of drugs produced. The company's representative stated that due to the unique challenges of producing the active ingredient of the drug, two companies were involved in manufacturing and packaging the drug. As a result of changes made in manufacturing the drug, the company reported investing several million dollars upgrading its manufacturing equipment and processes in order to meet updated FDA regulations.[44] This company considered its investment to produce a stable supply of the drug when pricing the product.

Other Factors: Representatives of the drug companies we reviewed for our case studies reported that they considered other factors when determining the price of their drugs. For example, one expert noted that extraordinary price increases may occur because a drug manufacturer updates the price of a drug after obtaining new information about certain demand and supply factors affecting the drug. Three of the drug companies reported that their products were difficult to manufacture. These companies employ third-party manufacturers that produce the drugs. One of these companies said that its drug was very toxic, and since its manufacturing equipment was used to make other drug products, the equipment must be decontaminated after each batch is produced. These drug companies factored in these additional costs when they raised the price of their products.

Some of the drug companies we reviewed revised the price of their brand-name drugs to bring them in line with the prices of what they regarded as similar drugs. One company reviewed the estimated annual cost of several orphan drugs when determining the price for its drug, which treats a rare disease. Three companies reviewed various drug products and priced their drugs in line with these drugs. This pricing strategy led, in part, to these drugs experiencing an extraordinary price increase. An official from one of these companies reported that the drug was underpriced, and the company increased the price of the drug based on the prices of competing drug products used for similar medical conditions. Some of the drug companies considered the financial solvency of their drug product and company, and their fiduciary responsibility to their shareholders when determining the price of their drug.

[44]These changes included upgrades to manufacturing equipment used to detect and reduce impurities and revalidation of the entire manufacturing process.

In some cases, representatives of drug companies cited the quantity of free or low-cost drugs donated through their patient assistance program and the level of rebates paid to the Medicaid program as factors that they considered when raising the price of their brand-name drugs.[45] Two drug companies said that the level of rebates paid to the Medicaid program was a factor for their drugs' extraordinary price increases.[46] The companies reported that they charged a higher retail price for their drugs, in part, to account for the large financial outlays to patient assistance and government programs. One company said that Medicaid beneficiaries represent a large portion of the patient population that uses their drug product. This company's representatives stated that over half of its drug sales were targeted to their patient assistance program for low-income, underinsured, or uninsured individuals or were reimbursed under Medicaid and therefore subject to rebates. These companies reported that they offered patient assistance programs that provide a large volume of free prescription drugs to patients who meet established criteria. The programs also provide financial assistance to insured patients who face financial hardship from paying copayments or coinsurance.

Expert Comments

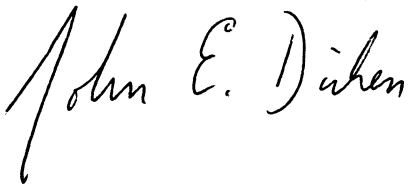
We provided a draft of this report to drug policy experts, who provided technical comments that we incorporated as appropriate.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to other interested parties. We will also provide copies to others upon request. In addition, the report is available at no charge on the GAO Web site at http://www.gao.gov.

[45]Drug manufacturers that wish to have their drugs available for Medicaid enrollees are required to enter into rebate agreements with the federal government on behalf of states. These rebate agreements are intended to ensure that Medicaid pays the lowest price that the manufacturer offers for the drug. Rebates are computed and paid by the drug manufacturer each quarter based on drug utilization data supplied by Medicaid.

[46]The basic Medicaid rebate is 15.1 percent of a drug's average manufacturer price (AMP) per unit, or the difference between AMP and a drug's best price, whichever is greater. If a brand-name drug's AMP rises faster than inflation, as measured by the consumer price index, an additional unit rebate may be calculated. See U.S.C. § 1396r-8(c). The two companies indicated that due to the application of additional unit rebates caused by increases in their drug prices, their Medicaid rebates actually exceeded their drugs' AMPs.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or at dickenj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs can be found on the last page of this report. GAO staff members who made major contributions to this report are listed in appendix IV.



John E. Dicken
Director, Health Care

Appendix I: Scope and Methodology

In this report we address the following objectives: (1) the frequency of extraordinary price increases for brand-name prescription[1] drugs from 2000 to 2008, (2) the characteristics of the brand-name drugs that had extraordinary price increases, and (3) the factors that contributed to the extraordinary price increases experienced by these brand-name drugs.

To determine the frequency of extraordinary price increases, we reviewed the average wholesale price (AWP)[2] for all brand-name drugs in Thomson Reuters' Red Book,[3] and identified all extraordinary price increases—a unit price increase[4] equal to 100 percent or more at a single point in time from 2000 to 2008. We calculated the percent change in unit AWP recorded in the Red Book for each 11-digit national drug code (NDC-11).[5] For example, where a NDC-11 had three unit prices reported in Red Book from 2000 to 2008 (unit price at point 1, unit price at point 2, and unit price at point 3), two data records were created. One record contained the percent change in unit price from point 1 to point 2, and the other record contained the percent change from point 2 to point 3. We identified extraordinary price increases by selecting only records (NDC-11s) with a percent change of 100 percent or more.

Drugs sold in different package sizes—for example, 30, 60, or 100 tablets—have different NDC-11 codes. Each NDC-11 record captures the label name of the drug which includes the dosage form of the drug. Because a brand-name drug may have several NDC-11 codes for different package sizes, we

[1]Unless otherwise noted, in this report "brand-name drugs" refers to brand-name prescription drugs.

[2]In this report, drug prices are measured by AWP. AWP is in most cases the manufacturer's suggested price and does not necessarily reflect the actual price charged by a wholesaler. AWP is a drug pricing benchmark that is commonly used in the pharmaceutical industry.

[3]Red Book is a proprietary database containing drug pricing and other drug-related information published by Thomson Reuters. Drug manufacturers and companies report the price of their drug—in AWP or other pricing benchmarks—to Thomson Reuters for publication in the Red Book. In some cases, Red Book calculates AWP values using other pricing benchmarks.

[4]A unit price is the (1) price per gram; (2) price per milliliter; or (3) price for each piece, such as for products sold in tablets. The unit price and other characteristics of the brand-name drugs cited in this report were those recorded in Red Book as of December 31, 2008.

[5]Drug prices are identified and reported in Red Book by an 11-digit number called the NDC-11 code. The NDC-11 code represents the name of the drug and its manufacturer, the strength of the drug, and the package size—or number of units (such as tablets) in the package.

identified the number of brand-name drug products that had an extraordinary price increase by their NDC-9 code, which represents the manufacturer and drug name, and strength. Where more than one package size of the same brand-name drug had an extraordinary price increase, we selected the package size with the highest extraordinary price increase.[6] We counted an NDC-9 with different package sizes that had an extraordinary price increase on the same date only once. In this report, we use three terms to refer to the brand-name prescription drugs recorded in the Red Book. Drug brand refers to the label name of a brand-name prescription drug; brand-name drug product refers to the different products of the same drug brand. Otherwise we use the term brand-name drug or drug when we do not need to distinguish between drug brand and brand-name drug product. We report the frequency of brand-name drugs that had extraordinary price increases by (1) drug brand (drug label name as recorded in Red Book), and (2) brand-name drug product (NDC-9 code). The frequencies of extraordinary price increases reported by brand-name drug products (NDC-9) include the same drug brand sold in different strengths and dosage forms (e.g., a 1mg or a 5mg tablet). The frequency of extraordinary price increases reported includes brand-name drug products that were repackaged by a distributor for resale to health care providers.[7,8] (See app. II for a list of the brand-name drugs that had extraordinary price increases.) To identify the characteristics of brand-name drugs that had an extraordinary price increase, we used Red Book data on therapeutic class and price.

[6]As a result, for these brand-name drugs we do not capture this variation in extraordinary price increase by package size.

[7]Prescription drugs may be repackaged from bulk drug purchases into individual dose packages and identified by the repackaging company's unique NDC. Repackaged drugs may be sold to health care providers, who then dispense them to their patients.

[8]To determine whether an extraordinary price increase was initiated by a drug's manufacturer or by the repackager of the drug, we matched all repackaged drugs that had an extraordinary price increase to the nonrepackaged equivalent drug brand sold by the manufacturer. Whenever a match between the repackaged and nonrepackaged drug was not found, we concluded that the repackaged drug had an extraordinary price increase without a corresponding increase by the drug's manufacturer for the identical nonrepackaged drug. To account for increases initiated by manufacturers of nonrepackaged drugs that had an increase of less than 100 percent and therefore were not captured from Red Book, we counted only repackaged drugs that had an increase of at least 200 percent for this analysis.

To identify the factors that may contribute to extraordinary price increases we interviewed drug policy experts; academic researchers; state and federal government officials; consumer advocates; insurance company representatives; and hospital, health insurance, and retail pharmacy associations representatives. To illustrate the factors that may contribute to extraordinary price increases, we developed case studies of six drugs from different companies identified from our analysis of Red Book data. Each brand-name drug (NDC-11) was eligible for inclusion as a case study if it was active in the market as of December 31, 2008, and had an extraordinary price increase. To achieve variability in the characteristics of the drugs reviewed for the case study, selection was based on several factors, such as the (1) unit price, (2) percentage increase in price, (3) year of increase, (4) number of increases, (5) availability from multiple sources, (6) orphan drug status, and (7) permanence of the price increase.

We also interviewed representatives of the companies that manufactured and distributed the case study drugs about the market dynamics leading to the drugs' extraordinary price increases. We gathered information on: (1) the characteristics of each drug, such as its patent and market exclusivity status, indication, volume, and utilization; (2) corporate business and marketing strategy for each drug; (3) factors that influenced the extraordinary price increase; and (4) agreements with the makers of drugs in the same therapeutic class. Some information provided by the representatives during these interviews is considered proprietary. As a result, the names of the participating companies and brand-name drugs are not identified. (See app. III for information on each of the drugs from the case studies.) Information was also obtained from drug companies' Web sites, annual and quarterly reports, and other resources.

We systematically reviewed Red Book to assess its reliability. The review involved an assessment of the frequencies of all numeric and date variables in Red Book to identify incorrect and erroneous entries or extreme outliers.[9] We compared a sample of the pricing data for brand-name drugs that had extraordinary price increases reported in Red Book with pricing data contained in another drug pricing compendium and found a high degree of concurrence between the prices recorded in both

[9]We deleted records from our data files in a few cases where a drug company provided evidence showing that an extraordinary price increase had not occurred. In one case, data entry errors recording an incorrect package size was the reason for an extraordinary price increase. We also deleted one record that showed an extraordinary price increase after December 31, 2008.

data sources. Based on this review, we determined that the data used in our report were adequate for our purposes. We conducted our work from October 2008 through December 2009 in accordance with all sections of GAO's Quality Assurance Framework that are relevant to our objectives. The framework requires that we plan and perform our engagement to obtain sufficient and appropriate evidence to meet our stated objectives and to discuss any limitations in our work. We believe that the information and data obtained, and the analysis conducted, provide a reasonable basis for any findings and conclusions in this product.

Appendix II: Brand-name Prescription Drugs with an Extraordinary Price Increase, 2000 to 2008

Using Thomson Reuters' Red Book,[1] we calculated the change in average wholesale price (AWP) and identified all unit price increases equal to 100 percent or more at a single point in time from 2000 to 2008. (See app. I for more information.) Based on this analysis, we identified the label names of drugs that had extraordinary price increases by their NDC-9 code.[2] AWP records in Red Book are reported by the drug manufacturer and published in Red Book. In some cases, when drug manufacturers do not report AWP, Red Book calculates AWP from other drug pricing benchmarks provided by drug manufacturers. GAO did not audit the drug pricing information reported to Red Book by drug manufacturers nor the calculations performed by Red Book to fill nonreported AWP data. Some of the drugs on this list were repackaged, or nonrepackaged, while other drugs were both repackaged and nonrepackaged. In a few cases, drugs were removed from the list because changes in the recorded package size led to errors in the calculated change in unit prices. See table 6 below for the label names of brand-name prescription drugs that had an extraordinary price increase between 2000 and 2008.

[1]Red Book is a database containing drug pricing and other drug-related information published by Thomson Reuters.

[2]The NDC-9 code represents the name of the drug and its manufacturer, and strength of the drug.

Table 6: Repackaged Brand-name Drug Products that Had an Extraordinary Price Increase, 2000 to 2008

Repackaged brand name drugs (Pricing for these drugs is typically set by the repackager and not the drug's manufacturer)		
Name and strength of drug	**Name and strength of drug**	**Name and strength of drug**
Abilify Tab 5MG	Floxin Tab 300MG	Provera Tab 2.5MG
Actos Tab 15MG	Floxin Tab 400MG	Prozac Cap 20MG
Actos Tab 30MG	Fulvicin P/G Tab 330MG	Restoril Cap 30MG
Adderall Tab 5MG	Glyset Tab 25MG	Risperdal Tab 1MG
Ambien Tab 5MG	Ionamin Cap 15MG	Risperdal Tab 0.5MG
Ambien Tab 10MG	Ismo Tab 20MG	Risperdal Tab 0.25MG
Amoxil Cap 250MG	Lamictal Tab 25MG	Robinul Inj 0.2MG/ML
Amoxil Cap 500MG	Lamictal Tab 200MG	Septra DS Tab
Anaprox Tab 275MG	Lanoxin Tab 0.25MG	Seroquel Tab 25MG
Anaprox-DS Tab 550MG	Levaquin Tab 250MG	Seroquel Tab 100MG
Ansaid Tab 100MG	Levaquin Tab 500MG	Seroquel Tab 50MG
Antabuse Tab 250MG	Levaquin Leva-pak 750MG	Silvadene Cre 1%
Aricept Tab 10MG	Levoxyl Tab 0.088MG	Singulair Tab 10MG
Arthrotec Tab 75MG-0.2MG	Lidoderm Patch 5%	Skelaxin Tab 400MG
Avandia Tab 4MG	Lipitor Tab 80MG	Skelaxin Tab 800MG
Axert Tab 12.5MG	Locoid Cre 0.1%	Soma Compound w/Code Tab
Bayhep B Inj	Lomotil Tab 0.025MG-2.5MG	Sumycin Cap 250MG
Bextra Tab 20MG	Lotensin Tab 40MG	Synalgos-DC Cap
Biaxin Sus 250MG/5ML	Lunesta Tab 1MG	Synthroid Tab 0.1MG
Bontril Cap ER 105MG	Lunesta Tab 2MG	Synthroid Tab 0.088MG
Bontril Slow Cap 105MG	Lunesta Tab 3MG	Terazol 3 Vag Cre 0.8%
Brevital Sodium Inj 500MG	Lyrica Cap 100MG	Tigan Inj 100MG/ML
Bromfed Tab	Lyrica Cap 200MG	Tobradex Opth Sus
Cataflam Tab 50MG	Lyrica Cap 50MG	Tobrex Opth Sol 0.3%
Ceftin Tab 125MG	Lyrica Cap 75MG	Topamax Tab 25MG
Ceftin Tab 250MG	Marcaine Inj 0.5%	Topamax Tab 100MG
Ceftin Tab 500MG	Maxitrol Opth Sus	Toprol XL Tab 50MG
Celebrex Cap 200MG	Mephyton Tab 5MG	Transderm Scop Patch
Celebrex Cap 100MG	Methergine Tab 0.2MG	Ultram Tab 50MG
Cerumenex Otic Sol 10%	Mevacor Tab 20MG	Ultram ER Tab ER 200MG
Cipro Tab 500MG	Miacalcin Spr 200iu/Act	Valium Tab 5MG
Cipro Tab 750MG	Miralax Pwd for Soln	Valtrex Tab 1GM
Claritin Tab 10MG	Mobic Tab 15MG	Vicodin Tab
Codiclear DH Syr	Mobic Tab 7.5MG	Vicoprofen Tab

Repackaged brand name drugs (Pricing for these drugs is typically set by the repackager and not the drug's manufacturer)		
Name and strength of drug	**Name and strength of drug**	**Name and strength of drug**
Combivir Tab	Motrin Tab 800MG	Vioxx Tab 25MG
Compazine Sup 25MG	Niferex-150 Forte Cap	Viracept Tab 250MG
Compazine Tab 10MG	Nitrolingu Spr 0.4/Spray	Viramune Tab 200MG
Coumadin Tab 2.5MG	Nitrostat SL Tab 0.4MG	Vivelle-Dot 0.1MG/24hrs
Cutivate Cre 0.05%	Norco Tab	Voltaren Tab 75MG
Cytotec Tab 200mcg	Norflex Tab 100MG	Zebeta Tab 5mg
Dalmane Cap 30MG	Norvasc Tab 10MG	Ziagen Tab 300MG
Daypro Tab 600MG	Norvir Cap 100MG	Zithromax Tab 250MG
Depo-Estradio Inj 5MG/ML	Ovral Tab	Zithromax Z-Pak Tab 250MG
Desowen CRE 0.05%	Paxil CR Tab 25MG	Zocor Tab 10MG
Diovan Tab 160MG	Paxil CR Tab 12.5MG	Zocor Tab 20MG
Dovonex Cre 0.005%	Paxil CR Tab 37.5MG	Zocor Tab 40MG
Dovonex Oin 0.005%	Pediazole Sus	Zoloft Tab 25MG
Duricef Cap 500MG	Pepcid Tab 40MG	Zyprexa Tab 10MG
E.E.S.-400 Film Tab 400MG	Peridex Liq 0.12%	Zyprexa Tab 2.5MG
Econopred Plus OP Sus 1%	Phenergan Tab 25MG	Zyprexa Tab 7.5MG
Effexor Tab 100MG	Phenergan Sup 12.5MG	Zyprexa Tab 5MG
Effexor XR Cap ER 75MG	Phenergan Sup 50MG	
Effexor-XR Cap 75MG	Phenhist Expectorant Liq	
Effexor-XR Cap 37.5MG	Phoslo Tab 667MG	
Eryc Cap 250MG	Plendil Tab 5MG	
Estrace Tab 1MG	Plendil Tab 10MG	
Flexeril Tab 5MG	Ponstel Cap 250MG	
Flovent Inh 0.22/Act	Premarin Tab 0.625MG	
Floxin Tab 200MG	Prilosec Cap 20MG	

Source: GAO analysis of Red Book data.

Note: Following the extraordinary price increase, some drugs may have become discontinued or transferred from one manufacturer to another. In some cases, an extraordinary price increase for a drug may not be attributed to the manufacturer that currently owns the drug.

Table 7: Nonrepackaged Brand-name Drug Products that Had an Extraordinary Price Increase, 2000 to 2008

Nonrepackaged brand name drugs		
Name and strength of drug	**Name and strength of drug**	**Name and strength of drug**
Adderall Tab 5MG	Hectorol Cap 2.5MCG	Omnipaque 300 Inj 64.7%
Ala-Scalp HP Lot 2%	Hectorol Liq Cap 2.5MCG	Oncoscint CR/OV Inj 1MG
Amytal Sodium Inj 0.5GM	Hep-Lock Inj 10U/ML	Optison IV Susp
Ancobon Cap 250MG	Histatrol Inj 0.275/ML	Oracit Sol
Ancobon Cap 500MG	Histatrol Soln 2.75MG/ML	Ortho-Prefest Tab
Bensal HP 60MG-30MG/1GM	Histussin HC 2.5-5-1/5	Pamelor Cap 10MG
Bontril PDM Tab 35MG	Hypaque-76 Inj	Pamelor Cap 25MG
Bontril Slow Cap ER 105MG	Inderal LA Cap 60MG	Panhematin IV 313MG
Brethine Inj 1MG/ML	Inderal LA Cap 80MG	Phrenilin Forte 50-650
Brevital Sodium 2.5GM	Inderal LA Cap 120MG	Prefest Tab
Brevital Sodium Inj 2.5GM	Inderal LA Cap 160MG	Prevacid SoluTab 15MG
Buprenex Inj 0.3MG/ML	Inderal LA Cap ER 120MG	Prevacid SoluTab 30MG
Capital w/Codeine Sus	Inderal LA Cap ER 160MG	Prevpac Kit
Cefazolin 1GM/50ML	Inderal LA Cap ER 60MG	Promit IV 150MG/1ML
Cefotan Inj 1GM	Inderal LA Cap ER 80MG	Quelicin Inj 100MG/ML
Cefotan Inj 2GM	Indocin IV Pwd for Soln	Quelicin Inj 20MG/1ML
Cellcept Cap 250MG	Indocin Susp 25MG/5ML	Regonol Inj Soln 5MG/1ML
Cenolate Inj 500MG/ML	Infumorph 200 Inj	Rejuvesol Inj
Ceretec Kit	Infumorph 500 Inj	Rescon-MX Tab ER
Cogentin Inj Soln 1MG/1ML	Inversine Tab 2.5MG	Robaxin Inj Soln 100MG/ML
Cognex Cap 10MG	Iodopen Inj 118MCG/1ML	Robinul Inj Soln 0.2MG/ML
Cognex Cap 20MG	Isuprel Inj 0.2MG/ML	Roxicet Tab 500MG-5MG
Cognex Cap 30MG	Kenalog Spr 0.147/GM	Ryna-12 S Sus
Cognex Cap 40MG	Lacrisert Opth Dev 5MG	Seconal Sodium Cap 100MG
Combipatch 0.05MG-0.14MG	Levo-Dromoran Tab 2MG	Septra DS Tab
Combipatch 0.05MG-0.25MG	Liposyn III Inj 10%	Sucraid Sol 8500 IU/ML
Cortrosyn Inj 0.25MG	Liposyn III Inj 20%	Sulfoxyl Regular Lot
Cosmegen IV 0.5MG	Liposyn III IV Emul 10%	Sulfoxyl Strong Lot
Cuprimine Cap 250MG	Liposyn III IV Emul 20%	Sumycin Tab 250MG
Cystadane 1GM/1Scoopful	Locoid Oin 0.1%	Sumycin Tab 500MG
D.H.E. 45 Inj 1MG/ML	Locoid Sol 0.1%	Syprine Cap 250MG
Dantrium IV 20MG	Locoid Crm 0.1%	Syrex Inj 0.9%
Demser Cap 250MG	Locoid Lipocrem 0.1%	Tenormin Inj 0.5MG/ML
Dermagraft Sheet	Lymphazurin Inj 10MG/ML	Testopel Pellets 75MG

Nonrepackaged brand name drugs		
Name and strength of drug	**Name and strength of drug**	**Name and strength of drug**
Digoxin Soln 0.05MG/1ML	Matulane Cap 50MG	Tetanus To Inj 10LF/0.5ML
Diprivan IV Emul 10MG/1ML	Maxipime Inj 1GM	Trasylol Inj 10,000kiu/ML
Diuril Sodium IV 0.5GM	Maxipime Inj 2GM	Tricitrasol Cnt 46.7%
Dopram IV Soln 20MG/1ML	MD-Gastroview 66%-10%	Tridesilon Cre 0.05%
Duramorph Inj 0.5MG/1ML	Mephyton Tab 5MG	Tridesilon Oin 0.05%
Duramorph Inj 1MG/1ML	Methylin Chew Tab 10MG	Trisenox IV Soln 1MG/1ML
Duramorph PF Inj 1MG/ML	Methylin Chew Tab 2.5MG	Tuinal Cap 50MG
Dynex Tab	Methylin Chew Tab 5MG	Uretron D/S Tab
Edecrin Sodium Inj 50MG	Methylin Soln 10MG/5ML	Utira-C Tab
Edecrin Tab 25MG	Methylin Soln 5MG/5ML	Virazole Sus 6GM
Elliotts B Inj	Minocin Cap 50MG	Vitrasert Imp 4.5MG
Ergotrate Tab 0.2MG	Minocin Cap 100MG	Westhroid Tab 130MG
Erythrocin Lac Inj 500MG	Muri-Lube Oil	Westhroid Tab 32.5MG
EtheDent Chew Tab 0.25MG	Mustargen IV Pwd for Soln	Westhroid Tab 65MG
EtheDent Chew Tab 0.5MG	Nascobal Gel 500mcg/0.1ML	
EtheDent Chew Tab 1MG	Nembutal Sod Inj 50MG/ML	
Fareston Tab 60MG	Nicomide Tab	
FazaClo Dis Tab 100MG	Nitropress Inj 50MG	
FazaClo Dis Tab 25MG	Norvir Cap 100MG	
Formalyde-10 Spr 10%	Norvir Sol 80MG/ML	
Fosrenol Chew Tab 500MG	Novahistine DH 7.25-2-5/5	
Geref Inj 50mcg	NovaPlus Diprivan IV 10/1	
H.P. Acthar Gel 80U/1ML	Nydrazid Inj 100MG/ML	

Source: GAO analysis of Red Book data.

Note: Following the extraordinary price increase, some drugs may have become discontinued or transferred from one manufacturer to another. In some cases, an extraordinary price increase for a drug may not be attributed to the manufacturer that currently owns the drug.

Appendix III: Characteristics of Case Study Drugs

To gain an understanding of the market dynamics leading to extraordinary price increases for brand-name drugs, we developed case studies of six brand-name drugs identified from our analysis of Red Book data. Selection for inclusion as a case study was based on several factors including price, the level of the percentage increase, whether the drug had more than one extraordinary price increase between 2000 and 2008, availability of the drug from multiple sources, and the permanence of the price increase. See table 8 for characteristics of the drugs selected for the case studies.

Table 8: Summary of Characteristics of the Six Case Study Drugs

Drug characteristics	Drug A	Drug B	Drug C	Drug D	Drug E	Drug F
Year of FDA approval	1987	1952	1969	1960	1985	1991
Year of unit price increase	2007	2001 and 2007	2004 and 2005	2004	2008	2001
Percent unit price increase[a]	1,100	1,800 and 1,300	900 and 700	100	100	1,400
Patent status at time of price increase	No patent	No patent	No patent	No patent	Under patent[b]	Under patent
Market exclusivity status at time of price increase[c]	None	None	None	None	None	None
Repackaged drug	No	No	No	No	No	Yes[d]
Year of drug acquisition[e]	2007	2001	1998	2000	N/A[f]	N/A[g]
Generic equivalent available on the market at time of price increase[h]	Yes	No	No	No	No[i]	No
Drug available through patient assistance program[j]	No	Yes	Yes	No	No	Yes[k]
Drug is considered low volume or high volume[l]	Low volume	Low volume	Low volume	Low volume	Low volume	High volume[m]

Source: GAO analysis of Red Book and interviews with drug company representatives.

Note: Changes in unit prices are calculated using average wholesale price (AWP) in Thomson Reuters' Red Book. An extraordinary price increase is a unit price increase equal to 100 percent or more at a single point in time from 2000 to 2008. Patent status is reported as of the date the extraordinary price increase occurred.

[a]Percent increase is rounded to the nearest hundred percent.

[b]This drug had a method-of-use patent.

[c]The Federal Food, Drug, and Cosmetics Act authorizes various periods of market exclusivity for new drug products. Generally, market exclusivities prevent the Food and Drug Administration (FDA) from approving any application for a competing drug compound for a stated period of time.

[d]This drug was sold by a repackager. The price of the drug was set by the repackager and not the manufacturer.

[e]Indicates the year that the rights to the drug were acquired from the previous manufacturer.

[f]This company owns the original rights to the drug.

[g]This drug was sold by a repackager.

[h]This information was obtained from the companies and publicly available information from the FDA.

[i]This drug's active ingredient is available as a generic in other dosage forms.

[j]Patient assistance programs are typically established to offer a company's drug products at low or no cost to low-income, underinsured, or uninsured individuals.

[k]This drug was sold by a repackager. At the time of its extraordinary price increase, the drug was available through the manufacturer's patient assistance program.

[l]Drug companies were asked to identify their drug as either low volume or high volume, depending on the amount manufactured annually.

[m]The manufacturer of the drug said that this drug was a high-volume product at the time of its extraordinary price increase. The repackager told us it sold a small amount of the drug at the time of its extraordinary price increase.

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

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Related GAO Products

Medicaid Outpatient Prescription Drugs: Second Quarter 2008 Federal Upper Limits for Reimbursement Compared with Average Retail Pharmacy Acquisition Costs. GAO-10-118R. Washington, D.C.: November 30, 2009.

Prescription Drugs: Overview of Approaches to Control Prescription Drug Spending in Federal Programs. GAO-09-819T. Washington, D.C.: June 24, 2009.

Medicare Part D Prescription Drug Coverage: Federal Oversight of Reported Price Concessions Data. GAO-08-1074R. Washington, D.C.: September 30, 2008.

Prescription Drugs: Trends in Usual and Customary Prices for Drugs Frequently Used by Medicare and Non-Medicare Health Insurance Enrollees. GAO-07-1201R. Washington, D.C.: September 7, 2007.

Prescription Drugs: Oversight of Drug Pricing in Federal Programs. GAO-07-481T. Washington, D.C.: February 9, 2007.

Prescription Drugs: An Overview of Approaches to Negotiate Drug Prices Used by Other Countries and U.S. Private Payers and Federal Programs. GAO-07-358T. Washington, D.C.: January 11, 2007.

Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs. GAO-07-239R. Washington, D.C.: December 22, 2006.

Prescription Drugs: Price Trends for Frequently Used Brand and Generic Drugs from 2000 through 2004. GAO-05-779. Washington, D.C.: August 15, 2005.

Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States. GAO-05-102. Washington, D.C.: February 4, 2005.

Medicaid: States' Payments for Outpatient Prescription Drugs. GAO-06-69R. Washington, D.C.: October 31, 2005.

Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies. GAO-03-196. Washington, D.C.: January 10, 2003.

Prescription Drugs: Expanding Access to Federal Prices Could Cause Other Price Changes. GAO/HEHS-00-118. Washington, D.C.: August 7, 2000.

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