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Factors Affecting the Growth of Prescription Drug Expenditures

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SUMMARY OF KEY FINDINGS

Spending on prescription drugs has increased much more rapidly than spending on other health care services in recent years, growing twice as fast as total national health spending between 1992 and 1997 (averaging over 11 percent growth per year compared to 5.5 percent per year for total health spending).¹

Growth in drug spending has been at double-digit rates since 1995 and has been accelerating each year since 1993. Preliminary estimates suggest the 1997-1998 growth rate will exceed 18 percent.

Table A. Growth in Prescription Drug Expenditures, 1992-1998

| Year | 1993 | 1994 | 1995 | 1996 | 1997 | 1998e |
|---|--------|--------|--------|--------|--------|--------|
| Dollar Amount (billions) | \$50.6 | \$55.2 | \$61.1 | \$69.1 | \$78.9 | \$93.4 |
| Percent Increase over Prior Year | 8.7% | 9.0% | 10.6% | 13.2% | 14.1% | 18.4% |

Source: Health Care Financing Administration, 1997 National Health Expenditure estimates (for 1993-1997). Estimate for 1998 from Scott-Levin Source Prescription Audit.

Much of this is well known. But why is prescription drug spending growing so fast? What kinds of drugs are we spending our money on? Is this rapid growth likely to continue? And, if so, what are the implications for Medicare and private health insurance?

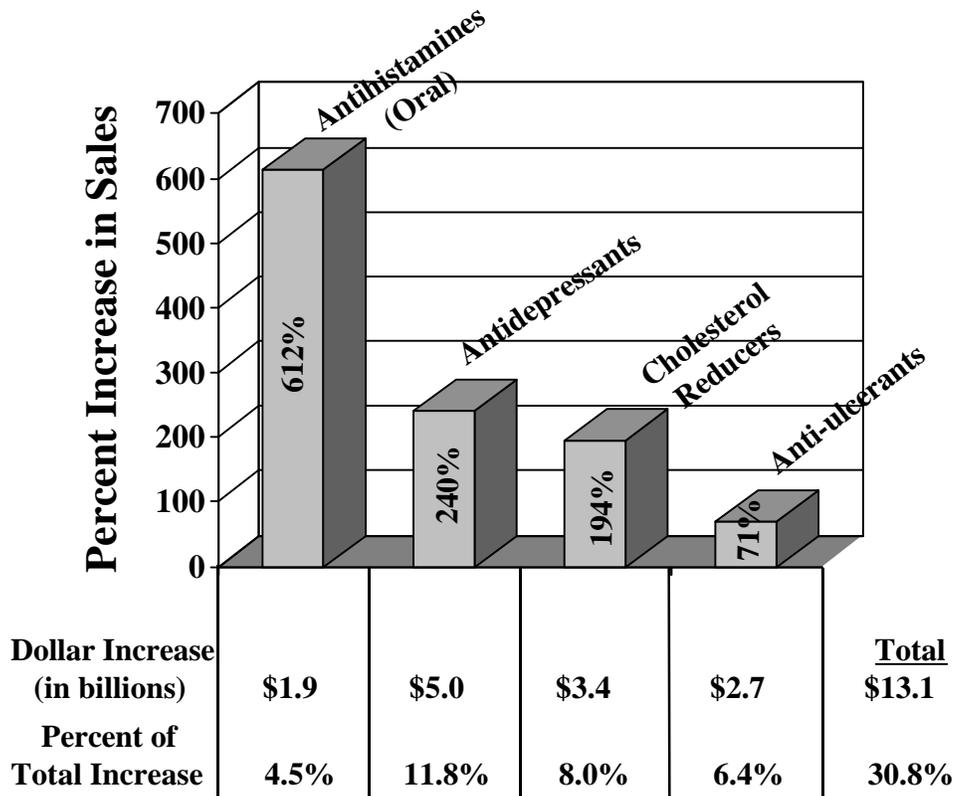
To answer these questions, this report examines the estimated \$42.7 billion (84 percent) increase in retail drug expenditures between 1993 and 1998 using a comprehensive dataset on sales of drugs at the retail level. Among the key findings of the report are:

Spending Growth Is Concentrated In a Few Therapeutic Categories, Which Tend To Include Heavily Advertised Drugs

- ◆ Increases in total drug spending have been concentrated in a relatively small number of therapeutic categories. Four categories of drugs accounted for 30.8 percent of the total \$42.7 billion increase in drug spending between 1993 and 1998. These four categories include seven of the ten drugs most heavily advertised to consumers in 1998 (indicated by asterisks).

¹ This report analyzes data for the most recent 5-year period available, which varies according to the source of the data. For overall national health spending estimates from the Health Care Financing Administration, 1997 is the latest year available, so we examine 1992-1997. For the detailed analysis of retail drug expenditures, we analyze 1993-1998.

Figure A. Percentage Increase in Spending for Four Top Therapeutic Categories, 1993-1998



Source: Barents Group analysis of Scott-Levin Source Prescription Audit Data for 1993 and 1998.

- ◇ Spending on oral antihistamines such as Claritin*, Zyrtec*, and Allegra* increased by 612 percent between 1993 and 1998, representing 4.5 percent or \$1.9 billion of the total increase in drug expenditures.
- ◇ Spending on antidepressants such as Prozac*, Zoloft, and Paxil increased by 240 percent between 1993 and 1998, representing 11.8 percent or \$5 billion of the total increase in drug expenditures over this time.
- ◇ Spending on cholesterol-reducing drugs such as Lipitor, Zocor*, and Pravachol* increased by 194 percent between 1993 and 1998, representing 8 percent or \$3.4 billion of the total increase in drug expenditures.
- ◇ Spending on anti-ulcerant drugs such as Prilosec*, Prevacid, and Pepcid increased by 71 percent between 1993 and 1998, representing 6.4 percent or \$2.7 billion of the total increase in drug expenditures.

Heavily Advertised Drugs Are a Major Source of Spending Increases

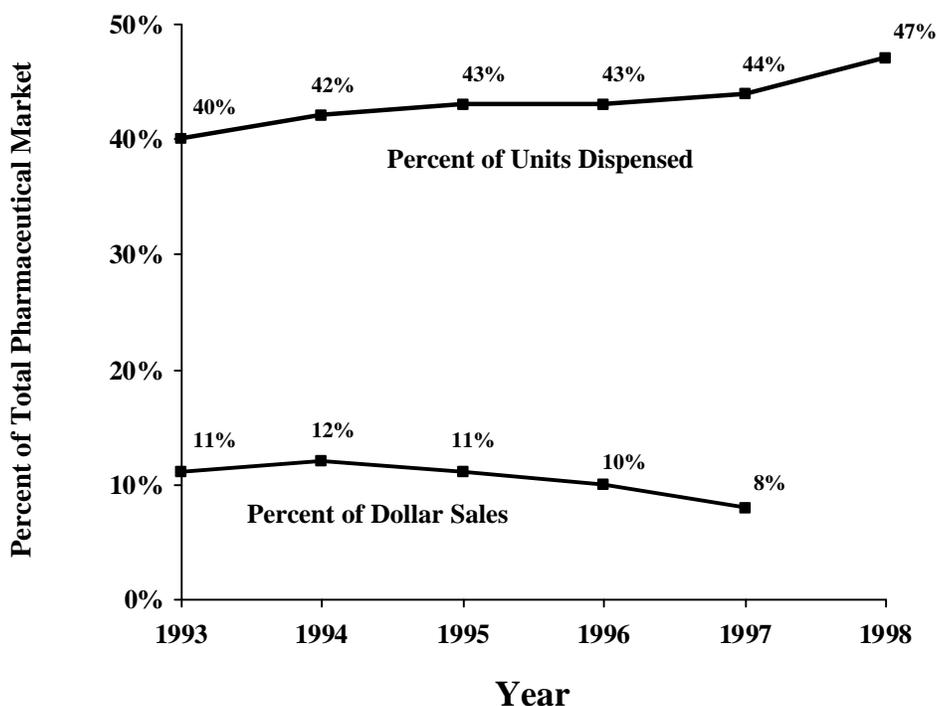
- ◆ The 10 drugs most heavily advertised directly to consumers in 1998 accounted for \$9.3 billion or about 22 percent of the total increase in drug spending between 1993 and 1998.
 - ◇ In addition to the seven drugs identified above, these drugs also included Propecia (a hair-loss treatment), Evista (an osteoporosis drug), and Zyban (a smoking deterrent).
 - ◇ Many heavily advertised drugs, particularly antihistamines, antidepressants and cholesterol reducers, are likely to be used on an ongoing basis.
- ◆ In 1998, pharmaceutical manufacturers spent \$8.3 billion promoting their products in the United States. About \$1.3 billion was spent on direct-to-consumer (DTC) advertising and \$7.0 billion on advertising and detailing to health care professionals.²
 - ◇ The makers of the antihistamines Claritin, Zyrtec, and Allegra spent \$313 million on DTC advertising for these products in 1998. Together, these three drugs accounted for 90 percent of sales of prescription antihistamines and 2 percent of total drug spending in that year.
- ◆ Policy changes by the FDA, particularly a 1997 relaxation of guidelines for broadcast advertising, have allowed drug manufacturers to engage in much more extensive direct-to-consumer advertising.

² Scott-Levin, "The Pharmaceutical Industry: More Reps and More Promotion Fuel New Launches," press release, 18 June 1999. Accessed June 29, 1999, from www.scottlevin.com.

Generic Drugs Have a Small Market Share, Despite Lower Prices

- ◆ In dollar terms, generic drugs accounted for only 8 percent of all prescription drug sales in 1997, despite accounting for a large share in terms of volume (46 percent of units dispensed in 1998). (See Figure B.)
- ◆ When newer products are introduced and heavily marketed, they tend to rapidly dominate sales in their therapeutic class. For example, for treatment of gastrointestinal diseases, the new branded proton pump inhibitors Prilosec and Prevacid have largely replaced the earlier indirect inhibitors like Zantac and its generic equivalent ranitidine, with the two new branded drugs attaining a 63-percent market share in 1998.

Figure B. Market Share of Generic Drugs in Units and Dollar Sales, 1993-1998



Source: IMS Health and IMS America. Sales figures for generic drugs in 1998 are not yet available.

Spending Is Up Because of Both Higher Prices and Increased Utilization

- ◆ As the following table shows, higher drug prices account for 64 percent of the total 1993-98 increase in drug spending, and increased utilization accounts for 36 percent of the increase.

| Table B. Percentage Contribution of Changes in Price and Utilization to 1993-98 Increase in Prescription Drug Spending | | |
|---|---------------------|---------------------------|
| | Price Effect | Utilization Effect |
| New Drugs (1992 and later) | 42% | 23% |
| Older Drugs | 22% | 13% |
| TOTAL | 64% | 36% |

Source: Barents Group analysis of Scott-Levin Source Prescription Audit Data for 1993 and 1998. For older drugs, the price effect measures additional spending due to the increase in the average price per prescription between 1993 and 1998 for these drugs. For newer drugs, the price effect measures increased spending due to the fact that the average price per prescription for these drugs in 1998 is higher than the 1993 average price per prescription for older drugs. For both new and old drugs, the increased spending due to a greater number of prescriptions filled is calculated using the 1993 average price per prescription for older drugs.

- ◆ Driving the increase in average price per prescription is the introduction and widespread use of costlier new drugs.
 - ◇ In 1998, the average price per prescription for new drugs (those introduced in 1992 or later) was \$71.49, more than twice the average \$30.47 price for previously existing drugs.
 - ◇ In some therapeutic categories, new branded drugs are many times more expensive than older products. For example, Imitrex, a non-narcotic analgesic, costs more than seven times the average price of older prescription drugs in its category.
 - ◇ More than half the increase in spending associated with new drugs can be attributed to the fact that they cost more than twice as much as older drugs, on average.
 - ◇ Use of newer, more expensive drugs increased the average price per prescription from \$26.61 in 1993 to \$37.38 in 1998.
 - ◇ Increases in the price of older drugs have been fairly modest. Between 1993 and 1998, the average price per prescription of these drugs increased by an average rate of 4.2 percent annually, about the same as overall medical inflation.

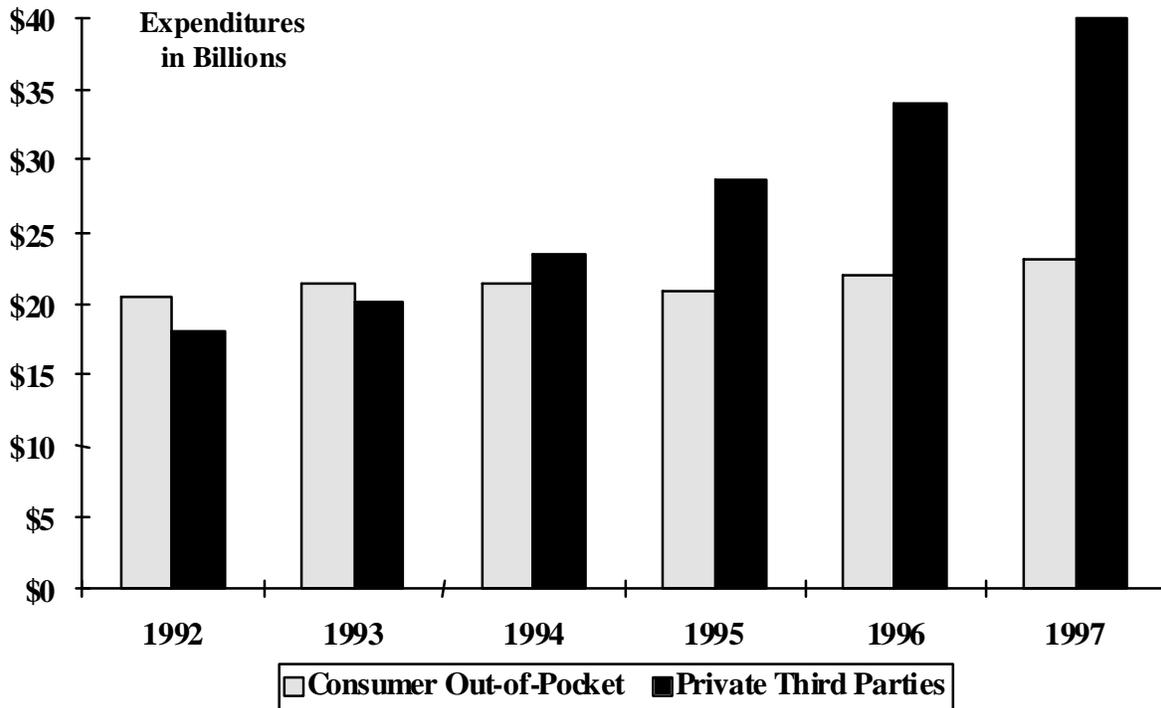
- ◆ The number of prescriptions filled increased by almost 600 million, growing from 1.9 billion in 1993 to 2.5 billion in 1998.
 - ◇ Total utilization of drugs in many leading therapeutic categories more than doubled between 1993 and 1998; for example, the number of prescriptions filled for antidepressants increased by 111 percent to 120 million in 1998, for cholesterol-lowering drugs by 162 percent to 68 million prescriptions, and for oral antihistamines by 500 percent to 41 million prescriptions.

Employers and Health Plans Have Borne Much of the Increased Cost of Prescription Drugs

Most of the recent increase in drug spending has been borne by private third-party payers — health plans and employers — which have seen their outlays for prescription drugs more than double.

- ◆ Between 1992 and 1997, prescription drug spending by private third parties grew 123 percent, from \$18 billion to \$40 billion, while consumer out-of-pocket spending on prescription drugs grew only 13 percent, from \$20 billion to \$23 billion. (See Figure C.)
- ◆ Consumers' out-of-pocket spending decreased from 53 percent to 37 percent of total private (non-government) spending on prescription drugs.
- ◆ The shift to managed care, in particular, has influenced drug spending. Low out-of-pocket costs in managed care (typically \$5-\$10 per prescription) increase patient access to doctors and often insulate consumers from most of the cost for their medications.

Figure C. Private Drug Spending, By Source of Payment, 1992-1997



Source: Health Care Financing Administration, Office of the Actuary, 1997 National Health Expenditure estimates

Drug Spending Increases Are Likely To Continue, If Not Accelerate

Recent trends in drug expenditures are likely to continue, if not accelerate, for several reasons:

- ◆ The pharmaceutical industry is both research intensive and marketing intensive.
 - ◇ In 1998, the industry spent over \$17 billion on research and development in the United States³ and about \$8.3 billion promoting its products in the U.S.
 - ◇ Both of these figures are expected to increase in future years. The Pharmaceutical Research and Manufacturers of America (PhRMA) projects 1999 R&D spending to grow by 17 percent from 1998⁴, while spending on DTC advertising is expected to grow 54 percent over 1998 levels.⁵

³ Pharmaceutical Research and Manufacturer's Association, "Pharmaceutical Industry Profile 1999," Figure 2-1. Accessed June 30, 1999, from www.phrma.org.

⁴ *Ibid.*

⁵ *The Wall Street Journal*, 8 June 1999, p. B14 (reporting on projections by IMS Health).

- ◇ Many new drugs are already “in the pipeline”; new computerized techniques are speeding up the process of developing potential new drugs; and advances in the basic sciences, particularly in genetic research, are expected to increase the number of targets for drug intervention exponentially over the next few years.
- ◆ Research advances coincide with demographic trends, such as the aging of the baby-boomers, that will greatly increase the number of Americans at risk for chronic and potentially disabling conditions.

Policy Implications

Pharmaceutical research has brought great improvements in health and longevity. Given the increasing investment in research and development, more such welcome advances can be expected in the future. But, while some new drugs are true breakthroughs, opening up new avenues of treatment that have not previously been available, others may offer more modest improvements on earlier therapies at considerably greater expense.

More research is needed on several important questions:

- ◆ How do we leverage the tremendous potential of pharmaceuticals and assure that the right drugs get to the right people safely and at the right time?
- ◆ Under what circumstances is each new drug the most appropriate treatment, compared to the available alternatives?
- ◆ Given the large increase in prescription volume, how can we best limit mistakes and adverse drug interactions?
- ◆ What are the positive and negative effects of DTC advertising, physician detailing and other promotional efforts?
- ◆ What impact will increasing expenditures on prescription drugs have on overall health care spending?

Affordability will increasingly be a concern. As the cost of covering prescription drugs continues to grow, health plans, purchasers and consumers will face difficult choices among promoting access to drug therapies, maintaining health insurance premiums at an affordable level, and continuing to offer other needed benefits. The money to pay for more expensive new drugs must come from higher premiums, higher out-of-pocket costs (e.g., “triple-tier” copayments), lower benefits, and/or more restricted access to drugs (e.g., formularies).

In addition, the possible inclusion of a prescription drug benefit in the Medicare program makes understanding what is driving the increase in pharmaceutical expenditures all the more important. For private third-party payers, which cover a younger, healthier population, prescription drugs already represent about 13 percent of health benefit outlays. Some plans with many retirees report that drug costs are approaching 30 percent of total benefits.⁶ Pharmaceutical research is focused on new drugs that will target the chronic and disabling diseases of the elderly. The experience of private insurers, particularly those covering older populations, suggests that the cost of Medicare coverage of prescription drugs will likely be substantial from the outset and increase significantly over time.

⁶ Testimony of the Blue Cross and Blue Shield Association on Prescription Drug Benefits and the Medicare Program for the Committee on Finance, U.S. Senate, presented by Dr. Morris B. Mellion, June 23, 1999, p. 5.

ACKNOWLEDGMENTS

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CHAPTER 1: INTRODUCTION

PRESCRIPTION DRUG SPENDING OVERVIEW

Hospital care and physician services have traditionally comprised a majority of national health expenditures. However, in recent years their share of health spending has declined and spending on prescription drugs has risen. Between 1992 and 1997, spending on prescription drugs grew twice as fast as total national health spending, averaging over 11 percent growth per year compared to 5.5 percent per year for total health spending. As a result, prescription drugs increased their share of total national health expenditures from 5.6 percent in 1992 to 7.2 percent in 1997. If recent trends continue, prescription drugs could account for as much as 16 percent of national health expenditures by 2008.⁷

Drug spending increases have been particularly pronounced in recent years and have been accelerating. From a low of 8.7 percent for 1992-93, the annual growth in drug spending reached 14.1 percent between 1996 and 1997 (Table 1). Data from the Scott-Levin Source Prescription Audit Database suggest the 1997-1998 growth rate will exceed 18 percent.

Table 1. National Health Expenditures: Annual Percentage Growth, 1992-1997

| | 1992 | 1993 | 1994 | 1995 | 1996 | 1997 | 5-Year Average |
|--------------------|-------------|-------------|-------------|-------------|-------------|-------------|----------------|
| Total | 9.1% | 7.4% | 5.5% | 4.9% | 4.9% | 4.8% | 5.5% |
| Hospital Care | 8.2 | 5.8 | 3.9 | 3.4 | 3.9 | 2.9 | 4.0 |
| Physician Services | 8.5 | 5.7 | 3.8 | 4.6 | 3.3 | 4.4 | 4.3 |
| Nursing Home | 9.0 | 6.7 | 7.0 | 6.2 | 5.2 | 4.3 | 5.8 |
| Prescription Drugs | 10.6 | 8.7 | 9.0 | 10.6 | 13.2 | 14.1 | 11.1 |

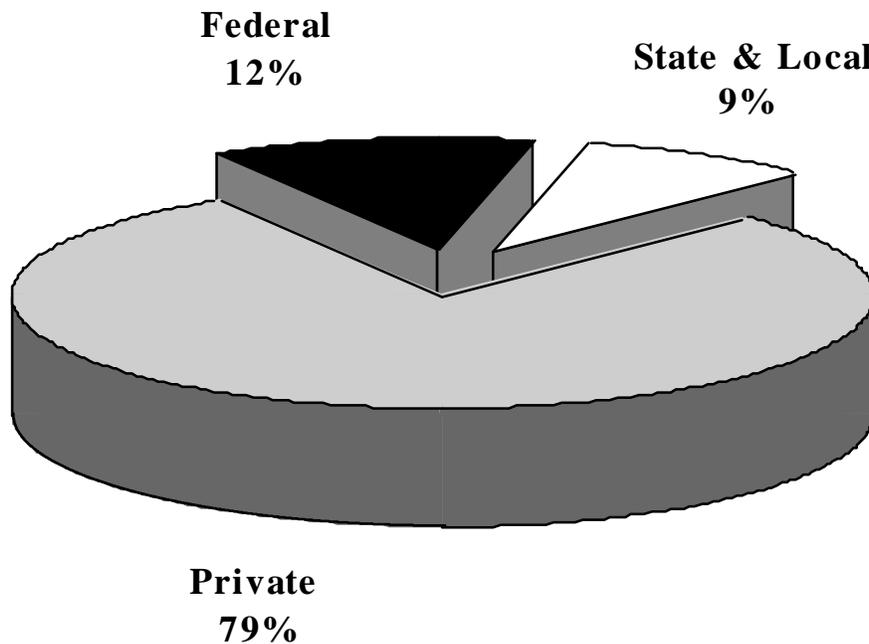
Source: Barents Group LLC analysis of HCFA National Health Expenditure data, 1997.

The increase in prescription drug costs has been borne primarily by private, third-party insurers and consumers, who together pay for about 80 percent of all prescription drugs costs; currently, public sources cover only about 20 percent of drug expenditures (Figure 1), mostly through the Medicaid program.⁸

⁷ Craig Copeland, "Prescription Drugs: Issues of Cost, Coverage, and Quality." *EBRI Issue Brief* 208. (April 1999). Earlier, more conservative projections from the Health Care Financing Administration (HCFA) estimated that prescription drug expenditures would account for 8 percent of national health expenditures by 2007; however, these projections used the 1996 release of national health expenditure estimates as their base.

⁸ Individuals covered by Medicaid receive prescription drug benefits. While the traditional fee-for-service Medicare program does not cover prescription drugs benefits, Medicare managed care plans typically provide prescription

Figure 1: Public vs. Private Spending on Prescription Drugs, 1997



Source: Health Care Financing Administration, 1997 National Health Expenditure estimates

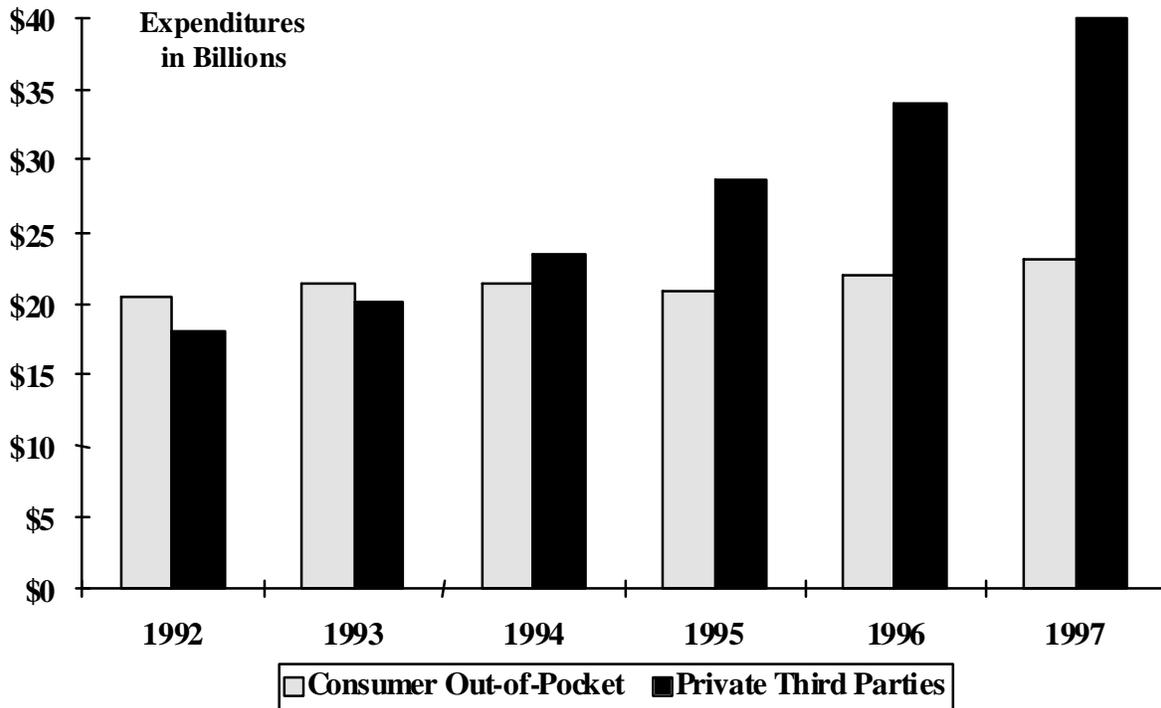
According to HCFA estimates, between 1992 and 1997:

- ◆ Spending on prescription drugs grew from 9.3 percent to 12.6 percent of total *private consumer* spending (out-of-pocket and third-party combined) on health care services.
- ◆ Prescription drug spending by private third parties—health plans and employers—grew 123 percent, from \$17.9 billion to \$39.9 billion, while total benefit payments grew only 25 percent.
- ◆ Consumer out-of-pocket spending on prescription drugs grew 13 percent, from \$20.4 billion to \$23.0 billion.
- ◆ Therefore, consumers' out-of-pocket spending decreased from 53 percent to 37 percent of total private (non-government) spending on prescription drugs paid.

Figure 2 compares consumer out-of-pocket and private third party payments for prescription drugs from 1992 through 1997.

drug coverage. About 16 percent of all Medicare beneficiaries are currently enrolled in Medicare HMOs, and most of these individuals have access to a prescription drug benefit.

Figure 2. Private Drug Spending, By Source of Payment, 1992-1997



Source: Health Care Financing Administration, Office of the Actuary, 1997 National Health Expenditure estimates

As these data demonstrate, increases in drug spending have affected private third-party payers significantly. In fact, prescription drugs alone accounted for 35 percent of the entire growth in benefit outlays by private third parties between 1992 and 1997 and 44 percent of the 1996-97 increase. As a percentage of private third-party benefit payments, prescription drugs rose from 7.2 percent in 1992 to 12.7 percent in 1997.

PURPOSE

This report examines and quantifies the factors that have influenced the growth of prescription drug expenditures. Explanations for the underlying causes of these increases include changes in utilization of existing products in the market, increases in the price of existing products, and the introduction of new or improved products.

In the following chapter, we provide a detailed analysis of Scott-Levin's Source Prescription Audit data, a comprehensive dataset on drug sales at the retail level. This analysis evaluates price and utilization trends among different types of drugs (including new drugs) from 1993 to 1998, and the impact of these factors on overall drug expenditures. Finally, Chapter 3 draws conclusions and examines the future implications of trends in drug spending.

METHODOLOGY

To examine the price and utilization of specific drugs, we used the Scott-Levin Company's Source Prescription Audit database for 1993 and 1998. These data are collected on a sample basis for prescription drugs dispensed through retail outlets such as chain drugstores, independent drugstores, and mass-market outlets such as pharmacies in food and department stores. The data are weighted so that they reflect the total universe of retail prescription drug sales for the country. The expenditures included in the Scott-Levin data represent the "full price" of a drug, i.e., the price the retailer charges without regard to how the total payment is divided between the insurer (if any) and the consumer. Thus, these prices include both the insurer's payment and the consumer's co-payment.

The Scott-Levin data cover prescriptions for all drugs sold at the retail level. For our analyses, we obtained data on total expenditures and prescription volume for the 500 molecular entities that made up 96 percent of retail sales in 1998. For each molecular entity, we obtained sales and prescription volume for up to 10 specific products sold containing that specific molecule. For many drugs, there is only one product sold for each molecular entity (e.g., the Prozac brand antidepressant is the only product sold that contains the fluoxetine molecule), whereas for other molecular entities (such as amoxicillin) several different products contain the particular molecule. We also obtained data for 1993 for these same molecular entities, which represented about 90 percent of expenditures for that year.

The Scott-Levin data also describe the therapeutic category for each molecule, so that individual products (and molecular entities) can be grouped together into categories according to the use for the products. For example, data for the products Prilosec, Prevacid, and Zantac (each of which is a distinct molecular entity) can be grouped into the therapeutic category of anti-ulcerants. By grouping individual drugs into their respective therapeutic categories, we can examine overall price and utilization trends within each category across the years 1993 and 1998 and explore the role of specific drugs in affecting these trends.⁹

The price of each drug used in this study is the average price per prescription, determined by dividing total expenditures for the drug by its total number of prescriptions. These expenditures are for all dosages and prescription sizes (i.e., number of pills) of individual drugs, and thus do not account for any changes in dosage or prescription size over time. When discussing trends in prices of individual drugs, therefore, the change in average price per prescription includes changes in dosage and size of prescriptions, in addition to the "pure" effect of change in the price of a given dosage and prescription size. It appears that there has been some shifting toward larger dosage sizes and more units per prescription over time, so our estimates of average changes in price per

⁹ The Scott-Levin data define therapeutic category at a five-digit level where the first three digits generally define a broad therapeutic category (e.g., HIV antivirals) and the additional digits further define drugs within the category (e.g., protease inhibitors such as Epivir versus Viracept, a reverse transcriptase inhibitor). In defining therapeutic categories, we have used three-digit classifications to group drugs together. In total, the data include 103 distinct three-digit categories, including the catch-all "other drugs category."

prescription are likely to somewhat overstate the extent to which prices for identical prescriptions have increased over time.¹⁰

To compare price and utilization of drugs that existed in both years 1993 and 1998 to new drugs, we used Federal Drug Administration (FDA) approval dates listed in the FDA and trade press to determine which drugs from the Scott-Levin data could be considered “new” drugs.

For the purposes of this study, we defined new drugs as those that were launched in 1992 or later. The use of 1992 data allowed us to capture drugs such as Zocor and Norvasc that were relatively new in 1993 (the first year covered by our data) and accounted for a small share of 1993 sales (4.5 percent) but had substantial share of sales by 1998 (12 percent). This reflects the fact that it takes some time for a new drug to become established and obtain significant sales volume. For example, Viagra was approved in mid-1998 and had sales of about \$520 million for the year; the drug’s sales are projected to be over a billion dollars in 1999.

¹⁰ Express Scripts, Inc., *1997 Drug Trend Report*. June 1998.

CHAPTER 2: ANALYSIS

Scott-Levin Source Prescription Audit data indicate that total drug expenditures at the retail level increased from \$50.7 billion dollars in 1993 to \$93.4 billion in 1998, an increase of \$42.7 billion or 84 percent over the five-year period (about 13 percent per year on average).¹¹ This report examines the key components of the increase in drug spending. Specifically, the report seeks to understand:

- ◆ Has drug spending increased across the board, or is it concentrated more in some therapeutic categories than in others?
- ◆ To what extent are increases in drug spending associated with drugs that are heavily promoted?
- ◆ Is overall spending growth driven more by price increases or by greater utilization of drugs?
- ◆ What role has the introduction of many new branded drugs in the past few years played in increased drug spending?
- ◆ What role have generic drugs played in reducing drug expenditures?

This chapter addresses each of these questions in turn. However, the value of pharmaceutical advances and increased pharmaceutical utilization is a complex, multi-faceted issue which this report does not attempt to address.

SPENDING GROWTH BY THERAPEUTIC CATEGORY

Spending Growth Is Concentrated in a Few Therapeutic Categories

Most of the growth in total drug expenditures has been concentrated in a small number of therapeutic categories.

Using Scott-Levin data, Table 2 indicates that the largest increase in spending for any therapeutic category was for antidepressants (for which spending increased by \$5.0 billion), followed by cholesterol reducers (for which spending increased by \$3.5 billion). The table also shows the share of the total increase in drug spending that can be attributed to expenditure increases in each specific therapeutic category. For example, expenditures on antidepressants alone accounted for almost 12 percent of the entire \$42.7 billion increase in drug spending between 1993 and 1998.

¹¹ This is comparable to the 11.5 percent average annual increase in prescription drug spending estimated by IMS, another private firm that collects data on prescription sales.

Table 2. Change in Total Drug Expenditures by Therapeutic Category, 1993-98

(Top 25 Therapeutic Categories ranked by contribution to overall 1993-98 increase in drug spending.)

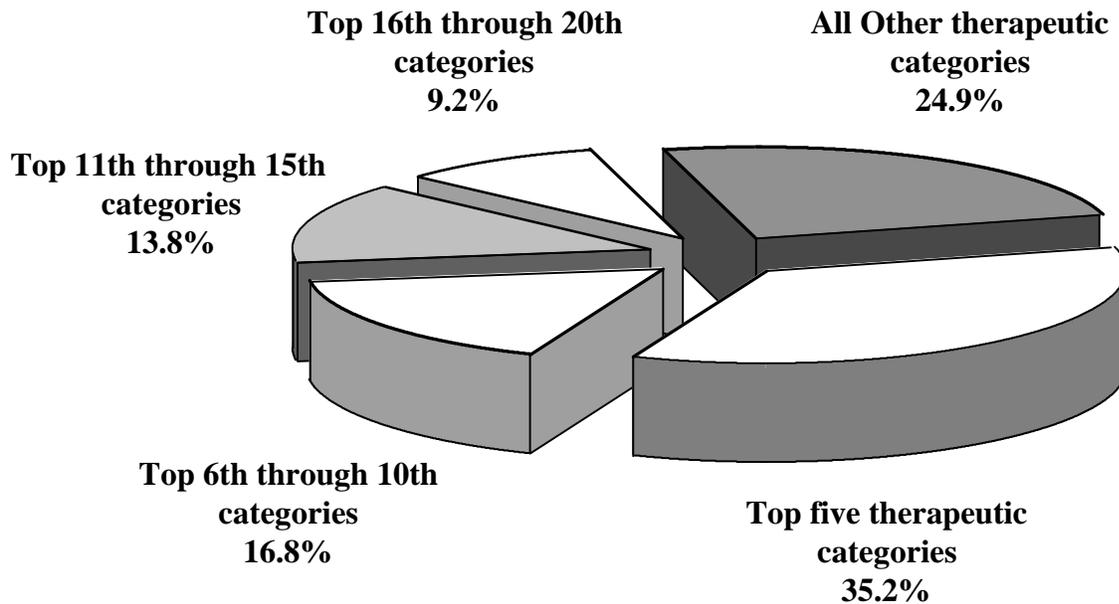
| Type of Drug | 1993 | 1998 | Category Change in Sales 1993-98 | As a Percent of Change in Total Drug Spending | Cumulative Impact on Change in Total Drug Spending |
|-------------------------------------|-------------------|-------------------|---|--|---|
| (Dollar amounts in millions) | Sales | Sales | | | |
| Antidepressants | \$2,090.6 | \$7,120.9 | \$5,030.3 | 11.8% | 11.8% |
| Cholesterol reducers | 1,771.0 | 5,207.4 | 3,436.3 | 8.0% | 19.8% |
| Anti-ulcerants | 3,848.3 | 6,588.0 | 2,739.7 | 6.4% | 26.3% |
| Antihistamine (oral) | 317.3 | 2,258.5 | 1,941.2 | 4.5% | 30.8% |
| Antihypertensive drugs | 2,150.9 | 4,047.1 | 1,896.2 | 4.4% | 35.2% |
| Diabetes (oral) | 811.5 | 2,537.7 | 1,726.1 | 4.0% | 39.3% |
| Antipsychotics | 309.1 | 1,737.1 | 1,427.9 | 3.3% | 42.6% |
| HIV antivirals | 129.2 | 1,481.7 | 1,352.5 | 3.2% | 45.8% |
| Antiseizure | 719.9 | 2,057.9 | 1,338.0 | 3.1% | 48.9% |
| Antibiotic, broad based | 4,886.0 | 6,216.3 | 1,330.3 | 3.1% | 52.0% |
| Sex hormones | 1,424.9 | 2,738.5 | 1,313.6 | 3.1% | 55.1% |
| Analgesics, non-narcotic | 869.3 | 2,166.8 | 1,297.5 | 3.0% | 58.2% |
| Respiratory steroids (inhaled) | 752.4 | 2,018.7 | 1,266.3 | 3.0% | 61.1% |
| Analgesics, narcotic | 1,453.0 | 2,486.1 | 1,033.2 | 2.4% | 63.6% |
| Fungicides | 685.1 | 1,674.0 | 988.9 | 2.3% | 65.9% |
| Calcium blockers | 3,316.9 | 4,175.8 | 858.9 | 2.0% | 67.9% |
| Oral contraceptives | 1,335.5 | 2,162.0 | 826.5 | 1.9% | 69.8% |
| Oral cold preparations (Rx) | 150.7 | 910.4 | 759.7 | 1.8% | 71.6% |
| Beta-blockers | 1,980.3 | 2,738.6 | 758.3 | 1.8% | 73.4% |
| Bronchodilators | 1,357.9 | 2,094.2 | 736.4 | 1.7% | 75.1% |
| Sexual function disorder | - | 608.0 | 608.0 | 1.4% | 76.5% |
| Bone density regulators | - | 516.5 | 516.5 | 1.2% | 77.7% |
| Dermal acne therapy | 343.4 | 843.6 | 500.1 | 1.2% | 78.9% |
| Interferon | 37.5 | 518.4 | 480.9 | 1.1% | 80.0% |
| Non-barbiturate sedative | 159.0 | 626.5 | 467.5 | 1.1% | 81.1% |
| All other categories | \$19,817.9 | \$27,875.2 | \$8,057.3 | 18.9% | 100% |
| Total | \$50,717.8 | \$93,405.7 | \$42,687.9 | 100% | 100% |

Source: Barents Group LLC analysis of Scott-Levin Source Prescription Audit Data.

The cumulative share of the total spending increase is stated in the last column of Table 2. The table shows that:

- ◆ More than one-third (35.2 percent) of the entire 1993-98 increase in drug spending was attributable to just five categories of drugs: antidepressants, cholesterol reducers, anti-ulcerants, oral antihistamines, and antihypertension drugs. The top four categories include seven of the ten drugs with the greatest spending on direct-to-consumer (DTC) advertising in 1998.
- ◆ More than half of the growth in total drug expenditures occurred in just 10 therapeutic categories. (See also Figure 3.)

Figure 3. Increases in Drug Expenditures Have Been Concentrated in Relatively Few Therapeutic Categories.



Source: Barents Group LLC analysis of Scott-Levin Source Prescription Audit Data

- ◆ Increased spending on antidepressants, cholesterol reducers, anti-ulcerants, oral antihistamines and antihypertensive drugs accounted for 35.2 percent of the increase in drug spending between 1993 and 1998.
- ◆ Increased spending on antipsychotics, oral anti-diabetes drugs, HIV antivirals, antiseizure drugs, and broad-based antibiotics accounted for an additional 16.8 percent of the increase in drug spending.
- ◆ The remaining drug categories accounted for the remaining 48 percent increase in drug spending.

A similar picture emerges when we examine spending increases due to new branded drugs. Of the total 1993-98 spending increase attributable to new drugs, fully 42 percent is accounted for by just five therapeutic categories. Three of these are also in the top five for overall spending increases — cholesterol reducers, antidepressants and oral antihistamines. The other two are oral anti-diabetics and non-narcotic analgesics, two categories in which new branded drugs have been recently introduced. The top ten categories account for 65 percent of the total increase.¹²

Growth Rate in Expenditures Varies Greatly Across Categories

Some therapeutic categories made large contributions to the overall 1993-98 increase in drug spending because they experienced average increases from a large base, while other categories experienced very large percentage increases from a smaller base.

This variation is illustrated in Table 3, which presents information on base 1993 expenditures and the percentage increase in expenditures from 1993 to 1998 by therapeutic category.

- ◆ For example, expenditures on oral antihistamines and antihypertensive drugs increased by approximately the same dollar amount (\$1.9 billion) between 1993 and 1998, but from very different spending bases.
- ◆ Total spending on antihypertensives increased by 88 percent (from a 1993 base of \$2.2 billion), while total spending for oral antihistamines grew by 612 percent (from a base of \$317 million).

The table highlights those therapeutic categories in which sales more than doubled between 1993 and 1998. The percentage increases in some categories are particularly striking. Figure 4 graphically illustrates the percentage increases in spending for the ten therapeutic categories which made the largest dollar contribution to the overall 1993-98 spending increase.

¹² Table not shown but available upon request.

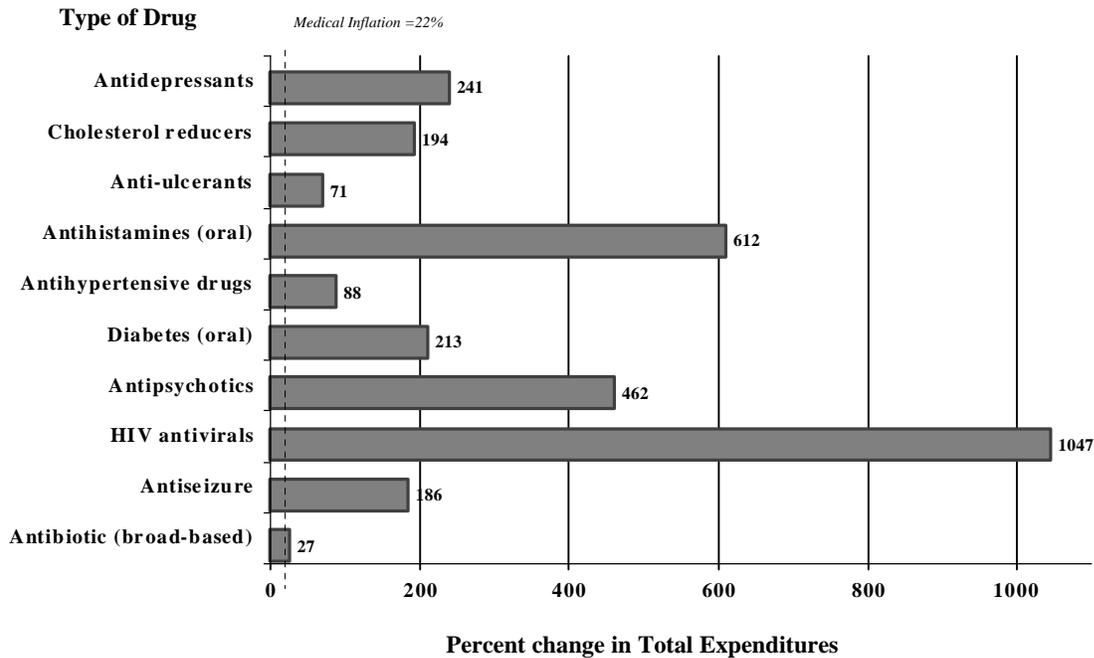
Table 3. Sales and Change in Total Drug Expenditures by Therapeutic Category, 1993-1998

(Top 25 Therapeutic Categories ranked by contribution to overall 1993-98 increase in drug spending. For highlighted categories, sales more than doubled.)

| Type of Drug (Dollar amounts in millions) | 1993 Sales | Share of Total 1993 Sales | 1998 Sales | Share of Total 1998 Sales | Change in Total Expenditures, 1993 - 1998 | |
|--|-----------------------|--|-----------------------|--|--|----------------|
| | | | | | Amount | Percent |
| Antidepressants | \$2,090.6 | 4.1% | \$7,120.9 | 7.6% | \$5,030.3 | 240.6% |
| Cholesterol reducers | 1,771.0 | 3.5% | 5,207.4 | 5.6% | 3,436.3 | 194.0% |
| Anti-ulcerants | 3,848.3 | 7.6% | 6,588.0 | 7.1% | 2,739.7 | 71.2% |
| Antihistamine (oral) | 317.3 | 0.6% | 2,258.5 | 2.4% | 1,941.2 | 611.7% |
| Antihypertensive drugs | 2,150.9 | 4.2% | 4,047.1 | 4.3% | 1,896.2 | 88.2% |
| Diabetes (oral) | 811.5 | 1.6% | 2,537.7 | 2.7% | 1,726.1 | 212.7% |
| Antipsychotics | 309.1 | 0.6% | 1,737.1 | 1.9% | 1,427.9 | 461.9% |
| HIV antivirals | 129.2 | 0.3% | 1,481.7 | 1.6% | 1,352.5 | 1,046.9% |
| Antiseizure | 719.9 | 1.4% | 2,057.9 | 2.2% | 1,338.0 | 185.8% |
| Antibiotic, broad based | 4,886.0 | 9.6% | 6,216.3 | 6.7% | 1,330.3 | 27.2% |
| Sex hormones | 1,424.9 | 2.8% | 2,738.5 | 2.9% | 1,313.6 | 92.2% |
| Analgesics, non-narcotic | 869.3 | 1.7% | 2,166.8 | 2.3% | 1,297.5 | 149.3% |
| Respiratory steroids (inhaled) | 752.4 | 1.5% | 2,018.7 | 2.2% | 1,266.3 | 168.3% |
| Analgesics, narcotic | 1,453.0 | 2.9% | 2,486.1 | 2.7% | 1,033.2 | 71.1% |
| Fungicides | 685.1 | 1.4% | 1,674.0 | 1.8% | 988.9 | 144.3% |
| Calcium blockers | 3,316.9 | 6.5% | 4,175.8 | 4.5% | 858.9 | 25.9% |
| Oral contraceptives | 1,335.5 | 2.6% | 2,162.0 | 2.3% | 826.5 | 61.9% |
| Oral cold preparations (Rx) | 150.7 | 0.3% | 910.4 | 1.0% | 759.7 | 504.0% |
| Beta-blockers | 1,980.3 | 3.9% | 2,738.6 | 2.9% | 758.3 | 38.3% |
| Bronchodilators | 1,357.9 | 2.7% | 2,094.2 | 2.2% | 736.4 | 54.2% |
| Sexual function disorder | - | - | 608.0 | - | 608.0 | - |
| Bone density regulators | - | - | 516.5 | - | 516.5 | - |
| Dermal acne therapy | 343.4 | 0.7% | 843.6 | 0.9% | 500.1 | 145.6% |
| Interferon | 37.5 | 0.1% | 518.4 | 0.6% | 480.9 | 1,282.5% |
| Non-barbiturate sedative | 159.0 | 0.3% | 626.5 | 0.7% | 467.5 | 294.0% |
| All other categories | \$19,817.9 | 39.1% | \$27,875.2 | 31.0% | \$8,057.3 | 40.7% |
| Total | \$50,717.8 | 100% | \$93,405.7 | 100% | \$42,687.9 | 84.2% |

Source: Barents Group LLC analysis of Scott-Levin Source Prescription Audit Data.

Figure 4. Change in Total Drug Expenditures by Therapeutic Category, 1993-98



Source: Barents Group LLC Analysis of Scott-Levin Source Prescription Audit Data

THE EFFECT OF ADVERTISING ON DRUG SPENDING

Direct-to-Consumer (DTC) Advertising

Revisions to FDA policies in 1985 and 1997 have released unprecedented marketing directly to consumers (DTC).¹³ Spending on DTC advertising increased more than 20-fold from \$55.3

¹³ The advertising of prescription drugs had traditionally been confined to medical journals and trade publications targeted to physicians. In 1983, the FDA issued a moratorium on DTC advertising while studies were conducted to assess the potential impact of such advertising. This moratorium was lifted in 1985, and pharmaceutical companies were allowed to directly advertise their products to consumers, provided that advertisements did not make false or misleading claims and also included a balanced representation of the benefits and limitations of the product.

In 1997, the FDA issued new guidance regarding broadcast advertising of prescription drugs. Under the Federal Food, Drug, and Cosmetic Act, a summary describing the benefits of the drug and related side effects must be included in the advertisement. Similar to advertisements directed to providers, broadcast advertisements may not be false or misleading. As a result of these relaxed guidelines, pharmaceutical companies have increased their use of television advertising. In 1998, television advertising accounted for over half of DTC advertising expenditures, compared to about one-quarter in the previous year.

million in 1991 to over \$1.3 billion in 1998,¹⁴ and is projected to increase another 54 percent in 1999, reaching \$2 billion.¹⁵

According to data from IMS Health, ten drugs accounted for \$707 million in DTC advertising in 1998, or more than half of total DTC spending for all drugs that year.¹⁶ The leading product in DTC advertising was Schering-Plough's Claritin, whose DTC budget increased from \$68 million to \$185 million between 1997 and 1998. Leading types of drugs marketed through DTC ads included cholesterol reducers (Pravachol and Zocor), antidepressants (Prozac, an older branded drug), and anti-ulcerants (Prilosec), three therapeutic categories that have experienced significant sales and utilization growth. One drug that has recently joined the list is Propecia, a treatment for baldness introduced in 1998 that had DTC spending of \$92 million in 1998.

The use of DTC advertising by pharmaceutical companies has often been cited as a factor in increased prescription drug spending. In fact, the 10 most heavily promoted drugs in 1998 (measured by DTC advertising outlays) accounted for over a fifth (about 22 percent) of the total growth in prescription drug expenditures between 1993 and 1998. Table 4 presents IMS Health data on DTC advertising spending for 10 leading drugs and Scott-Levin data on total 1998 sales. In total, these 10 drugs had 1998 sales of \$11.2 billion — about 12 percent of all retail drug spending.

Table 4 shows that most of the drugs that are subject to high levels of DTC advertising have significant share of sales within their therapeutic category. For example, the two leading oral antihistamines — Claritin and Allegra — have a combined market share of nearly 80 percent of the prescription oral antihistamine market. For these and other drugs, we cannot determine how DTC advertising spending affected overall levels of product spending. It is noteworthy, however, that much DTC advertising spending takes place in categories that have experienced significant increases in product utilization over time, largely as a result of the adoption and use of the drugs that are heavily marketed to consumers

¹⁴ Testimony of the Blue Cross and Blue Shield Association on Prescription Drug Benefits and the Medicare Program for the Committee on Finance, U.S. Senate, presented by Dr. Morris B. Mellion, June 23, 1999, p. 8.

¹⁵ *The Wall Street Journal*, June 8, 1999, p. B14 (reporting on projections by IMS Health).

¹⁶ IMS Health, Press release, 17 May 1999. Accessed June 7, 1999 from www.imshealth.com.

Table 4. Ten Leading Drugs in Terms of Direct-to-Consumer Spending, 1998

| Name of Drug | Drug Category | 1998 Sales (\$ millions) | Share of Total 1998 Retail Drug Sales | Share in Therapeutic Category, 1998 | Spending on DTC Advertising, 1998 (\$ millions) |
|-------------------------------|------------------------------|-----------------------------|--|--|---|
| Claritin | | \$2,140.0 | 2.3% | 62.2% | \$185.1 |
| <i>Claritin antihistamine</i> | <i>Antihistamine</i> | <i>1,421.8</i> | <i>1.5%</i> | <i>55.5%</i> | <i>*</i> |
| <i>Claritin decongestant</i> | <i>Cold preparation (Rx)</i> | <i>718.2</i> | <i>0.8%</i> | <i>78.9%</i> | <i>*</i> |
| Propecia | Hair related product | 72.7 | 0.1% | 41.4% | 92.0 |
| Zyrtec | Antihistamine | 454.9 | 0.5% | 18.6% | 75.6 |
| Zyban | Smoking Deterrent | 183.8 | 0.2% | 82.8% | 64.4 |
| Pravachol | Cholesterol reducer | 953.6 | 1.0% | 18.3% | 59.7 |
| Allegra | | \$432.0 | 0.5% | 13.6% | 52.5 |
| <i>Allegra antihistamine</i> | <i>Antihistamine</i> | <i>349.2</i> | <i>0.4%</i> | <i>15.5%</i> | <i>*</i> |
| <i>Allegra decongestant</i> | <i>Cold preparation (Rx)</i> | <i>82.9</i> | <i>0.1%</i> | <i>9.1%</i> | <i>*</i> |
| Prilosec | Anti-ulcerant | 2,944.9 | 3.2% | 44.7% | 49.7 |
| Zocor | Cholesterol reducer | 1,567.3 | 1.7% | 30.1% | 44.5 |
| Evista | Osteoporosis | 99.8 | 0.1% | 19.3% | 42.3 |
| Prozac | Antidepressant | 2,345.6 | 2.5% | 32.9% | 41.1 |
| Total above | | \$11,194.7 | 12.0% | | \$706.9 |
| Total all drugs | | \$93,409 | 100% | | \$1,310 |

*Note: Breakdown not available. Included in total.

Source: IMS, Barents Group LLC analysis of Scott-Levin Source Prescription Audit Data.

Other Evidence That DTC Advertising Works

Presumably, pharmaceutical manufacturers invest in DTC advertising because they believe it increases sales by more than the cost of the advertising. The sales figures in Table 4 support that belief, as does other available research. Market research by Scott-Levin has found an increase in doctors' appointments for heavily advertised conditions. Visits for those conditions rose 11 percent between January and September 1998, compared to a 2 percent increase in total office visits. For example, visits for high cholesterol were up 19 percent, while visits for hair-loss treatments rose by 30 percent.¹⁷

In addition to making more office visits, patients are also becoming more likely to ask for prescription drugs by brand name. A 1998 survey by IMS Health found that 53 percent of physicians reported an increase in brand name requests, up 30 percent from mid-1997 (before the relaxation of FDA guidelines for television advertising). More physicians also specified

¹⁷ Scott-Levin, "Patient Visits Up for DTC Conditions," press release, 6 November 1998.

manufacturer ads as a source of brand awareness among patients. This effect was especially felt by allergists, 97 percent of whom said that DTC ads had influenced their patients.¹⁸

When patients visit a doctor and ask for a specific prescription drug, evidence indicates that the doctor is likely to honor such requests. A 1997 study by *PREVENTION* magazine and the American Pharmaceutical Association (APhA) found that 73 percent of consumers said their doctors accommodated their request for a specific drug.¹⁹ Further, research by Scott-Levin found that patient requests for Claritin in the year ending September 1997 were honored 86 percent of the time.²⁰

Other Promotional Spending Is Also Increasing

Advertising aimed directly at consumers is a relatively new phenomenon. The bulk of pharmaceutical manufacturers' marketing efforts have always been and continue to be aimed at physicians and other health professionals. These efforts include advertising in professional journals, "detailing" (visiting physicians in their offices to promote a particular drug), and exhibiting at medical conferences.

Promotional spending aimed at professionals reached an all-time high of \$7.0 billion in 1998, according to Scott-Levin, and continues to grow. Detail spending grew 15 percent and event spending grew 28 percent over 1997.²¹

The Debate Over DTC and Other Drug Advertising

Advocates of DTC advertising argue that it expands consumers' knowledge of health conditions and potential treatment options, which facilitates the dialogue between consumers and their physicians. DTC ads may encourage more physician visits and subsequent discussion of treatment options. This notion suits the growing participatory nature of the health care system, in which consumers assume more responsibility for a range of health care decisions.

Critics say DTC advertising raises difficult issues of value and cost, since newer or more expensive products advertised through DTC marketing may not be the most effective for all patients with a given condition. Similar complaints have been lodged against advertising and promotional efforts aimed at physicians. For example, a study published in the *Journal of the American Medical Association* found that, even though the Fifth Joint National Committee on the Detection, Evaluation, and Treatment of High Blood Pressure in 1993 recommended diuretics and beta-blockers as first-line therapy for patients with hypertension (unless contraindicated),

¹⁸ IMS Health, "IMS Health Reports Direct to Consumer Advertising Increases Prescription Pharmaceutical Brand Requests and Awareness," press release, 15 September 1998.

¹⁹ *PREVENTION* and the American Pharmaceutical Association, "Navigating the Medical Marketplace: How Consumers Choose," a joint survey, Washington, D.C., 1997, pp. 25-29.

²⁰ Scott-Levin, "Direct-to-Consumer Pharmaceutical Ads 'Raising Consumer Awareness,' Says Scott-Levin", press release, 24 July 1998.

²¹ Scott-Levin, "The Pharmaceutical Industry: More Reps and More Promotion Fuel New Launches," press release, 18 June 1999. Accessed June 29, 1999, from www.scottlevin.com. Spending total clarified by Scott-Levin staff.

physicians wrote fewer prescriptions for these less expensive drugs and more prescriptions for the more expensive, brand-name calcium channel blockers and ACE inhibitors in 1995 than in 1992. As a percentage of antihypertensive prescriptions, calcium antagonists grew from 33 percent in 1992 to 38 percent in 1995 and ACE inhibitors grew from 25 percent to 33 percent, while beta-blocker use dropped from 18 percent to 11 percent and diuretic use from 16 percent to 8 percent.²² It has subsequently been suggested that the heavy promotion of brand name drugs contributes to this difference; in fact, calcium channel blockers are among the most heavily promoted drugs in the *New England Journal of Medicine*.²³

ANALYSIS OF UTILIZATION AND PRICE CHANGES

The increase in total spending on drugs can be broken down into two components: the increase due to the change in the total number of prescriptions written (a measure of utilization) and the increase due to the change in the average price per prescription.

As Table 5 shows, higher drug prices accounted for 64 percent of the total 1993-98 increase in drug spending, and increased utilization accounted for 36 percent of the increase.

| Table 5. Percentage Contribution of Changes in Price and Utilization to 1993-98 Increase in Prescription Drug Spending | | | |
|---|---------------------|---------------------------|--------------|
| | Price Effect | Utilization Effect | TOTAL |
| New Drugs (1992 and later) | 42% | 23% | 65% |
| Older Drugs | 22% | 13% | 35% |
| TOTAL | 64% | 36% | 100% |

Source: Barents Group analysis of Scott-Levin Source Prescription Audit Data for 1993 and 1998. For older drugs, the price effect measures increased spending due to the increase in the average price per prescription between 1993 and 1998 for these drugs. For newer drugs, the price effect measures increased spending due to the fact that the average price per prescription for these drugs in 1998 is higher than the 1993 average price per prescription for older drugs. For both new and old drugs, the increased spending due to a greater number of prescriptions filled is calculated using the 1993 average price per prescription for older drugs.

²² David Siegel, MD, MPH, Julio Lopez, PharmD, "Trends in Antihypertensive Drug Use in the United States: Do the JNC V Recommendations Affect Prescribing?" *JAMA* 278(21) (December 3, 1997) 1745-1748.

²³ Catherine Arnst, "Is Good Marketing Bad Medicine?" *Business Week*, April 13, 1998, p. 62. Accessed from www.scottlevin.com.

Driving the Increase in Average Price Per Prescription Has Been the Introduction and Widespread Use of Costlier New Drugs.

The introduction and utilization of new branded drugs (introduced in 1992 or later) has been *the* primary driver of the increase in total drug spending. New branded drugs accounted for \$27.6 billion, or 65 percent, of the \$42.7 billion increase in total retail drug spending from 1993 to 1998.

New branded drugs establish themselves in the marketplace very rapidly. In 1998, new drugs accounted for over \$30 billion (32 percent) of retail drug expenditures. In some therapeutic categories, new branded drugs account for over half of total spending (see Table 6). Particularly noteworthy are prescription antihistamines (98 percent of sales due to new branded drugs, including Claritin); cholesterol reducers (68 percent new drugs, including Lipitor and Zocor); and antidepressants (51 percent new drugs, including Paxil and Zoloft). In other therapeutic categories, new drugs have had a lesser impact.

Table 6. Share of Spending Represented by New Drugs, by Therapeutic Category

(Top 25 Therapeutic Categories in 1998 sales of new drugs, ranked by new drug sales. Shading indicates categories in which more than 50% of 1998 sales represent new drugs)

| Therapeutic Category | 1998 Sales (\$ millions) | 1998 Sales of New Drugs (\$ millions) | Percent of Total 1998 Sales Spent on New Drugs |
|--------------------------------|-------------------------------------|--|---|
| Antidepressants | \$7,120.9 | \$3,630.9 | 51.0% |
| Cholesterol reducers | 5,207.4 | 3,573.7 | 68.6% |
| Antihistamines | 2,258.5 | 2,225.9 | 98.6% |
| Antibiotics, broad based | 6,216.6 | 1,895.0 | 30.5% |
| Analgesics, non-narcotic | 2,166.8 | 1,667.9 | 77.0% |
| Oral antidiabetics | 2,537.7 | 1,628.8 | 64.2% |
| Antipsychotics | 1,737.1 | 1,409.4 | 81.1% |
| Anti-ulcerants | 6,588.0 | 1,248.1 | 18.9% |
| Calcium blockers | 4,175.8 | 1,239.4 | 29.7% |
| HIV Antivirals | 1,481.7 | 1,072.5 | 72.4% |
| Antiarthritics | 2,750.5 | 888.7 | 32.3% |
| Oral cold preparations | 910.4 | 801.1 | 88.0% |
| Fungicides | 1,674.0 | 741.3 | 44.3% |
| Antiseizure | 2,057.9 | 577.9 | 28.1% |
| Antihypertensive drugs | 4,047.2 | 539.4 | 13.3% |
| Sexual function disorder | 608.0 | 520.6 | 85.6% |
| Bone density regulators | 516.5 | 516.5 | 100.0% |
| Non-barbiturate sedatives | 626.5 | 515.0 | 82.2% |
| Sex hormones | 2,738.5 | 481.7 | 17.6% |
| Gastrointestinal stimulants | 498.4 | 458.1 | 91.9% |
| Respiratory steroids (inhaled) | 2,018.7 | 453.4 | 22.5% |
| Dermal acne therapy | 843.6 | 412.7 | 48.9% |
| Antivirals | 783.3 | 315.2 | 40.2% |
| Antiplatelet | 335.6 | 306.9 | 91.5% |
| Beta-blockers | 2,094.2 | 305.9 | 14.6% |
| All Drugs | \$93,405.7 | \$30,076.6 | 32.2% |

Source: Barents Group LLC analysis of Scott-Levin Source Prescription Audit Data.

Prices Are Higher for New Branded Drugs than for Older Products

Not only do new branded drugs rapidly replace the older drugs (if any) in their therapeutic class, they also tend to cost more than the drugs they replace.

Scott-Levin data indicate that the price of new branded drugs is significantly higher than for older drugs. The average price per prescription dispensed in 1998 for new drugs was \$71.49, more than twice the \$30.47 average price for older drugs.²⁴ To demonstrate the difference between the cost of new branded drugs and older drugs, Table 7 presents data on the price of leading new drugs in 20 therapeutic categories that represent two-thirds of total drug spending and 79 percent of all spending on new drugs. For comparison, the table also shows the average price of older drugs in each category. The entries in the table are sorted by total sales of drugs within the therapeutic category in 1998.

Table 7 shows that new branded drugs are typically much more expensive than other drugs in their therapeutic category. For example, among broad-based antibiotics, the average prescription prices of the two leading new drugs (defined in terms of share of sales) are 51 and 121 percent more expensive than more established drugs within the category. In one therapeutic category (non-narcotic analgesics), the average price per prescription for one leading new drug, Imitrex, was as much as seven times that of the existing drugs in the class.

More than half the increase in spending associated with new drugs can be attributed to the fact that they cost, on average, more than twice as much as older drugs.

²⁴The average price per prescription of older drugs increased by about 22 percent in total or 4.2 percent per year (holding the mix of older drugs constant at their 1993 levels). Because this calculation does not account for possible changes in dosage or size of prescription over this time, it may be an overstatement of the actual price increase. Nevertheless, price increases in existing drugs appear to be fairly modest over this period and in line with general medical inflation.

**Table 7. Price of New Drugs Compared to Old Drugs,
by Therapeutic Category, 1998**

| Therapeutic Category | Top Two New Drugs in Therapeutic Category | Price of New Drug | Average Price of Old Drugs | Price of New Drug Relative to Average Price of Older Drugs |
|--------------------------------|--|--------------------------|-----------------------------------|---|
| Antidepressants | Zoloft | \$76.08 | \$48.82 | 155.8% |
| | Paxil | \$70.59 | | 144.6% |
| Anti-ulcerants | Prevacid | \$112.46 | \$86.99 | 129.3% |
| | Prilosec | \$122.80 | | 141.2% |
| Antibiotics, broad based | Zithromax | \$39.19 | \$25.99 | 150.8% |
| | Cefzil | \$57.53 | | 221.3% |
| Cholesterol reducers | Lipitor | \$75.59 | \$71.89 | 105.1% |
| | Zocor | \$98.26 | | 136.7% |
| Calcium blockers | Norvasc | \$55.64 | \$49.57 | 112.3% |
| | Sular | \$33.29 | | 67.2% |
| Antihypertensive drugs | Cozaar | \$49.64 | \$40.03 | 124.0% |
| | Diovan | \$44.64 | | 111.5% |
| Beta-blockers | Coreg* | \$89.32 | \$26.49 | 337.1% |
| Sex hormones | Prempro* | \$28.10 | \$26.53 | 105.9% |
| Oral antidiabetics | Glucophage | \$48.54 | \$27.27 | 178.0% |
| | Rezulin | \$142.82 | | 523.8% |
| Antihistamines | Claritin | \$61.79 | \$65.27 | 94.7% |
| | Zyrtec | \$51.57 | | 79.0% |
| Analgesics, non-narcotic | Imitrex | \$153.58 | \$20.64 | 744.2% |
| | Ultram | \$42.15 | | 204.2% |
| Oral contraceptives | Desogen* | \$27.02 | \$29.57 | 91.4% |
| Bronchodilators | Serevent* | \$60.75 | \$27.54 | 220.6% |
| Antiseizure | Neurontin | \$97.15 | \$44.16 | 220.0% |
| | Lamictal | \$167.50 | | 379.3% |
| Respiratory steroids (inhaled) | Flonase | \$46.95 | \$51.48 | 91.2% |
| | Rhinocort | \$36.63 | | 71.2% |
| Antipsychotics | Zyprexa | \$242.66 | \$42.12 | 576.1% |
| | Risperdal | \$141.58 | | 336.1% |
| Fungicides | Lamisil | \$182.01 | \$31.22 | 582.9% |
| | Sporanox | \$195.65 | | 626.6% |
| HIV Antivirals | Viracept | \$516.03 | \$318.68 | 161.9% |
| | Zerit | \$252.77 | | 79.3% |
| Oral cold preparations | Claritin 12 hour | \$48.76 | \$17.30 | 281.8% |
| | Allegra - D | \$41.85 | | 241.8% |

*Note: Only one new drug introduced between 1993 and 1998 in therapeutic category.

Source: Barents Group LLC analysis of Scott-Levin Source Prescription Audit Data.

The Influence of Public Policy on New Drug Introduction

Regulatory changes have played an important role in speeding the flow of new pharmaceuticals to the marketplace. In recent years, the FDA has approved more drugs and has done so at a quicker pace. Figure 5 shows both the number of new molecular entities (NMEs) approved by year and the time required for approval.

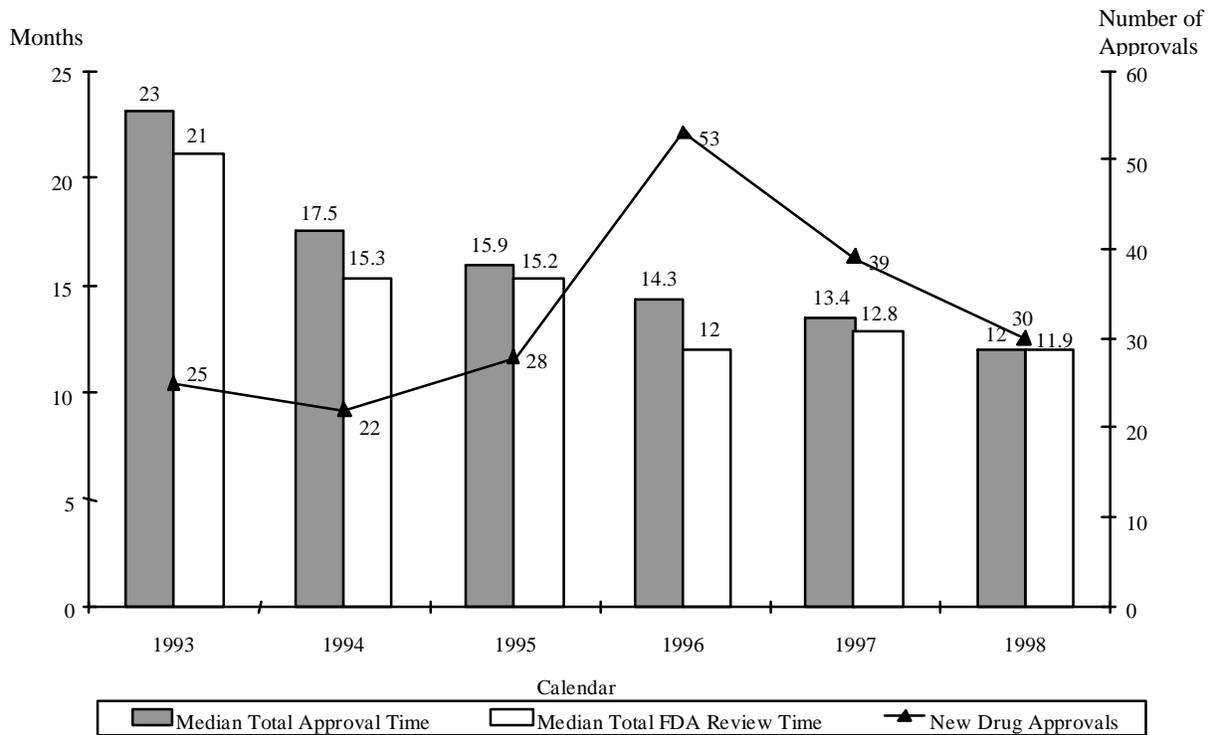
This heightened FDA activity in approving drugs has resulted from adoption of the Prescription Drug User Fee Act (PDUFA) of 1992. The Act authorized the FDA to collect fees from the industry to support the federal approval process. In exchange, the agency was required to meet rising annual performance targets, which is important to manufacturers because a decrease in approval time of one year is estimated to increase a drug's annual returns by about \$22 million.²⁵

Subsequently, Congress enacted the FDA Modernization Act (FDAMA) of 1997. FDAMA institutes the same basic approach as the PDUFA but, in addition to setting more ambitious targets for drug review, attempts to reduce *total* development time, not just regulatory review time. This distinction is important because regulatory review is a small part of the total review process, which includes clinical development.

As indicated in Figure 5, the FDA cut its review time nearly in half during the five-year period from 1993-1998. Total review time showed a similar drop and, accordingly, there was an overall increase in the approval of NMEs. Approvals tapered off in 1997 and 1998 after a peak of 53 approvals in 1996, but still remained higher than at the beginning of the five-year period.

²⁵ Congressional Budget Office. *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*. June 1998.

Figure 5. Approval of New Molecular Entities, 1993 - 1998



Note: Approval time includes FDA review time and industry response time to FDA requests for information

Increasing Utilization Is Also an Important Factor

On average, growth in the use of prescription drugs, particularly new drugs, accounted for 36 percent of the 1993-98 increase in drug spending. Overall, the number of prescriptions filled increased 31 percent, growing from 1.9 billion in 1993 to 2.5 billion in 1998. For older drugs, the number of prescriptions filled grew 11.5 percent; the remainder of the utilization increase was due to new branded drugs.

But the relative contribution of price and utilization varies greatly across therapeutic categories. For most large therapeutic categories, increases in total expenditures have been driven primarily by changes in utilization rather than changes in the average price per prescription. This is not to say that there have not been increases in the average price per prescription in any therapeutic categories, but rather that utilization increases have tended to be larger than price increases in most categories that had relatively strong sales in 1993.

Table 8 provides a breakdown of changes in overall utilization and average price per prescription for the 25 categories of drugs that accounted for 81 percent of the total increase in drug expenditures between 1993 and 1998. The entries in the table are ranked by the contribution that each therapeutic category made to overall increases in drug expenditures.

Table 8. Change in Average Price and Utilization by Therapeutic Category, 1993-1998

(Top 25 Therapeutic Categories ranked by contribution to overall 1993-98 increase in drug spending. For highlighted categories, the 1993-98 change in utilization exceeds the 1993-98 change in average price.)

| Type of Drug | 1998 Sales (\$ millions) | Share of Total 1998 Sales | Change in Average Price per Prescription 1993 - 1998 | Change in Utilization 1993 - 1998 (percent) |
|--------------------------------|-----------------------------|------------------------------------|---|--|
| Antidepressants | \$7,120.9 | 7.6% | 61.1% | 111.5% |
| Cholesterol reducers | 5,207.4 | 5.6% | 12.4% | 161.6% |
| Anti-ulcerants | 6,588.0 | 7.1% | 29.8% | 31.9% |
| Antihistamine (oral) | 2,258.5 | 2.4% | 18.6% | 500.2% |
| Antihypertensive drugs | 4,047.1 | 4.3% | -0.6% | 89.3% |
| Diabetes (oral) | 2,537.7 | 2.7% | 33.8% | 133.6% |
| Antipsychotics | 1,737.1 | 1.9% | 253.7% | 58.9% |
| HIV antivirals | 1,481.7 | 1.6% | 77.9% | 544.9% |
| Antiseizure | 2,057.9 | 2.2% | 63.1% | 75.3% |
| Antibiotic, broad based | 6,216.3 | 6.7% | 27.2% | 0.0% |
| Sex hormones | 2,738.5 | 2.9% | 17.4% | 63.7% |
| Analgesics, non-narcotic | 2,166.8 | 2.3% | 87.2% | 33.1% |
| Respiratory steroids (inhaled) | 2,018.7 | 2.2% | 38.5% | 93.7% |
| Analgesics, narcotic | 2,486.1 | 2.7% | 31.6% | 30.0% |
| Fungicides | 1,674.0 | 1.8% | 67.6% | 45.8% |
| Calcium blockers | 4,175.8 | 4.5% | 8.7% | 15.8% |
| Oral contraceptives | 2,162.0 | 2.3% | 31.4% | 23.2% |
| Oral cold preparations (Rx) | 910.4 | 1.0% | 142.8% | 148.8% |
| Beta-blockers | 2,738.6 | 2.9% | -9.8% | 53.2% |
| Bronchodilators | 2,094.2 | 2.2% | 24.3% | 24.1% |
| Sexual function disorder | 608.0 | 0.7% | - | - |
| Bone density regulators | 516.5 | 0.6% | - | - |
| Dermal acne therapy | 843.6 | 0.9% | 66.3% | 47.7% |
| Interferon | 518.4 | 0.6% | 123.4% | 518.8% |
| Non-barbiturate sedative | 626.5 | 0.7% | 103.8% | 93.4% |
| All other | \$27,875.2 | 29.8% | 26.3% | 10.9% |
| TOTAL | \$93,405.7 | 100.0% | 40.5% | 31.1% |

Source: Barents Group LLC analysis of Scott-Levin Source Prescription Audit Data.

The table shows that there is no typical range of price and utilization changes across the therapeutic categories considered. For most categories (those shaded in the table), increases in the utilization of drugs contributed more to expenditure growth than increases in the average price of drugs within the category.

- ◆ An example of a category affected primarily by utilization is oral antihistamines, a category dominated by the drug Claritin. Between 1993 and 1998, utilization of the drugs in the category increased by 500 percent, while the average price of prescriptions in this category increased by only 19 percent.
- ◆ An example of a category affected primarily by price is non-narcotic analgesics (pain killers), where use increased by 33 percent while price increased by 87 percent, largely as a result of increased use of significantly more expensive drugs such as Stadol, whose average price was \$96 per prescription.

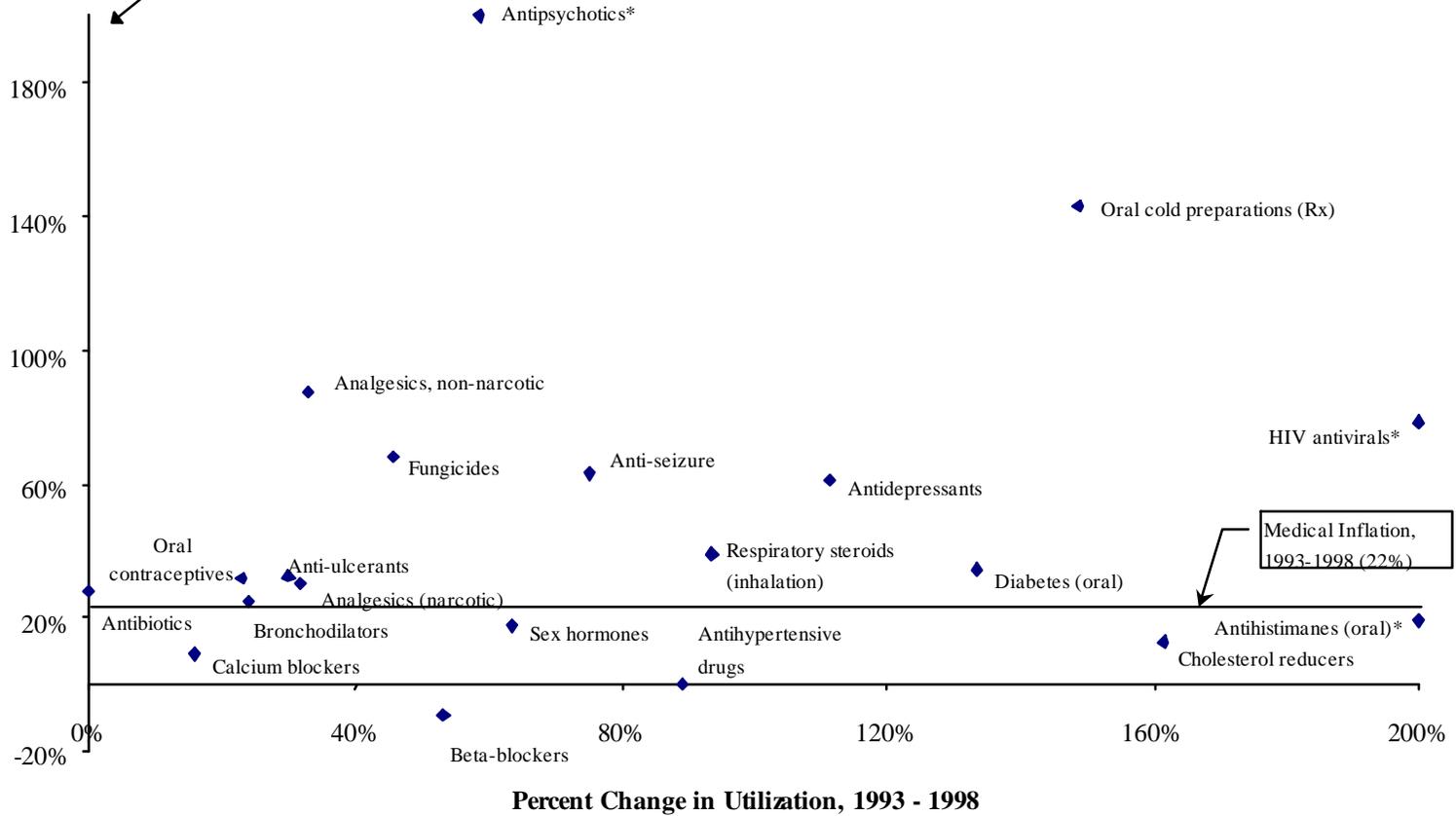
Variation across therapeutic categories can be more readily seen in Figure 6, which plots the percent change in the average price per prescription for individual therapeutic categories on the vertical axis against the percent change in utilization on the horizontal axis. Data are presented for the 20 therapeutic categories that accounted for about 75 percent of the total 1993-98 increase in drug spending. To put the percentage price increase in context of overall medical inflation, we have drawn a horizontal line to indicate that overall medical inflation (June to June) between 1993 and 1998 was 21.7 percent (or about 4 percent a year).

As can be seen, the change in the average price of drugs in a number of therapeutic categories was close to the overall level of medical inflation, but several of these categories (oral diabetes drugs, cholesterol reducers and oral antihistamines) experienced particularly high increases in utilization. As discussed earlier, many of the leading drugs in these categories were subject to extensive DTC advertising that undoubtedly increased the awareness and use of drugs in these categories.

The figure also shows that there was great variation in the average change in the price of drugs across therapeutic categories and that there were categories in which price increases were much greater than medical inflation. Examples of these categories include antipsychotics, oral cold preparations, non-narcotic analgesics, HIV antivirals, fungicides, anti-seizure drugs and antidepressants. The primary explanation for higher average prices is not that prices have gone up significantly for individual drugs. Rather, more expensive drugs have been used more extensively, thus raising the average price per prescription in the category.

Figure 6. Change in Average Price and Utilization for Leading Classes of Therapeutics, 1993 - 1998

Percent Change in Average Price per Prescription, 1993 - 1998



Source: Barents Group LLC analysis of Scott-Levin Source Prescription Audit Data

Note: These 20 therapeutic classes accounted for 75 percent of overall increases in expenditures

* Indicates over 200 percent change in utilization or price

THE ROLE OF GENERIC DRUGS

In terms of expenditures, generic drugs are not a major factor in the market. Between 1993 and 1997, their share of *sales* decreased from roughly 10 percent to 8 percent.²⁶ Sales volume has decreased despite the fact that generics' share of countable units (such as tablets) has increased somewhat from 39.7 percent in 1993 to 46.5 percent in 1998.²⁷ (See Figure 7.)

Generics find it difficult to compete when there are heavily marketed newer compounds in the same therapeutic classes. For example, one leading drug benefit manager with 7.2 million enrollees reports that use of ranitidine (the generic equivalent of Zantac) has fallen in the past four years from 41 percent to 19 percent of the gastrointestinal disease market, while the newer branded drugs Prilosec and Prevacid have increased their share from 9 percent to 36 percent among its members.²⁸

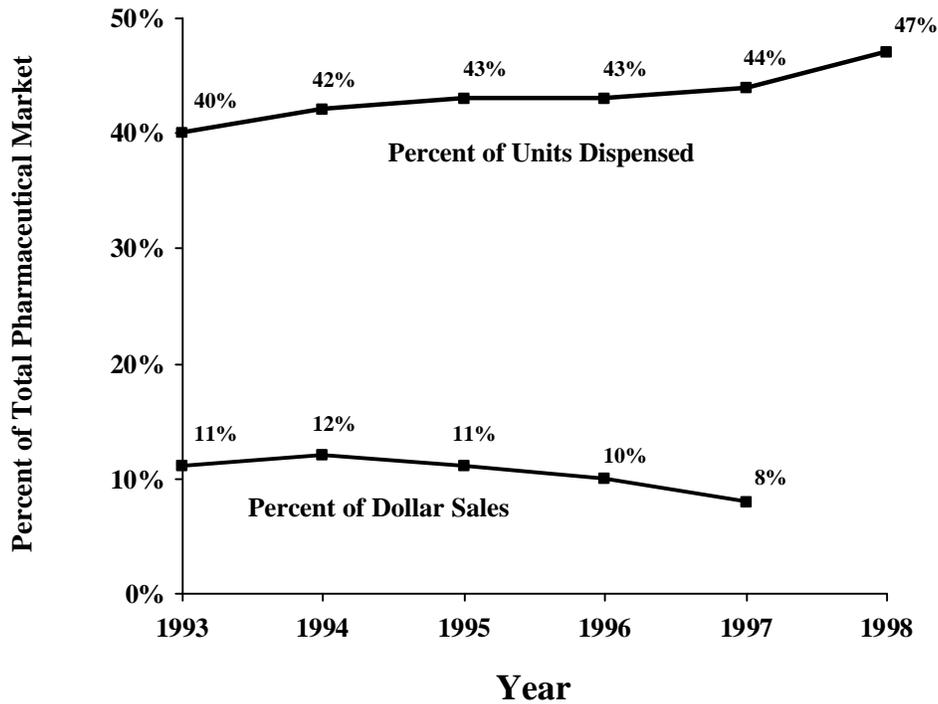
Scott-Levin data show that, although generic drugs exist in most therapeutic categories, sales in the largest therapeutic categories are often dominated by a few brand-name drugs. For example, Prilosec and Prevacid accounted for over 63 percent of anti-ulcerant spending in 1998, and three branded drugs — Prozac, Zoloft, and Paxil — accounted for 71 percent of total antidepressant sales.

²⁶ IMS Health and IMS America, as cited by the *Wall Street Journal*, 18 November 1998, p. A10. The *Journal* also reports that unit prices for generics fell each year from 1993 through 1997. Recently, there have been reports that unit prices for generics rose in 1998 and that they may now be contributing to the overall increase in drug spending.

²⁷ *Ibid.*

²⁸ Thomas M. Burton, "Why Generic Drugs Often Can't Compete Against Brand Names," *The Wall Street Journal*, 18 November 1998, p. A1. It is not clear in the source whether the base for the quoted percentages is patients, prescriptions or dollars spent.

Figure 7. Market Share of Generic Drugs in Units and Dollar Sales, 1993-1998



Source: IMS Health and IMS America. Sales figures for generic drugs in 1998 are not yet available.

THIRD-PARTY PAYERS HAVE BORNE MUCH OF THE INCREASED COST OF PRESCRIPTION DRUGS, DUE TO THE SHIFT TO MANAGED CARE

More than two-thirds (68 percent) of the total 1992-97 increase in drug spending was borne by private third-party payers.²⁹

Prescription drug spending has grown even faster for third-party payers than for the nation as whole in large part because of the lower out-of-pocket costs, both for doctor visits and for prescriptions themselves, that accompanied the major shift to managed care during the 1990s. Only 14 percent of covered employees were enrolled in conventional health insurance plans in 1998, compared to 71 percent in 1988.³⁰

The shift to managed care has influenced drug spending by providing generous outpatient drug benefits, increasing patient access to doctors, and often insulating consumers from most of the cost for their medications.

²⁹ Health Care Financing Administration, National Health Expenditures, 1997. Accessed from www.hcfa.gov.

³⁰ KPMG LLP, *Health Benefits in 1998* (June 1998): p. 40.

Prescription benefit levels are generally unrestricted in managed care settings, with less than 10 percent of HMOs capping the maximum drug benefits a member can receive.³¹ Moreover, managed care emphasizes primary care. Visits to primary care providers and other physicians in the managed care network are typically far less expensive than under traditional fee-for-service coverage. This arrangement encourages utilization of physician services, which in turn results in a greater demand for prescription drugs. Patients have more opportunities to request and receive prescriptions. (An estimated 60 percent of all physician visits result in a prescription.³²) It can also be argued that, because of generally lower out-of-pocket costs, typically a \$5 copayment for generics and \$10 for brand-name drugs, more prescriptions are ultimately filled under managed care than under fee-for-service coverage.³³

Although it is difficult to isolate the impact that managed care has had on overall prescription drug spending, the rise of managed care has certainly increased consumer use of outpatient drugs through increased access to prescribers. This effect has been magnified by the fact that responsibility for payment has largely been transferred to third parties.

While most observers expect managed care penetration to continue to increase, some analysts predict that the trend toward third-party coverage of prescriptions cannot sustain itself under the stress of recent spending increases and that plans will be forced to raise premiums or limit drug coverage. In fact, HMO member access to pharmacy benefits appears to be declining somewhat, with the Novartis Pharmacy Benefits Report indicating a two-year slide to 92.4 percent access for HMO members overall in 1997.³⁴

³¹ *Hoechst Marion Rousell Managed Care Digest Series/HMO-PPO Digest* (1998 ed.): 30.

³² Jonathan P. Weiner, Alan Lyles, Donald M. Steinwachs, and Katherine C. Hall, "Impact of Managed Care on Prescription Drug Use." *Health Affairs*. Spring 1991: 145-147.

³³ In 1996, 73.8 percent of HMO enrollees with prescription drug coverage paid \$5 per prescription for generic drugs. For brand-name drugs, 36.7 percent paid \$5 per prescription and 36.2 percent paid \$10 per prescription. The weighted average copayments were \$5.29 for generics and \$7.67 for branded drug. American Association of Health Plans, *Profile of Health Plans and Utilization Review Organizations*, 1997-98 edition.

³⁴ *Novartis Pharmacy Benefit Report: Facts and Figures*. (1998 ed.): 5.

CHAPTER 3: CONCLUSIONS AND IMPLICATIONS FOR THE FUTURE

This report has found that the increase in retail drug spending from 1993 to 1998 was concentrated in a relatively small number of therapeutic categories (e.g., antidepressants, cholesterol reducers, anti-ulcerants and prescription antihistamines), in which many new branded drugs have been heavily advertised.

Pharmaceutical manufacturers are spending large amounts to promote their new branded drugs, and a sizable proportion (22 percent) of the entire 1993-98 increase in drug spending is accounted for just by the ten drugs with the most direct-to-consumer advertising in 1998.

Of the overall increase in drug spending from 1993 to 1998, 64 percent was due to higher average prices per prescription, primarily because of the introduction and widespread use of costlier new drugs. The total number of prescriptions filled also increased significantly, growing from 1.9 billion to 2.5 billion.

Will Drug Spending Continue to Grow More Rapidly Than Other Health Care Services?

A key question is whether the growth in spending on prescription drugs is likely to continue at its present, or perhaps an even faster, pace. We believe that the answer is an unequivocal yes, for the following reasons:

- ◆ The pharmaceutical industry continues to invest billions to develop new drugs, and many new drugs are already “in the pipeline.”
 - ◇ Worldwide research and development expenditures in the industry have increased more than 12-fold from about \$2 billion in 1980 to an estimated \$24 billion in 1999.³⁵
 - ◇ The Pharmaceutical Research and Manufacturers’ Association (PhRMA) reports that 316 new drugs are under development to treat cancer, 87 to treat cardiovascular diseases such as congestive heart failure, coronary disease, hypertension and stroke, 93 to treat other chronic problems such as arthritis, osteoporosis, diabetes and asthma, and 17 to treat Alzheimer’s disease.³⁶
- ◆ Advances in the basic sciences, particularly in genetic research, are expected to increase the number of targets for drug intervention exponentially in just a few years.
 - ◇ Currently, there are about 500 known “targets” for drug innovation. Completion of the Human Genome Project is expected to increase the number of potential targets to at least 3,000 and perhaps as many as 10,000.³⁷

³⁵ Pharmaceutical Research and Manufacturers of America, “Pharmaceutical Industry Profile 1999,” Figure 2-1. Data from PhRMA’s Annual Survey 1999. Accessed June 28, 1999 from www.phrma.org.

³⁶ *Ibid.* Figure 1-10.

³⁷ Jurgen Drews, MD, “Genomic Sciences and the Medicine of Tomorrow: Commentary on Drug Development,” *Nature Biotechnology*, vol. 14, November 1996. Cited in Pharmaceutical Research and Manufacturers of America, “Pharmaceutical Industry Profile 1999,” Figure 1-9. Accessed June 28, 1999, from www.phrma.org.

- ◆ Advances in the application of computer-based technology to pharmaceutical research are greatly speeding the processes of developing potential new drugs.
 - ◇ For example, the *Wall Street Journal* recently reported on “software that allows researchers to test the potential activity of new chemicals in a sort of virtual reality. This ... system allows drug-hunting scientists to test thousands of potential chemicals without actually synthesizing them and testing them in the laboratory.”³⁸
- ◆ Pharmaceutical manufacturers continue to spend heavily to promote their products. Promotional spending reached at all-time high of \$8.3 billion in 1998. Detail spending grew 15 percent, event spending grew 28 percent, and DTC advertising grew 30 percent over 1997.³⁹ DTC advertising is expected to grow another 54 percent in 1999.⁴⁰
- ◆ Research advances coincide with demographic trends that will greatly increase the number of Americans at risk for chronic and potentially disabling conditions.
 - ◇ The single largest market for prescription drugs is the aging baby boom generation. According to U.S. Census data, the 54-to-64 age group will expand by 59 percent between 1998 and 2010.
 - ◇ According to PhRMA, about 70 percent of Americans over 65, representing about 24 million people, are now at risk for cardiovascular disease. If current demographic trends continue, this number could exceed 50 million by 2050.⁴¹
 - ◇ The drugs used by the middle aged and elderly tend to be expensive and often treat conditions, such as hypertension, high cholesterol, diabetes and arthritis, which require a steady regimen throughout the patient's life.⁴²

Policy Implications

Pharmaceutical research has brought great improvements in health and longevity. Given the increasing investment in research and development, more such welcome advances can be expected in the future. But, while some new drugs are true breakthroughs, opening up new avenues of treatment that have not previously been available, others may offer more modest improvements on earlier therapies at greater expense.

More research is needed on several important questions:

³⁸ Michael Waldholz, “Neurogen to License Rapid Drug-Discovery Technology to Pfizer,” *The Wall Street Journal*, June 17, 1999, p. B2.

³⁹ Scott-Levin, “The Pharmaceutical Industry: More Reps and More Promotion Fuel New Launches,” press release, 18 June 1999. Accessed June 29, 1999, from www.scottlevin.com. Spending total clarified by Scott-Levin staff.

⁴⁰ *The Wall Street Journal*, June 8, 1999, p. B14 (reporting on projections by IMS Health).

⁴¹ Pharmaceutical Research and Manufacturers of America, *op.cit.*, Figure 1-7.

⁴² Testimony of the Blue Cross and Blue Shield Association on Prescription Drug Benefits and the Medicare Program for the Committee on Finance, U.S. Senate, presented by Dr. Morris B. Mellion, June 23, 1999, p. 5.

- ◆ How do we leverage the tremendous potential of pharmaceuticals and assure that the right drugs get to the right people safely and at the right time?
- ◆ Under what circumstances is each new drug the most appropriate treatment, compared to the available alternatives?
- ◆ Given the large increase in prescription volume, how can we best limit mistakes and adverse drug interactions?
- ◆ What are the positive and negative effects of DTC advertising, physician detailing and other promotional efforts?
- ◆ What impact will increasing expenditures on prescription drugs have on overall health care spending?

Affordability will increasingly be a concern. As the cost of covering prescription drugs continues to grow, health plans, purchasers and consumers will face difficult choices among promoting access to drug therapies, maintaining health insurance premiums at an affordable level, and continuing to offer other needed benefits. The money to pay for more expensive new drugs must come from higher premiums, higher out-of-pocket costs (e.g., “triple-tier” copayments), lower benefits, and/or more restricted access to drugs (e.g., formularies).

In addition, the possible inclusion of a prescription drug benefit in the Medicare program makes understanding what is driving the increases in pharmaceutical expenditures all the more important. For private third-party payers, which cover a younger, healthier population, prescription drugs already represent about 13 percent of health benefit outlays. Some plans with many retirees report that drug costs are approaching 30 percent of total benefits.⁴³ Pharmaceutical research is focused on new drugs that will address the chronic and disabling diseases of the elderly. The experience of private insurers, particularly those covering older populations, suggests that the cost of Medicare coverage of prescription drugs will likely be substantial from the outset and increase significantly over time.

⁴³ *Ibid.*



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