
The Continuing Rise in Prescription Drug Expenditures

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June 2001

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Introduction:

Spending on retail outpatient prescription drugs increased 18.8% in 2000 to \$131.9 billion, according to a new report issued by the National Institute for Health Care Management (NICM).¹ This makes 2000 the seventh year out of the last thirteen in which prescription drug spending rose more than 12%.²

The issue of rising prescription drug prices is an important one worthy of examination, particularly given the historic aging of the U.S. population. By 2030, the U.S. Census Bureau projects that the proportion of persons aged 65 and older will rise to 20.0% of the population from the current 12.7%.³ This paper attempts to provide needed background information on the matter as well as a framework for reform.

The recent focus on prescription drug prices and benefits for Medicare recipients, provides policymakers with an excellent opportunity to introduce market-driven solutions for addressing issues pertaining prescription drugs. This approach could prove a model for reforms and could be applied on a more comprehensive basis to reform the U.S. health care system in the future.

A market-based approach would allow the prescription drug industry to respond quickly to changing consumer demands, increase access to pharmaceutical products for those who most need them, and ensure that the U.S. remains the world leader in creating innovative breakthrough prescription drugs.

By contrast, an anti-market approach—such as the introduction of price controls, or increased third-party involvement in the industry—could further distort the market for prescription drugs, reducing innovation, fostering rationing, and eroding the overall quality of U.S. health care.

An important ingredient for market-based health care reform is catastrophic coverage which seeks to protect health care consumers against unusual and devastating expenses while requiring them to pay for the cost of meeting their own routine health needs.

Rising Prescription Drug Expenditures:

Currently, the nation spends an estimated \$116.9 billion to \$145.1 billion per year on prescription drugs.⁴ Overall, prescription drug outlays amounted to 8.2% of total health care expenditures in 1999 and a projected 8.9% in 2000.⁵

Recently, much attention has been focused on the fact that prescription drug expenditures are increasing at a significantly faster rate than overall health care spending. This phenomenon is not new. Since 1980, prescription drug outlays have grown by double-digit rates in almost every year.⁶ Since the middle 1980s, money spent on prescription drugs has been, on average, increasing at a faster rate than the amount spent on health care overall.⁷ Since the 1990s, however, prescription drug spending has been rising at more than double the rate of growth in total health care expenditures.⁸

Drug Spending vs. National Health Spending: 1996-2000 (billions of dollars)

	1996	1997	1998	1999	2000 est.
Health Spending	\$1038.0	\$1093.9	\$1146.1	\$1210.7	\$1311.1
Drugs	\$67.2	\$75.1	\$85.2	\$99.6	\$116.9
Percent	6.5%	6.9%	7.4%	8.2%	8.9%

Source: Health Care Financing Administration, Office of the Actuary

A closer look at prescription drug spending reveals that disproportionate increases in five categories of drugs (oral antihistamines, antidepressants, lipid-lowering agents, anti-ulcerants, and antihypertensives) accounted for 33.8% of the increase in drug expenditures from 1993-2000.⁹

Category	Common Drugs	1993-2000 Change in Expenditures
Oral Antihistamines	Claritin, Zyrtec, Allegra	+1079%
Antidepressants	Prozac, Zoloft, Paxil	+ 399%
Cholesterol Reducers	Lipitor, Zocor, Pravachol	+ 365%
Antihypertensive Drugs	Zestril, Vasotec, Accupril	+ 168%
Anti-ulcerant Drugs	Prilosec, Prevacid, Ranatidine Hcl	+ 146%

Sales growth in these categories remained strong in 2000 with the following increases being recorded¹⁰:

- Oral Antihistamines: 26.0%
- Antidepressants: 20.9%
- Cholesterol Reducers: 27.4%
- Antihypertensive Drugs: 19.0%
- Anti-ulcerant Drugs: 20.0%

However, between 1999 and 2000 while three of these top categories continued to account for a sizable share of the total increase in drug spending, two new categories posted substantial gains as well.

Overall, the five fastest-growing categories in terms of the change in dollar sales (antidepressants, cholesterol reducers, anti-ulcerant drugs, narcotic painkillers, and oral diabetes drugs) accounted for 34.9% of the total increase in prescription drug spending between 1999 and 2000.¹¹ When the increase in spending on antihypertensive drugs, antiseizure medications, oral antihistamines, and antipsychotic drugs is included, these nine categories were responsible for 50.4% of the increase in drug spending.¹²

The market share commanded by the top ten drugs (\$24.2 billion in sales) was 47.7% in 1993. In 2000, the top ten drugs (\$61.7 billion in sales) still accounted for 46.8% of the prescription drug market.¹³

Why Prescription Drug Expenditures are Increasing:

Increasing drug utilization and a shift toward newer, and generally more expensive drugs, are largely responsible for the continuing rapid increase in prescription spending.¹⁴

Overall, the increased usage of prescription drugs was responsible for 42% of the spending increase while the shift toward higher-priced medicines contributed to 36% of this new spending.¹⁵ Price inflation was responsible for the remainder of increases in spending. After accounting for the changing mix in drug utilization, prescription drug prices rose 4.0% between 1999 and 2000.¹⁶

Rising national drug spending driven by a combination of increased utilization and a shift to newer, more expensive drugs is nothing new. Since 1993, an overwhelming portion of the increase in national drug outlays has been attributable to these two factors.¹⁷ Recent evidence pertaining to expenditures on new drugs seems to support the continuation of such a trend. Early projections reveal that pipeline drugs (those that are in the development and/or approval process) could account for 40% of new expenditures through 2005.¹⁸

Rising Utilization/Changing Mix:

Since 1992, total retail prescriptions increased 53% while the number of prescriptions per person rose 42.5%.¹⁹ In 2000 alone, the number of prescriptions increased 7.5%.²⁰

According to The National Institute for Health Care Management (NIHCM), three factors are responsible for this growth in prescriptions²¹:

- An increase in the population and changes in its age structure
- An increase in the number of people being prescribed a medication
- An increase in the number of prescriptions per person

At least part of the increased utilization appears to be the result of a substitution of drug therapies for alternative medical therapies. Since 1980, as prescription drug expenditures were increasing at double-digit rates in virtually every year, annual growth in hospital and physician service spending was slowing dramatically.²²

Research by economists at the National Bureau of Economic Research has found a substitution effect in the treatment of heart attacks and acute major depression, two conditions where drug therapies play an important role. In the case of heart attacks, the cost of treatment has fallen almost 1% per year from 1984-1991 (the period of the study) while the cost of treatment for depression fell a total of 25% during the 1991-1995 period.²³

In addition to these examples, there is a large body of medical literature that documents health cost savings realized from drug therapies for such conditions as ulcers, schizophrenia, asthma, strokes, migraine headaches, and kidney disease.²⁴ Some of these savings are sizable. For instance, schizophrenia drugs costing \$4,500 per year have helped patients suffering from this disorder avoid costs of institutional treatment amounting to \$73,000 per year.²⁵ Clot-buster medications have produced savings in the treatment of strokes that are some four times the cost of these medications.²⁶ According to the National Academy of Sciences and the National Institute on Aging, there is also evidence that the probability of elderly Americans being struck by devastating chronic disabilities such as stroke and dementia have fallen sharply, particularly during the 1990s, with “new drugs for heart problems and other illnesses” contributing to the decline.²⁷

In fact, if substitution is a major explanation for the increased utilization of prescription drugs, the rise in drug expenditures may well have helped slow the rise in overall health care costs. Put this way, increased prescription drug spending may represent a beneficial shifting in the structure of health care costs that could, in the longer-term, pave the way for smaller increases in overall health care expenditures.²⁸ Some researchers even argue that continuing improvements in the health of the elderly could cause Medicare spending to stop rising.²⁹

Moreover, should prescription drugs significantly reduce the incidence of disease, even at substantially higher prices, they could prove to be a significant bargain for the economy. Each year, for example, the economy suffers an estimated \$1.7 trillion in lost worker output from reduced job performance and missed work due to illness and premature death.³⁰

Consequently, prescription drug spending—particularly that resulting from newer drugs—should be judged within a broader framework than total expenditures. This framework should include:

- Their effect on advancing patient welfare
- Their impact on the overall health care system, both qualitatively and economically, e.g., savings generated from reduced reliance on invasive procedures, etc.
- Their economic and social effects in reduced sick days, increased productivity, etc.

Another factor that may be responsible for the increased utilization of prescription drugs, especially in recent years, is the dramatic growth in direct-to-consumer advertising for such products. Annual spending on such advertising increased from \$55 million in 1991 to \$1.8 billion in 1999 with 1999 spending representing a 40% increase over that of the previous year.³¹ Recent years have witnessed a substantial rise in TV ads. In 1996, TV advertising accounted for 11.4% of direct-to-consumer expenditures.³² By 1999, TV advertising had increased to 61% of direct-to-consumer spending. Total promotional activities on the part of pharmaceutical concerns amounted to \$13.9 billion in 1999.³³ The reach of this advertising is significant. By early 1999, an estimated 151 million to 177 million U.S. adults had heard or seen a prescription drug ad.³⁴

The majority of ads are used to promote drugs that are early in their product life cycle, are applicable to patients with chronic conditions, have few major side effects, and are used for illnesses and conditions that are not highly complex, according to a study published by Martin S. Roth of Boston College's Carroll School of Management.³⁵ Overall, 70% of direct-to-consumer spending is concentrated on 20 drugs.³⁶

Although a large body of rigorous evidence is not yet available concerning the impact of such direct-to-consumer advertising, there is some evidence that such spending does stimulate demand for the advertised drugs.³⁷

In a random consumer survey conducted by Dr. Michael S. Wilkes of the University of California, 29% of respondents said that they had asked their physicians for prescriptions after seeing direct-to-consumer ads for those drugs.³⁸ Of those respondents who requested the prescriptions for the advertised drugs, 25% said that they would try to persuade their doctors, should they refuse to write them the desired prescription, and 25% said that, if denied, they would change their physicians.³⁹ Also, evidence seems to indicate that prescriptions for heavily advertised drugs increase relative to drugs that are not advertised.⁴⁰ For instance, the four high-growth drug categories mentioned earlier contain 7 of the 10 most heavily advertised drugs.⁴¹

Why New Drugs Cost More:

Newer drugs are often substantially more expensive than those that they replace. This effect can be seen in the average price of the top 50 drugs, in terms of sales, which include a growing number of newer medications. Overall, the average price per prescription of these best-selling drugs came to \$67.15 in 2000, with the average price of

all other drugs coming to \$36.01.⁴² Overall, for drugs approved and marketed prior to 1992, the average prescription price came to \$30.47, while the average price for those approved and marketed afterward was \$71.49 per prescription.⁴³ The general rule that newer drugs cost significantly more per prescription than older ones applies across therapeutic categories⁴⁴:

Category	Increase in Price
Antidepressants	41.4% to 75.9%
Anti-ulcerants	44.8%
Cholesterol Reducers	14.9% to 56.3%
Arthritis/Osteoarthritis	160.3% to 192.3%
Broad Antibiotics	57.7% to 199.2%
Oral Antidiabetics	131.0% to 404.5%
Narcotic Painkillers	663.1%

On average, several factors account for newer drugs being more expensive than those that they replace. These include the average cost of \$500 million and 12-15 year time span required to develop these drugs, along with the enormous statistical odds faced by drug manufacturers in their development of new medications. Only 1 out of every 5,000 medicines tested are ever approved for patient use and only 3 out of every 10 drugs available generate revenues sufficient to meet or exceed average research and development costs.⁴⁵

The proliferation of generic medications (in 1996, 43% of U.S. prescription drug sales were for generic products vs. 19% in 1984), often seen as a panacea for rising prescription drug expenditures, has helped tame the growth of these expenditures.⁴⁶ However, because such drugs reduce the overall returns on investment from new drugs (the Congressional Budget Office has estimated that the spread of generic drugs has lowered average returns on new drugs by roughly 12% since the early 1980s)⁴⁷, the price savings from generic medicines could, in the future, tend to promote higher prices for new drugs barring meaningful improvements in the success and approval rates of such medications.

Quality-risk considerations also limit the potential of generic medications to reduce overall drug costs. Recent research has revealed that between 14.2% and 53.8% of those surveyed believe that generic drugs are riskier than brand name drugs depending on the condition being treated and that significantly larger cost savings would be needed to encourage health care consumers to purchase the generic drugs perceived to be risky.⁴⁸ Technological advances and advances in scientific understanding including data from the Human Genome Project could reduce these costs in the future.

In terms of pipeline drugs, the categories considered most likely to result in increased expenditures include genetic therapies, anti-hypertensives, antidepressants, cancer

therapies, oral diabetic agents, anti-arthritic agents, hormone replacement therapies, erectile dysfunction therapies, and cholesterol lowering agents.⁴⁹ These classes of drugs will increase overall expenditures for two reasons: (1) they are very costly; e.g., genetic therapies often cost more than \$1,000 per month, or (2) their usage will be very high; e.g., cardiac agents such as cholesterol lowering drugs that target the population with heart disease which either affects or is projected to eventually affect up to a quarter of all Americans.⁵⁰ It remains to be seen whether the cost of drug treatments like genetic therapies will eventually decline due to a combination of increased productivity and economies of scale generated over time as is typical of new technologies, and genetic breakthroughs (e.g., the map of the human genome) that would make research more efficient and effective).

Availability of Low-cost and Free Drugs for Low-income Patients:

Despite rising national drug expenditures and the higher cost of new medicines, low-income persons who lack adequate prescription drug coverage are not completely without options. A small number of truly needy persons (generally those who lack both private and public coverage and have inadequate financial resources) can receive relief in the form of free prescription drugs. Each year, the Pharmaceutical Research and Manufacturers of America provides a directory to physicians that lists drugs that can be given away for free to eligible patients. Physicians or providers merely apply on the behalf of eligible patients and a whole range of medications is made available. Those interested in reading the 2001-2002 directory, can obtain it over the Internet at: <http://www.phrma.org/searchcures/dpdpap/pa99.pdf>.

For example, Roche Laboratories makes most of its product line available “as an interim-solution to patients who lack third-party outpatient prescription drug coverage under private insurance, government-funded programs (e.g., Medicaid, Medicare, Veterans Affairs, etc.), or private/community sources and are unable to afford to purchase” the drugs on their own.⁵¹ Likewise, Bristol-Myers Squibb offers many of its products as “temporary assistance to patients with financial hardship who are not eligible for prescription drug coverage through Medicaid or any other public or private health program.”⁵²

Basic Principles for Prescription Drug Reforms:

Any prescription drug reforms will need to be carefully constructed so as to preserve the innovation and productivity of the U.S. pharmaceutical industry while helping ensure that all patients have access to the medications they need. The overall objective of such reforms would be to transform patients into true prescription drug consumers who would function within the marketplace. The principles of such reform would include:

- An absence of price controls: Virtually all economic research demonstrates that price controls lead to rationing, stifle innovation, and undermine overall access to potentially life-saving medicines. A recent study by the General Accounting Office (GAO) found that limited price control efforts by the Federal Government to mandate lower

prescription drug prices of beneficiaries of federal programs such as Medicare through negotiated discounts would likely lead to higher costs in the private marketplace for individual and employer-sponsored plans.⁵³

- A streamlined FDA approval process: A streamlined FDA review and approval process based exclusively on rigorous scientific evidence would expand the period of time medications are available under patent protection.⁵⁴ Patent protection should also run from the date of approval in order to assure that pharmaceutical products enjoy patent protection that is similar to goods that do not require an often lengthy approval process. These changes would afford pharmaceutical manufacturers a somewhat longer period of time in which to recover research and development costs. Already, the rise of a private clinical testing industry helping to reduce the lag time between new drug development and the introduction of those drugs into the marketplace.⁵⁵ At the same time, such factors as medical necessity, status of existing drugs in a new drug's class, etc. should determine whether new drugs receive prescription or over-the-counter status upon approval.

- A refundable health care tax credit for individuals and families⁵⁶ that could be used for the purchase of catastrophic prescription drug coverage: This would provide all patients with the resources necessary to protect themselves against the risk of financial ruin. The credit should not be so large as to encourage the purchase of low-deductible/low co-payment prescription drug coverage.⁵⁷

There is mounting evidence that prescription drug plans should be based on catastrophic coverage. This evidence increasingly suggests that first-dollar coverage (due to low deductibles or co-payments) at the expense of out-of-pocket spending for non-catastrophic prescription costs has helped fuel rising drug spending. According to the NIHCM, those with prescription coverage “today are paying a much smaller percentage of drug costs out-of-pocket than they did just 10 years ago (27.5% in 1998 versus 48.3% in 1990),⁵⁸ despite the recent rise in drug costs. That is part of the reason drug spending has been going up. Protected from all but a \$5, \$10 or \$15 flat co-payment per prescription, consumers have not been ‘price-sensitive’ to the drugs they buy.”⁵⁹ An analysis by the Department of Health and Human Services revealed that “Medicare beneficiaries with coverage fill nearly one-third more prescriptions than those without coverage” and that “total drug spending for beneficiaries with coverage is nearly two-thirds higher,” with those having coverage paying 45% less per year out-of-pocket.⁶⁰

In addition, given the purchasing clout of prescription plans (private and public), persons with coverage tend to pay significantly less per prescription and therefore purchase more prescriptions than those without such coverage.⁶¹

Consequently, for private third-party payers, prescription drug spending accounts for approximately 13% of total health care spending.⁶² Some plans that cover retirees, who are on average are less healthy than younger persons, have prescription drug expenditures that approach 30% of total outlays.⁶³

- Deductible thresholds could even be tied to a percentage of a patient's income. This would be most beneficial to lower-income persons. It would also benefit seniors, many of whom depend on fixed incomes and who, on average, consume more health care services, including prescription drugs than any other segment of the population. Today, 56.4% of seniors have incomes under \$15,000 per year and 77.7% have incomes below \$25,000 per year.⁶⁴ When it comes to females who comprise almost 60% of the population of people aged 65 and older, 68.7% have incomes below \$15,000 annually and 86.2% have annual incomes under \$25,000.⁶⁵
- Medical Savings Accounts (MSAs): These accounts should be made permanent and liberalized so they can be combined with a wider variety of insurance plans. Tax-free MSAs would be an important mechanism by which individuals and families could pay out-of-pocket for current routine medical needs and save for future needs.
- Insurance reform that would permit insurers to combine individuals into groups regardless of employer, employment status, or any other factor that could inhibit innovations in pooling risks designed to reduce overall costs of coverage. Under the reforms, insurers should also receive protection from state-or-locally-imposed mandates that could increase the costs of coverage for prescription drugs.
- Better informed customers. Patients who are better informed on the options available to them would be in a stronger position to safeguard their interests as health care consumers. Today, the U.S. National Library of Medicine makes available an online guide to more than 9,000 prescription and generic drugs. This information, along with warnings and recall news, can be found at: <http://www.nlm.nih.gov/medlineplus/druginformation.html>.

ENDNOTES

¹ “Prescription Drug Expenditures in 2000: The Upward Trend Continues,” National Institute for Health Care Management, May 2001, p.2.

² “Prescription Drug Expenditures in 2000: The Upward Trend Continues,” National Institute for Health Care Management, May 2001, p.3.

³ U.S. Census Bureau, Statistical Abstract of the United States: 2000 (120th edition), Washington, D.C., 1999, pp.13,15 Tables 12 and 14.

⁴ “Prescription Drug Expenditures in 2000: The Upward Trend Continues,” National Institute for Health Care Management, May 2001, p.5.

⁵ In 1999, total health care expenditures amounted to \$1,210.7 billion while prescription drug expenditures came to \$99.6 billion. The figures came to projected amounts of \$1,311.1 billion and \$116.9 billion respectively in 2000. “National Health Care Expenditures Projections: 2000-2010” Health Care Financing Administration, Table 2: National Health Expenditures Amounts, and Average Annual Percent Change by Type of Expenditure: Selected Calendar Years 1980-2010.”

⁶ “Prescription Drugs: Issues of Cost, Coverage, and Quality,” *EBRI Issue Brief*, April 1999, No. 208.

⁷ “Highlights—National Health Expenditures, 1998,” Health Care Financing Administration, Table 2: National Health Expenditures Aggregate Amounts and Average Annual Percent Change, by Type of Expenditure: Selected Calendar Years 1960-98 and “National Health Care Expenditures Projections: 2000-2010” Health Care Financing Administration, Table 2: National Health Expenditures Amounts, and Average Annual Percent Change by Type of Expenditure: Selected Calendar Years 1980-2010.”

⁸ “National Health Care Expenditures Projections: 2000-2010” Health Care Financing Administration, Table 2: National Health Expenditures Amounts, and Average Annual Percent Change by Type of Expenditure: Selected Calendar Years 1980-2010.”

⁹ “Factors Affecting the Growth of Prescription Drug Expenditures,” National Institute for Health Care Management, July 9, 1999, p.10 and “Prescription Drug Expenditures in 2000: The Upward Trend Continues,” National Institute for Health Care Management, May 2001, p.15.

¹⁰ “Prescription Drug Expenditures in 2000: The Upward Trend Continues,” National Institute for Health Care Management, May 2001, p.15.

¹¹ “Prescription Drug Expenditures in 2000: The Upward Trend Continues,” National Institute for Health Care Management, May 2001, p.15.

¹² “Prescription Drug Expenditures in 2000: The Upward Trend Continues,” National Institute for Health Care Management, May 2001, p.15.

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¹⁴ “Prescription Drug Expenditures in 2000: The Upward Trend Continues,” National Institute for Health Care Management, May 2001, p.2.

¹⁵ “Prescription Drug Expenditures in 2000: The Upward Trend Continues,” National Institute for Health Care Management, May 2001, p.2.

¹⁶ “The average retail price of all prescription drugs rose 10.5% from 1999 to 2000, from \$40.96 to \$45.27. We estimate that \$1.64 of that \$4.31 increase can be attributed to ‘pure’ price inflation at the manufacturer, wholesale, and retail level” in “Prescription Drug Expenditures in 2000: The Upward Trend Continues,” National Institute for Health Care Management, May 2001, pp.2, 10.

¹⁷ “Prescription Drugs: Issues of Cost, Coverage, and Quality,” *EBRI Issue Brief*, April 1999, No. 208.

¹⁸ C. Daniel Mullins, Ph.D., et. al., “The Impact of Pipeline Drugs on Pharmaceutical Spending,” Presented at a joint BlueCross BlueShield Association/Health Insurance Association of America Symposium, April 13-14, 2000.

¹⁹ “Prescription Drug Expenditures in 2000: The Upward Trend Continues,” National Institute for Health Care Management, May 2001, p.9.

²⁰ “Prescription Drug Expenditures in 2000: The Upward Trend Continues,” National Institute for Health Care Management, May 2001, p.9.

²¹ “Prescription Drug Expenditures in 2000: The Upward Trend Continues,” National Institute for Health Care Management, May 2001, p.9.

²² “Prescription Drugs: Issues of Cost, Coverage, and Quality,” *EBRI Issue Brief*, April 1999, No. 208.

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²⁴ John E. Calfee, Ph.D., “Hearing on Seniors’ Access to Prescription Drug Benefits” before the Subcommittee on Health of the House Committee on Ways and Means, February 15, 2000.

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²⁶ Nimish Vakil, “Guidelines for H. Pylori-Induced Peptic Ulcer Disease Treatment,” *Drug Benefit Trends*, 1996, pp.21-24, 32.

²⁷ Milt Freudenheim, “Decrease in Chronic Illness Bodes Well for Medicare Costs,” *The New York Times*, May 8, 2001, p.A24.

²⁸ “Evidence suggests that more appropriate utilization of prescription drugs has the potential to lower total expenditures and improve the quality of care.” (“Prescription Drugs: Issues of Cost, Coverage, and Quality,” *EBRI Issue Brief*, April 1999, No. 208).

²⁹ Milt Freudenheim, “Decrease in Chronic Illness Bodes Well for Medicare Costs,” *The New York Times*, May 8, 2001, p.A24.

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- ³² Michie I. Hunt, "Prescription Drug Costs: Federal Regulation of the Industry," BlueCross BlueShield Association, September 2000, p.9.
- ³³ IMS Health, "IMS Health Reports U.S. Pharmaceutical Promotional Spending Reached Record \$13.9 Billion in 1999," London: April 20, 2000.
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- ⁴² "Prescription Drug Expenditures in 2000: The Upward Trend Continues," National Institute for Health Care Management, May 2001, p.10.
- ⁴³ "Factors Affecting the Growth of Prescription Drug Expenditures," National Institute for Health Care Management, July 9, 1999, p.18.
- ⁴⁴ Data comes from Figure 7. Whenever possible, the average 1998 price of drugs approved prior 1992 was considered. Only in cases where such data was not available was the average price of all but the top four selling drugs for a given category employed. "Prescription Drug Expenditures in 2000: The Upward Trend Continues," National Institute for Health Care Management, May 2001, p.10.
- ⁴⁵ "Why do Medicines Cost So Much?" Pharmaceutical Research and Manufacturers of America.
- ⁴⁶ "How Increased Competition From Generic Drugs Has Affected Prices and Returns In The Pharmaceutical Industry," Congressional Budget Office, July 1998, p.ix.
- ⁴⁷ "How Increased Competition From Generic Drugs Has Affected Prices and Returns In The Pharmaceutical Industry," Congressional Budget Office, July 1998, p.ix.
- ⁴⁸ Julie M. Ganther and David H. Kreling, "Consumer Perceptions of Risk and Required Cost Savings for Generic Prescription Drugs," at <http://www.medscape.com>
- ⁴⁹ C. Daniel Mullins, Ph.D., et. al., "The Impact of Pipeline Drugs on Pharmaceutical Spending," Presented at a joint BlueCross BlueShield Association/Health Insurance Association of America Symposium, April 13-14, 2000.

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⁵¹ *Directory of Prescription Drug Patient Assistance Programs: 2001-2002*, p.24.

⁵² *Directory of Prescription Drug Patient Assistance Programs: 2001-2002*, p.6.

⁵³ “Prescription Drugs: Expanding Access to Federal Prices Could Cause Other Price Changes,” United States General Accounting Office, August 2000, pp.5-6.

⁵⁴ In general, patent protection on new drugs extends 20 years from the date of application for the patent. However, an average of 5.9 years of this time is consumed by clinical testing of the new drug and the FDA review process exhausts another 1.4 years. This leads to an average effective patent life of 12.7 years, which can be somewhat shorter in situations, where pharmaceutical companies apply for patents during the preclinical testing phase. Since the early 1970s, increasing clinical development and FDA approval times have significantly shortened the effective patent life of new drugs (Michie I. Hunt, “Prescription Drug Costs: Federal Regulation of the Industry,” BlueCross BlueShield Association, September 2000, p.47).

⁵⁵ John E. Calfee, *Prices, Markets, and the Pharmaceutical Revolution*, Washington, DC: The AEI Press, 2000, p.13.

⁵⁶ Employment-based health care subsidies have led to overinsurance in terms of health benefits, distorted the demand for medical care, and inflated the price of health services according to economic research (Robert B. Helms, “Positive Economics and Dismal Politics: The Role of Tax Policy in the Current Health Policy Debate,” at the Western Michigan University Lecture Series: Kalamazoo, Michigan, February 16, 2000.

⁵⁷ Evidence suggests that lower co-payments may lead to greater use of prescription drug usage (“How Increased Competition From Generic Drugs Has Affected Prices and Returns In The Pharmaceutical Industry,” Congressional Budget Office, July 1998, p.x). The same may well hold true for low deductible coverage or other plans that encourage first-dollar prescription drug coverage. In turn, overutilization of prescription drugs could tend to increase the growth in expenditures as well as the rise in prices of medications due to supply-demand factors.

⁵⁸ The Henry J. Kaiser Family Foundation, “Prescription Drug Trends: A Chartbook,” Menlo Park, California: July 2000, p.11.

⁵⁹ “Prescription Drug Expenditures in 2000: The Upward Trend Continues,” National Institute for Health Care Management, May 2001, p.4.

⁶⁰ “Prescription Drug Coverage, Spending, Utilization, and Prices,” Department of Health and Human Services, April 2000, <http://aspe.hhs.gov/health/reports/drugstudy/exec.htm>

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⁶² “Factors Affecting the Growth of Prescription Drug Expenditures,” National Institute for Health Care Management, July 9, 1999, p.ix.

⁶³ “Factors Affecting the Growth of Prescription Drug Expenditures,” National Institute for Health Care Management, July 9, 1999, p.ix.

⁶⁴ U.S. Census Bureau, *Statistical Abstract of the United States: 2000* (120th edition), Washington, DC, 2000, p.473 Table 750.

⁶⁵ 58.6% of seniors were female and 41.4% were male according to the 1999 Census figures (U.S. Census Bureau, *Statistical Abstract of the United States: 2000* (120th edition), Washington, DC, 2000, pp.13, 473 Tables 12 and 750).