

**AMERICA'S OTHER DRUG PROBLEM:  
A BRIEFING BOOK  
ON THE  
RX DRUG DEBATE**

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Prepared by Public Citizen's Congress Watch



## **Acknowledgments**

“America’s Other Drug Problem: A Briefing Book on the Rx Drug Debate” was prepared by Congress Watch Director Frank Clemente, Legislative Assistant April Greener, Legislative Representative Ben Peck, Researcher Andrew Benore, and former Research Director Bob Young and Senior Researcher Michael Surrusco.

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**Public Citizen’s Congress Watch**  
**215 Pennsylvania Ave S.E.**  
**Washington, D.C. 20003**  
**P: 202-546-4996**  
**F: 202-547-7392**  
**[www.citizen.org](http://www.citizen.org)**

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## Introduction

So you think you know about prescription drugs? Okay, let's see:

- 1) What little pill was more heavily advertised in 2000 than Bud and Pepsi?
- 2) What drug company had more profits in 2001 than all of the Fortune 500 homebuilding, apparel, railroad and publishing companies *combined*?
- 3) How many of the 50 most popular drugs were discovered with taxpayer-funded research?
- 4) Compared to all other industries, how much higher or lower is the federal tax burden on the drug industry?

If you answered 1) Vioxx; 2) Pfizer; 3) 45 and 4) 40% lower, you may not need this resource guide.

But those who are less expert, we hope, will find “America’s Other Drug Problem: A Resource Guide to the Rx Drug Debate” a valuable collection of easy-to-digest, bullet-point facts about key issues such as: prescription drug prices and company profits, research and development myths and facts, advertising budgets, tax breaks, patent extensions and political spending.

We’ve divided this resource guide into four main sections: “The Problem,” “Profits,” “Propaganda, Public Subsidies and Patents” and “Political Persuasion.” Within those sections are many sub-categories of information. Graphic illustrations of key facts are interspersed in the text. A bibliography lists all sources and includes Internet links to primary source documents. Occasionally, some facts may be in conflict with each other. That is not an oversight – just the result of different sources and dates of information that cannot be reconciled.

This resource guide will be particularly important as Congress debates a prescription drug plan for seniors and considers other drug legislation. It should also prove useful for many policy makers and advocates active in state-based prescription drug efforts. The graphics can easily be turned into transparencies and used in speeches and workshops. Some readers may see a pro-consumer bias in the selection of facts. That bias may well exist. But in creating this resource, we have used credible, independent sources and the most current data that we know of for each and every point we make.

We aim to regularly update the web-based version of the booklet whenever we can with important information from new research, studies and reports. Please have patience with those efforts, as our staff is small and resources limited.

## I. The Problem

**One-quarter of the American population lacks prescription drug insurance. Seniors are hit particularly hard because they use more prescription drugs – and data shows that drug coverage for seniors is declining and becoming more costly. Like other Americans without coverage, seniors say they sometimes go without medicine because they can't afford it. Even seniors who can afford prescription drug insurance find it increasingly expensive as insurers raise premiums, hike co-payments and impose spending caps. In addition, drug prices are climbing at dramatic rates and Americans now pay far more per prescription than consumers in other countries. Compounding the problem is a rising tide of TV ads that are boosting demand for expensive brand-name drugs. The upshot of all this – increased use, an aging population, high prices and proliferating ads – is that overall American spending on drugs is skyrocketing and will triple in 10 years, just as it did in each of the last two decades.**

### A. Coverage Issues: Who Has Insurance – and Who Doesn't

- Americans without drug insurance: Roughly 65 million Americans have no insurance for prescription drugs. (U.S. Department of Health and Human Services, “Prescription Drug Coverage, Spending Utilization, and Prices,” Report to the President, April 2000)
  - Medicare recipients (seniors and the disabled) without drug coverage: 11.6 million
  - Non-Medicare recipients without drug coverage: 53 million
- Drugs Medicare covers: While all seniors and the disabled are eligible for Medicare, the Medicare program pays for prescription drugs only if they are administered in institutional settings such as hospitals and nursing homes, or if the drugs belong to several special categories such as oral anti-cancer drugs and hemophilia clotting factors. (U.S. Department of Health and Human Services, “Prescription Drug Coverage, Spending Utilization, and Prices,” Report to the President, April 2000)
- Sources of drug coverage for Medicare beneficiaries: In the fall of 1999,
  - 37.7% of Medicare beneficiaries had no insurance coverage for prescription drugs
  - 28.3% had drug coverage through an employer-sponsored plan

- 6.8% had an individually purchased Medigap plan that helped pay for prescription drugs
  - 10% received drug coverage through Medicaid
  - 15.3% had coverage through a so-called Medicare HMO (Medicare+Choice plan). (Mary Laschober, et al., *Health Affairs Web Exclusive*, February 27, 2002) *See Figure I.A.1: "Sources of Prescription Drug Coverage for Medicare Beneficiaries, Fall 1999"*
- Seniors without drug coverage: Most of these seniors without coverage (7.6 million) are not affluent. They have incomes below \$20,900 (individual) or \$28,900 (couple). Furthermore, 3 million have incomes below 135% of poverty level (\$11,300 for individuals or \$15,200 for couples). (AARP, "The Cost of Prescription Drugs: Who Needs Help?" October 2000)
  - Seniors with inadequate drug coverage: A 2001 study surveying seniors in eight states found that more than one-third (37%) of low-income seniors with HMO drug benefits and 31% of those with Medigap drug benefits reported not filling prescriptions or skipping doses due to cost concerns. (The Henry J. Kaiser Family Foundation, The Commonwealth Fund, Tufts-New England Medical Center, "Seniors and Prescription Drugs: Findings from a 2001 Survey of Seniors in Eight States," July 2002)
  - Employer-sponsored drug coverage is declining: Large employers are scaling back retiree benefits. The number of large firms offering Medicare supplemental insurance (which generally covers prescription drugs) to their retirees fell from 35% in 1995 to 24% in 2000. (William M. Mercer, "Mercer/Forster Higgins National Survey of Employer-Sponsored Health Plans," Spring 2001)
  - Medicare+Choice plans are slashing drug coverage: Medicare HMOs have substantially reduced drug benefits and increased out-of-pocket costs for seniors, despite the fact that drug coverage was used by these HMOs to entice many seniors to join their plans. For example:
    - HMOs are dumping beneficiaries in record numbers. From 1999 through January 1, 2003, there have been more than 2.4 million occasions where seniors and people with disabilities have been dropped by their Medicare HMOs, where they typically received some prescription drug coverage. (Public Citizen analysis of Centers for Medicare and Medicaid Services

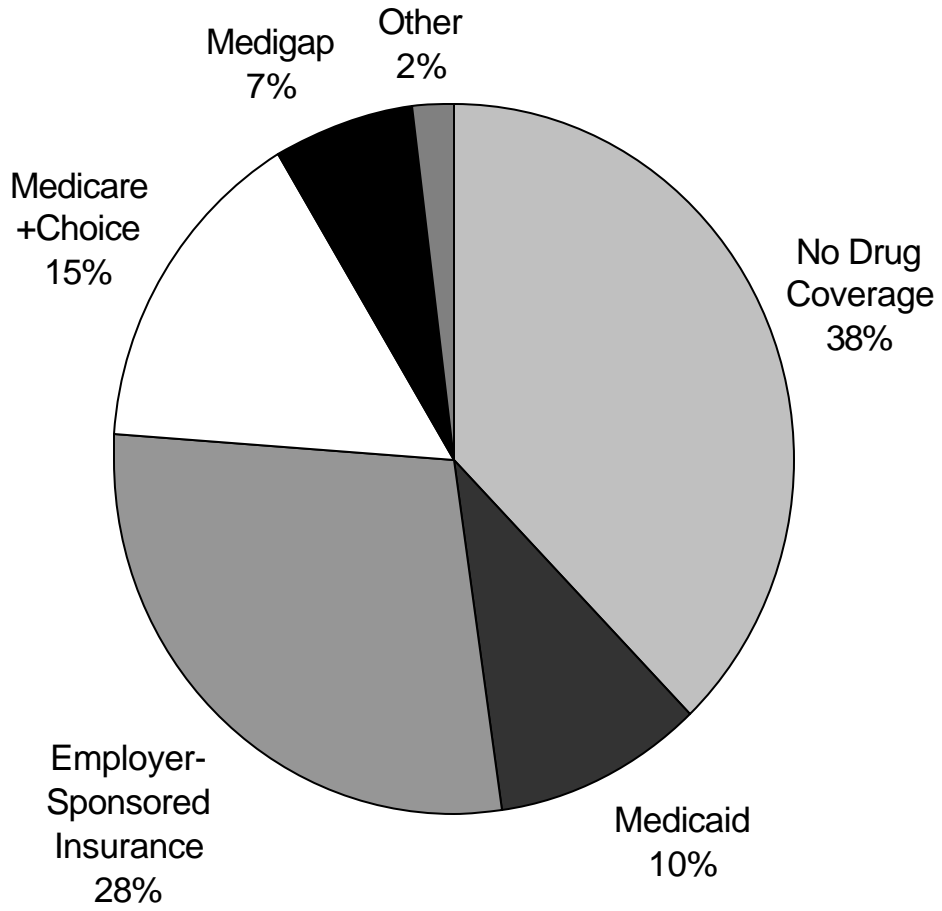
data; reported in Public Citizen's "Medicare Privatization: Bad for Seniors and People with Disabilities," February 2003)

- Only about 61% of all Medicare beneficiaries had the option of enrolling in a Medicare+Choice plan in 2003 compared to 74% in 1998. (Scott Harrison, "New Developments in the Medicare+Choice program," Medicare Payment Advisory Committee meeting, October 12, 2002)
- Even though 61% had the choice, only 11% of beneficiaries chose to enroll in a Medicare+Choice plan. (U.S. Department of Health and Human Services, FY 2004 Budget in Brief, January 2003)
- Only 19% of beneficiaries living in rural areas have the option of enrolling in a coordinated care Medicare+Choice plan today. (Scott Harrison, "New Developments in the Medicare+Choice Program," October 10, 2002)
- In 2002, 70% of Medicare+Choice HMOs' basic plans either offered no coverage for prescription drugs or offered coverage for generic drugs only. (Lori Achman and Marsha Gold, "Trends in Medicare+Choice Benefits and Premiums, 1999-2002," Mathematica, November 2002)
- By 2002, 69% of plans, enrolling 51% of beneficiaries in the Medicare+Choice program, had annual caps of \$500 or less on the drug benefits they offered, up from 23% in 1999. (Lori Achman and Marsha Gold, "Trends in Medicare+Choice Benefits and Premiums, 1999-2002," Mathematica, November 2002)



Figure I.A.1

**Sources of Prescription Drug Coverage  
for Medicare Beneficiaries, Fall 1999**



Source: Laschober, Mary et al. *Health Affairs Web Exclusive* February 27, 2002

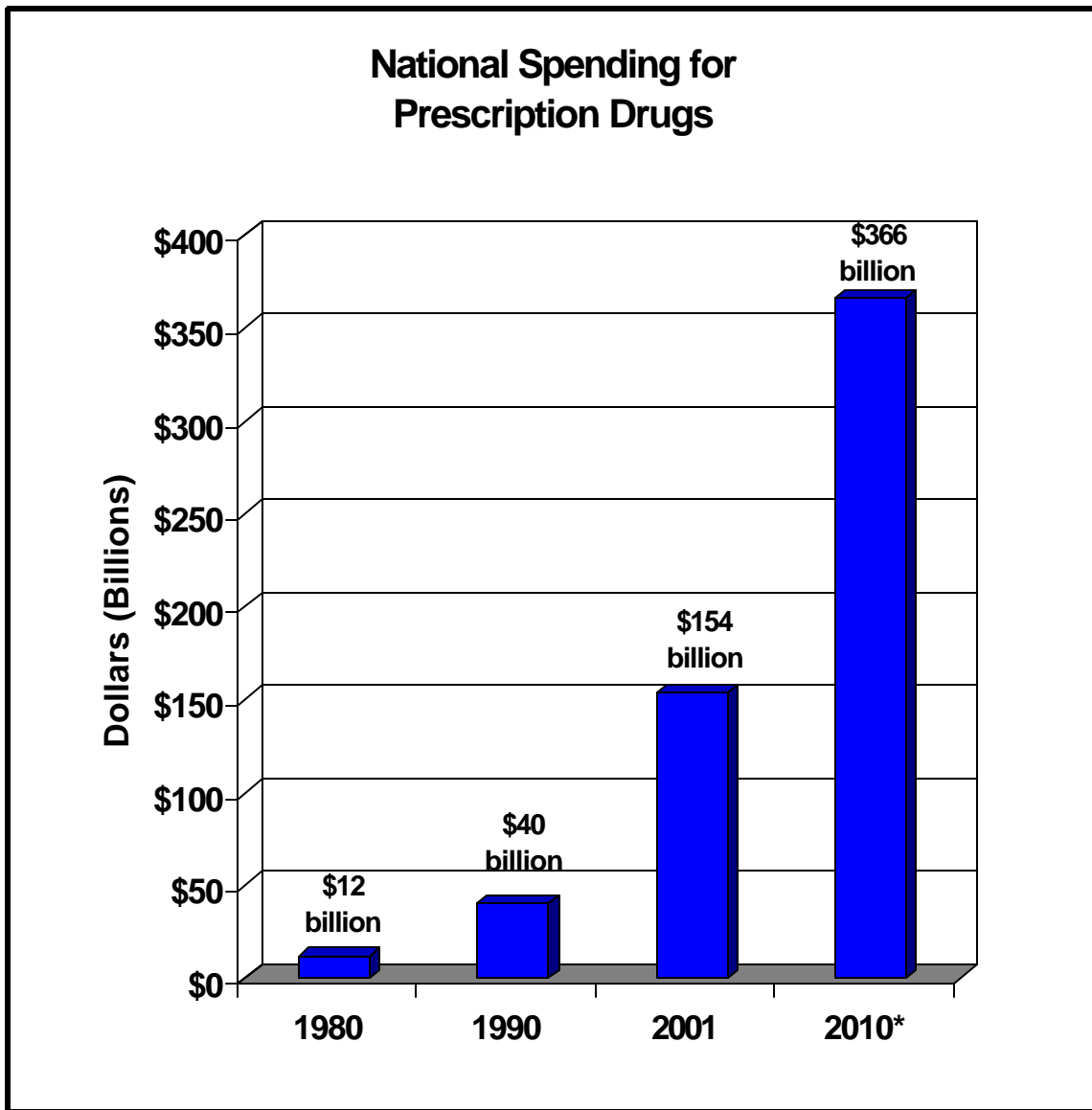
- Medigap plans are inadequate and expensive: More than 2.8 million seniors buy expensive Medigap plans. The three Medigap policies that offer drug coverage to seniors all have a \$250 deductible and a 50% co-pay up to maximum payment caps of \$1,250 or \$3,000. (Mary Laschober, et al., *Health Affairs Web Exclusive*, February 27, 2002)
  - For these Medigap plans which offer coverage for prescription drugs, seniors must pay average annual premiums that range from \$1,917 (for moderate benefits) to \$3,252 (for extensive benefits), in addition to co-payments and deductibles. On average, beneficiaries who purchase Medigap still pay 58% of their prescription drug costs out-of-pocket. (Families USA/PRIME Institute, “Cost Overdose: Growth in Spending for the Elderly, 1992-2010,” July 2000)
  
- An aging population will exacerbate problems: Drug spending by seniors will grow as baby boomers age and the elderly population swells. The number of American seniors will double to about 70 million by the year 2030, growing to 20% of the U.S. population from 13% today. (U.S. Census Bureau, “Projections of the Total Resident Population by 5-Year Age Groups, and Sex with Special Age Categories: Middle Series, 2025 to 2045,” 2000)
  
- Seniors are using more drugs: the average number of prescriptions per elderly person per year grew from 19.6 in 1992 to 28.5 in 2000, an increase of 45%. (Families USA/PRIME Institute, “Cost Overdose: Growth in Spending for the Elderly, 1992-2010,” July 2000)
  
- Lack of coverage is dangerous: 42% of uninsured Americans reported not filling prescriptions for financial reasons. (Donelan, et al., “The Cost of Health Care System Change: Public Discontent in Five Nations,” *Health Affairs*, May/June 1999)
  - Seniors without drug coverage are more likely to skip doses or not fill a prescription due to cost. A 2001 survey of seniors in eight states found that more than one-third without drug coverage either skipped doses or did not fill a prescription, a rate twice as high as for those with drug coverage. (The Henry J. Kaiser Family Foundation, The Commonwealth Fund, Tufts-New England Medical Center, “Seniors and Prescription Drugs: Findings from a 2001 Survey of Seniors in Eight States,” July 2002)

- Not just a problem for seniors: 57% of all workers earning \$7 an hour or less are not offered *any* health insurance coverage by their employer. (Families USA, “Go To Work, Do Not Collect Health Insurance: Low Income Parents Lose Medicaid,” June 2000)

## **B. Rising Drug Spending: Chronic Boom**

- U.S. drug spending is soaring: Estimates of national drug expenditures are based on statistical sampling. Different studies use different sampling methods. An often-cited study by one non-profit group showed that total prescription drug expenditures at retail outlets has almost doubled in five years from \$78.9 billion in 1997 to \$154.5 billion in 2001. (National Institute for Health Care Management, “Prescription Drug Expenditures in 2001: Another Year of Escalating Costs,” April 2002) *See Figure I.B.1, “National Spending for Prescription Drugs”*
  - National drug expenditures had the fourth straight year of increases over 17% – \$154.5 billion in 2001, up from \$131.9 billion in 2000. (National Institute for Health Care Management, “Prescription Drug Expenditures in 2001: Another Year of Escalating Costs,” April 2002)
  - Employers are reeling from prescription drug cost increases. General Motors’ drug costs for 1.2 million employees, retirees and their families have averaged a 19% annual increase over the past three years. Future costs are projected to rise at more alarming rates. (Moroni, “General Motors Coverage of Prescription Drugs for Employees and Retirees,” Testimony Before the U.S. House of Representatives Committee on Energy and Commerce, February 15, 2001)
- Prescription drugs are one of the fastest growing health expenditures in the U.S.: Drug spending rose an average of 14.5% a year between 1997 and 2001. Drug expenditures are projected to increase an average of 11.1% a year between 2002 and 2012. Physician expenditures are projected to increase an average of 6.8% a year during the same period. Hospital expenditures are expected to increase 7.7% in 2003 with the rate of increase dropping slightly to 5% by 2012. (Strunk et al, “Tracking Health Care Costs: Growth Accelerates Again in 2001,” *Health Affairs* Web Exclusive, September 25, 2002; Heffler et al, “Health Care Spending Projections For 2002-2012,” *Health Affairs* Web Exclusive, February 7, 2003)
  - Drug spending in 2010 is estimated to be 10% (\$366 billion) of all health care expenditures. In 1980, drug spending (\$12 billion) was only 5% of all health care expenditures. (Health Care Financing Administration, Office of the Actuary, “National Health Expenditure Projections: 2000-2010,” Table 2, March 2001)

Figure I.B.1

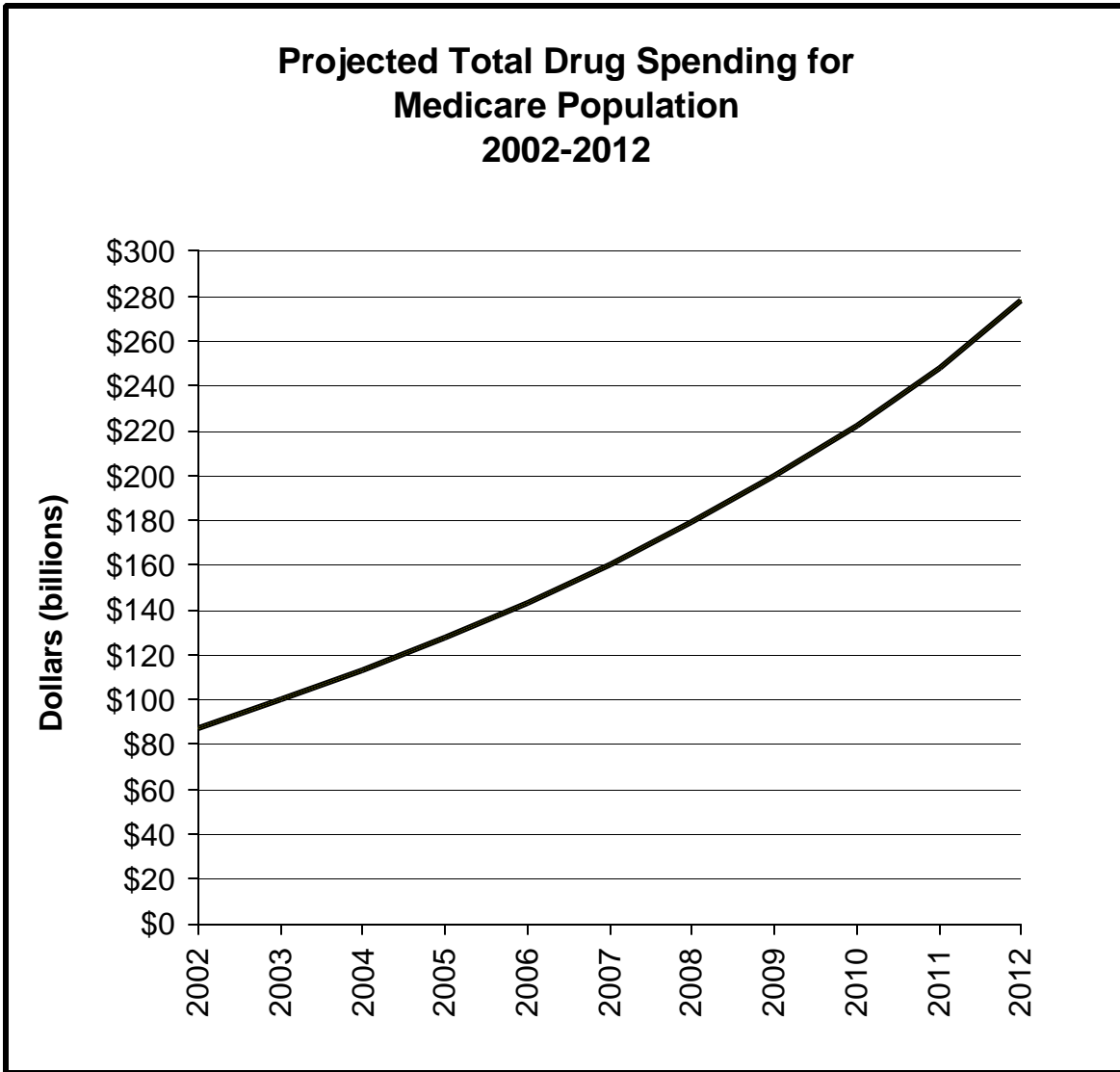


Source: National Institute for Health Care Management, "Prescription Drug Expenditures in 2001: Another Year of Escalating Costs," April 2002.

\*Projected

- Rising drug costs for seniors: Overall prescription drug spending for the elderly has increased 132% since 1992. It rose from \$18.5 billion in 1992 to \$42.9 billion in 2000. (Families USA/PRIME Institute, “Cost Overdose: Growth in Spending for the Elderly,” 1992-2010, July 2000)
  
- Rising drug costs for all Medicare beneficiaries (seniors & the disabled): The Congressional Budget Office (CBO) estimates that prescription drug spending for Medicare recipients will total \$87 billion in 2002 and increase to \$278 billion by 2012. Rising costs mean that drug spending for beneficiaries will rise at an average annual rate of 10% for the next decade. (Dan L. Crippen, Director of Congressional Budget Office, “Projections of Medicare and Prescription Drug Spending,” Testimony before the Committee on Finance United States Senate, March 7, 2002) *See Figure I.B.2: “Projected Total Drug Spending for Medicare Population 2002-2012”*
  - Prescription drug spending per Medicare enrollee is estimated at \$2,440 in 2003 and will increase to \$5,820 by 2012. (Dan L. Crippen, Director of Congressional Budget Office, “Projections of Medicare and Prescription Drug Spending,” Testimony before the Committee on Finance United States Senate, March 7, 2002)
  
  - CBO’s estimate of spending for prescription drugs among Medicare beneficiaries over the next 10-year projection period of 2003 through 2012 is roughly \$1.8 trillion – or 21% higher than last year’s projection for the 2002-2011 period. (Dan L. Crippen, Director of Congressional Budget Office, “Projections of Medicare and Prescription Drug Spending,” Testimony before the Committee on Finance United States Senate, March 7, 2002)
  
- Drug spending for Medicare beneficiaries has outpaced inflation: Drug spending per Medicare beneficiary (including private insurance/government and out-of-pocket spending) has far outpaced inflation. Senior spending rose at an annual rate of 9% from 1992 to 1996 and spending per prescription grew 4.7%. Both figures were well above general inflation, which averaged 2.8% from 1992 to 1996. (U.S. Department of Health and Human Services, “Prescription Drug Coverage, Spending Utilization, and Prices,” Report to the President, April 2000)

Figure I.B.2



Source: Dan Crippen, Director of the Congressional Budget Office, "Projections of Medicare and Prescription Drug Spending," Testimony before the United States Senate Committee on Finance, March 7, 2002.

- Seniors' out-of-pocket spending:
  - Seniors are expected to spend an average of \$1,051 out-of-pocket on prescription drugs in the year 2002. (Carey, "Much Variety, Little Traction in Medicare Drug Plans," *Congressional Quarterly Weekly*, July 13, 2002)
  - Nearly 2 million seniors spent more than \$2,000 out-of-pocket on prescription drugs in 1999. (U.S. Department of Health and Human Services, "Prescription Drug Coverage, Spending Utilization, and Prices," Report to the President, April 2000)
  - Half of all drug spending by Medicare beneficiaries in 1995 was paid out-of-pocket. (U.S. Department of Health and Human Services, "Prescription Drug Coverage, Spending Utilization, and Prices," Report to the President, April 2000)
  - Medicare beneficiaries without drug coverage spent 6% of their income on out-of-pocket drug purchases – \$900 a year for a senior with a \$15,000 income. Medicare beneficiaries with drug coverage spent 3% of their income out-of-pocket. (U.S. Department of Health and Human Services, "Prescription Drug Coverage, Spending Utilization, and Prices," Report to the President, April 2000)
- Why is spending on drugs climbing so dramatically? Increased spending is due to three factors:
  - Increase in number of prescriptions written: Doctors writing more prescriptions accounted for 39% of the increase in 2001. Some of this increase owes to a growing and "graying" population, but the main reason is that doctors are prescribing more medicines, such as antiplatelets (28.2% more prescriptions in 2001) and drugs to treat osteoporosis (29.9% more prescriptions). (National Institute for Health Care Management, "Prescription Drug Expenditures in 2001: Another Year of Escalating Costs," April 2002)
  - A shift toward the use of more expensive drugs: This accounted for 24% of the overall increase in spending in 2001. For instance, the average prescription price for antiarthritic drugs increased from \$58.11 in 2000 to



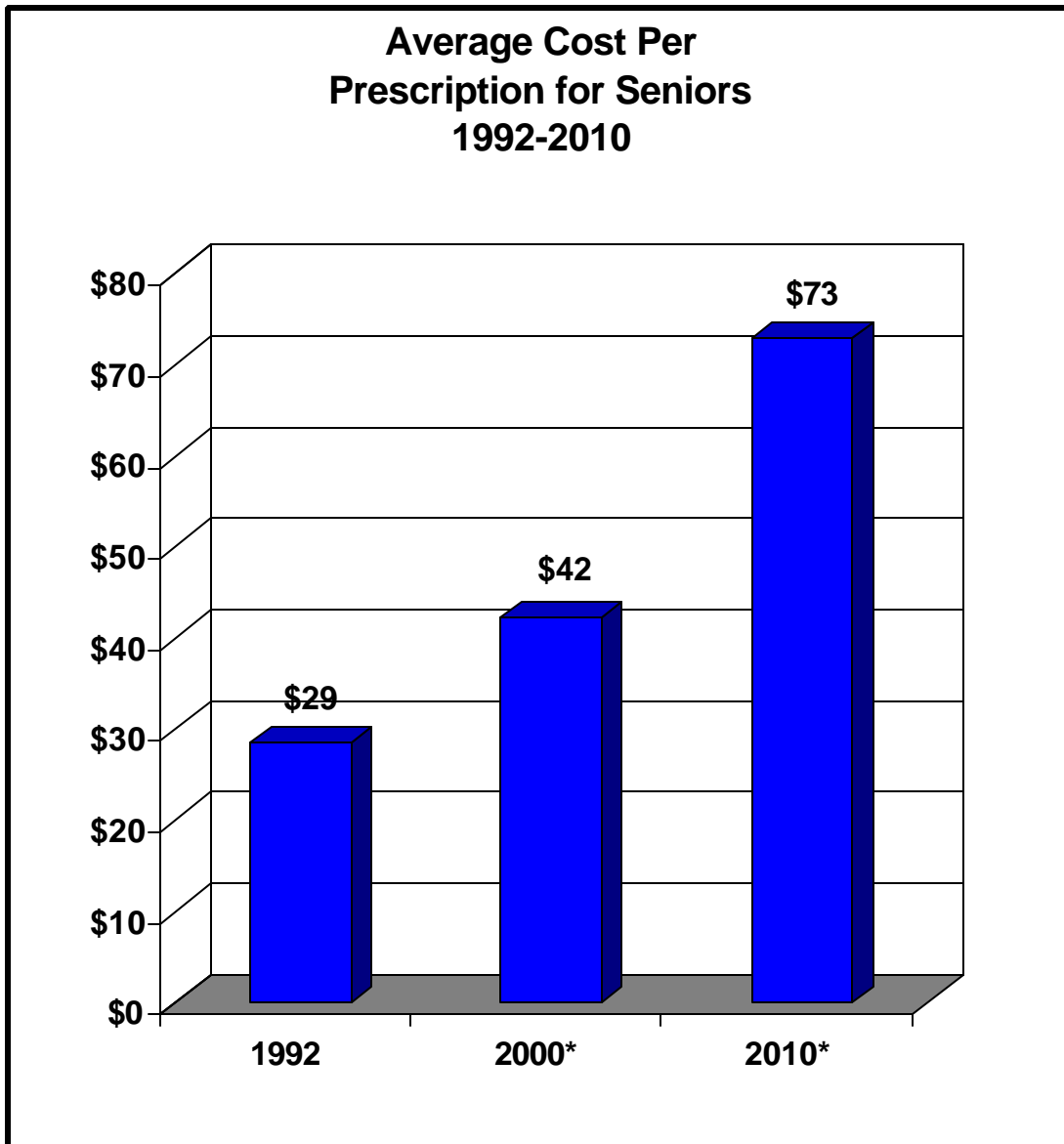
- \$64.37 in 2001. This reflects the fact that doctors are prescribing more of the more expensive antiarthritics such as Celebrex and Vioxx. These drugs represented 57% of the antiarthritic drug sales in 2001. (National Institute for Health Care Management, "Prescription Drug Expenditures in 2001: Another Year of Escalating Costs," April 2002)
- Price increases of individual drugs: This accounted for 37% of the overall spending boom. For example, the prices of some drugs rose substantially in 2001: Accutane (22.7%), Oxycontin (15.4%), Glucophage (14.4%), and Allegra (10.9%). (National Institute for Health Care Management, "Prescription Drug Expenditures in 2001: Another Year of Escalating Costs," April 2002)
  - A small group of popular drugs are driving the spending increase: 34 drugs (out of 9,482 on the market) accounted for 50.7% of the overall increase in national drug spending last year. (National Institute for Health Care Management, "Prescription Drug Expenditures in 2001: Another Year of Escalating Costs," April 2002)
    - Lipitor, a drug used to treat high cholesterol, was the top-selling drug in 2001 with \$4.5 billion in retail sales – representing 3.7% of the total increase in consumer spending on prescription drugs. (National Institute for Health Care Management, "Prescription Drug Expenditures in 2001: Another Year of Escalating Costs," April 2002)
    - Two antiarthritis drugs alone – Vioxx and Celebrex – accounted for 9.2% of the entire increase in prescription drug sales in the year 2000. (National Institute for Health Care Management, "Prescription Drug Expenditures in 2000," May 2001)
    - Although Vioxx and Celebrex totaled \$3.5 billion in sales in 2000, they do not represent significant improvements over older drugs. They are not more effective than ibuprofen at reducing pain and inflammation, and only slightly less likely to cause ulcers. (U.S. Food and Drug Administration, "The Pink Sheet: The News This Week," February 19, 2001)

### **C. Rising Drug Prices: Higher and Higher**

- Drug prices are increasing dramatically: The average price of prescriptions has risen dramatically in recent years:
  - Prescription prices rose at more than six times the rate of inflation in 2001. The average price per prescription increased 10% from 2000 to 2001, while the inflation rate was only 1.6% in 2001. (National Institute for Health Care Management, “Prescription Drug Expenditures in 2001: Another Year of Escalating Costs,” April 2002; U.S. Bureau of Labor Statistics, 2002)
  - The average prescription price increased from \$45.27 in 2000 to \$49.84 in 2001. (National Institute for Health Care Management, “Prescription Drug Expenditures in 2001: Another Year of Escalating Costs,” April 2002)
- There are several reasons prices are rapidly rising:
  - More prescriptions for popular drugs: The number of prescriptions written for the 50 best-selling drugs in 2001 rose more than 25% – the other 9,482 drugs on the market only experienced an increase of 1.7%. (National Institute for Health Care Management, “Prescription Drug Expenditures in 2001: Another Year of Escalating Costs,” April 2002).
  - The most popular drugs cost far more: Among the 50 best-selling drugs in 2001 – which accounted for 44.4% of all prescriptions – the average prescription price was \$71.56. The average price of all other drugs in 2001 was \$40.11 per prescription. (National Institute for Health Care Management, “Prescription Drug Expenditures in 2001: Another Year of Escalating Costs,” April 2002)
- Although “pure” price inflation wasn’t that large overall, the “pure” price increase for the 50 top-selling drugs was 8.8% in 2001. Examples include: Celebrex, 9.4%; Glucophage, 14.4%; OxyContin, 15.4%; Allegra, 10.9% and Accutane, 22.7%. (National Institute for Health Care Management, “Prescription Drug Expenditures in 2001: Another Year of Escalating Costs,” April 2002)

- Seniors feel the price pinch: Rising drug prices hurt seniors more than other groups – seniors are 13% of the population but account for 34% of all prescriptions dispensed. (Families USA/PRIME Institute, “Cost Overdose: Growth in Spending for the Elderly, 1992-2010,” July 2000)
  - Of the 50 drugs used most by seniors, the average prescription price for a year’s supply was \$1070 in January 2002. (Families USA, “Bitter Pill: The Rising Prices of Prescription Drugs for Older Americans,” June 2002)
    - Brand-name drugs averaged \$1,106 (average yearly supply)
    - Generics averaged \$375 (average yearly supply)  
 (Families USA, “Bitter Pill: The Rising Prices of Prescription Drugs for Older Americans,” June 2002)
  - The average prescription price of the most commonly used drugs among seniors has risen 27.6%, on average, since the beginning of 1997 through January 2002. (Families USA, “Bitter Pill: The Rising Prices of Prescription Drugs for Older Americans,” June 2002)
  - Some of the drugs used most by seniors have been on the market for over ten years, some over 20 years, and yet they still continue to increase in price – as much as four times the rate of inflation. (Families USA, “Bitter Pill: The Rising Prices of Prescription Drugs for Older Americans,” June 2002)
  - Seniors on fixed incomes are hit particularly hard by rising drug prices. Average retail prices for prescription drugs are growing more than twice as fast as Social Security benefits. (Kaiser Family Foundation, “Sourcebook for Journalists,” March 2000)
  - The cost of individual prescriptions has been rising rapidly. According to a Families USA study, a single prescription averaged \$29 in 1992 – in 2000, the average cost had risen to \$42. By 2010, it is expected to be as high as \$73. (Families USA/PRIME Institute, “Cost Overdose: Growth in Spending for the Elderly, 1992-2010,” July 2000) *See Figure I.C.1: “Average Cost Per Prescription for Seniors, 1992-2010”*

Figure I.C.1



Source: Families USA/PRIME Institute, University of Minnesota, "Cost Overdose: Growth in Spending for the Elderly, 1992-2010," July 2000.

\* Projected

- Certain types of drugs drove the overall drug price hike: The following kinds of drugs saw the greatest average price increase in 2001– narcotic painkiller, 17.7%; respiratory steroid, 16.9%; antipsychotic, 16.1%; oral diabetes, 14.9%; bronchodialator, 14.1%; non-narcotic painkiller, 11.7%. (National Institute for Health Care Management, “Prescription Drug Expenditures in 2001: Another Year of Escalating Costs,” April 2002)
  
- Brand-name drugs versus generics: Although they are only 58% of all drugs prescribed, because of their higher prices, brand-name drugs account for 92% (\$129.7 billion) of the retail cost to consumers of prescription drugs. (Generic Pharmaceutical Association, “Generic Price and Market Share,” accessed on August 9, 2002)
  - Average difference per prescription: The average difference in price between brand-name drugs and generic drugs has grown from \$16.87 per prescription in 1990 to \$45.96 in 2000. (Kaiser Family Foundation, “Prescription Drug Trends: A Chartbook Update,” November 2001.)
  
  - Brand-name prices increasing more than generics: Since 1990, the retail price of brand-name drugs has increased an average of 9.5% per year, and the retail price of generic drugs has increased an average of 6.7% per year. (Covington, “An Economic Prescription for America,” Managed Care Institute, November 2000)
  
- State drug price-gouging studies: Public Citizen studies conducted in 13 states and major metropolitan areas show the top 10 drugs used by seniors cost Medicare beneficiaries who are without prescription drug insurance nearly twice as much as drug companies’ most favored customers, such as the Department of Veterans Affairs. *See Figure I.C.2: “Results of Public Citizen Price-Gouging Surveys 1999 & 2000”*

Figure I.C.2

## Results of Public Citizen Price-Gouging Surveys 1999 & 2000

Area Surveyed	Price Difference
Arizona	96% more
Arkansas, 4th Congressional District	77% more
California, Los Angeles	110% more
California, San Diego	106% more
District of Columbia	97% more
Massachusetts	88% more
New Hampshire	103% more
New Jersey	88% more
New Mexico, Albuquerque	90% more
New York State	106% more
Pennsylvania State	113% more
Pennsylvania, Pittsburgh	112% more
Wisconsin, Southern	93% more
<b>Average Price Difference:</b>	<b>98% more</b>

\*Price Difference: Difference between what seniors without prescription drug coverage pay and what most favored customers, such as the Department of Veterans Affairs, pay.

To review each survey go to: <http://www.citizen.org/congress/drugs/statereports/stateindex.htm>

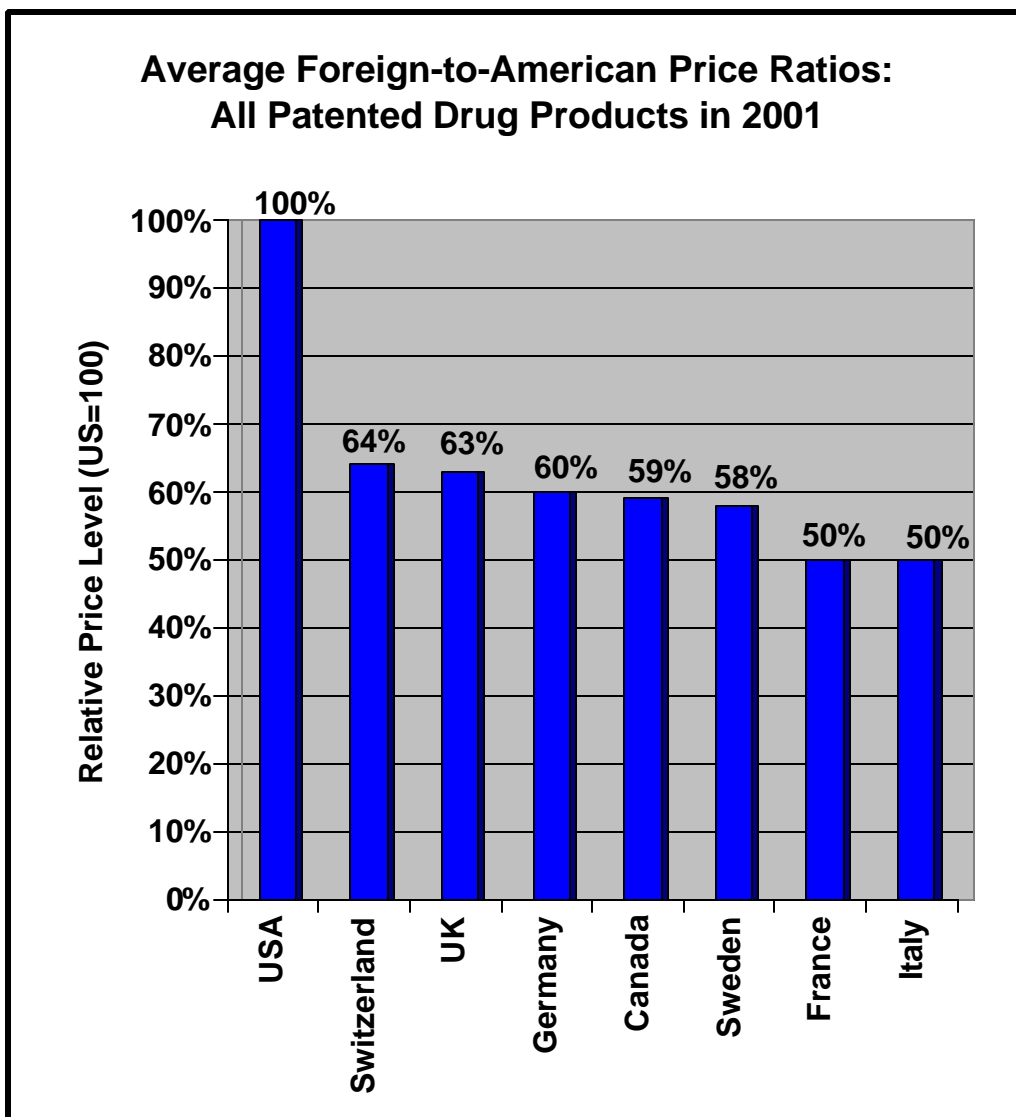
- Price vs. Costs of Production: Drug manufacturers charge prices based on many factors that don't just include the actual costs of production.
  - “The total amount of active ingredient in a product is only one of many factors in pricing,” said David Anstice, head of Merck’s American pharmaceutical operations. Other considerations include the cost of alternative treatments, such as hospital therapy, and what consumers perceive as the product’s value. (Tanouye, Elyse, “Drug Dependency: U.S. Has Developed An Expensive Habit; Now, How to Pay for It?” The Wall Street Journal, November 16, 1998)
  - For example, Merck’s baldness treatment, Propecia, is made from the same chemical, but in a different dosage form, as the company’s prostate-shrinking product Proscar. A one-milligram daily dose of the baldness treatment costs \$1.25, while a five-milligram daily dose of the prostate medicine costs only 35 cents per milligram. (Tanouye, Elyse, “Drug Dependency: U.S. Has Developed An Expensive Habit; Now, How to Pay for It?” The Wall Street Journal, November 16, 1998)

## **D. International Price Comparisons: Americans Pay Much More**

- Prescription drugs cost much more in the U.S.: Foreign drug prices are 36% to 50% less than U.S. prices for the same drugs, according to a 2001 Canadian survey of *all* patented drugs. In other words, Americans pay \$2 for a pill that costs the Italians, French and Swedes roughly \$1. (Patented Medicines Prices Review Board, “2001 Annual Report,” 2002) *See Figure I.D.1: “Average Foreign-to-American Price Ratios: All Patented Drug Products in 2001”*
- Main reason U.S. drug prices are higher: Drugs cost much more in the U.S. than in other nations, primarily because other countries impose some form of price controls. (U.S. Department of Health and Human Services, “Prescription Drug Coverage, Spending, Utilization, and Prices,” Report to the President, April 2000)
- General Accounting Office Studies: GAO, the investigative arm of Congress, has conducted several price comparisons of certain drugs in certain countries.
  - Canada: A 1992 GAO study of 121 prescription drugs found that they cost an average of 32% more (or 32 cents more on every \$1) in the United States than in Canada. (U.S. Department of Health and Human Services, “Prescription Drug Coverage, Spending, Utilization, and Prices,” Report to the President, April 2000)
  - United Kingdom: In 1994, the GAO estimated that 77 frequently dispensed drugs cost wholesalers 60% more in the U.S. than in the U.K. (U.S. Department of Health and Human Services, “Prescription Drug Coverage, Spending, Utilization, and Prices,” Report to the President, April 2000)
  - European survey: Price and profit controls in Europe do not stifle increased use of drugs. GAO found that France, Germany, Sweden and the U.K. experienced pharmaceutical spending increases comparable to the United States despite their price constraints. (GAO, “Spending Controls in Four European Countries,” May 1994)



Figure I.D.1



Source: Patented Medicines Prices Review Board, "2001 Annual Report," Province of Ontario, Canada, 2002 ([www.pmprb-cepmb.gc.ca](http://www.pmprb-cepmb.gc.ca)).

Note: Percentages reflect relative price levels of drugs sold by drug manufacturers to wholesalers, hospitals and pharmacies.

- Cardiovascular drugs: In 1998, a study of cardiovascular drugs by Patricia Danzon, whose work is often touted by the drug industry, concluded that prices in the U.S. were 28% to 54% higher than in the U.K. The same study found that price differentials between the U.S. and Germany, France, Italy, Switzerland and Sweden were comparable to the difference between U.S. and U.K. with respect to the cardiovascular drugs. (U.S. Department of Health and Human Services, “Prescription Drug Coverage, Spending, Utilization, and Prices,” Report to the President, April 2000)
  
- Methods for controlling drug costs in other countries: Almost all European countries impose price restraints on prescription drugs. These restraints take different forms and most countries use a combination of several price controls. (U.S. Department of Health and Human Services, “Prescription Drug Coverage, Spending, Utilization, and Prices,” Report to the President, April 2000) *See Figure I.D.2: “Methods Used by European Countries To Obtain Reasonable Drug Prices for Consumers”*
  - Governments in France, Italy and Portugal control the prices of individual drugs by direct negotiations with each manufacturer. The governments determine “fair” prices by reviewing the manufacturer’s price justification, or by examining the prices charged for similar products in other countries. (U.S. Department of Health and Human Services, “Prescription Drug Coverage, Spending, Utilization, and Prices,” Report to the President, April 2000)
  
  - A more common tactic, used in countries such as Germany, Belgium and the Netherlands, is “reference pricing.” In such a system, drugs are clustered into similar classes – because they are the same chemical or therapeutically equivalent drugs – then a reimbursement price is set for the whole cluster, which becomes a reference price. Drug companies may sell a product above the reference price if they believe the patient is willing to pay the cost difference but they won’t be reimbursed by insurers for the difference. (U.S. Department of Health and Human Services, “Prescription Drug Coverage, Spending, Utilization, and Prices,” Report to the President, April 2000)

- The United Kingdom and Spain control manufacturer profits. In the U.K., the government and the drug industry negotiate a rate of return on sales to the National Health Service (NHS). If a company exceeds a target rate (currently between 17% and 21%), it must either reimburse the NHS or reduce the price. The U.K. has the lowest prescription drug expenditures per capita among the G7 countries. (U.S. Department of Health and Human Services, “Prescription Drug Coverage, Spending, Utilization, and Prices,” Report to the President, April 2000)
  - Many countries, including Denmark, Spain and Ireland, also employ measures that encourage doctors to prescribe generic drugs rather than more expensive brand name drugs. (U.S. Department of Health and Human Services, “Prescription Drug Coverage, Spending, Utilization, and Prices,” Report to the President, April 2000)
  - France has negotiated with drug companies to reduce promotional expenditures and Canada regulates the entry price of newly patented pharmaceuticals “to prevent brand name firms from abusing their monopoly position during the market exclusivity period.” (U.S. Department of Health and Human Services, “Prescription Drug Coverage, Spending, Utilization, and Prices,” Report to the President, April 2000)
- Higher U.S. prices create a windfall for the global drug industry: U.S. sales account for about 60% of global drug industry profits. In other words, Americans pay, on average, 60 cents of every \$1 that any drug company in the world earns in profits. (Bowe, et. al., “Bankers See Quick Gains In Tough Times From Drug Disposals” *Financial Times*, May 8, 2001)

**Figure I.D.2**

**Methods Used by European Countries  
To Obtain Reasonable Drug Prices for Consumers**

<b>Country</b>	<b>Methods of Obtaining Reasonable Drug Prices</b>
Belgium	Individual price controls, reference price system, generic pricing policy, measures for generic prescribing
Denmark	Reference price system, generic pricing policy, measures for generic substitution by pharmacists
France	Individual price controls, generic pricing policy
Germany	Reference price system, generic pricing policy, measures for generic prescribing, measures for generic substitution by pharmacists
Greece	Individual price controls, generic pricing policy
Ireland	Individual price controls, measures for generic prescribing
Italy	Individual price controls, reference price system
Luxembourg	Individual price controls
Portugal	Individual price controls, generic pricing policy
Spain	Individual price controls, reference price system, measures for generic substitution by pharmacists
Netherlands	Reference price system, generic pricing policy, measures for generic substitution by pharmacists
United Kingdom	Profit control system, generic pricing policy, measures for generic prescribing

Individual price controls: refers to direct control of production prices by government for an individual drug.

Reference price system: products are first clustered into homogenous drug classes, then a reimbursement price set for the whole cluster becomes a reference price for the class.

Generic pricing policy: system of pricing generic drugs that does not cluster products but sets a reimbursement price for similar drugs.

Measures for generic prescribing: include mandatory clinical guidelines for certain categories of products as well as budgetary controls to influence generic prescribing.

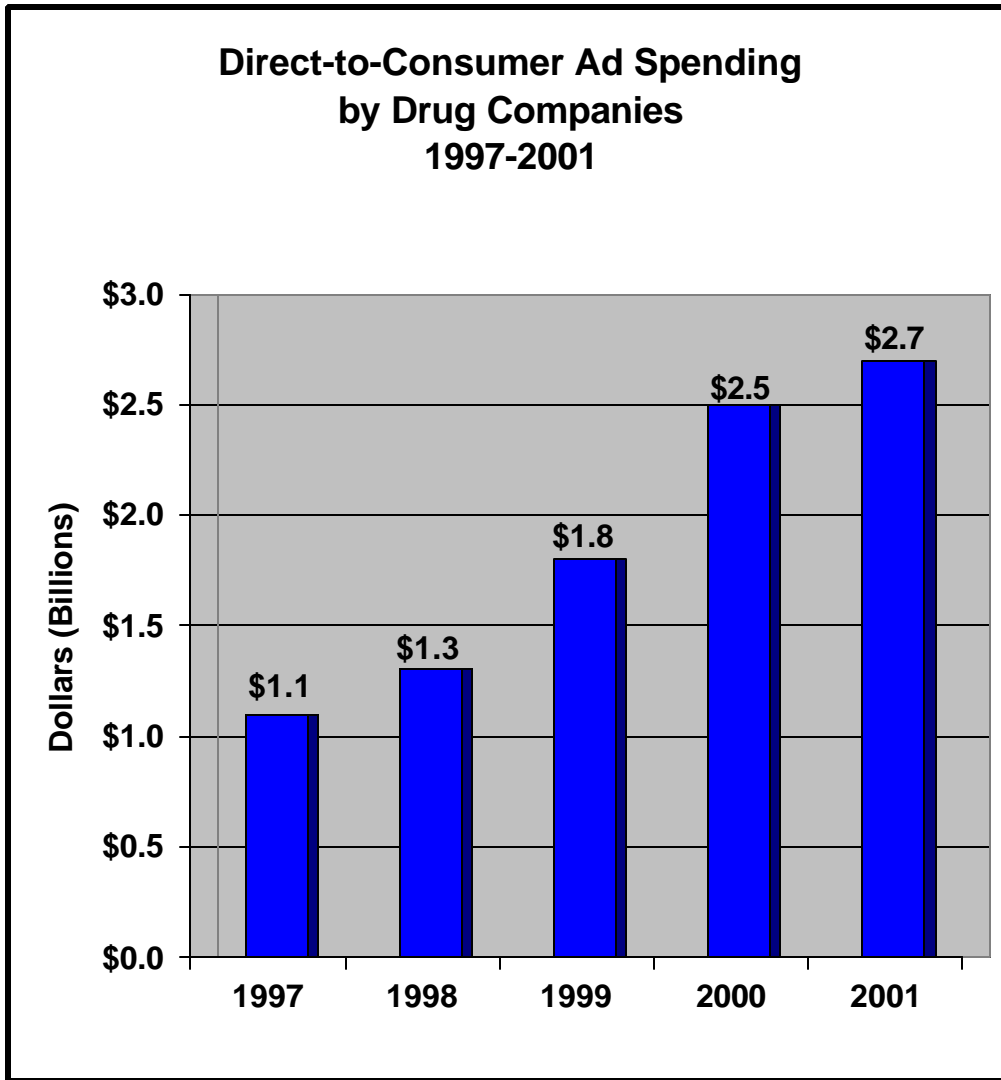
Source: Huttin, Christine, "Drug Price Divergence in Europe: Regulatory Aspects," *Health Affairs*, Vol. 19, No. 3, May/June 1999.

## **E. Advertising and Marketing: Creating a Habit**

- Spending on promotions and advertising: Promotions and advertising for prescription drugs aimed at doctors has mushroomed in recent years. Spending on promotions and advertising reached \$16.4 billion in 2001 (including more than \$10 billion in free samples to doctors). (IMS Study: U.S. Physicians Responsive to Patient Requests for Brand-Name Drugs, April 2002)
  - The drug industry's money is well-spent on samples. An IMS Health study found that more than 70% of physicians say they are more likely to prescribe a brand-name medication requested by a patient when a sample can be provided during an office visit. (IMS Study: U.S. Physicians Responsive to Patient Requests for Brand-Name Drugs, April 2002)
- Spending on Promotion vs. R&D:
  - In 2001, Fortune 500 drug companies devoted nearly three times as much of their revenue to marketing and administrative costs (30.4% of revenue) than to research and development (12.5% of revenue). (Company yearly earnings reports analyzed by Public Citizen, *Fortune Magazine*, "Fortune 500," April 2002)
- Direct-to-Consumer advertising spending is way up: The drug industry spent \$1.1 billion in direct-to-consumer (DTC) advertising in 1997. It is estimated that DTC spending totaled \$2.7 billion in 2001, an increase of 145% since 1997. (GAO, "Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Limitations," October 2002. GAO-03-177). *See Figure I.E.1: "Direct-to-Consumer Ad Spending by Drug Companies 1997-2001"*
  - Between 1999–2000 the number of prescriptions dispensed for the 50 most heavily advertised drugs increased more than 6 times the rate of all other drugs on the market. (GAO, "Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Limitations," October 2002. GAO-03-177)
  - In 2000, Merck increased its DTC advertising spending by 117.7% over 1999; Pfizer's \$126 million DTC-ad spending in 1999 swelled to \$250 million in 2000; and Bristol-Myers Squibb's DTC spending more than tripled from \$44 million in 1999 to \$140.6 million in 2000. (National Institute for Health Care Management, "Prescription Drugs and Mass Media Advertising: 1999-2000," November 2001)

- Merck spent more than \$160 million promoting the blockbuster drug Vioxx to consumers, making it the most heavily advertised drug in 2000. The increase in Vioxx sales accounted for a whopping 5.7% of the one-year increase in drug spending, more than any other drug. (National Institute for Health Care Management, “Prescription Drugs and Mass Media Advertising: 1999-2000,” November 2001)
  - One blockbuster drug was hyped more than Pepsi and Bud: Merck spent \$160 million in 2000 advertising Vioxx. That’s more than PepsiCo spent advertising Pepsi or Anheuser-Busch spent advertising Budweiser. (National Institute for Health Care Management, “Prescription Drugs and Mass Media Advertising: 1999-2000,” November 2001)
- DTC television ad spending increases: In 1997, the U.S. Food and Drug Administration (FDA) relaxed its rules governing TV advertising for prescription drugs. Since then, direct-to-consumer TV advertising has exploded. In 1996, drug companies spent \$220 million on TV ads; in 1999, they spent \$1.13 billion; in 2000, they spent \$1.57 billion. (Kaiser Family Foundation, “Prescription Drug Trends: A Chartbook Update,” November 2001)
- Problems with DTC television ads:
  - Prior to 1997, any TV ad that mentioned a drug’s therapeutic benefits also had to cite nearly all of the drug’s consumer warning label. This made 30-second ads impractical. Now, TV commercials only have to give information about major risks of the drug and other sources of detailed information about the drug, such as Web sites or toll-free numbers. (U.S. Food and Drug Administration, “Guidance for Industry, Consumer-Directed Broadcast Advertisements,” August 1999)
- DTC Advertising works: Data suggests that direct-to-consumer advertising is playing a significant role in driving up overall spending on prescription drugs.
  - Increased sales of the 50 most heavily advertised drugs represented 47.8% of the more than \$20 billion increase in retail spending on prescription drugs from 1999-2000. Increases in sales of all other prescription drugs (approximately 9,850) accounted for the other 52.2%. (National Institute for Health Care Management, “Prescription Drugs and Mass Media Advertising: 1999-2000,” November 2001)

**Figure I.E.1**



Source: General Accounting Office, "Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Limitations," GAO-01-177, October 2002. ([www.gao.gov](http://www.gao.gov))

- The 50 most advertised drugs amassed retail sales of \$41.3 billion in 2000, increasing at 2.3 times the rate of all other drugs on the market. (National Institute for Health Care Management, “Prescription Drugs and Mass Media Advertising: 1999-2000,” November 2001)
- In a survey of physicians in 1998, 97% of allergists said their patients were influenced by DTC advertising. (Barents Group LLC, “Factors Affecting the Growth of Prescription Drug Expenditures,” National Institute for Health Care Management Research and Educational Foundation, 1999)
- Nearly 1 out of every 3 adults has talked to a doctor and 1 in 8 has received a prescription drug in response to an advertisement. (Kaiser Family Foundation, “Understanding the Effects of Direct-to-Consumer Prescription Drug Advertising,” November 2001)
- Advertising is dominated by drugs that are not life-saving: Four of the five prescription drugs most advertised in 1999 were so-called “lifestyle” drugs: Claritin (antihistamine) \$136.8 million, Xenical (anti-obesity) \$76.2 million, Propecia (male pattern baldness) \$71.1 million, Zyrtec (antihistamine) \$57.1 million. (National Institute for Health Care Management, “Prescription Drugs and Mass Media Advertising,” September 2000)
- Advertising is becoming more important to drug companies:
  - The drug industry is shifting the core of its business away from the often unpredictable task of creating drugs and toward the steadier business of marketing them. (Harris, “Drug Firms, Stymied in the Lab, Become Marketing Machines,” *The Wall Street Journal*, July 6, 2000)
  - “The industry is pinning its growth hopes less on new products and more on persuading people, including healthy ones, to buy the pills already being sold.” Marketing of Viagra to healthy young men is an example. (Harris, “Drug Firms, Stymied in the Lab, Become Marketing Machines,” *The Wall Street Journal*, July 6, 2000)



- Prescription drug advertising is not always accurate:
  - Of the estimated 200 different drug commercials aired on TV since the FDA relaxed rules on advertising in 1997, the FDA has issued 45 “notices of violation” and 3 “warning letters” for failing to comply with federal regulations requiring accuracy and disclosure of side effects. (National Institute for Health Care Management, “Prescription Drugs and Mass Media Advertising: 1999-2000,” November 2001)
  - In 2001, the FDA told Pfizer and Pharmacia to stop airing a TV ad for their jointly marketed arthritis drug, Celebrex. It was the third time in 14 months the FDA had reprimanded Celebrex marketing. This time, the FDA said the ad overstated the drug’s effectiveness by showing arthritic people zipping around on scooters. (Adams, “FDA Scrambles to Police Drug Ads’ Truthfulness,” *The Wall Street Journal*, January 2, 2001)
  - The FDA scolded Glaxo Wellcome 14 times for misleading promotion of its asthma drugs Flonase and Flovent. One TV ad was never submitted to the FDA as required and the ad provided no risk information. (Adams, “FDA Scrambles to Police Drug Ads’ Truthfulness,” *The Wall Street Journal*, January 2, 2001)
  - Between 1998 and 2002, the FDA has issued four letters criticizing Pfizer for Lipitor ads. These letters were prompted by advertisements giving the false impression that Lipitor, a cholesterol-lowering drug, can reduce heart disease and falsely claiming that Lipitor is safer than other cholesterol-lowering drugs on the market. (GAO, “Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Limitations,” GAO-03-177, October 2002)
  - The FDA has singled out Schering-Plough 11 times since 1997 for its marketing of Claritin. Among the charges: one ad instructed viewers to call a toll-free number for information on Claritin’s side effects. An FDA reviewer called and had to listen to four minutes of promotional messages and respond to a marketing survey before getting limited risk information. (Adams, “FDA Scrambles to Police Drug Ads’ Truthfulness,” *The Wall Street Journal*, January 2, 2001)

- Misconceptions about drug advertising:
  - Drug advertising is not common in other countries. The United States and New Zealand are the only countries that allow direct-to-consumer advertising of prescription drugs. Drug companies only have to send a copy to the FDA when a new TV or magazine ad debuts – they don't have to get FDA clearance before running an ad. (Okie, "With TV Spots, Drug Firms Aim At Patients' Role," *The Washington Post*, May 22, 2000)
  - 50% of consumers in one survey believed that ads were subject to FDA review *before* airing (they are not); 22% mistakenly believed that advertising of drugs with serious side effects had already been banned (they have not). (Wilkes, MS, Bell, RA, Kravitz, RL, "Direct to Consumer Prescription Drug Advertising: Trends, Impact, and Implications," *Health Affairs*, March/April 2000)

## II. Profits

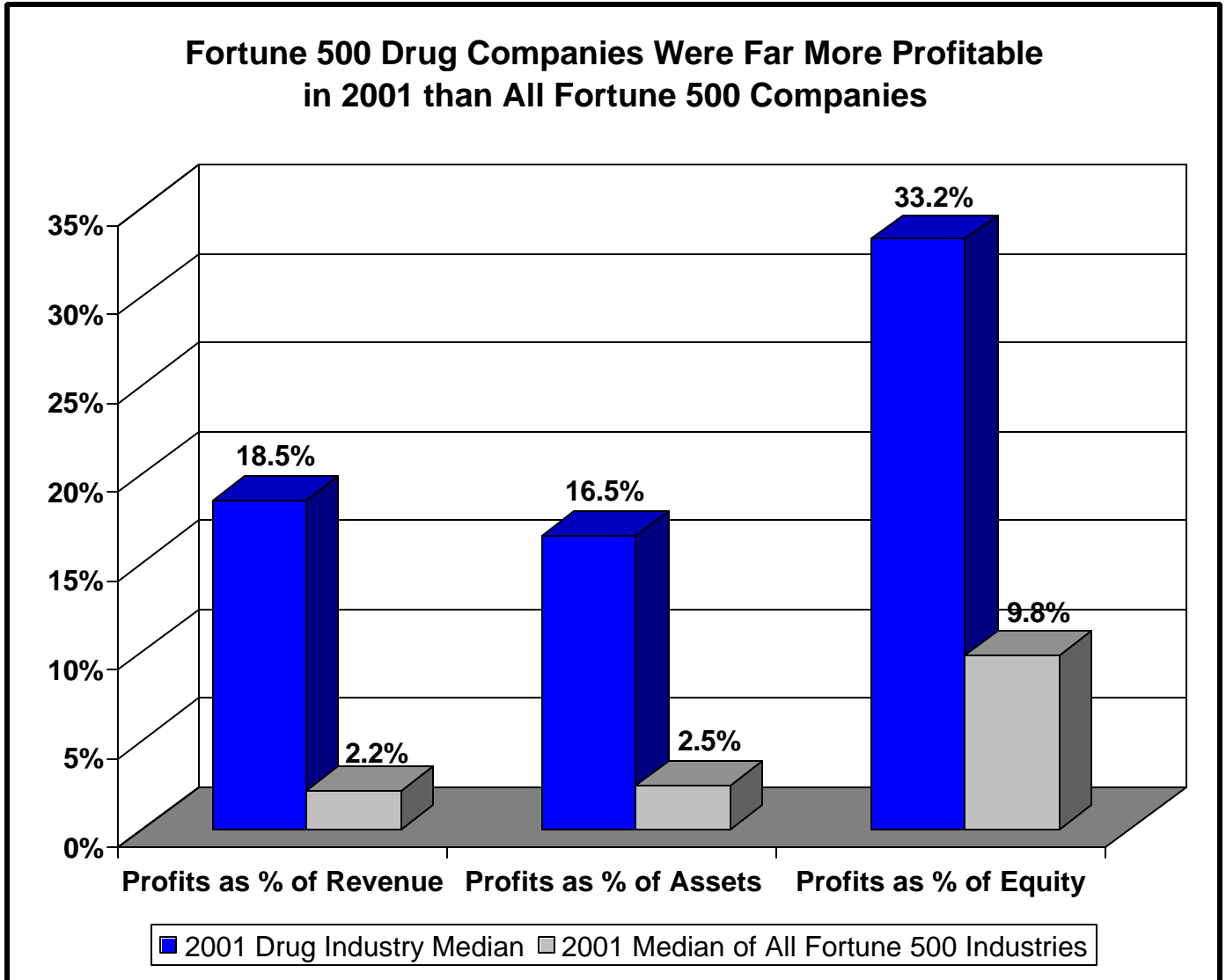
**In 2001, a year that saw a drop in employment rates, a plunge in the stock market and symbols of America’s economy literally come crashing down, once again the drug industry “was more profitable than any other” according to the Fortune 500 analysis of America’s largest companies. And the drug industry outpaced other industries by a wide margin in 2001, as Fortune 500 drug companies enjoyed a return on revenues that was *eight times higher* than the median for all Fortune 500 industries. No wonder *Fortune* magazine says that the pharmaceutical industry “showed some impressive gains.”**

### A. Rx Drugs: The Most Lucrative Industry in America

- Profits of the 10 biggest U.S. drug companies were way up in 2001: The 10 biggest U.S. drug companies saw their gross profits increase by 33% in 2001 – during an economic slowdown. Their profits climbed from \$28 billion in 2000 to \$37.3 billion in 2001. (*Fortune* magazine, “Fortune 500,” April 2002)
- Drug industry was on top of all industries in 2001: By most measures of profitability (for example, profits as a percentage of revenue and assets, not equity), the drug industry was the most profitable industry in America last year. (*Fortune* magazine, “Fortune 500,” April 2002) *See Figure II.A.1: “Fortune 500 Drug Companies Were Far More Profitable in 2001 than All Fortune 500 Companies” and Figure II.A.2: “Fortune 500 Drug Companies Profit and Revenue Increases in 2001”*
  - In 2001, the 10 drug companies in the Fortune 500 were eight times more profitable (as a percentage of revenue) than the median for all Fortune 500 companies. The Fortune 500 drug industry return on revenue was 18.5% compared to 2.2% for all Fortune 500 industries. (*Fortune* magazine, “Fortune 500,” April 2002)
  - Pfizer, the most profitable drug company, earned more in profits in 2001 (\$7.8 billion) than all the Fortune 500 companies in the homebuilding, apparel, railroad and publishing industries combined. (*Fortune* magazine, “Fortune 500,” April 2002) *See Figure II.A.3: “Pfizer Profits in 2001 Larger than Combined Profits of All Companies in Some Fortune 500 Industries”*

- Merck was the second most profitable drug company, netting \$7.3 billion, which is also significantly more than all the Fortune 500 companies in the crude oil production, semiconductors, pipeline, food production, and hotel, casino and resort industries combined. (*Fortune* magazine, “Fortune 500,” April 2002) *See Figure II.A.4: “Merck Profits in 2001 Larger than Combined Profits of All Companies in Some Fortune 500 Industries*
  
- Drug industry has been on top for 30 years: The drug industry was the most profitable industry over the last 10 years and was consistently among the top two most profitable industries for the 20 years before that. (Public Citizen update of Stephen W. Schondelmeyer calculation, *Competition and Pricing Issues in the Pharmaceutical Market*, PRIME Institute, University of Minnesota based on data found in *Fortune* magazine, 1958 to 1999; Public Citizen’s analysis of *Fortune* magazine data, 2000-2002)
  
- Profitability is accelerating: Drug companies have become even more profitable in recent years. For example, during the 1970s drug companies averaged 8.9% profit as a percentage of revenue compared to 4.4% for all Fortune 500 industries. In the 1980s, drug companies increased their margin by earning 11.1% compared to 4.4% for all Fortune 500 companies. During the 1990s, the gap grew to 15.1% compared to just 4.1%. (Public Citizen update of Stephen W. Schondelmeyer calculation, *Competition and Pricing Issues in the Pharmaceutical Market*, PRIME Institute, University of Minnesota based on data found in *Fortune* magazine, 1958 to 1999; Public Citizen’s analysis of *Fortune* magazine data, 2000-2002) *See Figure II.A.5: “Profitability of Fortune 500 Drug Industry and All Fortune 500 Industries 1970-2001”*
  
- Big CEO salaries: CEOs of the 10 top prescription drug makers averaged \$3.3 million each in salary in 2000. Together these 10 CEOs have in excess of \$100 million in unexercised stock options in addition to their yearly pay. (*Business Week*, “Executive Compensation Scoreboard,” April 16, 2001)

Figure II.A.1



Source: *Fortune* magazine, April 2002, Fortune 500 ([www.fortune.com](http://www.fortune.com)).

Figure II.A.2

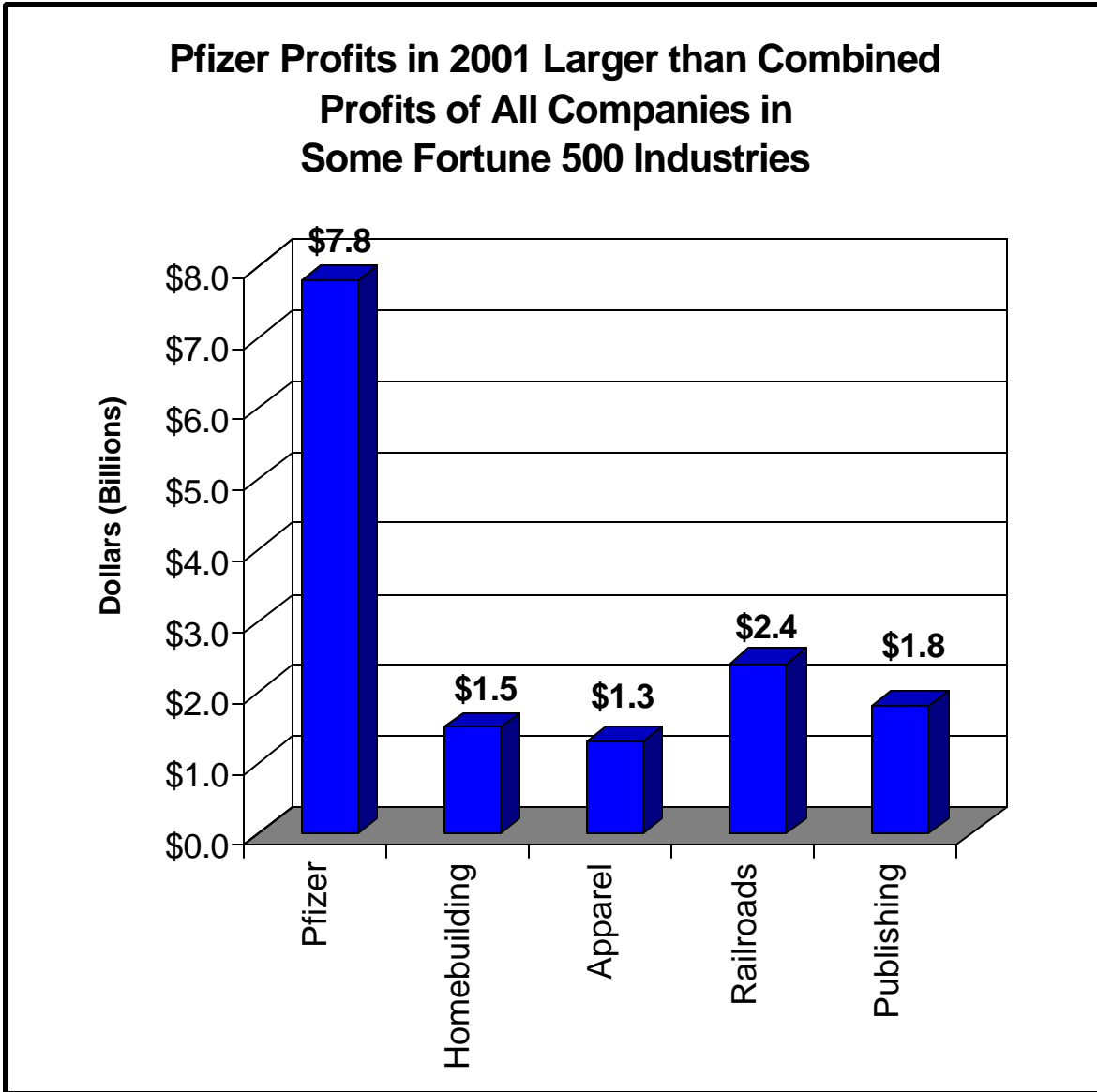
Fortune 500 Drug Companies Profit and Revenue Increases in 2001

Rank	Company	Revenues		Profits		Profits as % of		
		Millions \$	% Change From 2000	Millions \$	% Change From 2000	Revenues	Assets	Stockholders' Equity
1	Merck	\$47,716	18%	\$7,282	7%	15%	17%	45%
2	Johnson & Johnson	\$33,004	13%	\$5,668	18%	17%	15%	23%
3	Pfizer	\$32,259	9%	\$7,788	109%	24%	20%	43%
4	Bristol-Myers Squibb	\$21,717	2%	\$5,245	11%	24%	19%	49%
5	Pharmacia	\$19,299	4%	\$1,501	109%	8%	7%	12%
6	Abbott Laboratories	\$16,285	19%	\$1,550	-44%	10%	7%	12%
7	Wyeth*	\$14,129	2%	\$2,285	N/A	16%	10%	56%
8	Eli Lilly	\$11,543	6%	\$2,780	-9%	24%	17%	39%
9	Schering-Plough	\$9,802	0%	\$1,943	-20%	20%	16%	27%
10	Amgen	\$4,016	11%	\$1,120	-2%	28%	17%	22%
<b>Total</b>		<b>\$209,770</b>		<b>\$37,162</b>				
<b>Median</b>		<b>\$17,792</b>	<b>7.5%</b>	<b>\$2,533</b>	<b>7%</b>	<b>18.5%</b>	<b>16.5%</b>	<b>33.2%</b>

\*On March 11, 2002, American Home Products changed its name to Wyeth.

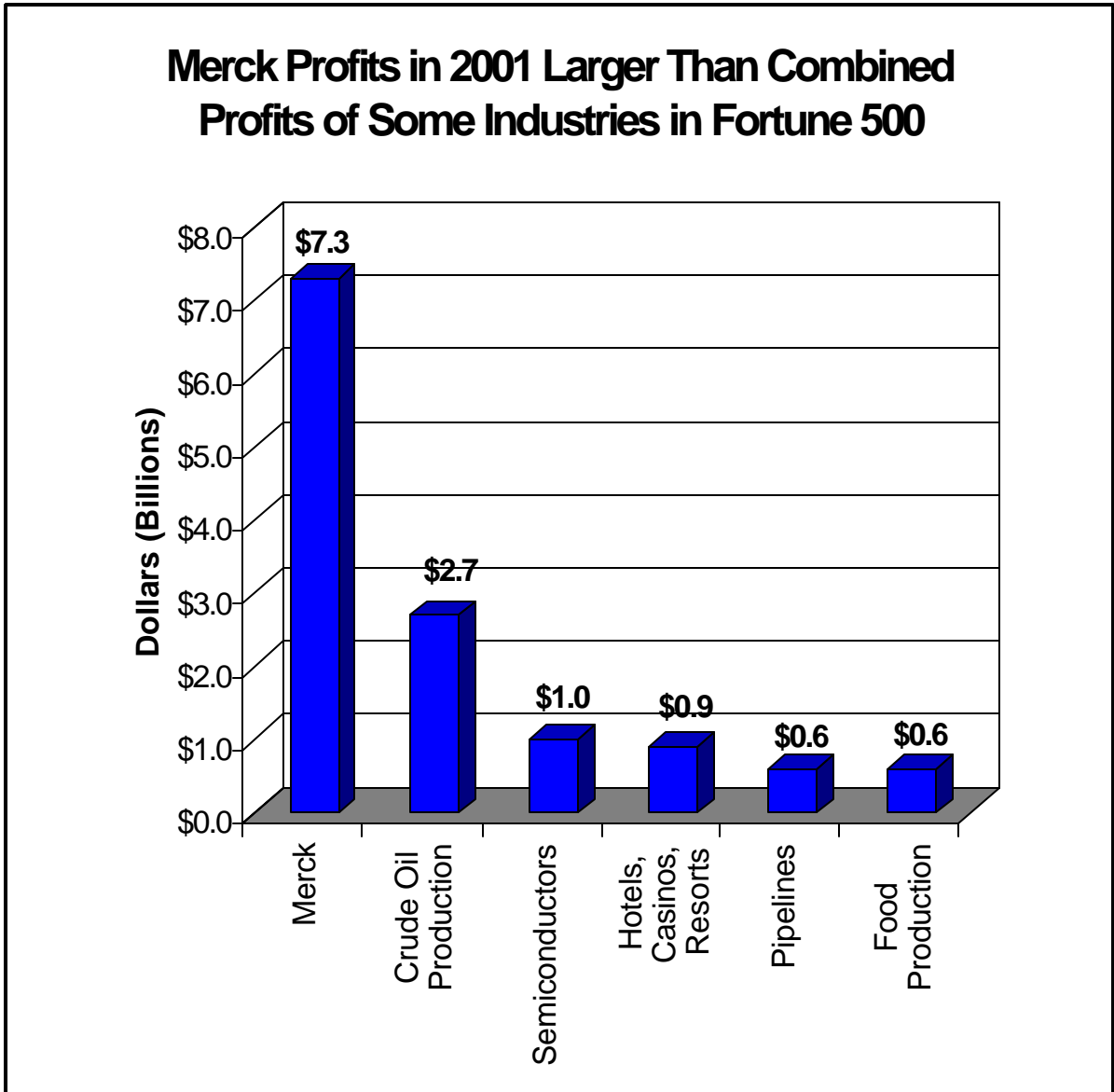
Source: *Fortune* magazine, April 2002, Fortune 500 (www.fortune.com).

Figure II.A.3



Source: *Fortune* magazine, April 2002, Fortune 500 ([www.fortune.com](http://www.fortune.com)).

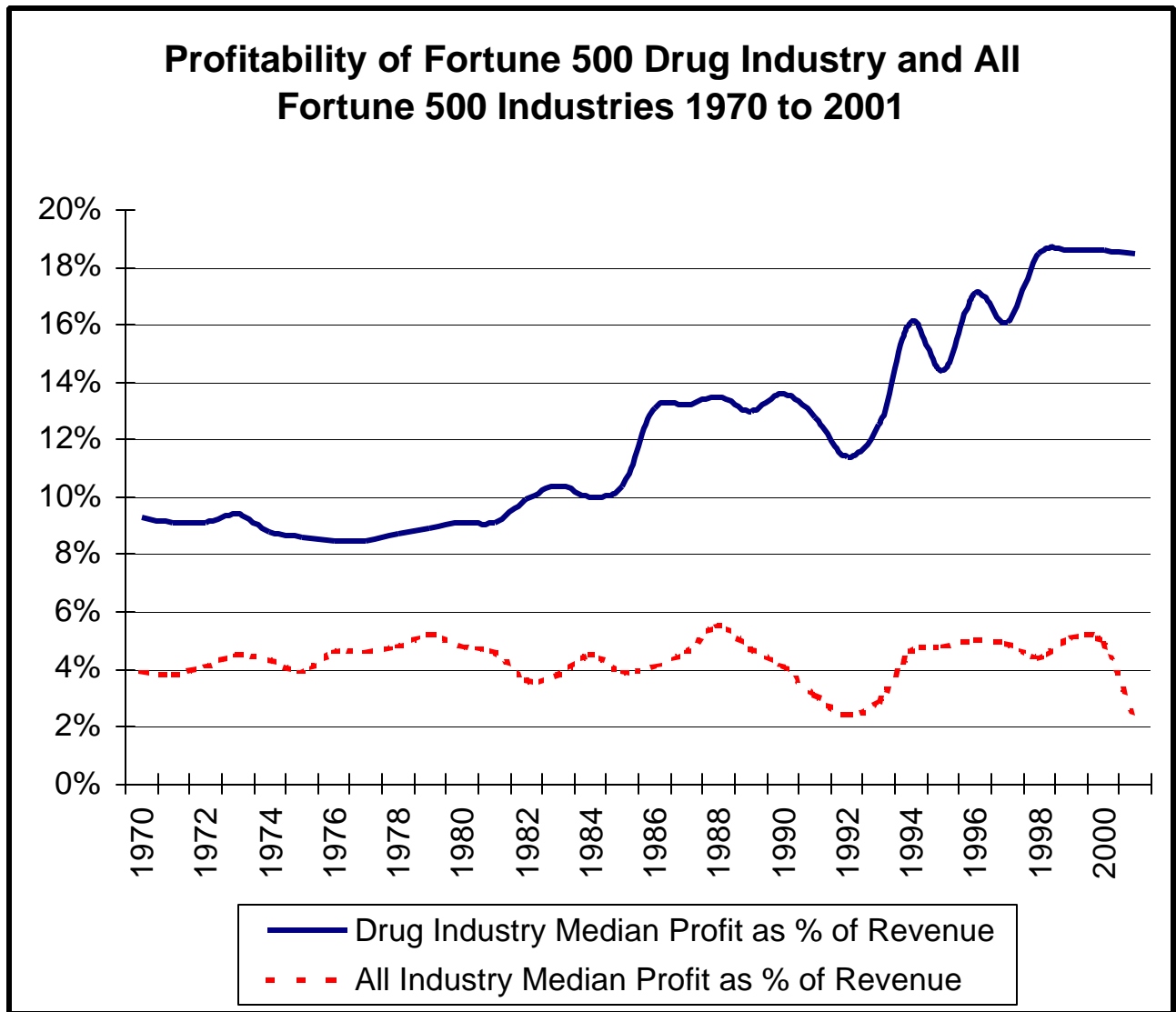
Figure II.A.4



Source: Fortune magazine, April 2002, Fortune 500 ([www.fortune.com](http://www.fortune.com)).



Figure II.A.5



Source: Public Citizen update of Stephen W. Schondelmeyer calculation, *Competition and Pricing Issues in the Pharmaceutical Market*, PRIME Institute, University of Minnesota based on data found in *Fortune* magazine, 1958 to 1999; Public Citizen's analysis of *Fortune* magazine data, 2000-2002.

### **III. Propaganda, Public Subsidies and Patents**

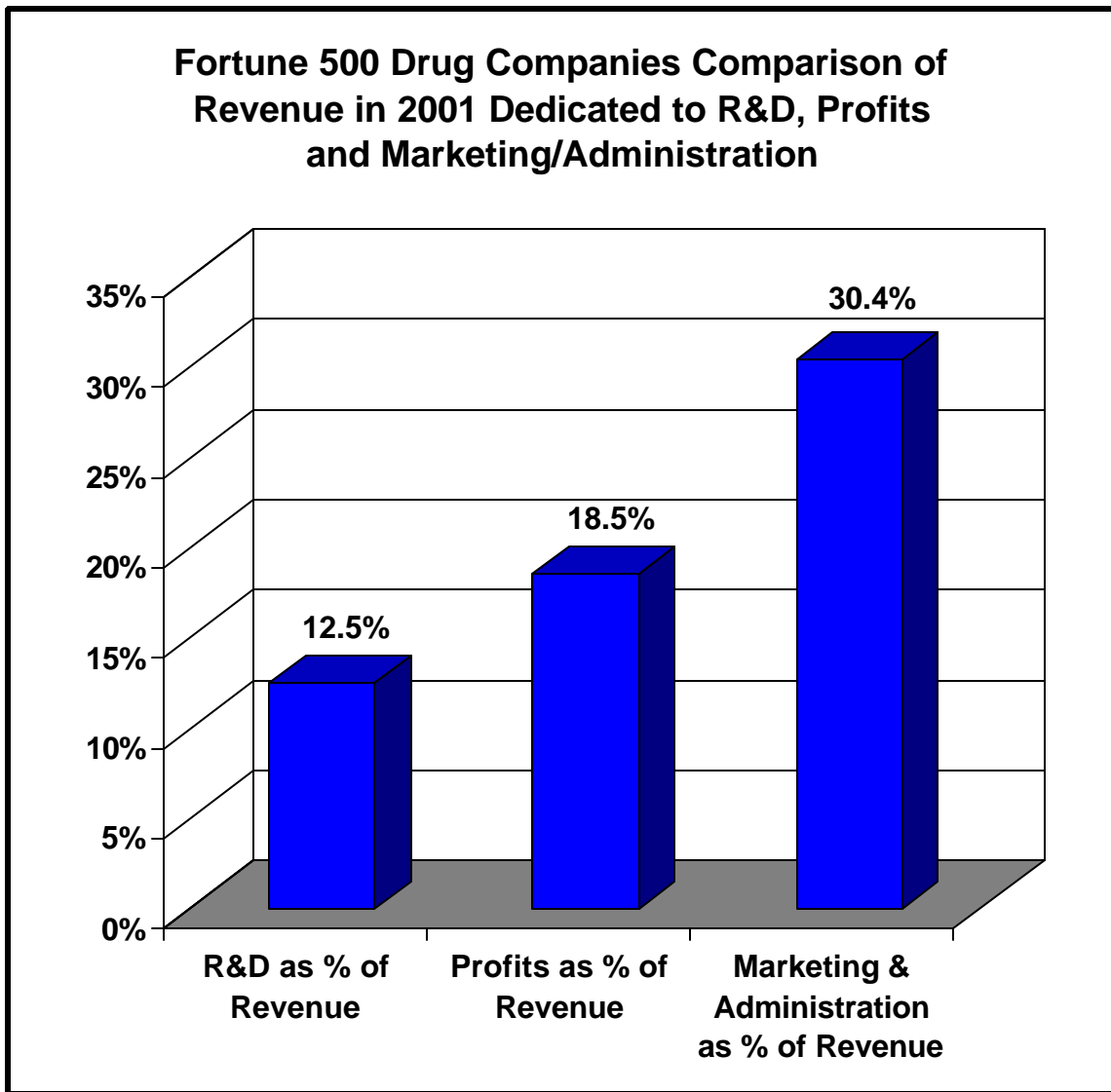
**Drug industry executives argue that they need extraordinary profits to fund the “risky” research and development (R&D) of innovative life-saving drugs. Industry officials claim they need to extend monopoly patents on drugs for similar reasons. But the evidence doesn’t support such contentions, for the following reasons: 1) For decades the drug industry has topped other industries in measures of profitability, showing that its research could not be too risky, or it would not consistently reap such high earnings. 2) Drug companies spend a significant share of their research efforts not on innovative new drugs, but on slight alterations to already successful drugs. 3) The industry benefits from federally funded research, which has played a part in developing the most popular drugs on the market – and in reducing industry research costs. 4) Drug companies receive huge tax breaks, which amount to another taxpayer-subsidy. 5) The federal government also has extended the life of drug patents through a series of new laws in recent years.**

#### **A. Research & Development Basics:**

- R&D spending by U.S. drug companies in 2001:
  - U.S. drug companies spent an estimated \$30.3 billion on research and development in the U.S. in the year 2001. Drug company R&D has increased in the U.S. at an average annual rate of 11.5% since the start of 1995. (Pharmaceutical Research and Manufacturers of America *2002 Industry Profile*; PhRMA, “Annual Report 2001-2002,” 2001)
  - Of all U.S. industries, the U.S. drug industry ranks second in total research and development spending (with roughly \$16 billion in 1997, the last year for which comparative statistics are available). The electronic computer and component industry spent the most – \$18 billion (does not include the software industry). (National Science Foundation, “U.S. Corporate R&D: Volume 1: Top 500 Firms in R&D by Industry Category” (NSF 00-301), 2000)

- Profits vs. R&D: Drug companies argue that they need high profits to fuel new research and development. But their spending reveals their priority is profits more than new drug discoveries.
  - In 2001, Fortune 500 drug companies devoted 12.5% of their revenue to R&D – compared to 18.5% to profits and 30.4% to marketing and administration. (*Fortune* magazine, “Fortune 500,” April 2002) *See Figures III.A.1 and III.A.2: “Fortune 500 Drug Companies Comparison of Revenue in 2001 Dedicated to R&D, Profits and Marketing/Administration”*
  - Eight of the 10 most profitable Fortune 500 drug companies devoted more of their revenue to profits than to R&D in 2001. (*Fortune* magazine, “Fortune 500,” April 2002) *See Figure III.A.3: “Profits vs. R&D of 10 Most Profitable Fortune 500 Drug Companies in 2001”*

Figure III.A.1



Source: Public Citizen analysis of company annual reports; *Fortune* magazine, April 2002, Fortune 500 ([www.fortune.com](http://www.fortune.com)).

**Figure III.A.2**

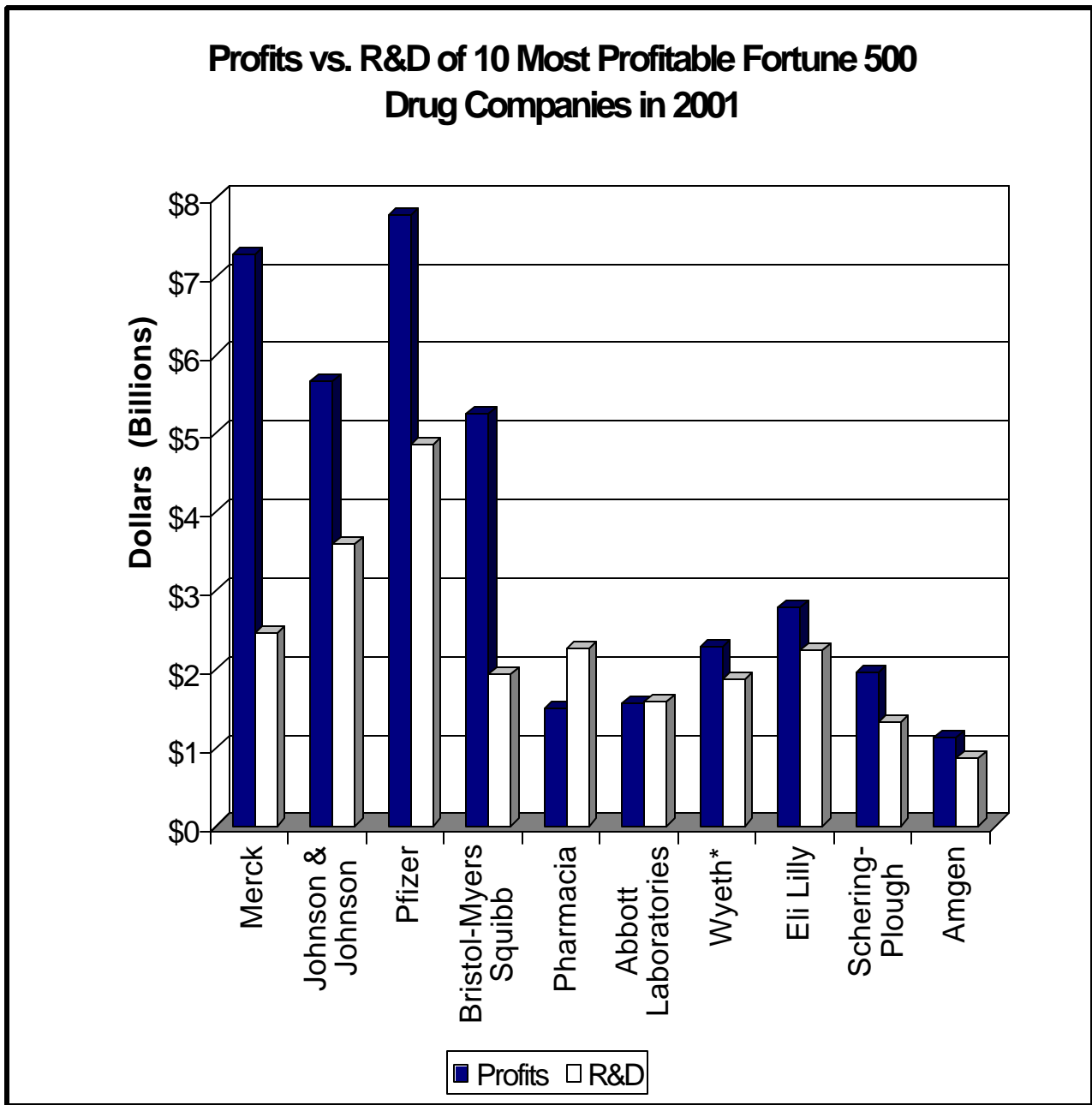
**Fortune 500 Drug Companies Comparison of Revenue in 2001  
Dedicated to R&D, Profits and Marketing/Administration**

Rank	Company	Revenues	Profits		Research & Development		Marketing & Administration	
		Millions \$	Millions \$	% of Revenue	Millions \$	% of Revenue	Millions \$	% of Revenue
1	Merck	\$47,716	\$7,282	15.3%	\$2,456	5.15%	\$6,224	13.0%
2	Johnson & Johnson	\$33,004	\$5,668	17.2%	\$3,591	10.88%	\$11,992	36.3%
3	Pfizer	\$32,259	\$7,788	24.1%	\$4,847	15.03%	\$11,299	35.0%
4	Bristol-Myers Squibb	\$21,717	\$5,245	24.2%	\$1,939	8.93%	\$4,020	18.5%
5	Pharmacia	\$19,299	\$1,501	7.8%	\$2,263	11.73%	\$6,034	31.3%
6	Abbott Laboratories	\$16,285	\$1,550	9.5%	\$1,577	9.68%	\$3,734	22.9%
7	Wyeth*	\$14,129	\$2,285	16.2%	\$1,869	13.23%	\$5,178	36.6%
8	Eli Lilly	\$11,543	\$2,780	24.1%	\$2,235	19.36%	\$3,417	29.6%
9	Schering-Plough	\$9,802	\$1,943	19.8%	\$1,312	13.39%	\$3,484	35.5%
10	Amgen	\$4,016	\$1,120	27.9%	\$865	21.54%	\$970	24.2%
<b>Totals</b>		<b>\$209,770</b>	<b>\$37,162</b>	<b>--</b>	<b>\$22,954</b>	<b>--</b>	<b>\$56,352</b>	<b>--</b>
<b>Median</b>		<b>\$17,792</b>	<b>\$2,533</b>	<b>18.5%</b>	<b>\$2,087</b>	<b>12.5%</b>	<b>\$4,599</b>	<b>30.4%</b>

\* On March 11, 2002, American Home Products changed its name to Wyeth.

Source: Fortune magazine, April 2002, Fortune 500 (www.fortune.com); Public Citizen analysis of company annual reports.

Figure III.A.3



\*On March 11, 2002, American Home Products changed its name to Wyeth.

Source: *Fortune* magazine, April 2002, Fortune 500 ([www.fortune.com](http://www.fortune.com)).

- What is R&D:
  - There are 11 main steps to pharmaceutical R&D. They include: discovering a new molecule; turning a new compound into a form and dose that humans can consume; testing the new compound on animals; conducting clinical trials of a drug's safety and usefulness on thousands of human subjects (the most expensive part of R&D); manufacturing design; and regulatory approval. (Office of Technology Assessment, U.S. Congress, "Pharmaceutical R&D: Costs, Risks and Rewards," 1993)
  - Drug companies exaggerate their R&D spending by stretching the definition of "research." "[T]he ongoing [Senate] Aging Committee investigation has found that many of the dollars that drug manufacturers claim are spent on research of new pharmaceutical products are actually spent on marketing research." (U.S. Senate Special Committee on Aging, "The Drug Manufacturing Industry: A Prescription for Profits," September 1991)

## **B. What Does It Really Cost to Develop a Drug?**

- The \$802 million myth: Drug industry officials claim it costs \$802 million to research and develop a new drug. This figure is from a 2001 Tufts Center for the Study of Drug Development study, authored by Joseph A. DiMasi. The evidence shows that the \$802 million figure is misleading and inaccurate. (Tufts Center for the Study of Drug Development, “News Release: Tufts Center of the Study of Drug Development Pegs Cost of a New Prescription Medicine at \$802 Million,” November 30, 2001)
  - 50% of the \$802 million figure is theoretical: Companies don’t actually spend \$802 million to discover and develop new drugs. That’s because one-half of the \$802 million figure represents the “opportunity cost of capital.” This is the “cost” associated with using money for drug research rather than using it to make other lucrative investments. It is highly misleading and substantially overestimates net expenditures for R&D. Subtracting the opportunity cost of capital, Public Citizen estimates the average pretax, actual cash outlay of developing a new drug is \$403 million. (Public Citizen’s “Critique of \$802 Million New Drug R&D Costs,” December 3, 2001, based on analysis in Office of Technology Assessment, “Pharmaceutical R&D: Costs, Risks and Rewards,” U.S. Congress, 1993)
  - DiMasi also *does not* account for huge R&D tax deductions: DiMasi’s figure is also a gross overestimate because it does not subtract the benefits of huge R&D tax deductions and credits that the industry takes advantage of. Every dollar spent on R&D must be reduced by the amount of tax avoided by that expenditure. The tax deduction reduces the cost of R&D by the amount of the corporate marginal tax rate (currently 34%). This means, in effect, that every dollar spent on R&D costs \$0.66. Accounting for the R&D tax deduction, DiMasi’s figure is lowered further – the after-tax, actual cash outlay for R&D on a new drug is \$240 million in year 2001 dollars. (Public Citizen’s “Critique of \$802 Million New Drug R&D Costs,” December 3, 2001, based on analysis in Office of Technology Assessment, “Pharmaceutical R&D: Costs, Risks and Rewards,” U.S. Congress, 1993) *See Figure III.B.1: “Public Citizen’s Analysis of \$802 Million R&D Cost Estimate”*



**Figure III.B.1**

**Public Citizen's Analysis of \$802 Million R&D Cost Estimate**

<b>DiMasi Pre-tax Estimate (Including Cost of Capital)</b>	<b>Public Citizen's Pre-tax Estimate (Excluding Cost of Capital)</b>	<b>Public Citizen's After- tax Estimate (Actual Cash Outlay)</b>
\$802 million	\$403 million	\$240 million

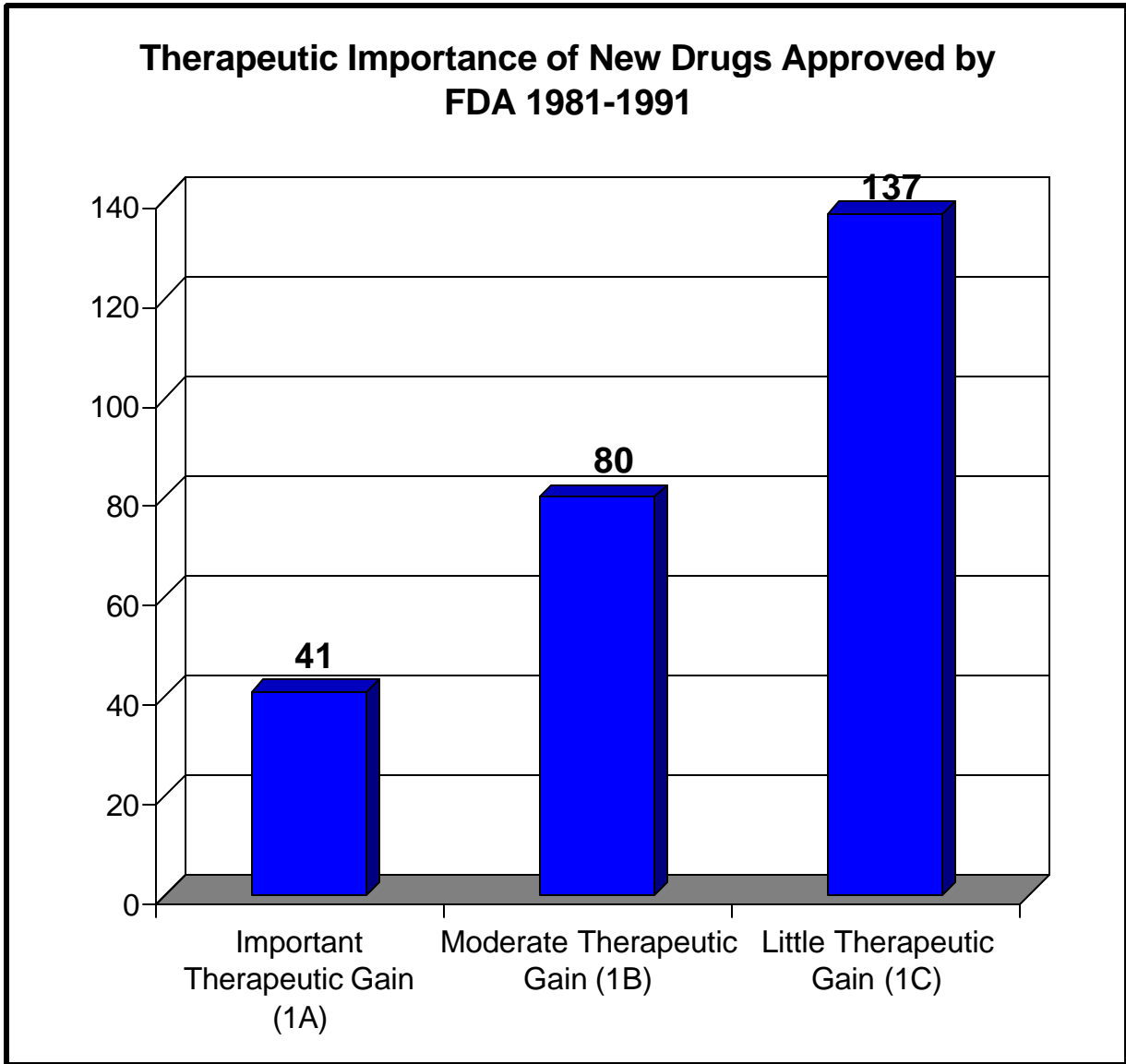
- Even the revised DiMasi \$240 million estimate overstates the R&D cost for the average new drug. DiMasi's study only included "self-originated new chemical entities" (NCEs). These are the most expensive class of new drugs for two reasons. First, many new drugs brought to market are not new chemical entities because they are too similar to existing drugs. Second, DiMasi admitted that none of the 68 drugs in his study received any government financial support, which is unusual. Both factors make his sample non-representative of all drugs brought to market. (Public Citizen's "Critique of \$802 Million New Drug R&D Costs," December 3, 2001)
  
- Drug companies refuse to disclose R&D cost data:
  - The main problem with R&D studies such as DiMasi's is that researchers must depend on the companies to supply detailed data. They cannot audit these estimates for accuracy or consistency. DiMasi relied on data from drug companies about 68 drugs. (Public Citizen's "Critique of \$802 Million New Drug R&D Costs," December 3, 2001; Office of Technology Assessment, "Pharmaceutical R&D: Costs, Risks and Rewards," U.S. Congress, 1993)
  
  - Although Congress has the power to subpoena company data, drug companies have actively resisted. The General Accounting Office tried to obtain data on drug company R&D but was ultimately foiled after nine years of effort that involved a decision in the U.S. Supreme Court. (Office of Technology Assessment, "Pharmaceutical R&D: Costs, Risks and Rewards," U.S. Congress, 1993)

- Other Problems with the DiMasi study:
  - Clinical trial costs account for the largest portion of DiMasi's new estimate. DiMasi's new study puts out-of-pocket clinical trial costs at \$282 million, based on the NCEs in his study. His estimate is four times more than an estimate of clinical trial costs (\$75 million) published by the Congressional Research Service. (Public Citizen's "Critique of \$802 Million New Drug R&D Costs," December 3, 2001; Congressional Research Service, "Pharmaceutical Research and Development: A Description and Analysis of the Process," April 2, 2001)
  - Moreover, DiMasi's estimate of clinical trial costs greatly exceeds the drug industry's own data on the subject. PhRMA's own survey of 1999 R&D expenditures states that clinical trial costs account for 29% of all R&D costs. Yet DiMasi's study says clinical trials account for 70% of all R&D costs (\$282 million out of \$403 million total out-of-pocket expenditures for each drug). (Public Citizen's "Critique of \$802 Million New Drug R&D Costs," December 3, 2001; PhRMA, "Pharmaceutical Industry Profile 2001," Table 6, "Domestic U.S. R&D By Function," 2001)

### **C. “Me-Too” Drugs: All in the Family**

- “Me-too” drugs refer to drugs that are brought to market that have little or no therapeutic gain over drugs that already exist. They are also known as “copycat” drugs. The drug companies never mention “me-too” drugs as they spend hundreds of millions of dollars to convince the public that they are engaged in nothing but the most innovative and beneficial research to society. In reality, they are often out to copy the latest blockbuster drug because it has proven to be a lucrative profit center not a breakthrough for improved public health.
- The government’s old ranking system revealed the prevalence of me-too drugs: Until 1992, the U.S. Food and Drug Administration (FDA) classified every new drug approved according to its significance for human health. The ranking system went from 1A (important therapeutic breakthrough) to 1C (little or no therapeutic gain, or “me-too” drugs, which duplicate products already available). The Bush Administration eliminated these rankings in 1992 in response to industry pressure. (Drake and Uhlman, “Making Medicine, Making Money,” Andrews and McMeel, 1993)
- More than half of the new drugs approved from 1981-1991 were “me-too” drugs: 53% (137 out of 258) of new drugs approved were classified as “1C” or representing little or no therapeutic improvement over existing drugs. (Drake and Uhlman, “Making Medicine, Making Money,” 1993) *See Figure III.C.1: “Therapeutic Importance of New Drugs Approved by FDA 1981-1991”*
- Only 16% (41) of the new drugs approved from 1981-1991 were ranked as important therapeutic gains by the FDA. (Drake and Uhlman, “Making Medicine, Making Money,” 1993)
- The government’s current system still shows emphasis on me-too drugs: Although the FDA abolished its 1A-1B-1C ranking system, it maintains a “priority review” and “standard review” system. From 1992-1999, the FDA rated 170 drug approval applications for “priority review” and 560 for “standard review.” “Priority review” is for drugs that represent “significant improvement compared to marketed products in the treatment, diagnosis, or prevention of a disease.” “Standard review” is for drugs that “appear to have therapeutic qualities similar to those of one or more already marketed drugs.” (FDA/Center for Drug Evaluation and Research, “NDAs Approved in Calendar Years 1990-1999,” December 31, 1999)

**Figure III.C.1**



Note: In 1992 the FDA discontinued the 1A-1B-1C classification system after complaints from the drug industry.

Source: Drake, D., & Uhlman, M., "Making Medicine, Making Money," Andrews and McMeel, 1993.

## **D. Taxpayer Subsidies for Drug R&D:**

- Federal R&D spending is crucial to drug companies: Studies show that many important and popular drugs were developed with taxpayer support. But, for most drugs, the National Institutes of Health (NIH) says it has no idea how much taxpayers invested and no way to determine if they're getting a fair return. Here is what we do know:
  - The NIH spent over \$1 billion of taxpayer money on drug research in 1996. The amount of this taxpayer subsidy could be much more, but NIH admits that it tracks its research spending very loosely. (Dembner, "Public Handouts Enrich Drug Makers," *The Boston Globe*, April 5, 1998)
  - According to NIH, taxpayer-funded scientists conducted 55% of the research projects that led to the discovery and development of the top 5 selling drugs in 1995. (National Institutes of Health, "NIH Contributions to Pharmaceutical Development," Administrative Document, February 2000)
  - 45 of the 50 top-selling drugs from 1992-1997 received government funding for some phase of development. In all, taxpayers spent at least \$175 million helping to develop these 50 drugs. (Dembner, "Public Handouts Enrich Drug Makers," April 5, 1998)
  - A study by the Massachusetts Institute of Technology (MIT) found that 11 of the 14 most medically significant drugs in the last 25 years had roots in studies paid for by the government. (Cockburn and Henderson, "Public-Private Interaction and the Productivity of Pharmaceutical Research," 1995)
  - A study of the 21 most important drugs introduced between 1965 and 1992 found that publicly funded research was instrumental in developing 71% of them (15 of 21). (Joint Economic Committee, "The Benefits of Medical Research and the Role of the NIH," May 2000)
- Public research tackles the tough work, making it easier for industry to profit: A National Science Foundation (NSF) study found that only 14% of the drug industry's total R&D spending went to basic research (38% went to applied

research and 48% was spent on product development). (National Institutes of Health, “NIH Contributions to Pharmaceutical Development,” Administrative Document, February 2000)

- This NSF study suggests that public researchers are doing the groundbreaking work of identifying possible new medicines, while most drug industry R&D spending occurs after companies believe they have a marketable drug. (National Institutes of Health, “NIH Contributions to Pharmaceutical Development,” Administrative Document, February 2000)
- The NIH can’t say if it is getting a fair deal: For most drugs, the NIH says it has no idea how much taxpayers invested and no way to determine if they’re getting a fair return. “Every time we’ve tried to work backwards, the picture gets very complex of how a drug or compound was created,” said Barbara McGarey, deputy director of NIH’s Office of Technology Transfer. (Dembner, “Public Handouts Enrich Drug Makers,” April 5, 1998)
  - NIH money comes with few obligations, “like a bank loan that never comes due.” NIH rarely asks for any return of taxpayers’ seed money. In 1996, NIH took in only \$27 million in royalties from all products produced with taxpayer money and currently sold by private industry. (Dembner, “Public Handouts Enrich Drug Makers,” April 5, 1998)
- Federal research produces huge money-making drugs:
  - The NIH study found that NIH-funded research “played a critical role” in discovering the top five selling drugs in 1995. The drugs were: captopril (Capoten and Vasotec, hypertension), fluoxetine (Prozac, depression), acyclovir (Zovirax, herpes simplex) and ranitidine (Zantac, anti-ulcer). (National Institutes of Health, “NIH Contributions to Pharmaceutical Development,” Administrative Document, February 2000)
  - Taxpayers spent \$27 million developing the cancer treatment drug Taxol before Bristol-Myers Squibb was granted exclusive rights to market the drug. Taxol had sales of \$1.6 billion in 2000. (National Institute for Health Care Management, “Prescription Drugs and Intellectual Property Protection,” August 2000)

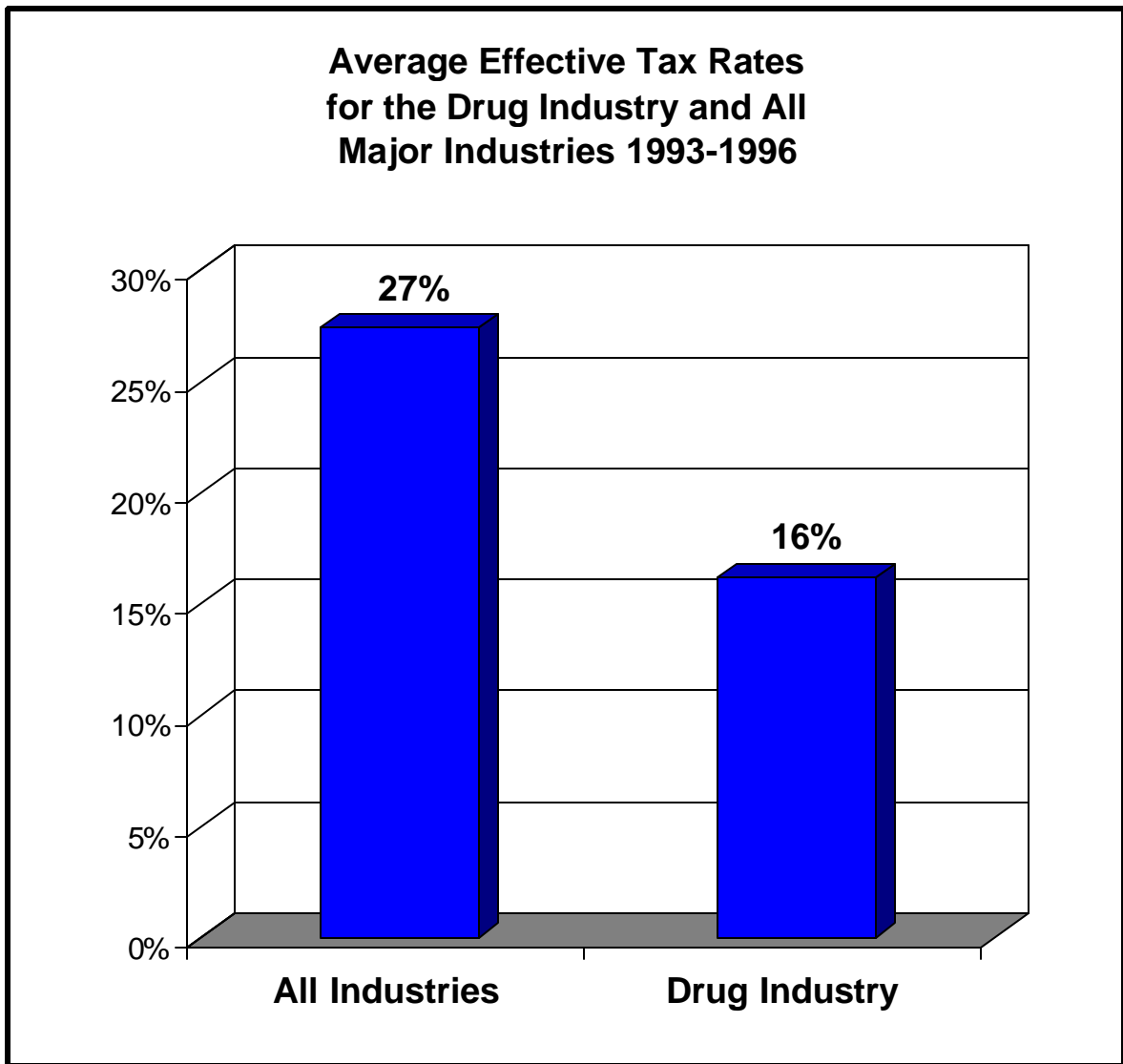
- The glaucoma medicine Xalatan was developed thanks to a \$4 million federal (NIH) grant to Columbia University. Pharmacia bought the rights to Xalatan for \$150,000. Today, the drug is made in Hungary at a cost of about \$5 million per year. The drug generated sales revenues of \$507 million in 1999. (Gerth and Stolberg, “Medicine Merchants: Drug Companies Profit From Research Supported by Taxpayers,” *The New York Times*, April 23, 2000)
  
- Even foreign competitors capitalize on taxpayer-funded research: Teva Pharmaceutical Industries of Israel sold about \$175 million of its Multiple Sclerosis drug, Copaxone, in the U.S. in the first three quarters of 2000, reaping the rewards of nearly \$5 million that NIH and FDA spent to test it. Patients pay more than \$10,000 a year for the drug. (Dembner, “Public Handouts Enrich Drug Makers,” April 5, 1998, updated by Public Citizen)
  
- Drug companies best at exploiting public research are the most successful: Drug firms that work most with publicly-funded researchers obtain more patents per research dollar, on average, than firms whose scientists work less closely with the public sector. (National Institutes of Health, “NIH Contributions to Pharmaceutical Development,” Administrative Document, February 2000)

## **E. Tax Breaks and Credits: Additional Taxpayer Subsidies**

- Tax rates for the drug industry are much lower than other industries:
  - The drug industry's effective tax rate averaged 16% from 1993 through 1996 compared to 27% for all major industries over the same period. (Congressional Research Service Memorandum, "Federal Taxation of the Drug Industry," December 1999) *See Figure III.E.1: "Average Effective Tax Rates for the Drug Industry and All Major Industries 1993-1996"*
  - The drug industry's effective tax rate has been lower – much lower in some cases – than that of almost every major industry, despite its relatively high profitability. (Congressional Research Service Memorandum, "Federal Taxation of the Drug Industry," December 1999)
  - The drug industry's effective tax rate (16.2% from 1993-1996) was approximately half of the tax burden of the Finance, Insurance and Real Estate industry (30.5%) (Internal Revenue Service, "Corporation Sources Book," cited in Congressional Research Service Memorandum, December 1999)
  
- Drug industry tax credits:
  - The drug industry used tax credits to cut its taxes by almost \$28 billion from 1990 through 1996. (Internal Revenue Service, "Corporation Sources Book," cited in Congressional Research Service Memorandum, December 1999)
  - The drug industry has historically realized significant savings from five federal tax provisions: the foreign tax credit, the possessions tax credit, the research and experimentation tax credit, the orphan drug tax credit and the expensing of research expenditures. (Congressional Research Service Memorandum, "Federal Taxation of the Drug Industry," December 1999)
  - The drug industry has also taken advantage of a tax break for companies that build factories in Puerto Rico. From 1980 through 1990, the GAO estimated that 26 pharmaceutical companies had tax savings of \$10.1 billion thanks to their Puerto Rico facilities. (GAO, "Pharmaceutical Industry: Tax Benefits of Operating in Puerto Rico," May 1992)



**Figure III.E.1**



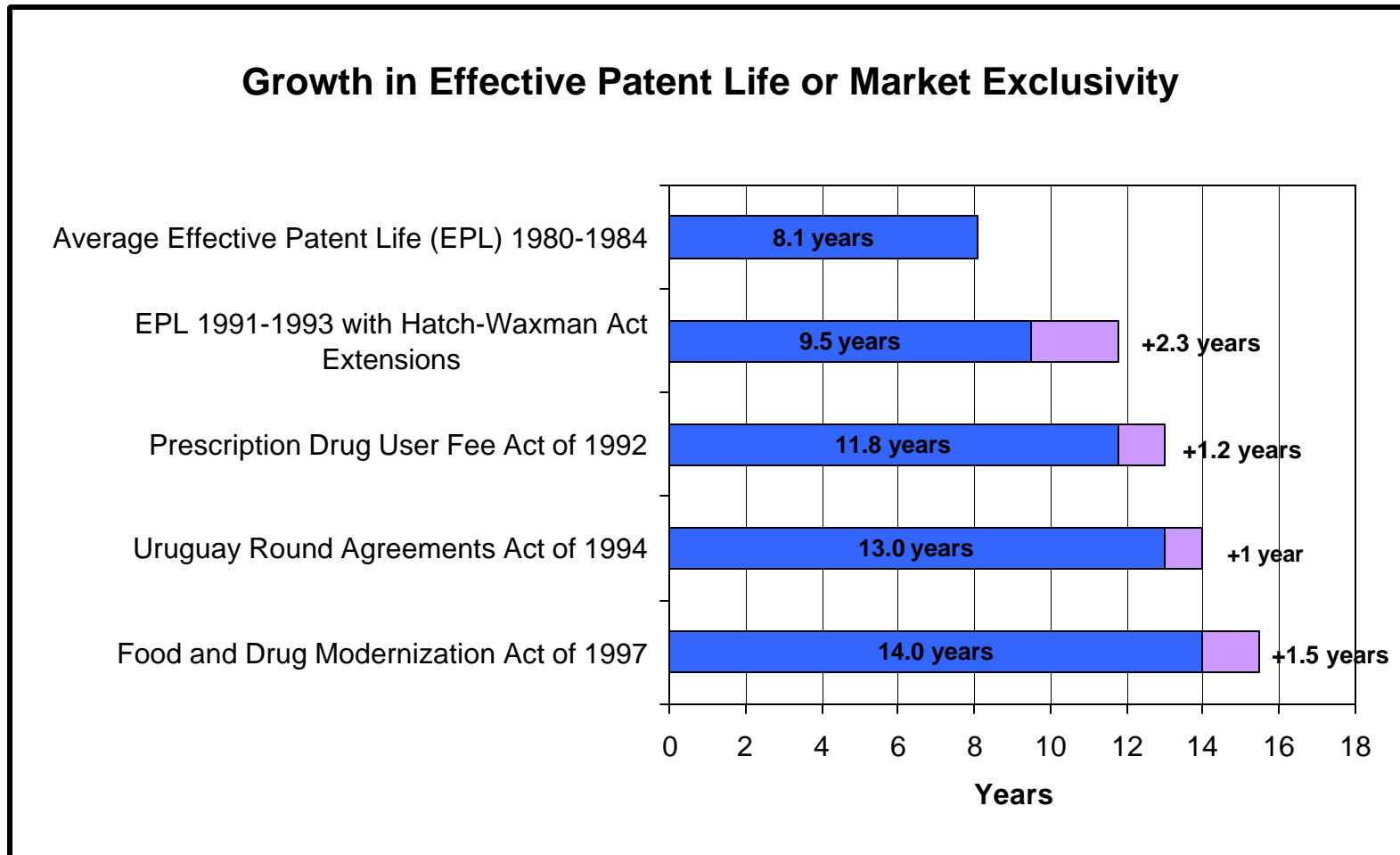
Source: Congressional Research Service Memorandum, "Federal Taxation of the Drug Industry from 1990 to 1996," December 1999.

## **F. Patent Issues: Monopoly Power**

- Patents create a monopoly for drug companies: On new drugs, companies get monopoly patents that last 20 years, from the date of patent application to expiration. (National Institute for Health Care Management, “Prescription Drugs and Intellectual Property Protection,” August 2000)
  - More important is the “effective patent life” of a drug, which is the time remaining in a drug’s patent term after the U.S. Food and Drug Administration approves the drug for market. Effective patent life now averages 14 to 15 years. (National Institute for Health Care Management, “Prescription Drugs and Intellectual Property Protection,” August 2000)
  - Patent laws encourage innovation but also encourage companies to make slight modifications to existing drugs and re-market them as “me-too” drugs. Since 1992, 560 out of 730 drugs approved by the FDA were drugs that had therapeutic qualities similar to ones already on the market. (FDA/Center for Drug Evaluation and Research, “NDAs Approved in Calendar Years 1990-1999,” December 31, 1999)
- Patent law delays the market entry of safe and less-costly generic drugs:
  - As a result of their monopoly patents and aggressive advertising, brand-name drugs dominate the U.S. market and account for more than 90% of total drug spending and about 60% of prescriptions filled. (National Institute for Health Care Management, “Prescription Drugs and Intellectual Property Protection,” August 2000)
  - The generic drug market share is low and declining. It was 10.4% of dollar sales in 1993 but only 8.6% in 1998. (National Institute for Health Care Management, “Prescription Drugs and Intellectual Property Protection,” August 2000)
  - The Congressional Budget Office (CBO) estimated that brand-name drug prices dropped by an average of 25% shortly after the introduction of a generic drug (the price drop is greater as more generic drugs enter the market over time). CBO concluded that Americans saved \$8 billion to \$10 billion in 1994 alone by purchasing generic drugs. (Congressional Budget Office, “How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry,” July 1998)

- Generic drugs are the same as brand-name drugs. Every generic drug approved by the FDA has been found by the agency to be precisely the same chemical, with the same dosage and equivalent absorption rate, and with the same manufacturing consistency that brand manufacturers must have. (Tanouye, “Drug Dependency: U.S. Has Developed An Expensive Habit; Now, How to Pay for It?” *The Wall Street Journal*, November 16, 1998)
  
- Growth of patent life for drugs: Starting in the mid-1980s, the federal government adopted a number of laws that extended the effective lives of drug patents by about 50%. Combined, various laws of the 1980s and 1990s have added 4.4 to 5.9 years of effective patent life. A drug’s effective patent life now averages 13.9 to 15.4 years. (National Institute for Health Care Management, “Prescription Drugs and Intellectual Property Protection,” August 2000) *See Figure III.F.1: “Growth in Effective Patent Life or Market Exclusivity”*
  - The major laws and the years they’ve added to the patent life of drugs are:
    - 1) The Hatch-Waxman Act of 1984 added, on average, 2.3 years to the patent life.
    - 2) The Prescription Drug User Fee Act of 1992 increased the efficiency of FDA drug review and approval and knocked 1.2 years off the review and approval process.
    - 3) The Uruguay Round Agreements Act of 1994, an international trade agreement, added 1 year to the effective patent life.
    - 4) The Food and Drug Modernization Act of 1997 reduced the average number of years for clinical study by 1 year; FDAMA also gave six months of “market exclusivity” to a patented drug if a manufacturer tests the safety of the drug in children. (National Institute for Health Care Management, “Prescription Drugs and Intellectual Property Protection,” August 2000)
  
- Longer patent lives costs consumers: One study showed that the additional patent protection provided by the Uruguay Round Agreements Act cost consumers more than \$6 billion due to delayed access to generic drugs. (Schondelmeyer, “Economic Impact of GATT Patent Extension on Currently Marketed Drugs,” PRIME Institute, College of Pharmacy, University of Minnesota, March 1995)

Figure III.F.1

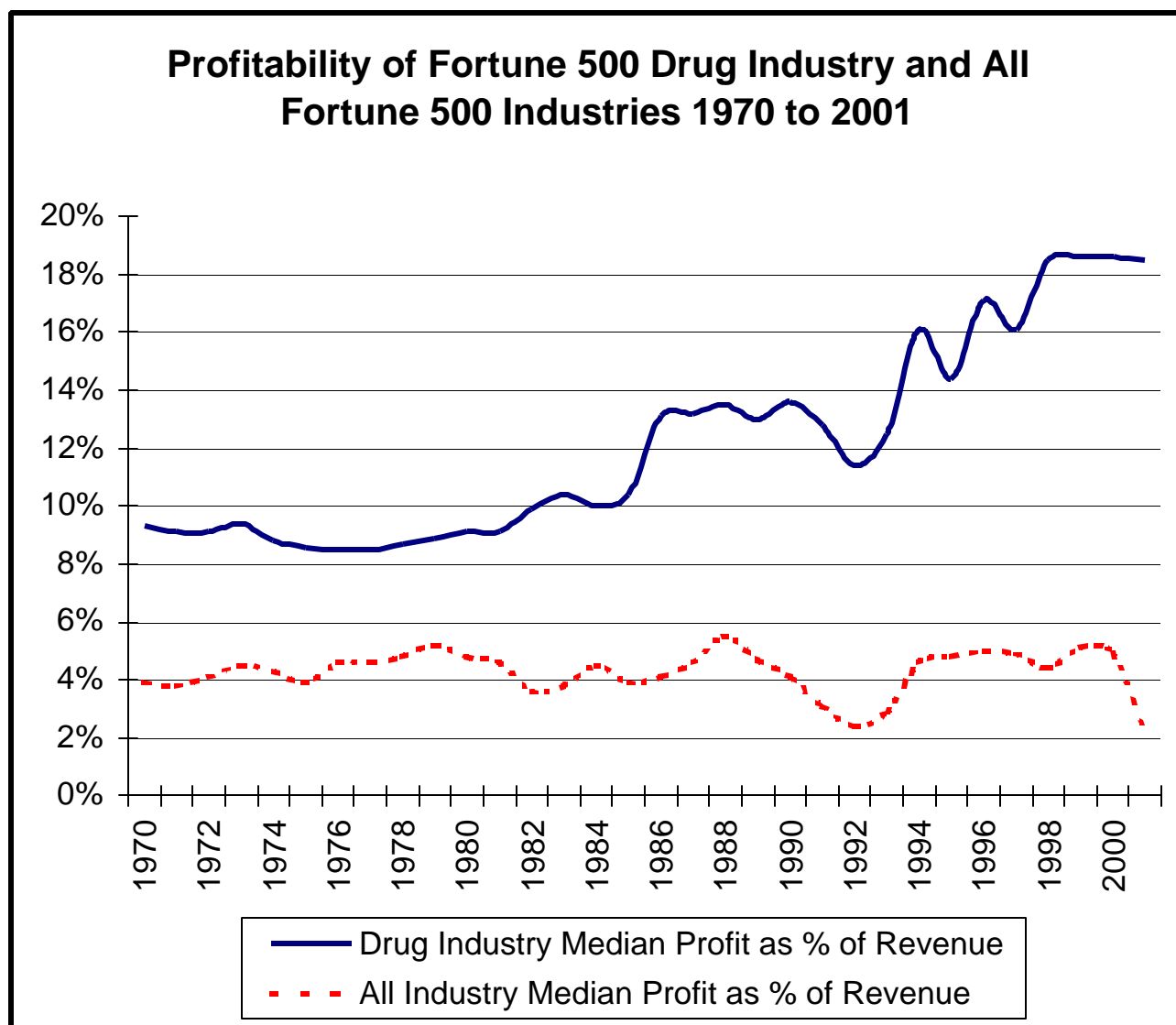


Source: National Institute for Health Care Management, "Prescription Drugs and Intellectual Property Protection," August 2000.

- Longer patent lives make the drug industry more profitable: The profitability gap between drug companies and other Fortune 500 companies has grown dramatically since the mid-1980s when the first of new patent extension laws were passed. (Schondelmeyer, “Competition and Pricing Issues in the Pharmaceutical Market,” PRIME Institute, University of Minnesota, August 1994, updated by Public Citizen; *Fortune* magazine, “Top Performing Industries,” 2002) *See Figure III.F.2: “Profitability of Fortune 500 Drug Industry and All Fortune 500 Industries 1970-2001” (Repeated on page 42)*
  - Drug companies stand to lose billions from expiring patents. It is estimated that the projected sales of drugs coming off patent between 2000 and 2004 are \$25.5 billion. (Mullins, et al., “Projections of Drug Approvals, Patent Expirations,” School of Pharmacy, University of Maryland, August 2000)
- Drug companies employ tricks to extend patents: With billions of dollars at stake, drug companies use several methods to extend patent protection.
  - Frivolous patent lawsuits: If a brand-name drug company files a lawsuit against a generic competitor, the FDA must automatically delay approving generic competition by 30 months. They are able to get the 30-month extension whether the lawsuit has merit or is frivolous and simply designed to block the generic drug from being produced. (Leary, “Antitrust Issues in Settlement of Pharmaceutical Patent Disputes,” Federal Trade Commission, November 3, 2000)
  - Apply for a patent for minor variations of drugs: One way to protect the franchise on a lucrative brand-name drug is to seek a new patent on a slight variation of the drug. When this new patent goes into effect, a company can encourage doctors to switch their patients from the old to the new form, adding years to the company’s monopoly. This is known as “Evergreening.” (National Institute for Health Care Management, “Prescription Drugs and Intellectual Property Protection,” August 2000)

- Payoff a generic company: Brand-name drug companies pay generic companies not to compete. In the spring of 2000, Abbott Laboratories paid Zenith Goldline Pharmaceuticals \$2 million a month, up to \$42 million, and Geneva Pharmaceuticals \$4.5 million a month, up to \$101 million, to stop production of a generic version of Hytrin, a blood pressure and prostate enlargement drug whose patent had expired in 1995. (Stolberg and Gerth, “Medicine Merchants: How Companies Stall Generics and Keep Themselves Healthy,” *The New York Times*, July 23, 2000)
  
- Drug company tricks lead to higher costs for consumers. Legislation curbing the ability of brand-name drug manufacturers to block generics from coming to market would significantly lower consumer costs. If legislation were to pass that would reduce the delay by 20% in consumer access to generic drugs due to patent litigation it would result in \$60 billion in savings to the government and consumers over 10 years. (Congressional Budget Office, “Estimate of S. 812,” July 18, 2002)
  
- Phony patents: Brand-name drug companies also delay generic entry by patenting the color of the pill or the shape of the drug bottle. (Stolberg and Gerth, “Medicine Merchants: How Companies Stall Generics and Keep Themselves Healthy,” *The New York Times*, July 23, 2000)
  - For instance, Bristol-Myers Squibb kept a generic version of the anxiety drug Desyrel off the market by claiming that the generic pill infringes on the form of the pill. Like the brand-name medicine, the generic pill, trazadone, has two grooves on it to split the tablet into thirds. (Tanouye, “Drug Dependency: U.S. Has Developed An Expensive Habit; Now, How to Pay for It?” *The Wall Street Journal*, November 16, 1998)
  
- A case study in patent extensions: Claritin, manufactured by Schering-Plough Inc., generated U.S. sales of \$2.3 billion in 1999 and American consumers pay almost four times as much for a pill as Canadians (\$1.94 to \$.54). Claritin’s patent was extended two years by the Hatch-Waxman Act – 22 months under Uruguay Round Agreements Act and six more months because the manufacturer tested the safety of the drug for children. (Adams, “Delays Disclosed in FDA Process to Approve Claritin, Other Drugs,” *The Wall Street Journal*, August 14, 2000; National Institute for Health Care Management, “Prescription Drugs and Intellectual Property Protection,” August 2000)

Figure III.F.2



Source: Public Citizen update of Stephen W. Schondelmeyer calculation, *Competition and Pricing Issues in the Pharmaceutical Market*, PRIME Institute, University of Minnesota based on data found in *Fortune* magazine, 1958 to 1999; Public Citizen's analysis of *Fortune* magazine data, 2000-2002.

## **G. Pediatric Patent Extension: Taking Advantage of Children**

- Pediatric patent extension gives additional monopoly protection: Federal law gives six months of additional monopoly patent protection, or exclusivity, to a drug in return for the manufacturer conducting studies to determine the drug's safety in children. The law was first passed in 1997 and was reauthorized in 2002. (Food and Drug Administration, "The Pediatric Exclusivity Provision," Status Report to Congress, January 2001)
- Pediatric patent extension has increased health care spending:
  - The incentive delays the introduction of lower-priced generic drugs, which temporarily raises the average price of prescription drugs. Thus, consumers will pay an additional \$13.9 billion over a 20-year period due to delayed generic competition. (Food and Drug Administration, "The Pediatric Exclusivity Provision," Status Report to Congress, January 2001)
  - All taxpayers are charged for the incentive: The government will bear at least 21% of the additional costs (through Medicaid, Medicare, etc.) and private payers 79%. (Food and Drug Administration, "The Pediatric Exclusivity Provision," Status Report to Congress, January 2001)
- Drug company profits soar: The revenues gained by patent-holding firms are estimated at \$29.6 billion over 20 years. Profits for these companies would rise by about \$592 million a year thanks to the six months of additional patent protection given for testing the safety of drugs for children. (Food and Drug Administration, "The Pediatric Exclusivity Provision," Status Report to Congress, January 2001)
- Child studies are not that expensive: The studies required to gain the additional patent protection are relatively small and inexpensive, costing anywhere from \$200,000 to \$3 million. (Zimmerman, "Drug Makers Find a Windfall Testing Adult Drugs on Kids," *The Wall Street Journal*, Feb. 5, 2001)
- Pediatric patent extension given for adult drugs: Critics complain that drug companies are sometimes gaining the six-month bonus by testing drugs that treat conditions uncommon in children, such as arthritis, ulcers and hypertension. For instance, pediatricians wrote less than 1% of the prescriptions



for Glucophage, an adult-onset diabetes drug, and Vasotec, a hypertension medicine. The extra exclusivity won by the drugs is worth nearly \$1 billion in sales. (Zimmerman, “Drug Makers Find a Windfall Testing Adult Drugs on Kids,” *The Wall Street Journal*, Feb. 5, 2001)

- FDA can require tests on children: Under a rule that became effective April 1, 1999, FDA can require pediatric studies of a new drug if the drug is likely to be used in a “substantial number of pediatric patients” (50,000 pediatric patients in the U.S.) or would provide “meaningful therapeutic benefit.” But the drug companies have challenged this regulation in court. (Zimmerman, “Drug Makers Find a Windfall Testing Adult Drugs on Kids,” *The Wall Street Journal*, Feb. 5, 2001)
- Stop the bribes: Public Citizen believes that no bribes should be given to the drug industry. Congress should pass legislation requiring drug companies to test the safety of their drugs in children in order to get their new products approved by the FDA.

## **IV. Political Persuasion**

The drug industry is one of the most potent political forces when it comes to influencing legislation in Washington. Through inside-the-beltway lobbying, campaign contributions, issue ads, funding front groups, and conducting “astroturf” grassroots lobbying, the industry largely gets what it wants from politicians in Washington. At the top of the industry’s agenda has been opposition to prescription drug coverage under Medicare and hostility to measures that would moderate rising drug prices. The industry’s political investments have paid off as Congress has failed to provide Medicare prescription drug coverage. Instead, Republican leaders have promoted proposals that would encourage seniors to get drug coverage through private insurance companies and HMOs, preventing the Medicare program from negotiating substantial price cuts.

### **A. Campaign Contributions, Lobbying and Issue Ads:**

- Drug industry campaign contributions (2001-2002): The drug industry has given \$12 million in soft money and PAC contributions to federal candidates and parties during the 2002 election cycle (2001-2002). (Public Citizen, “Brand-Name Companies Versus Generics: Campaign Contributions and Lobbying,” July 19, 2002)
  - During the 2002 election cycle, the prescription drug industry has given 74% of contributions to Republicans and 26% to Democrats. (Center for Responsive Politics, “Pharmaceutical Manufacturing: Long-Term Contribution Trends” June 2002)
  - About 65 percent of the drug industry contributions (\$7.8 million) during the 2002 cycle came in the form of soft money donations – unlimited contributions given to the political parties by corporations, unions and individuals. Top soft money contributors in the 2002 cycle include Bristol-Myers Squibb (\$1,090,397), Pfizer (\$839,264) and Pharmacia (\$758,947). (Public Citizen, “Brand-Name Companies Versus Generics: Campaign Contributions and Lobbying,” July 19, 2002)
  - The brand-name drug industry has given ten times the amount of campaign contributions as the much smaller generic-drug industry during the 2002 cycle. Brand-name drug companies and their trade groups have

given \$10.9 million while generic companies and their trade groups have given \$1.1 million. (Public Citizen, “Brand-Name Companies Versus Generics: Campaign Contributions and Lobbying,” July 19, 2002)

- Total political spending by the drug industry (1999-2000): The drug industry spent at least \$262 million in the 1999-2000 election cycle on lobbying, campaign contributions and issue ads – an amount that shattered the industry’s previous records. (Public Citizen, “The Other Drug War: Big Pharma’s 625 Washington Lobbyists,” July 2001)
- Drug industry lobbying: The total drug industry lobbying bill for 1997-2001 was \$403 million. This amount does not include the tens of millions of dollars the industry spent on advertisements or the many more millions the industry spent on “grassroots” lobbying efforts. (Public Citizen, “The Other Drug War II: Drug Companies Use an Army of 623 Lobbyists to Keep Profits Up,” June 2002) *See Figure IV.A.1: “An Army of Lobbyists: The Drug Industry’s Lobbying Operation”*
  - Drug companies spent \$78.1 million on federal lobbying activities in 2001. All drug companies and their trade association employed a total of 623 different individual lobbyists in 2001, more than six for every member of the Senate (100) and more than one for every member of the House (435). (Public Citizen, “The Other Drug War II: Drug Companies Use an Army of 623 Lobbyists to Keep Profits Up,” June 2002)
  - The 10 most active drug companies and industry groups boosted lobbying expenditures 16% from last year – from \$43 million in 2000 to \$49.8 million in 2001. They also increased the number of lobbyists they employed by 30%, from 417 to 540. (Public Citizen, “The Other Drug War II: Drug Companies Use an Army of 623 Lobbyists to Keep Profits Up,” June 2002)

Figure IV.A.1

# **An Army of Lobbyists**

## **The Drug Industry's Lobbying Operation**

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**\$403 million**

**Spent on lobbying (1997-2001)**

---

**\$78 million**

**Spent on lobbying (2001)**

---

**623 Hired Guns**

**More than one for every Member of Congress (2001)**

---

**340 Revolving Door Lobbyists**

**Who worked for Congress or another branch  
of the federal government (2001)**

---

**23 Former Members of Congress**

**With Special Access to Their Former Colleagues**

---

Source: Lobby Disclosure reports filed with the Secretary of the Senate and Clerk of the House pursuant to the Lobby Disclosure Act of 1995; Public Citizen, "The Other Drug War II: Drug Companies Use an Army of 623 Lobbyists to Keep Profits Up," June 2002.

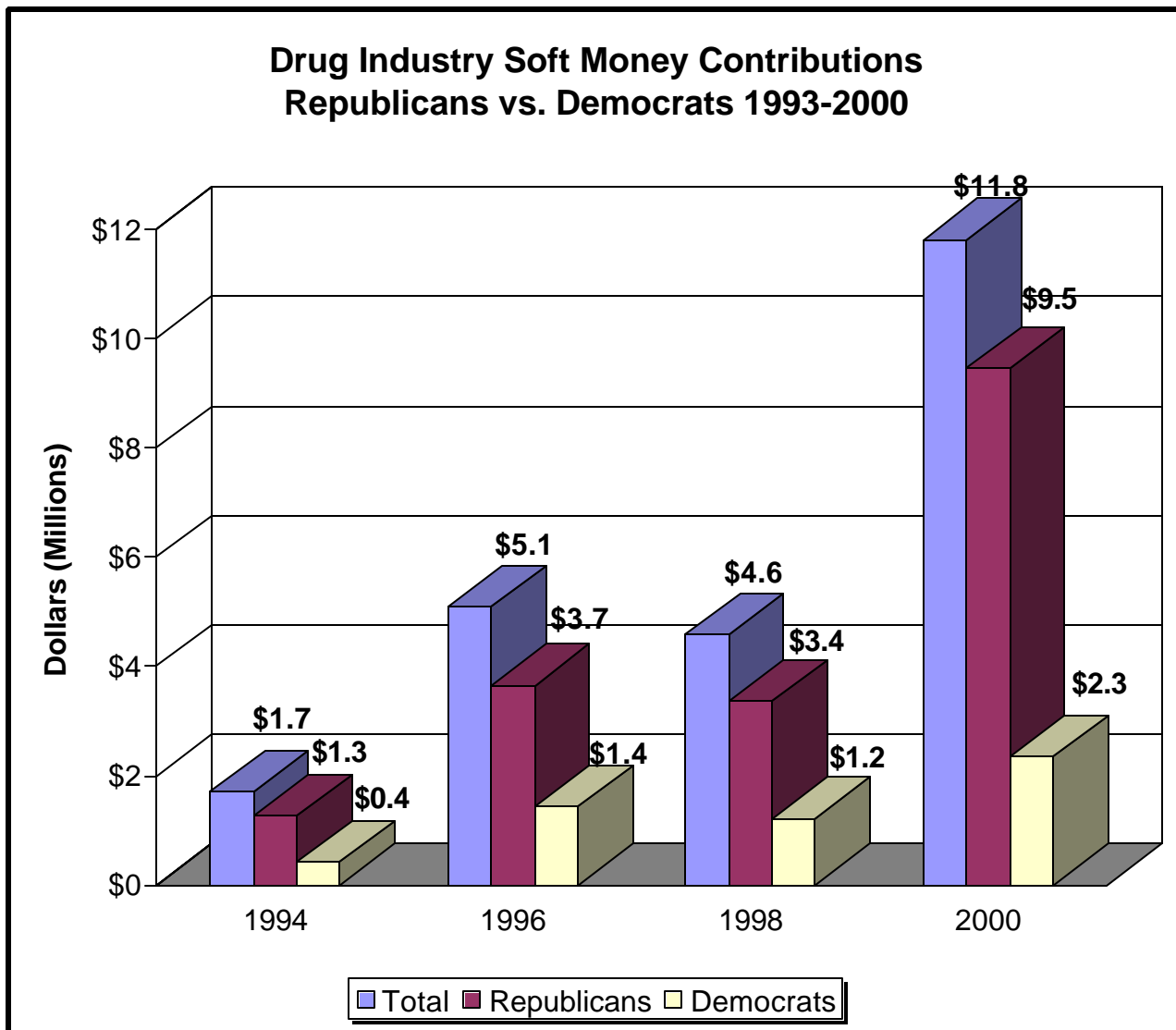
- The drug industry-government revolving door: Many members of Congress, their staff and executive branch employees leave government service to lobby for the drug industry:
  - 23 of the drug industry’s lobbyists are former members of Congress. (Public Citizen, “The Other Drug War II: Drug Companies Use an Army of 623 Lobbyists to Keep Profits Up,” June 2002)
  - 340 of those lobbyists (54%) previously worked in Congress or another branch of the federal government. (Public Citizen, “The Other Drug War II: Drug Companies Use an Army of 623 Lobbyists to Keep Profits Up,” June 2002)
- Drug industry lobbying vs. campaign contributions: The drug industry spends about 10 times as much on lobbying in Washington, D.C. as it spends on federal campaign contributions. (Public Citizen, “The Other Drug War II: Drug Companies Use an Army of 623 Lobbyists to Keep Profits Up,” June 2002)
- Brand-name vs. generic drug companies: In 2001, brand-name companies easily outgunned the generic companies they often compete with when it came to lobbying. Brand-name companies accounted for 97% of all pharmaceutical lobbying spending (\$75.7 million out of a \$78.1 million total). Brand-name companies also employed nine lobbyists for every one employed by generic companies. (Public Citizen, “The Other Drug War II: Drug Companies Use an Army of 623 Lobbyists to Keep Profits Up,” June 2002)
  - Generic drug companies and their trade groups have been overwhelmed on the lobbying front for the past five years and spent less than 2 percent of what the brand-name companies shelled out during that time. From 1997 to 2001, brand-name companies and their trade groups spent \$388.8 million on lobbying compared to generic companies’ \$6.8 million (these totals do not add up to \$403 million figure because they exclude some trade associations that could not be identified as affiliated with generic or brand-name drug companies). (Public Citizen, “Brand-Name Drug Companies Versus Generics: Lobbying and Campaign Contributions,” July 2002)
  - The brand-name companies’ trade group, Pharmaceutical Research and Manufacturers of America (PhRMA), spent more than \$11.2 million on lobbying in 2001 while the Generic Pharmaceutical Association (GPhA)

spent less than half a million. In 2001, PhRMA spent more on lobbying and hired more lobbyists (82) than any drug company or pharmaceutical trade group. (Public Citizen, “Brand-Name Drug Companies Versus Generics: Lobbying and Campaign Contributions,” July 2002)

- From 1997 to 2002, brand-name companies and their trade group contributed \$34.5 million to federal candidates and parties while generic companies contributed \$3.4 million. (Public Citizen, “Brand-Name Drug Companies Versus Generics: Lobbying and Campaign Contributions,” July 2002)
- The drug industry’s lobbying paid off: Although the industry faced mounting pressure in 2001 from employers, senior citizens and politicians to make prescription drugs more affordable, drug companies lost no battles last year. Instead, they actually gained ground – and additional profits – thanks to legislation that extends by six months lucrative monopoly patent protections for drugs if manufacturers test them for safety in children. (Public Citizen, “The Other Drug War: Big Pharma’s 625 Washington Lobbyists,” July 2001)
- 1999-2000 industry campaign contributions: In the 1999-2000 election cycle, campaign contributions by drug manufacturers soared to \$20.1 million – and were more than double the industry’s previous record of \$9.1 million in contributions to federal candidates and national party committees in the 1995-1996 election cycle. (Public Citizen, “The Other Drug War: Big Pharma’s 625 Washington Lobbyists,” July 2001)
- Drug industry soft money contributions doubled: Drug industry soft money contributions – which are unlimited donations to party committees controlled by party leaders – exploded last election cycle. Drug companies contributed \$11.8 million in soft money in 1999-2000, which is 131% more than the amount they contributed in the 1995-1996 cycle (\$5.1 million). (Public Citizen, “The Other Drug War: Big Pharma’s 625 Washington Lobbyists,” July 2001) *See Figure IV.A.2: “Drug Industry Soft Money Contributions Republican vs. Democrats 1993-2000”*
  - Overall, 59% of the drug industry’s campaign contributions in 1999-2000 were in soft money. (Public Citizen, “The Other Drug War: Big Pharma’s 625 Washington Lobbyists,” July 2001)

- Republicans are the main recipients of drug money: Drug companies increasingly wrote checks to Republicans, which helped ensure that Congress (which was controlled by Republicans in 1999-2000) blocked legislation that would provide prescription drug coverage through Medicare. In 1994, 60% of the industry's contributions went to GOP candidates and committees. In the 2000 cycle, 76% of industry contributions went to Republicans. (Public Citizen, "The Other Drug War: Big Pharma's 625 Washington Lobbyists," July 2001) *See Figure IV.A.3: "Party Shares of Contributions from Drug Industry 1993-2000"*
  
- The drug industry spent approximately \$65 million on issue ads in 1999-2000: All drug industry spending on issue ads is not a matter of public record, as the industry created two different tax exempt groups in the 1999-2000 election cycle to avoid disclosure. But media reports and academic analysis of TV ads in the nation's leading media markets have led to conclusions that the drug industry spent \$65 million on issue ads. (Jamieson, et al., "Issue Advertising in 1999-2000 Election Cycle," Annenberg Public Policy Center of the University of Pennsylvania, February 1, 2001)
  - Some of the ads were legitimate issue ads designed to oppose Medicare drug coverage. But many were phony issue ads designed to oppose or support candidates for Congress. One academic study said: "Although claiming not to engage in election-related activity, Citizens for Better Medicare ran a vast majority of ads (80%) that clearly opposed or supported a candidate..." (Magelby, "Election Advocacy: Soft Money and Issue Advocacy in the 2000 Congressional Elections," Center for the Study of Elections and Democracy, Brigham Young University, November 2000)
  
- In addition, drug companies contributed to the Bush inauguration: In all, drug companies gave \$625,000 to the inauguration committee of President George W. Bush, with \$100,000 checks from Abbott Laboratories, Bristol-Myers Squibb, Pfizer, and the Pharmaceutical Research and Manufacturers of America. (Public Citizen analysis of data from Center for Responsive Politics)

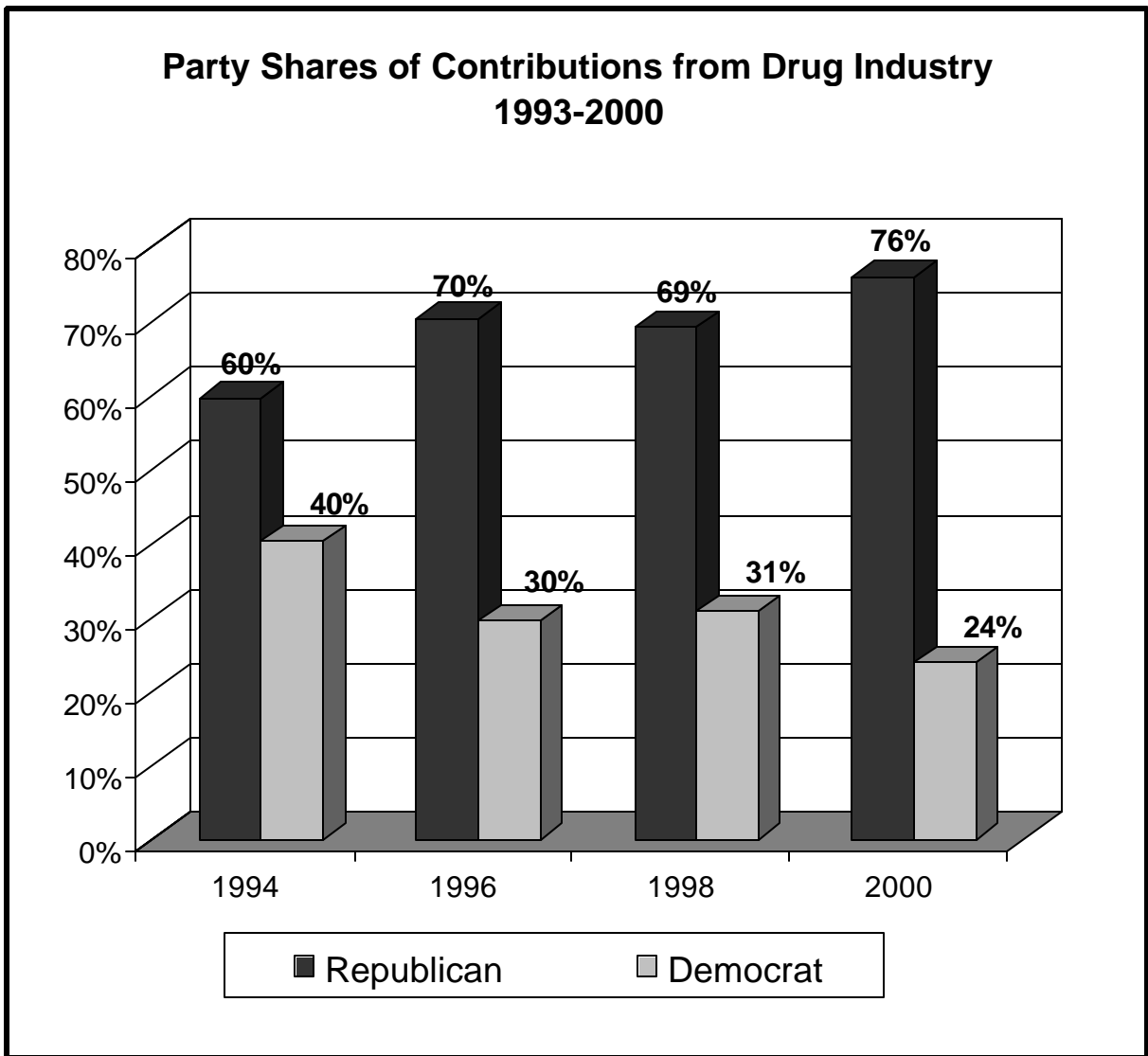
Figure IV.A.2



Source: Public Citizen, "The Other Drug War: Big Pharma's 625 Washington Lobbyists," July 2001.



Figure IV.A.3



Source: Public Citizen, "The Other Drug War: Big Pharma's 625 Washington Lobbyists," July 2001.

## **B. Front Groups & Hired Guns: Hiding Behind Other Messengers**

- Citizens for Better Medicare: The prescription drug industry created a sham “citizens” group, Citizens for Better Medicare (CBM), in 1999 as a vehicle to argue against drug policies the industry opposed. Using CBM, the drug industry spent about \$50 million in 1999-2000 on sham “issue” ads, most of which were designed to elect or defeat candidates. (Public Citizen, “Citizens for Better Medicare: The Truth Behind the Drug Industry's Deception of America's Seniors,” June 20, 2000)
  - CBM’s first wave of ads featured an actress posing as a character named “Flo.” The ads were modeled on the “Harry and Louise” ads that were effectively used to oppose the Clinton health care plan in 1993-1994. The ads were designed to help friends and punish enemies who supported prescription drug coverage under Medicare. (Public Citizen, “Citizens for Better Medicare: The Truth Behind the Drug Industry's Deception of America's Seniors,” June 20, 2000)
  - CBM claims to be a “broad-based bipartisan group.” In fact, since the beginning, it has been financially supported by the Pharmaceutical Research and Manufacturers of America (PhRMA). CBM’s first director was Tim Ryan. He was PhRMA’s former marketing director before joining CBM. (Public Citizen, “Citizens for Better Medicare: The Truth Behind the Drug Industry's Deception of America's Seniors,” June 20, 2000)
  - CBM spending kept secret: CBM was initially a secretive political group organized under Section 527 of the federal tax code, which covers groups whose purpose is to influence or attempt to influence elections. Taking advantage of a notorious loophole, CBM did not have to report its existence, much less its activities, to the IRS or the public. Fortunately, Congress closed the 527-loophole in June 2000. (Public Citizen, “Citizens for Better Medicare: The Truth Behind the Drug Industry's Deception of America's Seniors,” June 20, 2000)
  - Shortly after Congress closed the 527-loophole, CBM became a different kind of tax-exempt group – a 501(c)(4) non-profit, which is defined by the IRS as a civic league, social welfare organization or local association of employees. Under its new status, CBM does not have to disclose its

contributors or spending details. (Citizens for Better Medicare, IRS Form 1024, December 6, 2000)

- In its 501(c)(4) application, CBM said it planned to spend \$61 million between August 2000 and July 2003, with \$25 million of that spending occurring after July 2001 – in all likelihood trying to influence the 2002 congressional elections. (Citizens for Better Medicare, IRS Form 1024, December 6, 2000)
- The group’s IRS application listed only two paid employees: then Executive Director Tim Ryan, who made an annual salary of \$150,000 and Secretary/Treasurer Laura Dove, who made an annual salary of \$85,000. (Citizens for Better Medicare, IRS Form 1024, December 6, 2000)
- U.S. Chamber of Commerce: Just before the November 2000 election, the drug industry also funneled another \$10 million to the U.S. Chamber of Commerce so it could run phony “issue” ads aimed to elect or defeat congressional candidates. (Harris, “Prescription for Gridlock: A look at the competing players in the Medicare drug debates shows why it will be hard to get legislation passed,” *The Wall Street Journal*, February 21, 2001)
- United Seniors Association: In 2001 and 2002, the United Seniors Association (USA) began acting as a hired gun for major industries, especially pharmaceutical companies, seeking to influence federal policy and elections. This highly partisan organization was criticized for years for its overblown scare tactics in direct-mail fundraising letters. But during the past two years, USA has shifted its emphasis to TV and radio “issue” ads – underwritten by large corporate donations. (Public Citizen, “United Seniors Association: Hired Guns for PhRMA and Other Corporate Interests,” July 16, 2002)
  - Public Citizen estimates that USA spent \$12 million on issue ads from March 2001 to July 2002. The lion’s share of this spending – \$9.6 million – was used to promote President Bush’s and House Republican leaders’ prescription drug plan. (Public Citizen, “United Seniors Association: Hired Guns for PhRMA and Other Corporate Interests,” July 16, 2002)
  - Funded by Pharmaceutical Industry: PhRMA has admitted to funding much, if not all, of the \$4.6 million ad-buy in May and June 2002 through an “unrestricted educational grant.” PhRMA and USA would

neither confirm nor deny that the industry paid for the entire \$9.6 million. But the similar messages contained in the ads and significant overlap in the districts where they ran means it is quite likely that PhRMA's funding and strategy is behind them all. (Public Citizen, "United Seniors Association: Hired Guns for PhRMA and Other Corporate Interests," July 16, 2002)

- USA's ad spending appears to highlight a major expansion in the size and scope of the group's activities. The \$9.6 million spent on ads over the last 12 months is more than the group's \$9 million total budget in 2000, the last year for which information is available. Searches of media reports and the group's financial disclosure reports show no signs of ad spending prior to 2001. (Public Citizen, "United Seniors Association: Hired Guns for PhRMA and Other Corporate Interests," July 16, 2002)

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