



**FOLLOW THE
MONEY**

**THE PHARMACEUTICAL
INDUSTRY - THE OTHER
DRUG CARTEL**



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The Pharmaceutical Industry: The Other Drug Cartel

September 30, 2003

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EXECUTIVE SUMMARY

Section One and Two: Industry Profits

Approaching 15 percent of the gross national product, health care is the fastest growing, and one of the largest, sectors in the American economy. The segment within the health care sector growing fastest is prescription medication, which represents almost 18 percent of the health care dollar. By the end of this decade, the Medicare population alone will likely expend \$228 billion on prescription drugs. With a profit margin of 18.6 percent in 1999, the pharmaceutical industry has been the most profitable industry in the United States in each of the past ten years, approximately 5-1/2 times more profitable than the average Fortune 500 company.

Section Three: Research and Development

While the industry justifies its profit margins by claiming that it invests a large percentage of revenue in research and development (R&D), it fights every attempt by the government to verify the extent of R&D investment. In fact, experts estimate that up to 85 percent of R&D funding comes from National Institutes of Health (NIH), public tax credits, private foundations, and academia. Indeed, one tax credit alone allows a 50 cent credit on tax liability for each dollar spent by a pharmaceutical company on R&D. This tax credit, combined with other tax credits, rewards the pharmaceutical industry with the lowest effective tax bracket of any industry -- roughly half that of other corporations and half that of the average family.

Section Four: Public Funding of Research and Development

A substantial amount of profit comes from new drugs which are discovered and formulated through public foundations and universities, which then license the drugs to a pharmaceutical company for a small fraction of the company's ultimate profits. For instance, the breast cancer drug Taxol was developed with \$32 million in federal funding after approximately 30 years of research. The NIH licensed Taxol to Bristol-Myers Squibb in 1992, which then generated \$1 billion of revenue per year on the sale of the product. Bristol-Myers Squibb then extended its exclusive control over Taxol by manipulating the U.S. Patent Office with deceptive patent claims, keeping a generic form of Taxol off the market. Other examples of blockbuster medications developed with substantial public funding are Tamoxifan, Xalatin, AZT, Prozac, Zovirax, Capoten, Platinol, and Epogin. Experts indicate

that most of the R&D financed by the pharmaceutical industry appears to be directed to “me too” drugs that, for instance, change a molecule of a drug coming off patent so that the company can petition for a new patent on the modified drug which is then marketed as “new and improved.”

Section Five: Marketing in the Pharmaceutical Industry

While the extent of the pharmaceutical industry’s investment in R&D may be questioned, its commitment to marketing is crystal clear. For each dollar received by the pharmaceutical industry, approximately 37 percent is spent on administration and marketing, almost three times the amount allocated to research and development. According to one study, the industry’s marketing staffs increased by 59 percent between 1995 and 2000, while research staffs declined by two percent. One expert concludes that if drug prices were regulated, any reduction in expenditures by the industry would be in marketing, not research and development.

In 1996 the U.S. Food and Drug Administration relaxed regulation of “direct-to-customer” (“DTC”) advertising. As a result, the industry spent \$2.5 billion in DTC advertising in 2001. Experts believe that DTC advertising unnecessarily drives up the consumption of drugs. One survey found that, if their physicians turned down a request for an advertised drug, approximately 40 percent of patients would attempt to obtain the drug from a different doctor.

Section Six: Industry Dominance

Unlike most other industrialized countries which have laws to regulate the price of prescription drugs, the United States implements laws to protect the industry from competition. Because other countries regulate the price of drugs, Americans find that they can purchase medications in other countries, such as Canada, at approximately 50 percent of the U.S. price. Federal importation laws, however, inhibit the ability of Americans to purchase drugs in Canada. Another law which protects the industry requires the use of the “average wholesale price” in determining amounts paid for drugs by Medicare and Medicaid. These two government agencies are required to purchase medications at a fictitious “average wholesale price” which is reported to them by pharmaceutical companies. When the Medicaid or Medicare programs attempted to negotiate the price or utilize an “average wholesale price” established by the Department of Justice, Congress intervened and forced these agencies to pay a minimum price at the level reported by the drug manufacturers.

Yet another law which protects the industry is the Hatch-Waxman Act, which allows pharmaceutical companies to extend the life of a drug patent and eliminate competition from generic drug manufacturers, simply by claiming that the drug has been modified or is being used for different treatment.

Section Seven: Political Influence

The political influence of the pharmaceutical industry is unprecedented. The Attorney General's Office surveyed 17 pharmaceutical companies and their industry organization, PhRMA. PhRMA alone is expected to spend \$150 million in lobbying, political contributions and issue advertising in 2003. Individual pharmaceutical companies made federal political contributions totaling \$27 million in the 2001-2002 election cycle. In addition, PACs sponsored by the 17 companies appear to have spent over \$9 million during the 2001-2002 election cycle, two-thirds of which was spent on contributions to other political committees, particularly "Stealth PACs." PhRMA and the 17 pharmaceutical companies, also disclosed lobbyist expenditures of \$129.9 million for the 2001-2002 election cycle.

"Stealth PACs" are committees whose names are intended to connote an affiliation with a particular constituency when the committee's mission is, in fact, adverse to the constituency. Stealth PAC groups include Citizens for a Better Medicare, United Seniors Association, the 60 Plus Association, and the Seniors Coalition. All of these Stealth PACs are funded by pharmaceutical companies. Stealth PACs create the perception of representing senior citizens through "astroturf lobbying," which is high-tech telemarketing masked to look like grassroots lobbying. The Stealth PACs establish telemarketing banks to contact representatives in Congress, state legislators, and thought leaders and represent themselves to be senior citizens who oppose the regulation of pharmaceutical prices. The above Stealth PACs expended over \$25 million in lobbying expenses during the 2001-2002 election cycle.

Section Eight: Impact on Minnesota

The pharmaceutical industry has retained approximately 38 lobbyists in Minnesota to oppose legislation designed to regulate prescription drugs. Last year, the industry was successful in gutting the Fair Drug Pricing Act. Other legislation defeated by the industry included the False Claims Act and a bill that would have required pharmaceutical companies to certify under oath the validity of the average wholesale prices filed with the government.

Section Nine: Conclusion

The report concludes that the undue influence of the pharmaceutical industry on lawmakers is responsible for the current prescription drug crisis. The inaction of lawmakers, who campaign on pharmaceutical reform but repeatedly fail to implement it, is a scandal that will only be addressed when the media and other public commentators expose the issue.

Section One: Politics and the Pharmaceutical Industry

“The drug industry is once again on track to be the biggest industry-group spender in American elections.”

Dr. Ken Goldstein, Professor of Political Science
University of Wisconsin
AARP Bulletin, *Pulling Strings From Afar*,
February, 2003

Political influence fits the pharmaceutical industry like a glove on a hand. In the 2001-2002 election cycle, the pharmaceutical industry made direct federal political contributions totaling \$26,941,139, approximately eight times the \$3,219,892 that it spent in the 1989-1990 election cycle.¹ The industry also exercises financial influence through political action committees (“PACS”), soft money² and individual contributions. *Public Citizen* calculated that, since 1997, the industry has spent over \$477 million lobbying the federal government. It notes that in 2002, the industry employed 675 individuals to lobby Congress, substantially exceeding the total number of Senators and Representatives.³ The lobbying expenditures of the 18 pharmaceutical entities surveyed in this report totaled nearly \$200 million in the last three years alone.⁴

The pharmaceutical industry has aggressively fought efforts to change the United States reimportation regulations to allow American citizens to purchase medications at significantly lower prices from countries that implement price controls, such as Canada. The industry has also taken action to shape the debate surrounding Medicare drug benefits, decrying any and all attempts to regulate the price of such medications. In Minnesota, drug industry lobbyists have aggressively opposed legislative efforts such as the Fair Drug Pricing Act, which would allow Minnesotans to purchase medications at the rates paid by the Medicaid program. The industry has also opposed State attempts to bring greater transparency to the

¹ Center for Responsive Politics, “Pharmaceutical/Health Products: Long-Term Contribution Trends,” 2003; see www.opensecrets.org.

² “Soft money” is all political money which is not limited by the Federal Election Campaign Act.

³ *Public Citizen*, “The Other Drug War 2003: Drug Companies Deploy an Army of 675 Lobbyists to Protect Profits,” June 2003.

⁴ Secretary of the Senate, Office of Public Records, Lobby Filing Disclosure Program, available at <http://sopr.senate.gov>; Center for Responsive Politics, “Lobbyist Spending: Pharmaceuticals/Health Products,” available at www.opensecrets.org.

wholesale drug pricing system which dictates the price states pay for prescriptions under the Medicaid program and seniors' co-payments under Medicare.

This report reviews the pharmaceutical industry's influence on the legislative process at both the state and federal levels. It also surveys the practices of 17 pharmaceutical companies and their major trade association, the Pharmaceutical Research and Manufacturers of America ("PhRMA"). Finally, this report reviews the relationship between the industry and special interest groups that undertake public relations campaigns which are favorable to the industry.

Section Two: Pharmaceutical Industry Profits

"Whether you gauge profitability by median return on revenues, assets or equities, pharmaceuticals had a Viagra kind of year."

Senator Paul Wellstone
March 3, 2000

Approaching 15 percent of the gross national product, health care is one of the largest sectors in the American economy. The cost of health care is also growing fast -- far in excess of the Consumer Price Index. As a result, over 40 million people in the United States are unable to afford health care coverage.⁵ The Minnesota Department of Planning estimates that health care costs Minnesotans more than \$19 billion each year.⁶ Prescription drug expenditures are the fastest growing segment in health care, approaching 18 percent of all health care expenditures.⁷ According to the Kaiser Family Foundation, prescription drug spending doubled between 1995 and 2000, with expenditures reaching \$122 billion in 2000.⁸ Prescription drug spending grew at an average rate of 12.4 percent per year from 1993 to 1998, compared with a five percent average growth rate for overall health care expenditures, and compared with growth rates ranging from 1.6 percent to 5.7 percent for all items on the Consumer Price Index.⁹ This rapidly

⁵ Corlin, Dr. Richard, "Still 40 Million Uninsured: Why is There no Progress?" June 17, 2002, available at www.amednews.com.

⁶ *Minnesota Planning*, "Fiscal Futures: A Guide to Minnesota Health Care Spending," January, 2003.

⁷ Levitt, Larry, "Prescription Drug Trends," Kaiser Family Foundation, November 2001.

⁸ Kaiser Family Foundation, "Federal Policies Affecting the Cost and Availability of New Pharmaceuticals," July 2002.

⁹ Prescription Drugs: Increasing Medicare Beneficiary Access and Related Implications, Statement of William Scanlon, Director Health Financing and Public Health Issues, Health, (Footnote Continued on Next Page)

growing cost is particularly difficult for the senior population, which is especially vulnerable to the high cost of prescription drugs because it generally uses a higher volume of medicine. Exacerbating this problem is the fact that Medicare only covers a very small number of prescription drugs. The cost of prescription drug coverage is expected to continue to escalate, with one estimate being that the Medicare population alone will spend \$228 billion for prescription drugs in 2011.¹⁰

While almost all other industrialized countries regulate the price of prescription medication, and while prescription drug pricing has become a perennial issue in political campaigns at both the state and federal level, there has been little action taken to reign in the cost of prescription drugs. Commentators point to the millions of dollars that the industry contributes to political candidates and parties as the primary reason that legislative efforts are repeatedly stalled or defeated. Currently, as Congress debates the possibility of a Medicare prescription drug bill, the industry continues to oppose any bill which would allow the federal government to negotiate with the pharmaceutical companies for lower prices on behalf of Medicare beneficiaries. The political strategy of the pharmaceutical industry is clear: it opposes any government action which adversely affects its bottom line -- namely, its profits.

This is ironic because the pharmaceutical industry has been the most profitable industry in the United States for each of the past ten years.¹¹ In 2001, it was 5-1/2 times more profitable than the average of all other Fortune 500 companies.¹² In 2000, the profits of one drug company, Merck, were \$6.8 billion -- larger than the combined profits of all of the Fortune 500 companies in the airline industry and in the entertainment industry.¹³ With the top 12 pharmaceutical companies earning \$27 billion in profits in 1999, the industry does not, and indeed cannot, dispute its extraordinary profit margin, rated by *Fortune Magazine* to be 18.6 percent in 1999.¹⁴ It argues, however, that such margins are necessary because of the high cost of research and development (“R&D”) of new medicines.

(Footnote Continued From Previous Page)

Education, and Human Services Division, before Committee on Commerce U.S. House of Representatives (February 16, 2000).

¹⁰ Kaiser Family Foundation, “Prescription Drug Trends -- A Chartbook Update,” November 2001.

¹¹ *Families USA*, “Profiting from Pain: Where Prescription Drug Dollars Go,” July 2002.

¹² *Id.*

¹³ *Public Citizen*, “Rx R&D Myths: The Case Against the Drug Industry ‘Scare Card’,” 2001.

¹⁴ *Families USA*, “Profiting From Pain: Where Prescription Drug Dollars Go,” July 2002.

In an interview on PBS *Frontline*, Sidney Taurel, chief executive officer of Eli Lilly, explained the industry's position as follows:

It takes a very, very long time and a lot of money to bring a product to market -- 12 to 15 years, in terms of development cycle. A very, very small percentage of the products that we start with make it to the marketplace. A very small percentage of them actually recoup their costs. The costs have escalated from about \$200 million per molecule, 15 years ago, to about \$800 million today, as per the latest studies. Therefore, this is a very, very high-risk business.

When you look now at the patent system, patents are valid for 20 years. But this starts from the time when the patent issues, which is typically the very beginning of the development process. Once the product is on the market, it is protected effectively for a much, much shorter period of time, which today is like 10-12 years, maximum.

So it is a high-risk business, a small time to recoup the investment. As a result, investors demand a higher return.¹⁵

As discussed below, this industry justification for soaring drug prices is highly suspect.

Section Three: The Issue of Research and Development

The debate surrounding the amount that the pharmaceutical industry spends on research and development is highly contentious. The statistics cited by Mr. Taurel in the *Frontline* interview are based on two research projects that were undertaken by the Tufts Center for the Study of Drug Development in 1991 and 2001. These studies determined that the average cost to develop a new prescription drug today is \$802 million.¹⁶

Several organizations have criticized the Tufts' studies as flawed and have argued that the studies were bought and paid for by the pharmaceutical industry. *Public Citizen* points out that the sponsors of the Tufts' studies include drug

¹⁵ PBS *Frontline*, "The Other Drug War," aired June 20, 2003.

¹⁶ Tufts Center for the Study of Drug Development, November 30, 2001 Press Release.

companies such as Merck, Pfizer and Bayer.¹⁷ It also notes that the data utilized in the studies came directly from the 12 drug companies surveyed and that the information was not independently verified or checked for accuracy.¹⁸ Indeed, the Congressional Office of Technology Assessment (“OTA”) notes that the Tufts’ data is flawed since “any company that understood the study methods and the potential policy uses of the study’s conclusions could overestimate costs without any potential for discovery.”¹⁹

Critics of the Tufts’ studies also point out that the studies neglected to consider important factors in the R&D process, including the enormous tax breaks, tax credits and publicly funded research which benefits the industry. Indeed, *Public Citizen* conducted several extrapolations to make its own determination as to the cost of developing a new prescription drug. By using PhRMA figures for domestic R&D spending, and incorporating a system which includes a seven-year lag between R&D expenditure and drug approval, *Public Citizen* concluded that the average cost to bring a drug to market in 2000 was between \$87 million and \$149 million -- a fraction of the estimates of the Tufts’ studies.²⁰

The great disparity between the estimate of the Tufts Center and *Public Citizen* could be attributable to the industry’s steadfast refusal to divulge and substantiate their R&D costs, as illustrated in the following dialogue between Peter Jennings of ABC News and Alan Holmer, the president of PhRMA:

Jennings: You say over and over again, it costs \$800 million to develop a new drug. You say that to the public, you say that to the Congress. Without being rude about it, prove it to me.

Mr. Holmer: These are -- are business propriety pieces of information, often which will involve trade secrets that the companies understandably will not want to have disclosed publicly. I would note, though...

Jennings: (voice over) If you look at the companies’ annual reports, you won’t find any detailed breakdown of their research costs.

¹⁷ *Public Citizen*, “Rx R&D Myths: The Case Against the Drug Industry’s R&D ‘Scare Card,’” 2001.

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Id.*

Companies are not required to make this information public. Profit, on the other hand, is public, and the drug industry is the most profitable industry in the country.²¹

The pharmaceutical industry has aggressively opposed the reporting of R&D spending. Claiming that such disclosure is an infringement upon trade secrets, the industry went so far as to fight the United States General Accounting Office (“GAO”) in court, arguing that the GAO had no authority to investigate the expenditures of pharmaceutical companies that enter into contracts with the government. The industry was ultimately successful at thwarting the GAO’s efforts to obtain this R&D information. As noted in a Congressional Report:

[T]he courts were split on GAO’s right of access to indirect costs (research and development (R&D), marketing, promotion, distribution, and administration costs). In most cases the industry successfully argued that indirect cost data were not *directly pertinent* because only a small portion of indirect costs could be allocated to the Federal Government’s contracts, and GAO would have to examine a large amount of data not related to the Government’s contracts in order to discern the small amount. The Government unsuccessfully argued that GAO would not have to go on a fishing expedition through all the company’s unallocated costs, because the companies allocate costs to products and perform profitability studies for their own purposes. That argument fell on deaf ears, and GAO was given access only to direct cost data that the industry was willing to provide. From a practical point of view, these decisions left GAO with little meaningful data, since direct costs amounted to only about nine percent of the cost of a particular pharmaceutical product. The access granted by these courts was, therefore, virtually useless as an auditing tool.²²

²¹ ABC News Special Report with Peter Jennings, “Bitter Medicine: Pills, Profit and the Public Health,” aired May 29, 2003.

²² U.S. Congress, Office of Technology Assessment, “Pharmaceutical R&D: Costs, Risks and Rewards, OTA-H-522” (Washington, D.C.: U.S. Government Printing Office, February 1993).

The report notes that, while Congress has the authority to subpoena R&D data, it has not utilized this power. One might question whether this reluctance may be related to the hundreds of millions of dollars that the industry spends in lobbying Congress and in funding the campaigns of senators and representatives.

Section Four: Public Financing of Research and Development

Within the medical/health industry, no sector receives better treatment under the tax code than the pharmaceutical industry. Federal tax credits include the Research and Experimentation Tax Credit, the Orphan Drug Tax Credit and the Possessions Tax Credit. A 1999 study conducted by the Congressional Research Service noted that between 1990 and 1996, just one tax credit alone saved drug companies \$13 billion in federal taxes.²³ A tax credit, which is a dollar-for-dollar reduction on taxes, is substantially more lucrative than a tax deduction. The Research and Experimentation Tax Credit allows a pharmaceutical company to reduce its tax obligation on a dollar-for-dollar basis by claiming a tax credit equal to at least 50 percent of the R&D expended by the company during the year.²⁴ In other words, this tax credit alone publicly subsidizes 50 percent of all R&D research. Because of these tax credits, the pharmaceutical industry is the least taxed industry in the country.²⁵ *Families USA* sums up the industry's tax situation as follows:

Because research-related tax credits are reported along with other tax credits as "general business tax credits," there are no publicly available data showing the exact amount of tax relief that the industry receives for its investment in research. However, the effect of tax credits is clear. In 1999, the Congressional Research Service (CRS) studied industry taxation for the years 1990 to 1996. CRS found that the drug industry was taxed relatively lightly; total tax credits, many related to research investments, lowered the industry's effective tax rate from 35.2 percent to 17.1 percent. Given the favorable tax

²³ Common Cause, "Prescription for Power: How Brand-Name Drug Companies Prevailed Over Consumers in Washington," June 12, 2001.

²⁴ Kaiser Family Foundation, "Federal Policies Affecting the Cost and Availability of New Pharmaceuticals," July 2002.

²⁵ Common Cause, "Prescription for Power: How Brand-Name Drug Companies Prevailed Over Consumers in Washington," June 12, 2001.

treatment of R&D, it is unlikely that the industry would turn to R&D first for spending reductions.²⁶

Given the fact that the pharmaceutical industry is the most profitable industry in the country, it is ironic that its 16 percent tax rate is lower than that imposed on middle class Americans, who generally pay tax rates between 30 percent and 40 percent, or the average American business, which generally pays a federal tax of approximately 27 percent.²⁷

In addition to tax credits, the pharmaceutical industry receives additional public tax dollars from federal medical organizations such as the National Institutes of Health (“NIH”). In 1950, the NIH had a total appropriation of \$43 million.²⁸ By 1998, the NIH received an appropriation of \$13.6 billion.²⁹ Congress subsequently committed to double the budget of the NIH between 1998 and 2003.³⁰ By 2002, NIH’s budget was almost \$24 billion.³¹ The majority of NIH funding -- approximately 80 percent -- is awarded to research centers and universities; ten percent of NIH funding is used for research conducted by the NIH itself.³² At least one study of the 21 most important drugs introduced between 1965 and 1992 concluded that publicly funded research played a significant role in the development of 14 of the drugs.³³ The NIH examined the top five selling drugs in 1995, each of which had over \$1 billion in sales, and concluded that taxpayer funded researchers conducted 55 percent of the published research projects on these drugs.³⁴ It also concluded that federal taxes also paid for approximately 30

²⁶ *Families USA*, “Profiting from Pain,” July, 2002.

²⁷ Common Cause, “Prescription for Power: How Brand-Name Drug Companies Prevailed Over Consumers in Washington,” June 12, 2001.

²⁸ Varmus, H., “Special Report: Shattuck Lecture-Biomedical Research Enters the Steady State,” *The New England Journal of Medicine*, Vol. 333, No. 12, 1995.

²⁹ National Institutes of Health, “A Happy New Year, NIH Gets Generous ’98 Budget,” available at www.nih.gov/about/director/budget.htm.

³⁰ American Association for the Advancement of Science, “NIH Budget Growth Slows to Two Percent in FY2004,” February 25, 2003 REVISED.

³¹ *Id.*

³² “GRAVY TRAIN: The BIOTECH Bonanza -- Bush’s Effort to Double the Funding for NIH Has Local Companies Lining up for a Booster Shot to the Bottom Line;” *Washington Business Forward*, available at www.bizforward.com/wdc/issues/2001-06/gravytrain.

³³ *Public Citizen*, “Rx R&D Myths: The Case Against The Drug Industry’s R&D ‘Scare Card’,” 2001.

³⁴ *Id.*

percent of the published research of foreign academic institutions which participated in the development of these drugs.³⁵

The extent of the NIH subsidy is underscored in the following exchange between Peter Jennings of ABC News and Dr. Marcia Angell, former editor-in-chief of *The New England Journal of Medicine*, and Dr. Bernadine Healy, former head of the NIH:

Jennings: The federally-funded National Institutes of Health may be the drug industry's biggest benefactor. This government agency alone will spend more than \$23 billion on research this year, and much of the research benefits the drug industry. Dr. Bernadine Healy used to run the NIH.

Dr. Healy: If you would have just asked me, "What do you think NIH's contribution is to the major drugs of our time?", I would say 50, 60 percent.

Dr. Angell: Many of the new drugs -- most of the cancer drugs, for example, were developed by the NIH or by academic medical centers getting grants from the NIH.

Jennings: What's wrong with that?

Dr. Angell: Well, if -- if you like to see money in great gobs shifted from taxpayers to investors in the pharmaceutical industry, I suppose nothing is.

Dr. Healy: There's no other industry in which you have so much public investment in -- in the fundamental knowledge that enables the development of the commercial industry itself.³⁶

One example of publicly-funded research is the research that led to the development of Taxol, a breast and ovarian cancer medication developed with \$32 million in federal funding, and then licensed to Bristol-Myers Squibb in 1992 by the NIH. The R&D for Taxol included over 30 years of research funded in part by

³⁵ *Id.*

³⁶ ABC News Special Report with Peter Jennings, "Bitter Medicine: Pills, Profit and the Public Health," aired May 29, 2003.

the NIH.³⁷ From 1992 until the fall of 2000, Bristol-Myers Squibb used its monopoly power to sell the drug at a cost of between \$10,000 to \$20,000 for a full course of treatment.³⁸ The sale of Taxol brought over \$1 billion of revenue per year to the pharmaceutical company.³⁹

Although Bristol-Myers Squibb had exclusive rights to sell Taxol for a term of five years, it extended its control over the drug by manipulating the U.S. Patent and Trademark Office with deceptive patent claims.⁴⁰ As a result, the pharmaceutical firm was able to delay the entry of a generic form of Taxol by three years. During this period of time, Taxol generated approximately \$3 million of revenue per day.⁴¹ The *Miami Herald* estimated that Bristol-Myers Squibb had a profit margin of 90 percent on Taxol, a risk/reward ratio that is not found in any other industry.⁴²

Another prescription drug developed with government subsidies is Tamoxifen, a breast cancer drug which was the product of 140 NIH-sponsored clinical trials. Even though Tamoxifen was developed with the support of public funding in the United States, the cost of Tamoxifen was \$241 per treatment in the U.S. in 2000, compared to only \$34 per treatment in Canada.⁴³

Yet another example of a publicly-developed drug involves Dr. Laszlo Bito of Columbia University who, with the help of a \$4 million grant from the NIH, developed a drug that inhibits blindness in glaucoma patients.⁴⁴ Dr. Bito and Columbia University then made millions by licensing the drug -- eventually marketed as Xalatin -- to Pharmacia Corporation. Pharmacia in turn made \$500 million in sales in 1999 and projects billions more dollars in revenue from the

³⁷ Common Cause, "Prescription for Power: How Brand-Name Drug Companies Prevailed Over Consumers in Washington," June 12, 2001.

³⁸ *Id.*

³⁹ Federal Trade Commission, "FTC Charges Bristol-Myers Squibb with Pattern of Abusing Government Process to Stifle Generic Drug Competition," March 7, 2003 Press Release.

⁴⁰ White, Ronald, "Bristol-Myers Sued Over Taxol Generic," *The Los Angeles Times*, June, 5, 2002.

⁴¹ Common Cause, "Prescription For Power: How Brand Name Drug Companies Prevailed Over Consumers in Washington," June 12, 2001.

⁴² *Id.*

⁴³ Office of Representative Bernard Sanders, "Drug Companies and the NIH: How the Pharmaceutical Industry is Reaping Billions Off of Taxpayer-Funded Research and Development," available at <http://bernie.house.gov/prescription>.

⁴⁴ Gerth, Jeff and Sheryl Stolberg, "Birth of a Blockbuster," *New York Times*, April 23, 2000.

product.⁴⁵ While the drug was discovered with a federal grant, patients in the United States pay \$43 per bottle, almost triple the \$15 per bottle paid by Canadians.

Other blockbuster medications developed with substantial public funding include AZT, Prozac, Zovirax, Capoten, Platinol and Epogin.⁴⁶

According to Dr. Angell, approximately 85 percent of seminal research on which drug patents are based originates from work supported by the NIH and carried out in American academic medical centers.⁴⁷ In contrast, she estimates that only 15 percent results from private investment. In an interview for PBS *Frontline*, Dr. Angell points out the following:

In fact, if you look at where the original research comes from on which new drugs are based, it tends to be from the NIH [National Institutes of Health], from the academic medical centers, and from foreign academic medical centers. Studies of this, looking at the seminal research on which drug patents are based, have found that about 15 percent of the basic research papers, reporting the basic research, came from the industry. That's just 15 percent.

The other 85 percent came from NIH-supported work carried out in American academic medical centers. In one study, 30 percent came from foreign academic medical centers. So what we know about the numbers indicates that the foreign academic medical centers are responsible for more new drug discoveries than the industry itself.⁴⁸

Recent drug company filings with the U.S. Food and Drug Administration ("FDA") substantiate that original drug company research is the exception rather than the norm. The FDA has two categories for reviewing new prescription drugs: priority review and standard review. Medications which are believed to significantly improve clinical medicine are given priority review, while products that are similar to already-existing treatments are given standard review.

⁴⁵ *Id.*

⁴⁶ Office of Representative Bernard Sanders, "Drug Companies and the NIH: How the Pharmaceutical Industry is Reaping Billions Off of Taxpayer-Funded Research and Development," available at <http://bernie.house.gov/prescription>.

⁴⁷ PBS *Frontline*, "The Other Drug War," aired June 20, 2003.

⁴⁸ *Id.*

Dr. Angell notes that the industry's increased production of standard review drugs seems to contradict the industry's claims of innovation:

[I]n 2001, only 66 drugs were newly approved. Only 66 out of this whole gigantic industry, and that too has been going down. And of those 66, only 10 were classified as likely to be an improvement over whatever was already on the market. The other 56 were all "me too" drugs. That's pathetic, really, 10 out of 66 likely to be an improvement

They are not innovative businesses. They are giant marketing and PR machines that turn out predominantly "me too" drugs, and whose truly innovative drugs are based mainly on taxpayer-funded work. So they are not innovative.⁴⁹

The Kaiser Family Foundation's study makes a similar conclusion with regard to the industry's emphasis on "me too" prescription drugs:

According to a 2002 analysis by the National Institute for Health Care Management, a growing percentage of newly approved drugs are only incremental modifications of existing drugs. During the period 1995-2000, the report found that the FDA approved 81 percent more incrementally modified drugs that did not offer significant advances in efficacy or safety than it did in the period 1989-1994.⁵⁰

Section Five: The Pharmaceutical Industry: Marketing v. Research

Totaling billions of dollars every year, marketing is very likely the largest expense category for the pharmaceutical industry. Between 35-37 percent of industry revenue is allocated to administration and marketing, a figure which is almost three times larger than the 13-15 percent allocated for research and development.⁵¹ While it might suffer from investment malaise in the R&D category, the pharmaceutical industry is extremely innovative, and extremely aggressive, in the marketing category.

⁴⁹ Interview for PBS *Frontline*'s "The Other Drug War," aired June 20, 2003.

⁵⁰ Kaiser Family Foundation, "Federal Policies Affecting the Cost and Availability of New Pharmaceuticals," July 2002.

⁵¹ PBS *Frontline*, "The Other Drug War," Interview with Professor Uwe Reinhardt, aired June 20, 2003.

For instance, the industry uses “detail people” to make personal visits directly with physicians and to distribute free drug samples. In 1995, there was one pharmaceutical sales representative for every 19 physicians in the United States;⁵² by 2002, there was one pharmaceutical sales representative for every nine doctors in the United States.⁵³ To supplement personal visits by its sales representatives, the industry has an enormous budget for seminars, advisory committees and retreats which pay physicians to meet at luxurious conference centers to listen to pharmaceutical representatives discuss the merits of their products. In an interview on PBS *Frontline*, former-Oregon governor Dr. Kitzhaber noted that physicians are not necessarily provided objective information about particular drugs, noting that:

A lot of the information doctors get is market research provided by the drug companies’ representatives, the same people that fill your cupboards with samples and take your staff to the NBA game.⁵⁴

One can hardly dispute that pharmaceutical companies concentrate their resources more on marketing than research. At least one study concluded that the industry’s marketing staffs increased by 59 percent between 1995 and 2000, while the research staffs declined by two percent.⁵⁵ Indeed, in 2001 alone, Merck added 1,000 sales representatives to its U.S. operations.⁵⁶ Of the company’s 78,000 employees, 85 percent were engaged in nonresearch activities.⁵⁷ At least one study has concluded that if drug prices were regulated, the reduction in expenditures by the industry would be in marketing, not research and development.⁵⁸

In addition to personally soliciting physicians, the pharmaceutical industry also invests heavily in direct-to-customer (“DTC”) advertising. In 1996, prior to the relaxation of DTC standards by the FDA, the pharmaceutical industry spent \$791 million on advertising.⁵⁹ After the DTC standards were relaxed, it was estimated that DTC spending increased to \$2.5 billion for 2001 -- an increase of

⁵² *Harper’s Magazine Online*, “Harpers Index,” May 2003.

⁵³ *Id.*

⁵⁴ *PBS Frontline*, “The Other Drug War,” aired June 20, 2003.

⁵⁵ *Families USA*, “Profiting from Pain,” July 2002.

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *Public Citizen*, “Rx R&D Myths: The Case Against the Drug Industry’s R&D ‘Scare Card,’” 2001.

216 percent.⁶⁰ Not only are DTC advertisements expensive in terms of broadcast time and print media, but they may also unnecessarily drive up the consumption of prescription drugs by consumers. One survey asked patients how they would respond if their physician turned down their request for an advertised drug.⁶¹ Thirty-nine percent of the respondents said they would attempt to obtain the prescription from a different doctor or switch to a new doctor.⁶² Another 25 percent indicated they would try to change their physician's mind.⁶³

Some experts believe that the pharmaceutical industry uses this marketing power simply to drive up the consumption of expensive, newly approved "me too" drugs, which offer little or no improvement over cheaper, generic medicines. As Dr. Angell noted:

What's really interesting is what they spend on marketing and administration, by their own figures, on average 35 percent. That's over twice as much as what they spend on R&D. So if they point to their R&D costs as some sort of justification for the high prices, what on earth can they say about their marketing costs, which are over twice as much?

If a drug company produced a cure for AIDS or a cure for cancer, you wouldn't need a big marketing budget. The world would beat a path to its door. You have to have a huge marketing budget to convince the public that Nexium is better than Prilosec. That takes a great marketing budget. So that's where these marketing expenditures are going.⁶⁴

The industry has argued that regulation of prescription drug pricing would lead to large scale reductions in R&D, but it fails to address other potential cost cutting possibilities, such as marketing or administrative costs. In his *Frontline* interview, Dr. Uwe Reinhardt, a professor of economics and public affairs at Princeton University, remarked:

⁶⁰*Id.*

⁶¹Wilkes, Michael, Robert Bell, Richard Kravitz, "Direct-to-Consumer Prescription Drug Advertising: Trends, Impact and Implications," *Health Affairs*, v. 19, no.2 (2000).

⁶²*Id.*

⁶³*Id.*

⁶⁴PBS *Frontline*, "The Other Drug War," aired June 20, 2003.

If I take a dollar away from the drug industry, by how many cents will research shrink? Well, on average, R&D, research and development, by their own income statements, is about 13 cents of every dollar the pharmaceutical industry gets. It's about 28 cents for manufacturing, packaging, quality control. Its about 37 cents for administration and marketing. Its about 13 cents, maximally 15 cents for R&D, and then 18 cents as profit. So that's a big argument.⁶⁵

Since money spent on administration and marketing is almost three times the amount spent on R&D, it is far more likely that prescription drug reform will affect marketing, not R&D.

Section Six: Government Protection of Pharmaceutical Industry

“Even the New York Yankees sometimes lose, and it has been known that, on occasion, the Los Angeles Lakers lose a ballgame. But one organization never loses, and that organization has hundreds of victories to its credit and zero defeats in the United States Congress. And that is the pharmaceutical industry.”

Representative Bernie Sanders

Most industrialized countries regulate the price and availability of prescription medications, making them more accessible to the average citizen. With the cost of prescription drugs approaching 18 percent of the U.S. health care dollar, these other nations have government policies that attempt to control the cost of prescription drugs. Ironically, the United States approach is the opposite: government regulations act to protect industry profits and to insulate manufacturing companies from private competition. Three examples which reflect this government policy to boost prescription drug prices at the cost of taxpayers, employers and senior citizens include importation laws, Medicare (and Medicaid) and the Average Wholesale Price formula, and special patent protection.

⁶⁵ *Id.*

6.1 Importation Laws

American-made prescription drugs are frequently exported to other countries, such as Canada, where foreign government regulation keeps the price of the drugs significantly lower than the price of the same drugs sold in the United States. Accordingly, because of the price differential between the medication's cost in the U.S. and the foreign country, the prescription drug can be sold by a distributor or pharmacist in the foreign country to a United States citizen at a price far less than the retail price in the United States.

In recent years, American citizens have imported prescription drugs through internet orders, mail orders and by physically traveling to foreign countries. At least one authority calculates that internet sales of prescription drugs from Canada alone are projected to rise to \$1.4 billion this year.⁶⁶

The 106th Congress enacted the Medicine Equity and Drug Safety ("MEDS") Act, which established a program to allow pharmacies and wholesalers to reimport prescription drugs. The reimportation is only permitted under this Act, however, if the Secretary of Health and Human Services certifies that implementation of the Act imposes no additional risk to public health. Despite the passage of this law, the Secretary of Health and Human Services refuses to certify that there is no additional risk. Industry critics argue that the refusal of HHS Secretary Tommy Thompson to certify the safety of importation is connected to politics rather than science. Critics also point out that the budget director for the FDA, Mitch Daniels, formerly served as senior vice president of Eli Lilly.⁶⁷

The pharmaceutical industry has aggressively opposed the importation of drugs from other countries. The industry claims it is not concerned about profits, only safety.⁶⁸ Supporters of importation, such as Congressman Bernie Sanders, point out that such safety concerns are a pretext:

In Europe, reimportation is legal and most of these countries' health care systems are ranked higher than the U.S. by the World Health Organization. Additionally, the FDA already estimates that 80

⁶⁶ Mulligan, Kate, "Soaring Internet Drug Sales Raise Safety, Legal Concerns," *Psychiatric News*, June 6, 2003.

⁶⁷ Center for Responsive Politics, "The Bush Administration: Mitch Daniels, Director of the Office of Management and Budget," available at www.opensecrets.org.

⁶⁸ PhRMA Press Release, October 6, 2000.

percent of ingredients in the U.S. drugs are imported from other countries

Without citing proof, this (advertisement by PhRMA) implies that by allowing U.S. consumers access to lower prices in other countries, our overall health care system will somehow be diminished. The biggest health care problem facing American's seniors is the high prices for life saving medicines.⁶⁹

In the meantime, senior citizens in northern border states frequently take bus trips to Canada to take advantage of the large savings that Canadians receive due to their government's prescription drug policy. United States Senators such as Mark Dayton and Debbie Stabenow organized bus trips for seniors going to Canada in order to call attention to the price discrepancies. Riders of the Minnesota RxExpress (Senator Dayton's bus) estimate that they pay approximately half of what they would pay for their medications in the United States.⁷⁰ One report refers to a citizen named Melva McCuddy who takes the trips to Canada in order to fight what she calls her "big trifecta": heart disease, cancer and diabetes. She indicates that a three months' supply of Tamoxifen, a medication for cancer, costs \$287 in the United States but only \$38 in Canada.⁷¹

Another testimonial before a congressional committee regarding Canadian drug importation was made by Robert Hayes, president of the Medicare Rights Center. Mr. Hayes referred to a 74-year-old woman who lives with her husband on \$25,000 per year.⁷² Before going to Canada, she paid \$200 for a three months' supply of Evista, a medication for severe bone loss, while she now pays in Canada only \$77 for the same prescription.⁷³ Mr. Hayes also referred to a 76-year-old retired shirt factory worker from Waterville, Maine. Having a fixed income of only \$12,000 per year, the woman could not afford prescription drug coverage. As a result, she takes a bus trip to Canada organized by the Maine Council of Senior

⁶⁹ "New Ads Put Sanders Bill At Center-Stage in Debate Over Prescription Drug Prices," www.bernie.house.gov.

⁷⁰ Minnesota Senior Federation, "RxExpress to Canada Rolls Again," *Minnesota Senior News*, March 2003.

⁷¹ Hall, Mike, "What Drug Companies Aren't Telling You," *America@work*, AFL-CIO, 2003.

⁷² Medicare Rights Center, Testimony of Robert M. Hayes, President, Medicare Rights Center, Before the U.S. House of Representatives' Committee on Government Reform, Subcommittee on Human Rights and Wellness, International Prescription Drug Parity, April 3, 2003.

⁷³ *Id.*

Citizens, where she buys a supply of Prilosec, a medicine for severe acid reflux.⁷⁴ By buying her drugs in Canada, the woman saves over \$2,000 per year on the cost of Prilosec.⁷⁵

In spite of extensive lobbying by senior organizations, the pharmaceutical industry has successfully stopped any reform regarding drug importation. Because HHS Secretary Tommy Thompson refuses to certify the safety of drugs reimported from Canada, in July of 2002, the Senate passed a bill which permitted the reimportation of medicines from Canada even if the Secretary did not certify the safety of the reimported drugs. That bill, even though restricted only to drug importation from Canada, was defeated in the House of Representatives.

In the meantime, the FDA has not taken action to cease the importation of drugs by consumers. As a result, several pharmaceutical companies are threatening or implementing boycotts of Canadian wholesalers and pharmacies if they continue to sell drugs to citizens of the United States. For instance, GlaxoSmithKline has notified Canadian wholesale pharmacies that it will stop supplying them with its drugs if they continue to sell drugs to United States citizens. The Minnesota Attorney General's Office is reviewing these threats to determine whether they are illegal.

6.2 Medicare, Medicaid and the “Average Wholesale Price” Formula

“A document available to doctors on Centocor’s web site ... stated one benefit of prescribing Remicade was the ‘financial impact’ on the physician’s practice. The document included a worksheet where physicians could calculate their “estimated revenue per patient” from prescribing the drug ... (A rheumatologist) said the ... field is abuzz with discussion of the money to be made.”

Melody Peterson, “Methods Used For Marketing Arthritis Drugs Are Under Fire”, *New York Times*, April 11, 2002

Under federal law, the Medicare program pays for a portion of the cost of a very limited number of prescription drugs. These drugs, generally administered by a physician or used with certain medical equipment, include inhalants, such as

⁷⁴ *Id.*

⁷⁵ *Id.*

Albuterol for bronchitis and asthma, and oncology drugs, such as Taxol. The Medicare program reimburses the physician, hospital or health provider that dispenses the medicine according to a formula based on the “average wholesale price,” known in the industry as the “AWP”. The statutory reimbursement is 95 percent of the AWP.⁷⁶ The Medicare program then pays 80 percent of this reimbursement amount, while the patient pays the remaining 20 percent.

Similarly, most states operate a Medicaid program in which the state and federal government pay for medical benefits, including prescription drugs, for certain low income and disabled citizens. These Medicaid programs reimburse medical providers, including physicians and pharmacists, for certain drugs dispensed and administered to Medicaid recipients pursuant to various state-specific statutory formulas. In Minnesota, and in most states, the government uses a formula that is based upon the AWP of the drug. For instance, in Minnesota, the formula for reimbursement of pharmacists is the AWP minus 11.5 percent, plus a dispensing fee.⁷⁷

The drug AWP's are not, however, set forth in any statute. Rather, the drug manufacturers report the AWP's of their drugs to various price reporting services such as First Data Bank (formerly known as *Bluebook*), Medical Economics Company, Inc. (the *Redbook*), and Medispan. These price reporting services do not independently verify the prices that are provided by the manufacturers, nor do they require the manufacturer to certify the accuracy of the figures. The Medicare and Medicaid programs then use the manufacturers' reported AWP's to calculate reimbursement amounts. In addition, the manufacturers also provide their AWP figures directly to the federal and state government Medicaid and Medicare programs, once again never verifying the accuracy of the AWP's. Because the manufacturers often grossly inflate their reported AWP's,⁷⁸ both the Medicaid program and the Medicare program pay highly excessive amounts for prescription drugs. The manufacturers then sell their drugs to physicians, hospitals and pharmacists at a price that may be a small fraction of their reported AWP's. In some cases, these actual sales prices are a mere one percent of the reported AWP's.

⁷⁶ 42 U.S.C. § 1395u.

⁷⁷ Minn. Stat. § 256B.0625, subd. 13, as amended by 2003 Minn. Sess. Laws, 1st Special Sess., ch. 14, § 35.

⁷⁸ Indeed, within the industry, the AWP is commonly known as “ain't what's paid”.

Given the fact that the future of the Medicare budget is extremely tenuous, Congress should embrace the opportunity to save money by negotiating a lower price for prescription drugs. Instead, Congress has fought every opportunity to do so. For instance, in 1997, the President proposed that physicians and suppliers be reimbursed their “acquisition cost” for drugs, not the fictitious AWP reported by the manufacturers. Congress rejected the proposal. Instead, Congress decided that Medicare payments be based on 95 percent of the AWP of a covered drug.⁷⁹ The law directed Medicare to pay the AWP, minus five percent, for drugs that were covered by Medicare or, if Medicare administrators determined that the price was inherently unreasonable, the statute authorized them to negotiate directly with the manufacturers for a lower price.⁸⁰

In 1998, Medicare administrators attempted to use their authority to lower what they considered excessive reimbursement for several drugs, finding that the reimbursed amounts were inherently unreasonable.⁸¹ Before any lower prices could be implemented, however, Congress suspended the use of “inherent unreasonableness” by enacting a law which required the General Accounting Office (“GAO”) to complete a study on the effects of using the “inherent unreasonableness” standard before Medicare administrators could use the standard.⁸² Indeed, Congress was so captivated by the pharmaceutical industry that it enacted legislation which prohibited the Medicare administrators from paying anything *less than* the AWP minus five percent.⁸³ In other words, even though providers do not pay a price anywhere near the manufacturers’ inflated reported AWP, Congress set a statutory floor on the Medicare price for medication which was substantially above a free market price.⁸⁴ The GAO subsequently issued its report, which found that the inherent unreasonableness reduction for some drugs was justified.⁸⁵

Thereafter, on September 8, 2000, the Health Care Financing Administration (“HCFA”), which administers the Medicare program, announced that it would

⁷⁹ 42 U.S.C. § 1395u(o)(1) (as added by § 4556 of the Balanced Budget Act of 1997); 42 C.F.R. § 405.517.

⁸⁰ See Pub. L. 105-33 (§ 4316 of the Balanced Budget Act of 1997).

⁸¹ Department of Health and Human Services Office of Inspector General, “Medicare Reimbursement of Prescription Drugs,” January, 2001, available at www.hhs.gov/oig/oei.

⁸² *Id.*

⁸³ *Id.*, see also Pub. L. 106-113 (§ 223 of the Balanced Budget Refinement Act of 1999.)

⁸⁴ *Id.*

⁸⁵ *Id.*

supplement the AWP data published by the Redbook, the Bluebook and Medispan with a price list that was compiled by the Department of Justice (“DOJ”) in its review of the pharmaceutical market.⁸⁶ The prices on the DOJ list were substantially lower than the AWP’s reported by the industry catalogs. For instance, the DOJ reported that the average acquisition price for Albuterol Sulfate was \$22, substantially less than the \$73 price reported in the Redbook.⁸⁷

In response to the HCFA announcement that it would utilize the DOJ data, on December 21, 2000, Congress enacted a law which placed a moratorium on any decrease in the payment for drugs and biologicals furnished after September 1, 2000.⁸⁸

Even though federal and state tax dollars are being utilized to pay artificially high prices for prescription drugs, Congress continues to refuse to address the problem. Indeed, in 2000, Congress rejected the President’s proposal that the Medicare reimbursement statute be changed to require reimbursement at AWP less 17 percent. Hearing testimony revealed that:

- The drug reimbursement schedule is a broken system because of the false reports that are filed with the government.
- The state Medicaid programs face a crisis because of this false reporting.
- Both Medicare and Medicaid patients are harmed because the inflated prices induce health care providers to make decisions to prescribe and dispense drugs on the basis of profit rather than the best interests of the patient.
- Medicare patients are defrauded because their 20 percent co-payment alone often exceeds 100 percent of the true cost of the drug.
- Americans are deprived of newer and safer drugs when drug companies inflate price reports of older drugs to encourage physicians to keep prescribing them.

⁸⁶ Department of Health and Human Services Health Care Financing Administration, “Program Memorandum Intermediaries/Carriers,” Transmittal AB-00-86, September 8, 2000.

⁸⁷ *Id.*

⁸⁸ Pub. L. 106-554.

- Government programs are deprived of the benefits of price competition and as a result there is no expansion of health care coverage under either Medicare or Medicaid due to the high cost being paid to the manufacturers.⁸⁹

In 2001, the Office of the Inspector General of the Department of Health and Human Services (“OIG”) issued a report regarding its study of Medicare reimbursement of 24 prescription drugs.⁹⁰ The OIG’s report noted that the Veterans Administration (“VA”) negotiates directly with manufacturers concerning the price of drugs administered to veterans. The report then compared the price paid by Medicare for these drugs with the price paid by the VA. The report concluded that Medicare would save \$1.6 billion a year if it had negotiated a price on these 24 drugs similar to that paid by the VA. Accordingly, the OIG recommended that Medicare administrators negotiate a price similar to that paid by the VA.

Because of the refusal of Congress to act on this issue, U. S. attorneys and state attorneys general have filed lawsuits against several pharmaceutical companies, charging them with fraud in the reporting of their AWP. Some of these suits have been resolved with stunning results. For instance, TAP Pharmaceutical Products, Inc. paid \$875 million in federal fines to settle charges of fraud in reporting false average wholesale prices of Lupron, a cancer drug.⁹¹ Similarly, Fresenius Medical Care paid the U.S. government \$385 million to settle a lawsuit charging the company with defrauding Medicare and Medicaid with respect to the AWP of intradialytic parenteral nutrition, a therapy for dialysis patients.⁹²

Congressional investigators estimate that the average wholesale pricing system results in overpayments by government insurers of at least \$800 million

⁸⁹ Testimony of Zachary Bentley, President Ven-A-Care, Inc., “Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers,” The Committee on Energy and Commerce, Subcommittee on Oversight Investigations, Subcommittee on Health, September 21, 2001.

⁹⁰ Department of Health and Human Services Office of the Inspector General, “Medicare Reimbursement of Prescription Drugs,” January 2001.

⁹¹ Caffrey, Andrew, Scott Hensly and Russell Gold, “Drug Raids: States Go to Court to Rein in Price of Medicare,” *Wall Street Journal*, May 21, 2002.

⁹² The False Claims Act Legal Center, <http://www.taf.org/press/columbiaHCA.html>.

annually, while patients, through their co-pays, are overcharged approximately \$200 million per year.⁹³

6.3 Market Protection Under Patent Laws

Under current patent laws, pharmaceutical manufacturers have exclusive marketing rights for twenty years from the date that a drug patent is filed, which is usually at the time of its discovery. Since prescription drugs are development-intensive, pharmaceutical companies claim that more than half of this patent life elapses during the research and development phase of the drug's life, before it is actually marketed to the public. Thus, the industry asserts that the useful period of market protection is effectively reduced to eight to ten years. Accordingly, in 1984, Congress enacted the Hatch-Waxman Act, which provides that drug companies, if they contest the patent status of a drug, are automatically granted a thirty month extension of exclusive marketing rights while the patent dispute is pending. In some cases, multiple extensions have been granted, keeping cheaper generic versions of a drug off the market for extended periods.⁹⁴

The current patent process is manipulated by pharmaceutical companies in a number of different ways. For instance, AstraZeneca introduced the product Nexium in 2001 as a replacement for Prilosec, which is used for some types of heartburn. Nexium represents a minor modification of Prilosec's molecular structure.⁹⁵ While AstraZeneca cannot scientifically demonstrate that Nexium is clinically superior to Prilosec, it has fought in court to prevent generic versions of Prilosec from entering the market. Although the drug's primary patent expired in October of 2001, AstraZeneca claimed that its unique method of coating the drug, covered by another patent, has not expired and, therefore, competition from generic manufacturers is prohibited.⁹⁶

Another tactic to manipulate the patent system was demonstrated by Aventis Pharmaceuticals Inc. (formerly known as Hoechst Marion Roussel, Inc.) and its affiliates (collectively "Aventis"). In January 1996, Aventis held the United States

⁹³ "Drug Price Cuts Likely in Next Year," *Knight Ridder Tribune Business News*, September 22, 2001.

⁹⁴ Common Cause, "Prescription for Power: How Brand-Name Drug Companies Prevailed over Consumers in Washington," June 12, 2001.

⁹⁵ Kaiser Family Foundation, "Federal Policies Affecting the Cost and Availability of New Pharmaceuticals," July 2002.

⁹⁶ *Id.*

patent on the popular and lucrative heart drug Cardizem CD,⁹⁷ but it knew that its rival Andrx Corporation (“Andrx”) had an application pending before the U.S. Food and Drug Administration to market a generic version of Cardizem CD.⁹⁸ Recognizing that FDA approval of Andrx’s application was imminent, Aventis filed a lawsuit alleging that Andrx’s generic product infringed Aventis’ Cardizem CD patents. In September 1997, the FDA granted preliminary approval of Andrx’s application. One week after the FDA approved Andrx’s application, Andrx and Aventis reached an agreement whereby Andrx would keep its generic version of Cardizem CD out of the marketplace in exchange for \$10 million for every three months that the generic was not available, plus a \$60 million bonus at the end of each year the generic was not available. Aventis ultimately made payments to Andrx totalling \$89 million under the agreement. Note the stunning result that the company allegedly harmed -- Aventis -- paid money to the company it was suing -- Andrx. The state attorneys general subsequently brought suit, and the case settled for \$80 million.

Similarly, Bristol-Myers Squibb owned the patent on Taxol, a top selling breast cancer drug. It manipulated the patent office process by claiming that it had new treatment protocols for the drug.⁹⁹ The claim was clearly a tactic designed to prevent competitors from entering the market with a generic version of Taxol until the year 2000.¹⁰⁰ During the period that the company was able to keep competition out of the market, it generated \$1.6 billion in annual sales of Taxol.¹⁰¹ When a generic version of Taxol entered the market in 2001, Bristol-Myers Squibb slashed the price of Taxol by 45 percent.¹⁰²

The manipulation of the patent process also occurs by simply changing one element of a product and then marketing the product under a new name. By claiming a new patent on a similar drug, the drug company is able to maintain marketing exclusivity under federal patent laws. Peter Jennings of ABC News

⁹⁷ Cardizem CD is a widely-prescribed cardiovascular drug used to treat hypertension (high blood pressure) and angina (chest pain).

⁹⁸ See, generally, Third Amended Complaint, In re: Cardizem CD Antitrust Litigation, Master File No. 99-MDL-1278. U.S. District Ct., Eastern District of Michigan, Southern Division.

⁹⁹ Federal Trade Commission, “FTC Charges Bristol-Myers Squibb with Pattern of Abusing Government Processes to Stifle Generic Drug Competition,” March 7, 2001 Press Release.

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *Id.*

interviewed Dr. Sharon Levine, a member of the Kaiser Permanente Medical Group, who described the process as follows:

If I am a manufacturer, and I can change one molecule and get another twenty years of patent life and convince physicians to prescribe and consumers to demand the next form of Prilosec or weekly Prozac, instead of daily Prozac, just as my patent expires, then why would I be spending money on a lot less certain endeavor, which is looking for brand new drugs?¹⁰³

Because of this patent manipulation, industry critics and some lawmakers have attempted to reform the current patent system and allow generics to come to the market faster, exposing the industry to free market competition and potentially saving consumers billions of dollars. In 2001, Senator John McCain and Senator Charles Schumer introduced the GAAP Act, which would have eliminated the thirty month patent extension process.¹⁰⁴ After heavy lobbying by the pharmaceutical industry, the proposal was defeated. During the lobbying fight, it was noted that the pharmaceutical manufacturers not only lobbied Congress but also applied heavy pressure to businesses that sought reform in an effort to lower their health premiums. At least one article notes that companies such as Eli Lilly directly pressured corporations to withdraw their support of such legislation.¹⁰⁵

The pharmaceutical industry's success in preventing change is attributed to the financial clout of the industry in the political arena. One Congressman, Sherrod Brown, expressed his frustration in a memo: "The PhRMA doesn't need a lobby. The industry is in the White House already."¹⁰⁶ The industry's influence is not restricted to the White House.¹⁰⁷ The chairman of the Senate Judiciary Committee, which conducts hearings on patent legislation,¹⁰⁸ received \$340,000

¹⁰³ ABC News Special Report with Peter Jennings, "Bitter Medicine: Pills Profit and the Public Health," May 29, 2003.

¹⁰⁴ Kaiser Family Foundation, "Federal Policies Affecting the Cost and Availability of New Pharmaceuticals," July 2002.

¹⁰⁵ "The Economy: Georgia Pacific Curbs Push to Speed Generic Drugs," *The Wall Street Journal*, September 4, 2002.

¹⁰⁶ Borger, Julian, "Industry that Stalks the U.S. Corridors of Power," *The Guardian*, February 13, 2001.

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

during the election cycle from the pharmaceutical industry, which also provided him a plane to fly around the country in his bid for president.¹⁰⁹

6.4 Medicare Coverage of Prescription Drugs

Senior citizens who lack coverage for prescription drugs bear the brunt of the rising costs of prescription drugs. Senior citizens have more medical problems and take more prescription drugs than other Americans. Older Americans spend almost three times as much of their income (21 percent) on health care than those under the age of 65 (8 percent).¹¹⁰ In 1995, an average Medicare beneficiary had more than 18 prescriptions filled.¹¹¹ One survey found that one-third of older Americans with serious health problems but no drug coverage reported skipping doses to make their prescriptions last longer.¹¹²

For the most part, Medicare does not cover drugs prescribed on an outpatient basis. According to the Kaiser Family Foundation, 27 percent of Medicare beneficiaries lack prescription drug coverage.¹¹³ As a result, over 30 million Medicare beneficiaries pay for private, supplemental insurance, while over 10 million seniors go without any prescription drug coverage at all. The current economic situation is expected to cause more people to lose prescription drug coverage, some because of personal economic hardship and others because of budget cuts by states that have curtailed government assistance programs. The impact of prescription drug costs is exacerbated by the inadequate coverage for prescription drugs that is available to senior citizens in the private market.¹¹⁴ The

¹⁰⁹ *Id.*

¹¹⁰ Prescription Drug Pricing in the United States: Drug Companies Profit at the Expense of Older Citizens. Minority Staff, Special Investigations Division, Committee on Government Reform, U.S. House of Representatives, at 1 (November 9, 1999).

¹¹¹ Prescription Drugs: Increasing Medicare Beneficiary Access and Related Implications, Statement of William Scanlon, Director, Health Financing and Public Health Issues, Health Education and Human Services Division, Before the Subcommittee on Health and Environment, Committee on Commerce, U.S. House of Representatives at 6 (February 16, 2000).

¹¹² Kaiser Family Foundation, "Medicare and Prescription Drugs," April, 2003.

¹¹³ Kaiser Family Foundation, "Prescription Drug Trends: A Chartbook Update," November, 2001.

¹¹⁴ "Seniors Beware: The Need for Medicare Prescription Drug Coverage, How Drug Pricing has Harmed Seniors in Debunking the Myths of Drug Makers," Prescription Drug Task Force, U. S. House of Representatives, 4-6 (October 28, 1999).

insurance that is available to seniors to supplement Medicare frequently provides limited and inadequate coverage for prescription drugs.¹¹⁵

Different purchasers pay different prices for prescription drugs. In some instances, these differences are dramatic. Drug manufacturers typically offer discounts, rebates and other preferences to favored purchasers such as Health Maintenance Organizations (“HMOs”), other health insurers, mail order pharmacies, hospital pharmacies, and Pharmacy Benefit Managers (“PBMs”). PBMs manage the prescription drug benefits for approximately 80 percent of persons with non-Medicaid coverage for prescription drugs.¹¹⁶ Because PBMs manage drug benefits for a large number of individuals, they can negotiate discounts and rebates on prescription drug purchases with drug manufacturers and retail pharmacies. These negotiations have a significant impact on the prices paid by insured customers for prescription drugs.

In contrast, senior citizens and other cash-paying customers pay the highest prices for their drugs. One study reported on a survey of retail prescription drug prices in over 1,000 chain and independently-owned drug stores in nearly 100 congressional districts in 38 states.¹¹⁷ The study concluded that, of the five drugs investigated in the study, cash customers paid an average of 134 percent more than HMOs and other entities receiving rebates.¹¹⁸ The report concluded that it was the pricing practices of drug manufacturers, and not mark-ups by retail pharmacies, that accounted for the inflated prices charged to older Americans.¹¹⁹

During the 1990s, Congress repeatedly rejected attempts by President Clinton to cover prescription drugs under Medicare. Today, there appears to be bipartisan support for some coverage of prescription drugs in the Medicare program. Indeed, the United States Senate and the House of Representatives

¹¹⁵ “Report to the President: Prescription Drug Coverage, Spending, Utilization, and Prices,” U.S. Department of Health and Human Services (April, 2000).

¹¹⁶ *Id.*

¹¹⁷ “Prescription Drug Pricing in the United States: Drug Companies Profit at the Expense of Older Americans,” Minority Staff, Special Investigations Division, Committee on Government Reform, U.S. House of Representatives (November 9, 1999).

¹¹⁸ *Id.*

¹¹⁹ *Id.*

passed different Medicare drug legislation this summer. The bills, S.1 and H.R.1, are currently in the Medicare Conference Committee.¹²⁰

Both bills provide a voluntary stand alone drug benefit under Medicare Part D. This benefit would be available to individuals enrolled in Part A or Part B. Under both bills, the plan would not become effective until 2006.¹²¹ The monthly premium under each plan would be approximately \$35.¹²² There are differences in the cost-sharing and stop-loss thresholds under the two bills. The Senate bill proposes an annual deductible of \$275 in 2006, 50 percent coverage up to the initial \$4,500 coverage limit, 100 percent coverage between this limit and the indexed “stop loss,” and 10 percent coverage above the stop-loss.¹²³ The House bill proposes an annual deductible of \$250, 80 percent coverage above the deductible up to a \$2,000 limit, 100 percent coverage between this limit and the indexed stop loss, and no coverage above the stop-loss.¹²⁴ Each bill also contains provisions for subsidizing the premiums and co-payments of low income beneficiaries.¹²⁵ Medicare would be the primary payer under the program.¹²⁶ The cost of the program under the Senate bill is estimated to be \$421 billion.¹²⁷ The House bill’s program is estimated to cost \$405 billion.¹²⁸

While there are differences between the House and Senate versions of the bill, they both shamelessly protect the financial interest of the pharmaceutical industry. For instance, the Conference Committee has agreed to Title VI of the Bill, relating to Medicare Part B, where Medicare reimbursement payments for drugs administered in an out-patient setting will not fall below 88 percent of the average wholesale price in 2004 and 83 percent in 2005.¹²⁹ As discussed in Section 6.2, the misrepresentation of the average wholesale price by drug companies results in grossly excessive payments by Medicare, Medicare

¹²⁰ A side-by-side summary of the key provisions of the two bills, known as the *Medicare Prescription Drug and Modernization Act of 2003*, is available at the Kaiser Family Foundation website, www.kff.org.

¹²¹ *Id.*

¹²² *Id.*

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ *Id.*

¹²⁶ *Id.*

¹²⁷ *Id.*

¹²⁸ *Id.*

¹²⁹ American Public Health Association, “Tentative Medicare Conference Agreements for Titles I - VII,” available at www.apha.org.

beneficiaries and state Medicaid programs. The provision agreed to by the conferees, which establishes a floor on the price to be paid for drugs, perpetuates the fraudulent schemes that have been contrived by the pharmaceutical industry.

As important, Congress appears to have rejected the concept that Medicare administrators should use their clout to negotiate lower drug prices for this country's 40 million Medicare beneficiaries. Rather than permitting the government to use its power to bulk purchase medications, the bills that the Conference Committee is currently considering would require that Medicare beneficiaries purchase pharmaceutical coverage from one of several private insurance plans. Requiring the purchase of drugs through a private insurance plan would seriously undercut the bargaining clout of 40 million Medicare beneficiaries by fragmenting the program among competing private insurers. The only clear beneficiaries of such a proposal, which is the primary reason for delaying passage of the bill, is the pharmaceutical industry.

Section Seven: Political Activity of the Pharmaceutical Industry

“Our mantra is this: we will never allow for failure whenever the political circumstances are at all manageable.”

Alan Holmer, President of PhRMA
2002 Annual Meeting

This year, the Minnesota Attorney General's Office surveyed the political activity of seventeen pharmaceutical companies and their industry organization, PhRMA, as reported to various government offices.

The 18 entities that were surveyed for political contributions included the following: PhRMA, Abbott Laboratories (“Abbott”), Amgen, Inc. (“Amgen”), AstraZeneca L.P. (“AstraZeneca”), Aventis Pharma A.G. (“Aventis”), Baxter International, Inc. (“Baxter”), Bayer Corporation (“Bayer”), Bristol-Myers Squibb (“Bristol-Myers Squibb”), Eli Lilly and Company (“Eli Lilly”), Genentech, Inc. (“Genentech”), GlaxoSmithKline (“GlaxoSmithKline”), Hoffmann-LaRoche, Inc. (“Hoffman-LaRoche”), Novartis Pharmaceutical Corporation (“Novartis”), Merck and Company, Inc. (“Merck”), Pfizer, Inc. (“Pfizer”), Pharmacia Corporation (“Pharmacia”), Schering-Plough (“Schering-Plough”), and Wyeth-Ayerst (“Wyeth”). These 18 entities represent some of the most profitable pharmaceutical companies in the world. Two of the companies, Amgen and Genentech, are primarily biotech companies. Additionally, Baxter primarily provides drug delivery systems, such as those used in connection with injection drugs. This

survey does not include all of the political activities of the 17 companies nor does it include any activity of other industry members.

7.1 Contributions Reported to the Federal Elections Commission

“In the last election cycle, the industry contributed \$26.5 million to candidates and parties. And PhRMA spent more than \$50 million on television advertisements. As significant as that spending was, it appears that the industry will repeat it this year.”

Tom Hamburger, “Drug Industry moves to Bolster Image Before Vote,” *Wall Street Journal*
September 16, 2002

The *Wall Street Journal* was too conservative in its figures. Indeed, PhRMA alone is expected to spend over \$150 million, a 23 percent increase over the previous year.¹³⁰ While this budget is larger than any other industry trade association, it does not include the hundreds of million in additional money spent by pharmaceutical companies, pharmaceutical PACs, or pharmaceutical backed stealth groups. For instance, the pharmaceutical industry made federal political contributions totaling \$27 million in the 2001-2002 election cycle.¹³¹ This represents an eight-fold increase over the \$3.2 million that the industry contributed 10 years earlier in the 1989-1990 election cycle.¹³² These contributions include \$17 million that is described as “soft” money contributions, \$3 million in individual contributions and \$7 million contributed through PACs.¹³³ The Center for Responsive Politics allocates 75 percent of these contributions to the Republican Party and its candidates and 24 percent to the Democratic Party and its candidates.¹³⁴ The largest increase in industry contributions over the past decade has come in the area of soft money contributions.¹³⁵

As a whole, the 18 entities spent at least \$ 12,476,444 on political contributions in the 2001-2002 election cycle that were reported to the Federal

¹³⁰Pear, Robert, “Drug Industry Group Raises Spending, Seeking Influence,” *New York Times*, June 1, 2003.

¹³¹ Center for Responsive Politics, “Pharmaceutical/Health Products: Long-Term Contribution Trends,” available at www.opensecrets.org.

¹³² *Id.*

¹³³ *Id.*

¹³⁴ *Id.*

¹³⁵ *Id.*

Elections Commission.¹³⁶ Using figures from the Center for Responsive Politics, this represents approximately 60 percent of all donations given by the pharmaceutical/health products industry during that election cycle. The largest contributor was PhRMA, which contributed over \$3 million during the election cycle, and two companies, Pfizer and Pharmacia, which contributed over \$1 million each.¹³⁷ These three entities reported contributions alone totaling \$5,637,856.¹³⁸

The Minnesota Attorney General’s Office surveyed the records of the Federal Elections Commission to determine the amount of political contributions made by the 18 pharmaceutical entities. The following chart summarizes this research and lists contributions reported by each company to the Federal Elections Commission:¹³⁹

Federal Elections Commission Reports: 2001-2002 Election Cycle

Company	Total Contributions	Largest Recipient	Aggregate Contributions to Largest Recipient
PhRMA	\$3,026,200	National Republican Congressional Campaign Committee	\$1,942,500
Abbott	\$335,100	National Republican Senatorial Campaign Committee	\$200,550
Amgen	\$430,700	2002 President’s Dinner	\$150,000
AstraZeneca	\$265,818	National Republican Congressional Campaign Committee	\$62,568

¹³⁶ Federal Elections Commission “FEC Individual Contributions,” 2001-2002, *see* www.fec.gov.

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ *Id.*

Company	Total Contributions	Largest Recipient	Aggregate Contributions to Largest Recipient
Aventis	\$732,150	National Republican Senatorial Campaign Committee	\$300,400
Baxter	\$251,150	RNC Republican National State Elections Committee	\$92,750
Bayer	\$395	National Republican Senatorial Campaign Committee	\$395
Bristol-Myers Squibb	\$1,245,317	National Republican Congressional Campaign Committee	\$405,700
Eli Lilly	\$877,604	National Republican Congressional Campaign Committee	\$275,850
Genentech	\$111,665	National Republican Senatorial Campaign Committee	\$50,665
GlaxoSmithKline	\$576,843	2002 President's Dinner	\$225,000
Hoffmann-LaRoche	\$350	RNC Republican National State Elections Committee	\$350
Merck	\$85,900	RNC Republican Governors' Association Conference	\$80,000
Novartis	\$614,070	National Republican Senatorial Campaign Committee	\$184,702
Pfizer	\$1,337,764	RNC Republican National State Elections Committee	\$393,564

Company	Total Contributions	Largest Recipient	Aggregate Contributions to Largest Recipient
Pharmacia	\$1,273,892	National Republican Senatorial Campaign Committee	\$518,592
Schering-Plough	\$400,004	National Republican Senatorial Campaign Committee	\$285,004
Wyeth	\$911,522	National Republican Senatorial Campaign Committee	\$327,500
TOTAL	\$12,476,144		\$5,499,440

In addition to the contributions reported by each of the companies with the Federal Elections Commission, each of the 18 entities also organized at least one PAC which operated during the 2001-2002 election cycle.¹⁴⁰ Several of the companies fielded multiple PACs. The Attorney General's Office surveyed the amounts reported by the companies for their PACs with the Federal Elections Commission.¹⁴¹ The research is summarized in the following chart:

Industry Political Action Committees: 2001-2002

Company	Political Action Committee	Total Political Contribution	Amount Contributed to Other Committees
Abbott	Abbott Lab. Employee PAC	\$429,451	\$356,250
Amgen	Amgen PAC	\$254,677	\$254,592

¹⁴⁰ Federal Elections Commission, "FEC Committee Summary Reports," 2001-2002, *see* www.fec.gov.

¹⁴¹ *Id.*

Company	Political Action Committee	Total Political Contribution	Amount Contributed to Other Committees
Astra Zeneca	Zeneca, Inc. PAC	\$189,650	\$129,800
Astra Zeneca	Syngenta PAC	\$45,338	\$37,000
Aventis	Aventis Pharma PAC`	\$135,839	\$119,000
Aventis	Aventis Pharma Product PAC	\$67,126	\$15,267
Aventis	Aventis Pasteur PAC	\$174,914	\$171,040
Baxter	Baxter PAC	\$193,554	\$192,563
Bayer	Bayer Crop Science PAC	\$43,714	\$36,000
Bayer	Bayer PAC	\$291,500	\$277,000
Bristol-Myers Squibb	Bristol-Myers Squibb PAC	\$49,115	\$6,500
Bristol-Myers Squibb	Bristol-Myers Squibb Employee PAC	\$366,543	\$338,525
Ely Lilly	Ely Lilly PAC	\$1,504,196	\$722,000
Genentech	Genentech PAC	\$184,750	\$175,750
GlaxoSmithKline	SmithKlineBeecham PAC	\$1,749,836	\$1,164,224
Hoffman-LaRoche	Hoffman-LaRoche PAC	\$154,040	\$125,300
Merck	Merck PAC	\$710,265	\$497,131
Novartis	Novartis PAC	\$244,002	\$200,057

Company	Political Action Committee	Total Political Contribution	Amount Contributed to Other Committees
Pfizer	Pfizer PAC	\$1,001,969	\$574,500
Pharmacia	Pharmacia Employee PAC	\$313,765	\$253,250
Pharmacia	Monsanto PAC	\$122,524	\$78,000
Schering-Plough	Schering-Plough PAC	\$334,332	\$78,083
Wyeth	Wyeth PAC	\$375,586	\$197,897
TOTAL		\$8,936,685	\$6,230,979

The PACs representing the 17 companies surveyed appear to have spent \$8,936,685 during the 2001-2002 election cycle. Most of these funds, or \$6,230,979, was spent on contributions to other political committees. As can be seen in Section 7.3, some of these other political committees constitute “Stealth PACs”, meaning committees whose names are intended to connote the political mission of a different constituency. Many of the drug industry “Stealth PACs,” by their names, convey the false impression that they advocate for senior citizens.

7.2 Federal Lobbying Activity

“PhRMA, this lobby, has a death grip on Congress.”

Congressman Richard Durbin, as quoted in
The New York Times, June 1, 2003

The number of pharmaceutical lobbyists in Washington, D.C. has surpassed the number of legislators on Capitol Hill. In June, 2003, *Public Citizen* concluded that the industry employed 675 lobbyists during that legislative session.¹⁴² *Public Citizen* also determined that the industry expended over \$477 million in lobbying

¹⁴² *Public Citizen*, “The Other Drug War 2003: Drug Companies Deploy an Army of 675 Lobbyists to Protect Profits,” June 2003.

the federal government from 1997-2001.¹⁴³ According to the records of the Federal Elections Commission, these lobbyists contributed, in addition to the contributions of the pharmaceutical companies, their PACs, and their Stealth PACs, over \$4 million for political activity during the 2001-2002 election cycle.¹⁴⁴

The Minnesota Attorney General’s Office also reviewed records filed with the United States Senate Office of Public Records Lobby Disclosure Program. The following chart summarizes that research:

Lobbyists Expenditures in Washington, D.C.

Company	Total Lobbyists Expenditures For 2001	Total Lobbyists Expenditures For 2002	Total Lobbyists Expenditures 2001-2002 Cycle
PhRMA	\$11,280,000	\$14,260,000	\$25,540,000
Abbott	\$2,980,000	\$2,600,000	\$5,580,000
Amgen	\$3,080,000	\$2,940,000	\$6,020,000
AstraZeneca	\$970,000	\$1,160,000	\$2,130,000
Aventis	\$3,360,000	\$3,460,000	\$6,820,000
Baxter	\$2,200,000	\$1,882,209	\$4,082,209
Bayer	\$1,418,125	\$1,276,767	\$2,694,892
Bristol-Myers Squibb	\$3,860,000	\$4,900,000	\$8,760,000
Ely Lilly	\$6,500,000	\$6,800,000	\$13,300,000
Genentech	\$700,000	\$1,460,000	\$2,160,000
GlaxoSmithKline	\$4,000,000	\$4,100,000	\$8,100,000
Hoffman-LaRoche	\$2,977,938	\$2,569,810	\$5,547,748

¹⁴³ *Id.*

¹⁴⁴ See www.fec.gov.

Company	Total Lobbyists Expenditures For 2001	Total Lobbyists Expenditures For 2002	Total Lobbyists Expenditures 2001-2002 Cycle
Merck	\$6,200,000	\$7,330,294	\$13,530,294
Novartis	\$2,600,000	\$1,720,000	\$4,320,000
Pfizer	\$3,570,000	\$3,600,000	\$7,170,000
Pharmacia	\$1,337,840	\$1,351,580	\$2,689,420
Schering-Plough	\$1,680,000	\$1,840,000	\$3,520,000
Wyeth	\$3,880,000	\$4,134,375	\$8,014,375
TOTAL	\$62,593,903	\$67,385,035	\$129,978,938

The 18 entities surveyed disclosed lobbyist expenditures totaling \$129,978,938 for the 2001-2002 election cycle. The two companies with the largest lobbyist expenditures were Eli Lilly and Merck, each of which spent over \$10 million on lobbying during the 2001-2002 election cycle. The industry association, PhRMA, leads the pack by spending over \$25 million during this period of time.

7.3 Stealth Interest Groups

“This is an industry that is not only spending more on direct lobbying than any other industry but also spending more on front groups and related entities than any other industry.”

Frank Clemente, *Public Citizen’s Congress Watch*

In addition to lobbying, PAC disbursements and direct political contributions, the pharmaceutical industry forms stealth groups to represent its interests to the public and policymakers. These groups or special interest organizations frequently use a trade name which confuses the source of the funds and the interest of the organizers. For instance, the pharmaceutical industry formed an organization called “Citizens for a Better Medicare” that spent an estimated \$65 million, mostly without disclosure, in opposing Al Gore’s proposal

for a Medicare prescription drug benefit.¹⁴⁵ This \$65 million was in addition to the money coming from PACs, direct pharmaceutical contributions, and lobbyists. This money was also used for individual candidates. For instance, the coalition spent \$800,000 in 2000 in support of Congressman Brian Bilbray of California.¹⁴⁶

Citizens for a Better Medicare was formed in 1999.¹⁴⁷ Timothy Ryan, the group's marketing director, was hired by Alan Holmer, the president of PhRMA.¹⁴⁸ Three of the members of the Citizens for a Better Medicare are the Seniors' Coalition, the 60 Plus Association and the United Seniors' Association.¹⁴⁹ All three of these organizations were formed by the same individual and, while claiming to represent senior citizens, report no contributions from them.¹⁵⁰ Rather, these organizations are financed directly by the pharmaceutical industry.¹⁵¹ These organizations have been criticized as utilizing scare tactics to stop reform of the pharmaceutical industry.¹⁵² The Citizens for a Better Medicare was originally created as a I.R.C. § 527 political organization.¹⁵³ After the law was changed to require disclosure of contributors to § 527 organizations, the coalition changed its status to a 501(c)(4) social welfare organization, which does not have to disclose its contributors.¹⁵⁴

Other critics of Citizens for a Better Medicare include *Public Citizen*, which in 2002 estimated that the United Seniors' Association would spend \$17.6 million during the 2002 election cycle on prescription drug "sham issue ads" and "Internet/Direct Mail Activities."¹⁵⁵ As noted above, this is in addition to the

¹⁴⁵ Jackson, Brooks, "Study Shows Massive Soft Money Expenditures," CNN Network, February 5, 2001.

¹⁴⁶ The Campaign Finance Institute, "*Issue Ads: Recommendations for a New Approach*," available at www.cfinst.org.

¹⁴⁷ *Id.*

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

¹⁵¹ Hogan, Bill, "Pulling Strings From Afar," American Association of Retired Citizens, February, 2003.

¹⁵² The Campaign Finance Institute, "*Issue Ads: Recommendations For a New Approach*," available at www.cfinst.org.

¹⁵³ *Id.*

¹⁵⁴ *Id.*

¹⁵⁵ *Public Citizen*, "United Seniors Association: Hired Guns for PhRMA and Other Corporate Interests," October, 2002, www.citizen.org.

\$65 million expended by Citizens for a Better Medicare in the 2000 election year.¹⁵⁶

In addition to their use of television advertisements and newsletters, these stealth groups also undertake telemarketing campaigns. For instance, the 60 Plus Association hired Bonner and Associates to make telemarketing calls across the country to urge citizens to oppose pharmaceutical reform legislation.¹⁵⁷ Not by coincidence, one of Bonner's other clients is PhRMA.¹⁵⁸ The telemarketer told consumers that the calls were on behalf of "The Consumer Alliance."¹⁵⁹ The Consumer Alliance was, in fact, an organization with one employee whose office was located within Bonner and Associates.¹⁶⁰

These stealth groups also shape public opinion by writing opinion editorials in newspapers, journals and on their own web sites. For instance, the 60 Plus Association President, Jim Martin, wrote a commentary for the Knight Ridder/Tribune syndicate, blaming HMOs for high medical costs and less coverage and asserting that there were inherent dangers in generic prescription medicines.¹⁶¹ Mr. Martin also opposed cost cutting measures such as shifting coverage to generic versions of drugs. Other efforts by Mr. Martin include an open letter to the United States Senate, dated July 22, 2002, which supported the industry's call to protect patent rights and reject reimportation legislation.¹⁶² According to Mr. Martin and his 60 Plus Association, if Congress should alter the Hatch-Waxman Act, "[w]e would in effect be putting locks on the doors and shutting off the lights in our research laboratories throughout our country."¹⁶³

The United Seniors' Association also participated, along with HHS Secretary Thompson, in a Better Medicare Benefits press conference which then submitted a memo to Congress advocating a privatized Medicare prescription drug benefit favored by the industry. It also strongly opposed a universal Medicare

¹⁵⁶ *Id.*

¹⁵⁷ Center for Policy Alternatives: "Drug Companies Employ Astroturf Lobbying," available at www.cfpa.org.

¹⁵⁸ *Id.*

¹⁵⁹ *Id.*

¹⁶⁰ *Id.*

¹⁶¹ Martin, James, "HMOs Give Less and Take More," *Knight Ridder/Tribune Information Services*.

¹⁶² Martin, James, "An Open Letter to the United States Senate," The 60 Plus Association, July 22, 2002.

¹⁶³ *Id.*

prescription drug benefit.¹⁶⁴ In the 2002 election, more than \$8 million in advertisements was committed by United Seniors to promote two dozen House candidates favoring industry-backed legislation.¹⁶⁵ Another \$4 million was spent on one Internet ad direct mail campaign by the group. Most of the cost was supported by a “unrestricted educational grant” from PhRMA.¹⁶⁶

Similarly, the United Seniors’ Association President, Charles Jarvis, co-wrote a news article on June 27, 2003 entitled, *The Myths of the Canadian Health Care*, which opposed current importation efforts.¹⁶⁷

Of course, each of these organizations also engages in lobbying. For instance, the United Seniors’ Association expended \$297,838 for lobbying in 2001 and \$297,838 in 2002.¹⁶⁸ In the meantime, the 60 Plus Association declared lobbying expenses of \$1,107,000 for 2001 and \$11,440,000 for 2002.¹⁶⁹ Not to be outdone, the Seniors’ Coalition declared lobbying expenditures of \$4,382,606 for 2001 and \$9,459,355 for 2002.¹⁷⁰

The pharmaceutical industry also has other trade associations which engage in lobbying activities. These associations, while not as surreptitious as the stealth interest groups identified above, give additional “spin” to the industry. These groups include BIO, which represents the biotechnology industry and which shares an agenda with the pharmaceutical industry concerning price controls, patent protection and other issues. BIO declared lobbyists expenditures of \$3,506,000 in 2001 and \$3,540,000 for 2002.¹⁷¹ At the same time, GphA, the biotechnology industry’s equivalent of PhRMA, spent \$480,000 in lobbying expenses for 2001 and \$360,000 for 2002.¹⁷²

¹⁶⁴Jarvis, Charles W., “Seniors Want Choices, Not-One-Size-Fits-All,” United Seniors’ Association Press Release, July 2, 2003.

¹⁶⁵*Public Citizen*, “United Seniors Association: Hired Gun for PhRMA and other Corporate Interests,” July, 2002.

¹⁶⁶ *Id.*

¹⁶⁷Jarvis, Charles W., and Merrill Mathews, Ph.D., “The Myths of Canadian Health Care,” United Seniors’ Association, June 27, 2003.

¹⁶⁸Secretary of the Senate, Office of Public Records, Lobby Filing Disclosure Program, available at <http://sopr.senate.gov>.

¹⁶⁹ *Id.*

¹⁷⁰ *Id.*

¹⁷¹ *Id.*

¹⁷² *Id.*

In total, the above special interest groups disclosed lobbyist expenditures of at least \$34,870,637 for the 2001-2002 election cycle.¹⁷³ The big spender of this group was the Seniors' Coalition, which spent over \$13.8 million on lobbying during this period.¹⁷⁴

7.4 Federal Political Profiles of Eighteen Pharmaceutical Entities

The chart attached as Exhibit A consolidates a variety of information about the 18 pharmaceutical entities that were surveyed in this report. The purpose of the chart is to review the overall political impact of each entity and compare the political impact with its business operation. The financial information and lobbyist activity only refers to federal activity. A subsequent section will refer to the massive political clout of the industry at the state level. The information contained in the following chart was obtained from the Federal Elections Commission, the United States Senate Office of Public Records Lobby Disclosure Program, Hoovers.com, the Center for Responsive Politics, and the annual reports of the 17 companies surveyed.

Section Eight: State Political Activities: Minnesota

8.1 General

According to PhRMA's budget documents for 2003, the trade association will spend \$48.7 million for state lobbying.¹⁷⁵

Minnesota law prohibits corporations from making donations to political candidates or parties.¹⁷⁶ In spite of this prohibition, during the 2001-2002 election cycle, the pharmaceutical industry made \$1.6 million in contributions to one national political organization, which in turn contributed \$2.6 million to its Minnesota affiliate.¹⁷⁷

¹⁷³ *Id.*

¹⁷⁴ *Id.*

¹⁷⁵ Pear, Robert, "Drug Industry Group Raises Spending, Seeking Influence," *New York Times*, June 1, 2003.

¹⁷⁶ Minn. Stat. § 211B.15 (2002),

¹⁷⁷ Federal Elections Commission, "FEC Individual Contributions" and RNSEC Report, 2001-2002, available at www.fec.gov.

In addition to the above corporate contributions, the pharmaceutical industry makes its presence known in Minnesota through the retention of lobbyists and by contributions through these lobbyists. There are at least 38 different lobbyists representing the 18 entities in Minnesota. They include:

Company	Lobbyists
Abbott	Phillip Griffin
TAP Pharmaceuticals	Tracy Hiatt
Amgen	N/A
AstraZeneca	John Benske
Aventis	Julie Vojtech
Aventis Pasteur	James Genia, H. Theodore Grindal and Nora Stewart
Baxter	Corey Bennett, Thomas Keliher, and William Strusinski
Bayer	Craig Mischo and Randolph Morris
Bristol-Myers Squibb	Jennifer Breitinger and Michael VanDeVeer
Eli Lilly	Denise Gill, Cort Holten, Susan Landwehr, Kristine Poppie, Alan Shofe and Nancy Silesky
Genentech	N/A
GlaxoSmithKline	Mary Koenecke
Hoffman-LaRoche	N/A

Company	Lobbyists
Merck	Douglas Carnival, William McGrann, Randolph Morris, Sarah Psick, and James Vance
Novartis	Ronald Graham
Pfizer	John Choi and Thomas Schmidt
Pharmacia	Kelly Marshall
Schering-Plough	Vaun Olhausen
Wyeth	Robert Hentges, Nancy Hylden and Dennis Majeskie
PhRMA	Cristine Almeida, Linda Carroll Shern, Jean Cottington, Steve Knuth, and Robert Vanasek

According to the National Institute for Money in State Politics,¹⁷⁸ employees connected to the pharmaceutical/health products industry donated \$61,065 to Minnesota political campaigns in the 2001-2002 election cycle.¹⁷⁹ Individuals who are otherwise associated with the 18 entities also made political contributions to Minnesota candidates in the amount of \$53,700 in the 2001-2002 election cycle. In addition, the 18 entities surveyed in this report retained 38 registered lobbyists in Minnesota in 2002, incurring lobbying fees of \$476,886 for the year.¹⁸⁰ Further, the Minnesota lobbyists, their employees and their families made several hundred thousand dollars in contributions to Minnesota candidates.

¹⁷⁸ See www.followthemoney.org, National Institute on Money in State Politics.

¹⁷⁹ *Id.*

¹⁸⁰ Minnesota Campaign Finance Board's Report of Lobbyist Principal Expenditures in 2002.

8.2 Minnesota Legislation Proposed in 2003

There were at least three legislative proposals in the 2003 legislative session which would have affected prescription drug pricing in Minnesota.

One bill was known as the Drug Price Disclose and Certification Act (S.F.1053; H.F. 0701). As discussed in Section 6.2, under the Medicare and Medicaid programs, payment for certain drugs is based on a formula that utilizes the “average wholesale price” paid by medical providers to wholesalers. These government programs rely upon each pharmaceutical company to report its AWP for each drug. Rather than calculating the true price charged for medications, however, many manufacturers report a grossly excessive price for prescription drugs, resulting in billions of dollars being wasted in the Medicare and Medicaid system. Because of the flagrant violation of law by many pharmaceutical companies, a variety of states have debated legislation which would require that drug manufacturers report and certify their true average wholesale prices, and various other prices, to Medicaid programs. The State of Texas is the only state that has enacted this type of legislation.

The Minnesota legislation would have required drug manufacturers to certify the accuracy of their reported prices similar to the requirement that CEOs certify the accuracy of their financial statements to the Securities Exchange Commission. Although the bill only required the disclosure of truthful pricing information and did not make any attempt to modify or control drug prices, it was never even scheduled for a hearing in the House of Representatives. The bill passed the Senate Health and Family Security Committee and was then referred to the Senate Commerce Committee, where it did not receive a hearing.

The second bill affecting drug pricing was the Minnesota Fair Drug Pricing Act (H.F. 5; S.F. 535). While the Medicaid program, relying upon fraudulent AWP's provided by pharmaceutical companies, often pays more than appropriate for prescription drugs, it still pays less than the individual citizen who walks into a pharmacy and, without the benefit of negotiation, pays the highest price listed for a drug. This bill would have required pharmacies to offer discounts to Minnesotans who do not have prescription drug insurance, and the discount had to be the same as that offered to the Medicaid program. Because price discounts in the pharmaceutical industry are generally funded by supplemental rebates paid by drug manufacturers, the bill proposed that pharmacists implement the discount at the point of sale to the consumer and then be reimbursed by the state from the drug manufacturers' rebate payments. The bill would not have cost the state any money

other than that required to simply administer the payment of the rebates from the pharmaceutical company to the pharmacists. It is anticipated that the bill would have saved Minnesotans approximately 17 percent of the cost of prescription drugs. Minnesota's bill is similar to one enacted by the State of Maine and the State of Vermont. PhRMA challenged the Maine bill. While a federal court enjoined implementation of the bill, the U.S. Supreme Court reversed and threw out the injunction.

While the Fair Drug Pricing Act was enacted during the 2003 legislative session, its provisions were gutted. Rather than allowing any Minnesotan the opportunity to utilize the discount received by Medicaid, the legislature limited eligibility under the program to those individuals with income less than 250 percent of the federal poverty guideline. Because Medical Assistance already provides a drug benefit to many low income individuals, the House income limitation dramatically reduced the number of Minnesotans who would benefit from the bill. Further, the bill originally delegated authority to the attorney general to enforce its provisions if a pharmaceutical company refused to cooperate. Under the bill that was enacted, there is no enforcement provision and it is unclear if the law could be enforced by anyone. In addition, the effective date of the bill was delayed until 2005. Finally, the bill was rendered meaningless by a amendment in the House of Representatives which states that the statute expires upon the effective date of an expanded prescription drug benefit under Medicare. Because a new Medicare prescription drug benefit is likely to be enacted this year in Congress, the Fair Drug Pricing Act will likely never become effective. This is extraordinarily unfortunate, since the beneficiaries of the Fair Drug Pricing Act were not just senior citizens, but all Minnesotans who do not have insurance coverage or have limited insurance coverage.

As a result of the enactment of the Fair Drug Pricing Act, the pharmaceutical industry succeeded in allowing politicians to take credit for passing a drug pricing bill that, in fact, will not become effective, and even if it does, will have minimal impact.

Finally, a bill entitled the Minnesota False Claims Act (H.F. 1032, S.F. 1121) was introduced. While Minnesota has some criminal statutes relating to false claims filed with the government, it does not have a civil false claims act. The federal government and almost 20 other states have such acts, which have been effectively used to combat fraud on the government. The legislation introduced in the 2003 session was modeled after the federal False Claims Act and would have enabled the state to bring civil claims, and collect treble damages,

against those who submit false information to the government, including false prescription drug prices used to determine Medicaid reimbursements. The law also would have authorized the State to sue those who knowingly make false statements in order to avoid liability to the State including, for example, false representations by drug companies to avoid or minimize their liability under the state Medicaid rebate program.

The bill was eventually defeated in the House Judiciary Policy and Finance Committee. There was an attempt on the House floor to add the Minnesota False Claims Act as an amendment to the House Judiciary Policy and Finance Committee Omnibus Bill. The motion to amend the bill, however, was defeated.

According to AARP, the 60 Plus Association used money from Pfizer Inc., to hire Bonner and Associates, a Washington, D.C. based firm, to engage in “Astroturf lobbying” to stop legislation in Minnesota and New Mexico.¹⁸¹ Astroturf lobbying is so named because it is an artificial version of grass roots lobbying -- where telemarketers call officials and represent themselves to be members of the 60 Plus Association.

Section Nine: Conclusion

The United States Supreme Court has stated that regulation of campaign finances is necessary to prevent corruption and the appearance of corruption. *Buckley v. Valeo*, 424 U.S. 1, 25-26 (1976). The Supreme Court did not restrict the definition of corruption to bribery, “corruption being understood not only as *quid pro quo* arrangements, but also as undue influence on an office holder’s judgment, and the appearance of such influence.” *FEC v. Colorado Republican Federal Campaign Committee*, 533 U.S. 431, 441 (2001). The Supreme Court has further stated:

In speaking of “improper influence” and “opportunities for abuse” in addition to “*quid pro quo* arrangements,” we recognized a concern not confined to bribery of public officials, but extending to the broader threat from politicians too compliant with the wishes of large contributors.

Nixon v. Shrink, 525 U.S. 377, 389 (2000).

¹⁸¹ Hogan, Bill, “Pulling Strings from Afar,” American Association of Retired Persons, February, 2003, www.aarp.org.

Prescription medications, indeed health care in general, are a necessity. Other nations recognize that prescription medicine is on par with products provided by regulated utilities such as water and electricity. Accordingly, they regulate the product in order to protect against the abuses which can occur when a product or service required by the public goes unchecked.

In contrast, lawmakers in the United States, under the guise of promoting the research and development of new medications, have enacted laws and regulations which encourage higher prices for prescription medication and which protect manufacturers of the product. This is tragic.

Even though millions of Americans are forced to go without lifesaving medication, and even though millions of others now cross the borders to Canada and Mexico to purchase affordable medication, lawmakers enact laws which artificially inflate the price of medication. These laws include a prohibition on the reimportation of drugs manufactured in the United States (but not drugs manufactured in other countries), a floor on the price paid by Medicare and Medicaid for medication, an extension of monopolistic patents to keep out competition from generic competitors, and rejection of laws to allow states to negotiate prices on behalf of their citizens.

These laws, in stark contrast to the promises of lawmakers during election campaigns, are clearly driven by the mammoth political clout of the pharmaceutical industry. The enormous campaign contributions, lobbyist expenditures, and the use of surreptitious “Stealth PACs” contribute to the dominance of the industry over compliant lawmakers. The massive political clout of the pharmaceutical industry, which has resulted in our perverse legislation, certainly constitutes “undue influence” as defined by the United States Supreme Court.

Reform will come, but only when public commentators -- and particularly the media -- bring focus to such undue influence. Only when lawmakers face public shame will they muster the integrity to not only campaign for reform but to actually follow through and implement it.