



Alliance
for Retired
Americans®

EDUCATIONAL FUND

Outrageous Fortune

How the Drug Industry Profits from Pills

*A Report by the
Alliance for Retired Americans
Educational Fund*

August 2007

THIS NOTE
FOR ALL DEB



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About the Alliance for Retired Americans Educational Fund

This report is a publication of the Alliance for Retired Americans Educational Funds (ARAEF), the research and educational branch of the Alliance for Retired Americans. The ARAEF is a 501 (c) (3) organization that focuses primarily on retiree issues in three program areas: Research and development of written materials on public policy issues; building grassroots; and coalition activities.

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About the Alliance for Retired Americans

The Alliance for Retired Americans is a grassroots organization representing more than 3 million retirees and seniors nationwide. Headquartered in Washington, D.C. the Alliance's mission is to advance public policy that protects the health and economic security of older Americans by teaching seniors how to make a difference through activism.

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Summary

Drug interventions may forestall the hospitalization of many other older persons and help them to maintain lives outside of institutions. Consequently, the role prescription drugs play in the lives of older persons, in particular, has become much greater. However, although drugs have contributed to reducing costs associated with hospitalizations and surgeries, new drugs are more expensive than older drugs, and three times more costly than generic drugs.

The volume and expenditure for drugs sold has increased dramatically in recent years. Between 1994 and 2005, the number of prescription drugs purchased has increased 71 percent— from 2.1 billion to 3.6 billion—compared to a U.S. population growth of 9 percent. The U.S. Department of Health and Human Services projects national prescription drug spending will increase 148 percent from 2005-2016.

MORE PROBLEMS OR MORE SOLUTIONS?

Spending for prescription drugs was \$200.7 billion in 2005, five times the \$40.3 billion spent in 1990.

Despite the claims of supporters of the 2003 Medicare Modernization Act (MMA), the new drug benefit provided by private insurers has not reduced prescription drug prices for Medicare beneficiaries or the program. Overall, it is projected that Medicare beneficiaries will spend \$1.2 trillion on prescription drugs over the next decade. Since the MMA took effect, Medicare is now the largest public payer of prescription drugs with Medicare spending rising to 22 percent of total U.S. prescription spending in 2006, up from 2 percent in 2005.

It is extremely difficult to identify the actual cost of a drug because the pricing chains are complex. Variations in the price take place because of the power the drug companies

have in their market. Drug manufacturers charge different customers different prices for the same drug as large purchasers can obtain discounts and rebates. At the bottom of the pricing chain, it is the individual consumer without insurance coverage who pays the highest prices for prescription drugs.

The pharmaceutical industry claims that the high prices of new drugs are necessary to fund ongoing research and development (R&D) maintaining that it costs \$800 million to develop a new drug. However, an independent estimate places the R&D costs for a new drug at half the industry's claim. Most core research for drugs is actually funded by the federal government, primarily through the National Institutes of Health and universities. Moreover, much of the drug manufacturers' development of drugs is not for new drugs but rather copies of existing drugs.

Drug manufacturers also claim that drug prices must be higher in the United States because price controls in other developed countries do not pay sufficiently for R&D costs. Yet, European countries develop many innovative new drugs in the world market accounting for 36 percent of total R&D spending, 32 percent of new molecular entities, and 28 percent of world sales.

Pharmaceutical companies benefit from many tax deductions, tax credits and tax havens. Many enjoy greater profits as a percent of revenue than companies in other industries, even beating the three top-ranked companies in the Fortune 500 list. In 2005, the seven pharmaceutical companies with the highest revenues spent more of their revenues on profits than research and development—and even more on marketing. More than seventeen percent of their revenues were dedicated to profits, compared with 13.9 percent spent on R&D and 32 percent on marketing, advertising and administration.

A significant amount of prescription drug money goes straight to the chief executive officers (CEOs) of drug companies with most of them receiving total compensation packages of millions of dollars.

Drug manufacturers promote the use of new or altered drugs primarily through contacts with physicians and direct-to-consumer advertising (DTCA). The pharmaceutical industry employs 100,000 drug representatives or 2.5 for every practicing doctor in the country. Marketing directed toward doctors in 2005 amounted to \$7.2 billion and often includes meals and gifts. This does not include the retail value of samples left at doctors' offices, which totaled \$16 billion. Since 1997, DCTA has become a more significant part of marketing amounting to \$4.8 billion in 2006, a 13 percent increase over 2005 and five times the amount spent in 1996. Drug companies also spend millions in contributions to political candidates and to lobby Congress and state legislators.

Today, generics represent 63% of the total prescriptions dispensed in the United States, but less than 20% of all dollars spent on prescription drugs indicating how far less costly generic drugs are. Generic drugs are able to enter the market only after the brand-name company's patent expires. However, generic entry can be delayed when patents are extended by various means, including settlements with generic companies.

Ultimately, the best and most comprehensive approach to providing affordable prescription drugs for all the American people is to create a high quality, affordable, universal health care system, which provides comprehensive services and is based on a sound financing model similar to Medicare.

Introduction

Toward the end of the 20th century, changes were made in the way hospitals were compensated that prompted them to reduce the length of stay of patients. This “quicker and sicker” discharge from hospitals led physicians to increasingly rely on prescription drugs for treating patients. There is no doubt the introduction of many new drugs has extended and enhanced the quality of everyday life for millions of Americans. Technological advances in treating diseases include the utilization of new drugs that can arrest or cure many cancers, heart disease, high blood pressure, AIDS and other life-threatening conditions.

Drug interventions forestall the hospitalization of many other older persons and help them to maintain lives outside of institutions. Consequently, the role prescription drugs play in the lives of older persons, in particular, has become much greater. However, although drugs have contributed to reducing costs associated with hospitalizations and surgeries, new drugs are more expensive than older drugs, and three times more costly than generic drugs.

In May 2001, the Alliance for Retired Americans released its inaugural report, *The Profit in Pills: A Primer on Prescription Drug Prices*, to make the public aware of how price gouging by the pharmaceutical industry is allowing industry profits to soar at the expense of every American and every U.S. company providing health benefits. Since then, a number of books, news articles and other reports have exposed the extent and means by which the pharmaceutical industry protects its hold on high drug prices and profits.¹

This report revisits the pharmaceutical world to show that there have not been any improvements to prescription drug access nor lowering of drug costs. Rather, the pharmaceutical industry continues to exert wide-ranging influence in various areas to protect its profits and forestall attempts to lower prices. The launch of a flawed Medicare

prescription drug benefit in 2006 has been a particular windfall for drug manufacturers with expanded prescription drug sales but without an accompanying reduction in prices for beneficiaries.

Trends in the Price of Prescription Drugs

- Expenditures for prescription drugs was \$200.7 billion in 2005, five times the \$40.3 billion spent in 1990.²
- The U.S. Department of Health and Human Services projects national prescription drug spending will increase 148 percent from 2005-2016.³
- Eighty-nine percent of new drugs in the U.S. offer little or no additional benefit over existing drugs, yet U.S. drug prices are the highest in the world.⁴
- In 2006, the first year of the Medicare prescription drug benefit, U.S. medication sales increased by \$2.5 billion with the Medicare benefit accounting for one-sixth of the total increase in sales.⁵
- There are hidden prices, discounts and rebates for different purchasers. The pricing chain for drugs is complex and difficult to trace because the drug industry considers much of the information proprietary and hence is not publicly available.

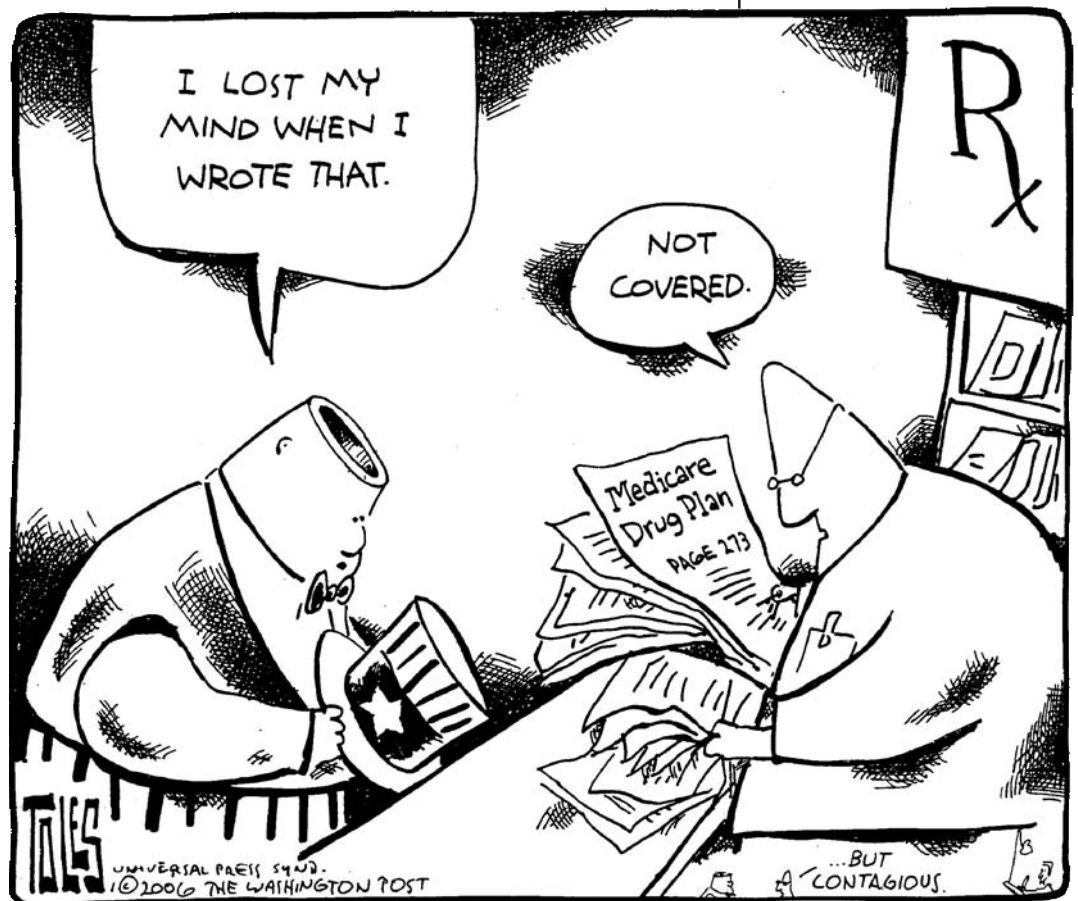
Why Are Drug Prices Continuing to Escalate?

The spending increases for prescription drugs are attributed largely to: utilization increases; higher prices for new expensive drugs for treating diseases; and changes in the types of drugs used.

The volume of drugs sold has increased dramatically in recent years. Between 1994 and 2005, the number of prescription drugs purchased has increased 71 percent— from 2.1 billion to 3.6 billion—compared to a U.S. population growth of 9 percent. Fifty-nine percent of the U.S. population under age 65 had a drug expense in 2004; for those over age 65, 92 percent had a drug expense.⁶

Although they do not comprise a significant portion of drug patents, new molecular entities (NME) entering the market generally are considerably higher-priced than older drugs. Biotechnology drugs in particular are very expensive, costing thousands of dollars a year.

Theoretically, as patent protection on a brand-name drug runs out and generic drugs enter the market, the amount spent on drugs should be reduced. In 2006, the average generic price was one-third the cost of the average brand name prescription price.⁷ However, many drug manufacturers circumvent the introduction of generics by altering dosages or shapes of their drugs for the sole purpose of obtaining another patent on essentially the same drug and charging higher prices.



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Unrealized Savings from the Medicare Part D Drug Benefit

The 2003 Medicare Prescription Drug, Improvement and Modernization Act (MMA) created a prescription drug benefit, known as Medicare Part D, which took effect January 1, 2006. The benefit is provided through stand-alone drug plans or Medicare Advantage managed care plans and is administered by private insurers and not the Medicare program. Beneficiaries who choose a stand-alone drug plan continue to receive their other Medicare benefits under Parts A and B through the traditional Medicare program. Beneficiaries enrolled in a Medicare Advantage plan with prescription drug coverage receive their other Medicare benefits through that plan.

Since the drug benefit is offered by private plans, the formulary or covered drugs, premiums, co-payments, and pharmacy network may vary substantially and change from year to year.

Under the provisions of the MMA, six million “dual eligibles,” those with both Medicare and Medicaid coverage, were transferred to Medicare for their prescription drug needs. The dual eligibles accounted for 14 percent of Medicaid beneficiaries and about 45 percent of Medicaid prescription drug spending in fiscal year 2003.⁸

Despite the claims of MMA supporters, the benefit has not reduced prescription drug prices for Medicare beneficiaries or the program. In contrast to most health insurance coverage plans, Part D has a “doughnut hole” or gap in coverage when the beneficiary pays all drug costs. In 2007, the hole spans \$2,400 to \$5,451 in drug costs. At the same time, the beneficiary continues to pay monthly premiums.

According to one calculation, out-of-pocket prescription drug costs for a couple retiring at age 65 in 2007 will account for 33 percent of their health care spending.⁹ Overall,

it is projected that Medicare beneficiaries will spend \$1.2 trillion on prescription drugs over the next decade.¹⁰ Yet, the drug benefit increased profits by over \$8 billion for drug companies in the first six months alone after the benefit plan started in 2006.¹¹ Since the MMA took effect, Medicare is now the largest public payer of prescription drugs with Medicare spending rising to 22 percent of total U.S. prescription spending in 2006, up from 2 percent in 2005.¹²

A number of studies show that drug prices under the Medicare Part D benefit cost far more than is necessary. In a comparison with the top 20 drugs prescribed for Medicare beneficiaries in Part D plans, the Veterans Administration's prices are substantially lower by a median difference of 58 percent.¹³ Investigators for a Congressional oversight committee found that prices for 10 of the most prescribed brand-name drugs used by Medicare beneficiaries have gone up an average of 6.8 percent between December 2006 and May 2007 alone while wholesale prices for the same drugs went up just 3 percent.¹⁴

THE REAL COST OF MEDICARE MODERNIZATION

Since the MMA took effect, Medicare is now the largest public payer of prescription drugs with Medicare spending rising to 22 percent of total U.S. prescription spending in 2006, up from 2 percent in 2005.

The MMA expressly blocks the federal government from saving on prescription drug costs. The Act prohibits the Medicare program from negotiating with pharmaceutical companies for lower prices for Medicare's 43 million beneficiaries. Instead, the insurers providing the Part D plans negotiate with drug manufacturers to cover their drugs in return for rebates on prices. However, the rebates that the insurers were expected to obtain from drug makers in 2007 is only 4.6 percent of total drug costs, down from 5.2 percent in 2006, and less than the 6 percent Medicare actuaries had predicted for 2007.¹⁵ That reduction in

anticipated rebates will cost beneficiaries and the American taxpayers \$17 billion in unanticipated costs, with all of that flowing to drug makers.¹⁶ In addition, the MMA does not allow importation of lower-priced drugs by pharmacies and drug wholesalers from Canada and other advanced countries. The Congressional Budget Office says that allowing for importation of drugs will save \$50 billion over the next decade, of which \$10 billion would be savings to the federal budget.¹⁷

ALLIANCE PRINCIPLES FOR A MEDICARE PRESCRIPTION DRUG BENEFIT

The Alliance for Retired Americans opposed passage of MMA. One reason for our opposition was that the law does nothing to control the escalating increases in drug prices and expressly prohibits Medicare from using its buying power to negotiate lower drug costs.

The Alliance believes that the Medicare Part D prescription drug program should be overhauled. Older Americans should have a genuine drug benefit in the Medicare program, which follows these guiding principles:

- Comprehensive benefits available to all Medicare beneficiaries; no gap in coverage; voluntary enrollment; affordable premiums; and low co-payments;
- No means testing of benefits; and
- Strong, enforceable provisions to bring down the costs of prescription drugs.

The Alliance supports legislation that addresses these principles, including measures that would lower prescription drug costs for all Americans such as allowing the importation of drugs with appropriate safeguards.

The Alliance also supports legislation that requires the federal government to negotiate lower drug prices on behalf of Medicare beneficiaries, expands availability of generic drugs, prevents agreements between brand and generic companies to keep generics off the market, and promotes the availability of the states to use the power of bulk purchasing in order to reduce costs.

Punitive features of Part D, such as the asset test for low-income recipients to receive help should be eliminated. The late enrollment penalty should also be eliminated until the problems with Part D are fixed.

The Pricing Chain: Who Pays?

It is extremely difficult to identify the actual cost of a drug because the pricing chains are complex. Variations in the price can take place because of the power the drug companies have in their market. Drug manufacturers charge different customers different prices for the same drug. For some large purchasers, such as federal government agencies and state Medicaid programs, they allow discounts and rebates in order to ensure their products are included in their formularies.

Insurers and pharmacy benefit managers may also obtain both discounts and rebates from the manufacturers. Most retail pharmacies, however, do not have the bargaining power for discounts.

On average, Americans use about 12.4 prescriptions a year but most do not pay full price for them. Nearly all of covered workers in employer-sponsored health plans, 177 million or 60 percent of Americans in 2006, have a prescription drug benefit. Approximately 90 percent (39 million) of Medicare beneficiaries have access to some drug coverage either under the Part D benefit or through a former employer, union or other source. Medicaid is the major source of outpatient pharmacy coverage for the non-Medicare low-income population.¹⁸ Approximately 46 million Americans are uninsured and do not have drug coverage. At the bottom of the pricing chain, it is the individual consumer without insurance coverage who pays the highest prices for prescription drugs.

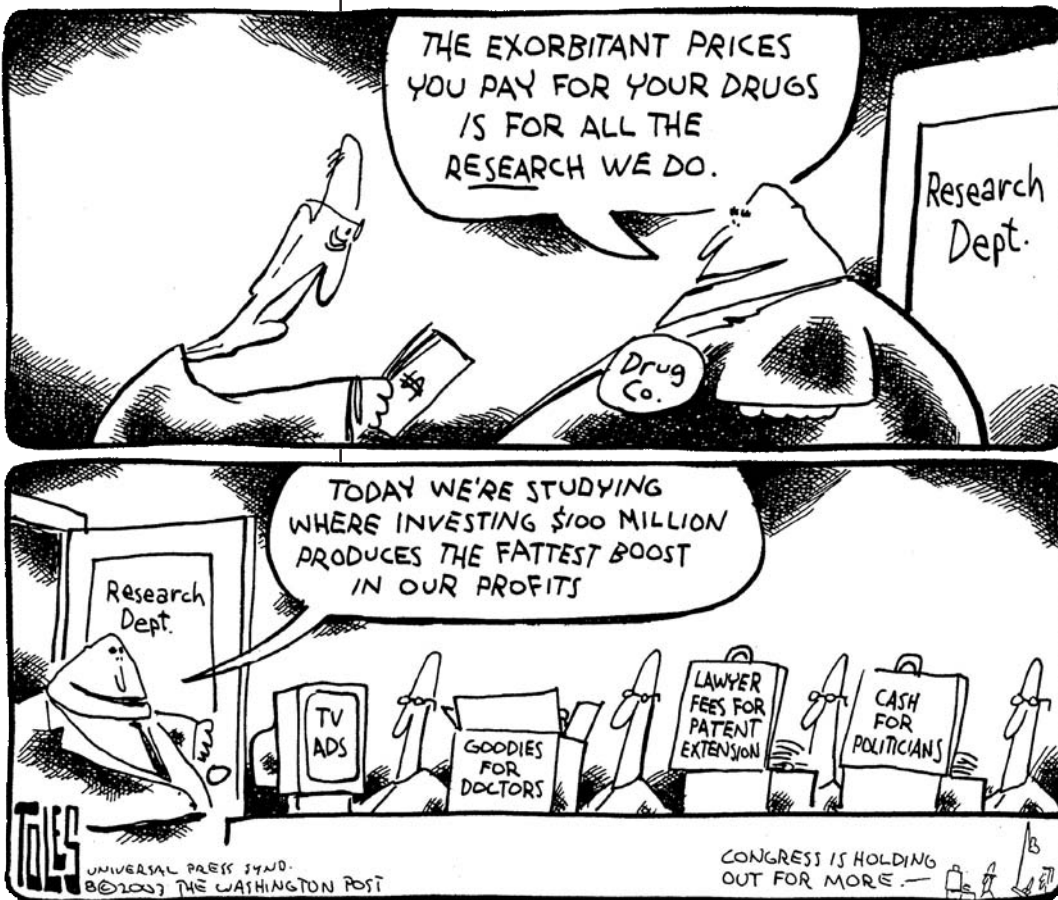
The Privileged Industry

In the United States, pharmaceutical companies have a unique position among industries because they:

- utilize research paid for at public expense
- have data exclusivity
- launch products that are copies rather than innovations
- acquire market exclusivity and patents with patent extensions freeing them from competition for about two decades
- experience few marketing restraints
- charge whatever they want for different customers, and
- pay less in taxes than other businesses

Debunking the Research and Development Argument

The pharmaceutical industry claims that the high prices of new drugs are necessary to fund ongoing research and development (R&D). They maintain that it costs approximately \$800 million to develop a new drug. However, the source and breakdown of that estimate is questionable.



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Source of Estimates

Most pharmaceutical companies report their R&D costs to the Center for the Study of Drug Development (CSDD) at Tufts University in Boston. Critics have maintained that CSDD is the drug industry's primary policy research center and is funded by unrestricted grants from pharmaceutical companies thereby negating any semblance of neutrality or validity. It is CSDD that reports R&D costs as \$800 million but the data used to reach that figure is not available

outside the center.¹⁹ What drug companies consider R&D costs vary significantly. Some may count their computer and software systems, others the cost of legal work and litigation protecting patents, and others the cost of land and buildings used substantially but not exclusively for R&D. Drug companies also sponsor post-approval trials i.e., testing of FDA-approved drugs for use for other conditions and include those costs as R&D.²⁰

An independent estimate from a report to the Global Forum for Health Research used the same data with more reasonable assumptions for the cost of capital and adjusting for tax savings from R&D, and came up with low, medium and high estimates for new molecular entities (NMEs). The estimates for R&D of a new drug range from \$316-\$406 million with the mostly likely figure to be \$358 million.²¹ The authors believe that if more accurate and detailed data were made available estimates would be even lower.

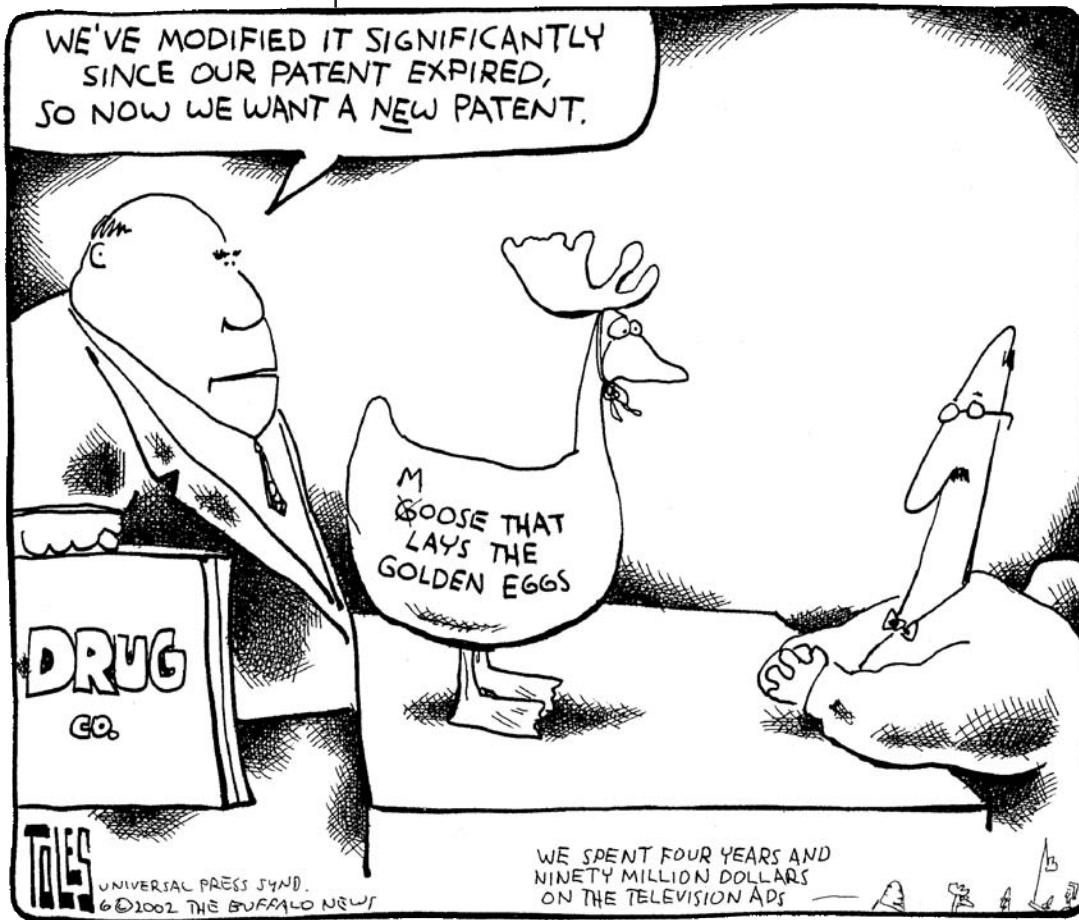
U.S. Government Research

In addition to the dubious research figure used by the drug industry, it is important to bear in mind that it is the federal government, primarily through the National Institutes of Health (NIH) or universities, that pays for the majority of the initial drug research in the United States.

For example, in the area of oncology, the Food and Drug Administration (FDA), the agency responsible for approving and regulating drugs as well as food products, approved 58 cancer drugs between 1955 and 2001. The National Cancer Institute played the lead role in the development of 50 of those drugs: it either found the molecule, assisted in late-stage preclinical trials, or directly sponsored the clinical trials. In some cases, it performed all three.²² In addition, many companies doing basic biotechnology research are sustained by government grants and programs.

Types of Drugs Developed

Most of the drug manufacturers' development of drugs is not for new drugs but rather copies of existing drugs. Of the drugs approved by the FDA from 1989 to 2000, only 35 percent were NMEs.²³ As expiration of patents appear on the horizon, drug companies develop so-called copy-cat or "me too" drugs which are therapeutically equivalent drugs to those going off patent. These are then submitted for approval as new patents. There were only 22 NMEs in 2006.²⁴ The remainder were merely applications of existing molecules, new formulations—active ingredients already on the market that have been modified—or combinations of two or more previously approved active ingredients in a single new medicine.



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The newly approved drugs frequently are not improvements over older drugs. A review by Prescrire, an independent review body, of nearly 3,000 newly approved drugs marketed from 1980 to 2002, including new uses and formulations of existing molecules, found that only about 1 in 9 new drugs

offered modest or significant therapeutic advantages over existing drugs.²⁵ A recent study of the comparative effectiveness of oral diabetes medications found that older, less-expensive drugs are equally as effective and safe as newer, costlier drugs.²⁶

EFFECTIVENESS OF THE FOOD AND DRUG ADMINISTRATION (FDA)

The FDA is the federal agency responsible for the safety of medicines and food and providing the public with accurate information about them. Two studies have concluded that the FDA is ineffective in a range of areas particularly regarding implementation of drug regulations.

The Institute of Medicine assessed the FDA drug safety system in 2006 and found it impaired by serious resource constraints and a lack of clear, unambiguous regulatory authority particularly with regard to enforcement. Enforcement includes fines, injunctions, and withdrawal of drug approval. Additionally, the study said that the FDA and the drug industry do not consistently demonstrate accountability and transparency to the public by communicating safety concerns in a timely fashion.

A Government Accountability Office study found that the FDA's ability is limited in preventing the use of direct-to-consumer prescription drug ads that violate FDA regulations.

Sources: Institute of Medicine. September 2006; Government Accountability Office. November 2006.

Facing patent expirations and lower revenues with generic competition, drug manufacturers often combine two or more medications into a single dose and obtain a new patent for a combination drug at a higher price. For example, the patent for Norvasc, for reducing blood pressure, expired in 2007 and the patent for Lipitor, for lowering cholesterol, expires in 2010. Pfizer, the manufacturer of both drugs, has combined the two into a new drug called Caduet. A study of 30 retail pharmacies and two online pharmacies found that while some combination drugs can save patients money, others are more expensive than buying the drugs separately.²⁷

Biological drugs, also called biotech or biologic products are the fastest-growing category of health spending—with sales of \$40 billion in 2006, up 20 percent from 2005.²⁸ More than 400 biotech products—proteins made by modifying the DNA of bacteria, yeast or mammal cells—are in development.²⁹ Often used in treating rare diseases, they are very expensive, some costing a patient tens of thousands of dollars a year. As patents are expiring on some biological drugs, drug companies use similar arguments to block the introduction of the less costly biogeneric alternatives as they do with the generic version of chemical drugs i.e., they claim that there will be problems of safety, effectiveness, and decreased research and innovation. Consequently they strenuously oppose creation of a regulatory framework for the FDA to review and approve biogenics.

Foreign “Free Riders”

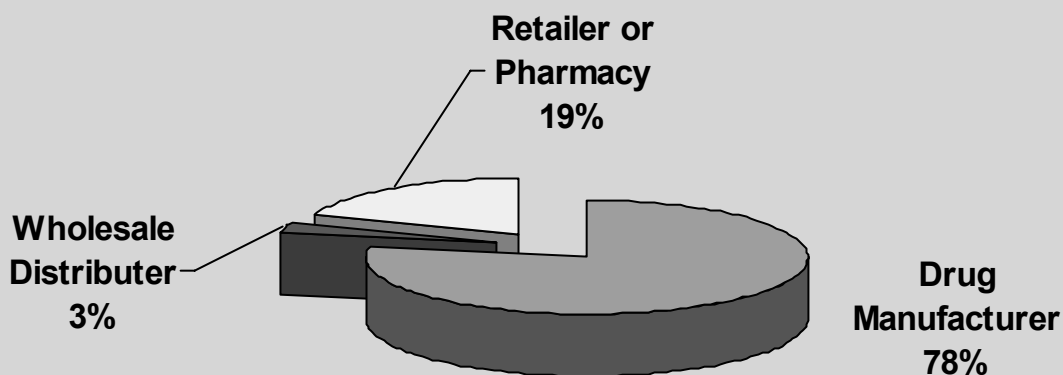
The pharmaceutical industry claims that drug prices must be higher in the United States because price controls in other developed countries do not pay sufficiently for R&D costs so it falls on the American consumer to pay for a disproportionate share of research costs. In other words, American drug companies portray foreign consumers as free riders and the prices they pay as a foreign rip-off. Yet, Europe develops many innovative new drugs in the world market. European countries account for 28 percent of world sales, 36 percent of total R&D spending, and 32 percent of new molecular entities.³⁰

A number of reports indicate that pharmaceutical companies in other developed countries invest more in R&D research than the U.S. and recover their R&D costs with substantial profits from domestic sales. For example, the United Kingdom Pharmaceutical Price Regulation Scheme reports that drug companies in the UK invest proportionately more of their revenues from domestic sales in research and development than do companies in the U.S.³¹

The Money Chain: Where Does the Money Go?

For every dollar that a consumer pays for a prescription drug at the pharmacy, 78 cents goes to the drug manufacturer, 3 cents goes to the wholesale distributor and 19 percent goes to the retailer or pharmacy.³²

WHERE THE PRESCRIPTION DRUG DOLLAR GOES



In 2005, the 7 pharmaceutical companies with the highest revenues spent more than twice as much of their revenue on marketing than they did on R&D. More than seventeen percent of revenues were dedicated to profits, compared with 13.9 percent spent on R&D and 32 percent on marketing, advertising and administration.³³

Profits, CEOs and Tax Havens

Profits

From 1995 to 2002, pharmaceutical companies were the most profitable industry. They ranked 3rd in 2003 and 2004 among the highest profit making businesses, 5th in 2005, and 2nd in 2006.³⁴

Many pharmaceutical companies enjoy greater profits as a percent of revenue than other companies, even beating the

three top-ranked companies in the Fortune 500 list. For example, in 2006 the profits as a percentage of revenues for Wal-Mart was 3 percent, for Exxon and Chevron, 11 percent and 8 percent respectively. In contrast, the 2006 profits as a percentage of revenues for the top three pharmaceutical companies was: Pfizer, 37 percent; Johnson & Johnson, 21 percent; and Merck, 20 percent. Overall, the after-tax median profits of pharmaceutical companies was 9.6 percent, considerably higher than the median after-tax profit level of 6.3 percent for the other Fortune 500 companies combined.³⁵

Compensation for CEOs

A significant amount of prescription drug money goes straight to the chief executive officers (CEOs) of drug companies. In 2006, the U.S. Securities and Exchange Commission (SEC) unveiled new rules for disclosing executive compensation. The rules go further than ever before in revealing just how much executives are paid, making transparent previously hard-to-find information such as pension and estimated severance package totals. SEC estimates of the total compensation for heads of the major drug companies in 2006 appear in the following chart.³⁶

DRUG COMPANY CEO TOTAL COMPENSATION 2006

Wyeth	\$32.8 million
Johnson & Johnson	\$28.5 million
Abbot Laboratories	\$26.9 million
Pfizer Inc.	\$19.4 million
Eli Lilly and Co.	\$15.2 million
Merck & Co., Inc.	\$10.2 million
Bristol-Myers Squibb Co.	\$ 9.7 million

Source: AFL-CIO. 2007 Executive PayWatch Database

Tax Safeguards

In addition to substantial profits, pharmaceutical companies enjoy many tax deductions, tax credits and tax havens not available to other industries. There are five federal tax provisions that result in greater tax savings for the drug companies than other major industrial categories. A Congressional Research Service report found that while the average tax rate for all industries was 27.3 percent over a four-year period, the rate for drug companies was only 16.2 percent.³⁷

In 2005, Congress granted companies with foreign subsidiaries a tax amnesty in an effort to persuade them to bring their profits home and create more American jobs. However, although drug companies repatriated about \$100 billion in foreign profits, and paid minimal taxes, they not only did not create jobs, they laid off American workers. The amnesty has expired but drug companies continue to use overseas tax shelters to hide profits and deflect tax obligations in the U.S. In 2006, Eli Lilly paid less than 6 percent of its profits of \$3.4 billion —considerably less than the official tax rate of 35 percent—to the U.S. government, according to its financial statement. In early 2007, Merck agreed to pay \$2.3 billion to the federal government to settle a claim by the Internal Revenue Service that it had hidden profits in a Bermuda partnership.³⁸

Tax Savings in Puerto Rico

Drug manufacturers have used even perceived taxation setbacks, such as occurred in Puerto Rico, to their advantage. In 1996, Congress eliminated over a ten-year period a tax credit, known as Section 936, used mostly by manufacturers in U.S. territories. At the time of repeal, it was anticipated that previously untapped taxes on corporate profits, particularly from the pharmaceutical industry's plants in Puerto Rico, would flow back to the Treasury. Instead, the drug companies continue to avoid taxes by registering their Puerto Rican subsidiaries as foreign-based thereby allowing them to avoid U.S. taxation on earned income there as long as they don't send the money to the

U.S. Using their advantages under the tax code, the companies have invested much of their profits in additional manufacturing facilities overseas, primarily in Ireland and Singapore. Of the 20 top-selling drugs in the U.S. in 2005, 14 of them including— Lipitor, Norvasc, Zocor, and Zoloft—were made in Puerto Rico. Fifty-two major prescription drugs with a retail value of nearly \$100 billion were produced in Puerto Rico in 2005.³⁹

Marketing

Detailing to Doctors

Manufacturers promote the use of new or altered drugs in a number of ways. The most common approach is through the personal contacts between drug company representatives, called detailers, and physicians. The goal is to create loyalty to their brand of drugs among those who prescribe the drugs. The pharmaceutical industry employs one of the largest sales forces among all industries—100,000 drug representatives, one for every six physicians—to persuade doctors to prescribe their products. However, since not all physicians practice and those who are “low-prescribers” are ignored by sales representatives, the actual ratio is one drug representative per 2.5 targeted doctors. The average sales force expenditure for drug companies is \$875 million annually.⁴⁰ Advertising directed toward doctors in 2005 was \$7.2 billion. This does not include the retail value of samples left at doctors’ offices, which totaled \$16 billion.⁴¹

Drug companies monitor their marketing investment by prescription tracking. They purchase physician databases from data-mining companies —including prescription records from pharmacies and demographic information on all U.S. physicians accumulated by the American Medical Association—to determine a physician’s prescribing behavior.⁴² Physicians may be relegated to categories such as “growers,” or early adopters of a brand who may increase their use of that brand; “spreaders” who use a little of all products; and “loyalists” who are very loyal to one particular product and use it for most patient types. The purpose of

physician segmentation is to have a different messaging strategy for each category.⁴³

Prescription sample distribution, gifts and meals are part of the approach to influencing physician prescribing behavior. The purpose of drug samples is to gain entry into doctor's offices and persuade them to test efficacy of usually expensive drugs with patients leading to prescriptions for the same drug. Some gifts—such as pens, notepads and coffee mugs—may appear commonplace but they are ways to keep the targeted drug's name before the physician. Doctors who are ranked “high prescribers” often receive expensive items such as golf bags, consulting arrangements as “thought leaders,” and educational forum sponsorships.⁴⁴

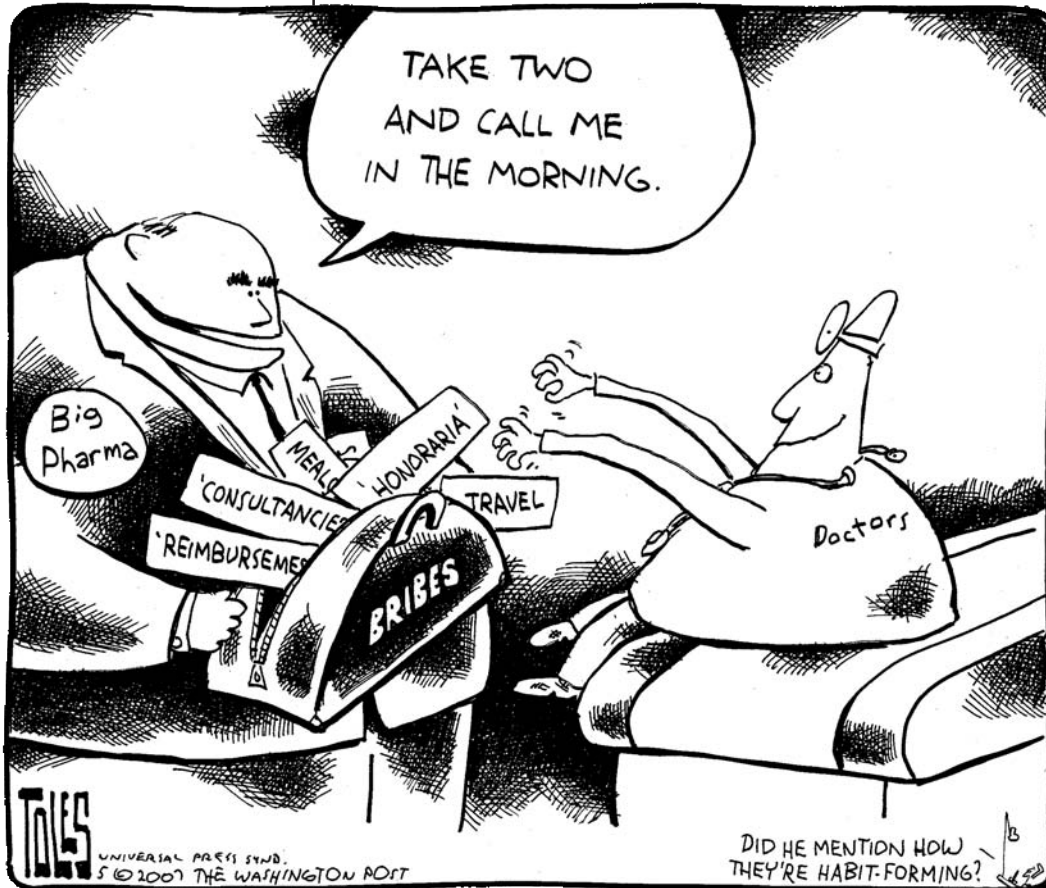
THE REAL COST OF FREE NOTEPADS

Prescription drug advertising directed toward doctors in 2005 amounted to \$7.2 billion. This does not include the retail value of samples left at doctors' offices, which totaled \$16 billion.

In 2002, the American Medical Association (AMA), the American College of Physicians, and the Accreditation Council for Continuing Medical Education adopted voluntary guidelines to discourage the gift-prescription collaboration between drug representatives and doctors. The inspector general of the Department of Health and Human Services issued similar guidelines in 2003. PhARMA, the trade association of the drug companies, also issued guidelines suggesting gifts be worth less than \$100 and should primarily benefit patients.⁴⁵ Five years later, a survey of physicians found that over four out of five (83 percent) receive food and drink from drug representatives. Twenty-eight percent continue to take consulting or lecture fees and 7 percent took free tickets for games and other events.⁴⁶

An analysis of records in Minnesota, the only state that requires public reports of all drug company marketing payments to doctors, found that from 2000 to 2005, drug

maker payments to Minnesota psychiatrists increased more than six times to \$1.6 million and prescriptions of anti-psychotics for children in the Minnesota Medicaid program rose more than nine times. Payments to the psychiatrists from drug companies ranged from \$51 to more than \$689,000 with a median of \$1,750.⁴⁷



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An investigation conducted by the U.S. Senate Finance Committee found that in 2005 and 2006 drug companies routinely used educational grants for continuing medical education (CME) programs as a way to increase the market for their newer and more lucrative products and, in some cases, promote them for uses beyond FDA approval. The report also found that oversight by the accrediting agency—the Accreditation Council for Continuing Medical Education—is insufficient for independence.⁴⁸

Traditionally, doctors learned of a drug's benefits and side effects through peer-reviewed articles in medical journals. Today, however, the reviewed studies are largely sponsored by drug companies. Drug studies sponsored by the drug

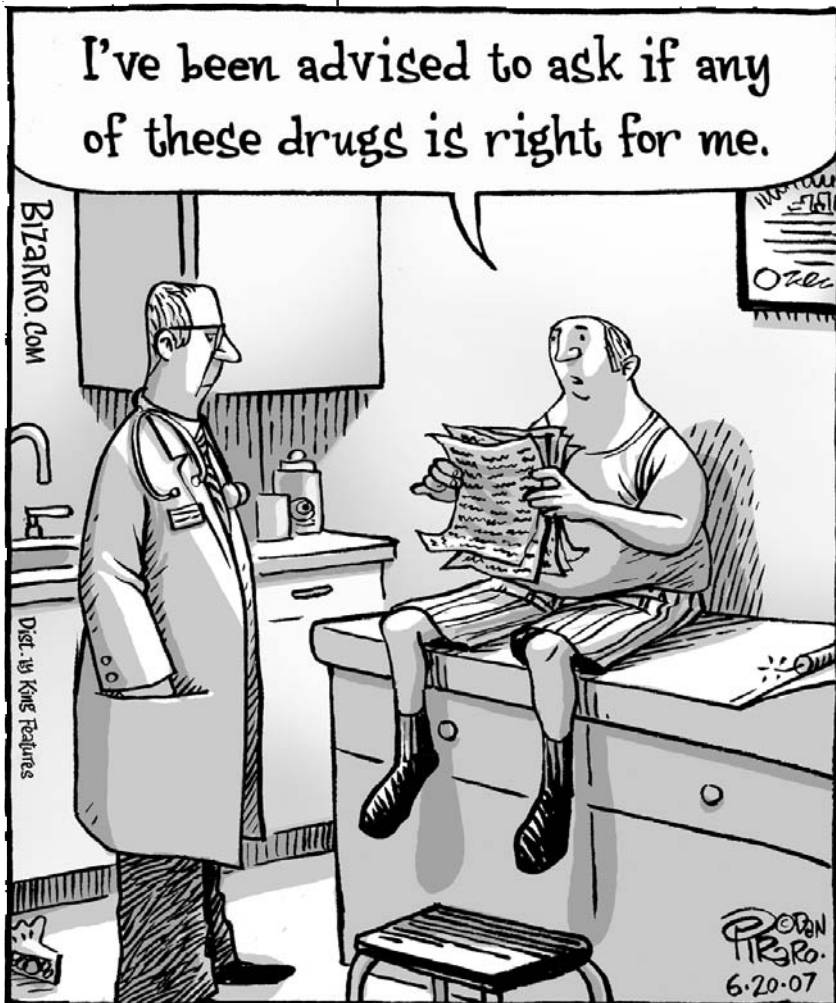
industry are four times more likely to be favorable to a drug than studies sponsored by the National Institutes of Health.⁴⁹

Advertising to Consumers

Changes to FDA policy in 1997 allowed drug manufacturers to expand advertising via mass media to consumers. Since then drug company spending on direct-to-consumer advertising (DTCA) has increased twice as fast as spending on promotion to doctors or on research and development. From 1997 through 2005, DTCA advertising increased almost 20 percent each year whereas spending on promotion to doctors and R&D increased by about 9 percent annually.⁵⁰ Pharmaceutical spending on direct-to-consumer advertising, primarily through television and magazine ads, amounted to \$4.8 billion in 2006, a 13 percent increase over 2005 and five times the amount spent in 1996 (\$0.8 billion), prior to the change in FDA policy.⁵¹ The U.S. and New Zealand are the only industrialized countries that permit DTCA. All others explicitly ban it.⁵²

The drug industry invests so much in DTCA because market demand is generated when consumers are introduced to and encouraged to request the brand-name drugs from their physicians who in turn have been courted by drug representatives and are responsive to patient requests. American television viewers see as many as 16 hours of prescription drug ads each year. Studies show that between one-fourth to two-thirds of consumers who have seen ads have requested a prescription for the drug advertised and that doctors fulfill the requests between 67 percent to 78 percent of the time.⁵³

Despite the claims by pharmaceutical companies that the ads serve an educational purpose, a study of the ads found that most (82 percent) made some factual claims for product use but few describe condition causes (26 percent), risk factors (26 percent) or prevalence (25 percent). None of the ads mention lifestyle change as an alternative to products and some ads (18 percent) portrayed lifestyle changes as insufficient for controlling a condition. The ads often framed medication use in terms of regaining control



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(85 percent) over some aspect of life and as engendering social approval (78 percent). Products were frequently (58 percent) portrayed as a medical breakthrough. The study concludes that the ads have limited educational value and may oversell the benefits of drugs in ways that might conflict with promoting population health.⁵⁴

Another marketing ploy used by drug companies is the use of coupons. Circulated through various venues, the coupons must be taken by consumers to their doctors and are redeemed with a written prescription at the pharmacy.

Marketing to consumers is essentially unrestrained. In 2006, the AMA called for a temporary ban on advertising newly approved drugs to no avail. PhRMA issued its own guidelines on DCTA, which are meaningless as they are vague and compliance is voluntary.⁵⁵ The Government Accountability Office found that the FDA's effectiveness at

halting the dissemination of DTCA that violate FDA regulations is limited.⁵⁶ There are too few staff and resources to monitor ads and lack of real enforcement powers.

Lobbying and Political Contributions

Pharmaceutical companies spend millions of dollars on political campaigns and lobbying to protect their interests. They obtained favorable provisions in the MMA and now lobby to obstruct legislation that would require Medicare price negotiation and allow importation of lower-priced drugs from Canada and other advanced countries.

The chair of the one of the key committees which wrote the MMA and which also regulates the pharmaceutical industry went on to become the president and chief executive officer of PhRMA immediately after he left Congress. He receives an annual salary of \$2 million. His former chief of staff is a lobbyist for the association.⁵⁷

From 1998-2006, the pharmaceuticals/health products industry spent \$1.1 billion on lobbying Congress, more than any other industry according to the Center for Responsive Politics. In the 2005-2006 election cycle alone, PhRMA spent \$18.1 million lobbying Congress; individual drug companies spent millions more on lobbying and contributions as shown in the following chart. Since 2000, drug manufacturers have contributed \$93 million to federal political candidates and parties, with more than three-quarters going to Republicans. In the 2005-2006 election cycle, contributions amounted to \$19.3 million.⁵⁸

THE COST OF DOING BUSINESS?

In the 2005-2006 election cycle, PhRMA, the trade association of drug manufacturers, spent \$18.1 million lobbying Congress; individual drug companies spent millions more. Political contributions from the drug makers amounted to \$19.3 million.

Millions of dollars are also spent on lobbying and political contributions in the states. The drug industry's state campaign donations more than doubled from \$4.6 million in 2000 to \$10.4 million in 2006 for a total of \$36 million over that period.⁵⁹ In 2003-2004, the pharmaceutical industry spent \$44 million lobbying state officials with much of the money going to fight proposals that would have reduced prescription drug costs.⁶⁰

Additionally, drug manufacturers donate substantial amounts of money to disease-focused organizations. These organizations generally promote research and specific treatment drugs for certain diseases or conditions and at times lobby for treatment programs that also benefit drug companies.⁶¹ For example, the Epilepsy Foundation and its state affiliates received between \$1-3 million from four drug makers in fiscal year 2006. They are now lobbying several state legislatures for laws that make it more difficult to switch patients from brand-name to inexpensive generic drugs.⁶²

Drug companies are also financial backers of such front groups as "United Seniors Association," "Seniors Coalition" and "60 Plus Association." As the Medicare prescription drug bill was developing in 2003, all three ran radio and television ads targeting members of Congress urging them to back the Republican bill. In that year, United Seniors spent more than \$24 million on ads and mailings, accounting for almost their entire annual revenue that year nearly all of which came from a single donor, according to their tax returns.⁶³ In 2005-2006, the Seniors Coalition spent \$3.9 million on lobbying.⁶⁴

Furthermore, drug companies are directing some of their resources to enlisting ordinary prescription drug users to lobby on their behalf. For example, Pfizer has sent form letters to consumers urging them to in turn send the letters on to their members of Congress with messages that benefit the drug companies, such as opposition to controlling the price of drugs.⁶⁵

EXPENDITURES ON LOBBYING AND CONTRIBUTIONS TO FEDERAL CANDIDATES AND PARTIES: 2005-2006

SELECTED COMPANIES

	Lobbying	Contributions
Pfizer Inc.	\$11.8 million	\$1.7 million
Amgen Inc.	\$10.2 million	\$1.2 million
Roche Group	\$ 8.9 million	\$ 495,630
Bristol-Myers Squibb	\$ 5.7 million	\$ 247,073
Johnson & Johnson	\$ 5.4 million	\$ 746,565
Merck & Co.	\$ 4.1 million	\$ 540,671
Eli Lilly and Co.	\$ 3.7 million	\$ 671,660

Source: Center for Responsive Politics

Fraudulent Practices

Drug companies have also inflated what is known as the average wholesale price (AWP) in order to boost their sales. The AWP is a benchmark figure drug manufacturers use to report to commercial publications that publish electronic databases of prescription drug prices. AWP's are not based on actual sales so are exposed to manipulation. Third party payors, such as private and public health plans, use these AWP's to determine how much to pay doctors and pharmacies for drugs. By inflating the figures, the manufacturers help increase the amount that doctors are paid for their drugs although the cost for doctors is much less (the difference is known as the "spread"), thereby promoting loyalty to their brand drugs over those of competitors.

As the result of cases brought by whistleblowers under the False Claims Act (FCA), drug companies have made settlements with the federal and state governments on charges of defrauding the Medicare and Medicaid programs through fraudulent pricing and marketing of drugs and presenting false claims for payments. In 2005 and 2006, drug manufacturers paid \$1.6 billion to resolve allegations of Medicare and Medicaid fraud. According to the Taxpayers Against Fraud Education Fund, that represents only the tip of the iceberg as more than 180 additional cases remain under seal. In total, more than \$3.9 billion has been recovered from drug manufacturers over the past six years as the result of just 16 FCA cases.⁶⁶

Why Not Have More Substitution of Generic Drugs?

Today, generics represent 63% of the total prescriptions dispensed in the United States, but less than 20% of all dollars spent on prescription drugs indicating how far less costly generic drugs are.⁶⁷ In 2006, the average retail price (the price paid by insured and uninsured patients) of a generic prescription drug was \$32.23; the average retail price of a brand name drug was \$111.02.⁶⁸ The Pharmaceutical Care Management Association found that Medicare beneficiaries who use generic drugs may be able to delay reaching the Part D coverage gap by an average of 74 days.⁶⁹

WHAT IS A GENERIC DRUG?

The FDA defines a generic drug as “a copy that is the same as a brand name drug in dosage, safety and strength, how taken, quality, performance and intended use.”

The FDA defines a generic drug as “a copy that is the same as a brand name drug in dosage, safety and strength, how taken, quality, performance, and intended use.” FDA approval requires that a generic drug must be absorbed into the body at essentially the same rate and to the same extent as the brand-name drug. The FDA says that generic drugs typically cost 20-80 percent less than their brand-name counterparts and prices for generic drugs in the U.S. are much lower than in many other countries.⁷⁰

Drug companies have a history of blocking generic drug competition. During the 1950s and 1960s, drug manufacturers persuaded doctors to prescribe brand-name drugs and state legislatures to prevent pharmacists from substituting generic drugs. Those laws were repealed during the 1970s and the drug companies then turned their attention to protecting their interest by obtaining patent extensions and using loopholes to stall the introduction of generic drugs. For example, many patents on drugs can be

extended beyond the 17-20 years of a patent by altering dosages or shapes of the drugs for the sole purpose of obtaining another patent on essentially the same drug.⁷¹

In 1984, Congress attempted to keep drug prices down through the Drug Price Competition and Patent Term Restoration Act, also called the Hatch-Waxman Act. The legislation's intent was to speed up the entry of generic drugs and encourage competition between companies producing generic and brand-name drugs. Under the law, when the first generic enters the market after a patent has expired, it has 180 days of exclusivity. Other generics are allowed to enter the market within a 12- to 18-month period, and the average generic drug price becomes a fraction of the brand-name drug price.

One loophole allows a brand company to introduce a so-called "authorized generic" drug—in reality the original brand-name drug marketed and sold as a generic—to the market during the 180 days of generic exclusivity thereby undermining the ability of generic drug companies to bring out cheaper drugs. Drug companies also are able to acquire a three-year exclusivity from the FDA when they switch their brand to an over-the-counter drug as long as they conduct new clinical studies on the drug.

Another obstacle to generic drugs coming on the market is the practice by brand-name companies of filing "citizen petitions" that require FDA investigation of issues raised in the petition. Citizen petitions originally were created to allow individuals to voice concerns to the FDA about the safety or efficacy of a generic drug. However, the drug firms abuse this provision by filing petitions around the time that patent protection for their products is about to expire for the purpose of delaying entry of generic competition.

In recent years, generic as well as brand-name companies have undermined the intent and potential benefits of the Hatch-Waxman Act through settlements that delay introduction of a generic drug in return for substantial compensation from the brand-name company. When a

generic drug company files an application with the FDA to market their generic drug, which was previously a brand-name drug, the brand-name company with the expiring patent will often file baseless patent infringement lawsuits against the generic company. The lawsuit grants the brand-name company an automatic 30-month extension of their patent. The brand-name company will then offer “reverse payment settlements” to the generic company as settlement of the lawsuit.

In 2003, reforms to the Act gave the Federal Trade Commission (FTC) authority to review all settlements of patent cases brought under the Act. Although the FTC has tried to stop the practice of patent settlements, two appellate court decisions in 2005 viewed the agreements with leniency and concluded that the settlements do not violate antitrust laws. These rulings make it more difficult for the FTC to bring antitrust cases for such practices.⁷² Settlements of this type weaken the effectiveness and intent of the Hatch-Waxman Act as evidenced by a number of settlements resulting in higher drug costs for all. The FTC reports that in fiscal 2006, half of the 28 patent agreements they reviewed were reverse payment settlements and predicts more such settlements and less generic competition.⁷³

If patent manipulation does not come into play, the potential for greater availability of generic drugs and lower prices is on the horizon as a number of high priced brand-name drugs will be coming off patent. Blockbuster drugs, such as Zocor, Zoloft and Norvasc, coming off patent in 2006-2008 are valued at \$22 billion in 2006, \$27 billion in 2007, and \$29 billion in 2008.⁷⁴ In addition, generic biologic drugs could save consumers \$71 billion over a decade according to the pharmacy benefit manager Express Scripts, Inc.⁷⁵

Proposed Solutions

The structure of the current system of drug development, availability, and prices serves the drug manufacturers to a much greater extent than it does the consumer. There are a number of measures that could nullify the stranglehold the pharmaceutical industry has on the prescription drug market.

Ameliorate MMA Damage

The MMA Part D prescription drug benefit has many deficiencies foremost of which is that it is not a benefit provided in the traditional Medicare program. The implementation of the drug benefit is costly nationally as well as individually. The ultimate solution is to have Medicare provide and administer the prescription drug benefit, just as it does Medicare Part A and Part B, with formularies based on clinical outcomes and comparative effectiveness of drugs as in other countries.

Other Remedies:

- Require the federal government to negotiate price reductions with pharmaceutical companies much as it does with such providers as hospitals, doctors and nursing homes. The high cost of prescription drugs for Medicare beneficiaries will not produce savings until the Secretary of Health and Human Services has the authority and duty to negotiate prices with pharmaceutical companies. The authority to negotiate is essential to reduce the overall cost of the Medicare program and prevent windfall profits to the drug companies. In early 2007, legislation (H.R. 4) to require negotiation passed in the House of Representatives but an effort to break a filibuster threat on a similar bill (S. 3) failed in the Senate. President Bush has threatened a veto.

- Allow safe reimportation of drugs from Canada and other advanced countries, which includes insuring the quality of the drugs. This would save \$50 billion over the next decade. Bipartisan legislation (S. 242, H.R. 380) has been moving through Congress.

Independent Education of Physicians

Providing scientific based evidence of the effectiveness of various drugs without a vested interest in physician prescribing behavior is one means of counter-acting the influence of drug representatives detailed to physicians. A \$1 million campaign in Pennsylvania utilizes a practice used widely in Europe and Australia, known as academic detailing. The Independent Drug Information Service project sends specially trained drug information consultants with backgrounds in pharmacy, nursing, or an allied health profession to inform physicians about the effectiveness of different medications using evidence-based data. Some are also former drug company detailers. Sponsored by the Pennsylvania Department of Aging and administered by the Brigham and Women's Hospital in Boston, the consultant team has made 1,200 visits to about 500 physicians in the state. Internists and Harvard medical school instructors provide talking points that doctors can use to discuss medications with patients.⁷⁶ Replication in other states may help reduce drug representative influence on physician prescribing behavior.

Education of Consumers

Generic companies do not promote their products to doctors to the extent that brand-name companies do. Consumers need to have usable, reliable data on both when deciding on the use of new drugs and how to evaluate relative merits of different drugs within the same class. Consumer Reports, in partnership with consumer groups including the Alliance for Retired Americans, has an initiative that compares a variety of prescription drugs on price, effectiveness, side effects and

safety to help consumers and their doctors identify the most effective and affordable medicines.⁷⁷ Availability of information on how to evaluate the merits of brand and generic drugs would likely lead to increased price sensitivity and cost savings.

Open the market to more competition by shortening the length of patents and/or eliminating the practice of patent extensions.

This approach actually might produce greater technological breakthroughs because, without the 17 to 20 years of exclusivity on patents, the drug manufacturers would have greater incentive to develop the next money-making drug. Patents spur innovation but so do their expiration. Once a drug manufacturer has a blockbuster drug, it is inclined to protect the patent on that drug as long as possible, including making copycat drugs, in order to continue reaping substantial profits. Closing loopholes on patent extensions could shift attention to new research.

Close loopholes that prevent or delay generic drugs from coming to the market.

Legislation introduced in the 110th Congress (S. 1088) would clarify current law to prevent abuse of the 30 month stay allowed to brand manufacturers when a generic drug is about to come on the market and prevent abuse of the citizen petitions process. Clarification of the FTC's ability to pursue aggressive prosecution of brand-generic reverse payment settlements is also needed if this practice is to end (H.R. 1902).

A Strengthened FDA

Studies have indicated that the FDA has insufficient resources for enforcement of the drug laws under its jurisdiction.⁷⁸ Legislation to reauthorize the Prescription Drug User Fee Act of 1992 (PDUFA) provides the

opportunity for Congress to include provisions that would build up the agency.⁷⁹ Improvements include: extend FDA's authority to do post-market surveillance of new drugs beyond three years; require drug companies to register their new drug clinical trials in a publicly available database; and impose stiff fines for failure to comply with FDA regulations. The introduction of money-saving biogenerics could be facilitated by setting up an approval structure within FDA.

As studies have shown that DTCAs do not increase knowledge but rather prompts consumers to request a brand-name drug from their doctors, FDA policy allowing drug companies to advertise via mass media to consumers should be reversed and such ads banned. At a minimum, ads should be scrutinized to insure that they provide essential information such as clear warnings of possible negative side effects.

In the 110th Congress, both the House and Senate have passed legislation (S. 1082, H.R. 2900) reauthorizing PDUFA and addressing some of these changes but the two bills have not been conferenced.

Pursue Legal Remedies

The Prescription Access Litigation project (PAL), of which the Alliance for Retired Americans is a partner, uses class action litigation and consumer education to challenge illegal drug industry tactics. Successes include a ruling from a district court in Massachusetts that found three drug manufacturers violated the state's consumer protection act by issuing false and inflated average wholesale prices for cancer and other drugs. In a 2006 settlement, Databank, the main publisher of AWP, agreed to roll back the AWP spreads on hundreds of drugs and to stop publishing AWP data within two years of the final settlement resulting in a 4 percent rollback of prices on hundreds of drugs and a nationwide savings of \$4 billion in drug costs in the first year alone.⁸⁰

Conclusion

Whatever solution or solutions are devised and implemented, the unending rise in prices indicates that immediate action is necessary.

Through patent extensions, inflated price information, superficial lawsuits, political contributions, lobbying and marketing, and lucrative opportunities with the MMA Part D benefit, the pharmaceutical industry has been able to increase as well as protect its profits while plundering the pockets of the American people.

High drug prices and inadequate insurance coverage are the major barriers to maintaining an acceptable quality of life for millions of Medicare beneficiaries and other Americans.

All developed countries with lower drug prices than the United States also have some form of universal health insurance coverage. While the presence of insurance coverage increases utilization and expenditures for prescription drugs, it also provides the means and incentives for governments to control expenditures.

Ultimately, the best and most comprehensive approach to providing affordable prescription drugs for all the American people is to create a high quality, affordable, universal health care system, which provides comprehensive services and is based on a sound financing model similar to Medicare.

Endnotes

- ¹ Most notable are: Angell, Marcia. *The Truth About the Drug Companies*. New York: Random House, 2004; and Gozner, Merrill. *The \$800 Million Pill: The Truth Behind the Cost of New Drugs*. Berkeley: University of California Press, 2004.
- ² Kaiser Family Foundation. *Prescription Drug Trends*. May 2007.
- ³ Ibid.
- ⁴ Light, Donald and Rebecca Warburton. *How Much Does It Cost Drug Companies to Discover and Develop New Drugs? Less Than You Have Been Led to Believe*. Report to the Global Forum for Health Research, Geneva, 2006.
- ⁵ Daily Health Policy Report. Kaisernetwork.org. Jan. 23, 2007.
- ⁶ Kaiser Family Foundation. May 2007
- ⁷ Ibid.
- ⁸ Ibid.
- ⁹ Daily Health Policy Report. 65-Year-Old Couple Retiring in 2007 Will Need \$215,000 for Future Health Care Costs, According to Fidelity Estimate. Kaisernetwork.org. March 28, 2007.
- ¹⁰ Weisman, Jonathan. Costs Grow for Common Medicare Drugs. *Washington Post*. May 13, 2007.
- ¹¹ Committee on Oversight and Government Reform. *Drug Company Profits Soar Under Medicare Drug Plan*. September 19, 2006.
- ¹² Kaiser Family Foundation. May 2007.
- ¹³ FamiliesUSA. *No Bargain: Medicare Drug Plans Deliver High Prices*. January 2007.
- ¹⁴ Weisman, Jonathan. . May 13, 2007
- ¹⁵ Ibid.
- ¹⁶ Ibid.
- ¹⁷ Congressional Budget Office. *Would Prescription Drug Importation Reduce U.S. Drug Spending?* April 29, 2004.
- ¹⁸ Kaiser. May 2007.
- ¹⁹ Light and Warburton. 2006.
- ²⁰ Ibid.
- ²¹ Ibid.
- ²² Ibid.
- ²³ National Institute for Health Care Management. *Changing Patterns*. May 2002.
- ²⁴ U.S. Food and Drug Administration. *CDEF New Molecular Entity (NME) and new Biologic Approvals in Calendar Year 2006*.
- ²⁵ Light and Warburton. 2006.
- ²⁶ Bolen, Shari et. Al. Systematic Review: Comparative Effectiveness and Safety of Oral Medications for Type 2 Diabetes Mellitus. *Annals of Internal Medicine online*. July 2007. www.annals.org
- ²⁷ Kritz, Francesca Lunzer. Two (or more) for one with prescription drugs. *Los Angeles Times*. April 30, 2007.
- ²⁸ Pear, Robert. Congress Seeks Compromise on Generic Drugs. *The New*

York Times. April 8, 2007.

²⁹ The FDA refers to generic versions of biological drugs as “follow-on-protein products.” Other terms sometimes used are “follow-on biologics” or “biosimilars.”

³⁰ Light, Donald and Joel Lexchin. Foreign free riders and the high price of US medicines. *BMJ*. Vol. 331. October 22, 2005.

³¹ Ibid.

³² Kaiser Family Foundation. May 2007.

³³ FamiliesUSA. *No Bargain: Medicare Drug Plans Deliver High Prices*. January 2007.

³⁴ Kaiser Family Foundation. May 2007.

³⁵ *Fortune* magazine. April 30, 2007. www.fortune.com

³⁶ AFLCIO. 2007 Executive PayWatch Database. www.aflcio.org/corporatewatch/paywatch/ceou/database.cfm

³⁷ Congressional Research Service. *Federal Taxation of the Drug Industry from 1990 to 1996, Memorandum to Joint Economic Committee*. December 13, 1999.

³⁸ Berenson, Alex. Tax Break Used by Drug Makers Failed to Add Jobs. *The New York Times*. July 24, 2007.

³⁹ Barshay, Jill. An Island of Avoidance. *CQ Weekly*. September 18, 2006.

⁴⁰ Fugh-Berman, Adriane and Shahram Ahari. How Drug Reps Make Friends and Influence Doctors. *PloS Medicine*. Vol. 4. No. 4 April 2007.

⁴¹ Kaiser Family Foundation. May 2007.

⁴² The AMA earns \$44 million a year from the sale of its database. New Hampshire is the first state to try to curtail the practice of data-mining but a federal district court ruled that the law was unconstitutional in April 2007.

⁴³ Fugh-Berman and Ahari. 2007.

⁴⁴ Ibid.

⁴⁵ U.S. Health and Human Services Office of Inspector General. *Compliance Program Guidance for Pharmaceutical Manufacturers*. 2003; PhRMA. *Code on Interactions with Healthcare Professionals*. 2002.

⁴⁶ *New England Journal of Medicine*. April 26, 2007.

⁴⁷ Daily Health Policy Report. NYT Analysis Looks at Psychiatrists Who Receive Payments from Drug Companies. Kaisernetwork.org May 10, 2007.

⁴⁸ U.S. Senate Finance Committee. *Use of Educational Grants by Pharmaceutical Manufacturers*. Committee Staff Report to the Chairman and Ranking Member. April 2007.

⁴⁹ Prescription Access Litigation Project. Ask Pharmie. *PAL News*. Winter 2006. www.prescriptionaccess.org

⁵⁰ Government Accountability Office. *Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising*. November 2006.

⁵¹ Kaiser Family Foundation. May 2007; West, Diane. Spend Trends 2007: Hang 10. *Pharmaceutical Executive*. May 1, 2007.

⁵² Frosch, Dominick L. et al. Creating Demand for Prescription Drugs: A Content Analysis of Television Direct-to Consumer Advertising. *Annals of Family Medicine*. 5:6-13. 2007.

⁵³ Prescription Access Litigation Project. Ask Pharmie. *PAL News*. Spring 2006.

⁵⁴ Frosch, Dominick L. et al.

⁵⁵ PhRMA. *PhRMA Guiding Principles Direct to Consumer Advertising About Prescription Medicines*. Rev. November 2005.

- ⁵⁶ Government Accountability Office. *Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising*. November 2006.
- ⁵⁷ Ismail, M. Asif. *Spending on Lobbying Thrives: Drug and health products industries invest \$182 million to influence legislation*. Center for Public Integrity. April 2, 2007.
- ⁵⁸ Center for Responsive Politics. *Pharmaceuticals/Health Products: Long Term Contribution Trends*. www.opensecrets.org
- ⁵⁹ National Institute on Money in State Politics. *Pharmaceuticals & Health Products Influence for All States*. www.followthemoney.org
- ⁶⁰ Center for Public Integrity. *Pharmaceutical Industry Lobbying and Campaign Donations in All States*. www.publicintegrity.org
- ⁶¹ Ginsberg, Thomas. Donations tie drug firms and non-profits. *Philadelphia Inquirer*. May 28, 2006.
- ⁶² Mantone, Joseph. Big PhRMA States Its Case. *The Wall Street Journal*. July 13, 2007.
- ⁶³ Poison pill: How Abramoff's cronies sold the Medicare drug bill. *Washington Monthly*. Nov.2006.
- ⁶⁴ Center for Responsive Politics. www.opensecrets.org/lobbyists
- ⁶⁵ Henderson, Diedra. Pfizer drafting customers to lobby: Drug maker hopes form letters opposing price controls get forwarded to Congress. *The Boston Globe*. January 27, 2007.
- ⁶⁶ Schneider, Andy. *The Role of the False Claims Act in Combatting Medicare and Medicaid Fraud by Drug Manufacturers: An Update*. Taxpayers Against Fraud Education Fund. March 2007.
- ⁶⁷ Kaiser Family Foundation. May 2007. Matthews, Anna Wilde and Leila Abboud. For Booming Biotech Firms, A New Threat: Generics. *The Wall Street Journal*. March 14, 2007.
- ⁶⁸ Generic Pharmaceutical Association. Statistics. www.Gphaonline.org
- ⁶⁹ Pharmaceutical Care Management Association. *Potential Beneficiary Savings Associated with Generics & Mail-Service Pharmacies for Five Conditions Common to Seniors*. September 7, 2006.
- ⁷⁰ Food and Drug Administration. www.fda.gov
- ⁷¹ Currently, drug patents in force prior to June 8, 1995, have a term of either 17 years from date of issuance of the patent award or 20 years from the date of filing an application for a patent, whichever is longer, plus allowance for a five-year extension under the Waxman-Hatch Act and international agreements and law. However, since patents are applied for before clinical trials begin, the *effective* life of most drug patents tends to be between seven and twelve years. Exclusivity is exclusive marketing rights granted by the FDA upon approval of a drug and can run concurrently with a patent or not. Generally, brand drugs have five years of market exclusivity, but three years can be added on if changes are made to improve the drugs.
- ⁷² Schering-Plough v. Federal Trade Commission, 403 F.3d 1056 (11th Cir. 2005); In re Tamoxifen Cirate Antitrust Litig., 429 F.3d 370 (2d Cir. 2005).
- ⁷³ Federal Trade Commission. *Anticompetitive Patent Settlements in the Pharmaceutical Industry: the Benefits of a Legislative Solution*. Prepared statement before the Senate Judiciary Committee. January 17, 2007.
- ⁷⁴ Dill, Gregory R. *Generic Drug Utilization: Medicare Prescription Drug Benefit*. CMS Union Forum. April 26, 2007.
- ⁷⁵ Matthews, Anna Wilde and Leila Abboud. For Booming Biotech Firms, A New Threat: Generics. *The Wall Street Journal*. March 14, 2007.
- ⁷⁶ Henderson, Diedra. Independent Lens: Counter-Detailers Help Doctors

Wade Through Drug Company Marketing. *The Boston Globe*. Feb. 27, 2007; Governor Rendell Directs Launch of Groundbreaking Initiative to Educate Doctors About Prescription Drug Options. PA Powerport. September 2005.

⁷⁷ *Consumer Reports*. Best Buy Drugs. www.CRBestBuyDrugs.org

⁷⁸ Institute of Medicine *The Future of Drug Safety: Promoting and Protecting the Health of the Public*. September 22, 2006; Government Accountability Office, November 2006.

⁷⁹ The goal of PDUFA was to speed up the FDA review of new drugs and medical devices. It created a “user fee” that manufacturers pay for the expedited process. FDA has used the fees largely for increased staffing.

⁸⁰ *In re Pharmaceutical Industry Average Wholesale Price Litigation*; Prescription Access Litigation Project. Settlement of Conspiracy Case Forces Major Restructuring of Prescription Drug Pricing System. October 6, 2006.

Acknowledgements

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