U.S.News ONLINE

U.S. News

Hang on to your wallet

Political scandals seem remote--but they take cash from your pocket

Get more on political scandals

BY PAUL GLASTRIS, JULIAN E. BARNES, KENT JENKINS JR., AND NANCY SHUTE

Enemies of Bill Clinton and friends of campaign finance reform are equally impatient with the American people. Each week brings fresh evidence that the White House traded access for campaign donations. And each week the public seems to respond with an irritable resignation. This frustrates conservatives, who feel the president deserves worse, and it worries liberals, who count on voter outrage to breathe life into campaign finance reform legislation.

Last week was typical. On Wednesday, more White House documents were released showing the brazenness of the administration's donations-for-access operation. On Thursday, Sen. Russell Feingold was out trying to rally support for the campaign finance reform bill he is cosponsoring as part of a national campaign that has drawn modest response. "It's easy to get people to the disgust level," says former Sen. Bill Bradley, an ally. "The question is, how do you get them to the action level?"

Aside from cynicism, there is a less acknowledged reason for this public passivity: The Clinton administration policies that may have been influenced by political money just don't seem that important to most people. Did the administration give officials in Guam more local authority in exchange for campaign donations? Did it pry open European markets to American bananas? Did it lobby for special financing to build Blockbuster stores in Thailand? The typical voter can be forgiven for not staying glued to CNN waiting for the answer.

This, alas, is the reason political money has an impact. Most issues Congress and the administration deal with are complicated and of concern only to very narrow segments of the population. So the press and public pay little attention, even though the cumulative effect of the tax breaks and subsidies is to make the deficit bigger and taxes higher.

Yet there are issues before Congress right now that do directly affect large numbers of voters. For instance, legislation to deregulate the electricity market--and cut consumers' electric bills--is in jeopardy

because of heavy lobbying (and campaign contributions) from electric utilities that fear competition.

What follows are a few cases in which consumers have already lost. In each, the interest group that contributed, and the lawmakers who received, campaign money deny any quid pro quo. And in each case, the affected industry made some legitimate arguments. It's just that campaign contributions seemed to make those arguments far more persuasive to lawmakers than they otherwise would have been. Here are the consequences:

Taxes are higher. The federal government last week finalized one of the largest interest-group giveaways in recent history: The Federal Communications Commission began implementing a law passed by Congress last year that gives to each television station--for free--a second frequency that will handle tomorrow's extra-sharp digital pictures. If these channels had been sold, as a broad range of political leaders wanted, they would have generated a staggering $30 billion in revenues to the treasury in a single year. That's enough to run the FBI for 10 years or give every tax filer a $260 rebate.

The broadcast industry argued this was the only deal that would coax media companies to make the transition to the digital world. But a free market could easily have settled that question: Companies could have been invited to bid for this valuable resource and, presumably, would have offered prices that still allowed them to make a lot of money.

The National Association of Broadcasters contributed more than $850,000 to candidates running for Congress last year and mounted a $500,000 public-relations campaign to tout its cause. And a word from a local television station executive carried special weight with lawmakers. "Individual broadcasters control a politician's access to the airwave. That's the power to elect or re-elect a politician," said Gigi B. Sohn, executive director of the Media Access Project. "They all feel that keenly."

Probably the biggest loss was not the money but an opportunity. Many experts agree that one of the most effective ways of reducing the influence of money would be to provide free TV time to candidates. The moment when such a change could have been forced on the broadcasters was during the consideration of the telecommunications bill. In other words, the main opportunity to reduce the influence of political money was overwhelmed by the influence of political money.

Drugs cost more. Every year, patents on brand-name drugs run out, thereby allowing generic-drug companies to offer the same product for less than half the price. And every year, brand-name companies hire lobbyists and flood politicians with contributions in an attempt to extend their patents and stave off that competition. Over the past two years, for instance, Searle & Co. and its parent, Monsanto, gave $127,875 to individual lawmakers and $129,000 in "soft" money to the parties, most of it to Republicans. Last spring, Searle's congressional allies slipped into a budget bill an amendment extending the patent on its anti-inflammatory drug Daypro. The amendment will allow Searle to sell Daypro (annual sales: $280 million) for two more years without competition from generics.

But that's small change compared with the biggest, weirdest drug-patent windfall of recent years. In 1994, harried White House and congressional staffers made a technical error when drafting a bill to enact the "fast track" General Agreement on Tariffs and Trade. They inadvertently gave 109 drugs extended protection from generic-drug competition. The error would eventually cost consumers and insurers over $6 billion in higher prices. One company, Glaxo Wellcome, stood to gain $2 billion by maintaining high prices on its popular ulcer drug Zantac.

After the error was detected, a group of mostly Democratic senators tried to insert the missing clause. But by then the pharmaceutical firms had come to see the windfall as their right. A group of largely GOP senators backed the industry, arguing that even a tiny change to GATT would invite massive cheating by Third World countries. The *New Republic* reported that the day after the Senate voted in 1996 not to make the correction, Glaxo gave $100,000 to the Republican National Committee. The firm would eventually contribute $487,000 to the RNC. A Glaxo spokesman says that the Senate voted "on the merits."

Consumers get charged big late fees. A couple of years ago, radio talk-show host Bruce Williams began hearing callers complain about being charged late fees on credit card bills because their checks were arriving late. (The U.S. Postal Service delivers about 22 percent of nonlocal mail late.) Banks, utilities, and other bill-collecting companies have been reducing or eliminating grace periods and raising late fees. The most common credit card late fee is now $20, up from $15 a year ago. Late fees have generated big profits for those who levy them. Credit card firms took in $2 billion in late fees last year, according to Robert McKinley of RAM Research Group.

Williams shared his baskets full of outraged letters with GOP Rep. John McHugh of New York. McHugh introduced the Postmark Prompt Payment Act, which would have forced banks and utilities to consider the postmark, not the day of receipt, as the date a bill was paid. Twenty congressmen quickly signed on as cosponsors.

Lobbyists for banks and credit card companies soon descended on McHugh and his supporters. They complained that the bill would impose serious costs on their clients, who would have to invest in technology to read postmarks. McHugh's bill never made it out of committee.

Talk-show host Williams sees merit in some of the bill collectors' objections, but he believes that these arguments played less of a role than the money. According to the Center for Responsive Politics, a group that tracks campaign contributions, eight lawmakers who originally cosponsored the bill but later withdrew received, in the 1995-1996 election cycle, $49,800 from political action committees of companies or groups that collect bills. All told, those companies gave $3.6 million in PAC and soft money during that period.

Cable TV costs more. Last year's Telecommunications Act was hailed as a free-market way to keep a lid on cable rates. The law allows cable firms and regional phone companies to get into each other's businesses. The resulting competition, said the law's sponsors, would keep cable rates in check. Since then, rates have jumped an average of 7.8 percent,

costing cable watchers $117 million, or about $1.80 per household a month. The major cable companies have announced hikes this year, too.

What happened looks like a legislative bait and switch. After the bill passed, the companies discovered there were technical reasons they couldn't start competing with each other quickly. Cable firms explained that they were having trouble getting phones to ring because their coaxial cables don't carry electricity. The Baby Bells discovered their networks could not easily--or cheaply--handle all of the data video requires. Bottom line: The analysts now say that real competition between them won't kick in for six to 10 years.

Meanwhile, the cable industry is free to boost its rates, thanks to another provision of the Telecommunications Act. In return for supporting the bill, cable-industry lobbyists demanded that price controls be dropped. The three largest cable companies, TCI, Time Warner, and Continental Cablevision, contributed $1.7 million to the two political parties. Cable industry PACs gave at least $1.2 million more to lawmakers.

Scared seniors get gouged. For decades, the health insurance market for senior citizens has been plagued by "dread disease" policies, which promise to pay if the buyer suffers cancer or another specific illness. Problem is, most of the buyers are already covered by Medicare and Medigap insurance. The General Accounting Office estimates that in 1991, 3 million elderly Medicare beneficiaries spent $1.8 billion on potentially duplicative policies, which typically cost $250 to $350 a year. For instance, a 76-year-old Wisconsin widow with dementia bought 15 redundant policies in two years.

In 1990, Congress outlawed the sale of duplicative policies to Medicare recipients. But in 1994, under heavy lobbying from the supplemental-insurance industry, Congress opened the door to selling them--as long as all policies came with written warnings saying "this insurance duplicates some Medicare benefits." AFLAC Inc. of Columbus, Ga., which last year sold $3 billion in cancer-only policies, led the charge.

But that wasn't enough. Last year AFLAC got a little-noticed provision into the Kennedy-Kassebaum health care reform bill. It replaced the clear warnings with more vague language. In 1995-96, AFLAC's PAC gave $474,750 to congressional campaigns; $10,000 went to GOP Rep. Michael "Mac" Collins of Georgia, who introduced the Kennedy-Kassebaum changes and let the AFLAC lobbyists regularly use his office.

HEADING, SUBJECT, RESULT, SYNOPSIS, DEBATE, TALLY
NEXT VOTE, PREVIOUS VOTE, SUBJECT INDEX, CHRONOLOGICAL LIST,
HOME, CAMERA COPY

SENATE RECORD VOTE ANALYSIS

Bill Bradley voted

104th Congress
1st Session
December 7, 1995, 8:46 p.m.
Page S-18222 Temp. Record
Vote No. 594

PARTIAL-BIRTH ABORTIONS/Hearings on Trade & Prescription Drugs

US - Glaxo

SUBJECT:

Partial-Birth Abortion Ban Act of 1995 . . . H.R. 1833. Smith (for DeWine/Dodd) second-degree perfecting amendment No. 3088 to the Pryor amendment No. 3082.

MOTION TO TABLE FAILED, 48-49

in 1995

SYNOPSIS:

As introduced, H.R. 1833, the Partial-Birth Abortion Ban Act of 1995, will prohibit partial-birth abortions. An affirmative defense will be provided if the physician reasonably believes a partial-birth abortion is necessary to save the life of the mother and no other procedure will suffice for that purpose. The term "partial-birth abortion" will be defined as an abortion "in which the person performing the abortion partially vaginally delivers the living fetus before killing the fetus and completing the delivery."

The Pryor amendment would amend current law to permit generic drug manufacturers to make drugs that have had their patents extended as a result of the Uruguay Round on the General Agreement on Tariffs and Trade (GATT) during those drugs' extension periods. Royalties would be paid to the patent holders.

The Smith (for DeWine/Dodd) perfecting amendment would strike the substance of the Pryor amendment and would substitute in lieu thereof language expressing the sense of the Senate that the Judiciary Committee should hold a hearing on the General Agreement on Tariffs and Trade as it relates to patent protection for pharmaceuticals.

Debate was limited by unanimous consent. Following debate, Senator Pryor moved to table the DeWine/Dodd amendment. Generally, those favoring the motion to table opposed the amendment; those opposing the motion to table favored the amendment.

NOTE: Following the vote, the Pryor amendment was withdrawn.

Those favoring the amendment contended:

The issue addressed by the underlying Pryor amendment is much more complex than our colleagues would have us believe. They are trying to rush this issue through the Senate on this unrelated bill without honestly acknowledging that many experts on this area of patent law strongly believe that the Pryor amendment would harm prescription drug consumers, would harm the pharmaceutical industry, and would do serious damage to the Uruguay Round trade agreement's patent protection provisions, thereby eroding patent protection for all U.S. patented products. We believe that detailed hearings on this matter would bring these points out for all Senators. Accordingly, we have offered the DeWine/Dodd substitute amendment to express the sense of the Senate that the Judiciary Committee, which has jurisdiction over patent issues, should hold hearings on this matter. The Chairman of the Judiciary Committee has assured us that he will schedule such hearings.

We believe that hearings will show that the failure to change patent protection law for drugs was not a mistake; that law was deliberately left unchanged. The patenting of drugs differs from the patenting of other products because of the lengthy approval process involved and because of the cost of developing a new product. Before 1984, the approval process created difficulties for both new product manufacturers and the generic drug companies that produce their products after their patents expire. The Food and Drug Administration is supposed to approve or disapprove a patent application for a new drug within 180 days, but it usually takes much longer than that amount of time. Before 1984, it took generic companies 2 to 3 years to gain approval of their copies of drugs once the patents on those drugs expired, but, with the passage of the Hatch/Waxman Act (the Patents Term Restoration and Drug Price Competition Act), that time has been cut down to almost instant approval. The reason is that generic drug companies, unlike any other companies in America, were given the right to use the original data that was used by the companies that developed the drugs they copied. New drug manufacturers, that spend an average of $350 million and take an average of 12 years to develop a new drug, and that only succeed in patenting 20 percent of the drugs they develop, have to let generic companies use their research for free. Companies that produce new drugs, of course, still face a lengthy approval process. Under the terms of the Uruguay Round, that approval process time will eat into their 20-year patent terms because it will run from the date of application instead of the date of issuance.

The portion of the Uruguay Round dealing with patents, the Intellectual Property Agreement (TRIPS), is the first large international agreement to protect intellectual property rights. In many countries, such rights have been virtually non-existent. American industries consequently have lost tens of billions of dollars in foreign sales, and they have lost huge sums domestically as well due to the sale of imported, pirated products. Many countries that signed on to the TRIPS agreement would happily back out of it. Passing the Pryor amendment would give them the excuse they need. The agreement allows protections such as are in the Pryor amendment when a country signs on to the agreement, but not after. If the United States, which is the country that fought for patent protection, became the first country to weaken that protection to protect one industry, the whole TRIPS agreement would unravel. The United States may experience a very short-term gain from the sale of a few generic prescription drugs by domestic companies, but in the long-term the result of approving this amendment would be disastrous.

We are aware that some trade experts, including in the Clinton Administration, contend that this change would not prove harmful, and we are very willing to listen to their views; perhaps they may persuade us that we are wrong. Those of our colleagues who are convinced that we are wrong should be willing to defend their position in hearings. Rushing through an amendment on an issue that may have such enormous consequences before having a chance to hear expert testimony from both sides would be a terrible mistake. Therefore, we strongly support adoption of the DeWine/Dodd amendment.

Those opposing the amendment contended:

Under the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) the signatory nations agreed to 20-year protection for patents starting from the filing date for patents. To conform to this international agreement, the United States changed its patent protection law from 17 years from the issuance of a patent to this new standard. Congress then gave existing patent holders the right to either remain under the old standard or to accept the new standard. As a result, some patent holders gained up to 3 years additional patent protection. For manufacturers who were preparing to make products on which patents were about to expire this extension created a severe problem--after investing often millions of dollars to begin production, they were being told that they could not begin for up to three years. To be fair to such manufacturers, Congress also agreed that generic manufacturers could make products for which patents were extended as long as they paid a royalty to the patent holders. However, in making conforming amendments to existing laws to implement this agreement, Congress made a mistake. It failed to change the law as it applied to drugs. As a result, prescription drug manufacturers that hold patents are receiving a windfall that no other patent holders are receiving. For some prescription drugs such as Zantac, this windfall is enormous. Consumers have to pay up to 3 times as much for patent-protected drugs, meaning that drug companies make billions of dollars in extra profits. In fairness to generic drug manufacturers and in fairness to consumers, the underlying Pryor amendment would correct Congress' mistake. According to the Clinton Administration, the failure to provide this protection was an oversight, and, in our reading of the TRIPS agreement, changes of the type advocated by the Pryor amendment were clearly anticipated. The Pryor amendment would not make a permanent change; it would only make a transitional change to be fair to generic drug manufacturers. The issue is clear--hearings are not necessary. We therefore urge our colleagues to vote against the DeWine/Dodd amendment, and in favor of the underlying Pryor amendment.

VOTING YEA:

Republicans:

(12 or 23%) Bond Brown Chafee Cohen Hatfield Jeffords Kassebaum Lugar McCain Pressler Roth Snowe

Democrats:

(36 or 80%) Akaka Baucus Bingaman Boxer Bradley Breaux Bryan Bumpers Byrd Conrad Daschle Dorgan Exon Feingold Feinstein Ford Glenn Graham Heflin Inouye Kennedy Kerrey Kerry Kohl Leahy Levin Mikulski Murray Nunn Pryor Reid Robb Rockefeller Sarbanes Simon Wellstone

VOTING NAY:

Republicans:

(40 or 77%) Abraham Ashcroft Bennett Burns Campbell Coats Cochran Coverdell Craig D'Amato DeWine Dole Domenici Faircloth Frist Gorton Gramm Grams Grassley Gregg Hatch Helms Hutchison Inhofe Kempthorne Kyl Lott Mack McConnell Murkowski Nickles Santorum Shelby Smith Specter Stevens Thomas Thompson Thurmond Warner

Democrats:

(9 or 20%) Biden Dodd Harkin Hollings Johnston Lautenberg Lieberman Moseley-Braun Pell

NOT VOTING:

Republicans:

(0)

Democrats:

(1) Moynihan-2

VOTING PRESENT:
(1) Simpson

ABSENCE CODE: 1-Official Business 2-Nec. absent 3-Illness 4-Other
Symbols: AY-Announced Yea AN-Announced Nay PY-Paired Yea PN-Paired Nay

Compiled and written by the staff of the Republican Policy Committee

Don Nickles, Chairman

TOP

The Effects of Managed Care on the Pharmaceutical Market

At the same time that the Hatch-Waxman Act has helped increase the supply of generic drugs, changes in the demand for pharmaceuticals have affected the frequency with which generic and brand-name drugs are prescribed and the prices paid for them. Those changes in demand were brought on by newer forms of health care delivery and financing. In particular, because of competitive pressure in the health insurance market, more private-sector health plans have adopted managed care techniques in an effort to hold down overall health spending. The net effect of those techniques on spending for prescription drugs, however, is unclear.

On the one hand, many health plans (including traditional fee-for-service plans) hold down drug costs by "managing" their outpatient prescription drug benefits--either themselves or through organizations called pharmaceutical benefit management companies (PBMs). Those plans and PBMs use computer networks at pharmacies and electronic card systems for enrollees that allow pharmacists, before filling an enrollee's prescription, to consult a list (or formulary) of the plan's suggested drugs. Formularies typically encourage substituting brand-name drugs with generic versions, or sometimes with other, less expensive brand-name drugs. Savings result not only because of that substitution but also because many manufacturers of brand-name drugs offer discounts to health plans or PBMs in exchange for being included on their formulary. In addition, because they represent a large pool of customers, PBMs can negotiate with pharmacies over the retail prices charged for prescriptions. Since the late 1980s, those various techniques have been putting downward pressure on the prices that PBMs and health plans pay for prescription drugs sold through pharmacies.

On the other hand, health maintenance organizations (HMOs) and some other managed care plans frequently charge lower copayments for health care services--including physician visits and prescription drugs--than traditional fee-for-service plans do. Those lower copayments may lead to greater use of prescription drugs by beneficiaries. The treatment practices of HMOs may also favor more intensive use of prescription drugs, perhaps as an alternative to costlier forms of treatment. As a result, the increasing prevalence of managed care plans may have helped boost the quantity of prescription drugs sold in the United States.

For brand-name drugs still under patent (which do not yet have generic competitors), managed care techniques may have only a small effect on profits, assuming that greater use offsets the downward pressure on prices. For brand-name drugs whose patents have expired, however, profits are probably lower than they would have been without the generic substitution promoted in part by managed care plans and PBMs; that substitution has cut dramatically into the market share of those drugs. (CBO's calculation of the change in returns accounts for the full increase in generic market share since 1984, part of which is attributable to the rise in managed care techniques, but it does not measure managed care's effect on profitability through other variables, such as increases in prescription drug use and changes in pricing.)

Pricing and Competition in the Pharmaceutical Market

Competition in the pharmaceutical market takes three forms: among brand-name drugs that are therapeutically similar, between brand-name drugs and generic substitutes, and among generic versions of the same drug. Manufacturers of brand-name drugs compete for market share primarily through advertising and the quality of their products (including efficacy and side effects), as well as through pricing. Manufacturers of generic drugs increase their market share mainly by lowering prices. (In general, companies produce either generic or brand-name drugs, not both, although some generic manufacturers are subsidiaries of brand-name manufacturers.)

Competition Among Brand-Name Drugs

Patents do not grant complete monopoly power in the pharmaceutical industry. The reason is that companies can frequently discover and patent several different drugs that use the same basic mechanism to

Summary

The pharmaceutical market has become increasingly competitive since the early 1980s, in part because of the dramatic growth of the generic drug industry. In 1996, 43 percent of the prescription drugs sold in the United States (as measured in total countable units, such as tablets and capsules) were generic. Twelve years earlier, the figure was just 19 percent. Generic drugs cost less than their brand-name, or "innovator," counterparts. Thus, they have played an important role in holding down national spending on prescription drugs from what it would otherwise have been. Considering only sales through pharmacies, the Congressional Budget Office (CBO) estimates that by substituting generic for brand-name drugs, purchasers saved roughly $8 billion to $10 billion in 1994 (at retail prices).

Three factors are behind the dramatic rise in sales of generic drugs that has made those savings possible. First, the Drug Price Competition and Patent Term Restoration Act of 1984--commonly known as the Hatch-Waxman Act--made it easier and less costly for manufacturers to enter the market for generic, nonantibiotic drugs. Second, by 1980, most states had passed drug-product substitution laws that allowed pharmacists to dispense a generic drug even when the prescription called for a brand-name drug. And third, some government health programs, such as Medicaid, and many private health insurance plans have actively promoted such generic substitution.

Greater sales of generic drugs reduce the returns that pharmaceutical companies earn from developing brand-name drugs. The Hatch-Waxman Act aimed to limit that effect by extending the length of time that a new drug is under patent--and thus protected from generic competitors. Those extensions compensate for the fact that part of the time a drug is under patent it is being reviewed by the Food and Drug Administration (FDA) rather than being sold. The act tried to balance two competing objectives: encouraging competition from generic drugs while maintaining the incentive to invest in developing innovative drugs. It fell somewhat short of achieving that balance, however, in part because the act shortened the average time between the expiration of a brand-name drug's patent and the arrival of generic copies on the market (so-called generic entry) from more than three years to less than three months. More important, it also greatly increased the number of drugs that experience generic competition and, thus, contributed to an increase in the supply of generic drugs. In the end, the cost to producers of brand-name drugs from faster generic entry has roughly offset the benefit they receive from extended patent terms. Meanwhile, the greater competition from generic drugs has somewhat eroded their expected returns from research and development.

CBO estimates that those factors have lowered the average returns from marketing a new drug by roughly 12 percent (or $27 million in 1990 dollars). In this study, "returns from marketing a new drug" refers to the present discounted value of the total stream of future profits expected from an average brand-name drug. Previous studies estimate that those profits had an average present discounted value of $210 million to $230 million (in 1990 dollars) for drugs introduced in the early 1980s. Those returns are valued at the date of market introduction, after subtracting production costs but not the costs of research and development. Also, because the drugs in those studies were not eligible for the patent-term extensions provided by the Hatch-Waxman Act, those estimates do not account for the benefits of the extensions now available under the act. Thus, those figures can be considered a minimum estimate of the returns from marketing. Only part of the estimated decline in returns can be attributed to the Hatch-Waxman Act; the other factors that have boosted sales of generic drugs have played a role as well.

This study relies on a variety of data to produce its estimates, including a data set that represents about 70 percent of prescription drug sales through retail pharmacies in the United States. The various sets of data all have strengths and weaknesses, which are discussed along with the estimates they generate. In general, the empirical estimates in this study are rough rather than precise measures. They help characterize the increase in competition in the pharmaceutical market and its effects on the profits of drug manufacturers and the prices paid for prescription drugs.

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Partners In Healthcare...

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NO. OF PAGES 8

Comments: Background from WSJ and conservative think tank on the brand industry to block generic competition. See last page of WSJ for citizen petition and Coumadin (nat. unpriv.) examples.

Response:

ARE YOU READY FOR THE NEW MILLENIUM?

GPIA's Annual Meeting 2000

New Date May 9-11, 2000
New Location Omni Shoreham Hotel
Washington, DC

Bested Interests

Why Generic Drugs Often Can't Compete Against Brand Names

Lower Prices Aren't Enough To Overcome Demand For 'New and Improved'

Doctoring the Applesauce

By THOMAS M. BURTON
Staff Reporter of THE WALL STREET JOURNAL

When Congress passed legislation in 1984 smoothing the way for fast marketing approval of low-cost generic drugs, one major intent was to reduce inflation in pharmaceutical costs.

Since then, generics have grown from 18% to 42% of all prescriptions written in the U.S. Generic drugs such as "beta-blockers" for preventing heart attacks are embraced as the medical standard of care.

So why are drug costs higher than ever?

In the personal-computer industry, it was the clone makers that ultimately won. But so far, big drug companies are staying one step ahead of their clone-making generic rivals at every turn.

Even as generic copies of popular brand-name medications like Prozac and Procardia are being planned for when the patents on these drugs expire, big pharmaceutical companies are developing the next generation of expensive, brand-name antidepressants and heart pills. To ensure demand for their new products, the pharmaceutical titans promote their drugs with direct-to-consumer advertising—an estimated $10.8 billion in ads and promotions this year alone, and growing. Behind the scenes, they employ an arsenal of legal and regulatory tactics so that generics don't make more headway.

HARD TO SWALLOW
America's Soaring Drug Costs
PART OF A SERIES

While generics have managed to prosper in certain categories like asthma treatment—where the only competition is from older brand-name drugs that are directly equivalent—they are consistently slammed in categories where a new, heavily marketed brand-name drug has entered the picture.

Witness how Astra Pharmaceuticals LP of Wayne, Pa., has beaten back generic heartburn and ulcer remedies with its drug Prilosec. Part of a class of new and powerful acid-fighting drugs called proton-pump inhibitors, Prilosec is designed to treat both serious ulcers and severe recurrent heartburn, called gastroesophageal reflux disease, or GERD.

The drug got a big boost from the American Digestive Health Foundation of Bethesda, Md., and the American College of Gastroenterology in Arlington, Va., which paid for extensive "public education" spots on television and in newspapers and magazines, telling people about ulcers and GERD. "Maybe there's a better medicine that will help you live pain-free," one ad says—without naming Prilosec. The two organizations receive financial support from Astra Pharmaceuticals, a joint venture of Astra AB of Sweden and Merck & Co.

'Ask Your Doctor'

Astra also launched an extensive ad campaign for the drug last year that ran on network television and cable, and in publications ranging from Woman's Day to National Geographic. One, showing a grimacing man holding his stomach in pain, encouraged, "Ask your doctor about the most prescribed acid medication in America."

Now, Prilosec, at a wholesale cost of $116 to $178 for a month's supply, is an industry blockbuster. Sales in the U.S. are expected to reach $3.5 billion this year, up from $2.2 billion last year. The drug is now the biggest single pharmaceutical cost at many companies that cover employee prescriptions.

Meantime, the generics are losing ground. Value Rx, a leading drug-benefits manager that is a unit of Express Scripts Inc. of St. Louis, reports a big decline in usage of ranitidine, whose brand name is Zantac and which costs about half as much as Prilosec. Among the plan's 7.2 million members, use of the generic has fallen in the past four years from 41% to 19% of the gastrointestinal-disease market. Over that same period, Prilosec and a similar drug, TAP Pharmaceuticals Inc.'s Prevacid, have jumped from 9% to 36%. Much of the rest of the GI-drug market is held by brand-name drugs, too.

Another Kind of Heartburn

Now, the people with heartburn are those whose job it is to keep medical costs down.

"We see use of a much more expensive product, Prilosec, when a less expensive therapy would work fine," says Thomas Snedden, director of Pennsylvania Assistance Contract for the Elderly, or PACE, a Pennsylvania state program that provides drugs for older people. "GERD used to be infrequent, and now it is frequent. Physicians just want to prescribe it, so they diagnose GERD."

An Astra spokesman, Jim Coyne, says its ads are "very specific and refer only to frequent and persistent heartburn." He contends that GERD actually is underdiagnosed and that as many as 21 million Americans may have a recurring form of it.

A large part of the reason generic-drug makers can't keep up is that they lack the marketing muscle of their big rivals.

Sales of cefaclor, a potent antibiotic used to treat sinusitis and ear infections, plunged after its patent expired in 1992. Prior to that,

Wall Street Journal
Nov. 18, 1998

Continued from First Page

the drug had been Eli Lilly & Co.'s leading product under the brand-name Ceclor, with nearly $1 billion in total sales. After the generic appeared in 1993, new prescriptions fell to less than 20% of their earlier level.

This was because Lilly salespeople ("detail" people in industry parlance) used to push Ceclor heavily during visits to medical offices. But when the patent expired, they stopped, virtually overnight. "Lilly just quit flogging it," says Paul Arnow, an infectious-diseases doctor at the University of Chicago Medical Center. A Lilly spokesman confirms that it "substantially reduced" marketing visits on Ceclor in a "short period of time" after the generic cefaclor appeared. Meanwhile, lots of prescriptions get written for expensive, heavily promoted antibiotics, when cefaclor or the even cheaper amoxicillin would do just fine, according to health-care and managed-care executives.

It is rare for generic-drug companies to dispatch salespeople to visit doctors, or to host medical seminars and pay marquee professors to laud their products, as brand companies do. Even leading generic makers, like Mylan Laboratories Inc. of Pittsburgh, with a market value of about $4.4 billion, and Barr Laboratories Inc. of Pomona, N.Y., at about $950 million, are dwarfed by leading brand companies like British drug giant Glaxo Wellcome PLC, at about $110 billion.

The free samples that detail people hand out to doctors are a key weapon in winning market share for a new drug. The pharmaceutical companies' hope is that doctors will give these drugs to patients instead of prescribing other medications. And once the freebies in these "starter kits" have run out, a patient often ends up on long-term, even lifelong, prescriptions for that drug.

Battle Over Beta-Blockers

This has happened with medications designed to ward off heart attacks. While there is powerful medical evidence that heart-attack patients generally should be put on generic beta-blockers to avoid further attacks, often, doctors who have free samples of more-expensive brand-name calcium channel-blocker drugs for hypertension will place patients on these instead.

One leading calcium channel-blocker, Hoechst Marion Roussel's Cardizem CD, wholesales for between $60 and $78 monthly for the most common doses. By comparison, two widely prescribed generic beta-blockers, atenolol and metoprolol, cost between $21 and $36 wholesale for a month's supply.

"There is clear evidence that beta-blockers are the drug of choice" after heart attacks, says University of Chicago cardiologist Matthew Sorrentino. But the expensive drug often gets prescribed instead, he says, "because the doctor has just been detailed on it, and he has samples in his closet." Also, he says, many doctors are unfamiliar with the precise appropriate usage of the drugs, so they are heavily influenced by salespeople. A Hoechst spokeswoman didn't return calls seeking comment.

"We're getting pharmaceutical overkill," says Woodrow A. Myers Jr., director of health-care management at Ford Motor Co., where pharmaceutical costs for employees rose 16% and 18% the past two years, respectively, driven by expensive brand-name ulcer drugs, antibiotics, antidepressants and allergy pills. "Because of advertising to consumers and marketing to doctors, great drugs are given to the wrong patient for the wrong disease."

Employers and managed-care companies could crack down, of course, by enforcing use of generics. But under attack in Congress and competing to woo customers, many managed-care plans are reluctant to antagonize patients any further.

"Many managed-care companies have gotten lenient in implementing drug cost-containment efforts," says Henry F. Blissenbach, former president of drug-benefits manager Diversified Pharmaceutical Services Inc., now a unit of Britain's Smith Kline Beecham PLC.

Lee N. Newcomer, medical director at managed-care company United HealthCare Corp., Minnetonka, Minn., says it is difficult for HMOs to insist on switching "without alienating our membership." Moreover, he says, it would be too expensive to inquire into the appropriateness of every use of an expensive drug. But he says United HealthCare is beginning to make it more costly for many of its patients—up to $20 more per prescription—to choose an expensive brand product instead of a generic.

Lawyers and Lobbyists

After all, the vast majority of generics are regarded by the FDA as substitutable for the brand drug in all medical cases. And every generic approved by the FDA has been found by the agency to be precisely the same chemical, with the same dosage and equivalent absorption rate, and with the same manufacturing-consistency that brand manufacturers must have.

The brand-name pharmaceutical industry isn't taking this pro-generic talk lying down. Instead, big drug makers are dispatching platoons of lawyers and lobbyists to protect their monopolies, even after their patents—which usually run for 20 years—expire.

Bristol-Myers Squibb Co. is seeking to keep certain generic versions of the anxiety drug trazadone off the market by claiming that the generic pill infringes on its patent—not on the chemical compound itself, but on the form of the pill. Like the brand-name medicine, called Desyrel, the generic pill has two grooves on it, to split the tablet into thirds. A Bristol-Myers spokeswoman says, "We do have a valid patent on the form of the tablet."

In some cases where litigation is pending, big pharmaceutical companies sometimes pay generic firms to keep the clones off the market. For instance, Abbott Laboratories, North Chicago, Ill., currently pays quarterly fees totaling several million dollars to two generic companies as patent litigation over Abbott's hypertension drug Hytrin proceeds. The recipients, the Zenith Goldline Pharmaceutical unit of Ivax Corp. and the Geneva Pharmaceuticals Inc. unit of Novartis AG, have agreed, for now at least, not to market a generic competitor.

Meanwhile, Hytrin is generating about $700 million in annual sales and growing at

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about 13% a year, at a typical drugstore cost of $53 monthly. Even though the original patent on the chemical expired in 1994, there is no generic on the market. Abbott says it can't comment on patent litigation. Zenith declined to comment, but confirmed that Abbott agreed to pay it $6 million each quarter. Geneva says that it fears marketing the drug now because it might end up owing damages.

Arsenal of Tactics

"There are anywhere from 10 to 20 tactics" pharmaceutical companies "use to protect their products," says Roger L. Williams, the Food and Drug Administration's director of pharmaceutical science.

Among these are "citizens' petitions" filed with the FDA to oppose generic drugs—often filed by citizens who happen to be lawyers for big drug companies. Alan F. Holmer, president of the brand drug industry's trade association, says, "The research-based industry does not oppose the generic industry. But if we think the FDA is about to make a mistake in approving a generic, we will let the FDA know about it."

Currently, the FDA is considering a petition from American Home Products Corp., Madison, N.J., against the generic version of the hypertension drug Verelan, called verapamil. Verapamil already has been shown to dissolve in the bloodstream at essentially the same rate as the brand product when in capsule form. But American Home says an additional test is necessary: It wants the generic company to sprinkle the drug on applesauce, have patients ingest it, and measure how fast it is absorbed. That is because the Verelan label says the medicine can "be administered by carefully opening the capsule and sprinkling the pellets on a spoonful of applesauce." Toronto-based Biovail Corp., the generic maker, says it believes it has successfully completed the applesauce test.

Even when petitions fail, they can keep generic drugs off the market for months or years. At least 40 were filed between 1990 and 1997 against generic drugs. Of the 29 already decided, 24 were rejected by the FDA. But it took the agency between seven months and four years to approve the generic drugs in question after the petitions were filed.

A Case Study

After the FDA approves a generic, there still can be serious roadblocks to getting the drug to consumers.

A case study is the drug Coumadin, whose generic form, called warfarin or warfarin sodium, won FDA approval last year. Coumadin, made by DuPont Pharmaceuticals Inc. of Wilmington, Del., is an anticoagulant used, for example, by stroke patients to ward off further episodes. The drug generates about $500 million in yearly sales for the DuPont Co. unit. A standard monthly dose has a typical drugstore price of $35.50, against the generic's $28.60. Despite the price difference, Coumadin has so far retained about 80% of the U.S. market.

DuPont has waged a campaign to convince state legislatures and state agencies to limit the ability of pharmacists to switch patients to warfarin. DuPont points out that Coumadin/warfarin is a "narrow therapeutic index" drug, meaning that there is a narrow range of safe blood levels of the drug. Too little can lead to strokes, too much to internal bleeding.

An FDA Warning

DuPont has produced slides, press releases and other promotional materials that question the safety of switching patients to the generic: "Once a patient is stabilized on Coumadin . . . he or she should not be switched to another formulation of warfarin sodium without the knowledge and approval of the patient and his or her physician so additional monitoring can be performed," DuPont asserted in a June, 1997 press release.

The FDA, which has deemed the two products equivalent, warned DuPont in January: "We cannot overstate the seriousness with which we regard DuPont's false and misleading promotion of Coumadin."

Nonetheless, DuPont is pursuing either legislation or agency action in as many as 20 states to prohibit switching unless a druggist first gets a doctor's verbal approval. DuPont's senior vice president for public policy, Robert W. Perkins, says the company is taking "a stand that physicians should be aware of which brand the patient is taking." But doctors already can prevent switching by specifying the brand medicine on a prescription pad. Generic companies, however, say requiring busy pharmacists to phone busy doctors over each prescription simply is a roadblock.

Contradicting Testimonies

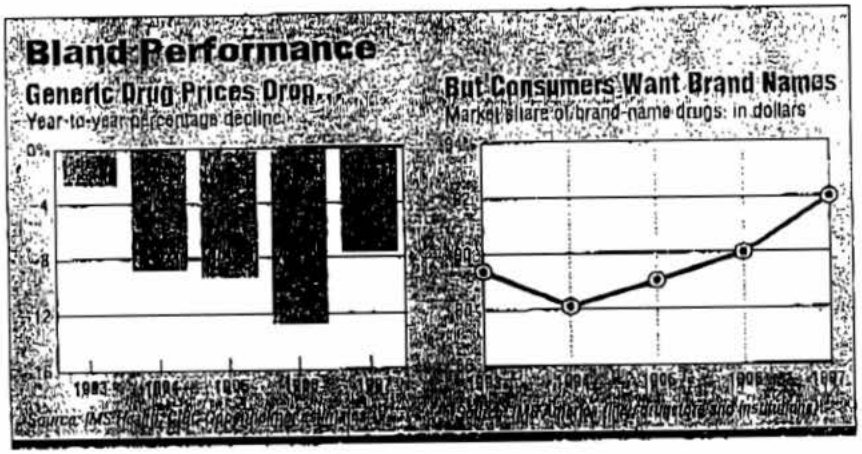
"You can't call all the physicians," says the FDA's Dr. Williams. "It effectively blocks generics." In North Carolina, where phone calls are required by law, generic warfarin recently made up 7.7% of the market. In Wisconsin, where switching can occur freely, the share was 25.3%.

In Chicago, a state council on generic medicines considered in late August whether switching to warfarin should be allowed. A pharmacist with the Group Health Cooperative in Redmond, Wash., Claudia Swenson, testified that 2,000 patients were successfully switched to generic warfarin without difficulty. "Our conclusion was that the two products were clinically the same," she testified.

DuPont's main outside witness was Steven M. Wilk, a Chicago suburban doctor who heads the Illinois Academy of Family Physicians. This group has received $160,000 from DuPont since 1986, though that fact wasn't mentioned at the hearing. Dr. Wilk testified he was concerned that doctors, not pharmacists, should oversee patients' care. "Physicians are quickly losing control," he testified. In a later interview with this newspaper, Dr. Wilk said he has no experience with any of his own patients switching.

In the end, the Illinois council prohibited druggists' switching prescriptions to generic warfarin. A member of the council, Robert Buckman, said that the group's role was to listen to Illinois doctors, explaining, "We've looked beyond the FDA."

The FDA's Dr. Williams sees it differently. To him, the scientific justification for restricting the generic came to this: "Absolutely none."



NBC News **Journal Link:** For more on the high cost of generic drugs, see NBC Nightly News With Tom Brokaw tonight on NBC.

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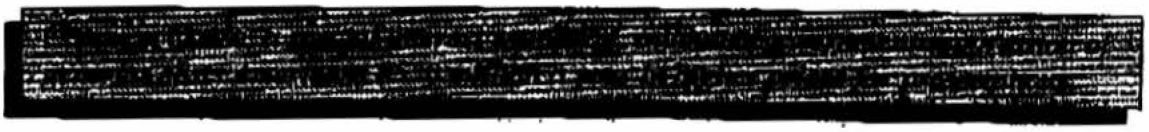
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ISSUE ANALYSIS

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Suppressing Generic Drugs Fleeces Consumers (and Lets the FDA off the Hook)

by Michael F. Cannon



Brand name pharmaceutical companies and federal and state governments are raiding consumers' pocketbooks by preventing them from buying generic drugs. Such restrictions can be an enormous financial drain, especially for low-income Americans and seniors who live on fixed incomes and pay for prescriptions out-of-pocket.

Generic drugs offer consumers more choices and keep prices down by competing with brand name pharmaceuticals, often at savings of 30 percent to 60 percent.[1] When government restricts access to generics, it forces consumers either to buy brand name drugs, which can cost one and a half to three times more, or to do without treatment altogether. This restriction also means higher costs for employers and unions (who provide health benefits); taxpayers (who fund government health programs); and individual consumers (especially seniors). According to Common Cause, a watchdog group that examines the influence of special interests on politics, government suppression of generics is costing Americans $550 million a year, hidden in higher prices for prescriptions.[2]

In effect, government restrictions on generics are hidden taxes that directly benefit brand name pharmaceutical companies. These companies lobby for restrictions on generics to offset the high costs imposed on brand names by the federal Food and Drug Administration (FDA). These companies also seek monopoly rents through lobbying for patent extension. Patents were intended to reward and encourage innovation. Extending patents that have already been granted do not create any additional incentives to innovate.

Michael F. Cannon authored this paper while a health care policy analyst at Citizens for a Sound Economy Foundation.

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[1] "Stock Prescription Drug Patent Extension in Appropriations Rider Would Increase Drug Prices for Seniors," Public Citizen press release, October 9, 1998.

[2] "Pocketbook Politics: How Special-Interest Money Hurts the American Consumer," *Common Cause News*, February 24, 1998.

SUPPRESSING CONSUMER ACCESS TO GENERICS

1. Extending Government-Granted Monopolies Keeps Generics Off the Market

- The federal government grants monopolies (20-year patents and periods of market exclusivity) to makers of new drugs, after which others may market generic versions. Much of that time is consumed getting the FDA's approval to market a new drug. Some argue the remaining monopoly period is not enough time to recoup the necessary investment, and therefore should be extended.

- One manufacturer spent over $1.5 million in the first half of 1998 to persuade Congress to extend one of their monopolies because their drug "was stuck in the [FDA] pipeline for . . . double the normal review time. All the drug company wants back is that lost time[.]"[3]

- However, it is the Food and Drug Administration's (FDA) lengthening approval process (now 15 years, up from eight years in the 1960s)[4] that eats up patent time. Extending monopolies merely hides that fact, shielding brand names from the cost of that "lost time" by passing it on to consumers. The root of the problem – the FDA's costly review process – is not addressed.

- One pharmaceutical giant has blocked generic versions of a highly effective cancer therapy by securing separate patents for different uses and ways of administering the drug — despite the fact that the government developed the drug at taxpayer expense.[5]

2. Holding up FDA Approval of Generics

- Brand names routinely file patent infringement lawsuits and FDA "citizens' petitions," which halt FDA consideration of generic rivals.

- Many "citizens' petitions" are frivolous (the FDA has rejected 83 percent of those filed against generics since 1990), yet can add years to a generics' approval time.[6]

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[3] Bill McAllister, "A Capital Way to Stop a Headache," *The Washington Post*, October 15, 1998, p. A21.

[4] Joseph A DiMasi, Ph.D., *et al.*, "New Drug Development in the United States from 1963 to 1992," *Clinical Pharmacology & Therapeutics*, 55(6):609-22, June 1994.

[5] Li Fellers, "Taxol Is One of the Best Cancer Drugs Ever Discovered by the Federal Government. Why Is It Beyond Some Patients' Reach?" *The Washington Post Magazine*, May 31, 1998, p. W10.

[6] Burton, *op. cit.*

- Brand names often sue for patent infringement even if the generic firm has no intention of going to market before the patent expires.

- The first generic to file for FDA approval can block out other generics for six months. Some brand names actually pay generic firms to delay this limited exclusivity period, which gives the brand name a longer period of complete exclusivity.[7]

3. Keeping Generics off Government Formularies

- Medicaid and Medicare have approved lists of prescription drugs, called a "formulary." Brand name manufacturers often try to keep generics off these formularies.

- In 1997, a pharmaceutical company filed a petition with the Massachusetts Drug Formulary Commission in an attempt to block the substitution of a generic version of their anticoagulant drug – a drug whose patent expired over thirty years ago, and whose price has increased by more than 400 percent.[8]

4. "Notification" and Other Regulatory Obstacles to Generics

- As a result of an ever-more-powerful regulatory regime, many pharmaceutical companies have found it more effective to shift their efforts to seeking profits through regulation, not competition.

- Brand name firms pressure state legislatures and Boards of Pharmacy to erect obstacles for patients who want generics.

- "Notification" laws require pharmacists to contact the prescribing physician before they make a generic substitution, despite the fact that physicians already may prevent substitution if they wish. According to an FDA official, a notification requirement "effectively blocks generics" because a pharmacist "can't call all the physicians."[9]

- One pharmaceutical giant hired a public relations firm to form a "patients' coalition" and launch a state-by-state campaign for "notification" laws to protect its market share of a blockbuster anti-coagulant. Where enacted, "notification" has driven generic market share below 8 percent, compared to 25 percent elsewhere. The firm alleges generics may not be equivalent to the original, a claim the FDA denounces as "false and misleading."[10]

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[7] *Ibid.*

[8] "DuPont Merck petition fails to block Barr's generic Coumadin anti-coagulant," *AFX News*, November 19, 1997.

[9] Burton, *op.cit.*

[10] *Ibid.*

Market Efficiency or Regulatory Profit? Blockbuster drugs can gross over $1 million in sales per day. Each day a firm extends its monopoly — each way it uses government to block its competitors — can mean millions in additional profits. Yet businesses that use the government to hurt their competitors make money at the expense of consumers, whose choices they restrict. Their profits are not a reflection of their value to society, but are in fact a measure of the cost of regulation. In this case, two factors drive the costs of regulation.

First, government constantly increases the cost of developing new medicines. The amount of time (15 years) and money (now $500 million) necessary to win approval of a new medicine continues to grow because the FDA is not held accountable for making patients wait too long or spend too much for prescription drugs.

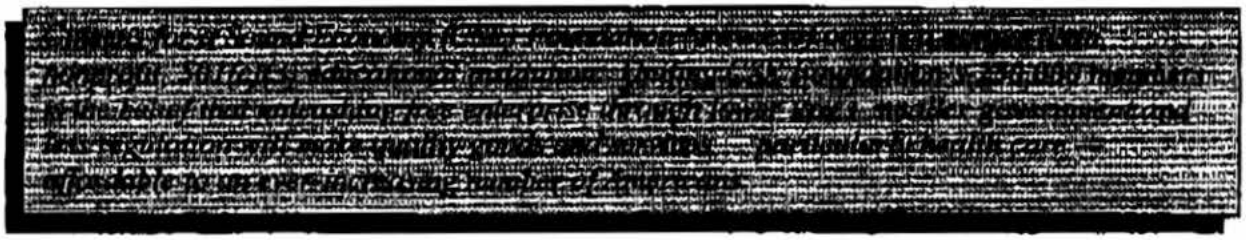
Second, convincing the government to regulate your competition is easier than convincing government to stop regulating you. Brand name firms are wary of angering the FDA with its $1 billion budget and power to bankrupt firms by slowing its review of their products. On the other hand, joining forces with government allows brand name firms to pass costs along to less organized interests (patients and other payers) and potential competitors (generics). Ultimately, this is a shortsighted strategy that creates an expanded FDA with more regulatory oversight.



It may be that brand names are not adequately rewarded for their investment in new medicines. But allowing them to shake down consumers for millions of dollars is not the answer. If makers of pioneer drugs are unable to make a profit without using government to block their competition, perhaps it is time to reexamine the costs the FDA imposes on these innovators.

Before government and the pharmaceutical industry injure more patients with further regulation, consumers should press both lawmakers and industry to curb the ever-expanding FDA bureaucracy.

Consumers should push for reforms that increase the resources available for drug approvals without sacrificing high safety standards. Private institutions (such as medical schools, peer-reviewed medical journals and the *U.S. Pharmacopeia*) already certify the safety and efficacy of "off-label" drug therapies. Congress should strengthen this process, eliminating the FDA's ban on "off-label" medical speech. Further, Congress should outsource initial FDA reviews to these and other private institutions (*e.g.* Underwriter's Laboratories, medical associations). These reforms would also lower the regulatory costs imposed on brand name and generic firms, but most of all, on consumers.



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Thank you Buddy. Thank you to GPIA chairman Marvin Samson and President Dr. Alice Till. Thank you to all of the members of the Generic Pharmaceutical Industry Association.

Well, I'm back.

Last year – when very few people thought I would be a United States Senator, you were kind enough to invite me to your convention and I spoke to you about my support for the generic drug industry.

Last year we were both underdogs, but I feel very optimistic about the future. And I want to thank GPIA for supporting me and being a friend when only a few had faith.

Now that I am in the Senate, I am very excited by the idea of helping consumers purchase less expensive generic pharmaceuticals. Last month, I met with Buddy Menn, Marvin Samson, and some of the officers of the leading generic companies -- I won't name names and give away trade secrets -- but we spent an hour talking about the challenges and opportunities in the Congress. We had a great meeting with a lot of creative ideas, and I cannot wait to get started.

Let me begin with my basic philosophy. I believe in good, old-fashioned American competition. I support Hatch-Waxman and I support the GATT provisions that give brand name pharmaceuticals an exclusive patent for a period of time to cover their R&D costs and to earn a healthy profit. That is fair.

But I also believe that 20 years is 20 years. I believe that when the exclusive patent period expires – it expires. And when it is time to open up to generic competition – there should be competition.

Let's look at the broader picture. Few segments of our economy are changing as rapidly as the health care sector. Few public policy debates will impact as many Americans as the health care debate that is underway in the Congress, in state capitals, and in corporate board rooms.

And there is a natural tension to the debate. On the one side we want to contain costs for consumers, businesses and government. On the other side we want to improve coverage.

What I hear from constituents in New York reflects what is happening across America: Patients sense they are getting less than they deserve; hospitals and doctors feel they are being squeezed by the budget and reporting requirements of insurers. This year, for the first time since 1993, health plan costs have increased faster than inflation. And costs are expected to continue to increase faster than inflation far into the future. One the biggest cost drivers is prescription drugs.

There is only one way that I know of to do reduce cost and increase care and that is to guarantee that low-priced generic drugs are available to every consumer. That is why I supported Hatch-Waxman in 1984. And that is why I blew the whistle when Congress tried to extend the patents of certain brand-name drugs in last year's budget bill.

Let me say a word about the brand name pharmaceutical companies. They have made a tremendous contribution to the economy and health of our nation. Their innovations and products have helped treat those suffering from depression, hypertension, heart disease, and diabetes. They have saved lives and I tip my hat to them.

They have also earned quite a profit from their work. According to the Wall Street Journal, profits for American drug manufacturers are expected to increase by 18 percent per year between now and 2002, a pace well above most industry sectors.

Second, no procedure – whether it's the citizens' petition or the orange book should have the effect of stopping the clock and keeping generics from coming to market. The citizens' petition has been abused, we all know it. The original purpose of allowing consumer organizations a voice as a watchdog in the approval process has long been lost. There must be no part of the process that is used simply to put up a roadblock.

Third, once FDA approves a generic drug, no state should be able to prevent the generic from coming to market. We cannot have 50 FDAs in 50 states especially when the sole purpose is to delay the approval of drugs that are identical in every way to the brand name, except price.

Fourth, to save federal dollars we should create an incentive system in Medicare, Medicaid and the VA that encourages our nation's largest health care providers to use generic drugs when they are available. One method would be to reimburse pharmaceuticals at only the generic price. A second method is to charge a smaller co-payment to beneficiaries who choose a generic drug at the pharmacy. I will push both measures.

And fifth, I want to limit the amount of time that FDA has to answer challenges from the brand name industry. I don't know what the appropriate amount of time is – whether it's three months or three years – but there must be a time limit so that no loophole has the effect of indefinitely keeping generic drugs off the market.

With medical costs rising again, with the aging of our population, and cost pressures we are facing with Medicare and Medicaid, there is no better time to press ahead and make sure that less expensive generic equivalents are on the market.

I look forward to coming back to the GPIA to commemorate the victories we won for consumers and taxpayers.

That's terrific. I don't begrudge them their profits -- so long as the playing field is fair.

But a level playing field means that they should not be shielded from competition when their exclusive patent rights come due.

U.S. consumers pay $550 million more each year because the brand name companies have exploited loopholes in the law to keep generics from the market. That's $550 million that senior citizens, parents with children and taxpayers shelled out for drugs that could have been – that should have been -- available for a cheaper price.

So when I look to my constituents and to the cost crises in Medicare, Medicaid and the VA -- one of the most important things we can do in Congress is ensure that the $42 billion in brand name pharmaceuticals that are due to lose their exclusive patents over the next twelve years, in fact, end their monopoly hold on the market and face generic competition.

At minium – at minimum, generic competition will save consumers $15 billion over the next twelve years. And that is on top of the $8 billion dollars that consumers save every year because of generics.

So here are my priorities for this Congress:

First, no patent for a brand-name drug should be extended through rifle shot legislation. A two year extension for Daypro was hidden into an emergency stop-gap budget bill. Three attempts were made to extend the life of Lodine, each time in a bill authored by members of Congress who have no jurisdiction over health care or patent law.

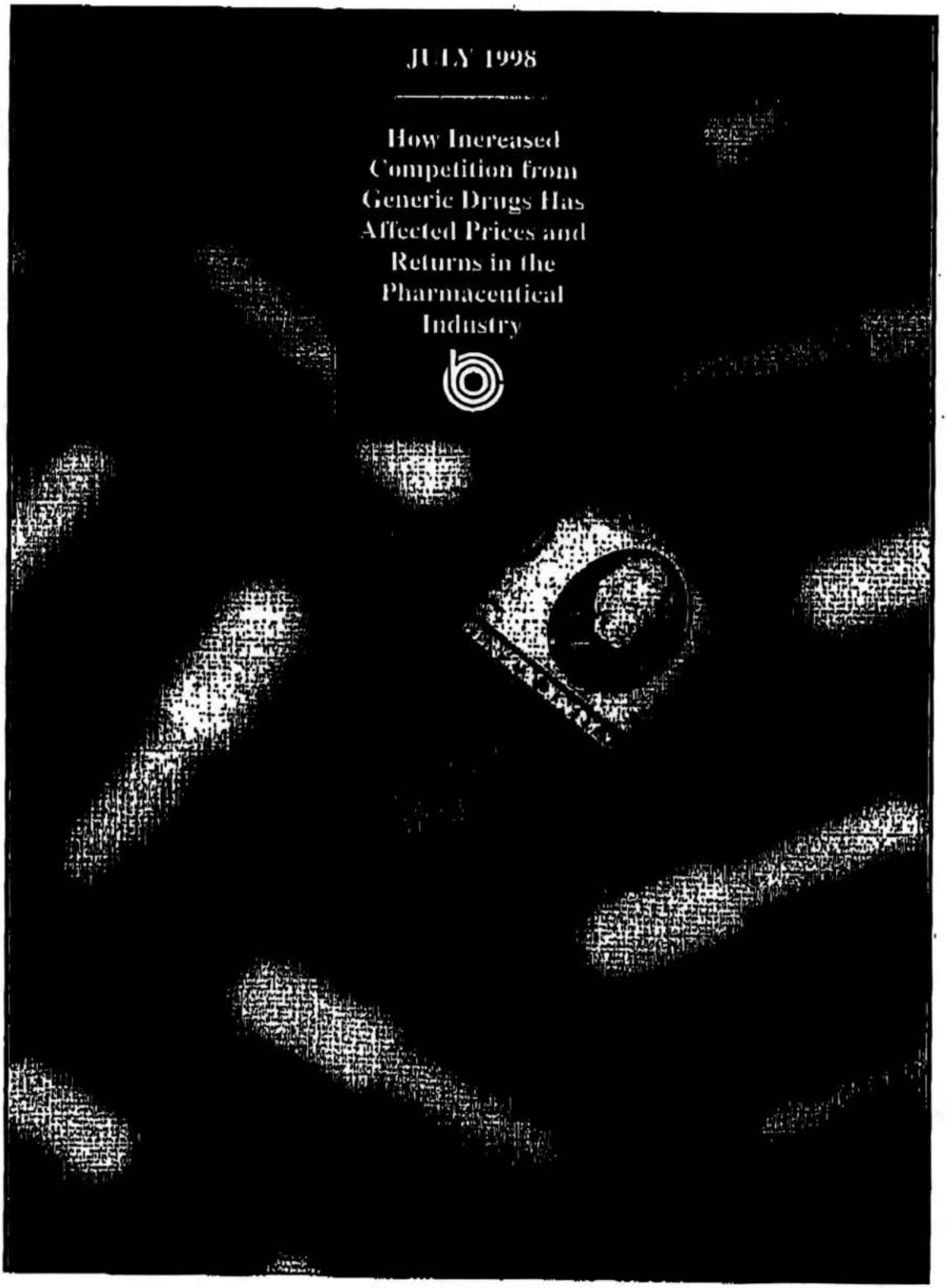
The law needs to be changed. Any time a patent is extended through legislation it should have to pass a series of tests and go through extensive hearings in Congress that demonstrate the necessity of an extension.

CONGRESS OF THE UNITED STATES
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JULY 1998

How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry

Chapter Three

Pricing and Competition in the Pharmaceutical Market

The federal government has competing policy objectives with respect to the pricing of prescription drugs. On the one hand, it wants to ensure that companies have enough incentive to invest in researching and developing innovative drugs. On the other hand, it wants to discourage them from charging excessively high prices. In general, the government achieves the first goal through a patent system that grants market exclusivity for a limited period of time, allowing companies to recoup their investment in R&D. For the second goal, it relies on competition between similar drugs to hold prices down.

This chapter examines price competition among manufacturers in the pharmaceutical market, including the impact of the dramatic growth in the generic drug industry since 1984. Such competition comes in three main forms: between brand-name drugs in the same therapeutic class, between brand-name drugs and their generic counterparts, and between different generic versions of the same drug. The pharmaceutical industry is also affected by other types of competition, such as the substitution that sometimes occurs between prescription drugs and other forms of medical treatment. However, the conditions under which prescription drugs can be substituted for other medical procedures are outside the scope of this study.

The patent system provides a period of protection during which manufacturers of innovator drugs can charge relatively high prices, earning profits that enable them to compensate for the costs of a drug's discovery and development. Although patents prevent other manufacturers from producing the same drug, they do not prevent manufacturers with a similar but slightly different drug from also obtaining a patent and entering the market. Limited empirical evidence suggests that the availability of several similar brand-name drugs tends to slow the rate of price growth, even before generic copies become available.

The dramatic rise in generic sales since 1984 has held down average prices for drugs that are no longer protected by a patent. However, those lower prices tend not to result from reductions in the price of the original brand-name drug when it begins facing competition from generic drugs. Rather, average prices fall primarily because consumers switch from the higher-priced innovator drug to the lower-priced generics. To be on the receiving end of that switch, generic manufacturers compete with each other intensely in the area of price, partly because they sell identical products.

The increased use of generic drugs has kept total spending on prescription drugs below what it might otherwise have been. Considering only drugs sold through retail pharmacies, the Congressional Budget Office (CBO) estimates that the purchase of generic drugs reduced the cost of prescriptions (at retail prices) by roughly $8 billion to $10 billion in 1994. That estimate assumes that all generic prescriptions dispensed would have been filled with a higher-priced brand-name drug if the generic was not available.

FDA approval before the patent on the innovator drug they were copying had expired. Those changes both increased the probability that a generic copy would become available after patent expiration and reduced the average delay between patent expiration and generic entry from more than three years to less than three months.

As generic drugs are substituted for their more expensive brand-name counterparts, the average price of a prescription falls. In CBO's retail pharmacy data set, the average retail prescription price for a brand-name drug with generic substitutes was $37 in 1994. However, including prescriptions that were filled with a generic drug, the average prescription price for a multiple-source drug was only $26. Thus, generic substitution lowered the average cost for a multiple-source prescription by $11. That result is only a rough estimate, however, since prescriptions may somewhat misrepresent the relative quantities of brand-name and generic drugs sold. For example, if generic drugs tend to have more pills dispensed per prescription than their brand-name counterparts, that estimate would understate the degree to which generic substitution reduces the average cost of a prescription. If generic drugs tend to have fewer pills dispensed, the reverse would be true.

Effect of Generic Entry on Sales

For many innovator drugs whose patents have recently expired, generic copies quickly gain a large share of the market. CBO's retail pharmacy data set includes 21 innovator drugs whose first generic competitors entered the market between 1991 and 1993. During the first full calendar year in which those 21 drugs faced generic competition, generics already accounted for an average of 44 percent of prescriptions dispensed through pharmacies.[49] Generics also cost one-fourth less than the brand-name drugs, on average, at retail prices. For seven of those drugs (Anaprox, Feldene, Lopid, Naprosyn, Pamelor, Tavist, and Xanax), generics had gained 65 percent or more of the innovator's market by 1994. For all but two of the 21 drugs, generic entry occurred within one year of patent expiration, and in many cases within three months.[50]

Other studies examining the size of the generic market after patent expiration have yielded slightly different results. Those appear to be attributable to differences in the sample of drugs studied as well as to small differences in method. A study by Grabowski and Vernon found that 11 drugs whose patents expired between 1989 and 1992 had an average generic market share (measured by quantity sold) of 50 percent in the first year after generic entry, and eight drugs whose patents expired in the 1986-1987 period had an average generic market share of 38 percent.[51] The study also found that the wholesale price of generic drugs was about half that of brand-name drugs in the first year after generic entry.

Grabowski and Vernon's average generic market share for the 1989-1992 period is higher than that measured by CBO for the 1991-1993 period in part because CBO included the quantity sold of all dosage forms of the brand-name drug, even those for which generic entry had not occurred, when calculating the percentage of total prescriptions filled with a generic drug. That method takes account of the option that brand-name manufacturers have to introduce a new dosage form (such as an extended-release capsule) just as a drug's patent is about to expire, so as to benefit from a three-year exclusivity period on that dosage form. Occasionally, manufacturers can even get a separate patent on a new dosage form. Of the 21 brand-name drugs that CBO analyzed, four had an advanced dosage form (Sinemet CR, Cardizem CD, Toprol XL, and Procardia XL) that was not yet available from generic manufacturers.

The Congress's former Office of Technology Assessment (OTA) also studied the erosion of brand-name drug sales after patent expiration.[52] In OTA's study of 35 brand-name drugs that lost patent protec-

49. The 44 percent average is weighted by sales revenues of the innovator drugs. The unweighted average is 42.8 percent.

50. The two drugs for which generic entry took more than a year after patent expiration had retail pharmacy sales of about $130 million in 1991.

51. Henry Grabowski and John Vernon, "Longer Patents for Increased Generic Competition in the U.S.: The Hatch-Waxman Act After One Decade," *PharmacoEconomics* (1996).

52. Office of Technology Assessment, *Pharmaceutical R&D*, Table F-3, p. 297.

The Survey

A Telephone Poll of Prescription Drug Issues & Usage Among Older Americans

By Richard Kriner, PhD

In September of 1995, the American Association of Retired Persons (AARP), the National Pharmaceutical Council, and *Pharmaceutical Executive* magazine collaborated on a survey of issues related to the usage of prescription drugs among U.S. patients aged 50 and older. The survey was conducted by AUS/ICR on their EXCEL weekly omnibus telephone survey. It asked questions on prescription drug issues of 874 persons (438 aged 50–64 and 436 aged 65 and older).

Results were weighted to reflect the U.S. population aged 50 and older. The margin of error for the total sample is plus or minus 3.5 percent at the 95 percent confidence level. For the subsamples aged 50–64 and 65+, the margin of error is plus or minus 4.5 percent.

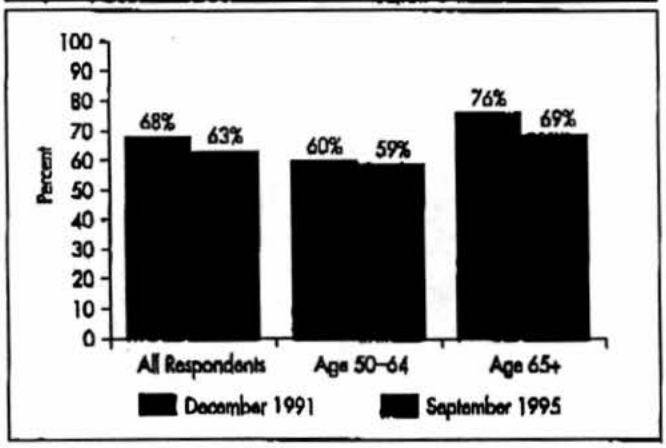
This article reports on those results, drawing clear implications for pharmaceutical companies and other health care players in meeting the needs of older prescription-drug users. Issues of patient compliance, education, and economics stand out prominently in the survey. (See "Survey in Summary.") Where appropriate, the report compares data from this survey with an earlier AARP survey conducted in 1991. Industry responses to these findings appear on page 80.

BASIC USES

In profiling the use patterns of two major age groups, the survey found that, compared to 1991, prescription-drug use is still higher for those who are 65+ than for the 50–64 age group, but the percent of the older group using prescriptions is down slightly. (See

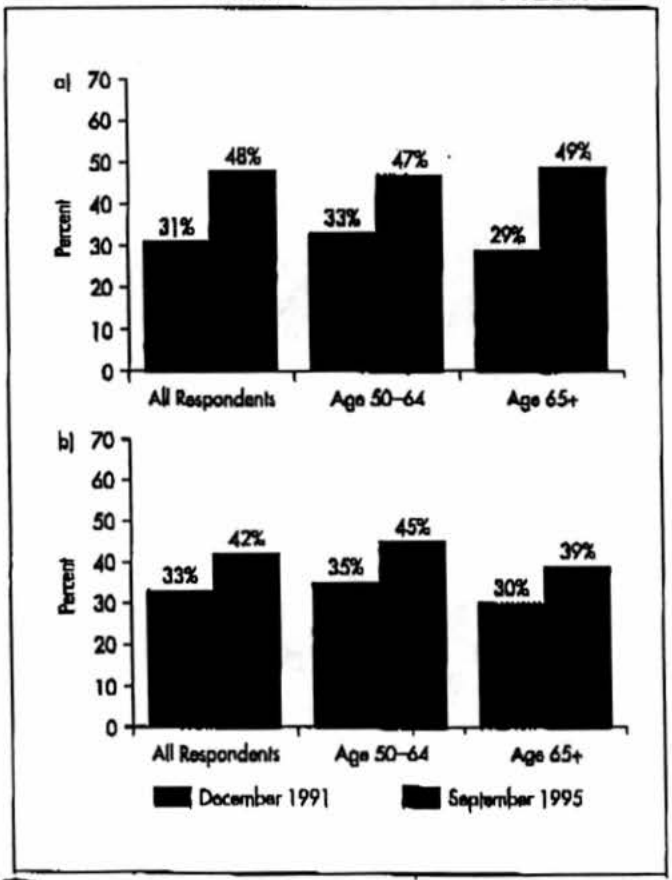
Richard Kriner, PhD, is former director of the survey design and analysis department in the research division of AARP.

MORE MEDICINE



Prescription-drug use is still higher for 65+ than for the 50–64 age group, but the percent using prescriptions is down from 1991. The figure shows the percent reporting use of any prescription drugs.

GENERIC REQUESTS



Requests for generic versions are up from 1991. The top graph (a) shows the percent of respondents who ask their doctor for a generic version of a prescription; the bottom (b) indicates the percent who ask the same of their pharmacist.

"More Medicine.") Among patients aged 50 and older, 63 percent say they are currently taking one or more prescription drugs. On average, those patients are currently taking two prescription drugs.

Those 65 and older are currently taking an average of 2.4 prescription drugs, considerably higher than the 1.7 average for the 50–64 age group and slightly higher than the 2.1 average for the 65+ group in the 1991 survey. However, the percentage of those 65 and older currently taking prescription medicine (69 percent) is slightly down from the 76 percent reported in 1991.

Requests for generic versions of prescription drugs are up from 1991. (See "Generic Requests.") Nearly half (48 percent) of respondents aged 50+ say they have requested generic versions of their prescription medicines from their doctor in the past—and nearly 3 in 10 (28 percent) say they always do so. This result is consistent for both the 50–64 and the 65+ age groups and is up significantly from the 1991 survey, when about one-third said they had requested generic versions of medications from their doctor. Requests of pharmacists for generic versions are also on the rise, with about 4 in 10 (42 percent) making such requests compared to one-third (33 percent) in 1991.

Though few respondents report problems with their medicines, there is some noncompliance. (See "What Problems Did You Have?") Most patients 50 and older (86 percent) have not encoun-

SURVEY IN SUMMARY

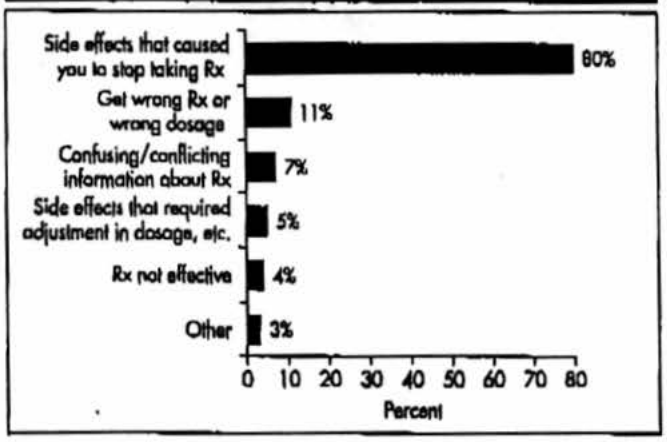
In September of 1995, the American Association of Retired Persons (AARP), the National Pharmaceutical Council, and *Pharmaceutical Executive* magazine collaborated on a national telephone survey of a representative sample of Americans aged 50 and older on their use of and attitudes toward prescription medicines. The survey, which tracked several issues from a similar 1991 AARP survey, addressed topics concerning information needs and sources regarding prescription medicines, use of generic versions of drugs, and the costs of medications. The following are highlights of the survey results.

- Americans aged 65 and older are currently taking an average of 2.4 prescription drugs, noticeably higher than the 1.7 average for those 50–64 and up from the 2.1 average reported by the 65+ age group in the 1991 survey. As in 1991, the average for women aged 50+ is somewhat higher than for men (2.4 versus 1.6).
- In 1995, more Americans aged 65+ say they have insurance that helps cover the cost of prescription drugs than was found in the 1991 survey (63 percent versus 49 percent). For those aged 50–64, there is only a slight increase in the percentage saying they have this coverage (74 percent versus 69 percent).
- More 50+ Americans in 1995 are asking their doctor or pharmacist for generic versions of their prescriptions than in 1991 (48 percent versus 31 percent asking their doctor; 42 percent versus 33 percent asking their pharmacist).
- Americans 50 and older still rely heavily on their doctor (77 percent) and/or their pharmacist (64 percent) for information about their prescription medicines—more so than in 1991, although the questions asked were slightly different.
- A great majority (86 percent) say they have encountered no problems with their prescription medications. However, 1 in 7 (14 percent) do report having had some problem in the past two years, and by far the most frequently mentioned problem (80 percent) involved side effects that caused them to stop taking their medications.
- About 4 in 10 Americans aged 50+ have, over the past two years, chosen not to comply fully with the doctor's prescription orders by either discontinuing the prescription before it ran out, taking less than prescribed, filling the prescription but deciding not to take it, or not filling the prescription at all.

Persons aged 50–64 are somewhat more likely not to comply (47 percent) than are those age 65 and older (39 percent). And in 1995, women were more likely than men (49 percent versus 35 percent) to fail to comply fully—a change from 1991 when there was no difference between men and women in the level of noncompliance.

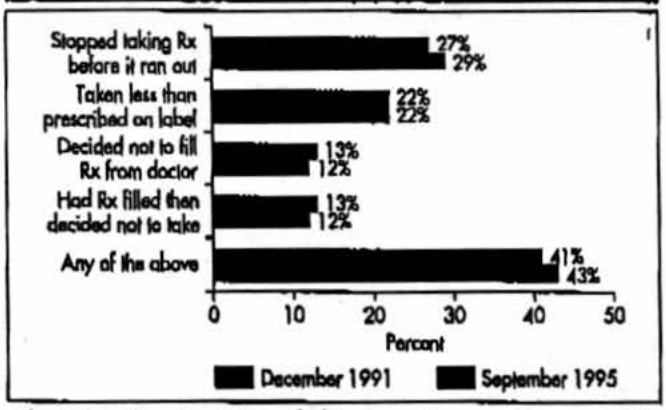
- Although most Americans aged 50+ (65 percent) say they did get written information with their last new prescription, 1 in 5 (22 percent) did not receive any. Those who did get this information generally obtained it from their pharmacist (85 percent), and 82 percent of them say it included information about possible side effects.
- Nearly 4 in 10 Americans aged 50 and older say that the types of information that would be most helpful to them are clear descriptions of the benefits and risks, including side effects, of their prescription medicines.
- In the 1991 survey, the great majority (70 percent) believed there should be someone keeping track of all the prescription medicines they take. But in the current survey, half (50 percent) of Americans aged 50 and older did not have anyone who reviewed all of their prescription and over-the-counter medications with them. For those who did, it was generally their doctor (69 percent) or, to a lesser extent, their pharmacist (44 percent).
- Low-income Americans are having even more difficulty today paying for their prescription medications than in 1991. Today, nearly 4 in 10 (37 percent) Americans 50 and older with annual incomes under $10,000 say they have sometimes had to cut back on necessary items such as food or heating fuel to pay for a prescription. That is significantly higher than was found in the 1991 survey when 2 in 10 (19 percent) said they sometimes had to make the same sacrifice to pay for a prescription.
- Only one-fifth of these low-income older Americans are aware that some drug manufacturers offer prescription medicines free of charge to low-income patients. Getting word out to these people about such programs could help prevent having to make a trade-off to get a prescription filled.

WHAT PROBLEMS DID YOU HAVE?



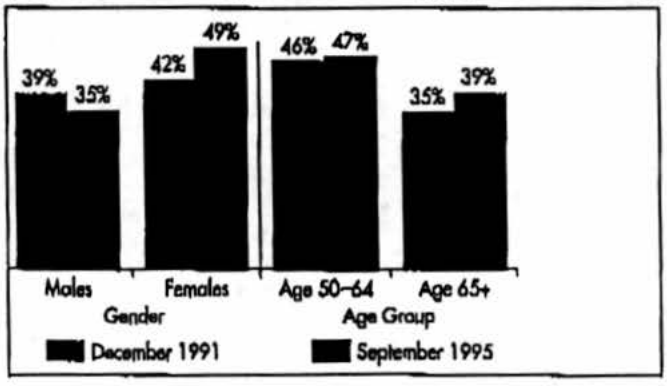
Though only 14 percent of total respondents encountered problems with their prescriptions in the past two years, those who did cited the above.

IN THE PAST TWO YEARS HAVE YOU EVER . . .



About 4 in 10 patients 50 and older have chosen not to comply fully with their doctor's prescription orders over the past two years.

SPLITTING DIFFERENCES



This chart shows, by gender and age, the percentage of respondents with any mention of noncompliance during the past two years.

tered any problems with their prescription medicines in the past two years. That applies equally to the 65 and older age group (85 percent) and the 50–64 age group (86 percent). However, among those who have experienced a problem (14 percent), by far the most frequently mentioned one was side effects that caused them to stop taking their medication (80 percent). Other problems were mentioned by fewer than 1 in 8.

More than 4 in 10 of the surveyed 50+ Americans (43 percent) have, over the past two years, chosen not to comply fully with their doctor's prescription orders either by discontinuing the prescription before it ran out (29 percent), taking less than prescribed on the label (22 percent), deciding not to fill the prescription (12 percent), or having the prescription filled but deciding not to take it (12 percent). (See "In the Past Two Years Have You Ever . . .")

Those 65 and older are somewhat less likely (39 percent) than those 50–64 (47 percent) to decide not to comply with the doctor's requirements. (See "Splitting Differences.") In 1995, women were more likely than men (49 percent versus 35 percent) to fail to comply fully with the doctor's prescription orders.

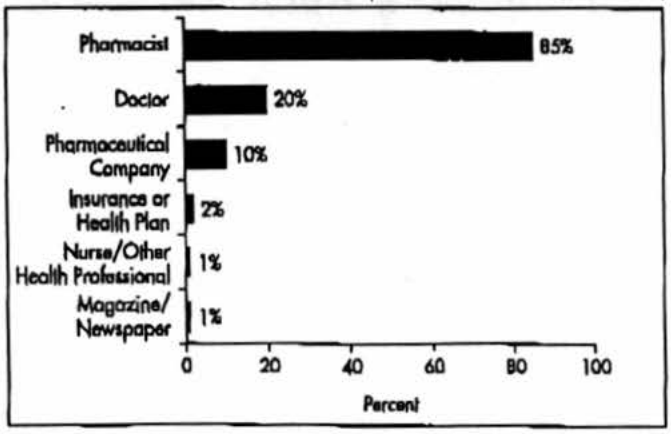
That represents a change from 1991, when there was essentially no difference between women and men (42 percent versus 39 percent) in their rates of noncompliance. In 1991, the reasons given for noncompliance were equally split between improvement in the condition for which the medicine was prescribed (42 percent) and side effects of the medication (40 percent).

NEED FOR INFORMATION

About a quarter (26 percent) of those surveyed who have used prescription drugs said they did not receive any written information with their most recent prescription. The majority of those who did get written information said they received it from their pharmacist. (See "Info Givers.") Others said they received it from their doctor (20 percent) or the pharmaceutical company (10 percent).

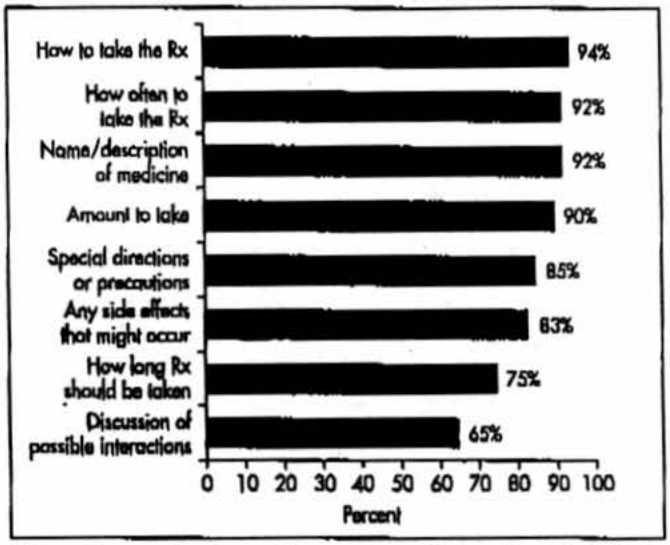
Those who received written information with their last new prescription were asked to indicate whether it included certain

INFO GIVERS



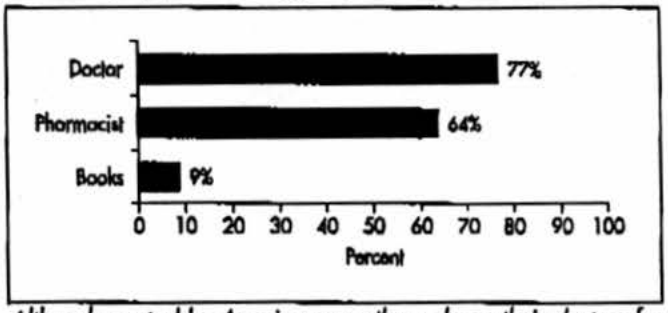
Most of those surveyed primarily receive written prescription-drug information from their pharmacist.

DID THE INFORMATION INCLUDE . . .



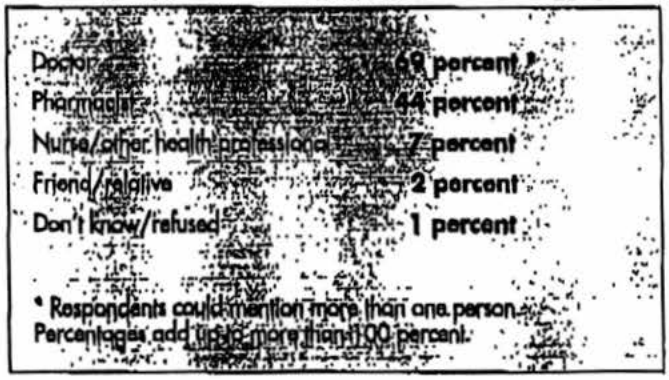
Information on drug interactions was least likely to be included with prescriptions, according to respondents who received written material with their last prescription.

RELIABLE SOURCE



Although most older Americans say they rely on their doctors for information, they actually receive written information from their pharmacist more often. (Based on 1995 figures only.)

WHO REVIEWED YOUR MEDICINES WITH YOU?



topics. (See "Did the Information Include . . .") For the most part, the written material did include information on how to take the medicine, how often to take it, the name or description of the medicine, and the prescribed dosage. Information on possible drug interactions was least likely to be included according to respondents who received written material (65 percent).

Although the pharmacist is clearly most often the one to provide written material, a doctor is the most frequently mentioned source that older Americans say they rely on for information about their prescription medicines (77 percent), followed by their pharmacist (64 percent). (See "Reliable Source.") Clearly there is a difference between the source of written material accompanying a new prescription and the source upon which most 50+ Americans say they rely.

When asked what kind of information would be most helpful to them in taking their medications, nearly 4 in 10 Americans aged 50+ mentioned information covering the benefits, risks, and side effects of the specific medicines. (See "Need to Know.") Other types of information mentioned as helpful were descriptions of potential interactions, a printed schedule of all their medications, information about the conditions for which the medicine is prescribed, and how and when to take the medication.

In the 1995 survey, respondents were also asked whether anyone had reviewed all of their prescription and OTC medications with them the last time they received a new prescription. (See "Who Reviewed Your Medicines with You?") Well over half (57 percent) who have used prescription medicines said they did not have such a review. Among the 4 in 10 who said they did have one, the majority (69 percent) said it was their doctor who reviewed the medicines with them. About 4 in 10 (44 percent) said their pharmacist completed the review with them.

ECONOMIC CHOICES

Most respondents have prescription-drug coverage, but some are having to make sacrifices to pay for medicines. (See "Payment Privileges.") In 1995, 7 in 10 of Americans over 50 (69 percent) said they were covered by insurance that helps to pay for prescription drugs, up from 60 percent in 1991. Although up from 1991, Americans 65 and older are still less likely to have coverage for prescription costs (63 percent) than those in the 50–64 age group (75 percent).

Coverage is also clearly related to income. (See "Incoming Prescriptions.") Those with annual incomes under $10,000 who had insurance coverage for prescriptions rose from 33 percent in 1991 to 47 percent in 1995. For those with incomes of $30,000 or more, the figure rises to 80 percent or higher. Though more low-income 50+ Americans (income under $10,000) have obtained prescription-drug insurance coverage, there has been a significant rise in the proportion who said they have had to make some sacrifices to pay for prescriptions. That suggests there may be some question regarding the adequacy of coverage that people have obtained.

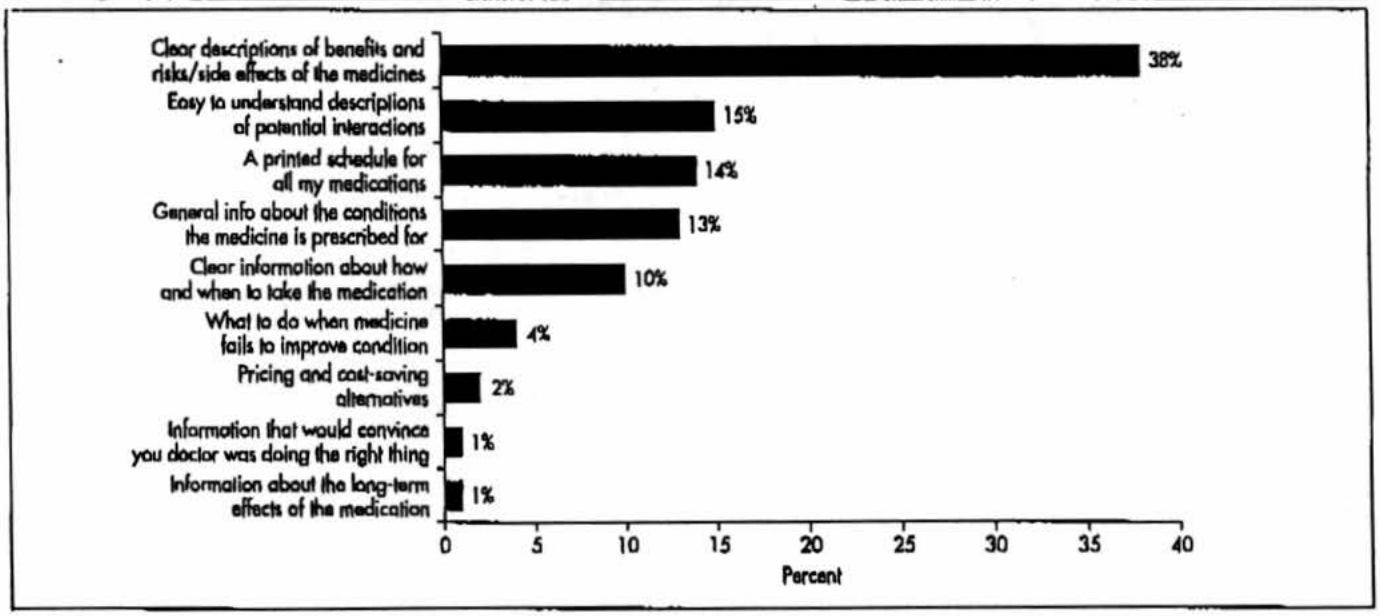
In 1995, nearly 4 in 10 (37 percent) of those low-income Americans said they have had to occasionally cut back on other basic

needs like food or heating fuel to be able to afford drugs. (See "Food or Medicine?") That is a significant increase from 1991, when 1 in 4 (25 percent) said they had made such a sacrifice. A 1994 survey of poor and near-poor persons 50 and older found that 33 percent of Americans 50–64 with incomes at or below 125 percent of the U.S. poverty threshold—$12,000 for a married couple with no children—said there had been times in the past year when they could not afford to pay for a prescription medicine. (AARP Research Division, 1994.)

In 1995, over a quarter of 50+ Americans (26 percent) were aware that many drug manufacturers offer prescription medications free of charge to low-income persons. (See "Knowledge Is Power.") Those with annual incomes under $15,000 had a significantly lower level of awareness of these programs (20 percent) than those with annual incomes of $50,000 or more (33 percent)—indicating that those for whom such benefits are intended are the least aware of the programs.

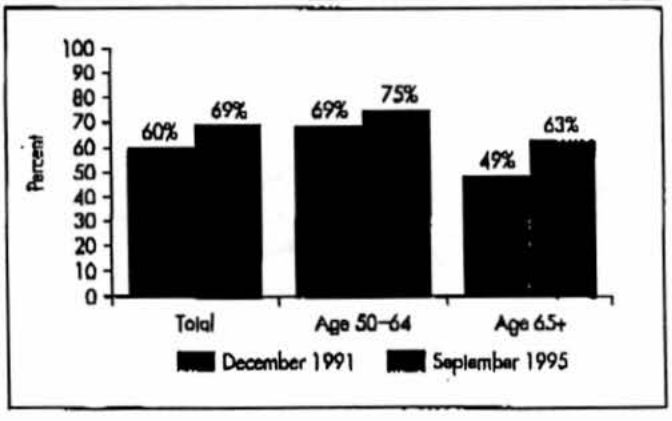
Similarly low levels of awareness of federal and local programs to assist low-income persons were found in the 1995 study of poor and near-poor Americans aged 50 and older. When asked if they had ever received prescription medications free through one of

NEED TO KNOW



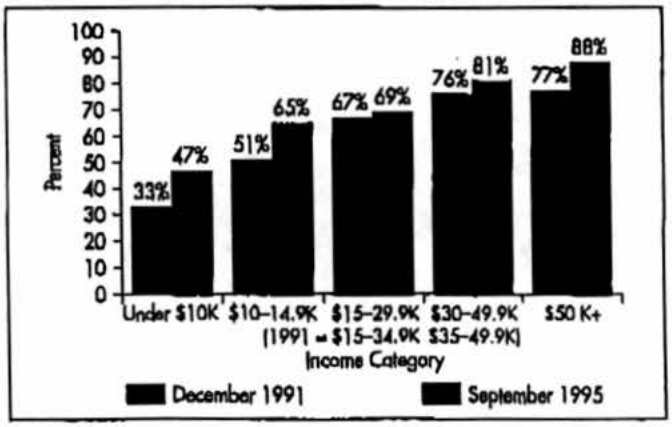
When asked (on an open-ended basis) what kind of information would be most helpful in taking medication, respondents indicated the above areas.

PAYMENT PRIVILEGES



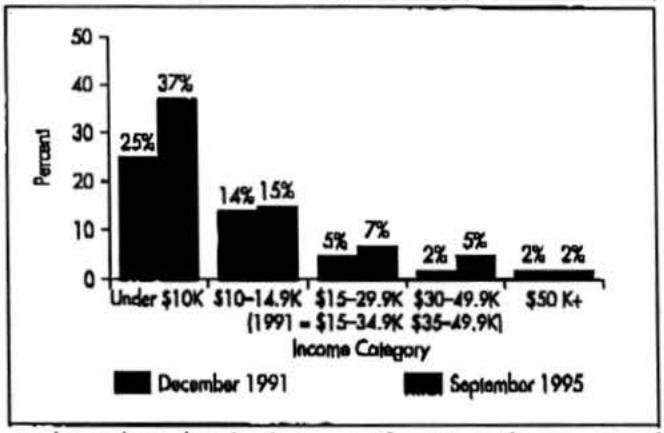
Most 50+ Americans have insurance coverage that helps pay for prescription drugs, but some may go without.

INCOMING PRESCRIPTIONS



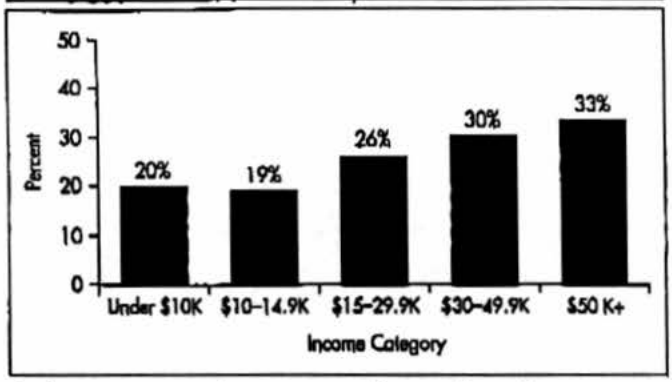
Percentage of those with prescription-drug coverage by income category.

FOOD OR MEDICINE?



As shown above, there has been a significant rise in the proportion of low-income patients 50 and older who said they have had to cut back on food or heating to afford prescriptions.

KNOWLEDGE IS POWER



By income category, the percentage of respondents who were aware that many drug manufacturers offer prescription drugs free of charge to low-income patients.

these programs offered by a drug manufacturer, only 1 percent or less within any income category said they had ever done so.

DRAWING AIM

Although several aspects of older Americans' use of and attitudes about their prescription medicines have changed little since 1991, there are some noteworthy exceptions. It is useful to highlight some of those points, because they suggest opportunities for pharmaceutical company responses.

Requests for generic versions of prescription drugs have significantly increased since 1991 among U.S. patients aged 50 and older. Faced with rising health care costs and an increasing availability of generic versions of many prescription medicines, that trend will undoubtedly continue.

For U.S. patients 50 and older and earning less than $10,000 annually, the cost of prescription medicines is an even bigger problem than in 1991. In 1995, nearly 40 percent—and 15 percent of those with incomes of $10,000–15,000—said they had to cut back on food or heating to pay for their prescriptions. Low-income older Americans are also the least aware of many of the programs and services available to them. That is clearly the case regarding awareness of programs that some pharmaceutical manufacturers offer to allow low-income persons to receive prescription medicines free of charge.

The information needs of the 50+ prescription-drug consumer still focus on the benefits and risks—and especially concerns about potential side effects—of their prescription medications. Though most are getting written material covering many of their information needs, discussion of possible interactions and potential side effects are less often received than other information. Moreover, though most 50+ Americans have had no problems with their prescription medications, those who have had difficulties most often said they had to do with side effects that caused them to stop taking the medication.

Some kind of noncompliance with their doctor's prescription orders occurs for about 4 in 10 Americans aged 50 and older at about the same rate as in 1991, and at a higher rate for women than for men. Noncompliance can include anything from stopping a medication before it runs out because the patient's condition improves to deciding not to fill a prescription from the doctor. But complete compliance with a doctor's prescription orders can be a critically important issue.

Concerns about side effects and potential drug interactions, as well as questions about compliance with prescription orders, point to a continuing need for physicians and the industry to provide prescription-drug consumers with as much clear information as possible. And though doctors are the ones on whom most patients rely for this information, pharmacists are a close second as an information source. A major challenge for AARP, the pharmaceutical industry, and medical professionals is the continued effort to provide improved information to the 50+ U.S. population regarding prescription medications and all of the issues related to their use and to leading healthier and longer lives. ■

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FROM: Diane Doman

NO. OF PAGES 8

Comments: Background from WSJ and conservative think tank re the brand industry to block generic competition. See last page of WSJ for citizen petition and Coumadin (nat. unpriv) examples.

Response:

ARE YOU READY FOR THE NEW MILLENIUM?
GPIA's Annual Meeting 2000

New Date May 9-11, 2000
New Location Omni Shoreham Hotel
Washington, DC

Bested Interests

Why Generic Drugs Often Can't Compete Against Brand Names

Lower Prices Aren't Enough To Overcome Demand For 'New and Improved'

Doctoring the Applesauce

By THOMAS M. BURTON
Staff Reporter of THE WALL STREET JOURNAL

When Congress passed legislation in 1984 smoothing the way for fast marketing approval of low-cost generic drugs, one major intent was to reduce inflation in pharmaceutical costs.

Since then, generics have grown from 18% to 42% of all prescriptions written in the U.S. Generic drugs such as "beta-blockers" for preventing heart attacks are embraced as the medical standard of care.

So why are drug costs higher than ever?

In the personal-computer industry, it was the clone makers that ultimately won. But so far, big drug companies are staying one step ahead of their clone-making generic rivals at every turn.

Even as generic copies of popular brand-name medications like Prozac and Procardia are being planned for when the patents on these drugs expire, big pharmaceutical companies are developing the next generation of expensive, brand-name antidepressants and heart pills. To ensure demand for their new products, the pharmaceutical titans promote their drugs with direct-to-consumer advertising—an estimated $10.8 billion in ads and promotions this year alone, and growing. Behind the scenes, they employ an arsenal of legal and regulatory tactics so that generics don't make more headway.

HARD TO SWALLOW
America's Soaring Drug Costs
PART OF A SERIES

While generics have managed to prosper in certain categories like asthma treatment—where the only competition is from older brand-name drugs that are directly equivalent—they are consistently slammed in categories where a new, heavily marketed brand-name drug has entered the picture.

Witness how Astra Pharmaceuticals LP of Wayne, Pa., has beaten back generic heartburn and ulcer remedies with its drug Prilosec. Part of a class of new and powerful acid-fighting drugs called proton-pump inhibitors, Prilosec is designed to treat both serious ulcers and severe recurrent heartburn, called gastroesophageal reflux disease, or GERD.

The drug got a big boost from the American Digestive Health Foundation of Bethesda, Md., and the American College of Gastroenterology in Arlington, Va., which paid for extensive "public education" spots on television and in newspapers and magazines, telling people about ulcers and GERD. "Maybe there's a better medicine that will help you live pain-free," one ad says—without naming Prilosec. The two organizations receive financial support from Astra Pharmaceuticals, a joint venture of Astra AB of Sweden and Merck & Co.

'Ask Your Doctor'

Astra also launched an extensive ad campaign for the drug last year that ran on network television and cable, and in publications ranging from Woman's Day to National Geographic. One, showing a grimacing man holding his stomach in pain, encouraged, "Ask your doctor about the most prescribed acid medication in America."

Now, Prilosec, at a wholesale cost of $116 to $178 for a month's supply, is an industry blockbuster. Sales in the U.S. are expected to reach $3.5 billion this year, up from $2.2 billion last year. The drug is now the biggest single pharmaceutical cost at many companies that cover employee prescriptions.

Meantime, the generics are losing ground. Value Rx, a leading drug-benefits manager that is a unit of Express Scripts Inc. of St. Louis, reports a big decline in usage of ranitidine, whose brand name is Zantac and which costs about half as much as Prilosec. Among the plan's 7.2 million members, use of the generic has fallen in the past four years from 41% to 19% of the gastrointestinal-disease market. Over that same period, Prilosec and a similar drug, TAP Pharmaceuticals Inc.'s Prevacid, have jumped from 9% to 36%. Much of the rest of the GI-drug market is held by brand-name drugs, too.

Another Kind of Heartburn

Now, the people with heartburn are those whose job it is to keep medical costs down.

"We see use of a much more expensive product, Prilosec, when a less expensive therapy would work fine," says Thomas Snedden, director of Pennsylvania Assistance Contract for the Elderly, or PACE, a Pennsylvania state program that provides drugs for older people. "GERD used to be infrequent, and now it is frequent. Physicians just want to prescribe it, so they diagnose GERD."

An Astra spokesman, Jim Coyne, says its ads are "very specific and refer only to frequent and persistent heartburn." He contends that GERD actually is underdiagnosed and that as many as 21 million Americans may have a recurring form of it.

A large part of the reason generic-drug makers can't keep up is that they lack the marketing muscle of their big rivals.

Sales of cefaclor, a potent antibiotic used to treat sinusitis and ear infections, plunged after its patent expired in 1992. Prior to that,

Wall Street Journal
Nov. 18, 1998

Continued from First Page

the drug had been an Lilly & Co.'s leading product under the brand-name Ceclor, with nearly $1 billion in total sales. After the generic appeared in 1993, new prescriptions fell to less than 20% of their earlier level.

This was because Lilly salespeople ("detail" people in industry parlance) used to push Ceclor heavily during visits to medical offices. But when the patent expired, they stopped, virtually overnight. "Lilly just quit flogging it," says Paul Arnow, an infectious-diseases doctor at the University of Chicago Medical Center. A Lilly spokesman confirms that it "substantially reduced" marketing visits on Ceclor in a "short period of time" after the generic cefaclor appeared. Meanwhile, lots of prescriptions get written for expensive, heavily promoted antibiotics, when cefaclor or the even cheaper amoxicillin would do just fine, according to health-care and managed-care executives.

It is rare for generic-drug companies to dispatch salespeople to visit doctors, or to host medical seminars and pay marquee professors to laud their products, as brand companies do. Even leading generic makers, like Mylan Laboratories Inc. of Pittsburgh, with a market value of about $4.4 billion, and Barr Laboratories Inc. of Pomona, N.Y., at about $950 million, are dwarfed by leading brand companies like British drug giant Glaxo Wellcome PLC, at about $110 billion.

The free samples that detail people hand out to doctors are a key weapon in winning market share for a new drug. The pharmaceutical companies' hope is that doctors will give these drugs to patients instead of prescribing other medications. And once the freebies in these "starter kits" have run out, a patient often ends up on long-term, even lifelong, prescriptions for that drug.

Battle Over Beta-Blockers

This has happened with medications designed to ward off heart attacks. While there is powerful medical evidence that heart-attack patients generally should be put on generic beta-blockers to avoid further attacks, often, doctors who have free samples of more-expensive brand-name calcium channel-blocker drugs for hypertension will place patients on these instead.

One leading calcium channel-blocker, Hoechst Marion Roussel's Cardizem CD, wholesales for between $60 and $78 monthly for the most common doses. By comparison, two widely prescribed generic beta-blockers, atenolol and metoprolol, cost between $21 and $36 wholesale for a month's supply.

"There is clear evidence that beta-blockers are the drug of choice" after heart attacks, says University of Chicago cardiologist Matthew Sorrentino. But the expensive drug often gets prescribed instead, he says, "because the doctor has just been detailed on it, and he has samples in his closet." Also, he says, many doctors are unfamiliar with the precise appropriate usage of the drugs, so they are heavily influenced by salespeople. A Hoechst spokeswoman didn't return calls seeking comment.

"We're getting pharmaceutical overkill," says Woodrow A. Myers Jr., director of health-care management at Ford Motor Co., where pharmaceutical costs for employees rose 16% and 15% the past two years, respectively, driven by expensive brand-name ulcer drugs, antibiotics, antidepressants and allergy pills. "Because of advertising to consumers and marketing to doctors, great drugs are given to the wrong patient for the wrong disease."

Employers and managed-care companies could crack down, of course, by enforcing use of generics. But under attack in Congress and competing to woo customers, many managed-care plans are reluctant to antagonize patients any further.

"Many managed-care companies have gotten lenient in implementing drug cost-containment efforts," says Henry F. Blissenbach, former president of drug-benefits manager Diversified Pharmaceutical Services Inc., now a unit of Britain's Smith Kline Beecham PLC.

Lee N. Newcomer, medical director at managed-care company United HealthCare Corp., Minnetonka, Minn., says it is difficult for HMOs to insist on switching "without alienating our membership." Moreover, he says, it would be too expensive to inquire into the appropriateness of every use of an expensive drug. But he says United HealthCare is beginning to make it more costly for many of its patients—up to $20 more per prescription—to choose an expensive brand product instead of a generic.

Lawyers and Lobbyists

After all, the vast majority of generics are regarded by the FDA as substitutable for the brand drug in all medical cases. And every generic approved by the FDA has been found by the agency to be precisely the same chemical, with the same dosage and equivalent absorption rate, and with the same manufacturing-consistency that brand manufacturers must have.

The brand-name pharmaceutical industry isn't taking this pro-generic talk lying down. Instead, big drug makers are dispatching platoons of lawyers and lobbyists to protect their monopolies, even after their patents—which usually run for 20 years—expire.

Bristol-Myers Squibb Co. is seeking to keep certain generic versions of the anxiety drug trazadone off the market by claiming that the generic pill infringes on its patent—not on the chemical compound itself, but on the form of the pill. Like the brand-name medicine, called Desyrel, the generic pill has two grooves on it, to split the tablet into thirds. A Bristol-Myers spokeswoman says, "We do have a valid patent on the form of the tablet."

In some cases where litigation is pending, big pharmaceutical companies sometimes pay generic firms to keep the clones off the market. For instance, Abbott Laboratories, North Chicago, Ill., currently pays quarterly fees totaling several million dollars to two generic companies as patent litigation over Abbott's hypertension drug Hytrin proceeds. The recipients, the Zenith Goldline Pharmaceutical unit of Ivax Corp. and the Geneva Pharmaceuticals Inc. unit of Novartis AG, have agreed, for now at least, not to market a generic competitor.

Meanwhile, Hytrin is generating about $700 million in annual sales and growing at

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about 13% a year, at a typical drugstore cost of $53 monthly. Even though the original patent on the chemical expired in 1994, there is no generic on the market. Abbott says it can't comment on patent litigation. Zenith declined to comment, but confirmed that Abbott agreed to pay it $6 million each quarter. Geneva says that it fears marketing the drug now because it might end up owing damages.

Arsenal of Tactics

"There are anywhere from 10 to 20 tactics" pharmaceutical companies "use to protect their products," says Roger L. Williams, the Food and Drug Administration's director of pharmaceutical science.

Among these are "citizens' petitions" filed with the FDA to oppose generic drugs—often filed by citizens who happen to be lawyers for big drug companies. Alan F. Holmer, president of the brand drug industry's trade association, says, "The research-based industry does not oppose the generic industry. But if we think the FDA is about to make a mistake in approving a generic, we will let the FDA know about it."

Currently, the FDA is considering a petition from American Home Products Corp., Madison, N.J., against the generic version of the hypertension drug Verelan, called verapamil. Verapamil already has been shown to dissolve in the bloodstream at essentially the same rate as the brand product when in capsule form. But American Home says an additional test is necessary: It wants the generic company to sprinkle the drug on applesauce, have patients ingest it, and measure how fast it is absorbed. That is because the Verelan label says the medicine can "be administered by carefully opening the capsule and sprinkling the pellets on a spoonful of applesauce." Toronto-based Biovail Corp., the generic maker, says it believes it has successfully completed the applesauce test.

Even when petitions fail, they can keep generic drugs off the market for months or years. At least 40 were filed between 1990 and 1997 against generic drugs. Of the 29 already decided, 24 were rejected by the FDA. But it took the agency between seven months and four years to approve the generic drugs in question after the petitions were filed.

A Case Study

After the FDA approves a generic, there still can be serious roadblocks to getting the drug to consumers.

A case study is the drug Coumadin, whose generic form, called warfarin or warfarin sodium, won FDA approval last year. Coumadin, made by DuPont Pharmaceuticals Inc. of Wilmington, Del., is an anticoagulant used, for example, by stroke patients to ward off further episodes. The drug generates about $500 million in yearly sales for the DuPont Co. unit. A standard monthly dose has a typical drugstore price of $35.50, against the generic's $28.60. Despite the price difference, Coumadin has so far retained about 80% of the U.S. market.

DuPont has waged a campaign to convince state legislatures and state agencies to limit the ability of pharmacists to switch patients to warfarin. DuPont points out that Coumadin/warfarin is a "narrow therapeutic index" drug, meaning that there is a narrow range of safe blood levels of the drug. Too little can lead to strokes, too much to internal bleeding.

An FDA Warning

DuPont has produced slides, press releases and other promotional materials that question the safety of switching patients to the generic: "Once a patient is stabilized on Coumadin . . . he or she should not be switched to another formulation of warfarin sodium without the knowledge and approval of the patient and his or her physician so additional monitoring can be performed," DuPont asserted in a June, 1997 press release.

The FDA, which has deemed the two products equivalent, warned DuPont in January: "We cannot overstate the seriousness with which we regard DuPont's false and misleading promotion of Coumadin."

Nonetheless, DuPont is pursuing either legislation or agency action in as many as 20 states to prohibit switching unless a druggist first gets a doctor's verbal approval. DuPont's senior vice president for public policy, Robert W. Perkins, says the company is taking "a stand that physicians should be aware of which brand the patient is taking." But doctors already can prevent switching by specifying the brand medicine on a prescription pad. Generic companies, however, say requiring busy pharmacists to phone busy doctors over each prescription simply is a roadblock.

Contradicting Testimonies

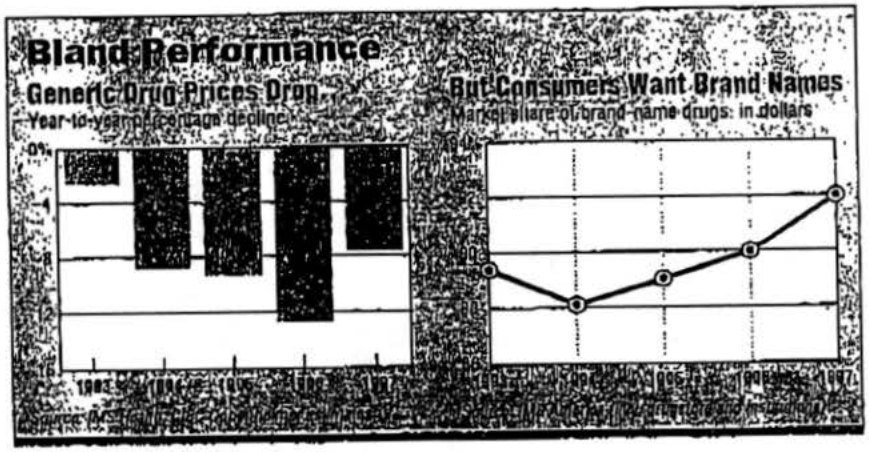
"You can't call all the physicians," says the FDA's Dr. Williams. "It effectively blocks generics." In North Carolina, where phone calls are required by law, generic warfarin recently made up 7.7% of the market. In Wisconsin, where switching can occur freely, the share was 25.3%.

In Chicago, a state council on generic medicines considered in late August whether switching to warfarin should be allowed. A pharmacist with the Group Health Cooperative in Redmond, Wash., Claudia Swenson, testified that 2,000 patients were successfully switched to generic warfarin without difficulty. "Our conclusion was that the two products were clinically the same," she testified.

DuPont's main outside witness was Steven M. Wilk, a Chicago suburban doctor who heads the Illinois Academy of Family Physicians. This group has received $160,000 from DuPont since 1996, though that fact wasn't mentioned at the hearing. Dr. Wilk testified he was concerned that doctors, not pharmacists, should oversee patients' care. "Physicians are quickly losing control," he testified. In a later interview with this newspaper, Dr. Wilk said he has no experience with any of his own patients switching.

In the end, the Illinois council prohibited druggists switching prescriptions to generic warfarin. A member of the council, Robert Buckman, said that the group's role was to listen to Illinois doctors, explaining, "We've looked beyond the FDA."

The FDA's Dr. Williams sees it differently. To him, the scientific justification for restricting the generic came to this: "Absolutely none."



NBC Nightly News

Journal Link: For more on the high cost of generic drugs, see NBC Nightly News With Tom Brokaw tonight on NBC.

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ISSUE ANALYSIS

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Suppressing Generic Drugs Fleeces Consumers (and Lets the FDA off the Hook)

by Michael F. Cannon

Brand name pharmaceutical companies and federal and state governments are raiding consumers' pocketbooks by preventing them from buying generic drugs. Such restrictions can be an enormous financial drain, especially for low-income Americans and seniors who live on fixed incomes and pay for prescriptions out-of-pocket.

Generic drugs offer consumers more choices and keep prices down by competing with brand name pharmaceuticals, often at savings of 30 percent to 60 percent.[1] When government restricts access to generics, it forces consumers either to buy brand name drugs, which can cost one and a half to three times more, or to do without treatment altogether. This restriction also means higher costs for employers and unions (who provide health benefits); taxpayers (who fund government health programs); and individual consumers (especially seniors). According to Common Cause, a watchdog group that examines the influence of special interests on politics, government suppression of generics is costing Americans $550 million a year, hidden in higher prices for prescriptions.[2]

In effect, government restrictions on generics are hidden taxes that directly benefit brand name pharmaceutical companies. These companies lobby for restrictions on generics to offset the high costs imposed on brand names by the federal Food and Drug Administration (FDA). These companies also seek monopoly rents through lobbying for patent extension. Patents were intended to reward and encourage innovation. Extending patents that have already been granted do not create any additional incentives to innovate.

Michael F. Cannon authored this paper while a health care policy analyst at Citizens for a Sound Economy Foundation.

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[1] "Sneak Prescription Drug Patent Extension in Appropriations Rider Would Increase Drug Prices for Seniors," Public Citizen press release, October 9, 1998.

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SUPPRESSING CONSUMER ACCESS TO GENERICS

1. Extending Government-Granted Monopolies Keeps Generics Off the Market

- The federal government grants monopolies (20-year patents and periods of market exclusivity) to makers of new drugs, after which others may market generic versions. Much of that time is consumed getting the FDA's approval to market a new drug. Some argue the remaining monopoly period is not enough time to recoup the necessary investment, and therefore should be extended.

- One manufacturer spent over $1.5 million in the first half of 1998 to persuade Congress to extend one of their monopolies because their drug "was stuck in the [FDA] pipeline for . . . double the normal review time. All the drug company wants back is that lost time[.]"[3]

- However, it is the Food and Drug Administration's (FDA) lengthening approval process (now 15 years, up from eight years in the 1960s)[4] that eats up patent time. Extending monopolies merely hides that fact, shielding brand names from the cost of that "lost time" by passing it on to consumers. The root of the problem – the FDA's costly review process – is not addressed.

- One pharmaceutical giant has blocked generic versions of a highly effective cancer therapy by securing separate patents for different uses and ways of administering the drug — despite the fact that the government developed the drug at taxpayer expense.[5]

2. Holding up FDA Approval of Generics

- Brand names routinely file patent infringement lawsuits and FDA "citizens' petitions," which halt FDA consideration of generic rivals.

- Many "citizens' petitions" are frivolous (the FDA has rejected 83 percent of those filed against generics since 1990), yet can add years to a generics' approval time.[6]

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- Brand names often sue for patent infringement even if the generic firm has no intention of going to market before the patent expires.

- The first generic to file for FDA approval can block out other generics for six months. Some brand names actually pay generic firms to delay this limited exclusivity period, which gives the brand name a longer period of complete exclusivity.[7]

3. Keeping Generics off Government Formularies

- Medicaid and Medicare have approved lists of prescription drugs, called a "formulary." Brand name manufacturers often try to keep generics off these formularies.

- In 1997, a pharmaceutical company filed a petition with the Massachusetts Drug Formulary Commission in an attempt to block the substitution of a generic version of their anticoagulant drug – a drug whose patent expired over thirty years ago, and whose price has increased by more than 400 percent.[8]

4. "Notification" and Other Regulatory Obstacles to Generics

- As a result of an ever-more-powerful regulatory regime, many pharmaceutical companies have found it more effective to shift their efforts to seeking profits through regulation, not competition.

- Brand name firms pressure state legislatures and Boards of Pharmacy to erect obstacles for patients who want generics.

- "Notification" laws require pharmacists to contact the prescribing physician before they make a generic substitution, despite the fact that physicians already may prevent substitution if they wish. According to an FDA official, a notification requirement "effectively blocks generics" because a pharmacist "can't call all the physicians."[9]

- One pharmaceutical giant hired a public relations firm to form a "patients' coalition" and launch a state-by-state campaign for "notification" laws to protect its market share of a blockbuster anti-coagulant. Where enacted, "notification" has driven generic market share below 8 percent, compared to 25 percent elsewhere. The firm alleges generics may not be equivalent to the original, a claim the FDA denounces as "false and misleading."[10]

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[7] *Ibid.*.

[8] "DuPont Merck petition fails to block Barr's generic Coumadin anti-coagulant," *AFX News*, November 19, 1997.

[9] Burton, *op.cit.*

[10] *Ibid.*.

Market Efficiency or Regulatory Profit? Blockbuster drugs can gross over $1 million in sales per day. Each day a firm extends its monopoly — each way it uses government to block its competitors — can mean millions in additional profits. Yet businesses that use the government to hurt their competitors make money at the expense of consumers, whose choices they restrict. Their profits are not a reflection of their value to society, but are in fact a measure of the cost of regulation. In this case, two factors drive the costs of regulation.

First, government constantly increases the cost of developing new medicines. The amount of time (15 years) and money (now $500 million) necessary to win approval of a new medicine continues to grow because the FDA is not held accountable for making patients wait too long or spend too much for prescription drugs.

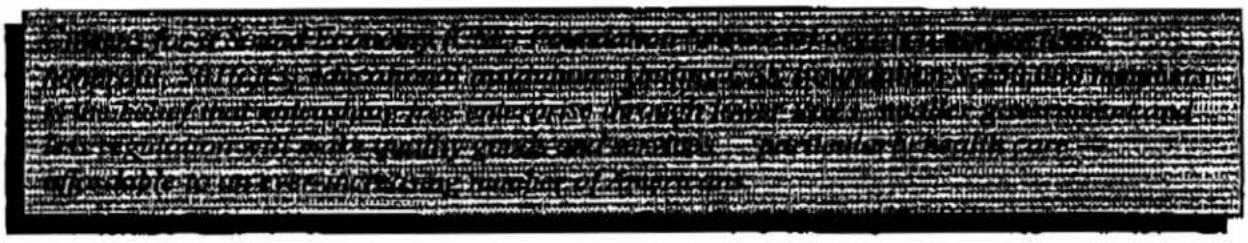
Second, convincing the government to regulate your competition is easier than convincing government to stop regulating you. Brand name firms are wary of angering the FDA with its $1 billion budget and power to bankrupt firms by slowing its review of their products. On the other hand, joining forces with government allows brand name firms to pass costs along to less organized interests (patients and other payers) and potential competitors (generics). Ultimately, this is a shortsighted strategy that creates an expanded FDA with more regulatory oversight.



It may be that brand names are not adequately rewarded for their investment in new medicines. But allowing them to shake down consumers for millions of dollars is not the answer. If makers of pioneer drugs are unable to make a profit without using government to block their competition, perhaps it is time to reexamine the costs the FDA imposes on these innovators.

Before government and the pharmaceutical industry injure more patients with further regulation, consumers should press both lawmakers and industry to curb the ever-expanding FDA bureaucracy.

Consumers should push for reforms that increase the resources available for drug approvals without sacrificing high safety standards. Private institutions (such as medical schools, peer-reviewed medical journals and the *U.S. Pharmacopeia*) already certify the safety and efficacy of "off-label" drug therapies. Congress should strengthen this process, eliminating the FDA's ban on "off-label" medical speech. Further, Congress should outsource initial FDA reviews to these and other private institutions (*e.g.* Underwriter's Laboratories, medical associations). These reforms would also lower the regulatory costs imposed on brand name and generic firms, but most of all, on consumers.



AL GORE
SUPPORTING GENERIC DRUGS

Throughout his career Al Gore has been fighting for better access to generic drugs. Gore has made increased access, affordability and a faster approval process for generic drugs a priority throughout his career.

- **Pushed for Medicaid Use of Generic Drugs.** In 1986, Al Gore called on President Reagan to implement a plan to provide Medicaid reimbursements for dispensing of generic drugs, in order to give pharmacists an incentive to use generic drugs instead of name brands. Stating that the Medicaid program could save from $100 to $250 million a year,.Gore told reporters that by blocking this plan "they [Reagan Administration] are saying we have to continue wasting this money because the major pharmaceutical companies like us to continue giving the money to them." Later, in 1987, the US Dept. of Health and Human Services announced a reform of regulations regarding the prescribing of generic drugs in lieu of higher cost name brand drugs if at least three generics are available in place of the name brand. [AP, 4/9/96; Drug Topics, 5/5/86; Drug Topics, 10/5/87; Washington Post, 8/1/87]

- **Cosponsor of the "Drug Price Competition and Patent Term Restoration Act."** In 1983, then Rep. Al Gore cosponsored, along with Rep. Henry Waxman, the "Drug Price Competition and Patent Term Restoration Act." The legislation, which was passed officially as the Senate version in 1984 and signed into law, aided generic drug manufacturers by ending the pharmaceutical industry's push for non-generic drugs. [Science, 10/83]
  - The bill permitted accelerated the FDA drug approval procedures for new generic drugs equivalent to approved new drugs;
  - Restored "time lost" for research-intensive pharmaceutical companies by allowing companies to regain up to five years' patent exclusivity on newly developed and FDA approved drugs. [HR 3605, 98th Congress, (S. 1538 Passed In Lieu, Public Law 98-417); Vote #334, HR 3605, 9/6/84, Rejected 66-304 (R16-130, D 50-174) Drug Topics, 7/16/84]

- **Opposed to Extending Patents on Drugs.** Gore opposed legislation in 1982 that would have extended the patents for new drugs an additional seven years. The seven years would be in addition to the already existent 17-year patent, provided by 1861 legislation. Gore, called a "leading opponent to the Katenmeier bill," stated that the research-intensive drug companies "stand to profit enormously...substantially increase[ing] prescription drug costs to consumers." The legislation ultimately failed to pass in the House. [New York Times, 7/28/82]

- **Criticized the Reagan Administration's Support of the Pharmaceutical Industry.** In 1981, Al Gore was a staunch critic of the Reagan Administration's pandering to the drug and pharmaceutical industry. The Administration had blocked implementation of a generic drug plan by freezing government approval of the new generic drugs. The Administration later revised its position on the process for generic drugs to reach the market. [AP, 3/10/81; AP, 4/16/81]

- **Held Congressional Hearings on Price Gouging by Pharmaceutical Industry.** Al Gore led Congressional hearings in 1978 into allegations that drug companies had put name brand labels on generic drugs. Gore stated "We have reason to believe that large drug companies have been regularly making profits with up to 5,000 percent markups on generic drugs simply because they were put under their brand name." Gore later told reporters that the reason for the hearings was that, "Families who need these drugs are being ripped off by these deceptive practices." [AP, 8/16/78; AP, 9/8/78]

SUPPORT OF PATENT EXTENSIONS FOR BRAND-NAME DRUGS GORE VS. BRADLEY

AL GORE: PRO CONSUMER

IN 1982, GORE OPPOSED PATENT EXTENSIONS FOR BRAND-NAME DRUGS

- Gore voted against the suspension of the rules to pass the Patent Term Extension bill that would extend the patent term of specified items that are subject to federal regulatory review. [CQ Almanac, Vote #305, HR 6444, 9/15/82, motion failed 250-132 (R 149-18, D 101-114)]

  - **New York Times: Gore Was One of a Few Legislators to Speak Out Against Drug Companies.** The New York Times reported, "One of the few legislators to speak out against the drug companies is Rep. Albert Gore, (D-Tenn.) and he has estimated that the new patent bill being voted on in the House this week would cost consumers an extra $3 billion to $5 billion in the next seven years, if passed. His figures are based on the 42 top-selling drugs last year and assume that without the new law, generics will continue to undercut and compete with them as they have been doing historically." [Washington Post, 9/12/82]

  - **Gore Said Bill Would Increase the Cost of Drugs for Consumers.** Gore, called a "leading opponent" of the brand-name drug patent extension bill stated that the research-intensive drug companies "stand to profit enormously" from the bill. Gore added that the change in the patent law "would substantially increase prescription drug costs to consumers" without evidence that the drug companies would reinvest the extra revenue in research and development. [New York Times, 7/28/82]

BILL BRADLEY: PRO DRUG COMPANIES

IN 1981, BRADLEY COSPONSORED LEGISLATION THAT WOULD EXTEND PATENTS FOR BRAND-NAME DRUGS

- Bradley cosponsored legislation that would extend patents for pharmaceutical companies that make brand-name drugs up to seven years beyond the seventeen years provided by current law. The legislation would extend patents for drug companies to up seven years to compensate for marketing time lost on new drugs while the companies perform tests and Government agencies conduct regulatory reviews of the drugs. The bill would also essentially work retroactively and extend existing patents. The bill passed the Senate by voice vote on 7/9/81. [New York Times, 8/15/82; S.255, 1/27/81]

  - **Bradley Defended High Prices Brand-Name Drug Companies Charge Consumers.** When asked if high drug prices for consumers troubled him, Bradley said brand-name companies were forced to charge high prices because government review limited the life of patents. [New York Times, 8/15/82]

  - **Bradley Said Drug Company Contributions Did Not Affect his Support of the Patent Extension and that the Patent Restoration Would Benefit the Entire Country and New Jersey.** "I don't think the contributions [from drug companies] had anything to do with it," said Senator Bradley. "There is no question that the interests of the country as a whole and certainly New Jersey would benefit from patent restoration." [New York Times, 8/15/82]

BILL BRADLEY AND GENERIC DRUGS

Bill Bradley recently encouraged using generic drugs whenever possible to help control costs as part of a health care plan. However, during his 18 years in the senate, Bradley cosponsored legislation that would protect patents for brand-name drugs for seven additional years. In fact, the New York Times said, "Senator Bill Bradley, Democrat of New Jersey, is widely viewed as the [pharmaceutical] industry's most effective defender in Congress."

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*"But we need to make this program [Medicare] better by expanding it to include costs of prescription drugs, **with generic drugs being the first choice of medication whenever possible.**"*

--Bill Bradley in health care speech, 9/28/99

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  - **Brand-Name Pharmaceutical Companies' PACs Donated $400,000 to Congressional Campaigns and $3,250 to Bradley in 1981-1982.** According to a survey done by a Washington-based trade publication, political action committees of the top 22 brand-name companies gave $400,000 to various Congressional campaigns after the legislation was introduced through late 1982. During the 1982 election cycle, which Bradley was not up for re-election, he received $3,250 from brand-name pharmaceutical PACs. [New York Times, 8/15/82, FECinfo]

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  - **Senior Group Said the Legislation was "Bad" Because "Drug Prices are So High."** William Hutton, executive director of the National Council of Senior Citizens, which had a membership of 4 million nationwide, criticized the legislation because it protected high drug prices. "This thing is so bad," Mr. Hutton said. "To think of an additional giveaway to the drug companies at a time when drug prices are so high." Mr. Hutton's group and other consumer groups were especially upset with the Senate bill because it worked retroactively on existing patents. [New York Times, 8/15/82]

  - **Consumer Groups Said the Bill Would Cost Billions.** Consumer advocates said the patent extension bill "would rob sick people of billions of dollars." [New York Times, 9/14/82]

  - **New York Times Said Bradley Was the Pharmaceutical Industry's Most Effective Defender:** "Senator Bill Bradley, Democrat of New Jersey, is widely viewed as the industry's most effective

defender in Congress. In recent years, Senator Bradley led a successful fight against legislation that would have prevented companies from raising prescription drug prices more than the Consumer Price Index and helped retain much of the valuable drug company tax breaks for manufacturing in Puerto Rico." [New York Times, 3/7/94]

- **1981-1991: Bradley #2 in Drug Industry PAC Money, Collected Over $99,000.** Bradley ranked 2nd in drug industry PAC donations from 1981-1991. Bradley received $99,707 during this time period. [Philadelphia Inquirer, 12/14/92]

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3. Keeping Generics off Government Formularies

- Medicaid and Medicare have approved lists of prescription drugs, called a "formulary." Brand name manufacturers often try to keep generics off these formularies.

- In 1997, a pharmaceutical company filed a petition with the Massachusetts Drug Formulary Commission in an attempt to block the substitution of a generic version of their anticoagulant drug – a drug whose patent expired over thirty years ago, and whose price has increased by more than 400 percent.[8]

4. "Notification" and Other Regulatory Obstacles to Generics

- As a result of an ever-more-powerful regulatory regime, many pharmaceutical companies have found it more effective to shift their efforts to seeking profits through regulation, not competition.

- Brand name firms pressure state legislatures and Boards of Pharmacy to erect obstacles for patients who want generics.

- "Notification" laws require pharmacists to contact the prescribing physician before they make a generic substitution, despite the fact that physicians already may prevent substitution if they wish. According to an FDA official, a notification requirement "effectively blocks generics" because a pharmacist "can't call all the physicians."[9]

- One pharmaceutical giant hired a public relations firm to form a "patients' coalition" and launch a state-by-state campaign for "notification" laws to protect its market share of a blockbuster anti-coagulant. Where enacted, "notification" has driven generic market share below 8 percent, compared to 25 percent elsewhere. The firm alleges generics may not be equivalent to the original, a claim the FDA denounces as "false and misleading."[10]

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[7] *Ibid.*.

[8] "DuPont Merck petition fails to block Barr's generic Coumadin anti-coagulant," *AFX News*, November 19, 1997.

[9] Burton, *op.cit.*

[10] *Ibid.*.

Market Efficiency or Regulatory Profit? Blockbuster drugs can gross over $1 million in sales per day. Each day a firm extends its monopoly — each way it uses government to block its competitors — can mean millions in additional profits. Yet businesses that use the government to hurt their competitors make money at the expense of consumers, whose choices they restrict. Their profits are not a reflection of their value to society, but are in fact a measure of the cost of regulation. In this case, two factors drive the costs of regulation.

First, government constantly increases the cost of developing new medicines. The amount of time (15 years) and money (now $500 million) necessary to win approval of a new medicine continues to grow because the FDA is not held accountable for making patients wait too long or spend too much for prescription drugs.

Second, convincing the government to regulate your competition is easier than convincing government to stop regulating you. Brand name firms are wary of angering the FDA with its $1 billion budget and power to bankrupt firms by slowing its review of their products. On the other hand, joining forces with government allows brand name firms to pass costs along to less organized interests (patients and other payers) and potential competitors (generics). Ultimately, this is a shortsighted strategy that creates an expanded FDA with more regulatory oversight.



It may be that brand names are not adequately rewarded for their investment in new medicines. But allowing them to shake down consumers for millions of dollars is not the answer. If makers of pioneer drugs are unable to make a profit without using government to block their competition, perhaps it is time to reexamine the costs the FDA imposes on these innovators.

Before government and the pharmaceutical industry injure more patients with further regulation, consumers should press both lawmakers and industry to curb the ever-expanding FDA bureaucracy.

Consumers should push for reforms that increase the resources available for drug approvals without sacrificing high safety standards. Private institutions (such as medical schools, peer-reviewed medical journals and the *U.S. Pharmacopeia*) already certify the safety and efficacy of "off-label" drug therapies. Congress should strengthen this process, eliminating the FDA's ban on "off-label" medical speech. Further, Congress should outsource initial FDA reviews to these and other private institutions (*e.g.* Underwriter's Laboratories, medical associations). These reforms would also lower the regulatory costs imposed on brand name and generic firms, but most of all, on consumers.



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Partners In Healthcare...

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TO: Sarah Biondi DATE: 11/5/99

COMPANY:

FAX NO. 456-5557

PHONE NO.

FROM: Diane Thomas

NO. OF PAGES 10

Comments: More on Claritin. See study indicating $11 billion to consumers

Response:

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Distributed to the entire US House and Senate on May 25, 1999

Taxpayers and Consumers Speak Out Against Anti-Consumer *Claritin* Monopoly Extension Act

Competition is the Motivation for Innovation

Oppose H.R. 1598

"There are many unresolved questions about this bill."

"...should a special, new office be created at the PTO to review just these specific drugs?"

"...will [H.R. 1598] put this tough decision-making into a bureaucratic black hole, away from public scrutiny?"

"...competition is also good for research and generic companies should be able to market their products as soon as a patent's life is over without having to face legislative barriers."

Citizens Against Government Waste

"...if H.R. 1598 becomes law the company's [Schering-Plough] windfall profits will cost consumers and the U.S. health care system between $1.6 and $3.2 billion."

"If Schering-Plough is successful, it will be rewarded not for investing in new research and development, but instead for investing in lobbying Congress to erect a protectionist barrier that prevents generic competition and maintains *Claritin's* high monopoly price."

"The issue that should be on the legislative agenda is... how to rein in the outrageously high and escalating cost of prescription drugs that is fueling health care inflation and hurts seniors and people with chronic diseases – those who can least afford it."

Public Citizen's Congress Watch

GPIA GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION

(202) 833-9070 ext. 314

Congress of the United States

Washington, DC 20515

March 17, 1999

David M. Walker
Comptroller General
General Accounting Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Mr. Walker,

We are writing to request that the General Accounting Office (GAO) review the Food and Drug Administration's (FDA) approval of the prescription drug, Claritin.

Over the past two years, the manufacturer of Claritin, Schering-Plough, has proposed creating an administrative process at the Patent and Trademark Office (PTO) to grant patent extensions to compensate for "regulatory delays" during the FDA's review and approval of new drug applications (NDA).

While proponents of this proposal argue that the FDA was responsible for unwarranted delays in the approval of Claritin, critics point out that the product review was slowed by the sponsor's reformulation of the product and by substantial scientific concerns regarding Claritin's carcinogenicity, which arose in the midst of the product's review.

The proposal also follows on the heels of Schering's questionable, long-standing efforts to extend patent protections for Claritin, a prescription antihistamine with over $900 million in annual U.S. sales. Last year, Schering lobbied the Senate for an amendment to omnibus patent reform legislation for outright five-year patent term extensions for a number of drugs, including Claritin. In 1996, Schering tried unsuccessfully to attach Claritin patent extensions to the omnibus appropriations bill, the continuing resolution and the agriculture appropriations bill.

In April 1993, the GAO issued a report on "FDA Premarket Approval: Process of Approving Lodine as a Drug" (GAO/HRD-93-81). The report found that delays in the approval of Lodine were attributable to increases in average new drug approval times, and clinical data submitted by sponsor Wyeth-Ayerst which was "difficult to review" because of "poor organization" and "weaknesses in the clinical data." Conducting this type of study of Claritin, including a rigorous review of the

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scientific issues raised during its approval and the quality and adequacy of Schering's application, would be of great assistance.

Please contact our offices with any questions regarding this request. We look forward to your response.

Sincerely,

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Drug Patent Extensions Will Cost Consumers $11 Billion, Says Prime Institute Report

August 3, 1999 11:39 AM EDT

WASHINGTON, Aug. 3 /PRNewswire/ -- A report issued today by the Prime Institute of the College of Pharmacy at University of Minnesota concludes that pharmaceutical patent extension legislation pending in Congress would cost consumers over $11 billion from 2002-2012. The report finds that delayed generic drug competition would extend the market monopoly of selected brand drugs at the sacrifice of lower drug costs and with minimal stimulation of research and development leading to new drug discovery.

The study by Dr. Stephen W. Schondelmeyer was released on the eve of a Senate hearing on a bill that would grant extensions of up to three years to eight drugs whose patents are due to expire by 2002. The extensions proposed under the "Drug Patent Term Restoration Review Procedure Act of 1999" (S 1172) would be in addition to previous special protections and extensions already granted to these so-called "pipeline drugs."

Pipeline drugs are drugs that received special 2-year patent term extensions as part of a compromise between the brand and generic sectors of the pharmaceutical industry. The patent extensions were legislated under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act).

"If legislation is passed to award additional years of patent monopoly to the pipeline drugs, American consumers would experience a delay in the opportunity for savings which result from generic competition in the pharmaceutical market_ [P]harmaceutical firms stand to benefit from extended patent monopolies, while consumers and payers in health care will experience an increase in expenditures due to lack of competition," the report states.

Claritin(TM)

Dr. Schondelmeyer's report, entitled Patent Extension of Pipeline Drugs: Impact on U.S. Health Care Expenditures, focuses primarily on Claritin(TM), an allergy drug that generated $1.8 billion in U.S. revenues for Schering-Plough in 1998. Claritin accounts for two-thirds of the total value of the eight drugs covered by S1172 and its counterpart in the House of Representatives, the "Patent Fairness Act of 1999" (HR 1598).

Using Claritin as a case study, Dr. Schondelmeyer finds that a 3-year delay in generic competition for Claritin would cost American consumers $5.31 billion from 2002-2007, and another $2.05 billion from 2008-2012. During this ten-year period, Schering-Plough would generate an additional $9.64 billion from Claritin. Based on current R&D spending by Schering-Plough and industry trends, the report projects that only 3.6% of this windfall for Schering-Plough would be

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used for the discovery of new drugs.

"If the intent of this legislation is to stimulate R&D, this is very inefficient legislation because it requires a cost to the public of $9.64 billion to achieve $350 million in R&D discovery," Dr. Schondelmeyer states.

At the same time, the report points out that pharmaceutical R&D expenditures have multiplied since Hatch-Waxman was enacted. The industry's R&D expenditure rate doubled from 1984 to 1990, and doubled again from 1990 to 1998, reaching $17.2 billion. This suggests that additional patent extensions are not necessary to stimulate R&D investment. Dr. Schondelmeyer cites a Congressional Budget Office study that concluded that "reducing FDA approval times – if it is done without sacrificing safety concerns – would be much more effective in helping both the drug industry and consumers than would lengthening the patent-protection period."

Generic Competition

According to an October 1994 market analysis of generic drugs, generics enter the market at a price averaging 73% of the originator price. After one month, the generic price is typically at 67% of the originator's price and at 12 months at 55%. After two years, the average generic price falls to 39% of the originator's price.

American consumers can expect to save $7.33 billion by 2007 if generic competition for Claritin begins in 2002 when its patent expires under current law, the report states. Those savings would be reduced to $2.02 billion in the same period if generic competition is delayed until 2005, sacrificing $5.31 billion in potential consumer savings for the benefit of one company.

Since Claritin represents 66% of the market value for the eight pipeline drugs that would benefit from patent extensions, Dr. Schondelmeyer estimates that the total cost impact for consumers and taxpayers would be $11.15 billion from 2002-2012.

Proposed Medicare Prescription Drug Benefit

"The added cost of prescription medications from this proposed patent extension legislation would be borne proportionately by individuals and institutional payers for health care services including federal and state governments," the Prime Institute report notes.

The study projects that the government's total share of U.S. outpatient prescriptions, now at 20%-25% of all expenditures, will double to 45%-50% if a Medicare Rx benefit is enacted. The cost of the patent extension bill to government will be a minimum of $1.89 billion, with that figure rising to $5.0 billion if a prescription drug benefit is added to Medicare.

Testimony

Testifying for the Coalition for Affordable Pharmaceuticals before the House Subcommittee on Courts and Intellectual Property on July 1, Andrew Berdon, Vice President and General Counsel of Faulding Inc. and Purepac Pharmaceutical Company, stated: "We believe it is ironic that as this Congress debates ways to reduce the high cost of prescription medications to the elderly and Medicare Reform, we are here today to discuss HR 1598, which would grant patent extensions of up to three years to eight brand name drug products_ HR 1598 denies the American consumer the choice

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of selecting a more affordable generic version of these brand products. It not only costs the consumer, particularly the elderly, billions of dollars, but also has a tremendous fiscal impact on government programs offering a drug benefit..."

Mr. Berdon is a Board member of the National Association of Pharmaceutical Manufacturers (NAPM), which provided a research grant for the Prime Institute study.

Patent Extension of Pipeline Drugs:
Impact on U.S. Health Care Expenditures

Executive Summary

Background
-- HR 1598 will affect 7 drug firms and 8 drugs worth $2.7 billion; that is 3.3% of U.S. Rx sales in 1998.
-- Congress addressed additional exclusivity for the 'pipeline drugs' when it passed the Hatch-Waxman Act.
-- Pipeline drugs have already benefitted from 2 to 5 years of additional protection from generic competition.
-- Drugs covered by this legislation currently have effective patent lives ranging from 6.8 to 13.8 years.

Drug Products Affected
-- Claritin(TM) had sales of $1.9 billion in 1998, Relafen(TM) had $450 million, and Daypro(TM) had $300 million.
-- There are 45 million allergy sufferers and 40 million arthritis sufferers who may be affected by this bill.
-- U.S. sales of Claritin(TM) ($1.9 billion) in 1998 accounted for 84% of Claritin(TM) worldwide revenue ($2.3 billion).
-- Claritin(TM) sales provide 34% of Schering-Plough's total worldwide revenue of $7.3 billion in 1998.
-- The Canadian price of Claritin(TM) is one-third of the U.S. price for the identical drug from Schering-Plough.
-- Claritin(TM) 10 mg (#30) in the U.S. costs $54.72, while the same drug costs $18.34 in Canada (mfg price).

Cost to Consumers from Three-Year Delay in Generic Competition
-- A case study of Claritin(TM) was done to estimate the economic impact of a 3-year delay in generic competition.
-- Claritin(TM) sales are expected to reach $3.46 billion by 2002 and

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$3.78 billion (NPV, 2000 $) by 2005.
-- Generic competition for Claritin(TM) is expected to begin in July 2002; with a delay, it is expected in July 2005.
-- Consumer savings from generic competition for Claritin(TM) is estimated at $0.70 billion (NPV 2000 $) in 2003; $1.15 billion in 2004; $1.55 billion in 2005; $1.82 billion in 2006; and $2.01 billion in 2007.
-- Consumers can expect to save $7.33 billion (NPV, 2000 $) from generic versions of Claritin(TM) in the first 5 years.
-- A 3-year delay in competition for Claritin(TM) will cost consumers $5.31 billion (NPV, 2000 $) from 2002 to 2007; and $7.36 billion (NPV, 2000 $) from 2002 to 2012.
-- The total cost to consumers from an exclusivity extension for the 8 'pipeline drugs' will be about $11.1 billion.

Effect on Schering-Plough
-- Two Schering-Plough products (Claritin(TM) and Eulexin(TM)) represent 68% of the market value of affected product.
-- Schering-Plough's marketing, advertising & admin. expenses are above industry average (39% vs. 25%-30%).
-- Schering-Plough's R&D expenditures are considerably below the industry average (12.5% vs. 20.0%).
-- This legislation will add $9.64 billion to Schering-Plough revenue from 2002 to 2012.
-- More than 60% (-$5.83 billion) of Schering-Plough's added revenue will go to marketing, sales, and profits.
-- Less than 30% of R&D expenditures is typically allocated to discovery of new medicines.
-- Less than 3.6% of the added costs to the American public is expected to go toward discovery of new drugs.

Effect on Pharmaceutical Firms
-- Pharmaceutical firms had higher net profit as a % of revenue than any U.S. industry group for 20 years.
-- The profitability gap between pharmaceutical firms and the median Fortune 500 firm (America's best corporations) has grown wider since passage of Hatch-Waxman.
-- Both R&D expenditures and drug firm profits have shown dramatic growth since the Hatch-Waxman Act.
-- The rate of return to pharmaceutical firms is higher than other

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industries in the U.S., even when risk-adjusted.
-- CBO says lengthening patent periods is not the most effective means of encouraging R&D.
-- Reduction of FDA review times is a more effective means of stimulating research and development.
-- The FDA's NDA review time has been reduced substantially from more than 30 months (1984) to 11.7 months in 1998.

Economic Impact on Consumers and Government
-- The cost to American consumers from this proposed legislation exceeds $11 billion (NPV, 2000 $)
-- Medicaid will bear about $1.34 billion of the cost and other government programs will bear $0.55-$1.34 billion.
-- Govt. programs will bear a cost of about $2.5 billion, and with a Medicare drug benefit about $5.0 billion.
-- This legislation will have very real costs in terms of increased

pharmaceutical expenditures for Americans. SOURCE Prime Institute of the College of Pharmacy at University of Minnesota

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Hard to Swallow
Rising Drug Prices for America's Seniors

a report by Families USA

November, 1999

The following are the introduction and key findings from this report by Families USA. To access the complete report, you may download the PDF version. In order to read the PDF version, you must have the *Adobe Acrobat Reader* VERSION 4.0 software on your computer. This software may be **downloaded for FREE** from the Adobe web site.



A hard copy of the report is available at a cost of $20.00. To order, send check or money order payable to Families USA Foundation to: "Hard to Swallow" c/o Families USA, 1334 G St. NW, Washington, DC 20005.

For older Americans, the affordability of prescription drugs has long been a pressing concern. Outpatient prescription drug coverage is one of the last major benefits still excluded from Medicare, and the elderly are the last major insured consumer group without access to prescription drugs as a standard benefit. Although many Medicare beneficiaries have access to supplemental prescription drug coverage, too often that coverage is very expensive and very limited in scope. What is more, such coverage is on the decline. As a result, older Americans-who are by far the greatest consumers of prescription drugs-pay a larger share of drug costs out of their own pockets than do those who are under 65. This means the prices of prescription drugs have a greater impact on older Americans than on younger persons.

Four years ago, Families USA found that the prices of prescription drugs commonly used by older Americans were rising faster than the rate of inflation.1 To determine if this trend of steadily increasing prices for prescription drugs has improved, remained the same, or worsened, Families USA gathered information on the prices of the prescription drugs most heavily used by older Americans over the past five years. Using data from the Pennsylvania Pharmaceutical Assistance Contract for the Elderly (PACE) program, we analyzed the prices of the 50 top-selling prescription drugs most heavily used by older persons.

Our analysis shows that, in each of the past five years, the prices of the 50 prescription drugs most used by older Americans have increased considerably faster than inflation. While senior citizens generally live on fixed incomes that are adjusted to keep up with the rate of inflation, the cost of the prescription drugs they purchase most frequently has risen at approximately two times the rate of inflation over the past five years and more than four times the rate of inflation in the last year.

FINDINGS

- The prices of the 50 prescription drugs2 most frequently used by the elderly rose by more than four times the rate of inflation during calendar year 1998.* On average, the prices of these top 50 drugs increased by 6.6 percent from January 1998 to January 1999, though the general rate of inflation in that period was 1.6 percent. (See Table 1.)

- From January 1998 to January 1999, of the 50 drugs most commonly used by the elderly:

- More than two-thirds of these drugs (36 out of 50) rose two or more times faster than the rate of inflation.

- Nearly half of these drugs (23 out of 50) rose at more than three times the rate of inflation.

- Over one-third of these drugs (17 out of 50) rose at more than four times the rate of inflation.

- Among the 50 drugs most frequently used by seniors, the following drugs rose most significantly in price from January 1998 to January 1999:

- Lorazepam (manufactured by Mylan and used to treat conditions such as anxiety, convulsions, and Parkinson's), which rose by over 279.4 percent (more than 179 times the rate of inflation);

- Furosemide (a diuretic manufactured by Watson that is used to treat conditions such as hypertension and congestive heart failure), which rose by 106.6 percent (more than 68 times the rate of inflation);

- Lanoxin (manufactured by Glaxo Wellcome and used to treat congestive heart failure), which rose by 15.4 percent (almost 10 times the rate of inflation);

- Xalatan (manufactured by Pharmacia & Upjohn and used to treat glaucoma), which rose by 14.5 percent (more than nine times the rate of inflation); and

- Atrovent (manufactured by Boehringer Ingelheim and used as a respiratory agent in the treatment of asthma, bronchitis, and emphysema), which rose by 14.1 percent (more than nine times the rate of inflation).

- Over the five years from January 1994 to January 1999, the prices of the 50 prescription drugs most frequently used by older Americans rose twice as fast as the rate of inflation. On average, the prices of these drugs rose by 25.2 percent-twice the rate of inflation, which was 12.8 percent over that period. (See Table 2.)

- Of the 50 drugs most frequently used by older Americans, 39 have been on the market for the five-year period from January 1994 to January 1999.

- The prices of 36 of those 39 drugs increased faster than the rate of inflation over the five-year period.

- More than two-thirds of those drugs (28 out of 39) rose at least 1.5 times as fast as the rate of inflation over the five-year period.

- Nearly half of those drugs (19 out of 39) rose at more than two times the rate of inflation over the five-year period.

- More than one-fourth of those drugs (10 out of 39) rose at least three times the rate of inflation over the five-year period.

- Of the 39 drugs that were used most frequently by seniors and that were on the market for the period from January 1994 to January 1999, the drugs that rose most significantly in price are:

- Lorazepam, which rose by over 385 percent (more than 30 times the rate of inflation);

- Imdur (manufactured by Schering and used to treat angina), which rose by 111 percent (almost nine times the rate of inflation);

- Furosemide, which rose by 107 percent (more than eight times the rate of inflation);

- Lanoxin, which rose by 88 percent (almost seven times the rate of inflation); and

- Klor-Con 10 (manufactured by Upsher-Smith and used as a potassium replacement), which rose by 84 percent (more than six times the rate of inflation).

- Of the 39 drugs that were used most frequently by seniors and that were on the market for the period from January 1994 to January 1999, 31 increased in price on at least five occasions during those five years. During those years, the following drugs increased in price at least seven times:

- Imdur, which increased 10 times;

- Premarin (manufactured by Wyeth-Ayerst and used as an estrogen replacement), which increased eight times;

- Atrovent, which increased eight times;

- Pravachol (manufactured by Bristol-Myers Squibb and used to reduce cholesterol), which increased seven times;

- Synthroid (manufactured by Knoll and used as a synthetic thyroid agent), which increased seven times; and

- K-Dur 20 (manufactured by Schering and used as a potassium replacement), which increased seven times.

- During the last two years, there has been an acceleration in price increases of the drugs most commonly used by seniors. From 1995 to 1996 and 1996 to 1997, those drug prices rose 1.3 and 1.2 times faster, respectively, than the rate of inflation. From 1997 to 1998 and 1998 to 1999, those drug prices rose 1.7 and 4.2 times faster, respectively, than the rate of inflation.

- The median net profit for manufacturers of the 50 most prescribed drugs for senior citizens was 20.0 percent in 1998-4.5 times larger than the median net profit of 4.4 percent for all Fortune 500 companies

Press Release on the Report



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FamiliesUSA
The Voice for Health Care Consumers

PRESS RELEASE

Contact: Lorie Slass, 202-628-3030

November 3, 1999

Drug Companies Put the Squeeze on Older Americans

Seniors' Most Popular Drugs Increase in Cost Four Times the Rate of Inflation

Every year for the last five years, the prices of the 50 drugs most used by older Americans have increased faster than the rate of inflation, with increases in 1998, on average, four times the rate of inflation, according to a new report by the consumer watchdog group Families USA. From January 1998 to January 1999 the rate of inflation increased 1.6 percent and the prices of the 50 most prescribed drugs for older Americans increased 6.6 percent.

Chart: Price Increase of Top 10 Drugs Used by Seniors vs. Inflation

"While the pharmaceutical industry continues to be the most profitable industry in America, it keeps drastically raising the prices of the drugs most commonly used by seniors," said Ron Pollack, executive director of Families USA. "Pharmaceutical companies are raising drug prices on the backs of America's seniors and these vital medicines are increasingly unaffordable for older Americans."

Chart: Drug Company Profits Higher than Fortune 500

Among the drugs examined in the new report by Families USA, Hard To Swallow: Rising Drug Prices for America's Seniors:

- Lorazepam, used to treat Parkinson's disease, cost $97 for a year's supply in 1994, now costs $469 per year. The cost increased by 279 percent from January 1998 to January 1999 (179 times the rate of inflation) and by over 385 percent in the last five years (30 times the rate of inflation).
- Imdur, used to treat angina and the seventh most prescribed drug for seniors, increased in price ten times over the last five years, going from $237 per year in 1994 to $525 per year in 1999. It increased in cost by more than 111 percent over the last five years (almost nine times the rate of inflation).
- Lanoxin, used to treat congestive heart disease and the most prescribed drug for seniors, increased in price by over 87 percent in the last five years (almost 7 times the rate of inflation), increasing 15 percent from 1998-1999 alone (almost ten times the rate of inflation).
- Atrovent, used to treat respiratory illnesses, increased in price eight times and went from $382 per year in 1994 to $546 per year in 1999. From January 1994 to January 1999, the drug increased over 37 percent in price, almost three times the rate of inflation. In calendar year 1998 alone, the drug increased over 14 percent in price (nine times the rate of inflation).
- Propulsid, used to treat gastrointestinal problems, went from $876 per year in 1994 to $1,171 per year in 1999. From January 1994 to January 1999 the drug increased in cost almost 30 percent, over two times the rate of inflation. Propulsid increased in cost by nine percent from 1998-1999 alone, almost six times the rate of inflation.

Chart: Costs of the Most Popular Drugs Used by Seniors Increasing Faster Than the Rate of Inflation

While older Americans fill over 18 prescriptions per year, and nearly half of all Medicare beneficiaries live on less than $15,000 per year, the elderly are the last major insured consumer group without access to prescription drugs as a standard benefit.

"It is unconscionable that the sickest and oldest Americans go without prescription drug coverage as part of their basic benefit package," added Pollack. "Each year their social security checks increase only at the rate of inflation, while the costs of the drugs they take rise at two, three or four times the rate of inflation."

The report found that, in the last year, among the 50 most prescribed drugs for seniors :

- forty-two of the 50 drugs increased in price faster than the rate of inflation (tables 1 & 2);
- more than two-thirds (36 out of 50) rose two or more times faster than the rate of inflation;

- nearly half (23 out of 50) rose at more than three times the rate of inflation; and
- one-third (17 out of 50) rose at more than four times the rate of inflation.

While the median profit for all Fortune 500 companies was 4.4 percent in 1998, for the manufacturers of the 50 most prescribed drugs for seniors their median profits were almost five times higher at 20 percent (table 3). Astra, Pfizer, Schering, Eli Lilly and Merck, which manufacture 19 of the 50 most prescribed drugs for seniors, enjoyed profits at or above 20 percent in 1998.

"Seniors can't take advantage of the many discounts in the marketplace for prescription drugs," added Pollack. "HMOs and other institutional purchasers get sharp discounts on prescription drug prices, but for most seniors who don't have a prescription plan or have a very expensive one, they can't reap the reward of these benefits and have to pay full, not discounted, prices for drugs."

The price increase data in the report are based on price increases in average wholesale prices. Data for the report were prepared for Families USA by the PRIME Institute of the University of Minnesota.

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BRADLEY AND PHARMACEUTICALS

Bill Bradley has consistently sided with the Pharmaceutical Industry in numerous debates throughout his 18 years as a United States Senator. In fact, many newspapers and magazines have commented frequently on Bradley's ties to the pharmaceutical industry. The New York Times wrote that Bradley "is viewed as the industry's most effective defender in Congress," and Pharmaceutical Executive said that Bradley was "extraordinarily helpful" during the 1994 health care debate. Lastly, Bradley has repeatedly fought to keep Section 936, a tax loophole that benefits pharmaceutical companies even when the new revenues were intended to reduce Medicare cuts.

"Asked if he was influenced by the drug companies during his career in the Senate, he [Bradley] said there had been 'zero influence.'"

[Portsmouth Herald, 9/1/99]

BRADLEY DESCRIBED AS A FRIEND OF THE PHARMACEUTICAL INDUSTRY

NEWSPAPERS REPORT THAT BRADLEY IS A FAVORITE OF THE PHARMACEUTICAL INDUSTRY

- Bradley has built a reputation as a friend of the pharmaceutical industry. He has been called a "favorite" and a "defender" of the pharmaceutical industry. The following are examples of Bradley's ties to pharmaceuticals.

  - **The Nation:** "Bradley writes a good deal about how he raised money but does not identify the donors. He was in fact a favorite beneficiary of the pharmaceutical industry and the largest recipient of illegal contributions in 1990 from Prudential Securities, a subsidiary of the insurance giant. (Bradley returned his share, $75,000, in 1993; Prudential paid a fine.) Although they were consulted at the outset, both industries came to oppose Clinton's national health plan in 1994. And so did Bradley." [The Nation, 2/5/96]

  - **Pharmaceutical Executive:** "Both Sen. Bill Bradley (D., New Jersey) and Sen. Joseph Lieberman (D., Connecticut) were extraordinarily helpful as they bore in mind the needs of their pharmaceutical industry constituents, such as Pfizer, Bristol-Myers Squibb, Miles, and others during last year's (health care) debate." [Pharmaceutical Executive, March 1995]

  - **New York Times:** "Senator Bill Bradley, Democrat of New Jersey, is widely viewed as the industry's most effective defender in Congress. In recent years, Senator Bradley led a successful fight against legislation that would have prevented companies from raising prescription drug prices more than the Consumer Price Index and helped retain much of the valuable drug company tax breaks for manufacturing in Puerto Rico." [New York Times, 3/7/94]

  - **Bergen Record:** "Governor Florio and Sen. Bill Bradley and Frank R. Lautenberg, all Democrats and all liberal, took the side of the embattled drug industry against their own president. Florio even accompanied pharmaceutical executives on a lobbying trip to Washington." [The Record, 5/26/93]

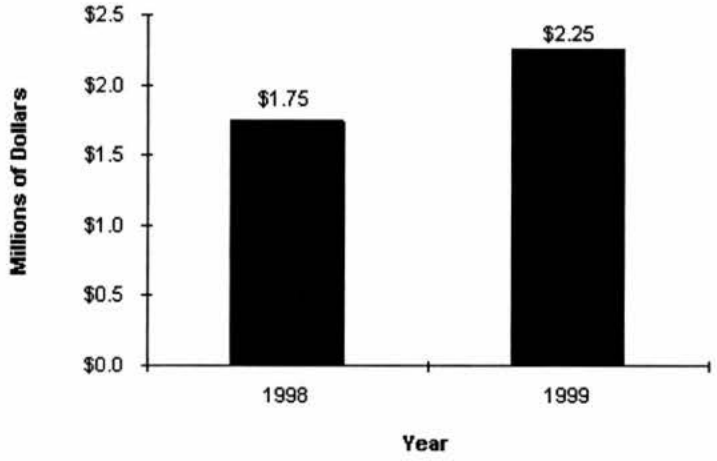
  - **Washington Post:** "Gerald J. Mossinghoff, chief lobbyist for the pharmaceutical industry, spent much of the week visiting Sen. Bill Bradley (D-N.J.) and other lawmakers drug companies consider their better friends in Congress." [Washington Post, 2/20/93]

Public Citizen

Schering-Plough Plows Ahead with High-Priced Lobbying Campaign for a Claritin Patent Extension

Schering-Plough's high-priced campaign to get Congress to award a patent extension to its best-selling allergy drug Claritin plowed $2.25 million into lobbying in the first half of 1999, a 29% increase over the $1.75 million the firm spent in the same period last year.1

Schering-Plough Lobbying Expenditures for First Half Year 1998 and 1999



Since 1996, the first year that a Claritin patent extension was attempted, Schering-Plough has spent more than $11 million total on lobbying Congress and the Administration. (See Public Citizen's previous report, "Can Schering-Plough's Aggressive Lobbying Buy a Claritin Patent Extension?" at http://www.citizen.org/congress/drugs/splobby.htm for a year-to-year breakdown and list of lobbyists.)

High Stakes for Consumers and Taxpayers - $11 Billion

The stakes are high for consumers, workers, health plans and taxpayers, as well as for Schering-Plough shareholders. Claritin's patent is due to expire in July 2002. If Congress approves H.R. 1598/S. 1172, which would allow a three-year patent extension, a staggering $3.5 billion savings that would have resulted from generic competition during the first three years the drug is off patent will be shifted directly from consumer and taxpayer pocketbooks into Schering-Plough's corporate coffers. The ten year loss to consumers is estimated to be more than $11 billion.2

High Priced Democratic and Republican Lobbyists Join Claritin's Team

A number of well-connected players signed on to lobby for Schering-Plough in 1999 coming from both sides of the political spectrum. Early in the year the firm signed up several key Democrats with strong ties to both the Clinton Administration and liberal leaders in Congress, especially on the Judiciary Committees. In June, as the Appropriations bills came into play on the Hill, a Republican consulting firm linked to Senate Majority Leader Trent Lott (R-Miss.) and Appropriations Committee member Richard Shelby (R-Ala.) joined the team.

Richard Ben-Veniste, currently a partner in the law firm of Weil, Gotschal & Manges, LLP, signed on to lobby the House and the Senate on H.R. 1598/S. 1172 effective 2-1-99. The former Assistant Special Prosecutor and Chief of the Watergate Task Force and Democratic Minority Counsel for the Senate Whitewater hearings netted his firm ***$100,000*** over the five month period February - June 1999.

Linda Daschle of Baker, Donelson, Bearman & Caldwell, P.C., is a newly registered lobbyist on H.R. 1598 and S. 1172, joining such power players as former Republican Senate Majority Leader Howard Baker on the Claritin team. The firm received ***$220,000*** for the first six months of 1999 for lobbying the House and Senate. Daschle, wife of Senate Minority Leader Tom Daschle, "does not lobby U.S. Department of Transportation by law and voluntarily will not lobby U.S. Senate" [7-30-99 Lobbying Report, p. 2.]

Vic Fazio, former California Democratic Representative and Chair of the House Democratic Caucus, partner in the firm of Clark & Weinstock, has also newly registered to lobby the White House on H.R. 1598 and S. 1172 [while the firm lobbies the House, Senate and White House; Fazio's form is noted "Executive Branch only"]. The firm reported ***$160,000*** for the first six months of 1999, double its last half-year 1998 amount of $80,000.

Hall, Green & Associates bring strong ties to the Senate Republican Leadership and the Appropriations process to the Claritin team, registering effective June 1, 1999 to lobby the House and Senate on H.R. 1598 and S. 1172. They reported ***$20,000*** for the month of June alone. According to biographies provided by the firm, John Green was formerly the Executive Director of the New Republican Majority Fund, the political action committee of U.S. Senate Majority Leader Trent Lott as well as Deputy Chief of Staff for Senator Lott. Stewart Hall was Senator Richard Shelby's Legislative Director from 1992 to 1996, acting as the Senator's liaison to the Senate Appropriations Committee.

White House, Patent and Trademark Office also Targeted

In addition to Congress, Schering-Plough also needs the Administration to gain its special patent extension for Claritin. Not surprisingly, several key firms report lobbying the Patent and Trademark Office - the agency to which H.R. 1598/S. 1172 would give authority to grant the extension - and the White House, which would have to agree to sign the legislation (or not oppose an appropriations rider).

Two firms registered to lobby for the Claritin patent extension list the "White House" as well as Congress on their disclosure firms:

Clark & Weinstock - White House. The firm's new partner, former Representative Vic Fazio (D-CA), lists the Executive Branch as his sole lobbying target. The firm was paid ***$160,000*** for the first six months of 1999.

Wunder, Knight, Thelen, Forscey & DeVierno - White House. Partner Peter Knight was a top fundraiser for Clinton-Gore and campaign manager for the 1996 Clinton-Gore campaign. The firm reported ***$100,000*** for the first six months of 1999.

Three firms reported lobbying the Patent and Trademark Office:

Schering-Plough Legislative Resources L.L.C. - Robert Lively, Schering-Plough Vice President for Congressional Relations, reported lobbying the Department of Commerce, Patent & Trademarks Office, on H.R. 1598/S. 1172. He reported ***$333,000*** for the first half of 1999.

Swidler, Berlin, Shereff, Friedman - Also listed the Patent and Trademark Office on their disclosure forms. The firm received ***$120,000*** during the first six months of 1999.

Parry & Romani Associates, Inc. - The firm's partners include Thomas Parry, former Chief Counsel to Senator Orrin Hatch (R-UT), Chairman of the Senate Judiciary Committee which has jurisdiction over S. 1172, and former Senator Dennis DeConcini (D-AZ). It reported ***$60,000*** for lobbying the Patent and Trademark Office as well as the Senate and House in the first half of 1999.

H.R. 1598/S. 1172 allow three year patent extensions for Claritin and six other "pipeline" drugs [so-called because they were in the FDA approval process at the time the Waxman-Hatch Act was passed in 1984] by creating a slam-dunk review process at the Patent and Trademark Office that will all but inevitably result in the extension being granted. Claritin accounts for approximately two-thirds of the bills' total estimated $11 billion cost to consumers, workers, health plans and taxpayers.

The real impact of the legislation on U.S. healthcare costs could be much worse. Waiting in the wings to see how the Claritin special patent extension bills do are the makers of 20 other blockbuster drugs with combined annual sales of almost $20 billion and patents that expire in the next five years. If H.R. 1598/S. 1172 become law, Congress would likely be bombarded by their manufacturers to "tweak" the new patent extension process to fit each of these drugs special circumstances. And if Congress doesn't say no to Claritin's special pleading, how will it turn down Prilosec (ulcers), Prozac (depression), and Vasotec (hypertension)?

September 30, 1999
For more information contact Maura Kealey, Deputy Director of Congress Watch, at (202) 454-5116.

For a more detailed critique of the legislation, see www.citizen.org/congress/drugs/stopclaritin.htm

Click here for a complete text of the bill, list of co-sponsors, and current status.

NOTES

1. Schering-Plough lobbying disclosure forms filed under the 1995 Lobby Disclosure Act. These records do not provide an expenditure breakdown between lobbying on patent extension and other issues.

2. Steven Schondelmeyer, *Patent Extension of Pipeline Drugs: Impact on U.S. Health Care Expenditures*, PRIME Institute, University of Minnesota College of Pharmacy, July 28, 1999. Schondelmeyer puts the total cost of H.R. 1598/S. 1172 over ten years at $11 billion, with Claritin accounting for approximately two-thirds. Government programs (Medicaid, Veterans Administration, Department of Defense, Public Health Service) would bear $2.5 billion of that amount. Taxpayers' share would increase to about $5.0 billion with a Medicare drug benefit.

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Statement for the Congressional Record before the Senate Judiciary Committee from Maura Kealey, Deputy Director of Public Citizen's Congress Watch, expressing opposition to S. 1172, the Drug Patent Term Restoration Review Procedure Act of 1999.

August 11, 1999

Honorable Orrin Hatch, Chairman
Senate Judiciary Committee
221 Hart Senate Office Building
Washington, D.C. 20510

Dear Chairman Hatch:

Thank you for the opportunity to provide these comments on S. 1172, the Drug Patent Term Restoration Review Procedure Act of 1999, for inclusion in the August 4, 1999 Senate Judiciary Committee hearing record.

Public Citizen opposes S. 1172 because of its serious cost impact on consumers and taxpayers. According to Steven Schondelmeyer, Director of the PRIME Institute at the University of Minnesota's College of Pharmacy, the total cost to consumers of the patent extensions allowed by this legislation will amount to $11.1 billion between 2002 - 2012. Taxpayers would bear about $2.5 billion of the total due to higher costs in the Medicaid, Veterans Administration, and other government health programs; there does not appear to be a corresponding offset in the bill. With a Medicare drug benefit, the cost to government would rise to about $5.0 billion.

Thus at a time when one of the most pressing questions before Congress is how to create an affordable Medicare prescription drug benefit, this bill would go in exactly the opposite direction by substantially increasing drug costs. When S. 1172 is judged on its merits as public policy, it fails the test.

That is why the proponents of this special patent extension proposal attempt to clothe it in the mantle of redressing an alleged wrong arising out of your legislation, the 1984 Drug Price Competition and Patent Term Restoration [Hatch-Waxman] Act. As you know, the Act granted up to two years of additional patent protection to the pipeline drugs, so-called because extensive research and development had already been conducted and the drugs were already in the FDA review process. It provided up to five years of additional protection for drugs that had not reached that stage as an incentive for future research and development. The Committee Report clearly explains the basis for this disparate treatment:

> "The Committee established different maximum periods of extension to provide greater incentive for future innovations. By extending patents for future innovations for up to five years for products developed in the future, and by providing for up to fourteen years of market exclusivity, the Committee expects that research intensive companies will have the necessary incentive to increase their research and development activities." *[House Committee on Energy & Commerce, Report 98-857, Part I, 98th*

Congress, d. Session, p. 41]

Notwithstanding this crystal-clear legislative history, proponents attempt to justify this special patent extension legislation as redressing an inequity to these seven drugs because they spent much longer than average in the FDA approval process.

The false dichotomy contained in a question asked at the Committee hearing neatly encapsulates the faulty logic underlying that argument. In response to the question whether S. 1172 is a revision to the Hatch-Waxman Act or an exercise in the law of equity, all witnesses in support of the bill said it is the latter and not the former. But that is impossible, since the disparate treatment afforded pipeline vs. post-pipeline drugs by the Act is the sole basis for any claim about the equity or inequity of the amount of patent term extension a drug received. To change the standard set by the Act for these seven pipeline drugs is by definition to revise the Hatch-Waxman Act.

As other witnesses at the hearing testified, to revise the Hatch-Waxman rules for just these seven drugs would create, not resolve, inequities. Consumers would be the big losers - they would be deprived of the speedier access to less costly generic drugs the Act promised without any offsetting benefit.

S. 1172 would also create an inequity vis-a-vis the pipeline drugs that experienced the same longer-than-average FDA review period as those covered by S. 1172, but for which the patent has already expired. If there were any merit in the argument that a longer-than-average FDA review time justified changing the terms of the Hatch-Waxman Act, it should certainly have been raised in a timely manner so that all those similarly situated could receive equal treatment.

Drug patents are intended to provide an *incentive* for pharmaceutical companies to invest in *new* research and development to bring *new* drugs to market. This bill subverts that purpose, and turns patent protection into profit protection at consumers and taxpayers expense. As former Senator Howard Metzenbaum testified, S. 1172 is a tax on the poor, the sick and the elderly.

Sincerely,

Maura Kealey
Deputy Director, Public Citizen's Congress Watch

Click here for more information on this bill, including full text, list of co-sponsors, and current status.

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Public Citizen

Stop Claritin's Billion Dollar Patent Extension Grab!
Bad Medicine for U.S. Consumers and Health Care Costs

Click here for a complete text of the bill, list of co-sponsors, and current status.

Schering-Plough, a major pharmaceutical company, is pushing special interest legislation [H.R. 1598 and S. 1172] to extend monopoly patent protection for Claritin, the firm's best selling allergy drug. If successful, this high profile attack on consumer pocketbooks will have an annual cost of between $1.6 billion and $3.2 billion.

In an effort to sell the Claritin Patent Extension Grab as a "fair process" - which it's not - the company appears willing to put the same kind of money into lobbying Congress that it spends on its "blue skies" TV ads that blanket the air waves. But before Congress - or the American people - buy in, let's look at the facts about the Claritin patent extension grab:

1. Legislative history: H.R. 1598/S. 1172's proponents attempt to rewrite - and in the process seriously misrepresent - history by characterizing this special interest legislation as a remedy for "consequences unintended by Congress" in enacting the Drug Price Competition and Patent Term Restoration Act of 1984 [Waxman-Hatch Act].

2. Economic impact: H.R. 1598/S. 1172 would cost some individual American consumers hundreds of dollars more a year, and the U.S. health care system as a whole hundreds of millions of dollars more. If Schering-Plough got the full three year patent extension they are seeking, the price tag would run between $1.6 billion and $3.2 billion more during these three years.

3. Subversion of patent system: H.R. 1598/S. 1172 subverts the drug patent system from its true purpose, which is to promote research and development of new pathbreaking drugs, into an anti-competitive shield to protect the monopoly profits of an old drug.

4. Not a fair and open process: H.R. 1598/S. 1172 creates a "stacked deck" review process with all the aces in Schering-Plough's hand. Although S. 1172 purports to allow challenges based on "public interest," cost to consumers and the U.S. health care system is *excluded from* the bill's definition of "public interest."

5. Future impact: If Schering-Plough gets away with this one, every other company with a profitable drug about to go off-patent will think it is entitled to the same special treatment.

Public Citizen's analysis of H.R. 1598/S. 1172 is attached.

Legislative History

In opposing Schering-Plough's effort to extend Claritin's patent, Representative Waxman, the principal House sponsor of the 1984 Act, testified [jointly with Representative Stark] last year that "the Act...strikes a careful balance between promoting innovation and ensuring that consumers have timely access to affordable medicines."

Schering-Plough's justification for this special interest legislation would upset that balance and rewrite legislative history. The company claims that the two-year patent extension granted to seven "pipeline" drugs [so-called because they were in the FDA review and approval process when the Act was under consideration], including Claritin, should be extended because the FDA review process for these drugs took much longer than average. The company claims that in order to "remedy" an "unintended consequence," Claritin should be made eligible for an additional three years of patent protection.

This "fairness" claim rests on a clever attempt to confuse two unrelated parts of the 1984 Act:

1. ***The five-year patent term restoration process.*** Congress made this provision of the Waxman-Hatch Act ***prospective only.*** It deliberately chose to exclude the pipeline drugs from this section because it was intended as an incentive to stimulate ***new*** research and development. Since the research and development phase for the pipeline drugs had already occurred, they were not meant to be covered by it.

As the House Committee on Energy and Commerce report clearly stated: [Congress] ***"established different maximum periods of extension to provide greater incentive for future innovations."*** H.R.Rep. No.98-857, pt.1 at page 41 (1984)

2. ***Special protections for pipeline drugs.*** This does not mean that Congress ignored the competitive situation of the pipeline drugs. Other sections of the Act provided them two types of protection: (a) two years of patent extension, and (b) a variety of special non-patent exclusivity provisions, which prevented or delayed generic competition. Claritin got the two-year patent extension to which it was entitled under the Act plus another 22.5 months extension from the Uruguay Rounds Agreement Act (URAA) of 1994, the U.S. enabling legislation for the General Agreement on Trade and Tariffs (GATT). (On average, the URAA extended pharmaceutical patents by only 14 months.)

It is retrospective wishful thinking on Schering-Plough's part to read into Waxman-Hatch any intent to provide pipeline drugs with more protection that the Act gave them. If Congress had wanted to make the length of the FDA review and approval process a factor for pipeline drug patent extension terms, it could - and would - have done so.

All interested parties signed off on the tradeoffs incorporated into the Waxman-Hatch Act. What ***would*** be unfair would be to permit Schering-Plough to retroactively - and unilaterally - write themselves a better deal at the expense of consumers and generic competitors.

Economic Impact

Rising prescription drug expenditures are a leading cost-driver in the U.S. health care system. Prescription drug expenditures rose 85% between 1993 and 1998, with double digit annual increases projected for the foreseeable future. The daily newspaper and the nightly news regularly feature stories about seniors who must choose between paying for their medicines and buying food. Moreover, out-of-control drug prices remains the chief barrier to making outpatient prescription drugs a covered benefit under Medicare.

Legislation to clamp down on brand name prescription drug monopoly pricing abuses should be at the top of the Congressional agenda. Instead, H.R. 1598/S. 1172 would make things worse. Using a Congressional Research Service study, the following chart shows the potential savings to consumers and the U.S. health care system that would result from generic competition to the seven brand name "pipeline" drugs that H.R. 1598/S. 1172 would protect.

Potential Savings to Consumers and U.S. Health Care System from Generic Competition to the "Pipeline Drugs"

Drug	**Manufacturer**	**1998 US Sales**	**30% Savings**	**60% Sav**
Claritin	Schering-Plough	$1.8 billion	$540 million	$1.08 bi
Relafen	SKB	$450 million	$135 million	$270 mi
Cardiogen-82	BMS	$93 million*	$28 million	$56 mi
Eulexin	Schering-Plough	$64 million	$19 million	$38 mi
Nimotop	Bayer	$21 million	$ 6 million	$12 mi
Dermatop	HMS	$ 3 million	$ 1 million	$ 2 mi
Penetrex	RPR	$211 thousand	$63 thousand	$126 thou
Annual Total		**$2.4 billion**	**$730 million**	**$1.5 bi**

3 Year Total	**All 7 Drugs**	**$7.2 billion**	**$2.2 billion**	**$4.5 bi**
3 Year Total	**Claritin**	**$5.4 billion**	**$1.6 billion**	**$3.2 bi**

*1996 U.S. Sales.

Notes: SKB = SmithKline Beecham; BMS = Bristol-Myers Squibb; RPR = Rhone-Poulenc-Rorer; HMR = Hoechst Marion Roussel. The drugs are called "pipeline" because they were in the review process at FDA when the Waxman-Hatch Act passed. A three-year total is given because that is the length of time by which H.R. 1598 could extend pipeline drug patents. A 1996 Congressional Research Service (CRS) report found that generic competition reduced the price of a drug between 30% - 60%.

Claritin's patent is due to expire in 2002. But if H.R. 1598/S. 1172 becomes law and Schering-Plough uses the bill's stacked-deck process to gain a three-year patent extension, the company's windfall profits will cost consumers and the U.S. health care system between ***$1.6 and $3.2 billion***. This is a conservative estimate; since Claritin has had double digit annual sales growth in recent years, the actual cost to consumers - and windfall profit to Schering-Plough - could be much higher. The cost to many individual allergy sufferers would be hundreds of dollars annually.

Subversion of the patent system

Patent protection is supposed to be an incentive. The Waxman-Hatch Act's purpose in providing for up to five years of patent term restoration was to stimulate investment into new research and development to find new treatments. H.R. 1598/S. 1172 would subvert the Waxman-Hatch Act and the drug patent system by turning it into an anti-competitive profit-protection scheme. If Schering-Plough is successful, it will be rewarded not for investing in new research and development, but instead for investing in lobbying Congress to erect a protectionist barrier that prevents generic competition and maintains Claritin's high monopoly price.

To buy into Schering-Plough's "fairness" argument - that Claritin was denied the full patent period to which it was entitled because of the length of the FDA review process - is to redefine the incentive drug patents are supposed to provide from stimulating research into protecting vested interests.

As a pipeline drug, Schering-Plough had already invested heavily in the development of Claritin *before* passage of the Waxman-Hatch Act. The nearly four years of additional patent protection [two years from Waxman-Hatch; 22.5 months due to GATT] could not have been contemplated when it began to develop the drug. But instead of being satisfied with four years of windfall profits, Schering-Plough has constructed a vested-interest argument that subverts the ostensible purpose of the drug patent system in order to make ever greater profits thanks to Congress.

Stacked-deck process

The stacked-deck review process designed to give the drug company asking for the patent extension the winning hand before the cards are dealt is constructed slightly differently in S. 1172 than H.R. 1598. But both bills:

1. Cut FDA, the agency with expert knowledge about the drug review process, out of the decision-making process. Under the Waxman-Hatch Act's patent term restoration review process, FDA is charged with making the key determinations about a drug's eligibility and the appropriate length of extension based on the regulatory review period. FDA determines whether the manufacturer acted with due diligence. If that determination is challenged, FDA rules on the challenge and convenes an informal hearing to hear appeals of that ruling.

Both H.R. 1598 and S. 1172 transfer the decision-making function from FDA to the Commissioner of Patents and Trademarks.

2.. ***Set short timelines/narrow criteria.*** The Waxman-Hatch Act provides 180 days for opponents to challenge FDA's due diligence determination; moreover, opponents are entitled to an informal hearing. But under H.R. 1598 and S. 1172, the timelines are much shorter - 30 and 60 days respectively - and there is no right to a hearing.

- H.R. 1598 narrows the decisional criteria to due diligence - and puts the burden of proof on opponents.

- S. 1172's criteria ostensibly include "public interest and fairness." But the five factors the bill enumerates to constitute "public interest and fairness" completely exclude the consumer's interest in lower prices, or the negative impact of high prescription drugs costs on taxpayers and the health care system.

3. ***Grant automatic interim extensions.*** Both bills automatically grant an extension to drugs for which the patent expires during the bill's review process. Even if an application is denied, the extension continues for 60 days after the decision and the applicant is authorized to apply to the Court of Appeals to continue the extension pending judicial review.

Future Impact

The final point that must be made about H.R. 1598/S. 1172 is that it would certainly teach by example. If Congress passes H.R. 1598/S. 1172, it would create one "fairness" argument for all other companies with a profitable drug about to go off patent that ***would*** have merit: ***"You did it for Claritin, why not for us?"***

Congress should reject Schering-Plough's specious claims about fairness and reject H.R. 1598/

S. 1172. The issue that should be on the legislative agenda is the real crisis confronting consumers and the U.S. health care system: how to rein in the outrageously high and escalating cost of prescription drugs that is fueling health care inflation and hurts

seniors and people with chronic diseases - those who can least afford it - the most.

Rev: July 30, 1999
For more information: Maura Kealey 202 454-5116

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Economic Impact

Rising prescription drug expenditures are a leading cost-driver in the U.S. health care system. Prescription drug expenditures rose 85% between 1993 and 1998, with double digit annual increases projected for the foreseeable future. The daily newspaper and the nightly news regularly feature stories about seniors who must choose between paying for their medicines and buying food. Moreover, out-of-control drug prices remains the chief barrier to making outpatient prescription drugs a covered benefit under Medicare.

Legislation to clamp down on brand name prescription drug monopoly pricing abuses should be at the top of the Congressional agenda. Instead, H.R. 1598/S. 1172 would make things worse. Using a Congressional Research Service study, the following chart shows the potential savings to consumers and the U.S. health care system that would result from generic competition to the seven brand name "pipeline" drugs that H.R. 1598/S. 1172 would protect.

Potential Savings to Consumers and U.S. Health Care System from Generic Competition to the "Pipeline Drugs"

Drug	**Manufacturer**	**1998 US Sales**	**30% Savings**	**60% Sav**
Claritin	Schering-Plough	$1.8 billion	$540 million	$1.08 bi
Relafen	SKB	$450 million	$135 million	$270 mi
Cardiogen-82	BMS	$93 million*	$28 million	$56 mi
Eulexin	Schering-Plough	$64 million	$19 million	$38 mi
Nimotop	Bayer	$21 million	$ 6 million	$12 mi
Dermatop	HMS	$ 3 million	$ 1 million	$ 2 mi
Penetrex	RPR	$211 thousand	$63 thousand	$126 thou
Annual Total		**$2.4 billion**	**$730 million**	**$1.5 bi**

3 Year Total	**All 7 Drugs**	**$7.2 billion**	**$2.2 billion**	**$4.5 bi**
3 Year Total	**Claritin**	**$5.4 billion**	**$1.6 billion**	**$3.2 bi**

*1996 U.S. Sales.

Notes: SKB = SmithKline Beecham; BMS = Bristol-Myers Squibb; RPR = Rhone-Poulenc-Rorer; HMR = Hoechst Marion Roussel. The drugs are called "pipeline" because they were in the review process at FDA when the Waxman-Hatch Act passed. A three-year total is given because that is the length of time by which H.R. 1598 could extend pipeline drug patents. A 1996 Congressional Research Service (CRS) report found that generic competition reduced the price of a drug between 30% - 60%.

Claritin's patent is due to expire in 2002. But if H.R. 1598/S. 1172 becomes law and Schering-Plough uses the bill's stacked-deck process to gain a three-year patent extension, the company's windfall profits will cost consumers and the U.S. health care system between ***$1.6 and $3.2 billion***. This is a conservative estimate; since Claritin has had double digit annual sales growth in recent years, the actual cost to consumers - and windfall profit to Schering-Plough - could be much higher. The cost to many individual allergy sufferers would be hundreds of dollars annually.

Subversion of the patent system

Patent protection is supposed to be an incentive. The Waxman-Hatch Act's purpose in providing for up to five years of patent term restoration was to stimulate investment into new research and development to find new treatments. H.R. 1598/S. 1172 would subvert the Waxman-Hatch Act and the drug patent system by turning it into an anti-competitive profit-protection scheme. If Schering-Plough is successful, it will be rewarded not for investing in new research and development, but instead for investing in lobbying Congress to erect a protectionist barrier that prevents generic competition and maintains Claritin's high monopoly price.

To buy into Schering-Plough's "fairness" argument - that Claritin was denied the full patent period to which it was entitled because of the length of the FDA review process - is to redefine the incentive drug patents are supposed to provide from stimulating research into protecting vested interests.

As a pipeline drug, Schering-Plough had already invested heavily in the development of Claritin *before* passage of the Waxman-Hatch Act. The nearly four years of additional patent protection [two years from Waxman-Hatch; 22.5 months due to GATT] could not have been contemplated when it began to develop the drug. But instead of being satisfied with four years of windfall profits, Schering-Plough has constructed a vested-interest argument that subverts the ostensible purpose of the drug patent system in order to make ever greater profits thanks to Congress.

Stacked-deck process

The stacked-deck review process designed to give the drug company asking for the patent extension the winning hand before the cards are dealt is constructed slightly differently in S. 1172 than H.R. 1598. But both bills:

1. Cut FDA, the agency with expert knowledge about the drug review process, out of the decision-making process. Under the Waxman-Hatch Act's patent term restoration review process, FDA is charged with making the key determinations about a drug's eligibility and the appropriate length of extension based on the regulatory review period. FDA determines whether the manufacturer acted with due diligence. If that determination is challenged, FDA rules on the challenge and convenes an informal hearing to hear appeals of that ruling.

Both H.R. 1598 and S. 1172 transfer the decision-making function from FDA to the Commissioner of Patents and Trademarks.

2.. ***Set short timelines/narrow criteria.*** The Waxman-Hatch Act provides 180 days for opponents to challenge FDA's due diligence determination; moreover, opponents are entitled to an informal hearing. But under H.R. 1598 and S. 1172, the timelines are much shorter - 30 and 60 days respectively - and there is no right to a hearing.

- H.R. 1598 narrows the decisional criteria to due diligence - and puts the burden of proof on opponents.

- S. 1172's criteria ostensibly include "public interest and fairness." But the five factors the bill enumerates to constitute "public interest and fairness" completely exclude the consumer's interest in lower prices, or the negative impact of high prescription drugs costs on taxpayers and the health care system.

3. ***Grant automatic interim extensions.*** Both bills automatically grant an extension to drugs for which the patent expires during the bill's review process. Even if an application is denied, the extension continues for 60 days after the decision and the applicant is authorized to apply to the Court of Appeals to continue the extension pending judicial review.

Future Impact

The final point that must be made about H.R. 1598/S. 1172 is that it would certainly teach by example. If Congress passes H.R. 1598/S. 1172, it would create one "fairness" argument for all other companies with a profitable drug about to go off patent that ***would*** have merit: ***"You did it for Claritin, why not for us?"***

Congress should reject Schering-Plough's specious claims about fairness and reject H.R. 1598/

S. 1172. The issue that should be on the legislative agenda is the real crisis confronting consumers and the U.S. health care system: how to rein in the outrageously high and escalating cost of prescription drugs that is fueling health care inflation and hurts

seniors and people with chronic diseases - those who can least afford it - the most.

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DRAFT

U.S. Senate Special Committee on Aging
"The Boomers are Coming: Aging in the New Millennium"
Testimony for Mrs. Gore
Monday, November 8, 1999

Senator Grassley, Senator Breaux, and members of the Committee, thank you for your leadership on issues affecting elderly Americans and thank you for inviting me to testify. Senator Grassley, I enjoyed the conference on women's health that Barbara, Dodi Boswell, and Christine Vilsack put together in Iowa.

[Acknowledgements to other Senators]

The baby boom generation is one of the most fortunate and prosperous in history. We grew up in a time when America made significant economic gains, technological advancements, and huge strides in civil rights and gender equality.

As you know, today the baby boom is aging and the data are startling. In the next decade and a half, the 76 million baby boomers born between 1946 and 1964 will start joining the ranks for America's elderly. As a new grandmother and like other women my age, I feel too young to say I am a grandmother. But, I know we will grow old. Since that is an unmistakable fact, we ought to prepare ourselves for the changing needs of an aging baby boom generation. Our impact on American society will be enormous as it always has been, but it will be different than our parents' impact. The baby boom generation will grow old differently.

Over the next decade, the numbers of Americans between the ages of 55 and 64 will grow by 47 percent. The fastest growing segment of the elderly population will be those 85-years-old and older. In the next 30 years, we will see millions more Americans facing the challenges of chronic illnesses and disabilities.

These numbers have enormous political and cultural implications. Later this afternoon, you will hear from three experts in the fields of demography, aging and entitlement policy who will offer a more academic take on what this means for our social insurance programs and our economy.

I come before you today as a daughter, a wife, a mother, and a grandmother concerned that the kitchen table issues important to all of us be taken seriously by leaders who are making decisions today that will improve our lives tomorrow. We are here today to discuss a new challenge that has only begun to receive the attention it deserves. There are television shows, movies, books, and news reports about the Baby Boom and Generation X. But, a new generation now is taking hold of popular culture—Generation Y and not enough study or analysis has been directed toward the problems and needs of the "Sandwich Generation."

For our generation – the first ever to have more parents than children – there is the dual challenge of caring for an aging parent while also caring for growing children. So far Al and I have raised three wonderful daughters and our youngest son, who is still at home. Al and I also have our mothers to care for, who are still active and healthy. We are part of the sandwich generation—baby boomers who care for children on one side and aging parents on the other side.

It is a great blessing that Americans are living longer, healthier lives. The wisdom gained by years is truly one of our most treasured national resources. But despite all of the medical advances that have been made, people still age. Nearly half of the people over the age of 85 -- the fastest growing segment of our population -- need help with basic everyday tasks.

This problem is exacerbated by the fact that Americans have always had a penchant for exploring new places. More than ever before our families are separated by geography.

It used to be more likely that Mom and Dad would live nearby or, at the very least, in the same city. But, that's not the case today. What do you do if your Mother lives in Phoenix, you live in Washington, and she's fallen and broken her hip? After the initial crisis ends, how can we help parents care for their parents over the long term? How do we honor our parents and maintain the dignity of Americans with long-term care needs? I know Al struggles with this problem with his own mother, who lives in Tennessee. We are always grateful for the extended family that can take care of her should something go wrong.

We must work together to find ways not only to care for those with long-term care needs, but also to support the caregivers—the people who undertake the crucially important but often physically and emotionally difficult job of caring for a loved one who is aging or ill.

Women typically bear a greater burden in caring for an aged parent or adult; African-American women bear a greater burden than most other women. Moreover, many caregivers work full-time jobs, making informal, long-term care even more difficult. Caring for a family member is one of the most valuable and important jobs someone can do, and as a nation we need to support those who do it.

I am proud that Al and President Clinton have been working with both sides of the aisle—including the senators on this committee—so that our public policies reflect our private needs. Senator Breaux, Al and I especially appreciate your leadership on Medicare issues.

Government can help families raise children and care for their elderly parents. We can offer a tax credit for long-term care to ease the financial burden. Congress can reauthorize the Older Americans Act to create the National Family Caregiving Support Program and support other direct services, like Meals on Wheels, to older Americans. Congress and the Administration can study ways to provide incentives to private insurers to offer affordable long-term care insurance.

These initiatives can help relieve and address families' emotional and financial burdens that caregiving imposes. We should not pretend that any government program can ease families'

emotional and financial strains. We should not pretend that there is a one-size-fits-all, long-term care program. At the end of the day, families will still have to provide the necessary care. In so many cases, though, something remarkable often happens. Families not only survive, they actually thrive. We ought to give more credit for the empathy, the resilience, and the downright individual strength that we see in families facing a medical crisis, whether the crisis affects a sibling, a parent, or a grandparent.

In the process of keeping our families together and on the right track women often forget about our own needs. We shuttle the kids between soccer practice and piano lessons, but forget to exercise and enjoy a personal hobby. We rush home to put dinner on the table or stay up late to pack lunches, but often neglect our own nutrition. We make sure our children get their shots and our parents get to the doctor, but we skip check-ups and important health screenings.

Women and men need to place a higher priority on keeping body and soul together. And we must understand that a healthy mind and a healthy body go hand-in-hand. The emotional and financial responsibilities of caring for children and an aging parent compounds these problems and can make us more susceptible to mental health illnesses. We need to be able to talk about our mental health concerns as openly as we have learned to talk about issues such as cancer and heart disease.

One powerful myth out there today is that mental illness and depression are a normal part of aging. This is not true. People can look forward to many things as they get older, but depression and mental illness does not have to be one of them. Nearly 5 million of the 32 million Americans age 65 and older suffer from clinical depression. I would like every older American living with mental illness who are suffering in silence and secrecy to know that treatment is available, treatment works, and treatment can change your life. There is hope. But you have to get help.

Today's retirees and retiring boomers are and will be a highly valued resource. Being old is no longer considered being a drain on society and baby boomers will erase that fallacy for good. Having come of age when President Kennedy challenged us to "ask not what your country can do for you, but what you can do for your country," we will continue contributing to our communities through work and volunteerism. The public and private sectors ought to work together to find creative ways to harness our collective energy and drive to improve our schools, communities, and our country.

Mr. Chairman, Ranking Member Breaux, you know all too well that our work is cut out for us. American families face extraordinary pressures, two of which are becoming more and more common. How can I care for my children? How can I care for myself? And, how, if one or both of my parents fall ill, can I care for them? We need to work together to solve these problems, to develop tools and programs for families to get help who need help. With your leadership and expertise, together, we can address these problems and help these families.

COMPARISON BETWEEN H.R. 827 (DEGETTE) AND GORE CAMPAIGN PROPOSAL

PROVISION	**DEGETTE CHILD HEALTH BILL, H.R. 827**	**GORE CHILD HEALTH PROPOSAL**
Single, Simplified Application for Medicaid and SCHIP		
New Presumptive Eligibility Options for Child Coverage		
Incentives to Eliminate or Required Elimination of Assets Test for Eligibility	incentives to states	requirement
Enhanced Matching Rate for Improved Outreach and Enrollment	enhanced matching rate for outreach & enrollment efforts	performance bonus and penalties for enrollment
Mail-In Applications/Toll-Free Hotlines	requires states to participate in toll-free number	requires mail-in application access (unclear if Medicaid)
Optional Coverage of Pregnant Women or Families in SCHIP	pregnant women	cover parents
Optional Coverage for Legal Immigrant Children and Pregnant Women		in President's budget proposal
Continuation of Outreach Funds to Continue Medicaid Coverage for Families Leaving Welfare		in President's budget proposal
Oustationed Workers in Safety Net Hospitals and Community Health Centers		
Reassessment Prior to Loss of Coverage from Medicaid or SCHIP		
Reducing the Use of Waiting Periods in SCHIP		
Grace Period Before Disenrollment for Nonpayment of Premiums		
Require One-Year Continous Eligibility of Coverage		
Enabling Link of SCHIP to School Lunch Programs		

adoption of this bill poses serious problems."

The President states that one of his objections to the bill is the amount proposed for defense. He says this because Congress, in its wisdom, cut $2.1 billion from his excessive request for Pentagon spending, including a $30.7 million reduction in the Pentagon's nuclear weapons program.

Another problem the President has with the bill is the funding of various domestic programs. Mr. Speaker, I strongly endorse the Appropriations Committee's proposed $211 million for community service employment for the elderly poor. I applaud the $148 million for college grants for disadvantaged students. I commend the committee for proposing $26.5 million for handicapped education; $217 million for student financial assistance; and $10 million for aid to colleges with large numbers of minority students.

President Reagan is opposing a bill which includes $500,000 for the Center for Disease Control's preventive health services program to continue efforts to discover the cause and cure for Kaposi's sarcoma. This funding is critical for the fight against a pernicious and often fatal disease. People in San Francisco and the Nation are appalled that Mr. Reagan's veto will halt this vital program.

The people of San Francisco and other major American cities must wonder why Mr. Reagan opposes $37 million for urgently needed urban mass transportation. Those people concerned for our Nation's environment must wonder why he opposes $13.3 million to fund efforts to return land ravaged by strip mining to a useful and esthetic state.

Mr. Speaker, I will vote to override this veto and I urge all my colleagues to uphold the right of Congress to set Federal spending priorities.

VETO OF PRESIDENT A CON JOB

(Mr. MITCHELL of Maryland asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. MITCHELL of Maryland. Mr. Speaker, this veto is the biggest scam, con job that has been attempted by the White House up to this point. There is no point in calling it anything else but that. It is a con job. It is a scam. The President knows darn well that this is not any budget buster. He knows that. It is way below his figures.

What he wants to do and does not apparently have the will and support to do is to eliminate all Federal programs. That is what he wants.

Way back when we passed the Social Security Act, it was the Republicans who voted overwhelmingly to send it back to committee, and that would have killed the Social Security Act. A leopard does not change its spots.

What we have here is a scam job and we have got to deal with it. We have to be honest with the people. I tell the Members, the President is afraid. He is afraid to say, "I do not like housing; Government should not provide it. I do not like to help senior citizens; the Federal Government should not do that. I do not like to help students; the Federal Government should not do that."

He does not have the guts to say that. What he is doing is nibbling away at these programs every chance he gets. Cut, cut, cut.

Come on out. Be the true conservative that you are, Mr. President, and say end all Federal programs. I would have a lot more respect for you.

VOTE AGAINST THE PATENT TERM EXTENSION BILL

(Mr. GORE asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. GORE. Mr. Speaker, the issue of the day is the supplemental veto and the effort to override which I strongly support, but I rise to discuss another bill that has just been scheduled for debate next Monday with a vote to occur on Wednesday. Although it has been scheduled as a suspension, I rise to alert my colleagues that this measure is anything but noncontroversial. It is extremely controversial.

Since a lot of Members will be out of town on Monday and Tuesday for the primary elections, they will come back on Wednesday to face this vote without benefit of a lot of the debate. So I just want to alert my colleagues on this occasion.

I am speaking of the patent term extension bill which is an extremely important measure that will raise the price of medicine by giving up to a 7-year extension on patent terms to pharmaceutical companies.

It is based on false premises. The fact is that there has been no decline in innovation whatsoever by pharmaceutical companies since 1962.

Second, there have been huge increases in real dollar terms in research and development by pharmaceutical companies and enormous increases in profits. In addition, we just gave them a 25-percent tax credit for research and development expenditures.

Do not be hornswoggled on this bill. Consumer groups are strongly against it. Senior citizen groups are strongly against it, as well as many others.

The pharmaceutical industry is trying to pull the wool over the eyes of this Congress, do not let it happen. Vote "no" next Wednesday.

THE IMPORTANCE OF TITLE V FOR OLDER WOMEN

(Mr. BONKER asked and was given permission to address the House for 1 minute and to revise and

Mr. BONKER. Mr. number of my colleagues spoken to the possible el title V of the Older Amer the Congress today does the President's veto on the tal appropriations bill.

Recently the Select Co Aging conducted hearin Northwest on the impac cuts on older women. C WYDEN and myself par these hearings and we hea nesses who reaffirmed the tance of the title V senior program, particularly women. Older women no 72 percent of the elderly truly dependent on mar Federal programs.

Despite the crucial need President Reagan has vet piece of legislation that a the $211 million in additio keep title V seniors emplo June of 1983. If the Con override this veto, over 5 will be out of work after 30. Of the 54,000 part-time services jobs provided fo income elderly, two-third employing women.

I urge the Congress toc ride the President's veto this important program.

□ 1100

HUMAN NEEDS JU OVERRIDING VE

(Mr. DASCHLE asked an permission to address the minute and to revise and remarks.)

Mr. DASCHLE. Mr. Sp today, this House will hav tunity to show that ou senior citizens, handicapp and young people are jus tant to this country as B MX missiles, and M-1 tan do this by voting to overri on a supplemental appropr a bill that, far from bein buster," appropriates almo less than the administratio This bill was not vetoed spent too much money. It because it tried to meet s instead of military concern make sure that we stre country through programs Thumb, so that senior cit have the opportunity t useful community services life of dignity instead of c It tried to make sure that capped would have the opp fully participate in the system. It tried to make su young people would not be opportunity for a college ed

agency is engaged. It is during that period that any bureaucratic delay would occur.

Many of us were prepared to support an amendment that would say that the day the companies hand in a completed application to the FDA, from that moment forward they would get extra time.

Another amendment we wanted to have is related, because as the bill now stands, there is no mechanism for deciding who was at fault for the delay. Under the current bill a company which suffers delay because of its own ineptitude or its own shortcutting in not properly testing this drug would be rewarded with an extension of its patent term. I would like the opportunity to offer an amendment, supported by a substantial partisan minority of the subcommittee, to allow someone to intervene in that process and say, "wait, this is not the problem of bureaucratic delay."

□ 1345

Mr. RAILSBACK. Mr. Speaker, will the gentleman yield?

Mr. FRANK. I yield to the gentleman from Illinois.

Mr. RAILSBACK. I thank the gentleman for yielding.

I wanted to point out that there is, as the gentleman knows, a great deal of testing before it actually goes into the chemical testing stage, before they ever even apply for a patent. There are all kinds of testing before it ever reaches that stage.

Mr. FRANK. I thank the gentleman. I am glad there is. But I do not regard that as a favor at any point that the companies are doing for us. I regard that as an integral part of the process by which one determines the fitness of the drugs to go forward.

Let me say further I agree with the gentleman that this is a fit subject for debate. What we are asking for today is not defeat of the whole bill but defeat of the suspension process so that the gentleman from Illinois and I could in fact conduct this debate for the benefit of the Members in a somewhat more open fashion, not constrained as we are by the time.

I do not think, given the kinds of issues the gentleman from Illinois would like further to discuss, that the suspension process adequately contains this.

The cost of this is that generic drugs, a means of saving money for consumers and for the Government, a means of effective cost control that does not sacrifice the quality of care, will be put further out of the reach of consumers. I think that would be a mistake.

Mr. Speaker, I yield such time as I have remaining to the gentleman from Tennessee (Mr. GORE).

Mr. GORE. I want to thank by colleague and pay my respects to the chairman of the subcommittee and the full committee.

I respectfully oppose this bill as strongly as I possibly can as an unnecessary giveaway for which nothing will be given in return. It proceeds from false premises and I want to outline them one by one.

No. 1, the impression is given that this industry is in distress. That is false. This industry is the third most profitable industry in the United States. This fact comes not from the debate of the chairman of the subcommittee this morning, but in the arguments and the general presentation of the industry. The profits of this industry are going up and up and up.

No. 2, that there is some problem with R. &. D. expenditure. Research and development spending has been skyrocketing and it has been going up in real terms, deflated dollars year after year after year. Let me read you a recent quote from Fortune magazine within the past year.

> Merck is pouring a colossal $280 million into R&D this year, nearly four times more than ten years ago, while Eli Lilly's $210 million for 1980 was three times more than in 1971. Pfizer's research expenditure, which quintupled from 1970 to 1980, will grow by nearly 16% this year, to around $180 million, while Squibb has boosted spending 84% in the last five years to $91 million.

Where is the problem with incentive for research and development? And as if there was a problem, we already gave them just this past year a new 25-percent tax credit to stimulate them even more. How much encouragement do they need?

The second false premise is that innovation has been declining, it is said. Innovation has not been declining.

The statement has been made that there are half as many drugs approved this year as in 1960. That is misleading because 1962 was the year the modern era of drug regulation began. There were fewer new drugs approved in 1962 than there were this year.

The third false premise, that there is a problem with the effective patent life. Let us look at the effective patent life for not just the ones that the drug industry averages in but let us look at the top selling drugs for this year.

An average number of years of patent monopoly protection after FDA approval is not 17 years but 18½ years, more than the 17 years.

How could that be? It is because they use the patent system, they pyramid patents, and they evergreen patents. Even after the patent period expires they still control the market.

Take the example of librium.

I urge my colleagues to vote no when the occasion arises.

Mr. SHAW. Mr. Speaker, I yield 1 minute to the gentleman from Kansas (Mr. GLICKMAN).

Mr. GLICKMAN. Mr. Speaker, I cosponsored this legislation and I still believe that there changes in the law made.

But I would urge n cosponsor, to vote a the Suspension Cale

This is a very serio tion. One of the am offered in committe amendment, would h the extension perio counted as to the va ered from the time to the Federal ager proved. That is a cr The length of the p to be extended unde modified significantl tant amendment tha opportunity to be of

While it is true m that have been said of this industry and vation, I think the of the patent extens mands the attentic under a separate flo fore, I would urge a pension of the rules.

Mr. SHAW. Mr. minutes to the gent gan (Mr. SAWYER).

Mr. SAWYER. Mr support of this legisl

Right at the outse correction or two in ments made by th Tennessee; namely, inflation the pharm as a percentage of s 35 percent from 196

During the same effective patent te 14.6 years to 7.4 ye the effective patent 6.8 years.

I would also sugge man from Tennesse ticle not too long a tributed this bill to istration. This bill a tleman had done h its genesis in the tion. President Ca blue ribbon panel t ject, to find out w patent applications the United States a this industry; name tical and chemical they had declined since 1960.

This panel came major recommendat we computerize an Patent Office to n cient. Second, that restudy process patent examiners. up a new Patent called the Court Fourth, that we do rect this intrusion that this process o

tion and licensing before it could be marketed that applied in both the pharmaceutical and chemical industries.

The first three of those have been accomplished by the Congress, and this is the fourth one that is being implemented to try and get some life back in our innovation and our patent applicatons and in our progress.

This bill has been endorsed by approximately 50 of the major newspapers in the country, including the New York Times and the Washington Post, which are certainly liberal and consumer-oriented newspapers.

Not only has it been endorsed by these major newspapers on the basis of fairness, but by every one of the major medical and health care organizations, including the American Medical Association, the American Bar Association, the Patent Division, and the American Association of University and American Association of Medical Schools, the Heart Association, the Cancer Association, who are all behind this legislation.

May I say that when we have a patent term for 17 years for the inventor of a toy, to say that the inventor of an important pharmaceutical can only have 6.8 years of patent protection is not a question of plain fairness. All of them had 17 years historically as indicated by the Constitution. Then in 1962 we started this Federal process of patent, but before marketing, that gradually chewed up that patent as to pharmaceuticals and pesticides and certain chemicals.

In just plain fairness it is merely to give back that time or a portion of

the pyramiding and evergreening has been alluded to and would be corrected by this bill which wipes that

This is just in plain fairness to this industry and to reencourage the investment of research and development

Fundamentally, we are getting very little for it. There is no effect on the patent life for almost 20-years down the road from today if we do adopt the legislation nothing will change except the reinvestment of R. & D. money into the development of pharmaceuticals and drugs.

Mr. HILLSBACK. Mr. Speaker, will the gentleman yield?

Mr. WYLIE. I yield to the gentleman from Illinois.

Mr. HILLSBACK. I thank the gentleman for yielding.

I just want to make one point, which is that the New York Times and the Washington Post I think have now come out with a subsequent editorial opposing an amendment.

The gentleman is absolutely correct initially they were very strong

I think the gentleman has made some excellent points. I think the gentleman from Texas (Mr. BROOKS) is also for the bill.

Mr. SHAW. Mr. Speaker, I yield 1 minute to the gentleman from Texas (Mr. BROOKS).

Mr. BROOKS. Mr. Speaker, I rise in support of H.R. 6444, the Patent Term Restoration Act of 1982. This bill would allow the extension of the term of a patent for products which are subject to review by Federal agencies when the owners of those patents are prevented from marketing their inventions during the agency approval process.

Mr. Speaker, this bill has the important purpose of encouraging innovation by restoring full value to patents on inventions subject to agency review. It would grant patent owners an extension of their rights for up to 7 years beyond the traditional 17-year patent term. The knowledge that the regulatory review and approval process will not diminish the value of their patents is certain to encourage research and development in these regulated fields.

Mr. Speaker, under the able leadership of my friend, Chairman BOB KASTENMEIER, the Judiciary Subcommittee on Courts, Civil Liberties, and the Administration of Justice has made several changes to the original patent term bill, H.R. 1937. These amendments insure that the original purpose of the legislation will be carried out and that there will be minimum negative impact from the bill on the generic drug industry and on consumers.

I urge support of H.R. 6444.

Mr. SHAW. Mr. Speaker, I yield 4 minutes to the gentleman from California (Mr. WAXMAN).

Mr. WAXMAN. Mr. Speaker, there is one proposition that I think both the proponents and opponents of this bill would agree upon that is the fact that when we give an extension of the patent interest period it is going to lead to a longer period of time in which there will be higher prices for drugs. That is logical, because a patent means you have a monopoly over the production and sale of a drug.

That monopoly means that there cannot be a competitor who can produce the same drug and sell it at a cheaper price.

What this bill will do will be to insist on the highest price for drugs to be paid by those people who need to buy drugs.

Who are the people who need to buy drugs? Primarily the elderly and certainly the sick. Eighty-four percent of drug purchases in this Nation are paid for out of the pockets of the people who must buy medications.

This bill will add a shift and it will add to the cost of drugs billions which will mean a shift out of the pockets of the elderly primarily into the pockets of the pharmaceutical manufacturers. We are told that we ought to support this shift of billions of dollars from those who are on limited, fixed incomes to those who are some of the wealthiest corporations in this Nation because it is going to be fair and it is going to bring about innovation.

But if we look at those claims, they just do not hold up because what they see with the pharmaceutical industry was, according to the Wall Street Journal, a 25-percent increase in profits in its in 1981. For 1982, a 20-percent increase in profits. And at a time when everyone else in this Nation is suffering from recession.

What we have seen in expenditures for research and development is a continuous increase year after year.

When the drug manufacturers manufacture drugs they get their investment back and they get a tremendous profit. I do not begrudge them that but what I do begrudge them is to come to Congress a year after year passed the tax break for them for research and development of 25 percent and to ask us to help them out by giving them a longer period of time over which they are going to ask the elderly of this Nation to pay higher prices for drugs.

I do not think that is fair and a number of my colleagues agree that it is not fair who originally thought the idea of this bill seemed right.

□ 1400

A number of my colleagues joined even coauthoring the bill, who accepted that superficial argument that was advanced for it; and then later, when they looked at the legislation more carefully, they decided to oppose it.

Two of the leading newpapers in the Nation originally supported the bill when they heard from the pharmaceutical industry. But when they looked at it a little more carefully, they backed away from it. The New York Times and the Washington Post both told us to support this legislation, and then later came out with editorials asking us to either oppose it or to severely curtail it.

Now, this legislation is different from that which the other body has proposed, and it is still not legislation that the drug industry will support because the drug industry wants the bill passed by the other body—because that is a much more generous bill for them. And this compromise which we are being urged to vote for is a compromise which they still do not accept.

I urge that on this suspension vote we defeat this bill, that we defeat it because as it stands today before us we have only one choice to vote up or down, and I say let us vote down this bill. I urge my colleagues to join me in doing so.

Mr. SHAW. Mr. Speaker, I yield 1 minute to the gentleman from Tennessee (Mr. GORE).

Mr. GORE. I thank my colleague for his courtesy.

Mr. Speaker, just to correct the record once and for all, the Post changed its position, the New York Times changed its position, too, and the Times did not just ask for amendments. I say to my colleagues; it came out flat, foursquare against the whole thing. Let me read to my colleagues what they said:

> The pharmaceutical industry is efficient, profitable and healthy. It has no demonstrable need for any special break. The patent system as a whole may need reform, but that is a different issue. Monopoly rights should not be doled out to anyone with a hard-luck story, as Congress seems to believe. The proposed extension is unjustified, unsuited to the stated purpose of increasing research and offensive to the basic principle of a free economy.

To sum up, research and development spending is increasing. Profits are increasing. Innovation is stable. The industry does not need this bill. The only thing it will accomplish is to raise the price of medicine by an estimated $3 billion to $5 billion each year.

Mr. Speaker, I urge my colleauges to vote "no."

Mr. SHAW. Mr. Speaker, I yield myself the balance of my time.

The SPEAKER pro tempore. The gentleman from Florida (Mr. SHAW) is recognized for 1 minute.

Mr. SHAW. Mr. Speaker, I think in our desire to finish up the legislative business of this Congress, we are probably going to be doing a lot of things and voting on a lot of things that we have no business doing. In looking around this hall today, we see that most of the Members are apparently not here. I think that if we would check, we would find that they were not in their offices, that they are in their home districts doing important business. But this is important business. What we must do is to vote this bill down under suspension, get it here on the floor, with an open rule, so that we can present amendments to take the bad part out of this bill and pass it in a preferred form.

What we are talking about is the pocketbooks of the elderly. And for us to go running out of this hall so that we can get home to campaign and tripping over the limited earnings of the elderly in doing so, I think it would be a tragedy. We must take out of the bill the portion that would allow the extention of the patent, the period of time the prices are set without competition, to take out that portion which the company has complete control of, and come up with a good bill that all of us can support.

● Mr. CORRADA. Mr. Speaker, I rise in support of H.R. 6444, the Patent Term Restoration Act, which would restore the period of useful life of patents lost hurdling over Federal regulations. Currently, manufacturers of such products as drugs, medical devices, and chemicals, use more than half of the 17 years of their patents exclusivity period complying with FDA's premarketing requirements.

It is only fair play that we correct this inequity in the law. It is ironic that medical breakthroughs be penalized for having to meet Federal regulatory requirements directed to protect the public health.

With this kind of disincentive, it comes as no surprise that in the past 20 years there has been a dramatic decline in the number of new medicines introduced in the United States. Our research intensive industries feel betrayed when Congress incentives are diminished by subsequent regulations and nothing is done about it.

The future well-being of our citizens and the economic situation of our Nation demands the drafting of incentives for economic investment in high-risk areas that could bring about economic growth and new lifesaving products. This bill provides a simple, equitable, and uncostly way of stimulating this capital investment in areas that could lead us to a new era of economic stability and a healthier life for our people.

I urge my colleagues to vote for the passage of this legislation.●

● Mr. PEYSER. Mr. Speaker, while I am very sympathetic with the problems confronting pharmaceutical companies in the loss of patent protection time due to the delays in final approvals by the FDA, I think that this bill, in its present form where it cannot be amended, is not in the best interest of the public and particularly the elderly.

I would be willing to support an amendment to this legislation, such as the Frank amendment which would limit the extension time to the time elapsed between the actual filing for drug approval and final approval by the FDA. Drug research is obviously of great importance, and companies should not be penalized by needless loss of protection under their patent by delays over which they have no control.

It is certainly my intention to support this legislation with the type of amendment I have spoken of when it comes to the floor in the next Congress. In the meantime, it is certainly my hope that pharmaceutical companies, both for their good and for the good of the American public, will continue their active research work that has done so much good in improving the health of all Americans.●

● Mr. HOLLENBECK. Mr. Speaker, I rise in support of H.R. 6444, the Patent Term Restoration Act of 1982.

Mr. Speaker H.R. 6444 is a balanced bill which will assure more rapid technological innovation in the pharmaceutical and chemica
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● Mrs. SCHNEIDER
rise today in support
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UNITED STATES OF AMERICA

Congressional Record

PROCEEDINGS AND DEBATES OF THE 98th CONGRESS

FIRST SESSION

VOLUME 129—PART 14

JULY 11, 1983 TO JULY 19, 1983

(PAGES 18429 TO 19847)

UNITED STATES GOVERNMENT PRINTING OFFICE, WASHINGTON, 1983

crats to effect changes in regulatory policy.

My bill, "The Women's Economic Parity Act" changes pension and tax laws to assure women equitable treatment and coverage under retirement plans. My bill acknowledges the economic worth of the homemaker and her community volunteer participation. My legislation draws from the strengths of several women's rights bills and modifies certain provisions to provide economic parity and justice for a greater number of women.

The Women's Economic Parity Act (WEPA) makes key changes in the Employment Retirement Insurance Security Act (ERISA) regarding joint and survivor benefits, divorced spouses, working aged women 21 to 24, and women on company-approved maternity leave. This bill allows homemakers to set up separate individual retirement accounts (IRA's), employers to take a tax credit for hiring a displaced homemaker, and individuals who perform substantial volunteer services to take a tax credit for child care expenses.

Under current law, pension plans do not provide for a joint and survivor benefit unless the plan participant chooses this option. Therefore, if a wife lost her husband when he was 53 years old—2 years short of retiring from a 32-year career with his company—and he had not signed up for survivor benefits, she would be left with nothing.

Under WEPA, joint and survivor benefits are automatic unless both the plan participant and the spouse consent in writing not to choose this option. This provision should improve current statistics which show that 85 percent of the elderly poor are elderly women living alone.

Currently, the law is unsettled in domestic relations cases to the extent to which State courts can alienate benefits under pension plans governed by ERISA. Furthermore, there are no clear-cut procedures outlined for pension plans to comply with a court order.

Under WEPA, the payment of benefits to a participant under an employee benefit plan is subject to the requirements of qualified domestic relations court orders. Procedures for making these adjustments are defined in WEPA to guarantee fairness to everyone who would be affected by the court order—the plan administrator, the plan participant, and the divorced spouse, and children.

Under current law, men and women cannot begin to count toward vesting in a pension plan governed by ERISA until age 22, and become vested in a pension plan until age 25.

By lowering the age limitation for both of these provisions to age 21, approximately 12 million more working men and women can become vested in pension and retirement plans. Studies show that the greatest number of women for any one age group in the labor force are women aged 21 to 24. This provision is designed to specifically give these individuals credit toward their retirement.

Under current law, pension plans do not have to provide credit for women who are absent from work due to maternity leave. This penalizes working women who take time from work to have children.

Under WEPA, women can continue to accrue 20 hours a week pension credit, for up to 3 months, while on company-approved maternity leave. In order for the accrued pension credit to count, women must either return to work for the same employer or offer to return to work but not be reemployed by the same employer.

As demonstrated by the number of legislative initiatives to change the current IRA law, nonworking and part-time employed spouses are presently penalized and cannot establish a separate IRA. A person must have earnings in the traditional sense—salary and wages—to establish an individual retirement account.

Under WEPA, women with earned or unearned income can establish a separate IRA and take up to the maximum $2,000 income tax deduction limit. We are all familiar with cases where a woman with several children has been divorced by her husband. She is in her thirties or forties and never before had to manage the family finances, nor has she ever had to work outside of the home since her husband had been sole supporter. Women in this situation have been labeled displaced homemakers. Estimates indicate there are over 3 million displaced homemakers in America. They have been forced to compound their traditional responsibilities of child-rearing with those of being the sole supporter as a result of losing family financial support through separation, divorce, abandonment, or death of their spouse.

My bill attempts to alleviate some of this traumatic adjustment by encouraging employers to hire displaced homemakers. Under WEPA, employers who hire a displaced homemaker will be permitted to take a tax credit for a percentage of her salary for up to 2 years. The maximum total credit allowed under this legislation is $4,500 for the 2-year period.

Finally, this legislation recognizes the valuable contribution women can make to their communities through volunteer work. By providing a tax credit for child care expenses for married women who perform substantial volunteer work, the distinction between the value of a paid job versus volunteer work is eliminated.

Mr. Speaker, I want to reemphasize that I believe it is important for Congress to act now to give women the economic parity, justice, and fairness long overdue them, and I encourage my colleagues to cosponsor this legislation.●

CHIEF STANLEY R. SARBARNECK

HON. WILLIAM O. LIPINSKI

OF ILLINOIS

IN THE HOUSE OF REPRESENTATIVES

Wednesday, July 13, 1983

● Mr. LIPINSKI. Mr. Speaker, after more than 50 years of providing dedicated service and protection to the people of Chicago and Bridgeview, Ill., Chief Stanley R. Sarbarneck of the Bridgeview Police Department, is retiring.

Chief Sarbarneck's past involvment in the welfare of our community is both extensive and impressive. He has been the chief of police of Bridgeview since 1971. He was a supervisor of training at the Chicago Police Academy, president of the Chicago Police Benevolent Association, and a professor of criminal justice at Moraine Valley College. Stanley is an executive member of the National Executive Law Enforcement Advisory Board and a member of the State of Illinois Athletic Board. He was also an honorary lieutenant colonel in the Alabama State Militia.

Stanley's expertise in the martial arts is well known. He is the director of the International Jujitsu Institute, former chairman of the AAU Judo Educational Committee and a holder of the black belt in judo and jujitsu.

Chief Sarbarneck has also been active in his own neighborhood. He served as president of the St. Stephen Church Holy Name Society and the St. Stephen Church Senior Men's Club.

All of us in the Fifth District are proud to have known and worked with Stanley. He is dedicated, hard working and honest, and has set an example of community service that we would all do well to follow. Chief Sarbarneck has shown people young and old of the value of hard work and integrity, and I offer Stanley my congratulations, best wishes and thanks for his years of service, both past and future.●

OPPOSITION TO H.R. 3502

HON. ALBERT GORE, JR.

OF TENNESSEE

IN THE HOUSE OF REPRESENTATIVES

Wednesday, July 13, 1983

● Mr. GORE. Mr. Speaker, I rise in opposition to H.R. 3502, legislation to extend the patent term for certain pharmaceutical products by up to 7 years. This bill represents an unwar-

ranted boost to the profits of an extremely successful industry at the expense of the public, particularly the poor and the elderly, and I urge my colleagues to oppose it.

Proponents of the legislation argue that pharmaceutical innovation is in a state of decline due to premarket regulatory review requirements. But the facts refute this contention. The pharmaceutical industry is among the most profitable of all major American manufacturing industries. While most sectors of the economy reeled during the recession of 1981-92, pharmaceutical profits increased dramatically. In 1981, profits increased 20 percent. In 1982, profits increased an additional 25 percent. If, as is asserted, there is a regulatory review "problem," it is not reflected in the industry's profits.

Nor is there any evidence of a decline in pharmaceutical innovation. Twenty-seven new drugs were approved for marketing in 1981; 28 were approved in 1982. The number of new drugs approved by the Food and Drug Administration (FDA) for marketing in 1981 and 1982 has been higher than in any year since 1962, when the efficacy testing requirements were added to the Federal Food, Drug and Cosmetic Act in landmark changes.

Industry expenditures for research and development have increased substantially over time, even after adjustment for inflation, according to a 1981 report prepared by the Office of Technology Assessment. This trend is expected to continue. The coming decades have been characterized by industry observers as a "golden era" for new drug development, based in part on the potential for dramatic advances in the application of genetic engineering.

Even if, in the face of the overwhelming evidence of the current prosperity of the pharmaceutical industry, it is believed that a stimulus to innovation is desirable, that stimulus already exists. The Economic Recovery Tax Act of 1981 provided a new 25 percent R&D tax credit for firms that increase R&D expenditures. In fact, the pharmaceutical industry is taking advantage of this new provision, according to the National Science Foundation (NSF). According to NSF, pharmaceutical R&D is growing at a 20-percent annual rate, spurred by the tax credit, reduced FDA approval time, and recent research breakthroughs and new marketing opportunities.

The R&D tax credit has an obvious advantage over patent term extension. It insures that additional revenue will be channeled into research and development. In contrast, drug companies have repeatedly refused to commit themselves to reinvesting even one dime of the additional profits that they will reap if patent term extension legislation is enacted. While the companies talk in general terms about the possibility of greater R&D expenditures, they will make no commitments. Their silence on this point is notable.

Moreover, even if the pharmaceutical companies reinvest the percentage of extra sales that they have historically reinvested, approximately 8.5 cents of every sales dollar, it is a poor investment for the public to spend $1 to get 8.5 cents of research. The existing R&D tax credit avoids this problem as well.

The final argument advanced by proponents of the legislation is the so-called equity claim. The argument that it is unfair for products subject to premarket regulatory review to lose market exclusivity that nonregulated products retain is based upon a fundamental misapprehension of the nature and purpose of the patent system. The patent system is not intended to and does not operate to grant an inventor any period of market exclusivity. Rather, the inventor is granted the right to exclude others from marketing the product for the statutory 17-year period.

This is an important distinction to bear in mind. It is based upon the recognition that no inventor enjoys 17 years of market exclusivity. Marketing considerations and other factors involved in refining an invention into a commercially viable form significantly limit the period of market exclusivity for all inventors, irrespective of whether the product is subject to premarket regulatory review.

In fact, it would be inequitable to give inventors of regulated products a period of patent-term extension for the regulatory review period when the product would not be marketed anyway because it is not in a commercially viable form. Inventors of nonregulated products do not have this regulatory umbrella that under the legislation would allow time to be recovered even when the product would not otherwise be marketed.

The drug companies have implicitly acknowledged another aspect of this fatal flaw in the premise of the legislation. The companies concede that most of the safety and efficacy testing that they conduct would be done even if there were no regulatory requirements, in order to protect themselves from product liability claims. Yet still they seek special treatment.

There is an additional reason why the time is not ripe for consideration of this legislation. The Congress does not yet have the factual information necessary to evaluate accurately the effect of the regulatory process on patent protection, or the effect of the companies' own internal decisionmaking process on patent protection. We have requested this information and hope it will be provided in the near future.

I ask that my colleagues carefully review the arguments on both sides of this bill. It is not a simple issue, but I believe the public interest is best served by rejection of this legislation. It will simply guarantee substantially higher profits for an industry that is already extraordinarily profitable. In a period in which health care costs are skyrocketing out of control, the public can ill afford such an additional burden.●

SALUTE TO LECH WALESA

HON. MICHAEL D. BARNES

OF MARYLAND

IN THE HOUSE OF REPRESENTATIVES

Wednesday, July 13, 1983

● Mr. BARNES. Mr. Speaker, on June 13, the Friendship Heights Village council, representing the Village of Friendship Heights in Montgomery County, passed a resolution declaring Lech Walesa an honorary citizen of the Village of Friendship Heights, and adopting the city of Gdansk as its big sister city. The Friendship Heights community, of approximately 5,000 people, honors each year on Independence Day, dedicated men and women who exemplify what independence means to us as Americans. The council has made a fine choice this year in bestowing this honor to Lech Walesa, and I wanted to share with my colleagues the following letter to Mr. Walesa from the council, as well as the text of their resolution:

FRIENDSHIP HEIGHTS VILLAGE COUNCIL,
Chevy Chase, Md., July 4, 1983.

DEAR MR. WALESA: It is my pleasure and privilege to inform you that on June 13th, 1983, a majority of our seven-person elected Village Council approved the enclosed resolution, making you an honorary citizen of Friendship Heights, Maryland. This vote was confirmed on June 28, 1983.

We represent a small community of approximately 5,000 people, who live in eight tall apartment buildings just two blocks from our capital, Washington, D.C.

There are many diplomats and foreign-born residents in our Village, but only a small number from Poland. However, we are reminded of a quotation from our American President Andrew Jackson, almost 150 years ago: "One man with courage makes a majority."

In that sense you symbolize for many the courage and hopes of people in many lands, representing solidarity with the ideals of our Independence Day, July 4th.

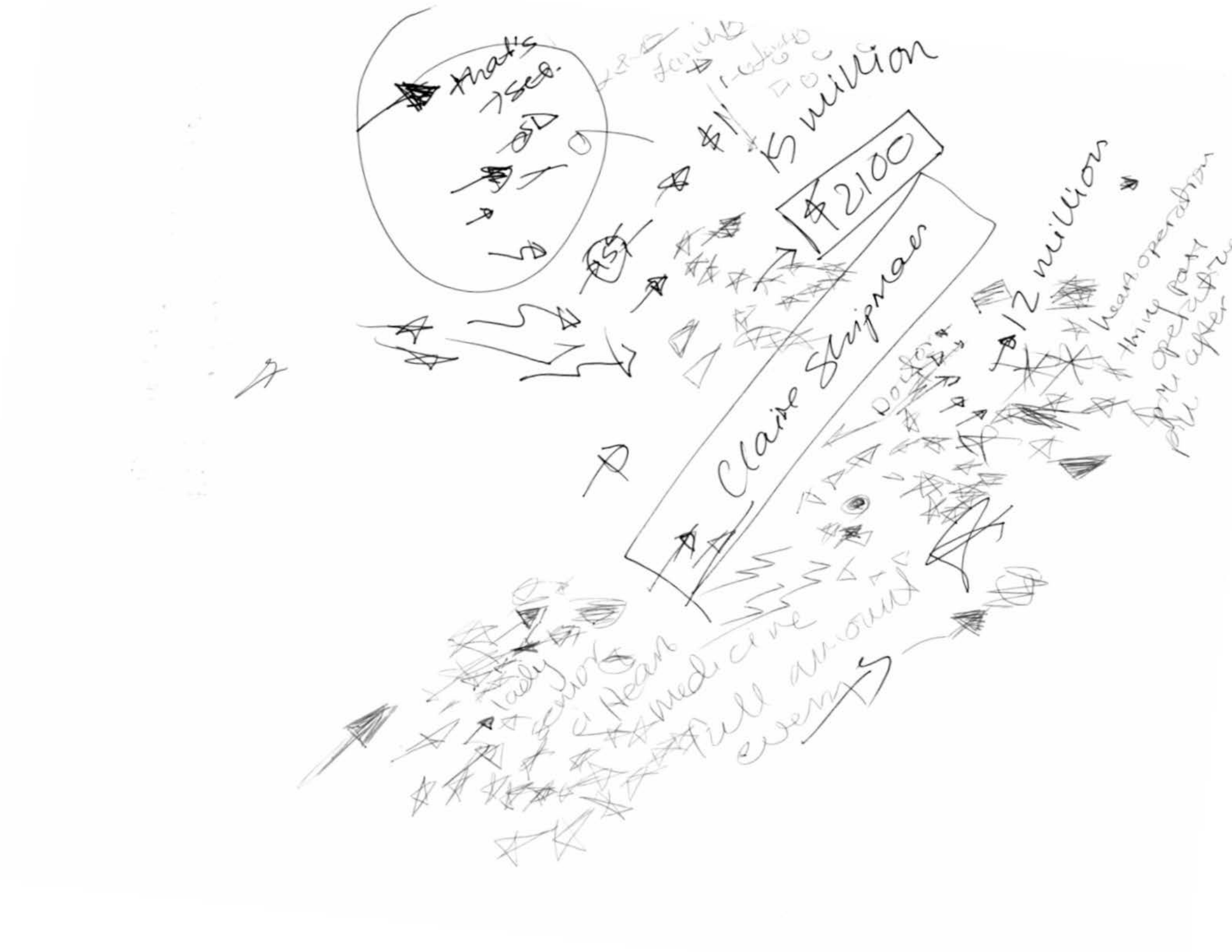
At the entrance to our Village Park lies inscribed in stone the words of a former United States Vice-President Hubert H. Humphrey:

"The greatest gift in life is the gift of friendship."

It is this gift which we offer to you and the people of Poland.

Sincerely,

ALFRED MULLER, M.D.,
Chairman, Friendship Heights Village Council.


that's
$5 million
$2100
Claire Shipman
$2 million

→ patent free standing
larger bill

Generic Pharmaceutical Industry Association
1620 I Street, NW, Suite 800
Washington, DC 20006
202.833.9070
fax: 202.833.9612
e-mail: info@gpia.org
http://www.gpia.org

Partners In Healthcare...

FACSIMILE TRANSMITTAL

TO: Sarah Bianchi DATE: 11/5

COMPANY:

FAX NO. 456-5557

PHONE NO.

FROM: Diane Doman

NO. OF PAGES 25

Comments: The attached is a presentation Buddy gave to House Democrats a few months ago. More to come.

Response:

ARE YOU READY FOR THE NEW MILLENIUM?

GPIA's Annual Meeting 2000

New Date May 9-11, 2000
New Location Omni Shoreham Hotel
Washington, DC

NOV. -05' 99(FRI) 19:13 GPIA FAX:202 833 9612 TEL:202 833 9070 P.001

GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION

Are Brand-Name Companies Acting to Shield Themselves from Generic Competition?

U.S. House of Representatives

Prescription Drug Task Force

April 29,1999

NOV.-05'99(FRI) 19:13 GPIA FAX:202 833 9612 TEL:202 833 9070 P.002

Overview

- The Value of Generic Pharmaceuticals
- The Generic Blockade
- Hatch-Waxman Act

GPIA GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION

NOV.-05' 99(FRI) 19:13 GPIA FAX:202 833 9612 TEL:202 833 9070 P.003

WHAT IS A GENERIC DRUG?

- Generics contain the same active ingredients, and deliver the same medication in the same amount and time as their brand name equivalents.
- Generics must meet the same FDA standards as brand name drugs for identity, purity, strength and quality.
- Generic manufacturers are held to the same FDA rules of inspection as brand name drugs and subject to same strict post-market surveillance.

GPIA GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION

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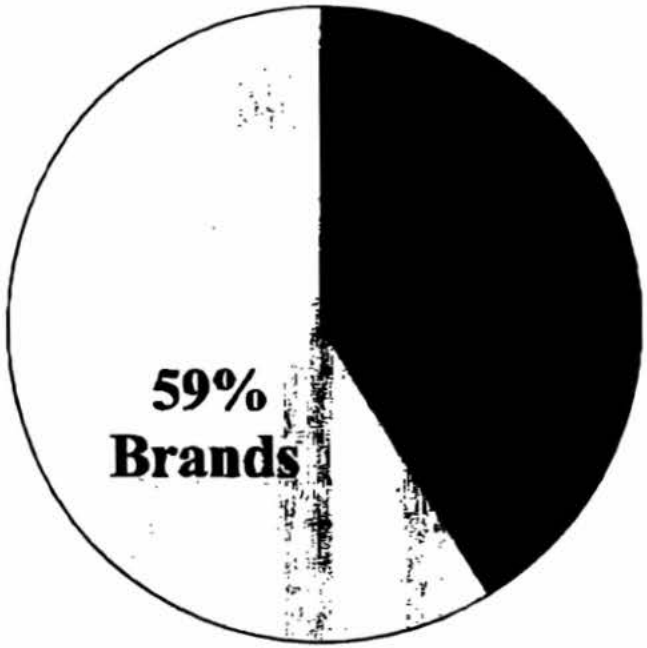
Generic Drugs Save Money

- Generics typically enter the market priced over 25% less than the brand. Consumer savings increase to 60% on average after two years.
- Six months after ranitidine hit the market, the average selling price was less than half of the generic introductory price with some product being sold at 18% of the brand price. On an annualized basis, ranitidine was saving the American public almost $500 million.
- CBO estimates generic substitutions in 1994 saved purchasers between $8 to $10 billion.

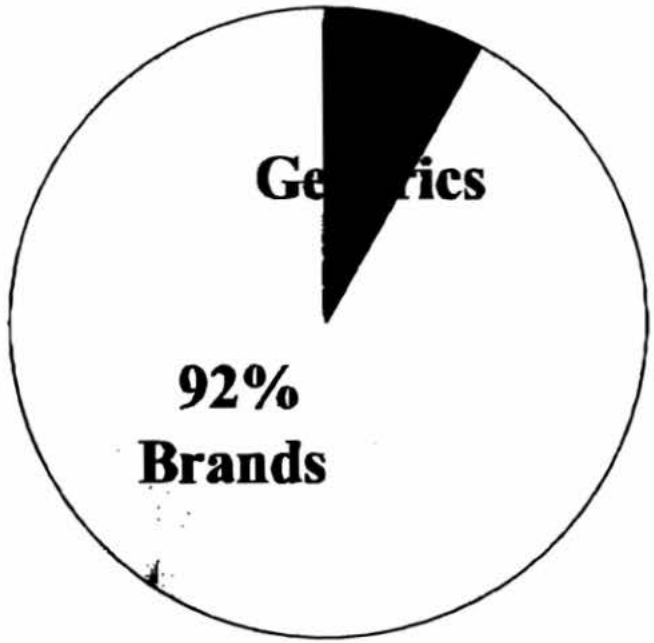
GPIA GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION

NOV.-05' 99(FRI) 19:13 GPIA FAX:202 833 9612 TEL:202 833 9070 P. 005

Market Share vs. Dollar Volume



Total Prescriptions Written



Total Rx Dollars

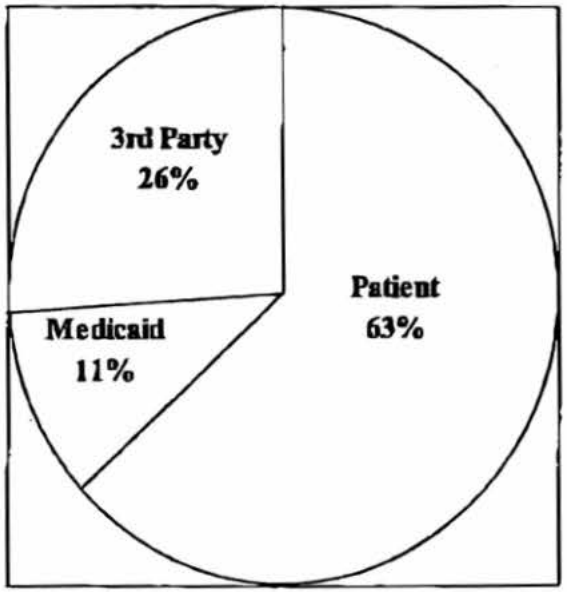
Source: IMS Health and Gruntal & Co.

GPIA GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION

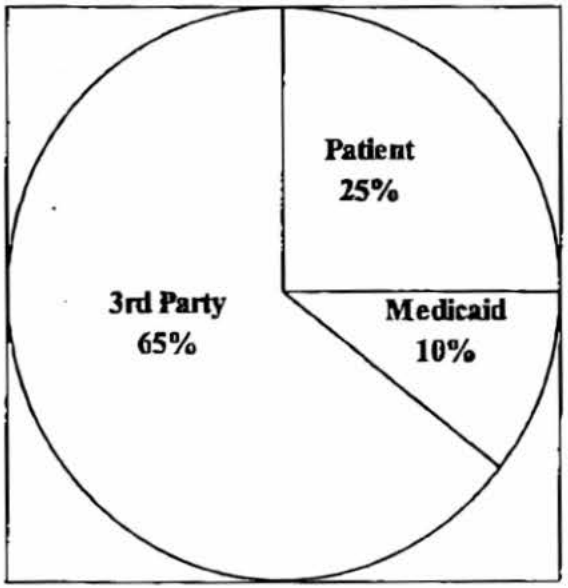
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Who Pays for Prescriptions?

1990



1998 (2nd qtr.)



Source: IMS Health

GPIA GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION

The Rx Cost to Managed Care

- The Rx benefit is the fastest growing expense for health plans. Drug costs continue to increase by more than 16% a year for managed care firms.
- According to Blue Cross/Blue Shield of Michigan, 28% of total expenditures are for Rx costs, eclipsing the 20% paid in MD fees.
- Cigna's average cost per brand prescription in 1998 was $48, nearly double the $25 average in 1995.
- Every percentage point increase in generic drug utilization translates into a $1 per prescription savings to managed care plans.

GPIA GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION

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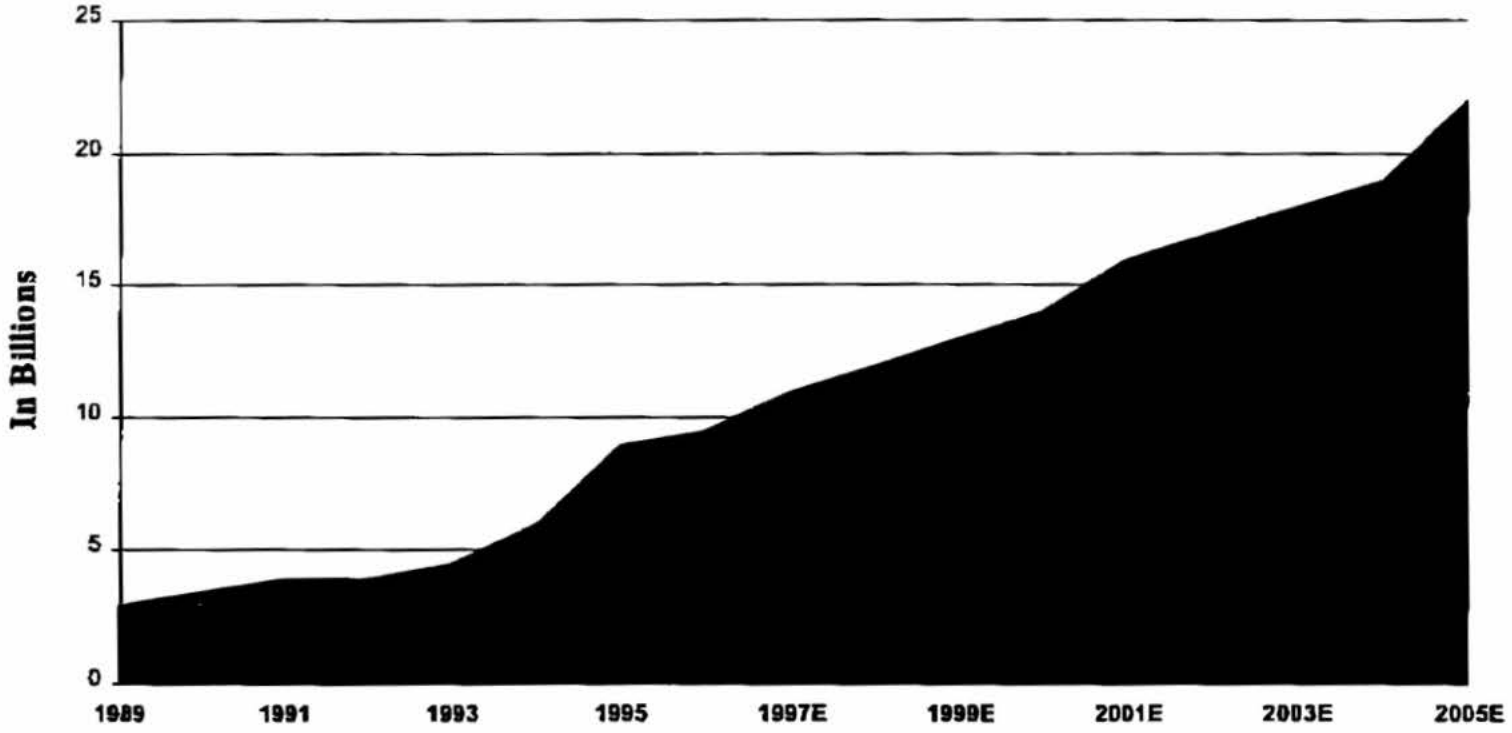
The Rx Cost to Employers

- Rx benefit costs rose more than overall medical costs for about half of employers' health benefit plans in 1997.
- Employer health costs to rise between 5.6% and 12.6% in 1999, with drug benefits up nearly 15%.
- Ford Motor Company's percentage of direct spending on drugs has risen to 19%, close to the 21% spent on hospital care.
- Retiree drug costs increasing up to 18% annually.

GPIA GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION

NOV.-05'99(FRI) 19:14 GPIA FAX:202 833 9612 TEL:202 833 9070 P.009

Projected Use of Generics

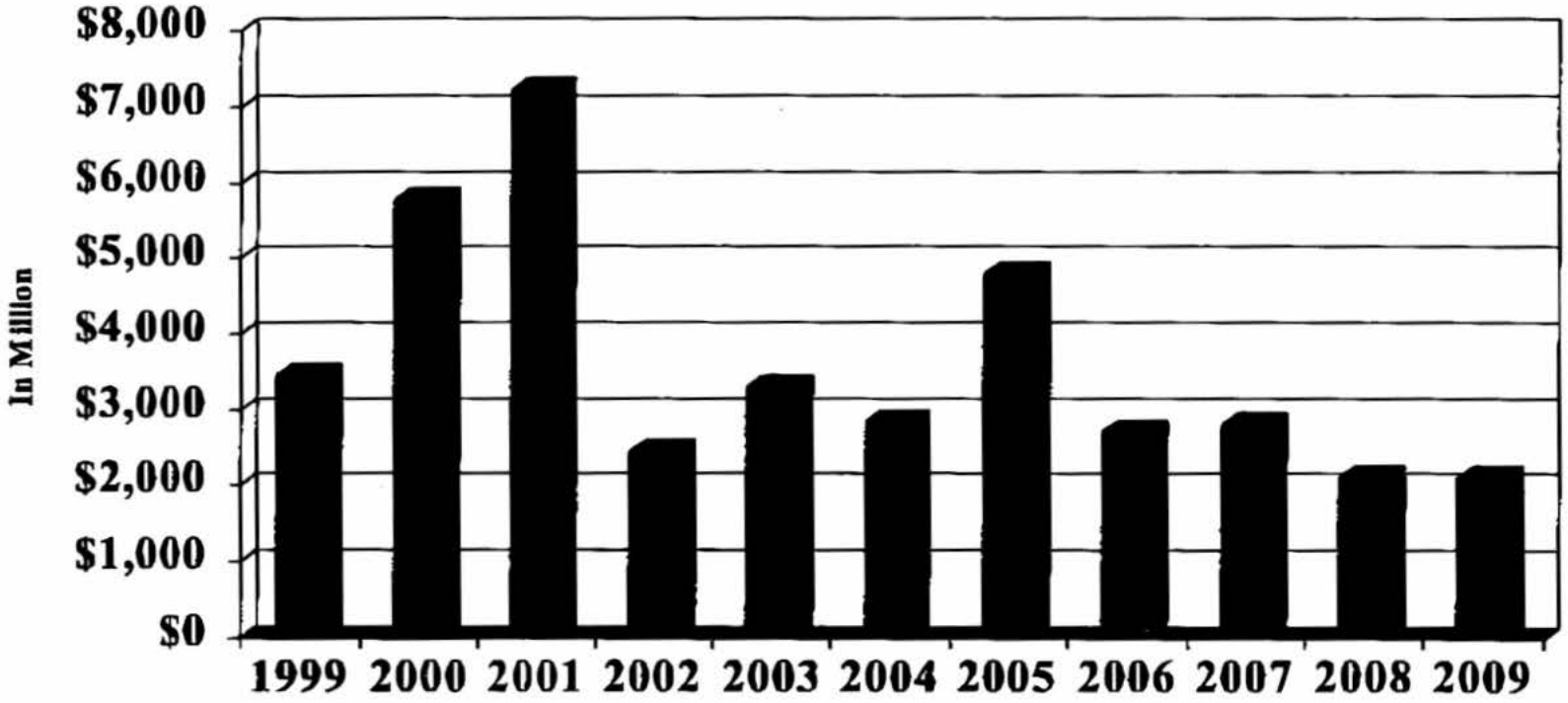


Source: SBC Warburg Dillion Read

GPIA GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION

NOV.-05'99(FRI) 19:14 GPIA FAX:202 833 9612 TEL:202 833 9070 P.010

$40 Billion in Brand Name Drugs Will Lose Patent Protection



Source: FDA Orange Book, US PTO, IMS America, and SBC Warburg Dillon Read Inc. estimates.

GPIA GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION

What is the Generic Blockade?

- A campaign by the brand name industry to prevent competition from more affordable generic pharmaceuticals.
- The campaign protects monopoly markets that prevent consumers, employers and pharmacies from having access to lower cost drugs that could generate billions in savings.
- U.S. consumers pay $500 million more each year for drugs because brand companies erect unfair barriers to generic medicines.

GPIA GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION

NOV.-05'99(FRI) 19:14 GPIA FAX:202 833 9612 TEL:202 833 9070 P.012

Impact on Generic Competition

Stagnant generic share

- 1995 40%
- 1996 42%
- 1997 42%
- 1998 41%

Substitution rate flattens

- **1.2** billion new Rxs in 1997. 842 million DAW and 381 million were substituted (31.1%).
- **1.3** billion new Rxs in 1998. 883 million DAW and 399 million were substituted (31.2%).
- If the blockade is not dismantled, potential savings to consumers and the federal government (VA, DOD, etc.) will not be realized.

GPIA GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION

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The Brand Industry Barriers

- Legislative
- Regulatory
- Litigation
- State
- International

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Legislative

Product specific protection

- two year extension for *Daypro* slipped in CR to avoid government shut down.
- *Lodine*: three unsuccessful attempts in 1996
  - House Agriculture Appropriations bill
  - Senate floor amendment to Defense Dept. bill
  - Conference Agreement on Kassebaum-Kennedy bill

New tactics

- *Toradol* and disaster relief
- *Taxol* and the Project to Fund Biomedical Research
- *Claritin* (pipeline drugs) and the 1998 Omnibus bill

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Regulatory and Legal

- Abuse of the Citizen Petition process
  - FDA considered 1994 Sandoz petition for 2.5 years, delaying approval of generic clozapine tablets for almost 2 years after the brand patent expired in 1995.
- Improper Orange Book patent listing
  - Congress intended for compound and use patents only.
  - Listing after generic application filed
- No method to remove improper listing.
- Automatic 30 month stay

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CITIZEN PETITION REFORM

- Congressional members interested and HHS Inspector General conducted investigation.
- Objective:
  - Review petitions under a scientific standard.
- Petition should not delay generic approval unless petitioner demonstrates by clear and convincing scientific evidence that a serious health and safety risk is present to patients.

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State

- Attack therapeutic equivalence and substitutability of generic products after FDA approval.
- If state campaign successful, then no value to FDA approval of generic drug and resulting patchwork of state therapeutic equivalence requirements will lead to higher costs for buyers.
- DuPont's campaign to prohibit switching for NTI drugs unless a pharmacist first gets verbal approval from the MD is one example. "Critical care" drugs is the next target.
- One solution is H.R. 805--national uniformity of FDA's therapeutic equivalence determinations.

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International

- Objective:
  - Undermine U.S. Bolar through isolation
- Generic Counter-Initiatives:
  - Israel patent law reform
  - The Transatlantic Business Dialogue (TABD)
  - EU vs. Canada WTO dispute over Bolar

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The 1984 Hatch-Waxman Act

- Principal objective: create access to cost effective pharmaceuticals from <u>increased competition</u> in the Rx industry by making generic drugs available <u>at patent expiration.</u>
- The carefully balanced compromise:
  - Extended patent life and new marketing exclusivity (5 & 3 years) for branded industry.
  - Abbreviated approval process and use of patented materials (Bolar provision) for generic applications.

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The Generic Industry Since Hatch-Waxman

- The generic industry has grown steadily from less than $2 billion to almost $8 billion in 1997.
- The number of prescriptions filled with generics increased from 18% in 1984 to 42% in 1997.
- "The dramatic rise in generic sales since 1984 has held down average prices for drugs that are no longer protected by a patent."

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The Brand Industry Since Hatch-Waxman Act

- Already received over 500 years of additional patent life, excluding market exclusivity grants.
- Between 1983 and 1997 brand sales have increased from $17 billion to over $77 billion.
- R&D annual outlays have risen from $3 billion to $21 billion in 1998.
- Percentage of sales allocated to R&D have increased from 14.7% to an estimated 20% in 1998.
- Branded industry invests higher percentage of sales in R&D than virtually and other industry.

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Hatch-Waxman Reform in the 106th Congress

- The goal of the brand industry is to lengthen patent life, reduce competition and continue with monopoly pricing.
- The brand industry game plan:
  - Expand 14-year cap
  - Increase 3 and 5-year market exclusivity
  - Full credit for IND research time
  - Repeal the Bolar provision
- The call for more patent life comes at a time when brand Rx pricing is escalating and seniors are without Medicare drug coverage.

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Recent CBO Assessment of Rx Market Since Hatch-Waxman

- "Overall, then, the changes that have occurred since 1984 appear to be favoring investment in drug development."
- "Some representatives of the pharmaceutical industry have called for amending the Hatch-Waxman Act to lengthen patent-term extensions. However, doing that would not encourage innovation as much as accelerating the FDA approval process by the same amount."
- Thus, reducing FDA approval times…would be much more effective in helping both the drug industry and consumers than would lengthening the patent-protection period."

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The View From the Other Side

According to PhRMA President Alan Holmer:

The research-based companies are "willing to face fierce generic competition upon patent expiration -- anywhere around the world."Generic competition..."is the free market's most efficient form of cost containment."

Pink Sheet, April 5, 1999

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Time Magazine on Corporate Welfare and patent extensions

- *To*: pharm-policy <pharm-policy@essential.org>
- *Subject*: Time Magazine on Corporate Welfare and patent extensions
- *From*: James Love <love@cptech.org>
- *Date*: Tue, 10 Nov 1998 19:54:33 -0500
- *Organization*: http://www.cptech.org
- *Sender*: jamie@essential.essential.org

Interesting story in Time. Jamie

SPECIAL REPORT/CORPORATE WELFARE
NOVEMBER 16, 1998 VOL. 152 NO. 20

SEARLE & CO.: A CASE STUDY
The Mysterious Midnight Favor
Sometimes members of Congress debate long and loud about specific programs that represent corporate welfare. Other times they resort to arcane paragraphs tucked into unrelated legislation during late-night sessions, hoping no one will notice the giveaway.

Even hotly debated legislation--and even legislation meant to cut costs--can end up containing handsome gifts for targeted corporations. That's what happened with the Balanced Budget Down Payment Act of 1996, a long and bitterly debated piece of legislation. So long and bitter that the country went without a budget for seven months and endured two partial Federal Government shutdowns.

In the end Congress carved $22 billion out of the budget, prompting Representative John Kasich, the Ohio Republican who chairs the House Budget Committee, to declare that the new law made "the most significant reductions in Washington spending since World War II."

Well, maybe. But buried in the thousands of words that slashed government spending on everything from legal aid to the poor to helping the needy pay their home-heating bills was this intriguing sentence:

"In General: Any owner on the date of enactment of this Act of the right to market a nonsteroidal anti-inflammatory drug that (1) contains a previously patented active agent; (2) has been reviewed by the Federal Food and Drug Administration for a period of more than 120 months as a new drug application; and (3) was approved as safe and effective by the Federal Food and Drug Administration on October 29, 1992, shall be entitled, for the two-year period beginning on October 29, 1997, to exclude others from making, using,

offering for sale, selling, or importing into the United States such active agent, in accordance with section 154(a)(1) of Title 35, United States Code... "

Those 112 words obviously had nothing to do with cutting funds to departments and programs of the U.S. government. On the contrary, they would end up costing consumers many tens of millions of dollars--and fattening up G.D. Searle & Co. by the same amount.

The words, planted in the legislation by friendly members of Congress, extended for two years Searle's patent protection on Daypro, an anti-inflammatory drug that is the second best-selling drug for arthritis in the country. They also meant that for two more years, no cheaper generic versions of the drug could be sold.

Searle is a subsidiary of Monsanto Co., a global chemical and pharmaceutical giant with annual revenues of $7.5 billion. How important was Daypro to Searle and Monsanto? The company sells $300 million worth of the stuff a year.

Most lawmakers were unaware of the handout. It was not in the original bill passed by the House nor in the one passed by the Senate. As often happens with special interests, the stealth provision was slipped into the legislation during a conference session, when the two houses were ironing out differences between their respective bills.

No record exists identifying the lawmaker who inserted it. To this day, no one claims credit. But it is worth noting that in December 1995, four months before the budget bill was passed, then Senator Paul Simon, Democrat from Chicago--the home of G.D. Searle--introduced on the floor of the Senate a bill to specifically extend Daypro's patent protection. The bill was co-sponsored by Senator Carol Moseley-Braun, also a Chicago Democrat, and Senators John Ashcroft and Christopher Bond, both Republicans from Missouri, the home of Searle's parent, Monsanto. That bill went nowhere.

Not all drug companies are as lucky as Searle. American Home Products later sought to have the patent extended on one of its arthritis drugs, Lodine. Following Searle's lead, American Home Products arranged for a friendly member of Congress to drop the required paragraphs into an unrelated piece of legislation: the Health Insurance Portability and Accountability Act of 1996.

Once again, the wording was not in either the House bill or the Senate bill. Rather, it was slipped into the conference-committee report in the middle of the night. And again no one seemed to notice.

No one, that is, until Senator Edward Kennedy, Massachusetts Democrat, blew the whistle two days later. Kennedy denounced this legislative gimmick and noted that Lodine brought in $275 million a year for American Home Products. Paul Wellstone, the Democratic Senator from Minnesota, chimed in, assailing "the mysterious manner in which [the] giveaway [was added to the legislation late at night] at the expense of patients and senior citizens."

The furor was so great that Trent Lott, Mississippi Republican, Senate majority leader and the bill's original

sponsor, ordered the offending paragraphs removed.

As it turned out, however, American Home Products almost prevailed after all. Last June the company announced that it would acquire Monsanto and its G.D. Searle unit for $34.4 billion in stock. The merger, however, soon unraveled and by last month both companies had decided that it was "not in the best interests" of either.

- Prev by Date: **Aid for AIDS in Zimbabwe**
- Next by Date: **Sneak Prescription Drug Patent Extension in Appropriations Rider**
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  - **Date**
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debate. Lott noted the Senate has a list of things it must accomplish before the August recess, adding that "whatever it takes, we're going to do those things." He said he hopes Wellstone and Livingston will take a "reasonable amount of time" on the issue and then permit a vote.

House Democrats today asked the Rules Committee to make in order a motion to recommit the health bill to conference with instructions that the mental health compromise be included in the final bill. The conference report is expected on the House floor this afternoon. Meanwhile, President Clinton today said he is "disappointed" the mental health parity language was taken out of the conference agreement. Speaking to reporters in the Rose Garden today, the president said, "I certainly hope we can get it as soon as possible in the future. It should remain a high priority."

... As Stark Blasts Lott's Ethics On Drug Patent Provision

House Ways and Means Health Subcommittee ranking member Pete Stark, D-Calif., today accused **Senate Majority Leader Lott** of a possibly "serious" ethical breach by requesting that a patent extension provision benefiting a single drug company be inserted late Wednesday into the health insurance reform bill. Testifying before the House Rules Committee, Stark said the provision benefiting a drug company owned by the American Home Products Company was added to the bill "at the request of Sen. Lott" and that its 11th-hour inclusion in the health bill represents "a bipartisan issue of the integrity of the House" if it remains in the bill. Stark was talking with House Democratic leaders to see if an expected motion to recommit the health bill would include instructions to remove the item.

Stark said the provision, which extends the patent of the company's arthritis drug Lodine, raises "serious ethical questions about the majority leader in the Senate" and said its inclusion may be "illegal." He said American Home Products, which owns the Wyeth-Arynst subsidiary that makes Lodine, got a patent extension in 1992, as did other firms. "It is one of these cats that has nine lives that somebody is trying to sneak in," Stark told the Rules panel. "It was just slipped in at the request of Sen. Lott." Stark argued the patent should not be extended and that "it is now time for the generic [drug] makers to have a chance to make this product" at a lower price.

House Republican Health Reform Task Force Chairman Dennis Hastert of Illinois, testifying at Rules alongside Stark, said Monsanto, which makes a competing drug to Lodine, won an extension of its patent in an appropriations bill and now Monsanto has "the competitive advantage" over American Home Products. "I would rather see this done in the light of day," said Hastert, who said he had no idea who was behind the recent Monsanto patent extension. "We refer to these as 'tooth fairy' amendments," Stark said. "They just show up under your pillow at night and there they are." Asked this afternoon about Stark's allegation, Lott told *CongressDaily*, "Hey, it's Pete Stark — what do you expect?" Asked if he had requested the patent extension provision be added to the bill, Lott said, "There are lots of people interested in that issue" and that he did not believe the provision benefitted his home state of Mississippi.

ENVIRONMENT

Drinking Water Agreement Hits Snag On Project Funding

The House Commerce Committee has objected to an agreement reached between the Senate Environment and Public Works and House Transportation and Infrastructure committees on the last remaining issue in the conference on safe drinking water legislation, sources said today. A House Commerce Committee source said **Commerce Health and Environment Subcommittee ranking member Henry Waxman**, D-Calif., objected to the agreement be-