GENETICS

WASHINGTON Watchdog
Common Cause

CAMPAIGN FINANCE REFORM

FACT SHEETS

TAKE ACTION

How The Current Campaign Finance System Affects the Lives of America's Seniors

The campaign money chase allows pharmaceutical companies, health insurers, and other big-money special interests extraordinary access to lawmakers. It gives vested interests influence to shape public policies that directly affect the lives of America's seniors:

- **Social Security:** Wall Street firms are pushing hard for privatization of the Social Security system. If successful, they stand to gain an estimated $60 billion a year in new assets flowing into the mutual fund industry. Wall Street is a master of the most popular political investments in Washington today - special-interest PAC contributions to politicians and huge soft money donations to the political parties. A Common Cause analysis shows the securities industry invested $12 million in PAC contributions to candidates and $19 million in soft money contributions through the political parties during the past decade.

  Leading the industry in political giving during the decade was Merrill Lynch & Co, whose total PAC and soft money donations topped $2 million, according to Common Cause. The Investment Company Institute, the trade association leading the mutual fund industry's lobbying effort, invested $1.3 million in PAC contributions to candidates.

- **Medicare Cuts:** Republican congressional leaders and President Clinton want to cut Medicare $115 billion by 2002. How will these cuts and revisions to the Medicare system end up affecting recipients? The devil will be in the details worked out in the coming months. Washington's big money special interests know this. And they know that the access and influence their political contributions buy provides a key advantage during this complex process.

  Two interests with the most to gain or lose in Medicare revisions - health insurers and doctors - are also "preferred providers" of campaign cash to politicians. The health insurance industry gave more than $25 million in PAC and soft money during the decade 1985 through 1995, according to Common Cause. Doctors and their association PACs,

including AMA PAC, gave more than $23 million during the period.

- **Higher Drug Prices:** When patents expire on prescription drugs, the generic drug makers get a chance to market them, at substantially lower costs to the consumer. But big brand-name drug companies lobby hard in Washington and give hefty campaign contributions to prevent those patents from running out. The result? Millions more in profits for the brand-name companies for each year they hold on to their patents … and billions in higher drug prices for the rest of us.

  G.D. Searle & Co, and its parent company Monsanto, which got a patent extension on its Daypro anti-inflammatory drug last year, gave $114,000 in PAC money to candidates and $129,000 in soft money to the parties during the last Congress, according to Common Cause. Glaxo Wellcome gave $925,000 in PAC and soft money during the session, including a $100,000 soft money donation to the RNC the day after the company won a key patent extension vote on its Zantac ulcer drug. The company stands to gain $2 billion by maintaining the higher drug prices.

  Overall, drug companies gave nearly $25 million in PAC and soft money during the past decade, according to Common Cause.

- **Nursing Home Standards:** Industry lobbyists that made substantial campaign contributions to the Democratic party received access to key policy makers in the Health Care Finance Administration last year. According to Time magazine, Alan Solomont, a nursing home executive, "gave the Democrats $160,000 and helped raise $1.1 million more from nursing-home owners." The result? A change in policy that eases up on state and federal regulation of nursing homes. Guidelines were issued in January 1997 that eased fines against nursing homes for non life-threatening violations of the rules - like poor nutrition and lack of privacy - that consumer advocates say account for the vast majority of offenses affecting nursing home life.

  The nursing home industry as a whole gave nearly $3.4 million in soft money to both parties in the past decade, led by $1 million in soft money from Integrated Health Services, according to a Common Cause analysis.

- **Health Insurance Rip-Offs:** "Dread disease" insurance policies promise to pay if the buyer suffers cancer or another specific illness. The problem is, according to a recent Business Week article, most of the buyers are already covered by Medicare and Medigap. Congress once banned selling duplicative policies to Medicare recipients, but, in 1994 and again last year, lawmakers weakened these protections.

  Lobbying hard to get back in the senior citizen market, the leading seller of "dread disease" policies had some political

* *Prescription Drug Pricing in the U.S.: Drug Companies Profit at the Expense of Older Americans. Minority staff report,* Committee on Government Reform, U.S. House of Representatives, October 20, 1998. This column shows the price increase paid by seniors compared to drug companies most favored customers.

** 1998 profits, as reported to Securities & Exchange Commission. The amount shown for Astra/Merck (a joint venture) is 1998 Merck profits and 1997 Astra profits combined. The amount for Knoll is profits for its parent company BASF in 1997.

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

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insurance of its own -- millions of dollars in campaign contributions. AFLAC Inc, which last year sold $3 billion in cancer-only policies, gave nearly $3 million in PAC and soft money to candidates and the political parties during the past decade, according to Common Cause.

HOME INDEX SEARCH FEEDBACK JOIN

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FACSIMILE TRANSMITTAL

TO: Sarah Branch DATE: 11/5

COMPANY:

FAX NO. 456-5557

PHONE NO.

FROM: Diane Dornan

NO. OF PAGES 10

Comments: See pgs 4+5 of Cong. Brown [D-OH] remarks on citizen petitions

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

GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION

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CITIZEN PETITIONS

Citizen petitions are being filed with FDA by brand pharmaceutical firms to delay or foreclose the approval and dispensing of generic drugs. Because the agency must consider, by law, the merits of each citizen petition, these administrative challenges almost always result in regulatory delay – providing brand firms with months or even years of additional market dominance. The success of these challenges is not defined by whether the requested action is ultimately granted or denied, but rather, by the amount of time the generic drug application is delayed while agency officials review the citizen petition.

In addition to placing an unjust burden on consumers who would benefit from the availability of lower cost, equivalent therapies, the misuse of the citizen petition process burdens the already constrained resources of the FDA's Office of Generic Drugs (OGD). According to OGD, a substantial percentage of senior staff time is diverted to reviewing the 40 citizen petitions that have been filed since 1990 to delay generic drug approvals.

Solution

Statutory changes are necessary to discourage brand firms from using the citizen petition process as a tactic to preserve their competitive advantage. A way to reform the process would be to amend the Food, Drug, and Cosmetic Act to provide that a citizen petition should not delay the approval of a generic application unless the petitioner can establish by clear and convincing scientific evidence that its proposed changes are necessary to ensure patient safety.

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF THE FOOD AND DRUG ADMINISTRATION'S CITIZEN PETITION PROCESS

JUNE GIBBS BROWN
Inspector General

JULY 1998
A-15-97-50002

EXECUTIVE SUMMARY

BACKGROUND

This final report provides the results of our review of the Food and Drug Administration's (FDA) effectiveness in handling citizen petitions. The FDA regulations[1] permit any person to submit a citizen petition to FDA requesting the Commissioner of Food and Drugs to: (1) issue, amend, or revoke a regulation or order; or (2) take or refrain from taking any other form of administrative action.

OBJECTIVE

The objective of this review was to assess FDA's effectiveness in handling citizen petitions and identify ways that the process can be improved.

SUMMARY OF FINDINGS

The FDA does not have an effective process for handling citizen petitions in a timely manner, as evidenced by a backlog of approximately 250 petitions that have not been fully answered, some dating to the 1970's and early 1980's. The FDA regulations require tentative or final responses to citizen petitions within 180 days. The backlog of pending petitions includes issues that the petitioners believe are matters of public safety, and some have requested FDA to ban or withdraw approval of certain products. When FDA does not answer petitions in a timely manner, the public may lose confidence in the regulatory process. Because the citizen petition process is not a high priority among FDA's various responsibilities, the agency has provided limited resources to the process, and there is little central oversight of the process across FDA program areas. Recognizing its problems with the petition process, FDA developed options during the early 1990's to improve the process; and since the start of our review, closed out slightly more petitions than it has received. We believe, however, that more can be done to reduce the backlog.

RECOMMENDATIONS

We recommend that the Commissioner of Food and Drugs:

1. Correspond with petitioners whose requests are of long standing to determine if they still want FDA to take action on their petitions;

[1] Code of Federal Regulations (C.F.R.) Title 21, Part 10, Subpart B, Section 10.30.

STATEMENT OF THE HONORABLE SHERROD BROWN

RANKING MEMBER, HOUSE SUBCOMMITTEE ON HEALTH

AND THE ENVIRONMENT

FLOOR STATEMENT ON LEGISLATION REFORMING FDA

OCTOBER 7, 1997

Mr. Speaker, today the House considers a major piece of legislation, about which we have heard considerable discussion over the last 2 years. The FDA reform debate has progressed from irrational and unfounded accusations about FDA's regulation of medical products to much more sensible discussions about how to modernize this important agency's regulatory policies and procedures in a way that will reduce unnecessary regulation without reducing public health essential protections.

As I have stated since the beginning of this process our first goal must be to ensure that patients have access to safe and effective new products as quickly as humanly and scientifically possible.

While I am not completely convinced this legislation has fully achieved those difficult balances, it is a vast improvement over legislation introduced in the last Congress.

Of course, since compromise is necessary in Bipartisan legislation rarely includes everything everyone wants, since compromise is always necessary.

This bill is no exception.

However, I would like to thank Chairman Bliley and Bilirakis for their efforts to open up the discussions that led to this bill. I genuinely appreciate attempts to listen to everyone, and try to take account of a variety of perspectives.

Again, while this bill continues to include some provisions that give me pause, I also believe it includes provisions that are workable, positive, and contribute to the goal of ensuring an FDA operation that works in the best interests of its most important customers -- patients.

Nevertheless, as we proceed with this discussion, I think it is important to put a few facts in perspective.

Many have argued that FDA reform is essential because new and improved drugs and medical devices are not reaching American patients quickly enough.

The facts simply do not bear this out.

For example, through FDA's own management initiatives, and without any change in legislation, FDA's Center for Devices has overhauled its operations and dramatically improved its review times for new products.

Further, I think a majority of medical device manufacturers will agree that the center is more user-friendly, and more efficient, than ever before. Thus, I hope as we proceed to conference with this legislation, we look carefully at the provisions of the bill relating to medical devices, to ensure that we are not increasing requirements for FDA in a way that will set back the progress that has been made.

One of the most important provisions included in this legislation is the reauthorization of the Prescription Drug User Fee program. PDUFA has provided the agency with the resources it clearly needed to allow it to continue to be the world leader in the review and approval of new drugs.

]

If there were one single reason for the House to pass this bill today, drug user fees is that reason.

I am also pleased that the legislation includes some process improvements related to FDA's regulation of generic drugs. While these products are not the breakthrough "miracle drugs" we read about in headlines, generic drugs are no small miracle to millions of elderly patients – especially those living on fixed incomes who depend on these alternatives which many times are vastly less expensive than name-brand products.

Generic drugs literally save billions of dollars in health care costs.

Much of that savings accrues to the federal government, which pays for prescription drugs under the Medicaid program, for Veterans, and in Department of Defense facilities.

I was disappointed that the bill did not go further in addressing what I believe are several difficult problems related to the review of generic drugs – frivolous citizens petitions filed by lawyers representing brand name companies to divert resources and slow the approval of generic alternatives.

These petitions and lawsuits frequently are simply ploys to delay the marketing of safe and effective generic drugs, that can save our citizens substantial money in health care costs. I hope that we can continue to work on these matters, perhaps in the context of future legislation.

I remain concerned about provisions of the bill that allow manufacturers to distribute information about off-label uses of their products. I am not convinced by the arguments that this kind of system is necessary for physicians to have the information they need to treat patients -- especially given the companies financial interest in promoting their products.

Fortunately, this provision sunsets after seven years, requires FDA approval of materials to be disseminated, and also requires that manufacturers submit applications for approval of these off-label uses. If that part of the program works, it will be good for patients. I am skeptical, however, and will closely monitor whether this program is in the best interests of patients or simply serves to enrich drug and device companies.

Mr. Speaker, I was especially pleased that a number of issues raised by Democratic Members of the Health and Environment Subcommittee were addressed in this legislation. Several particularly important matters relating to medical devices were worked out with our Members, and the FDA, after the bill was reported by the Committee, and I appreciate the willingness of the bills' sponsors and the Chairman to engage in these negotiations. I hope as we proceed to conference with the Senate, the kind of bipartisan cooperation that led to many of this bill's compromise provisions will continue.

Mr. Speaker, FDA is a remarkably effective agency. I have never been persuaded, throughout this long debate, that massive changes in law are needed to correct some dreadful problem lurking under the surface. Thus, I am pleased that this legislation focuses more on modernizing this premier public health agency than completely overhauling it. I believe this is, on the whole, a reasonable compromise that I will support.

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FACSIMILE TRANSMITTAL

TO: Sarah Branch DATE: 11/5

COMPANY:

FAX NO.

PHONE NO.

FROM: Diane Daman

NO. OF PAGES 13

Comments: Nat. uniformity background. Coumadin is great example. See last page of 11/18/98 for more on Coumadin.

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

GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION

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NATIONAL UNIFORMITY

There have been repeated efforts to compel state legislatures to adopt bioequivalence and therapeutic equivalence standards different from those established by the Food and Drug Administration (FDA). The purpose of these efforts is to ban or interfere with generic substitution and preserve market monopolies despite the expiration of patent life and the FDA approval of generic alternatives. Since January 1997, a multimillion dollar lobbying campaign has been taking place in over 25 states that attacks the bioequivalence and substitutability of generic versions of allegedly narrow therapeutic index (NTI) drugs. Given the sales volumes of these drugs, success in any large state will more than pay for the costs of this campaign.

For example, California considered a bill that would have required certain drugs to go through an additional approval process after being approved by FDA. Other state bills would establish a variety of practical hurdles to generic substitution, such as requiring doctors to personally contact pharmacists prior to filling the prescriptions, or banning substitution unless the doctor first explains why the generic was recommended and the patient agreed to sign a waiver. In North Carolina, such legislation passed in two weeks. The justification for these bills is the same; namely that generic drugs are not safe, are not bioequivalent and at times are actually dangerous.

The FDA also has issued a letter asserting that there is no scientific basis for questioning the substitutability of NTI or other "A" rated drugs. A copy of the agency's letter is attached.

While we do not expect Congress to interfere with the right of states to regulate the practice of pharmacy, we do believe it is appropriate for Congress to ensure that there is a national uniformity of the FDA's bioequivalent and therapeutic equivalence determinations. State generic substitution laws should not undermine the FDA's findings on clinical effect and safety. If the state campaign described above is successful, there will be no value to FDA approval of any generic drug. Instead, generic companies will have to demonstrate bioequivalence and therapeutic equivalence in each state they wish to market. The resulting patchwork of state bioequivalence and therapeutic requirements will only lead to higher generic costs to consumers and taxpayers.

Solution

The Food, Drug and Cosmetic Act should be amended to expressly preempt state generic substitution laws and regulations that impose standards different from, and in addition to, FDA's generic bioequivalence and therapeutic equivalence determinations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

January 28, 1998

Dear Colleague:

As you may be aware, certain individuals and groups have appeared recently before state legislatures, state boards of pharmacy, and drug utilization review committees, to express concerns about the interchangeability of certain products they characterize as narrow therapeutic index (NTI) drug products. A particular concern being raised by them is whether the safety and efficacy profile of these products could change if a switch were made from a brand-name product to an FDA-designated therapeutically equivalent generic product. FDA wishes to comment on the issue of interchanging any brand-name drug with a therapeutically equivalent generic drug and requests that you inform your association's members of this information.

For both brand-name and generic drugs, FDA works with pharmaceutical companies to assure that all drugs marketed in the U.S. meet specifications for identity, strength, quality, purity and potency. In approving a generic drug product, the FDA requires many rigorous tests and procedures to assure that the generic drug is interchangeable with the brand-name drug under all approved indications and conditions of use. For these reasons, FDA approved product labeling does not recommend that any additional tests need to be performed by the health care provider when a switch occurs from a brand-name drug product to a generic equivalent drug product, from a generic equivalent to a brand-name product drug, or from one generic product to another when both are deemed equivalent to a brand-name drug product. Brand-name drug products and therapeutically equivalent generic drug products are identified in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," frequently called the "Orange Book."

In addition to tests performed prior to market entry, FDA regularly assesses the quality of products in the marketplace and thoroughly researches and evaluates reports of alleged drug product inequivalence. To date, there are no documented examples of a generic product manufactured to meet its approved specifications that could not be used interchangeably with the corresponding brand-name drug. Questions have been raised in the past, as well, regarding brand name and generic products about which there could be concern that quality failures might represent a public safety hazard. FDA has performed post-marketing testing on many of these drugs to assess their quality. In one instance, more than 400 samples of 24 marketed brand-name and generic drug products were tested and found to meet the

established standards of purity and quality. Because patients may pay closer attention to their symptoms when the substitution of one drug product for another occurs, an increase in symptoms may be reported at that time, and anecdotal reports of decreased efficacy or increased toxicity may result. Upon investigation by FDA, no problems attributed to substitution of one approved drug product for another has occurred.

FDA works with both brand-name and generic drug product manufacturers after a drug product is in the marketplace to assure its quality. For example, brand-name and generic drug product manufacturers may want to change the drug formulation, site of manufacture, or manufacturing process after the drug is in the marketplace. These types of changes can be put in place only after the drug manufacturer provides the FDA with sufficient evidence that the drug identity, strength, quality, purity and potency will not change.

There are products in which small changes in the dose and/or blood concentration could potentially result in clinically important changes in drug efficacy or safety. Usually, these drugs require frequent adjustments in the dose of the drug and careful patient monitoring irrespective of whether the drug is a brand or generic drug product. These drugs may sometimes be described in FDA approved drug labeling as narrow therapeutic range drugs.

FDA may recommend to the manufacturers additional tests for approval of both brand-name and generic products, depending on the complexity of a drug substance or drug product and also depending on whether small changes in the dose and/or blood concentration could result in changes in drug efficacy or safety. It may also require additional tests for certain post-approval changes in manufacturing. The agency's recommendation to the manufacturer for these additional tests is designed to give the practitioner and patient additional assurance of product quality and interchangeability. These additional requirements should not be construed to mean that additional clinical scrutiny is necessary when interchange occurs. If anything, the additional tests required of pharmaceutical manufacturers are designed to reduce, not increase, concerns on the part of patients and practitioners.

Based on FDA's determination of therapeutic equivalence between generic and innovator drug products, the FDA concludes that:

- Additional clinical tests or examinations by the health care provider are <u>not</u> needed when a generic drug product is substituted for the brand-name product.

- Special precautions are not needed when a formulation and/or a manufacturing change occurs for a drug product provided that the change is approved according to applicable laws and regulations by the FDA.

- As noted in the "Orange Book," in the judgment of the FDA, products evaluated as therapeutically equivalent can be expected to have equivalent clinical effect whether the product is brand name or generic drug product.

- It is not necessary for the health care provider to approach any one therapeutic class of drug products differently from any other class, when there has been a determination of therapeutic equivalence by FDA for the drug products under consideration.

In considering drug product selection decisions, FDA acknowledges and supports the importance of good communication between the patient and the health care provider, particularly with regard to medications that require frequent monitoring of performance. We hope this information is useful to health care providers when making decisions regarding drug product selection.

We thank you for seeing that this information reaches the members of your organization.

Sincerely,

Stuart L. Nightingale

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

COMMERCE COMMITTEE:
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ENERGY AND POWER SUBCOMMITTEE
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DEMOCRATIC POLICY COMMITTEE:
COMMUNICATIONS VICE CHAIR

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FRANK PALLONE, JR.
6TH DISTRICT, NEW JERSEY

Congress of the United States
House of Representatives
Washington, DC 20515–3006

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January 25, 1999

HELP BRING PRESCRIPTION DRUG PRICES UNDER CONTROL!
COSPONSOR THE GENERIC DRUGS ACCESS ACT OF 1999

Dear Colleague:

The high cost of prescription drugs is one of the most pressing health care issues confronting the country's senior citizens, employers, managed care plans, state and federal drug programs. Controlling drug costs will be no easy task. One time-tested method, however, is timely access and availability of generic medicines once the patent on brand name drugs expires.

Generic competition has a dramatic impact on pharmaceutical costs. When a generic drug first comes onto the market, it typically costs 30 percent less than the brand name version. After two years on the market, the prices drop further to 60 or 70 percent of the brand name drug. The price of some generic drugs drop by as much as even 90 percent.

While these competitively priced alternatives are good for consumers, employers and government purchasers, they are not good for the brand name producer trying to maintain and protect monopolistic pricing. If there is no generic alternative available, consumers who need medicine have no choice but to buy the available brand drug and pay whatever it costs. It is for this reason that brand name drug companies launch aggressive campaigns to block or delay generic competition.

One tactic used by the brand industry to prevent generics from reaching the consumer is to convince state legislatures to pass unnecessary restrictions to the substitution of generic versions of brand name drugs. These restrictive laws are being advanced despite a scientific finding by the Food and Drug Administration (FDA) that the generic drug is equivalent and substitutable to the brand name product. The state campaign is nothing more than an attempt by the brand name companies to protect market share.

If these tactics are successful with the states, generic manufacturers could end up having to comply with 50 different sets of state laws before their products could ever reach the consumer. It would render the FDA stamp of approval meaningless. And it will only add extraordinary hoops for doctors and pharmacists to jump through before a generic medicine is dispensed. The ultimate losers are the senior citizens and other prescription drug purchasers who will be denied the access to equivalent generics and are forced to continue paying excessive brand prices for their medicines.

The Access to Generic Drugs Act would prevent drug companies from gaming the system. Very simply, this bill prohibits states from passing laws keeping generic drugs off the market once the FDA has determined that a generic drug is "therapeutically equivalent" to a brand name product. Most importantly, it will ensure that generic drugs get to the market in a timely fashion and provide consumers with access to low cost alternatives at the earliest possible time. ***If you would like to cosponsor this bill or would like more information, contact Steve Giuli of my staff at 5-4671.***

Sincerely,

Frank Pallone, Jr.

Frank Pallone, Jr.

Congress of the United States
House of Representatives
Washington, DC 20515

March 10, 1999

Dr. Jane E. Henney
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Henney,

Generic drugs play an important role in controlling health care costs, both in state and federally funded programs, and for individual consumers. Last year, the Congressional Budget Office estimated savings from generic medicines exceeded $8 billion in 1994 alone.

However, we understand that during the past year, several brand pharmaceutical companies have sought to confuse state legislators and regulators about the safety, efficacy and interchangeability of generic pharmaceutical products. These efforts led to a "Dear Colleague" letter from the FDA in January 1998 stating: "As noted in the *Orange Book* ...products evaluated as therapeutically equivalent can be expected to have equivalent clinical effect whether the product is a brand-name or generic product."

We are also concerned about reports that some brand-name companies are attempting to dissuade the FDA from providing expertise and testimony in state legislative and regulatory hearings regarding the generic approval process, bioequivalence, and the safety and efficacy of generic substitution.

The FDA approval process for generic pharmaceutical products is the gold standard for assuring consumers and health care providers of the safety and efficacy of these drugs. In addition, the *Orange Book* has become a trusted source of information about whether one or more generics are therapeutically equivalent to, and may be substituted for, the brand product. It is critical that the FDA strongly defend its approval process and bioequivalence standards in any state forum where misinformation about this process is being used to create barriers to substitution.

State legislative and regulatory bodies can and will make their own independent decisions on pharmacy-related matters. However, such judgments must be guided by the continued provision of scientifically valid information provided directly by the FDA, a body without peer on questions related to bioequivalence and substitutability.

Thank you for your attention to this important matter.

Sincerely,

Pete Stark
Member of Congress

Henry Waxman
Member of Congress

Frank Pallone Jr.
Member of Congress

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AMCP Position Statement on Interchange of Narrow Therapeutic Index (NTI) Drugs

The Academy of Managed Care Pharmacy (AMCP) opposes legislation that restricts the appropriate generic substitution of drugs which have a narrow therapeutic index (NTI). AMCP supports allowing pharmacists to exercise professional judgment, based on scientific information, when determining whether a generic drug is appropriate for substitution for its equivalent brand name product.

When the patent or exclusivity protection on a brand name drug expires, drug manufacturers may gain approval to market a generic version. Generic products are commonly substituted for brand name drugs as allowed by state law. The practice of dispensing generic drugs results in a substantial cost-savings for patients and payers while producing the same clinical effect as the branded product.

The generic version of a brand name product must contain the same active ingredient(s) as the brand name product. Using a rigorous review process, the Food and Drug Administration (FDA) reviews generic drug applications to assure that the proposed drugs are pharmaceutically and therapeutically equivalent[1] to the brand name product.

A drug is commonly said to have a narrow therapeutic index when small variances in blood levels can change the effectiveness or toxicity of the drug. Safe and effective use of these drugs requires careful dosage adjustment and patient monitoring, regardless of whether the generic or brand name product is used. However, due to its strict approval process, the FDA does not consider NTI drugs as a separate category for purposes of generic substitution. The FDA has stated that they have not received data suggesting clinical problems with the use of approved NTI generic drugs which would support proposed state NTI legislation. Consequently, the FDA has taken the position that when an FDA approved and therapeutically equivalent generic drug is selected, patients, physicians, and pharmacists can be assured that they will see the same clinical results and safety profile as with the equivalent brand name product.

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[1] Drug products are considered pharmaceutical equivalents if they contain the same active ingredient(s), are of the same dosage form, and are identical in strength, and route of administration as the reference brand name product. Drug products are considered therapeutic equivalents only if they are pharmaceutical equivalents, and can be expected to have the same clinical effect when administered to patients under the conditions specified in the labeling.

AMCP believes pharmacists and prescribers, not legislative entities, are in the best position to evaluate the appropriateness of generic interchange, both in general and on a case-by-case basis. AMCP opposes legislation that is designed to restrict the generic interchange of NTI drugs. AMCP believes pharmacists, in consultation with prescribers, should have the right to use their professional judgment and knowledge of the available scientific information in determining when to substitute a generic product.

About the Academy of Managed Care Pharmacy

The Academy of Managed Care Pharmacy is the national professional society dedicated to the concept and practice of pharmaceutical care in managed health care environments. AMCP's mission is to promote the development and application of pharmaceutical care in order to ensure appropriate health care outcomes for all individuals. Its sole purpose is to represent the views and interests of managed care pharmacy. The Academy has more than 4,000 members nationally who are part of more than 600 health care organizations that provide comprehensive coverage to the millions of Americans served by managed care.

Adopted by the Board of Directors of the Academy of Managed Care Pharmacy on November 24, 1997.

CITIZENS AGAINST GOVERNMENT WASTE

NEWS

For Immediate Release
February 2, 1998

Contact: Jim Campi
(202) 467-5300

CAGW CRITICIZES EFFORTS IN STATES TO RESTRICT ACCESS TO GENERIC DRUGS

Washington, D.C. – Citizens Against Government Waste (CAGW) issued the following statement today on the release of a study on Coumadin and Warfarin published in the February issue of *Cardiovascular Reviews and Reports*. The statement was delivered by Elizabeth Wright, Director of CAGW's Health and Science Division.

"It has come to the attention of Citizens Against Government Waste (CAGW) that Dupont Merck's lobbyists are spending a lot of time and money to get state legislatures to pass laws that restrict access to generic pharmaceuticals. In particular, they are putting pressure on legislators to pass laws that would restrict access to generic Narrow Therapeutic Index (NTI) drugs.

"Warfarin is a blood thinner and is considered a NTI drug. In states where these restrictive laws have been passed, consumers – particularly the elderly – will find their access to generic drugs have been limited and their healthcare costs will go up. In other states, legislatures are now considering passing tougher regulations for dispensing generic pharmaceuticals. If these laws pass, they also will limit choice and drive up the costs, not only to consumers and private insurance companies, but to the taxpayers as well. CAGW objects to this failure to spend tax dollars wisely.

"Many states have programs that provide pharmaceuticals to the poor and the elderly. Using generics saves more tax dollars. But if doctors and pharmacists have to go through extraordinary hoops to prescribe a generic drug, the generic will simply not be dispensed to the consumer. This will raise the cost of these government programs to taxpayers and will decrease care in other areas.

"Dupont Merck may claim these restrictive laws are necessary because of safety issues. The study released today proves just the opposite. Dupont Merck's efforts are not about safety. They are more interested in protecting their market share.

"CAGW is hopeful that this study will empower state legislatures to say "no" to the brand-name drug company and "yes" to protecting taxpayers. Generics have been shown to save anywhere from 25 to 80 percent per prescription. This frees up healthcare dollars that can be spent in other areas, such as cancer screening or immunizations.

"In September, 1995 the Agency for Health Care Policy and Research (AHCPR), as part of their Patient Outcome Research Team (PORT), announced findings on the best methods of preventing strokes in people who are at high risk. The study found that two commonly known and effective interventions, one of which is warfarin, are not being used appropriately to prevent strokes. They found that if warfarin's use is expanded, it could cut in half the 80,000 strokes that occur each year due to atrial fibrillation. It is estimated that proper anticoagulation therapy could save approximately $600 million per year.

"The AHCPR points out that the necessary monitoring of warfarin therapy can be made more efficient and affordable by assigning the routine testing to nurse practitioners or physician assistants. This is particularly important for managed care organizations, which are enrolling increasing numbers of the elderly who are at highest risk for stroke. Considering that the study being released today shows Barr Laboratories' generic product is as safe and as effective as the brand name and is 30% less expensive, imagine the additional people that can be helped and the dollars that can be saved by Medicare, insurance companies and consumers!

"CAGW understands and appreciates the important role research pharmaceutical companies play in discovering new therapies that cure or control serious diseases. We want research companies to have a return on their investment so that it encourages them to find new discoveries. But competition also encourages innovation. It increases quality and keeps costs down. A 40 year monopoly is more than enough time for a company to recoup its investments. It is time for competition to begin. This study should give confidence to physicians and healthcare organizations to use this generic blood thinner, follow AHCPR's valuable research in preventing 40,000 strokes a year, and save healthcare dollars for all Americans."

Citizens Against Government Waste is a 600,000 member organization dedicated to the elimination of waste, inefficiency, mismanagement and abuse in the federal government.

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THE

"USA TODAY hopes to serve as a forum for better understanding and unity to help make the USA truly one nation."
—Allen H. Neuharth
Founder, Sept. 15, 1982

USA TODAY

David Mazzarella
Editor
Karen Jurgensen
Editor of the Editorial Page
Thomas Curley
President and Publisher

Today's debate: USING GENERIC DRUGS

Drugmaker tries end run to kill off competition

OUR VIEW: If the maker of Coumadin gets new state laws on generics, watch prescription prices skyrocket.

When pharmaceutical giant DuPont Merck saw a generic substitute for its popular blood thinner Coumadin emerging earlier this year, it faced a choice. It could watch its profits decline. Or it could find some way to slow the challenger.

Today the plan it chose threatens to push up drug prices while undercutting the system that has allowed the use of safe, effective generics for two decades.

Even a brief glance tells you how high the stakes are for DuPont Merck.

Coumadin is a $500 million-a-year cash cow. A dollar's worth costs less than 10 cents to make — ample margin to entice cheaper competition. It's prescribed for 2.5 million heart patients, most over 60, a market that will grow as the baby boom ages.

So with Barr Laboratories on the verge of getting a generic substitute approved in January, DuPont Merck went into action.

Having already failed at every regulatory level to block the competing drug, it set out to rewrite state laws. Generic substitutions wouldn't be allowed for Coumadin or other drugs for which dosages must be closely controlled unless pharmacists first got the prescribing doctor's permission.

The company says this is a safety measure. Legislators are targeted with anecdotes supposedly showing the risks of generic substitution seen in other drugs.

It truth, it's closer to a scare tactic. Having failed to persuade review panels, the company is peddling a superficially appealing argument to legislators who know less.

The facts:

▶ There's no compelling reason to treat generics differently. The Food and Drug Administration, which passes on drug safety, says approved generics don't vary from their equivalents any more than the original maker's product would vary from lot to lot. So the horror stories establish nothing.

▶ The law already gives doctors control. All they need do is say on a prescription that no generic substitution is allowed. Requiring more only adds time and cost to discourage generic substitution.

Despite this, two states already have bought DuPont Merck's pitch, and it's under consideration in 18 others.

If the pattern continues, other drugs no doubt would be subjected to the same process, and consumers would be the losers.

Generics have grown to 13% of pharmaceutical sales and are used to fill about 50% of all new prescriptions. They've driven down the cost of drugs and helped stem cost increases for health insurance.

Whatever the merits of DuPont Merck's argument, the place to resolve them is before the FDA. It's hard to think of a reason 50 state legislatures would do a better job.

The industry, ironically, has criticized the FDA as being too slow to approve new drugs. The Coumadin case is a reminder that its concerns are less about threats to patients than threats to profits.

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FACSIMILE TRANSMITTAL

TO: Sarah Biondi DATE: 11/5

COMPANY:

FAX NO. 456-5557

PHONE NO.

FROM: Diane Dorman

NO. OF PAGES 5

Comments: Schumer Speech at our annual meeting for good themes.

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

Generic Pharmaceutical Industry Association Meeting
Senator Charles Schumer – March 27, 1999

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.

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.

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.

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FACSIMILE TRANSMITTAL

TO: Sarah Branch DATE: 11/5

COMPANY:

FAX NO.

PHONE NO.

FROM: Diane Doman

NO. OF PAGES 13

Comments: Nat. university background. Coumadin is great example. See last page of 11/18/98 for more on Coumadin.

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

GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION

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NATIONAL UNIFORMITY

There have been repeated efforts to compel state legislatures to adopt bioequivalence and therapeutic equivalence standards different from those established by the Food and Drug Administration (FDA). The purpose of these efforts is to ban or interfere with generic substitution and preserve market monopolies despite the expiration of patent life and the FDA approval of generic alternatives. Since January 1997, a multimillion dollar lobbying campaign has been taking place in over 25 states that attacks the bioequivalence and substitutability of generic versions of allegedly narrow therapeutic index (NTI) drugs. Given the sales volumes of these drugs, success in any large state will more than pay for the costs of this campaign.

For example, California considered a bill that would have required certain drugs to go through an additional approval process after being approved by FDA. Other state bills would establish a variety of practical hurdles to generic substitution, such as requiring doctors to personally contact pharmacists prior to filling the prescriptions, or banning substitution unless the doctor first explains why the generic was recommended and the patient agreed to sign a waiver. In North Carolina, such legislation passed in two weeks. The justification for these bills is the same; namely that generic drugs are not safe, are not bioequivalent and at times are actually dangerous.

The FDA also has issued a letter asserting that there is no scientific basis for questioning the substitutability of NTI or other "A" rated drugs. A copy of the agency's letter is attached.

While we do not expect Congress to interfere with the right of states to regulate the practice of pharmacy, we do believe it is appropriate for Congress to ensure that there is a national uniformity of the FDA's bioequivalent and therapeutic equivalence determinations. State generic substitution laws should not undermine the FDA's findings on clinical effect and safety. If the state campaign described above is successful, there will be no value to FDA approval of any generic drug. Instead, generic companies will have to demonstrate bioequivalence and therapeutic equivalence in each state they wish to market. The resulting patchwork of state bioequivalence and therapeutic requirements will only lead to higher generic costs to consumers and taxpayers.

Solution

The Food, Drug and Cosmetic Act should be amended to expressly preempt state generic substitution laws and regulations that impose standards different from, and in addition to, FDA's generic bioequivalence and therapeutic equivalence determinations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

January 28, 1998

Dear Colleague:

As you may be aware, certain individuals and groups have appeared recently before state legislatures, state boards of pharmacy, and drug utilization review committees, to express concerns about the interchangeability of certain products they characterize as narrow therapeutic index (NTI) drug products. A particular concern being raised by them is whether the safety and efficacy profile of these products could change if a switch were made from a brand-name product to an FDA-designated therapeutically equivalent generic product. FDA wishes to comment on the issue of interchanging any brand-name drug with a therapeutically equivalent generic drug and requests that you inform your association's members of this information.

For both brand-name and generic drugs, FDA works with pharmaceutical companies to assure that all drugs marketed in the U.S. meet specifications for identity, strength, quality, purity and potency. In approving a generic drug product, the FDA requires many rigorous tests and procedures to assure that the generic drug is interchangeable with the brand-name drug under all approved indications and conditions of use. For these reasons, FDA approved product labeling does not recommend that any additional tests need to be performed by the health care provider when a switch occurs from a brand-name drug product to a generic equivalent drug product, from a generic equivalent to a brand-name product drug, or from one generic product to another when both are deemed equivalent to a brand-name drug product. Brand-name drug products and therapeutically equivalent generic drug products are identified in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," frequently called the "Orange Book."

In addition to tests performed prior to market entry, FDA regularly assesses the quality of products in the marketplace and thoroughly researches and evaluates reports of alleged drug product inequivalence. To date, there are no documented examples of a generic product manufactured to meet its approved specifications that could not be used interchangeably with the corresponding brand-name drug. Questions have been raised in the past, as well, regarding brand name and generic products about which there could be concern that quality failures might represent a public safety hazard. FDA has performed post-marketing testing on many of these drugs to assess their quality. In one instance, more than 400 samples of 24 marketed brand-name and generic drug products were tested and found to meet the

established standards of purity and quality. Because patients may pay closer attention to their symptoms when the substitution of one drug product for another occurs, an increase in symptoms may be reported at that time, and anecdotal reports of decreased efficacy or increased toxicity may result. Upon investigation by FDA, no problems attributed to substitution of one approved drug product for another has occurred.

FDA works with both brand-name and generic drug product manufacturers after a drug product is in the marketplace to assure its quality. For example, brand-name and generic drug product manufacturers may want to change the drug formulation, site of manufacture, or manufacturing process after the drug is in the marketplace. These types of changes can be put in place only after the drug manufacturer provides the FDA with sufficient evidence that the drug identity, strength, quality, purity and potency will not change.

There are products in which small changes in the dose and/or blood concentration could potentially result in clinically important changes in drug efficacy or safety. Usually, these drugs require frequent adjustments in the dose of the drug and careful patient monitoring irrespective of whether the drug is a brand or generic drug product. These drugs may sometimes be described in FDA approved drug labeling as narrow therapeutic range drugs.

FDA may recommend to the manufacturers additional tests for approval of both brand-name and generic products, depending on the complexity of a drug substance or drug product and also depending on whether small changes in the dose and/or blood concentration could result in changes in drug efficacy or safety. It may also require additional tests for certain post-approval changes in manufacturing. The agency's recommendation to the manufacturer for these additional tests is designed to give the practitioner and patient additional assurance of product quality and interchangeability. These additional requirements should not be construed to mean that additional clinical scrutiny is necessary when interchange occurs. If anything, the additional tests required of pharmaceutical manufacturers are designed to reduce, not increase, concerns on the part of patients and practitioners.

Based on FDA's determination of therapeutic equivalence between generic and innovator drug products, the FDA concludes that:

- Additional clinical tests or examinations by the health care provider are <u>not</u> needed when a generic drug product is substituted for the brand-name product.

- Special precautions are not needed when a formulation and/or a manufacturing change occurs for a drug product provided that the change is approved according to applicable laws and regulations by the FDA.

- As noted in the "Orange Book," in the judgment of the FDA, products evaluated as therapeutically equivalent can be expected to have equivalent clinical effect whether the product is brand name or generic drug product.

- It is not necessary for the health care provider to approach any one therapeutic class of drug products differently from any other class, when there has been a determination of therapeutic equivalence by FDA for the drug products under consideration.

In considering drug product selection decisions, FDA acknowledges and supports the importance of good communication between the patient and the health care provider, particularly with regard to medications that require frequent monitoring of performance. We hope this information is useful to health care providers when making decisions regarding drug product selection.

We thank you for seeing that this information reaches the members of your organization.

Sincerely,

Stuart L. Nightingale

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

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FRANK PALLONE, JR.
6TH DISTRICT, NEW JERSEY

Congress of the United States
House of Representatives
Washington, DC 20515–3006

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January 25, 1999

HELP BRING PRESCRIPTION DRUG PRICES UNDER CONTROL!
COSPONSOR THE GENERIC DRUGS ACCESS ACT OF 1999

Dear Colleague:

The high cost of prescription drugs is one of the most pressing health care issues confronting the country's senior citizens, employers, managed care plans, state and federal drug programs. Controlling drug costs will be no easy task. One time-tested method, however, is timely access and availability of generic medicines once the patent on brand name drugs expires.

Generic competition has a dramatic impact on pharmaceutical costs. When a generic drug first comes onto the market, it typically costs 30 percent less than the brand name version. After two years on the market, the prices drop further to 60 or 70 percent of the brand name drug. The price of some generic drugs drop by as much as even 90 percent.

While these competitively priced alternatives are good for consumers, employers and government purchasers, they are not good for the brand name producer trying to maintain and protect monopolistic pricing. If there is no generic alternative available, consumers who need medicine have no choice but to buy the available brand drug and pay whatever it costs. It is for this reason that brand name drug companies launch aggressive campaigns to block or delay generic competition.

One tactic used by the brand industry to prevent generics from reaching the consumer is to convince state legislatures to pass unnecessary restrictions to the substitution of generic versions of brand name drugs. These restrictive laws are being advanced despite a scientific finding by the Food and Drug Administration (FDA) that the generic drug is equivalent and substitutable to the brand name product. The state campaign is nothing more than an attempt by the brand name companies to protect market share.

If these tactics are successful with the states, generic manufacturers could end up having to comply with 50 different sets of state laws before their products could ever reach the consumer. It would render the FDA stamp of approval meaningless. And it will only add extraordinary hoops for doctors and pharmacists to jump through before a generic medicine is dispensed. The ultimate losers are the senior citizens and other prescription drug purchasers who will be denied the access to equivalent generics and are forced to continue paying excessive brand prices for their medicines.

The Access to Generic Drugs Act would prevent drug companies from gaming the system. Very simply, this bill prohibits states from passing laws keeping generic drugs off the market once the FDA has determined that a generic drug is "therapeutically equivalent" to a brand name product. Most importantly, it will ensure that generic drugs get to the market in a timely fashion and provide consumers with access to low cost alternatives at the earliest possible time. ***If you would like to cosponsor this bill or would like more information, contact Steve Giull of my staff at 5-4671.***

Sincerely,

Frank Pallone, Jr.

Frank Pallone, Jr.

Congress of the United States
House of Representatives
Washington, DC 20515

March 10, 1999

Dr. Jane E. Henney
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Henney,

Generic drugs play an important role in controlling health care costs, both in state and federally funded programs, and for individual consumers. Last year, the Congressional Budget Office estimated savings from generic medicines exceeded $8 billion in 1994 alone.

However, we understand that during the past year, several brand pharmaceutical companies have sought to confuse state legislators and regulators about the safety, efficacy and interchangeability of generic pharmaceutical products. These efforts led to a "Dear Colleague" letter from the FDA in January 1998 stating: "As noted in the *Orange Book* ...products evaluated as therapeutically equivalent can be expected to have equivalent clinical effect whether the product is a brand-name or generic product."

We are also concerned about reports that some brand-name companies are attempting to dissuade the FDA from providing expertise and testimony in state legislative and regulatory hearings regarding the generic approval process, bioequivalence, and the safety and efficacy of generic substitution.

The FDA approval process for generic pharmaceutical products is the gold standard for assuring consumers and health care providers of the safety and efficacy of these drugs. In addition, the *Orange Book* has become a trusted source of information about whether one or more generics are therapeutically equivalent to, and may be substituted for, the brand product. It is critical that the FDA strongly defend its approval process and bioequivalence standards in any state forum where misinformation about this process is being used to create barriers to substitution.

State legislative and regulatory bodies can and will make their own independent decisions on pharmacy-related matters. However, such judgments must be guided by the continued provision of scientifically valid information provided directly by the FDA, a body without peer on questions related to bioequivalence and substitutability.

Thank you for your attention to this important matter.

Sincerely,

Pete Stark
Member of Congress

Henry Waxman
Member of Congress

Frank Pallone Jr.
Member of Congress

ACADEMY OF AMCP MANAGED CARE PHARMACY®
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AMCP Position Statement on Interchange of Narrow Therapeutic Index (NTI) Drugs

The Academy of Managed Care Pharmacy (AMCP) opposes legislation that restricts the appropriate generic substitution of drugs which have a narrow therapeutic index (NTI). AMCP supports allowing pharmacists to exercise professional judgment, based on scientific information, when determining whether a generic drug is appropriate for substitution for its equivalent brand name product.

When the patent or exclusivity protection on a brand name drug expires, drug manufacturers may gain approval to market a generic version. Generic products are commonly substituted for brand name drugs as allowed by state law. The practice of dispensing generic drugs results in a substantial cost-savings for patients and payers while producing the same clinical effect as the branded product.

The generic version of a brand name product must contain the same active ingredient(s) as the brand name product. Using a rigorous review process, the Food and Drug Administration (FDA) reviews generic drug applications to assure that the proposed drugs are pharmaceutically and therapeutically equivalent[1] to the brand name product.

A drug is commonly said to have a narrow therapeutic index when small variances in blood levels can change the effectiveness or toxicity of the drug. Safe and effective use of these drugs requires careful dosage adjustment and patient monitoring, regardless of whether the generic or brand name product is used. However, due to its strict approval process, the FDA does not consider NTI drugs as a separate category for purposes of generic substitution. The FDA has stated that they have not received data suggesting clinical problems with the use of approved NTI generic drugs which would support proposed state NTI legislation. Consequently, the FDA has taken the position that when an FDA approved and therapeutically equivalent generic drug is selected, patients, physicians, and pharmacists can be assured that they will see the same clinical results and safety profile as with the equivalent brand name product.

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[1] Drug products are considered pharmaceutical equivalents if they contain the same active ingredient(s), are of the same dosage form, and are identical in strength, and route of administration as the reference brand name product. Drug products are considered therapeutic equivalents only if they are pharmaceutical equivalents, and can be expected to have the same clinical effect when administered to patients under the conditions specified in the labeling.

AMCP believes pharmacists and prescribers, not legislative entities, are in the best position to evaluate the appropriateness of generic interchange, both in general and on a case-by-case basis. AMCP opposes legislation that is designed to restrict the generic interchange of NTI drugs. AMCP believes pharmacists, in consultation with prescribers, should have the right to use their professional judgment and knowledge of the available scientific information in determining when to substitute a generic product.

About the Academy of Managed Care Pharmacy

The Academy of Managed Care Pharmacy is the national professional society dedicated to the concept and practice of pharmaceutical care in managed health care environments. AMCP's mission is to promote the development and application of pharmaceutical care in order to ensure appropriate health care outcomes for all individuals. Its sole purpose is to represent the views and interests of managed care pharmacy. The Academy has more than 4,000 members nationally who are part of more than 600 health care organizations that provide comprehensive coverage to the millions of Americans served by managed care.

Adopted by the Board of Directors of the Academy of Managed Care Pharmacy on November 24, 1997.

CITIZENS AGAINST GOVERNMENT WASTE

NEWS

For Immediate Release
February 2, 1998

Contact: Jim Campi
(202) 467-5300

CAGW CRITICIZES EFFORTS IN STATES TO RESTRICT ACCESS TO GENERIC DRUGS

Washington, D.C. – Citizens Against Government Waste (CAGW) issued the following statement today on the release of a study on Coumadin and Warfarin published in the February issue of *Cardiovascular Reviews and Reports*. The statement was delivered by Elizabeth Wright, Director of CAGW's Health and Science Division.

"It has come to the attention of Citizens Against Government Waste (CAGW) that Dupont Merck's lobbyists are spending a lot of time and money to get state legislatures to pass laws that restrict access to generic pharmaceuticals. In particular, they are putting pressure on legislators to pass laws that would restrict access to generic Narrow Therapeutic Index (NTI) drugs.

"Warfarin is a blood thinner and is considered a NTI drug. In states where these restrictive laws have been passed, consumers – particularly the elderly – will find their access to generic drugs have been limited and their healthcare costs will go up. In other states, legislatures are now considering passing tougher regulations for dispensing generic pharmaceuticals. If these laws pass, they also will limit choice and drive up the costs, not only to consumers and private insurance companies, but to the taxpayers as well. CAGW objects to this failure to spend tax dollars wisely.

"Many states have programs that provide pharmaceuticals to the poor and the elderly. Using generics saves more tax dollars. But if doctors and pharmacists have to go through extraordinary hoops to prescribe a generic drug, the generic will simply not be dispensed to the consumer. This will raise the cost of these government programs to taxpayers and will decrease care in other areas.

"Dupont Merck may claim these restrictive laws are necessary because of safety issues. The study released today proves just the opposite. Dupont Merck's efforts are not about safety. They are more interested in protecting their market share.

"CAGW is hopeful that this study will empower state legislatures to say "no" to the brand-name drug company and "yes" to protecting taxpayers. Generics have been shown to save anywhere from 25 to 80 percent per prescription. This frees up healthcare dollars that can be spent in other areas, such as cancer screening or immunizations.

"In September, 1995 the Agency for Health Care Policy and Research (AHCPR), as part of their Patient Outcome Research Team (PORT), announced findings on the best methods of preventing strokes in people who are at high risk. The study found that two commonly known and effective interventions, one of which is warfarin, are not being used appropriately to prevent strokes. They found that if warfarin's use is expanded, it could cut in half the 80,000 strokes that occur each year due to atrial fibrillation. It is estimated that proper anticoagulation therapy could save approximately $600 million per year.

"The AHCPR points out that the necessary monitoring of warfarin therapy can be made more efficient and affordable by assigning the routine testing to nurse practitioners or physician assistants. This is particularly important for managed care organizations, which are enrolling increasing numbers of the elderly who are at highest risk for stroke. Considering that the study being released today shows Barr Laboratories' generic product is as safe and as effective as the brand name and is 30% less expensive, imagine the additional people that can be helped and the dollars that can be saved by Medicare, insurance companies and consumers!

"CAGW understands and appreciates the important role research pharmaceutical companies play in discovering new therapies that cure or control serious diseases. We want research companies to have a return on their investment so that it encourages them to find new discoveries. But competition also encourages innovation. It increases quality and keeps costs down. A 40 year monopoly is more than enough time for a company to recoup its investments. It is time for competition to begin. This study should give confidence to physicians and healthcare organizations to use this generic blood thinner, follow AHCPR's valuable research in preventing 40,000 strokes a year, and save healthcare dollars for all Americans."

Citizens Against Government Waste is a 600,000 member organization dedicated to the elimination of waste, inefficiency, mismanagement and abuse in the federal government.

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—Allen H. Neuharth
Founder, Sept. 15, 1982

USA TODAY

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Today's debate: USING GENERIC DRUGS

Drugmaker tries end run to kill off competition

OUR VIEW: If the maker of Coumadin gets new state laws on generics, watch prescription prices skyrocket.

When pharmaceutical giant DuPont Merck saw a generic substitute for its popular blood thinner Coumadin emerging earlier this year, it faced a choice. It could watch its profits decline. Or it could find some way to slow the challenger.

Today the plan it chose threatens to push up drug prices while undercutting the system that has allowed the use of safe, effective generics for two decades.

Even a brief glance tells you how high the stakes are for DuPont Merck.

Coumadin is a $500 million-a-year cash cow. A dollar's worth costs less than 10 cents to make — ample margin to entice cheaper competition. It's prescribed for 2.5 million heart patients, most over 60, a market that will grow as the baby boom ages.

So with Barr Laboratories on the verge of getting a generic substitute approved in January, DuPont Merck went into action.

Having already failed at every regulatory level to block the competing drug, it set out to rewrite state laws. Generic substitutions wouldn't be allowed for Coumadin or other drugs for which dosages must be closely controlled unless pharmacists first got the prescribing doctor's permission.

The company says this is a safety measure. Legislators are targeted with anecdotes supposedly showing the risks of generic substitution seen in other drugs.

It truth, it's closer to a scare tactic. Having failed to persuade review panels, the company is peddling a superficially appealing argument to legislators who know less.

The facts:

▶ There's no compelling reason to treat generics differently. The Food and Drug Administration, which passes on drug safety, says approved generics don't vary from their equivalents any more than the original maker's product would vary from lot to lot. So the horror stories establish nothing.

▶ The law already gives doctors control. All they need do is say on a prescription that no generic substitution is allowed. Requiring more only adds time and cost to discourage generic substitution.

Despite this, two states already have bought DuPont Merck's pitch, and it's under consideration in 18 others.

If the pattern continues, other drugs no doubt would be subjected to the same process, and consumers would be the losers.

Generics have grown to 13% of pharmaceutical sales and are used to fill about 50% of all new prescriptions. They've driven down the cost of drugs and helped stem cost increases for health insurance.

Whatever the merits of DuPont Merck's argument, the place to resolve them is before the FDA. It's hard to think of a reason 50 state legislatures would do a better job.

The industry, ironically, has criticized the FDA as being too slow to approve new drugs. The Coumadin case is a reminder that its concerns are less about threats to patients than threats to profits.

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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Public Citizen

Testimony of Maura Kealey
Deputy Director, Public Citizen's Congress Watch
before the House Judiciary Subcommittee
on Courts and Intellectual Property
on H.R. 1598, the "Patent Fairness Act of 1999"

July 1, 1999

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

Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to testify this afternoon. I am Maura Kealey, Deputy Director of Public Citizen's Congress Watch. Public Citizen is a 150,000-member nonprofit organization that advocates for the rights, health and safety of American consumers. For more than 25 years Public Citizen's Health Research Group, under the direction of Sidney M. Wolfe, M.D., has been at the forefront of the fight to ensure that consumers have access to safe, effective, and affordable medicines.

Prescription drugs is one of the top challenges facing consumers in the United States today. Two days ago, President Clinton announced a serious effort to provide Medicare coverage for outpatient prescription drugs in order to make medicines affordable for two groups who need drugs the most, seniors and individuals with disabilities.

Ironically, in the same week this Subcommittee is considering H.R. 1598, the special patent extension bill that is the subject of this hearing, which goes in exactly the opposite direction. While the Clinton bill seeks to expand drug coverage while placing Medicare on a sound financial footing, this bill would have no benefit for the health of consumers and would increase costs that would extend beyond Medicare.

If Congress passes H.R. 1598, the message it will send to the American people is that Congress is in favor of protecting drug company monopoly pricing practices - not helping seniors and the rest of us afford the medicines we need.

In judging H.R.1598, the fundamental question is this: Does it advance the goal of making prescription drugs more affordable for and hence more accessible to American consumers?

The answer is a resounding no. H.R. 1598 attempts to undo a compromise reached in 1984 when all affected parties were at the table and reached agreement on the Drug Price Competition and Patent Term Restoration Act of 1984 [Waxman-Hatch Act]. Now one side is attempting to rewrite the rules to their benefit. This is not only unfair; it would set a bad precedent for the future.

A three-year patent extension for Claritin would alone cost American consumers an additional $1.6 billion - $3.2 billion.(1) For all seven drugs affected by the bill, the additional cost to consumers and the U.S. healthcare system would be between $2.2 billion and $4.5 billion over the three years. For individual allergy sufferers, this could mean up to hundreds of dollars a year in additional drug costs.

The billions of dollars that H.R. 1598 would cost consumers would, of course, translate directly into billions of dollars of additional revenue to Schering-Plough, Claritin's manufacturer. This is an unwarranted transfer of income particularly in the case of Claritin, a drug that has already more than amply repaid its maker. Claritin had worldwide sales of $2.2 billion in 1998, and accounted for 28 percent of Schering-Plough's total sales. Public Citizen estimates that between its initial marketing in 1993 and 1998, Claritin earned at least $1.3 billion in profits. Before its patent expires in 2002, we estimate that it will earn another $2.2 billion.(2)

Thus when H.R. 1598 is evaluated on the basis of its economic impact on U.S. consumers and the U.S. healthcare system, it fails to pass the test of good public policy. That is perhaps why the bill's proponents attempt to clothe it in the mantle of defending intellectual property rights or stimulating research and development into new treatments. Before explaining why we believe those arguments are without merit, let me quickly sketch how H.R. 1598 would work.

H.R. 1598 would create a special patent extension review process for seven "pipeline" drugs [so-called because they were in the FDA new drug review process at the time the Waxman-Hatch Act] became law: in addition to Schering-Plough's Claritin, the main drug affected, Smith-Kline Beecham's Relafen, Bristol-Myers Squibb Cardiogen-82, Bayer's Nimotop, Hoechst Marion Roussel's Dermatop, Rhone-Poulenc-Rorer's Penetrex, and Schering-Plough's Eulexin would be eligible. Manufacturers could petition the Commissioner of Patent and Trademarks for three additional years of patent protection for these drugs. The sole basis on which the extension could be challenged would be a showing that a firm failed to exercise "due diligence" during some part of the review process; the burden of proof would be on the opponents. FDA would have no role in the review process. Public interest considerations, such as how higher prices would affect consumers, would be irrelevant. If a patent expired during the review process, an automatic extension would be granted, which could be extended during any period of judicial review.

H.R. 1598's proponents make three claims for their bill. We believe the Subcommittee should reject all three, for the reasons explained below.

Claim #1: Claritin was denied the full patent term restoration to which it should have been entitled under the 1984 Waxman-Hatch Act.

In an attempt to justify this windfall profits scheme, H.R. 1598's proponents have attempted to rewrite legislative history. They claim that the two-year patent extension granted to seven "pipeline" drugs, including Claritin, should be extended because the FDA review process for these drugs took much longer than average. Proponents claim 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 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 patent term restoration 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.

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. Schering-Plough got its two years for Claritin. (In addition, it later received another 22 months extension due to the General Agreement on Tariffs and Trade [GATT]).

It is wishful thinking on Schering-Plough's part to read into the Waxman-Hatch Act 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 have - and would have - done so.

Claim #2: H.R. 1598 is somehow a necessary incentive for companies to continue to do research and development to find new treatments.

Brand-name pharmaceutical companies frequently play what has been called the "R&D scare card" - that is, raising the threat that they will not be able or motivated to invest in new research and development unless they get their way on whatever legislation Congress is considering. Although this argument can be a successful scare tactic, playing on the fears that a vitally needed treatment for a disease won't be discovered, its premise is false.

There are two reasons why it is false. The first is that brand-name companies rely on R&D to make money: it is the source of new patents, new products, and future profits. Over the 15 years since the Waxman-Hatch Act passed, according to the Pharmaceutical Research and Manufacturers of America (PhRMA), brand-name company R&D has increased from $3.4 billion in 1985 to $17.2 billion in 1998. In the five years after Congress imposed price restraints on Medicaid drug prices in 1990, which also had been opposed by the brand-name industry on the grounds that they would have a chilling effect on research and development, R&D expenditures almost doubled, going from $6.8 billion to $11.9 billion. These firms are not going to commit business suicide by curtailing R&D.

Secondly: The brand-name industry's profit margins are more than sufficient to increase R&D. According to *Fortune Magazine*, in 1998 the pharmaceutical industry was the most profitable in the U.S. based on rate of return on sales, assets, and equity.(3) Its profit margin of 28.7 percent is nearly three times higher than the profit margin of other manufacturers of branded consumer goods.(4) This industry does not operate on such razor-thin margins that some equitable price relief for consumers will drive brand-name pharmaceutical

companies to cut research and development.

The record shows that for Schering-Plough, as well as other leading brand-name pharmaceutical companies, profits are a much higher priority than R&D. In 1998, Schering-Plough allocated almost 22 percent of its net sales to profit (net income) and just 12.5 percent to research and development. None of the top ten U.S. pharmaceutical companies ranked by sales in 1998 spent more on R&D than they generated in profits (net income). The median for the ratio of net income to R&D for the top ten was 1.5.

Leading Pharmaceutical Companies Place Profits above R&D

Company	Net income as a percent of sales	R&D as a percent of sales	Ratio of net income to R&D
Bristol-Myers Squibb	17.2%	8.5%	2.0
Abbott	18.7%	9.8%	1.9
Merck	19.5%	10.6%	1.8
Schering-Plough	**21.7%**	**12.5%**	**1.7**
Am. Home Products	18.4%	12.2%	1.5
Pfizer	26.4%	18.0%	1.5
Warner-Lambert	12.3%	8.6%	1.4
Johnson & Johnson	13.0%	10.3%	1.3
Amgen	31.8%	24.4%	1.3
Eli Lilly	22.7%	18.8%	1.2

(*Fortune Magazine*'s top ten pharmaceutical companies ranked by sales, in this chart in declining order by ratio of net income to R&D. Company figures from 1998 annual reports.)

These numbers show three things: (1) the enormous profitability of brand-name pharmaceutical companies; (2) that they all earn enough to allocate more money to research and development than they now do and still maintain enormous profits; and (3) that without exception, the top ten place a higher priority on profits than R&D. The R&D scare argument is particularly laughable as a justification for a three-year patent extension for Claritin, in view of Schering-Plough's enormous profits and the imbalance between profits (net income) and research and development expenditures.

Claim #3: H.R. 1598 merely sets up a "fair and open" review process to resolve disputes about these patent term extensions objectively instead of through "stealth" riders

The first thing that's wrong with this argument is that Schering-Plough, the company whose aggressive lobbying is driving H.R. 1598, tried for three years to get a patent extension for Claritin with just those stealth tactics. It is only because they were unable to put their special interest provision as a last minute rider onto various appropriations and other bills, due to alert legislators and attention from the media, that a legislative strategy is underway this year. But if it succeeds, the consequences for consumers will be no different.

Next, H.R. 1598's review process is neither fair nor open. The bill gives the drug company asking for the patent extension the winning hand before the cards are dealt by, as noted above, placing the burden of proof upon the opponents and constructing the review criteria so that a favorable outcome for the petitioner is all but inevitable.

Some of H.R. 1598's proponents have sought to find a way to profit from adversity. In responding to widespread criticism of their stacked deck process, they attempt to re-focus the entire debate on this question, as if getting the process right could "fix" the problems with the bill. Should the Court of Claims hear the case rather than the Commissioner of Patents and Trademarks? Should the review criteria be changed?

But to enter into that discussion is to have taken the bait - that is, to have accepted proponents' claim that there is any legitimate reason for Congress to establish any review process - no matter how structured or where located - that could result in three-year monopoly patent extensions for drugs already on the market, one of which is enormously profitable. Since H.R. 1598's proponents have utterly failed to meet the threshold burden of showing that some past wrong was done them that should be righted, their attempt to cloak this special interest bill in the sacred mantle of defending intellectual property rights should be rejected as the sophistry it is.

In conclusion, I want to come back to the contrasting stories with which I began - the President's proposal two days ago finally to provide a Medicare prescription drug benefit to help seniors and persons with disabilities afford the medicines they need. The bill that is the subject of today's hearing goes in exactly the opposite direction by making medicines less, rather than more, affordable.

That is the context in which we hope this Subcommittee will evaluate H.R. 1598. We are certainly not opposed to either pharmaceutical patents or intellectual property rights. But drug patent protection should not, to paraphrase former Senator Pryor, be viewed as a God-given right, but instead as something government creates to fulfill a public purpose.

An examination by this Subcommittee of how the U.S. drug patent monopoly price system is actually working - and whether it is truly promoting the public good as it should - would be welcome. But in the meantime, we would urge you to reject H.R. 1598. The public interest demands that medicines be made more affordable for

American consumers - not less.

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1. Public Citizen fact sheet, "Stop Claritin's Billion Dollar Patent Extension Grab," May 24, 1999, p. 3.

2. Public Citizen fact sheet, "Claritin Patent Extension Bill: Don't Be Fooled by the R&D Scare Card," June 21, 1999.

3. "Drug Dependency: U.S. Has Developed an Expensive Habit," *Wall Street Journal* (Nov. 16, 1998).

4. Houlihan Lokey Howard & Zukin, *Expert Analysis of Profitability* (Feb. 1998).

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Can Schering-Plough's Aggressive Lobbying Buy a Claritin Patent Extension?

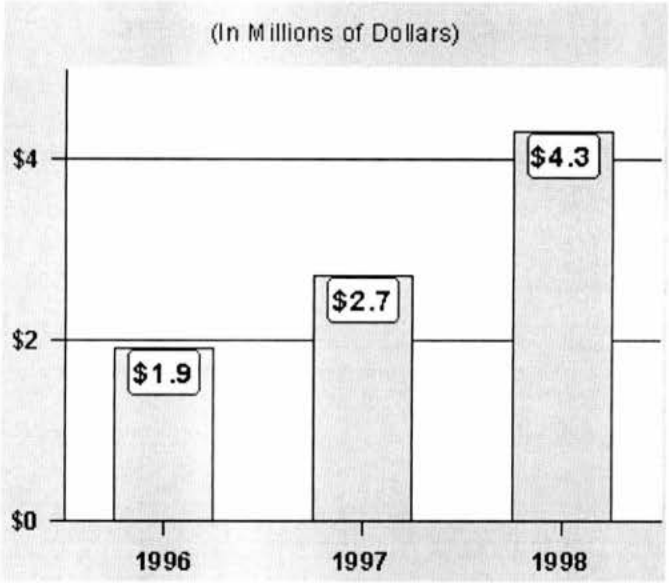
Click here for a complete text of the bill, list of co-sponsors, and current status.

Consumers will pay through the nose if Schering-Plough's lobbying campaign for H.R. 1598/S. 1172 succeeds in getting a patent extension for its best-selling allergy drug Claritin. Claritin users would be forced to pay between $1.6 billion and $3.2 billion more over three years because of delayed generic competition.(1)

Schering-Plough broke records in drug advertising in 1998, spending $267 million for Claritin advertising. Such expenditures were two-and-one-half times greater than spending on the second most advertised drug, Propecia.(2) Will 1999 be another record-breaking year for Claritin - this time, for making Schering-Plough Washington's top spending pharmaceutical firm on lobbying? If recent trends continue, that could be the case.

- Between 1996 and 1998, Schering-Plough's lobbying expenditures more than doubled: from $1,895,000 in 1996 to $4,268,000 in 1998.(3)
- The number of outside lobbying firms retained to lobby on the patent extension also doubled, from five to ten. And 1999 got off to a brisk start, with Democratic power lobbyist Richard Ben-Veniste signing on to the team.
- While Schering-Plough ranks only ninth in sales among pharmaceutical companies, in 1998 the company was fourth highest in lobbying expenditures, moving up from its seventh-place rank in 1997.

Schering-Plough Lobbying Expenditures, 1996-1998



Not All of Schering-Plough's Capitol Hill Advocates Are Registered Lobbyists

In addition to the highly paid promoters who are registered to lobby for a patent extension for Claritin, Schering-Plough has benefited from the support of another prominent promoter, C. Everett Koop, M.D. Since leaving his position as Surgeon-General of the United States, Dr. Koop has engaged in several business ventures with pharmaceutical companies in addition to recently becoming an Internet multi-millionaire by selling stock in his drkoop.com web site, which offers medical advice.

- **$1 million Schering-Plough grant.** According to the June 20, 1999 New Jersey *Star Ledger,* Schering-Plough gave Dr. Koop's nonprofit group, The Koop Foundation, a $1 million grant. The company also advertises on Dr. Koop's web site.
- **Koop support for the Claritin patent extension bill.** On the Hill, Dr. Koop has actively promoted the Claritin patent extension bill. April 29, 1999, the day after H.R. 1598 was introduced, he sent a letter to all House members urging approval of the bill. On June 10, 1999, he spoke at a forum in the Capitol organized by the International Intellectual Property Institute to showcase H.R. 1598 and the proposed Claritin patent extension.(4) Moreover, Dr. Koop had been listed on the proposed witness list released by staff of the House Judiciary Subcommittee on Courts and Intellectual Property for the July 1, 1999, hearing on H.R. 1598, but his name did not appear on the final witness list.

- **Koop's non-disclosure.** When Dr. Koop spoke at the June 10 forum, he did not disclose his financial support from Schering-Plough. Nor was it was mentioned in his April letter supporting H.R. 1598.
- **Koop meets with the House Commerce Committee to support Schering-Plough's controversial Hepatitis C bundled kit of two drugs.** The *Star Ledger* reports that the Claritin bill is not the only Schering-Plough issue on which Dr. Koop has been active on the Hill. According to its June 20 story, on May 5, 1999, Dr. Koop attended a closed-door meeting of the House Commerce Committee and defended Schering-Plough's marketing of Rebetron, a kit that bundles two Hepatitis C drugs together and costs up to $18,000 a year. In response to consumer protests, FDA wrote Schering-Plough encouraging the drug

maker to unbundle the kit, but the company refused. At the May 5 meeting, Koop reportedly distributed a three-page statement that "largely reiterated Schering-Plough's position." [reporter's words]

Which Lobbying Firms Are Sharing Schering-Plough's Wealth?

Some of the best connected law firms in Washington have worked for Schering-Plough over the last three years (1996-1998). Former Members of Congress, former Congressional staffers, and other powerful Washington insiders are among the company's cadre of highly-priced outside lobbyists.

Former Members of Congress Lobbying for Schering-Plough

Some of the most effective lobbyists are former Members of Congress. Having come recently from positions inside the House or Senate, these individuals have extensive knowledge of the legislative process and, even more important, close connections to current Members.

Name	Employer
Howard Baker (R-TN)	Baker, Donelson, Bearman & Caldwell
Dennis DeConcini (D-AZ)	Parry, Romani & DeConcini
W. Wyche Fowler (D-GA)	1996 Solo Practice/ Ambassador to Saudi Arabia since 1997
Vin Weber (R-MN12)	Clark & Weinstock

Former Staffers Lobbying for Schering-Plough

In addition to former Members of Congress, many ex-Congressional staff members lobby or have lobbied for Schering-Plough. These staffers, in many cases, worked closely with current Members of Congress or key Congressional Committees involved in Schering-Plough's legislative agenda.

Name	Current Employer	Former Employer
Keith Kennedy	Baker, Donelson, et al.	Staff Dir., Senate Appropriations Cmte.
Terry Lierman	Capitol Associates	Chief of Staff, Senate Appropriations
Ed Kutler	Clark & Weinstock Inc.	Asst. to Former Speaker Gingrich (R-GA)
Mimi Simoneux	Clark & Weinstock Inc.	Staff, Rep. Billy Tauzin (R-LA), Member of Commerce Cmte.
Edward Baxter	Parry, Romani & DeConcini	Counsel, Senate Judiciary Cmte.
Shannon Davis	Parry, Romani & DeConcini	Staff, Rep. Sam Johnson (R-TX), Member of Ways and Means Cmte.
Romano Romani	Parry, Romani & DeConcini	Staff, Sen. Dennis Deconcini (D-AZ)
Thomas Parry	Parry, Romani & DeConcini	Chief of Staff, Sen. Orrin Hatch (R-UT), Chair of Judiciary Committee
Phillip Mosely	Van Scoyoc Associates	Chief of Staff, Cmte. on Ways & Means
Jeffrey Trinca	Van Scoyoc Associates	Chief of Staff, Comm. to Restructure IRS
Nicholas P. Wise	Wise & Associates	Counsel, Sen. Mike DeWine (R-OH), Member of Judiciary Committee

Other Notable Washington Insiders

Peter Knight

A long-time assistant to then-Senator Al Gore, Peter Knight lobbied for Schering-Plough in 1997 and 1998 on behalf of Wunder, Knight, Levine, Thelen & Forscey receiving $420,000. Knight was a top fund raiser for the Clinton-Gore campaigns and was campaign manager for the 1996 Clinton-Gore campaign.

Richard Ben-Veniste

The law firm of Weil, Gotshal & Manges, of which Ben-Veniste is a partner, registered to lobby for Schering-Plough in February of 1999. Ben-Veniste's extensive resume includes stints as: Assistant Special Prosecutor and Chief of the Watergate Task Force; Democratic Minority Counsel for the Senate Whitewater Hearings, and Assistant U.S. Attorney. He is well connected with Judiciary Committee members which must first approve patent extension legislation.

Linda Daschle

Though not registered specifically as a Schering-Plough lobbyist, the Senate Minority Leader's wife is a registered lobbyist for Baker, Donelson, Bearman & Caldwell, Schering's leading outside lobbying firm. According to staff accounts, she has personally lobbied members of the House Judiciary Committee on H.R. 1598.

Jack Martin

Before joining Parry, Romani & DeConcini as a lobbyist, Jack Martin worked at the Food and Drug Administration as Special Assistant to the Commissioner for Policy from 1985 until 1992.

Claritin Doesn't Deserve - or Need - a Patent Extension

Proponents of H.R. 1598/S. 1172 try to play the "R&D scare card" - they make the argument that the Claritin patent extension is in some way connected to the drug company continuing to do research and development. In Schering-Plough's case, the numbers tell a different story. With a profit rate of almost 22 percent, the company allocated a scant 12.5 percent to R&D in 1998.(5)

Nor does Schering-Plough need three additional years of patent protection to reap ample rewards for developing Claritin. According to a Public Citizen analysis, Schering-Plough has already earned $1.3 billion in profits on Claritin, and is expected to earn another $2.2 billion before the drug's patent expires in 2002.(6) New product formulations and licensing agreements extend some patent protection for the #1 advertised drug in America to 2014. This is not a drug in need of a patent extension.

Schering-Plough's Costly Lobbying Campaign for the Claritin Patent Extension Is Inversely Related to the Merits of the Bill.

- **Legislative history:** There is no basis in legislative history for Schering-Plough's claim that Claritin got less than the full patent term restoration to which the Waxman-Hatch Act of 1984 should have entitled it.

- **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.[1]

- 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.

- Not a fair and open process: H.R. 1598/S. 1172 creates a "stacked deck" patent extension review process with all the aces in Schering-Plough's hand. The negative impact of high drug prices on consumers, taxpayers and the U.S. health care system are irrelevant under H.R. 1598/S. 1172.

- 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.

Conclusion

H.R. 1598/S. 1172 is not about patent integrity or drug research and

development. Above all, this bill would reward Schering-Plough's aggressive Congressional lobbying campaign with additional billions in profits which, if the company's past priorities are a guide, would go in large part to fuel aggressive marketing campaigns like that waged for Claritin, arguably the most aggressive in U.S. pharmaceutical history. That may be a legitimate reason for Schering-Plough stockholders to support the bill - but not for Congress to pass it.

July 30, 1999
For more information contact Maura Kealey 454-5116

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1. A 1996 Congressional Research Study found that generic competitors typically cost 30 percent - 60 percent less than brand-name drugs. See Public Citizen's May 24, 1999 fact sheet, "Stop Claritin's Billion Dollar Patent Extension Grab." www.citizen.org/congress/drugs/stopclaritin.htm.

2. IMS Health and Competitive Media Reporting, cited in *Medical Marketing & Media*, May 1999, p. 72.

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

4. The International Intellectual Property Institute was formed by Bruce A. Lehman in December 1998. Prior to that Mr. Lehman was the Commissioner of Patents and Trademarks; while in that office he wrote a letter in support of last year's effort to gain a patent extension for Claritin. Before going to the PTO, Mr. Lehman was an attorney with Swidler & Berlin, which reported $140,000 in lobbying income from Schering-Plough in 1997-1998. In an April 5, 1999 interview about the Institute with the *Washington Times*, Mr. Lehman revealed that he had funding from "U.S. private sector companies" but did not state which ones. One of the two major intellectual property projects he discusses in the interview concerns pharmaceutical issues in Brazil.

In addition to Dr. Koop, other speakers at the June 10 forum included H.R.1598's sponsors, Representatives Jim McDermott (D-Wash.) and Ed Bryant (R-Tenn.); former PhRMA Executive Director Gerald Mossinghoff; Gerald Meyer, former FDA staff person who currently acts as a consultant to biotechnology firms; as well as former Judiciary Committee staff. When Mr. Lehman was questioned by a participant about the lack of balance in the program, he stated that his Institute's purpose was "to promote intellectual property rights."

5. Schering-Plough 1998 *Annual Report*, p. 33.

6. "Claritin Patent Extension Bill: Don't be Fooled by the 'R&D' Scare Card," Public Citizen fact sheet, June 21, 1999. www.citizen.org/congress/drugs/claritinrd.htm

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Albuquerque Seniors Pay More for Prescription Drugs While Pharmaceutical Profits Soar:

An Investigation into Prescription Drug Price Discrimination in the First Congressional District of New Mexico

By Public Citizen and The Gray Panthers of Greater Albuquerque

Contents

Executive Summary

Thousands of Albuquerque-area senior citizens without prescription drug coverage face ***price discrimination*** by pharmaceutical manufacturers. A price survey of 24 area pharmacies, conducted by the national consumer group Public Citizen and the Gray Panthers of Greater Albuquerque, shows local seniors are being charged retail prices ***almost double*** the prices charged by prescription drug makers to their most favored customers like HMOs, large insurers and federal agencies.

Instead of offering most favored prices to Medicare beneficiaries because of their huge collective buying power, pharmaceutical makers practice price discrimination against seniors by charging them their highest retail prices. The 14 million older adults and people with disabilities on Medicare who have no prescription drug coverage constitute a far larger purchasing block than any current customer most favored by the pharmaceutical manufacturers.

Senior volunteers surveyed the prices of ten of the most widely prescribed drugs for older adults at randomly selected Albuquerque-area pharmacies. The retail price was compared to the best federal price, which according to the U.S. General Accounting Office is equivalent to the price pharmaceutical manufacturers charge their most favored customers. Prices charged to Albuquerque seniors were ***almost double - about 90% more*** - than the most favored customer price.

Millions of American seniors are suffering under this discriminatory pricing as Medicare does not cover outpatient prescription drugs. One out of three senior citizens (14 million) have no coverage for prescription drugs and must pay high retail prices totally out-of-pocket. Many more older adults have inadequate or insecure insurance coverage with high deductibles and co-payments and low annual caps. Moreover, Medicare HMOs and employer plans are reducing drug coverage or raising costs for retirees.

The pharmaceutical industry profits handsomely from price discrimination. Brand name prescription drug makers have consistently been among the most profitable industries in America for decades. In 1998, pharmaceutical companies ranked first among all industries in rates of return on equity, assets, and revenues. CEOs of the top ten pharmaceutical companies last year averaged $20 million in annual compensation, including stock options, and now hold nearly $1 billion in stock options.

The industry claims that high U.S. prescription drug prices are necessary to fund research and development. But R&D is a lower priority than profits for the manufacturers. In 1998, the top ten firms put one-and-a-half times as much money into profits as into research and development. And not everyone pays high prices. Foreign consumers get U.S.-made drugs at a fraction of the price paid by American senior citizens because their governments negotiate fair prices with prescription drug makers.

Congress is currently considering legislation to prohibit price discrimination against seniors and the disabled in the Medicare program and to add a comprehensive prescription drug benefit to Medicare:

> "The Prescription Drug Fairness for Seniors Act" (H.R.664/S.731) would harness the buying power of 39 million Medicare beneficiaries to allow seniors and the disabled access to the same low prices as most favored customers. Pharmacies would purchase prescription drugs for Medicare beneficiaries from the manufacturer at the same low prices available to the Departments of Defense and Veterans Affairs and other large purchasers. Since these prices are nearly half the retail prices paid by Medicare beneficiaries, seniors will benefit from large cost savings even after fair pharmacy dispensing fees are included.
>
> President Clinton and Congressional leaders have proposed that a comprehensive prescription drug benefit be added to Medicare. To be cost effective, such a benefit must use the bargaining power of the federal government and Medicare beneficiaries to negotiate significantly lower drug prices, as do HMOs and other large private insurers, similar to the savings

that could be achieved under the "Prescription Drug Fairness for Seniors Act." Negotiated prices are the first step in constructing an affordable benefit plan - with low premiums, low or no co-payments, and good coverage for those with high as well as low or moderate drug expenditures.

Senator Jeff Bingaman and Representative Tom Udall are already sponsors of "The Prescription Drug Fairness Act for Seniors" (H.R. 664/S. 731). New Mexico seniors want the other members of our congressional delegation to sponsor H.R. 664 and S. 731 and to support a comprehensive Medicare prescription drug benefit that negotiates lower drug prices for beneficiaries.

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

Skyrocketing Prescription Drug Costs Hit Seniors Hard

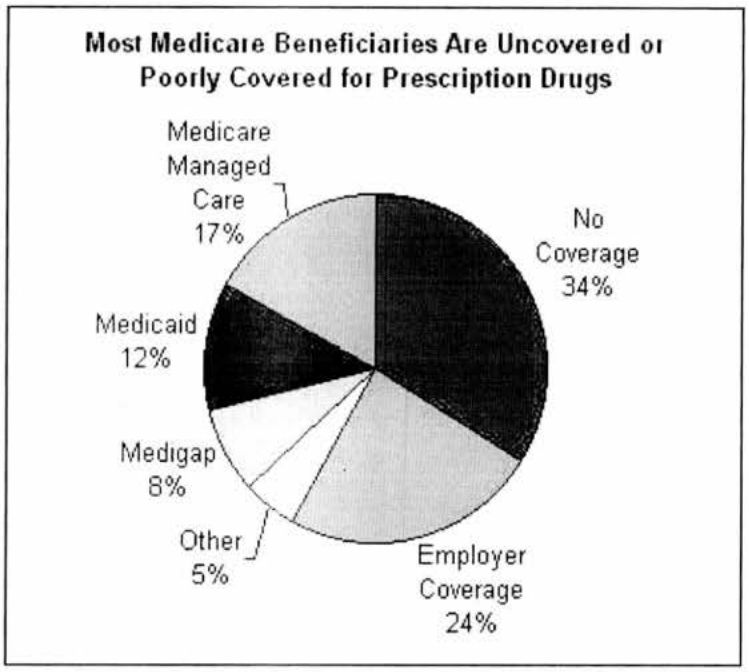
Prescription drugs are the fastest growing health care expenditure in the United States. The number of retail prescriptions grew 8% from 1998 to 1999, rising to almost three billion prescriptions annually.[1] But prices for prescription drugs are rising even faster. Americans will spend more than $121 billion for retail pharmaceutical drugs in 1999, an increase of 18% over 1998.[2] Prescription drugs rank behind only hospital and physician costs among all health care expenditures.[3]

Prescription drug spending is projected to rise more than twice as fast as all other health care costs this year.[4] The federal Health Care Financing Administration (HCFA) forecasts a 138% increase in total drug spending over the next ten years.[5] This rate of increase would be almost four times the projected growth in the Consumer Price Index, which determines increases in Social Security payments, the lifeblood of many seniors.[6]

Medicare Does Not Cover the Prescription Drugs Seniors Rely On

Medicare recipients are especially dependent on prescription drugs in order to maintain good health. Senior citizens are 12% of the population but account for about one-third of all prescription drug spending.[7] The average Medicare beneficiary fills eighteen prescriptions a year.[8] Moreover, 80% of retired Americans take at least one prescribed drug every day, spending on average $942 a year.[9]

About 39 million Americans have most of their health care costs paid for by Medicare because they are over the age of 65 or disabled. Yet, Medicare offers almost no outpatient prescription drug coverage. Medicare only covers prescription drugs used in a hospital or nursing home, immunosuppressive drugs, erythroprotien, oral anti-cancer drugs, hemophilia clotting factors, and some vaccines. Generally, any drug that can be self administered is not covered.



One in Three Seniors Has No Drug Coverage; Millions More Need Help

Most Medicare recipients have few options to reduce or contain their prescription costs. At least one in three, or more than 14 million beneficiaries, has no drug insurance coverage at all.[10] They must pay all costs out-of-pocket.

Another one-quarter or 24% of retirees are covered through employer group plans. But the number of firms offering retiree health coverage has dropped from 40% to 30% in the past four years.[11] And many of these retirees are still at risk since employers are capping prescription drug coverage, charging higher deductibles, and requiring co-payments of as much as $30 per prescription.

About 8% purchase expensive Medigap insurance policies, which provide inadequate prescription drug coverage and require high cost sharing and whose premiums increase with age. Almost all of the seniors who have purchased Medigap drug coverage are enrolled in two plans with an annual premium of $1,080 and a cap of $1,250 in coverage, with a 50% co-pay and a $250 deductible.[12]

About one out of six seniors, or 17%, has coverage through Medicare HMOs. Almost 60% of these plans indicate they will cap coverage below $1,000 next year.[13] Meanwhile, Medicare HMOs have dumped more than 734,000 seniors from coverage in 1999 and 2000.[14]

Medicaid, the Department of Veterans Affairs, and other public programs provide prescription drug coverage for those who are often the poorest or most medically needy beneficiaries, covering 17% of the seniors and people with disabilities on Medicare.

Elderly Struggle with Rising Out-of-Pocket Costs for Drugs

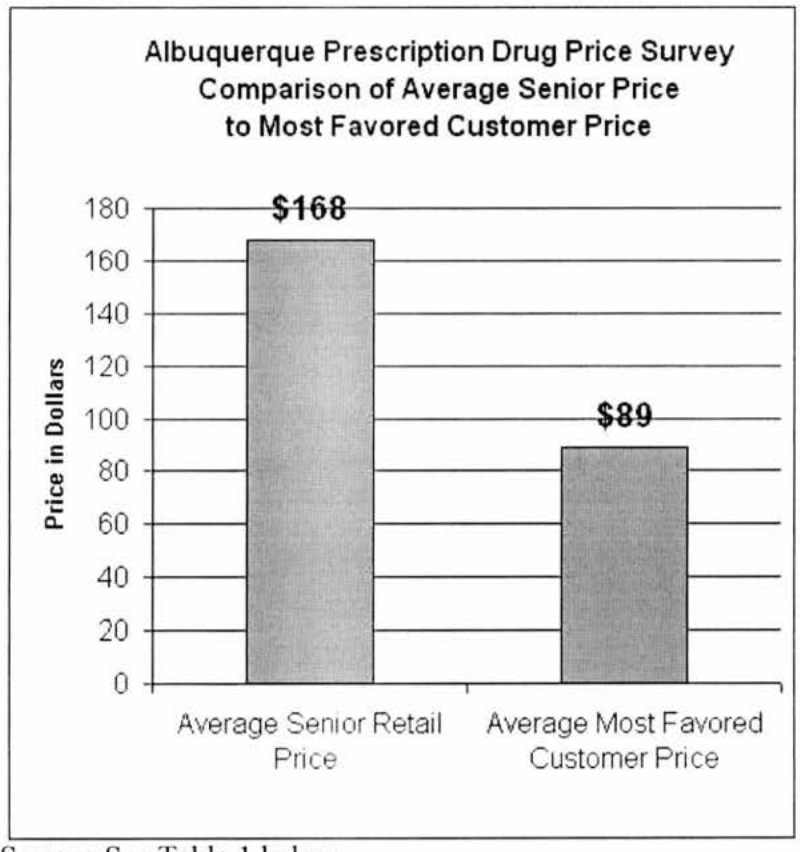
Senior citizens pay almost 20% of their income in out-of-pocket health care costs.[15] Medicare beneficiaries pay about half of the cost of their prescription drugs out-of-pocket; the population as a whole pays one-third of their total drug

costs out-of-pocket. Beneficiaries with Medigap coverage pay on average 80% of their drug costs out-of-pocket.[16]

Senior citizens need pharmaceutical coverage because they use more drugs than any other age group. Most working Americans get coverage for pharmaceutical expenditures through their workplaces. But having retired on fixed incomes, too many older adults cannot afford to pay for the prescription drugs they need to stay alive and well.

Albuquerque Seniors Pay Almost Twice as Much as Favored Customers

The prescription drug price survey conducted by Public Citizen and the Gray Panthers of Greater Albuquerque found that Albuquerque-area seniors without prescription drug coverage are victims of price discrimination by pharmaceutical manufacturers. The random scientific sampling of 24 local pharmacies in the First Congressional District found that seniors pay almost twice as much for retail prescription drugs as most favored customers such as HMOs, large insurers and federal agencies like the Departments of Veterans Affairs and Defense. For standard dosages of ten brand name patent drugs most commonly prescribed for seniors, the survey found that Albuquerque-area older adults pay 90% more than most favored customers - $168 versus $89.



Source: See Table 1 below.

Prescription drug makers practice price discrimination by offering price discounts and rebates to their larger and more dependable customers. But Albuquerque Medicare beneficiaries who purchase retail prescription drugs are penalized instead of benefitting from their huge share of the pharmaceutical market. Many seniors and people with disabilities have no or poor prescription

drug coverage because they are low or moderate income, or worked for employers who do not provide retiree coverage. They are victims, not beneficiaries, of price discrimination by the prescription drug makers.

The survey found that the price difference paid by Albuquerque seniors ranged from 216% for the cholesterol drug Zocor to 41% for the ulcer drug Pepcid.

Table 1: Albuquerque-Area Prescription Drug Price Survey Results

Prescription Drug	Use	Median Retail Price For Senior Citizens	Most Favored Customer/ Best Federal Price	Price Differential for Seniors Who Pay Retail
Fosamax	Osteoporosis	$199	$111	179%
Lipitor	Cholesterol	$182	$127	143%
Norvasc	Blood Pressure	$114	$64	178%
Pepcid	Ulcer	$54	$38	141%
Prevacid	Ulcer	$371	$164	226%
Prilosec	Ulcer	$117	$61	192%
Rezulin	Diabetes	$140	$93	151%
Ticlid	Stroke	$70	$37	191%
Zocor	Cholesterol	$215	$68	316%
Zoloft	Depression	$214	$130	165%
Average price (Mean)		$168	$89	190%

(See Appendix: Survey Methodology for sources and notes)

The most favored customer price was determined by the best federal price, which has been found by the U.S. General Accounting Office to be the equivalent of the most favored customer price. (See Appendix: Survey Methodology.) Since the most favored customer and best federal price does not include a pharmacy mark-up, a retail mark-up of $4.00 was added, based on average mark-ups for HMOs, Medicaid, and state pharmacy assistance programs for seniors.

Stories of Albuquerque Seniors Who Can't Afford Prescription Drugs

There are an estimated 20,000 senior citizens in the First Congressional District of New Mexico without any prescription drug coverage.[17] Thousands more are having a hard time trying to pay for their prescription drugs. Here are the stories of five older adults from central New Mexico struggling to get the drugs they need. They would all benefit from legislation that would allow them to purchase drugs at the most favored prices paid by HMOs, large insurers, and federal agencies.

Dorothy Brannon is a 70-year-old widow and long time resident of NE Albuquerque. She has successfully fought cancer twice since 1989. But her chemotherapy resulted in congestive heart failure. She is also a type 2 adult onset diabetic with high blood pressure and lymphocemia who has undergone

cataract surgery. Dorothy is enrolled in the best Medigap insurance supplement plan available. But the drug coverage includes a $200 deductible, a 50% co-pay, and an annual cap of $3,000. Dorothy uses eight prescription drugs a day plus insulin. Despite her insurance plan coverage, Dorothy spends more than $2,500 a year on prescription drugs and aids for her lymphocemia - more than a quarter of her income.

Luegena Brazil is a native New Mexican and a widow in her seventies. She wages a painful battle with Crone's disease, which has destroyed her stomach with ulcers and resulted in 25 operations. Her small intestine is sewn directly to her duodenal. Luegena also suffers from glaucoma, arthritis in her spine, and osteoporosis. She uses nine prescription drugs daily. She relies on Medicare and charity care for her health needs. Social Security is her principal source of income and she lives in subsidized housing. She had to quit her HMO when it refused to pay for her drugs after five months because she exceeded its cap. Her retail prescription drug bill runs more than $2,400 a year but she gets some drugs through charity care. Even with charity, Luegena still spends more than 15% of her income on prescription drugs. Her charity care is up for review in October.

Susan Benhoff is a 66-year-old disabled, retired accountant in LaJoya, New Mexico. She suffers from three chronic lung diseases - asthma, chronic bronchitis, and emphysema. She had a kidney bypass because of blood pressure problems. She is under federal poverty guidelines but does not qualify for Medicaid and cannot afford a health plan. Susan spends hundreds of dollars a year on prescription drugs. This spring she suffered both flu and pneumonia, spending at least $400 on prescription drugs for her condition. Her doctor prescribed two new brand name patent prescription drugs to help Susan breathe. A sample of the new drug Flovent increased her lung capacity by a third, better than it has been in many years. But she can't fill the prescriptions because the two drugs cost over $90 a month. Instead, she is homebound at least one-and-a-half weeks each month and has lost weight, down to 107 pounds. Susan says she hopes Medicare covers drugs soon. She says, "Maybe they hope I'll die and get off the rolls. But I'm not cooperating with that yet."

Frances Royal is a 52-year-old severely diabetic widow who is on Medicare disability. She has had a kidney transplant, is blind in one eye and has glaucoma in the other eye, suffers from high blood pressure and angina, and is losing all sensation in her feet. Several of her toes are broken. Her husband died of cancer last August. After being repeatedly turned down for insurance because of her health problems, she succeeded in obtaining a part-time job with the city, which allowed her to get into an HMO. She uses 17 drugs every day to prevent total blindness, bladder infections, stroke, glaucoma, and kidney rejection. Despite her HMO coverage, Frances still spends over $2,500 a year on prescription drug co-payments. If she should lose her job because of her health, her drug bills will easily exceed $10,000 to $12,000 a year.

Celia Lynd is a 74-year-old low-income resident of HUD housing. She suffers from high blood pressure and osteoporosis, and has broken her arm repeatedly as well as her knee cap. Her total drug bills run well over $1,500 a year. Her HMO has a $500 annual cap with a $7 co-pay. She usually exceeds the annual limit before June. To help her increase bone mass and prevent more broken limbs, her doctor has prescribed one of the drugs in the senior drug pricing study, Fosamax, but Celia is not taking it because she can't afford its $800 annual price. Because she can't afford her blood pressure medicine, Celia is a medical volunteer in an experimental drug study by her current HMO. Additionally, she purchases two hormone replacement drugs. She switched

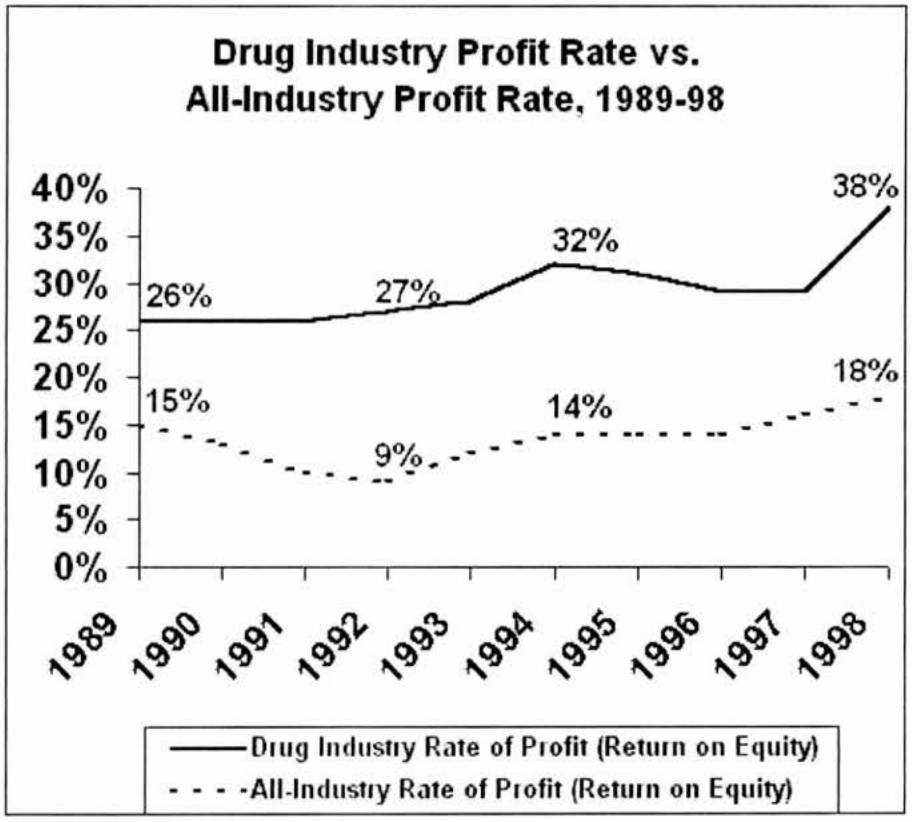
HMOs to get more drug coverage, but can't switch again. Celia doesn't know what she will do when the study is over.

Pharmaceutical Companies Profit Handsomely from Price Discrimination

The Most Profitable Industry in America

Prescription drug company earnings are skyrocketing along with drug prices. Pharmaceutical manufacturers are the most profitable industry in America - and have been for a long time.

- The prescription drug business ranked most profitable among 37 industries in 1998, as measured by rates of return on revenue, equity, and assets, according to Fortune Magazine. The profit rate was an extraordinary 38% for return on equity.[18]
- Pharmaceutical makers rank as the most profitable industry for the past ten years and are consistently among the top two most profitable industries for the past thirty years.[19]
- In the 1990s, the median profit rate for prescription drug makers has been two-and-a-quarter times that of other Fortune 500 corporations.[20]
- CEOs of the top ten prescription drug makers averaged $10 million in salaries last year - and doubled their compensation by receiving nearly $10 million apiece in stock option grants. These ten CEOs now hold more than $920 million in stock options.[21]



Foreign Consumers Pay Less for U.S.-Made Drugs than U.S. Consumers

U.S. pharmaceutical manufacturers charge lower prices overseas for U.S.-made prescription drugs than they charge American consumers. American seniors can cross the border to Canada or Mexico and purchase American-made drugs for 25% to 50% less than at home.[22] The contrast is even greater with other industrial countries: on average, the Swedish pay 69%, the British 64%, the French 57%, and the Italians only 51% of the prices paid by Americans for the same prescription drugs.[23] Because their governments negotiate fair prices with American drug makers, foreign consumers pay far less than American senior citizens and still benefit from our research and development.

Research and Development Myths and Facts

Pharmaceutical manufacturers deny that they practice price discrimination. Instead, they justify high prices as the cost for research and development. Their industry trade association, Pharmaceutical Research and Manufacturers of America or PhRMA, argues research would decrease and production of wonder drugs would decline if consumers paid lower prices. This scare tactic seeks to obscure the fact that R&D is a much lower priority than profits for this industry.

Let's look at the record of the ten largest U.S. prescription drug makers, which account for more than one-third of industry revenues. Their 1998 annual reports were reviewed to examine how their revenues were allocated between profits and research and development.[24] The findings are revealing:

Table 2: Profits Vs. R&D: Top Ten U.S. Pharmaceutical Companies 1998

Company	Net income as a percent of net sales	R&D as a percent of net sales	Ratio of net income to R&D
Bristol-Myers Squibb	**17.2%**	**8.5%**	**2.0**
Abbott	**18.7%**	**9.8%**	**1.9**
Merck	**19.5%**	**10.6%**	**1.8**
Schering-Plough	**21.7%**	**12.5%**	**1.7**
American Home Products	**18.4%**	**12.2%**	**1.5**
Pfizer*	**24.7%**	**16.8%**	**1.5**
Warner-Lambert	**12.3%**	**8.6%**	**1.4**
Johnson & Johnson	**13.0%**	**10.3%**	**1.3**
Eli Lilly	**22.7%**	**18.8%**	**1.2**
Pharmacia & Upjohn	**10.2%**	**17.7%**	**0.6**

*Includes Alliance revenue.
(*Fortune Magazine*'s top ten pharmaceutical companies ranked by sales, in this chart in declining order by ratio of net income to R&D. Company figures from 1998 Annual Reports, Table of Consolidated Statement of Earnings.)

In summary:

- The median profits (net income) exceeded R&D expenditures by 50%.[25]
- Nine of the ten companies had higher profits (net income) than research and development expenditures.

Conclusion: Congress Must End Price Discrimination and Let Seniors Use Their Buying Power to Get Fair Drug Prices

While thousands of Albuquerque-area seniors and millions of older adults across America face price discrimination by prescription drug manufacturers, Congress is now debating bills that would end this practice of discrimination against seniors and add a comprehensive prescription drug benefit to Medicare.

"The Prescription Drug Fairness for Seniors Act" (H.R. 664/S. 731) would end price discrimination and harness the purchasing power of 39 million seniors and people with disabilities on Medicare. The Act requires pharmaceutical manufacturers to give local pharmacies the same "best" price for Medicare beneficiaries as they give their most favored customers.

Pharmacies would then purchase prescription drugs for Medicare beneficiaries from the manufacturer at the same low prices available to the federal government and other large purchasers. Since these prices are nearly half the retail prices paid by Medicare beneficiaries, seniors would be able to benefit from large cost savings after fair pharmacy dispensing fees are included. The Act creates no federal bureaucracy and requires little taxpayer money. "The Prescription Drug Fairness for Seniors Act" has more support than any other prescription drug reform legislation in Congress - 124 House co-sponsors and 12 Senate co-sponsors as of September 14, 1999.

President Clinton and Congress are also debating adding a comprehensive prescription drug benefit to Medicare. To be truly cost-effective for both seniors and taxpayers, a comprehensive outpatient prescription drug benefit must use the bargaining power of the federal government and Medicare beneficiaries to negotiate significantly lower drug prices, similar to the "Prescription Drug Fairness for Seniors Act." Negotiated prices are the first step in constructing an affordable benefit plan - with low premiums, low or no co-payments, and good coverage for those with high as well as low or moderate drug expenditures.

New Mexico seniors want their U.S. Senators and Representatives to oppose price discrimination against Medicare beneficiaries by pharmaceutical manufacturers. Our federal lawmakers should join Senator Jeff Bingaman and Representative Tom Udall in sponsoring the "Prescription Drug Fairness for Seniors Act." The New Mexico congressional delegation should also support a comprehensive Medicare drug benefit, which also uses the bargaining power of the federal government to reduce drug prices for all seniors.

About Public Citizen and the Gray Panthers of Greater

Albuquerque

Public Citizen is a 150,000 member national non-profit, non-partisan public interest group based in Washington, D.C. Public Citizen has nearly 500 members and supporters in New Mexico. Since its founding by Ralph Nader in 1971, Public Citizen has fought for consumer rights, government and corporate accountability, campaign finance reform, a clean environment, and health and safety protection through lobbying, public education, research, and media outreach. Public Citizen has launched the Campaign for Affordable Prescriptions to educate the public and mobilize grassroots support for fair pharmaceutical prices. This report was prepared by Congress Watch, a division of Public Citizen.

The Gray Panthers of Greater Albuquerque is the local grassroots chapter of the national Gray Panthers organization. The Gray Panthers are intergenerational activists committed to social and economic justice issues, with a special focus on concerns of the elderly. Albuquerque is the newest local chapter with over 100 members, joining fifty other community based Gray Panther member networks across the nation. The Albuquerque chapter has been extremely active on Social Security and health care issues, advocating against privatization of Social Security and for a Medicare prescription drug benefit.

For more information about this survey, please contact:

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-or-

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Appendix: Survey Methodology

The survey followed standard social scientific methodological protocols for a cross-sectional study with descriptive and analytic components.

Survey Drug Sample

The ten drugs selected for this survey were the most widely prescribed prescription drugs for senior citizens as drawn from the 1998 list of the Pennsylvania Pharmaceutical Assistance Contract for the Elderly (PACE), as determined by dollar volume of sales. PACE is the largest state pharmaceutical assistance program for older adults and is frequently used as a data base for studies on prescription drug utilization by seniors. The dosages were the most commonly prescribed amounts according to the PACE data base. The top ten drugs did not include any generic drugs.

Most Favored Customer/Best Federal Price

The most favored customer price was determined by the best federal price, usually the federal supply schedule price. Neither the pharmaceutical industry nor the HMOs and large insurers make public drug prices paid by most favored

private sector customers. But the U.S. General Accounting Office has held that "federal supply schedule prices represent the best publicly available information of the prices that pharmaceutical makers charge their most favored customers."[26] The study incorporated the best federal price provided by the Pharmacy Strategic Benefit Management Group of the Department of Veteran Affairs, which oversees the federal supply schedule prices.

Because the most favored customer/best federal price does not include a pharmacy dispensing fee, an average fee was added. Large purchasers like the federal and state governments and HMOs negotiate a fixed dispensing fee per prescription. Here are some sample fixed dispensing fees:

- HMOs: Specific fees are proprietary information, but industry observers indicate the fee is $4.00 or less per prescription paid to participating pharmacies.[27]

- New Mexico: The federal government requires states to establish "a reasonable dispensing fee" for the pharmacies participating in the Medicaid prescription drug program.[28] The New Mexico dispensing fee is $4.00 per prescription.[29]

- Other states: Eleven states (not including New Mexico) have pharmacy assistance programs to help subsidize prescription medicines for senior citizens. These programs pay dispensing fees to participating pharmacies, ranging from $2.50 to $4.75, and average $3.64 per prescription.[30]

  Based upon the best evidence, a $4 dispensing fee was added to the most favored customer/best federal price for each prescription.

Pharmacies

Twenty-four Albuquerque-area retail pharmacies were selected randomly by lot (dice rolls) from the phone book Yellow Pages. The sample is representative of pharmacies in the First Congressional District of New Mexico. The ratio of independent and chain drug stores in the sample was reflective of the overall ratio in the district. Similarly the distribution of urban, suburban, and rural pharmacies among the 24 drugstores was also characteristic of the area as a whole. The sample represented more than one-quarter of the pharmacies in the survey area.

Survey Administration, Quality Control, and Data Management

A draft survey instrument and written instructions to solicit surveys were developed. A pretest was administered to four retail pharmacists. The results were evaluated and the instrument, instructions, and training curriculum were modified to improve the administration of the survey questionnaire.

The final standard survey instrument was designed. Revised instructional materials, including an interviewing script explaining the study, were prepared. Interviewers were recruited and received training on interviewing techniques, the questionnaire, and a script. Interviewers were supervised by staff of survey sponsor organizations. Pharmacists in 24 drug stores in the First Congressional District were interviewed with the survey instrument and script during weekday morning and afternoon hours by the volunteer interviewers. Results were

analyzed by Public Citizen staff. Questionnaires were dated, coded for anonymity, and entered into a standard statistical spreadsheet program.

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26. Correspondence by Williams J. Scanlon, Director, Health Financing and Public Health Section, U.S. General Accounting Office, April 21, 1999.

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Public Citizen Drug Price Studies Back Clinton Attack on Pharmaceutical Industry

For immediate release:
Oct. 25, 1999

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WASHINGTON, D.C. -- Public Citizen welcomed President Clinton's announcement today that the administration will take on the pharmaceutical industry's deceptive $30 million media campaign against legislation requiring Medicare to pay prescription drug costs for seniors.

"The drug industry gouges U.S. consumers, particularly those on Medicare who pay full retail price. Then it puts its enormous profits into a 'Big Lie' media campaign to block a prescription drug benefit by scaring seniors with a grandmother named Flo," said Public Citizen President Joan Claybrook.

Public Citizen has teamed with local seniors' organizations across the country to compare drug prices charged to seniors who pay full retail prices with those paid by drug companies' most favored customers, such as large HMOs and the U.S. Defense and Veterans Affairs departments. The first study released, conducted jointly with the Gray Panthers of Albuquerque, N.M., found that the 10 drugs most commonly prescribed for seniors cost 90 percent, on average, more in local pharmacies than drug companies charge their most favored customers. The differences ranged from 41 percent more for the ulcer drug Pepcid to 216 percent more for the cholesterol drug Zocor. (Click here for the full text of the Albuquerque study.)

"In all industrial countries except the United States, the government negotiates with the pharmaceutical industry to obtain prices that are fair to consumers and taxpayers," said Dr. Sidney M. Wolfe, director of Public Citizen's Health Research Group. "Using the purchasing power of 39 million Medicare beneficiaries to negotiate for fair prescription drug prices is good business."

Without such negotiations, high and rapidly increasing prescription drug expenditures threaten to make any Medicare drug coverage unaffordable. A Public Citizen analysis of the Medicare drug plan proposed by the administration found that by 2008 the benefit will lose almost three-fifths of its value in 1999 dollars if inflation is not restrained. (Click here for a details of Public Citizen's analysis.)

"For too long, the pharmaceutical industry has held American consumers hostage to high prices with its favorite Big Lies -- demonizing government price negotiations to help Medicare beneficiaries as 'a government takeover of the prescription medicine business' and threatening that research and development will cease if its price-gouging is in any way restrained," Wolfe

said. "It's high time these lies are exposed."

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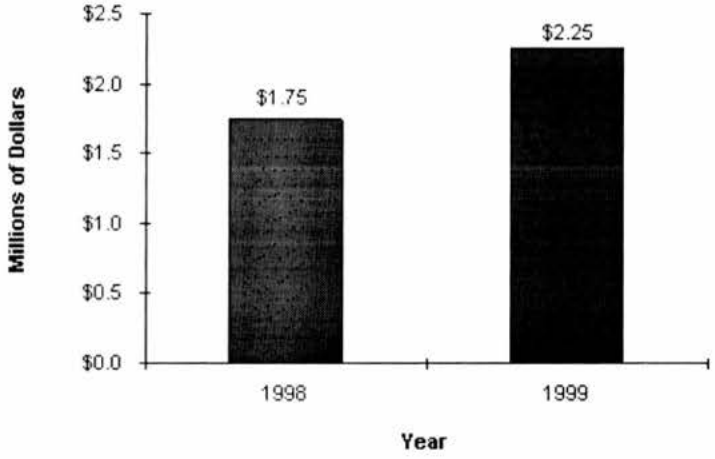
Schering-Plough Plows Ahead with High-Priced Lobbying Campaign for a Claritin Patent Extension

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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Partners In Healthcare...

FACSIMILE TRANSMITTAL

TO: Sarah Branch DATE: 11/5

COMPANY:

FAX NO. 456-5557

PHONE NO.

FROM: Diane Doman

NO. OF PAGES 8

Comments: Background on the legislative Rx Patent ~~extension~~ attempts

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

United States Senate

WASHINGTON, DC 20510

Oct. 9, 1998

Mr. Erskine Bowles
Chief of Staff
The White House
1600 Pennsylvania Ave
Washington, DC 20502

Dear Erskine:

We would like to bring to your attention another attempt by Schering-Plough to obtain a pharmaceutical patent extension and to enlist the Administration's help to make sure that no patent extension provisions are included in the Omnibus Appropriations bill.

This is at least the fourth attempt in the last 16 months to circumvent our legislative process by including patent extension/market exclusivity riders into must-pass legislation. These riders would have a grave economic impact on all consumers and the federal government. They have not been debated and have not been voted on by a subcommittee or committee. This current, anti-competitive amendment is being offered by Schering-Plough to secure passage of a provision that would grant its blockbuster allergy drug, Claritin, yet another patent extension.

It is no secret why Schering-Plough wants a patent extension for Claritin. In 1997, U.S. sales exceeded $907 million, and estimates for 1998 show that sales may reach $1 billion. It is also no secret that this patent extension will cost consumers and the government hundreds of millions of dollars. This proposal is currently being scored by CBO. Allergy sufferers would be deprived access to lower-cost alternatives and would continue to have to pay monopoly prices because competition would be prohibited. The proposal would also give the Patent and Trademark Office new authority to re-review claims for patent extensions based on "regulatory delay" at the Food and Drug Administration.

Schering-Plough circulated this amendment last year, but it was not included in any legislation due to objections about the backdoor method being used to obtain this extension. Claritin has already received two patent extensions — a two-year patent extension under the 1984 Hatch-Waxman Act and another 22-month patent extension under GATT in 1994. Schering-Plough must learn that Congress has a legislative process that should be honored. To pass this amendment that would so clearly disadvantage consumers, that would remove authority from FDA, and that has not been the subject of Senate hearings would be unconscionable.

We hope that we can count on your efforts and others in the Administration to oppose these anti-consumer riders in the Omnibus Appropriations bill.

Sincerely

Richard J. Durbin

Patrick Leahy

Paul D. Wellstone

GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION

1620 I Street, NW Suite 800
Washington, DC 20006
(202) 833-9070
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Pharmaceutical Patent Extensions Threaten Consumers

Introduction and Summary

Last year there were several efforts by brand name pharmaceutical manufacturers to obtain special patent extensions for their drugs. In April 1996, a two-year extension for *Daypro*, a G.D. Searle product, was slipped into a continuing resolution passed to avoid a government shutdown. In early June 1996, the House Appropriations Committee passed a two-year extension for *Lodine*, a Wyeth-Ayerst drug, in the FY 1997 Agriculture/FDA Appropriations Bill. Later that month, a floor amendment to the Senate FY 1997 Defense Authorization Bill also included a *Lodine* patent extension. Both of these provisions were dropped in conference, but not before an effort was made to add a patent extension for *Claritin*, a Schering-Plough drug, in the conference report on the Agriculture Appropriations Bill. During the night of July 31, 1996, Senator Lott added the *Lodine* provision to the conference agreement on the Kassebaum-Kennedy health insurance portability bill, but this language was deleted on a point of order on the Senate floor on August 2, 1996.

Similar efforts are underway in 1997. Two weeks before Hoffman-LaRoche's patent for *Toradol* was due to expire, Senator Hollings attached an amendment on April 30, 1997, to the FY 1997 Emergency Supplemental Appropriations Bill. The Hollings amendment extended the *Toradol* patent for more than one year and granted 17 other drugs patent extensions by overturning a key ruling of the U.S. Court of Appeals for the Federal Circuit in Merck v. Kessler. The Hollings amendment was ultimately removed from the appropriations bill by an amendment introduced by Senator Wellstone on the Senate floor and approved by a voice vote. GPIA anticipates similar attempts to extend other patents during the 105th Congress, including those for Schering-Plough drugs *Eulexin* and *Claritin*, SmithKline Beecham's *Relafen*, and Bristol-Myers Squibb's *Taxol* drug.

In late May 1997, Senator Thompson circulated an amendment, which he intended to propose to S. 507, a bill making sweeping changes to the operation of the U.S. Patent and Trademark Office. The Thompson amendment would have extended the patents of 7 drugs whose 1996 sales exceeded $1.2 billion. Senator Thompson was persuaded not to offer his amendment when the S. 507 passed the Judiciary Committee, but the amendment may be offered to this or other legislation later in this year.

As will be explained below, these *ad hoc* actions circumvent the normal committee process, undermine the intent of the statute that already provides for patent extensions due to regulatory delays and, when successful, cost taxpayers and consumers millions of dollars.

Existing Law Provides for Patent Extensions

The 1984 Waxman-Hatch Drug Price Competition and Patent Term Restoration Act (the Waxman-Hatch Act) already provides a mechanism to grant patent extensions because of excessive regulatory delay. More than 440 such extensions have already been granted, including a two-year extension for *Claritin*. In all, these extensions have provided well over 546 years of additional patent protection. Furthermore, numerous 3 and 5-year market exclusivity grants have also been awarded under the Waxman-Hatch Act. In short, the existing system works well and there is no real need for extra, *ad hoc* extensions.

FDA review time for new drugs has declined dramatically, and is already quite low for breakthrough drugs. The estimated average review time for all new drug approvals in Fiscal Year 1997 is 15.4 months, and drugs for AIDS or other life-threatening illnesses or conditions for which there is no remedy are often approved in a year or less.

Uruguay Round Has Extended Many Patents

In addition to the hundreds of years of patent extensions and market exclusivity grants under the Waxman-Hatch Act, the Uruguay Round Agreements Act (URAA), the implementing legislation for the General Agreement on Tariffs and Trade (GATT), provides for the extension of 100 or more pharmaceutical patents. The URAA changed the term of patents from 17 years from the date of issuance to 20 years from the date of filing. One independent expert has calculated that an average of 136 days is added to the patent life of pharmaceuticals and chemicals under the new 20-years-from-filing system. [See M.A. Lemley, 22 AIPLA Q.J.361,397 (1994)]

Moreover, all patents whose original 17-year term had not expired on June 8, 1995, can enjoy both a Waxman-Hatch and a URAA extension.

Patent Extensions Cost Billions

The URAA patent extensions continue to add several billion dollars in revenue to the large drug companies who already earn a return on equity among the very highest of any sector in the American economy. In the five years between 1989 and 1994, sales of brand name pharmaceuticals in drug stores rose from $28.17 billion to $47.38 billion. Brand name companies enjoyed an average return on equity of 20.9% during this same period, nearly double the all-industry average, and profit margins were double the industry average.

The Congressional Budget Office estimated that a patent extension for *Lodine*, a drug American Home/Wyeth-Ayerst sought an extension for in 1996, would cost the Federal Government $10 million per year. The increased cost to state Medicaid programs, private payers and, especially, consumers would raise this figure to as much as $50 million per year. Similar estimates have not been released for *Claritin*, *Taxol* or *Relafen*. However, based on sales in 1996 of $657 million, $516 million and $389 million respectively, patent extensions for these drugs would cost consumers and taxpayers tens of millions of dollars.

Controlling Patent Extension Legislation

Consequently, a realistic solution to this problem would be to create a formal, legislative process for considering and acting upon patent extension legislation. Under such a process, all patent extension legislation would have to be referred to specific committees, such as the House and Senate Judiciary Committees. Hearings would be required to explore the merits of the extension request and the facts raised by both the proponents and opponents of a specific bill would have to be reviewed by an independent investigatory body, such as the General Accounting Office (GAO), the investigative agency of the Congress. The GAO would also be responsible for determining the economic and health consequences of the proposal and addressing issues such as the cost to the government of granting the patent extension. Each bill would have to be considered on its own, and points of order would automatically lie against any attempts to circumvent this process. In addition, these bills could not be added to appropriations measures.

While such a process would not permanently preclude passage of a patent extension, it would create a level playing field for the generic industry and would ensure that such legislative efforts are exposed to the public and the press. Moreover, the fight over these bills would be confined, and the brand name companies would no longer be able to use their political clout to attach these kinds of bills to every piece of legislation moving through Congress.

There is precedent for this kind of formal legislative process, namely the procedures established for private relief legislation benefiting individuals. Currently, these bills must be referred to either the Committee on Foreign Affairs or the Committee on the Judiciary.[1] Moreover, a point of order can be made to refer a private relief bill to the United States Court of Claims for a report on the validity of the private claim against the government.[2] And these bills cannot be added to appropriations bills.[3]

All of the above rules would be subject to a point of order. Under current rules, when a point of order is made to the procedures relating to private relief legislation, the Chair must make a ruling. The Chair also has the option of submitting the questions to the Senate for a decision.[4]

For additional information, please contact Buddy Menn, Director of Federal Government Affairs for the Generic Pharmaceutical Industry Association (GPIA), at 202/833-9070. GPIA represents the leading manufacturers and distributors of generic medicines, and related companies. Its members account for more than 75 percent of all prescriptions dispensed with generic medicines in the United States. GPIA's mission is to insure that the American public is provided with high-quality, low cost generic drugs.

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[1] "No bill for the payment or adjudication of any *private claim* against the government shall be referred, except by unanimous consent, to any other than the following committees, namely: To the Committee on Foreign Affairs or to the Committee on the Judiciary." (Rules of the House of Representatives, Rule 21, Sec. 845).

[2] "Whenever a private bill, except a bill for a pension, is under consideration, it shall be in order to move the adoption of a resolution to refer the bill to the Chief Commissioner of the Court of Claims for a report in conformity with section 2509 of title 29, United States Code." (Standing Rules of the Senate, Rule 14.9).

[3] "On a point of order made by any Senator, no amendment, the object of which is to provide for a private claim, shall be received to any general appropriation bill, unless it be to carry out the provisions of an existing law or treaty stipulation, which shall be cited n the face of the amendment." (Standing Rules of the Senate, Rule 16.5).

[4] "When a point of order is made, the Chair must rule thereon unless he submits the questions to the Senate for decision; if submitted to the Senate for decision, a motion to table the point of order would be in order. The Chair rules on points of order, not the Parliamentarian; the Parliamentarian merely advises the Chair." (See Jan. 17, 1917, 64-2, *Record*, p.1524: Sept. 29,k 1969,91-1, *Record*, p. 27525).

Secrecy Was Lost. So Was the Favor

THE FINE PRINT

A close look at special legislation.

By JANE FRITSCH

WASHINGTON, Aug. 5 — Last week, Senator Trent Lott of Mississippi, the majority leader, decided to help out his colleagues from Pennsylvania, who had had no luck in pushing for special legislation sought by a drug company that employs hundreds of people around Philadelphia and has given large donations to the Republican Party.

Mr. Lott tried a time-tested maneuver that works best when senators are loaded with work and itching to leave for vacation, as they were last week. He quietly attached the provision for the American Home Products Corporation to a major piece of legislation with wide bipartisan support — in this case, the health insurance bill.

So common are such maneuvers that Mr. Lott's effort is remarkable only because it failed. And it failed because people noticed it, the death knell for special-interest legislation.

In the end, Mr. Lott retreated, saying, "I ain't got no dog in this fight."

But the skirmish demonstrates the ease with which special-interest legislation can often get through Congress as long as it draws little public attention.

At issue was a provision to add two years to the patent for Lodine, an arthritis medication manufactured by Wyeth-Ayerst of St. Davids, Pa., a subsidiary of American Home Products. The patent extension would mean millions of dollars in additional profit for the company, but would keep a cheaper generic form of the drug off the market.

The patent for Lodine is to expire next February, and Wyeth-Ayerst has been pushing for an extension for several years. Last week, Senator Arlen Specter, Republican of Pennsylvania, tried to attach the patent extension to bills in two committees, but was rebuffed both times.

With Congress about to break for summer vacation and time running out, Mr. Specter and Senator Rick Santorum, Republican of Pennsylvania, asked Mr. Lott for help.

At the same time, a House-Senate conference committee was meeting to iron out differences in versions of a health insurance bill that had been passed by both chambers.

Because conference committees meet in secret, Mr. Lott was able to attach the Lodine provisions to the health insurance bill with little notice last Wednesday. He said the company deserved the patent extension because a competitor, the Monsanto Corporation, had received an extension for a similar product, Daypro.

Because time was short, the likelihood was small that major objections would arise. And there was little chance that President Clinton would veto the legislation because of a relatively insignificant provision that would cost the Treasury nothing.

But the strategy only works if no one notices.

Senator Paul Wellstone, for one, did. Mr. Wellstone, a Minnesota Democrat, had been tipped off about the Lodine provision by former Senator Howard Metzenbaum, an Ohio Democrat who had made a practice of watching for such end-of-session maneuvers while he was in the Senate.

"I had no idea this kind of action could be taken really in the dark of night," Mr. Wellstone said on Friday on the floor of the Senate, as he forced a vote on whether the attachment of the Lodine measure had been improper.

And public-interest groups heard about it and put out a press release.

"This is a special-interest goody, a Christmas-tree bauble hung on this must-do legislation," said Joan Claybrook, the president of Public Citizen, a Ralph Nader group.

American Home Products, based in Madison, N.J., has been a heavy contributor to Republican causes. Since 1991, the company has given $50,000 to the the Republican Party, and its political action committee has given $91,500 to Republican candidates, according to Public Citizen. In that time, the Democratic Party has received nothing form the company and Democratic candidates have received $43,900, Public Citizen said.

Paul Hosefros/The New York Times

Senator Trent Lott, the majority leader, helped colleagues from Pennsylvania with special-interest legislation. He worked at his desk with his chief of staff, David Hoppe, seated, and his counsel, Kyle McSlarrow.

For special-interest legislation, publicity is often a death knell.

To make matters worse for the Lodine supporters, Congress Daily, a publication of the National Journal, put out a report on Friday afternoon that Vicki Hart, a Lott aide who had worked on the insurance legislation, was married to Steve Hart, a lobbyist who represented American Home Products. A spokeswoman for Mr. Lott said Mrs. Hart had removed herself from any role on the issue and added that Mr. Hart had never lobbied Mr. Lott. But the damage was done.

The Lodine provision went down in a voice vote.

"No wonder people are cynical and skeptical and angry about the political process," Mr. Wellstone said today. "This is outrageous. It's a ripoff. People were embarrassed, and they should have been."

Asked why he had not objected to the patent extension for Daypro that was approved by Congress earlier this year, Mr. Wellstone said: "Because they snuck it past me. It happens too often."

Company News:
Tuesday through Saturday,

A16 THE WALL STREET JOURNAL FRIDAY, AUGUST 2, 1996

House Approves Health-Insurance Bill As Both Parties Take Credit for Measure

By LAURIE MCGINLEY
Staff Reporter of THE WALL STREET JOURNAL

WASHINGTON—Long-awaited legislation to improve access to health insurance was approved by the House, 421-2, as politicians scrambled to claim credit for the popular election-year measure.

At an afternoon news conference, House Speaker Newt Gingrich (R., Ga.), said the legislation, which will make it easier for workers to keep coverage when they change jobs or get sick, is a "direct descendant" of earlier Republican health proposals.

In contrast to President Clinton's failed bid to "centralize control" in his sweeping proposal, the new legislation represents "the market-oriented free choice of citizens that we think is so important in order to improve and strengthen the health system," Mr. Gingrich said.

Democrats retorted that the bill would have been delayed indefinitely by Republican leaders if President Clinton hadn't pressured Congress to pass the legislation. Now, they said, the Republican-controlled Congress is rushing to improve its record in advance of the elections. "Today, Republicans are tripping over themselves to claim credit for a Democratic health-care bill and a minimum-wage increase, bills that under normal circumstances would be Newt Gingrich's worst nightmare," House Minority Leader Richard Gephardt (D., Mo.) said.

The Senate is expected to vote on the measure today and President Clinton has said that he would sign the bill. The bill contains several provisions designed to end "job lock," a situation that occurs when a worker doesn't change jobs for fear of losing coverage.

It also would guarantee people who leave employer-group plans the right to buy insurance in the individual market. For Republicans, one of the proudest achievements is the establishment of a four-year test project for medical-savings accounts, private accounts that are tax deductible and designed to handle routine medical expenses.

One provision in the bill that was causing a last-minute dustup yesterday was slipped in late Wednesday by Senate Majority Leader Trent Lott (R., Miss.). The provision, which Sen. Lott's spokeswoman said was inserted at the behest of a number of members of Congress, would provide a two-year patent extension for Lodine, an arthritis drug made by Wyeth-Ayerst Laboratories, a division of American Home Products Corp. in Madison, N.J.

Rep. Fortney "Pete" Stark (D., Calif.) complained to the House Rules Committee that the patent extension was sneaked in at the last minute. "Procedurally," he said in an interview, "it's close to obscene." He said it would hurt consumers by protecting the drug from competition from generic manufacturers. Without an extension, Lodine's patent will expire in February, and the company has been trying to add the provision to a number of measures in recent days. Senate Democratic leaders, including Edward Kennedy of Massachusetts and Minority Leader Thomas Daschle of South Dakota, also were upset about the addition of the provision.

Sen. Kennedy said that the patent provision could "run into a lot of flak" on the Senate floor. But the dispute isn't likely to affect the ultimate fate of the bill.

A spokeswoman for Wyeth-Ayerst said that the patent extension was justified because regulatory delays at the FDA in handling marketing applications for non-steroidal anti-inflammatory drugs had reduced Lodine's patent life. Congress earlier this year approved a similar extension for a competing product, called Daypro, which is made by G.D. Searle, a division of Monsanto Co.

The House approved the health bill last night after rejecting a Democratic-led move, 228-198, to send the legislation back for modifications. The Democrats wanted to change the bill to require improved mental-health coverage and to delete the Lodine provision.

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-

News
COMMON CAUSE

TAKE ACTION

Pocketbook Politics:

How Special-Interest Money Hurts the American Consumer

Bad Medicine

The makers of brand-name pharmaceuticals have long relied on the same prescription to protect the profits of their $90-billion drug industry - large doses of political contributions. Since 1991, the companies that belong to the Pharmaceutical Research and Manufacturers of America (PhRMA), the trade group for brand-name drugmakers, have given $18.6 million in political contributions, including $8.4 million in soft money donations to the political parties.

With the help of that influence, brand-name drug companies have kept their bottom lines healthy by successfully convincing Congress to let them hold on to their drug patents longer. Brand-name drug companies lose profits when the patents on their most popular drugs expire, permitting generic drug companies to manufacture much cheaper versions of the same medicines, without having to repeat the clinical studies used to develop the brand-name drugs. The loss of patents can mean billions of dollars to the major drug companies, leading them to fight fiercely to hold on to those patents for as long as possible.

"There should be no mistake that the whole thing is about cash," Princeton University Healthcare Economist Uwe Reinhardt told Newhouse News Service. "If I worked for one of these [brand-name] companies, I'd do whatever I could to block a product that took cash away from me. That's the name of the game."

Restricting access to generic drugs has cost consumers as much as $550 million a year. Much of these costs have been borne by senior citizens. People over age 65 accounted for more than one-third of all the spending on drugs in 1991, and older Americans were much less likely to have insurance coverage for medication, according to the health care advocacy group Families USA. Being denied access to a generic version of just one brand-name drug, the ulcer medication Zantac, could ultimately cost a senior consumer more than $850.

That cost can be traced to a loophole that benefits brand-name drug companies that was unintentionally created in 1994 when Congress passed legislation implementing the latest round of the General Agreement on Tariffs and Trade (GATT).

The GATT changed the rules on patents, and as a result, many companies were permitted to keep their patents for an extra year or two. This change hurt competitors preparing to market generic versions of these patented products. Therefore Congress included a provision in the trade agreement that said that competitors that had made substantial investments in bringing generic versions of brand-name drugs to market could move forward with their plans, provided they gave adequate compensation to the patent holder. This GATT

provision, however, was in direct conflict with the 1984 Hatch-Waxman Act, which forbids the Food and Drug Administration (FDA) from approving generic versions of any brand-name drug before its patent expires.

As a result of these conflicting provisions, brand-name drug companies were insulated from competition from generics for an additional period of up to two years.

Pharmaceutical Research & Manufacturers of America PAC & Soft Money Contributions 1/1/91- 6/30/97	
PAC Money to Candidates	$10,178,913
Soft Money to National Parties	$8,384,921
Total PAC & Soft Money	$18,563,834

In the 104th Congress, consumer groups and the generic drug industry asked Congress to eliminate this windfall created in the aftermath of the GATT, but they were unsuccessful. This victory for brand-name drug companies and their trade group, PhRMA, delayed the introduction of generic versions of more than 100 prescription drugs, including Glaxo Wellcome's Zantac (ulcer), Merck's Mevacor (cholesterol), and Bristol-Meyer Squibb's Capoten (heart).

Over the next 17 years, as the GATT patent extension plays out, the consumer may ultimately pay an estimated $6.2 billion in higher drug prices, according to a study on GATT's impact by the Prime Institute at the University of Minnesota. This study was funded by a grant from the generic drug industry. Prime director Stephen Schondelmeyer put GATT's 1997 cost to consumers at about $550 million.

Consumer wallets were getting thinner as brand-name company bottom lines were getting fatter. For example, Glaxo Wellcome was able to hold on to the patent for Zantac, which was originally slated to expire in the beginning of December 1995, for an additional 19 months. That extension gave the company a $1-billion windfall, Schondelmeyer estimated.

But Glaxo's victory cost the consumer dearly.

In 1996, for example, a two-month supply of Zantac cost about $180. A generic version would have cost about half that price, or $90, according to Schondelmeyer. The 19-month extension Glaxo received for Zantac could have cost a consumer who pays for prescription drugs about $855.

Glaxo has given more than $2 million in political contributions since 1991, including more than $876,000 in soft money donations to both major political parties.

At the time that Glaxo was lobbying hard on GATT, it was increasing its political giving. The company gave its first $100,000 soft money contribution to the Republican party on June 28, 1996, the day after it won a key Senate vote.

Congress' failure to eliminate the unintended windfall created by the GATT "proves that a majority of Senators choose to side with major campaign contributors such as the giant pharmaceutical companies, and not consumers,

taxpayers and senior citizens," said James P. Firman, president of the National Council on the Aging and chairman of the Generic Drug Industry Coalition.

Senior citizens, who are major users of prescription drugs, were so riled by Glaxo's lobbying campaign that the Grey Panthers awarded Glaxo its first annual "Green and Greedy" or GAG award.

There have been other attempts by drug companies to extend the life of their patents. In 1996, for example, G.D. Searle & Co., who with its parent company, Monsanto, has given more than $618,000 in political contributions since 1991, convinced Congress to extend the patent on its arthritis drug, Daypro. This drug is one of the company's most popular products and brought in more than $280 million in sales in 1996. Searle argued that it was entitled to the extra time because of FDA delays in approving the drug. The extension, which is worth millions of dollars to Searle, was quietly dropped into the 1996 omnibus budget bill, with the help of Representative John Porter (R-IL), who represents many Searle employees.

Pharmaceutical Research & Manufacturers of America
Top PAC & Soft Money Donors
1/1/91- 6/30/97

Donor	Democrats	Republicans	Total
Glaxo Wellcome Inc	$553,403	$1,519,992	$2,073,395
Pfizer Inc	486,580	1,322,599	1,809,179
Eli Lilly & Co	394,300	1,027,061	1,421,361
Novartis Pharmaceuticals Corp	346,200	1,013,513	1,359,713
Bristol-Myers Squibb Co	313,425	846,235	1,159,660
Schering-Plough Corp	210,650	864,335	1,074,985
Hoffman-La Roche Inc	446,980	537,702	984,682
Hoechst Marion Roussel AG	340,100	570,998	911,098
Zeneca Pharmaceuticals Group	351,632	540,783	892,415
Merck & Co	258,686	451,026	709,712
Rhone-Poulenc	213,650	487,225	700,875

Note: Totals may include donations from executives and/or subsidiaries.

Next: Car Fare

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Washington, DC 20006
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e-mail: info@gpia.org
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Partners In Healthcare...

FACSIMILE TRANSMITTAL

TO: Sarah Branch DATE: 11/5

COMPANY:

FAX NO. 456-5557

PHONE NO.

FROM: Diane Dornan

NO. OF PAGES 10

Comments: See pgs 4+5 of Cong. Brown [D-OH] remarks on citizen petitions

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

GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION

1620 I Street, NW Suite 800
Washington, DC 20006
(202) 833-9070
FAX (202) 833-9612

CITIZEN PETITIONS

Citizen petitions are being filed with FDA by brand pharmaceutical firms to delay or foreclose the approval and dispensing of generic drugs. Because the agency must consider, by law, the merits of each citizen petition, these administrative challenges almost always result in regulatory delay – providing brand firms with months or even years of additional market dominance. The success of these challenges is not defined by whether the requested action is ultimately granted or denied, but rather, by the amount of time the generic drug application is delayed while agency officials review the citizen petition.

In addition to placing an unjust burden on consumers who would benefit from the availability of lower cost, equivalent therapies, the misuse of the citizen petition process burdens the already constrained resources of the FDA's Office of Generic Drugs (OGD). According to OGD, a substantial percentage of senior staff time is diverted to reviewing the 40 citizen petitions that have been filed since 1990 to delay generic drug approvals.

Solution

Statutory changes are necessary to discourage brand firms from using the citizen petition process as a tactic to preserve their competitive advantage. A way to reform the process would be to amend the Food, Drug, and Cosmetic Act to provide that a citizen petition should not delay the approval of a generic application unless the petitioner can establish by clear and convincing scientific evidence that its proposed changes are necessary to ensure patient safety.

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF THE FOOD AND DRUG ADMINISTRATION'S CITIZEN PETITION PROCESS

JUNE GIBBS BROWN
Inspector General

JULY 1998
A-15-97-50002

EXECUTIVE SUMMARY

BACKGROUND

This final report provides the results of our review of the Food and Drug Administration's (FDA) effectiveness in handling citizen petitions. The FDA regulations[1] permit any person to submit a citizen petition to FDA requesting the Commissioner of Food and Drugs to: (1) issue, amend, or revoke a regulation or order; or (2) take or refrain from taking any other form of administrative action.

OBJECTIVE

The objective of this review was to assess FDA's effectiveness in handling citizen petitions and identify ways that the process can be improved.

SUMMARY OF FINDINGS

The FDA does not have an effective process for handling citizen petitions in a timely manner, as evidenced by a backlog of approximately 250 petitions that have not been fully answered, some dating to the 1970's and early 1980's. The FDA regulations require tentative or final responses to citizen petitions within 180 days. The backlog of pending petitions includes issues that the petitioners believe are matters of public safety, and some have requested FDA to ban or withdraw approval of certain products. When FDA does not answer petitions in a timely manner, the public may lose confidence in the regulatory process. Because the citizen petition process is not a high priority among FDA's various responsibilities, the agency has provided limited resources to the process, and there is little central oversight of the process across FDA program areas. Recognizing its problems with the petition process, FDA developed options during the early 1990's to improve the process; and since the start of our review, closed out slightly more petitions than it has received. We believe, however, that more can be done to reduce the backlog.

RECOMMENDATIONS

We recommend that the Commissioner of Food and Drugs:

1. Correspond with petitioners whose requests are of long standing to determine if they still want FDA to take action on their petitions;

[1] Code of Federal Regulations (C.F.R.) Title 21, Part 10, Subpart B, Section 10.30.

STATEMENT OF THE HONORABLE SHERROD BROWN

RANKING MEMBER, HOUSE SUBCOMMITTEE ON HEALTH

AND THE ENVIRONMENT

FLOOR STATEMENT ON LEGISLATION REFORMING FDA

OCTOBER 7, 1997

Mr. Speaker, today the House considers a major piece of legislation, about which we have heard considerable discussion over the last 2 years. The FDA reform debate has progressed from irrational and unfounded accusations about FDA's regulation of medical products to much more sensible discussions about how to modernize this important agency's regulatory policies and procedures in a way that will reduce unnecessary regulation without reducing public health essential protections.

As I have stated since the beginning of this process our first goal must be to ensure that patients have access to safe and effective new products as quickly as humanly and scientifically possible.

While I am not completely convinced this legislation has fully achieved those difficult balances, it is a vast improvement over legislation introduced in the last Congress.

Of course, since compromise is necessary in Bipartisan legislation rarely includes everything everyone wants, since compromise is always necessary.

This bill is no exception.

However, I would like to thank Chairman Bliley and Bilirakis for their efforts to open up the discussions that led to this bill. I genuinely appreciate attempts to listen to everyone, and try to take account of a variety of perspectives.

Again, while this bill continues to include some provisions that give me pause, I also believe it includes provisions that are workable, positive, and contribute to the goal of ensuring an FDA operation that works in the best interests of its most important customers -- patients.

Nevertheless, as we proceed with this discussion, I think it is important to put a few facts in perspective.

Many have argued that FDA reform is essential because new and improved drugs and medical devices are not reaching American patients quickly enough.

The facts simply do not bear this out.

For example, through FDA's own management initiatives, and without any change in legislation, FDA's Center for Devices has overhauled its operations and dramatically improved its review times for new products.

Further, I think a majority of medical device manufacturers will agree that the center is more user-friendly, and more efficient, than ever before. Thus, I hope as we proceed to conference with this legislation, we look carefully at the provisions of the bill relating to medical devices, to ensure that we are not increasing requirements for FDA in a way that will set back the progress that has been made.

One of the most important provisions included in this legislation is the reauthorization of the Prescription Drug User Fee program. PDUFA has provided the agency with the resources it clearly needed to allow it to continue to be the world leader in the review and approval of new drugs.

]

If there were one single reason for the House to pass this bill today, drug user fees is that reason.

I am also pleased that the legislation includes some process improvements related to FDA's regulation of generic drugs. While these products are not the breakthrough "miracle drugs" we read about in headlines, generic drugs are no small miracle to millions of elderly patients – especially those living on fixed incomes who depend on these alternatives which many times are vastly less expensive than name-brand products.

Generic drugs literally save billions of dollars in health care costs.

Much of that savings accrues to the federal government, which pays for prescription drugs under the Medicaid program, for Veterans, and in Department of Defense facilities.

I was disappointed that the bill did not go further in addressing what I believe are several difficult problems related to the review of generic drugs -- frivolous citizens petitions filed by lawyers representing brand name companies to divert resources and slow the approval of generic alternatives.

These petitions and lawsuits frequently are simply ploys to delay the marketing of safe and effective generic drugs, that can save our citizens substantial money in health care costs. I hope that we can continue to work on these matters, perhaps in the context of future legislation.

I remain concerned about provisions of the bill that allow manufacturers to distribute information about off-label uses of their products. I am not convinced by the arguments that this kind of system is necessary for physicians to have the information they need to treat patients -- especially given the companies financial interest in promoting their products.

Fortunately, this provision sunsets after seven years, requires FDA approval of materials to be disseminated, and also requires that manufacturers submit applications for approval of these off-label uses. If that part of the program works, it will be good for patients. I am skeptical, however, and will closely monitor whether this program is in the best interests of patients or simply serves to enrich drug and device companies.

Mr. Speaker, I was especially pleased that a number of issues raised by Democratic Members of the Health and Environment Subcommittee were addressed in this legislation. Several particularly important matters relating to medical devices were worked out with our Members, and the FDA, after the bill was reported by the Committee, and I appreciate the willingness of the bills' sponsors and the Chairman to engage in these negotiations. I hope as we proceed to conference with the Senate, the kind of bipartisan cooperation that led to many of this bill's compromise provisions will continue.

Mr. Speaker, FDA is a remarkably effective agency. I have never been persuaded, throughout this long debate, that massive changes in law are needed to correct some dreadful problem lurking under the surface. Thus, I am pleased that this legislation focuses more on modernizing this premier public health agency than completely overhauling it. I believe this is, on the whole, a reasonable compromise that I will support.

treat an illness. The first drug using the new mechanism to treat that illness--the breakthrough drug--usually has between one and six years on the market before a therapeutically similar patented drug (sometimes called a "me-too" drug) is introduced. Economic theory and various studies suggest that the presence of several therapeutically similar drugs limits manufacturers' ability to raise prices as much as would otherwise be the case. In addition, brand-name manufacturers are more likely to agree to give purchasers a discount if those purchasers have the option of switching to a generic or me-too competitor.

The factors that limit the number of similar but slightly differentiated brand-name drugs on the market are unclear. In some cases, perhaps, only a limited number of slightly different chemicals that target a given enzyme can be developed into drugs. Or, as one economist has suggested, the high cost of developing a drug may limit the number of similar brand-name drugs that are eventually brought to market. Companies will undertake such investment only if they believe the market is not already saturated or their drug has some quality advantage that could enable it to compete effectively and earn an adequate return. For that reason, competition among patented brand-name drugs probably results in companies' earning roughly a normal rate of return on their investment in research and development (R&D), on average.

Overall, the pharmaceutical market is not highly concentrated, but when that market is divided into narrowly defined therapeutic classes, it becomes quite concentrated. The top manufacturers of brand-name drugs, ranked by pharmaceutical sales, each account for no more than 7 percent of the entire market for prescription drugs (which totaled $60.7 billion in 1995 at manufacturer prices). Within each therapeutic class, however, higher levels of concentration appear. In 35 of the 66 therapeutic classes that CBO examined in this study, the top three innovator drugs together constituted at least 80 percent of retail pharmacy sales in their class.

Studies of the average prices paid by pharmacies and hospitals have shown that manufacturers of brand-name drugs do compete with each other through pricing. The markups they charge over the marginal cost of producing a drug are consistent with economic models of price competition in which entry by manufacturers is limited (such as by patents). Offering discounts to some buyers may also be an important dimension of price competition for brand-name drugs. But its extent is difficult to measure because of lack of data.

Discounts on Brand-Name Drugs

Different buyers pay different prices for brand-name prescription drugs. In theory, when companies are permitted to charge different types of purchasers different prices, those purchasers least sensitive to price will pay the most. In today's market for outpatient drugs, purchasers that have no insurance coverage for drugs, or third-party payers that do not use a formulary to manage their outpatient drug benefits, pay the highest prices for brand-name drugs.

Manufacturers offer discounts on brand-name drugs based not only on the volume purchased but also on the buyer's ability to affect the drug's market share by using a formulary to systematically favor one brand-name drug over another for a large number of patients. Pharmacies themselves do not generally promote substitution between brand-name drugs, so they do not generally receive large discounts or rebates from manufacturers. Rather, it is the PBMs and insurers who manage benefits for drugs sold through pharmacies that promote brand-name substitution and receive discounts.

Such price discrimination, or discounting, may be an important mechanism for facilitating price competition in the pharmaceutical market. It rewards institutional purchasers that organize their patient base through formularies so as to encourage the use of less costly drugs. Prohibiting discounts, as some policymakers have called for, could decrease price competition.

Drug companies usually do not make their discounts public, but CBO was able to obtain limited information on the prices paid by different types of purchasers for prescription drugs. The prices that pharmacies pay can be seen as a proxy for the final price paid by customers who do not have a managed drug benefit or PBM to negotiate rebates from manufacturers. Based on the average invoice prices for top-selling drugs sold primarily to retail pharmacies, hospitals and clinics pay 9 percent less than retail pharmacies, on average, and HMOs pay 18 percent less. Federal facilities, such as veterans' hospitals, get an even more substantial discount--over 40 percent, on average, compared with the price paid by retail

Public Citizen

It's no secret....

Why Medicare Doesn't Cover Prescription Drugs

...it's a scandal!

It's a national scandal that Medicare doesn't cover prescription drugs as a benefit, except when you're in the hospital. But it's no secret why not: big drug companies want to protect the multi-billion dollar profits they earn from price-gouging Medicare beneficiaries!

Medicare beneficiaries who must buy their own outpatient drugs are charged 'full sticker price' -- twice as much on average -- as the drug companies charge their most favored customers like large HMOs, and the Departments of Veterans Affairs and Defense. Price gouging seniors translates directly into mega-profits for drug companies!

Drug Companies Earn Billions in Excess Profits by Price Gouging Consumers

Company	Drug	**Price Mark-up for Consumers***	**Company Profits****
Merck	Zocor [high cholesterol]	+144%	$5.2 billion
Astra/Merck	Prilosec [ulcers]	+99%	$6.5 billion
Pfizer	Norvasc [high blood pressure]	+93%	$3.4 billion
Knoll	Synthroid [hormone treatment]	+1446%	$1.8 billion
Pharmacia/ Upjohn	Micronase [diabetes]	+363%	$691 million

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

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]

  - **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]

  - **Bradley Said 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 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]

  - **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]

- **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]

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]

BRADLEY TAKES PHARMACEUTICAL MONEY

1999: BRADLEY HAS RAISED $42,500 FROM PHARMACEUTICALS FOR HIS PRESIDENTIAL RACE

- According to the Center for Responsive Politics and Bradley's FEC reports, Bradley has raised $42,500 from the pharmaceutical/health products industry up through the second quarter of 1999. Bradley has also raised $302,078 from health professionals. [CRP webpage, www.opensecrets.org, Bradley's FEC reports]

  - **Bradley Spoke to Rhone Poulenc on his Lecture Circuit.** Bradley spoke to Rhone Poulenc, a pharmaceutical manufacturer, on his lecture circuit. Although the exact amount is not known for what Bradley made speaking to Rhone Poulenc, from 1998 to mid-1999, he pocketed $1,638,500 from 62 speeches to special interest groups, or an average of more than $26,000 per speech. [Bradley PFD, 1999]

  - **Bradley Received $59,000 from Pharmaceuticals for 1990 Senate Race.** According to the Center for Responsive Politics, Bradley received almost $59,000 from the prescription drug industry during his 1990 Senate campaign. [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]

BRADLEY HAS A HISTORY OF PROTECTING PHARMACEUTICALS

BRADLEY FOUGHT TO PROTECT PHARMACEUTICAL LOOPHOLE--COMPANIES SAVED MILLIONS

- Bradley fought to preserve a tax loophole that gives pharmaceutical companies huge tax breaks for each worker they employ in Puerto Rico. For many companies, this loophole eliminates their federal income tax owed on profits in Puerto Rico. Entitled "section 936," Clinton tried to eliminate the loophole in 1993, saving the Treasury $7.3 billion over five years. Bradley fought the rollback and negotiated a compromise that cut the proposed cuts in half. [Washington Post, 9/16/95; The Record, 11/8/93; Inter Press Service, 8/12/93; FEC Reports (FECInfo, www.tray.com/fecinfo), Philadelphia Inquirer, 12/14/92]

  - **New Jersey Pharmaceuticals Win Big:** According to the General Accounting Office, the Section 936 loophole provides more than $71,000 in tax benefits for every worker in Puerto Rico, while the companies pay those workers an average of $33,757. Most of the big winners of the loophole are pharmaceuticals located in New Jersey – and they donate to Bradley:

NEW JERSEY DRUG COMPANIES WHO CONTRIBUTED TO BRADLEY	Tax Savings In Millions, 1980-90	2000* DONATIONS	CAREER* # DONATIONS
Johnson & Johnson	$ 1,117	$1,000	$18,350
SmithKline Beecham	987	0	$4,200
Merck & Co.	749	$7,750	$24,500
Schering-Plough	655	$2,000	$14,000
Bristol-Myers Squibb	627	$1,000	$7,960

Warner-Lambert	337	$1,000	$24,950
American Cyanamid	225	0	$1,500
Becton, Dickinson	111		

[Christian Science Monitor, 8/12/93; The Record, 11/8/93]

*Estimates from FECInfo online through 3/31/99 and Center for Responsive Politics online
#Includes individuals and PACs

- **Bradley Said He Got Involved to Help Puerto Rico**: In 1993, Bradley said he got involved because he felt Clinton's cuts to the program would throw Puerto Rico's economy in "chaos." His spokesman, however, admitted that the state's pharmaceutical industry was also a factor. [The Record, 11/8/93]

- **Sam Donaldson Criticized Deal:** Sam Donaldson, during "This Week with David Brinkley," on Bradley's actions: "But at the final hour, Bill Bradley from New Jersey, who is known as 'Mr. Cut the Tax Loopholes,' got his Puerto Rican 936, 'Let's give all of the pharmaceuticals based in my state a continued exemption of 100 percent.'" [ABC, "This Week with David Brinkley," 6/27/93]

IN 1993, BRADLEY PROTECTED PHARMACEUTICAL LOOPHOLE OVER MEDICARE

- Just days before passing on a chance to close a loophole that benefits pharmaceutical companies, Bradley had promised to cut loopholes if it would reduce Medicare cuts.

  - **FLIP: Bradley Voted to Protect Pharmaceutical Loophole Over Medicare.** Bradley voted against an amendment to eliminate the Section 936 corporate tax break, which benefits many pharmaceutical companies in New Jersey, and recommend that the resulting revenue be spent on Medicare. [CQ Almanac, Vote #180, 6/24/93, motion to waive the budget act failed 20-78 (D 14-41; R 6-37)]

  - **FLOP: Days Before, Bradley Had Promised He Would Cut Loopholes Before Cutting Medicare.** Talking about modifying the Clinton budget plan to make sure Medicare does not suffer large cuts, Bradley said, "If I had to choose between the tax loopholes and cutting Medicare, I'd cut the loopholes." [The Bond Buyer, 6/11/93]

IN 1993, BRADLEY SIDED WITH THE PHARMACEUTICALS AGAINST CLINTON'S EFFORTS TO PROVIDE VACCINES FOR ALL CHILDREN

- In 1993, citing that the cost of immunizing a child had risen from $23 to $200 in ten years, President Clinton announced a solution to the rising cost of vaccines. President Clinton proposed that the federal government buy and distribute vaccines to all children at no cost. The program would cost $1.1 billion a year and would help the United States guarantee that all children are properly immunized. [Washington Post, 2/13/93]

  - **Drug Companies Respond with Meetings with "Friendly" Lawmakers.** As the president was criticizing the pharmaceutical companies because of the rising cost of vaccines, pharmaceutical lobbyists were meeting "Senator Bill Bradley and other lawmakers drug companies consider their better friends in Congress." Bradley met with Gerald Mossinghoff, chief lobbyist for the Pharmaceutical industry, and executives from Hofman-La Roche, American Home Products Corp. and Pfizer, Inc. [The Record, 2/20/93, Washington Post, 2/20/93]

  - **Drug Companies Respond with Ads.** In response to President Clinton's criticism of high vaccine costs, Merck & Co. Inc., responded with advertisements in major newspapers defending the

industry's pricing policies. The ads said that the health care crisis in the United States requires a "search for the truth, not scapegoats." [The Record, 2/20/93]

- **President Clinton Changed Plan to Only Cover Medicaid Patients and Those with No Insurance.** Backing away from his plan to provide vaccines for all children, President Clinton changed his plan to provide vaccines for children on Medicaid and for those children whose vaccinations are not paid for by insurance. Funding for the revised plan totaled $500 million and was included in the President's 1993 Budget Plan. [The Record, 5/26/93, AP, 8/3/93, 1993 CQ Almanac, 136]

- **Bradley Joined the Pharmaceutical Companies against the President's Effort to Expand Child Vaccines.** After Clinton announced changes to his vaccine plan, The Record reported that some lawmakers sided with the pharmaceutical industry in the fight against President Clinton's plan to provide vaccines to all children. The Record said, "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]

IN 1992, BRADLEY VOTED AGAINST CONTROLLING DRUG PRICES TO PROTECT PHARMACEUTICAL COMPANIES TAX BREAKS

- Bradley voted to kill an amendment that would contain the cost of prescription drugs by denying Section 936 tax breaks to drug companies that raise prices above the rate of inflation as reflected in the CPI. (Gore voted against Bradley.) [CQ Almanac, Vote #38, 3/11/92, motion to table passed 61-36 (D 20-34; R 41-2)]

- **Bradley Said it was Not Fair to Single Out Drug Industry.** In defending his vote, Bradley said that prescription drugs account for only 7 percent of health costs. Bradley said the proposal would "hurt one segment of the health-care industry and do nothing about the overhaul cost of health care. . . . But we have to recognize that piecemeal efforts to control costs for health care, such as singling out prescription drugs, simply hasn't worked." [Bergen Record, 3/12/92]

- **In 1992, Prescription Drug Prices Up 146 Percent Over 10 Years.** The Bergen Record reported the senate's failure to control drug prices and noted that the price of prescription drugs is up 146 percent over 10 years, or three times the rate of inflation. [Bergen Record, 3/16/92]

- **Price Controls May Not Be Pro-Consumer.** Bradley spoke about the issue during his floor debate. "Certainly lower prices will help consumers to be able to afford prescription drugs," Bradley said. "But the question is, what are they going to be able to buy? If you asked those whose lives have been saved due to innovations in the pharmaceutical industry, price controls may not be pro-consumer." [Philadelphia Inquirer, 12/14/92]

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. [New York Times, 8/15/82; S.255, 1/27/81]

- **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]

- **Bradley Says Contributions Did Not Affect his Support of the Patent Extension.** "I don't think the contributions 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]

- **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]

STATEMENT OF

PETER BARTON HUTT

BEFORE THE

SUBCOMMITTEE ON COURTS AND INTELLECTUAL PROPERTY

OF THE

COMMITTEE ON THE JUDICIARY

UNITED STATES HOUSE OF REPRESENTATIVES

ON

THE IMPACT OF REGULATORY DELAY ON PATENTS

MAY 21, 1998

Mr. Chairman and Members of the Subcommittee, I am Peter Barton Hutt. I am a partner in the Washington, D.C. law firm of Covington & Burling.

I have been asked to present testimony on patent term restoration. For almost forty years, I have been engaged in the practice of food and drug law. During 1971-1975, I served as Chief Counsel for the Food and Drug Administration (FDA). I am the co-author of the casebook used to teach food and drug law in law schools throughout the country.(1) I teach a full course on food and drug law during Winter Term at Harvard Law School and during Spring Term at Stanford Law School. When the Drug Price Competition and Patent Term Restoration Act of 1984 was being considered during 1983-1984, I served as counsel to the Pharmaceutical Manufacturers Association (now the Pharmaceutical Research and Manufacturers of America) and was deeply involved in the development, negotiation, and drafting of the provisions in that statute.(2) I have published articles on the subject of

patent term restoration both before(3) and after(4) enactment of the 1984 Act. Finally, I have twice before testified on legislation intended, and ultimately enacted, to provide patent term restoration for specific products as a matter of fairness and equity.(5)

THE ORIGIN AND PURPOSE OF THE

DRUG PRICE COMPETITION AND

PATENT TERM RESTORATION ACT OF 1984

In 1962, Congress enacted new legislation to increase the regulatory requirements for new drugs. The

Drug Amendments of 1962(6) replaced the 1938 requirement of premarket notification with a more stringent requirement of premarket approval, and added a requirement of proof of effectiveness to the 1938 requirement of proof of safety. In the years that followed, the time required to obtain the necessary evidence of safety and effectiveness increased, and the time required for FDA review and approval of a new drug application (NDA) also increased. As a result, instead of receiving the full statutory patent term of seventeen years, the effective patent life for a new drug gradually was reduced to less than ten years and at times to zero. The longer it took a company to prove safety and effectiveness and the longer it took FDA to review and approve the NDA, the shorter the effective patent life became.

By 1980, the average effective patent life of new drugs had deteriorated to such an extent that many concluded it required remedial legislation. During 1981 and 1982, Congress considered legislation relating solely to patent term restoration. This legislation narrowly missed enactment in September 1982.

Following enactment of the Drug Amendments of 1962, FDA approved the marketing of generic versions of pioneer drugs under abbreviated NDAs for those pioneer new drugs first marketed before the 1962 Amendments, but not for new drugs with NDAs approved after the 1962 Amendments. For two decades, generic versions of post-1962 new drugs were virtually precluded from the market. Both administrative and legislative approaches were considered during this time to permit FDA approval of generic drugs, but none was successful.

In 1983 and 1984, the pending patent term restoration legislation was combined with legislation authorizing FDA approval of generic versions of post-1962 new drugs through an abbreviated NDA. That legislation was ultimately enacted in September 1984 as the Drug Price Competition and Patent Term Restoration Act of 1984 (which is shortened in this testimony to the "Patent Term Restoration Act" or the "1984 Act").(7)

The 1984 Act was an attempt to balance two competing interests. The research-based drug industry obtained up to five years of patent term restoration for pioneer new drugs, to compensate for part of the diminished effective patent life resulting from the FDA requirements for the investigation and approval of a new drug. The generic drug industry received the assurance that generic versions of a pioneer drug would be approved by FDA following expiration of applicable patents and market exclusivity through an abbreviated NDA that did not require duplicative testing for safety and effectiveness.

THE PIPELINE DRUG EXCEPTION

As noted above, the general rule under the Patent Term Restoration Act of 1984 was that the pioneer drug received up to five years of patent term restoration. There was, however, one important exception to this general rule. A pipeline drug was limited to two years of patent term restoration. Pipeline drugs are defined in what is now 35 U.S.C. 156(g)(6)(C) as any drug for which a patent had been issued and an investigational new drug (IND) application had been submitted to FDA prior to the date of enactment of the 1984 Act, which was September 24, 1984. Accordingly, there was a full three years difference in patent term restoration between two new drugs that were being developed at the same time, simply by reason of the fact that the IND for one was submitted shortly before the enactment date and the other was submitted shortly after the enactment date.

THE CONGRESSIONAL RATIONALE FOR THE REDUCED

PATENT TERM RESTORATION FOR PIPELINE DRUGS

The three-year disparity between the two years of patent term restoration provided where an IND had been submitted before the date of enactment and the five years provided for all other new drugs has provoked substantial interest and concern. A year ago, the Chief Counsel for the Senate Committee on Government Affairs asked about the origin of this disparity. I provided a letter in May 1997 describing the two reasons for the two-year limitation on pipeline drugs. A copy of that letter is attached to this testimony.

As already noted, I participated in the development, negotiation, and drafting of the 1984 Act on behalf of the industry trade association. My clear recollection of the reasons for the two-year limitation for pipeline drugs, as set forth in that May 1997 letter, are as follows:

There were two fundamental reasons why the two-year limitation was included for pipeline drugs in what is now 35 U.S.C. 156(g)(6)(C). These reasons were frequently discussed among those of us who were involved in the daily negotiations.

First, it was felt that the pipeline drugs would be approved by FDA shortly after enactment of the 1984 legislation. Accordingly, it was thought that the five year period of patent term restoration granted to all post-enactment drugs would be unjustified for pipeline drugs, and that a two-year period of patent term restoration would more appropriately reflect the anticipated short period of time between the date of enactment and the date of FDA approval for pipeline drugs. (While this assumption has in large part proved to be true, I understand that for a handful of pipeline drugs the time between date of enactment and FDA approval has extended beyond the time needed for approval of post-enactment drugs and has in fact exceeded ten years -- something clearly not contemplated by any of us when we were drafting the legislation in 1984.)

Second, it was felt that, for any drug for which an IND had been submitted to FDA prior to the date of enactment, the manufacturer had already made the decision to invest resources in the drug and therefore less of an economic incentive was needed to assure continued pursuit of the drug to final FDA approval -- particularly when it was anticipated that approval would come not long after enactment of the legislation. Accordingly it was concluded that two years, rather than five, would provide sufficient economic incentive to assure that a pipeline drug would not be abandoned.

These were the two considerations that led to the two-year limitation on patent term restoration for pipeline drugs, as contrasted with the five-year grant of patent term restoration for post-enactment drugs, in the 1984 Act. To the best of my recollection, they were the only two considerations that were discussed at that time.

In October 1997, I discussed this matter with John P. McLaughlin when I saw him at a meeting and then sent him my May 1997 letter to ask his recollection. Mr. McLaughlin had served as Counsel to the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce, and was involved in the legislation on a daily basis, throughout 1983 and 1984. At the time I wrote him, Mr. McLaughlin was Executive Vice President of Genentech, a highly successful biotechnology company. Genentech has no interest of any kind in any pipeline drug. Mr. McLaughlin wrote back to confirm my recollection of the above reasons for the pipeline drug limitation. Copies of my letter to Mr. McLaughlin and his reply are also attached to this testimony.

THE OUTLIER PIPELINE DRUGS

For most of the pipeline drugs, the assumption that FDA approval would come shortly after enactment of the 1984 Act turned out to be accurate. At that time, the average time for FDA approval of an NDA was approximately 2.25 years.(8)

For a few outliers, however, this assumption turned out to be quite inaccurate. For these outlier pipeline drugs, the time for FDA review and approval of an NDA was more than twice the average, and they therefore suffered an even greater reduction in effective patent life. A number of post-1984 new drugs

that received a full five years of patent term restoration were in fact approved by FDA before the agency approved these pre-1984 outlier pipeline drugs that received only two years of patent term restoration. This produced the anomalous result that the outlier pipeline drugs, whose NDA approval time was more than twice the average, received less than half the normal patent term restoration. None of us who participated in the drafting of the 1984 Act anticipated or intended this result.

These outlier situations, with approval times more than double the average, reflect the large new drug review workload imposed on FDA in the late 1980s and early 1990s, the increasingly restricted resources available to the agency to do this work, and thus the growing shortfall in the personnel assigned to these tasks. FDA was doing everything it could to meet its new drug review obligations throughout this time. But the resources simply were not there to satisfy the workload needs.

Congress squarely faced this issue in the early 1990s and found a solution in the Prescription Drug User Fee Act of 1992.(9) Using the additional funds made available under the 1992 Act, FDA has hired approximately 650 new employees to handle NDAs in a more expeditious manner. As a result, the time for NDA approval has been cut in half. If this approach had been adopted earlier, there would have been no outlier pipeline drugs and no need for legislation to redress the inequity in patent term restoration that has in fact occurred for these drugs.

LEGISLATIVE ATTEMPTS TO REDRESS THE INEQUITY FOR OUTLIER PIPELINE DRUGS

The two-year limitation for pipeline drug patent term restoration in the 1984 Act was intended to deal with the expected FDA average approval time of about 2.25 years. It made no attempt to address unusual or unique situations of lengthy regulatory review for which accepted principles of fairness and equity would justify exceptions.

As a result, Congress has on seven specific occasions enacted legislation to address particular FDA-regulated products where application of the general rules in the 1984 Act would have been unfair and inequitable. Two of those occurred in the middle of the congressional consideration of the 1984 Act, two occurred at the end of the congressional consideration of the 1984 Act and were enacted a month later, and the remaining three occurred in 1988, 1993, and 1996. In all seven instances, Congress concluded that the general rules applicable under the 1984 Act were insufficient to address the particular situations involved, and thus that legislation was necessary and appropriate. The following table lists those seven statutes:

Statutory Patent Term Restorations Since 1980

Product	Statute
Aspartame (food additive)	95 Stat. 2049, 2065 (January 4, 1982)
Forane (new drug)	97 Stat. 831, 832 (October 13, 1983)
Impro (new animal drug)	98 Stat. 3430 (October 19, 1984)
Glyburide (new drug)	98 Stat. 3434 (October 19, 1984)
Lopid (new drug)	102 Stat. 1107, 1569 (August 23, 1988)
Olestra (food additive)	107 Stat. 2040 (December 3, 1993)
Daypro (new drug)	110 Stat. 1321, 1321-320 (April 26, 1996)

DONE PUBLICLY AFTER HEARINGS

DONE COVERTLY

In a number of other instances, similar legislation has been considered by Congress for other FDA-related products but has not yet been enacted.

I have in the past supported this type of legislation, because I believe it is entirely appropriate for Congress to enact legislation addressing the inequities that inevitably arise in the application of general rules to unique situations.

It is, however, time-consuming and inefficient for Congress to examine and take action on each specific product where a general problem has been identified, such as outlier pipeline drugs. During a Senate hearing held in August 1991 to consider patent term restoration bills for three specific products, Bruce Lehman, who now serves as Commissioner of Patents and Trademarks, offered the thoughtful suggestion that Congress establish some type of new administrative procedure to consider identified problems of fairness and equity rather than to handle each individual product on an ad hoc legislative basis.(10)

As Mr. Lehman pointed out at that time, this alternative way of approaching the matter offers substantial advantages. I am aware that this type of approach for outlier pipeline drugs has been discussed since 1991, but no legislation of this nature has been introduced.

CONCLUSION

Without doubt, outlier pipeline drugs have not been treated fairly. These drugs received only two years of patent term restoration, whereas competitors who submitted their IND applications later but received their NDA approvals earlier received a full five years of patent term restoration. This result cannot be justified on any principled basis. The assumptions on which the two-year pipeline drug limitation was based have turned out to be erroneous for this limited category of drugs. Under these circumstances, Congress has in the past enacted legislation to redress the resulting inequity. In the case of outlier pipeline drugs, this could be accomplished either by drug-specific legislation or, more efficiently, by establishing a new administrative procedure to evaluate the few remaining outlier pipeline drugs involved.

 Judiciary Homepage

1. Peter Barton Hutt & Richard A. Merrill, Food and Drug Law: Cases and Materials (1st ed. 1980 & 2d ed. 1991).

2. See, e.g., my testimony on behalf of PMA in "Patent Term Extension and Pharmaceutical Innovation," Hearing before the Subcommittee on Investigations and Oversight of the Committee on Science and Technology, U.S. House of Representatives, 97th Cong., 2d Sess. 123 (1982).

3. Peter Barton Hutt, The Importance of Patent Term Restoration to Pharmaceutical Innovation, 1 Health Affairs, No. 2, at 6 (Spring 1982).

4. Ellen J. Flannery & Peter Barton Hutt, Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984, 40 Food Drug Cosmetic Law Journal, No. 3, at 269 (July 1985).

5. "Lopid Patent Term Restoration and Fairness Act of 1987," Hearing before the Subcommittee on Courts, Civil Liberties, and the Administration of Justice of the Committee on the Judiciary, House of Representatives, 100th Cong. 1st Sess. 41, 72 (1987), 101 Stat. 1107, 1569 (August 23, 1988); "Patent Extension Hearing," Hearing before the Subcommittee on Patents, Copyrights and Trademarks of the Committee on the Judiciary, United States Senate, 102d Cong., 1st Sess. 44 (1991), 107 Stat. 2040 (December 3, 1993).

6. 76 Stat. 780 (1962).

7. 98 Stat. 1585 (1984).

8. FDA, New Drug Evaluation Statistical Report 53 (October 1985) (FDA mean approval time of 26.9 months for new molecular entities approved in 1984).

9. 106 Stat. 4491 (1992).

10. "Patent Extension Hearing," note 5 supra, at 218.