

Patently Offensive
**Congress Set to Extend Monopoly Patents
for Cipro and Other Drugs**



**Congress Watch
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Acknowledgments

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Patently Offensive

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Executive Summary

This new Public Citizen report shows how leading pharmaceutical companies employed well-connected lobbyists, took advantage of campaign contributions and funneled money to groups advocating for children's health – all as part of a campaign to push for legislation that would lengthen by six months the monopoly patents of many of the most lucrative drugs on the market, including Cipro.

The industry's goal was reauthorization of a law first passed in 1997 that gives a financial windfall to drug companies for testing the safety and efficacy of their products in children. The government does not pay companies to test the safety of drugs in other population groups, such as women and minorities. It requires the companies to conduct such tests. But in this instance, Congress is poised to hand the pharmaceutical industry a huge incentive – that will cost ordinary consumers billions of dollars – to conduct tests that would cost the industry a relative pittance. “Patently Offensive®” shows the following:

- While federal policymakers debated whether to override, or “break” Bayer's monopoly patent on Cipro – and then struck a deal to get lower-priced Cipro for government supplies – the U.S. Senate passed a bill (S.838) on October 18 that would extend the monopoly patent for Cipro and other drugs by six months. The House of Representatives is likely to approve the same legislation the week of November 12, 2001.
- Because the patent extensions in this legislation would delay access to cheaper generic drugs, it would give patent-holding drug companies \$29.6 billion in added sales, according to the U.S. Food and Drug Administration (FDA), and hand those drug companies \$592 million a year in additional profits.
- Bayer, the exclusive manufacturer of Cipro, would garner an extra \$358 million in sales due to a six-month patent extension for the anthrax-fighting antibiotic. Bayer lobbied for the patent-extension legislation and has spent \$3.7 million on campaign contributions and lobbying since 1999. A six-month patent extension for Cipro would pay for all of Bayer's contributions and lobbying since 1999 *in just two days*.
- Pediatric tests cost an average of \$3.87 million per drug, according to an industry survey by the Tufts Center for the Study of Drug Development. The FDA has requested tests on 188 drugs. Therefore, tests on these 188 drugs would cost the industry a total of \$727 million. The FDA estimates that pediatric patent extensions are worth at least 40 times that, or \$29.6 billion, in added sales for the patent-holding companies.
- One of the groups that urged lawmakers to pass this bill was the Coalition for Children's Health. The Coalition for Children's Health, which describes itself as the “leading coalition

in Washington on children’s health policy,” is financially supported by the drug industry, chaired by a former drug industry lobbyist, and comprised of several groups financially supported by the drug industry.

- Three of the four congressional sponsors of the patent-extending law were among the top congressional recipients of drug industry campaign contributions in recent years. Senate sponsors Chris Dodd (D-Conn.) and Mike DeWine (R-Ohio) ranked third and seventh, respectively, among the Senate’s leading recipients of drug industry contributions from 1990-2000. House co-sponsor Rep. Anna Eshoo (D-Calif.) ranked sixth among the House’s leading recipients of drug industry contributions since 1992 (when Eshoo was first elected).
- The patent extension bill faced a major test on October 4 in the Health Subcommittee of the House Energy and Commerce Committee. Several amendments aimed at reducing the cost of the patent extension to consumers were defeated. Republicans (with the help of some Democrats) rejected proposals that would: guarantee drug companies a 100 percent return on pediatric test expenditures; limit drug companies to a 10,000 percent return on certain drugs; and curtail the incentive only for the best-selling drugs (those with over \$800 million in annual sales).
- The subcommittee members who voted to leave the six-month patent extension untouched have received far more in campaign contributions from the drug industry (an average of \$64,691 since 1990) than those voting for the amendments to reduce the patent extension (an average of \$25,493 since 1990).
- Drug companies employed lobbyists with connections to key congressional committees, particularly to key Democrats who were most likely to oppose this legislation. For instance, Merck – which has 12 drugs eligible for the pediatric patent extension – hired as a lobbyist the former health care aide to Rep. Anna Eshoo (D-Calif.). Shortly afterwards, Eshoo became the chief Democratic sponsor of the patent extension bill when the original co-sponsor, Rep. Henry Waxman (D-Calif.), sought to eliminate the monopoly patent extension.

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Congress Set to Extend Monopoly Patents for Cipro and Other Drugs

Introduction

Many drug companies are capable of manufacturing ciprofloxacin, the antibiotic known by its brand name, Cipro. But only one company can sell it by law. That's Bayer, the giant German pharmaceutical firm which holds the monopoly patent on Cipro.

Department of Health and Human Services Secretary Tommy Thompson considered overriding Bayer's patent on Cipro for public health reasons. Instead Thompson struck a deal with Bayer enabling the government to buy Cipro at a discount. But while Thompson claimed a victory in lowering the government's price for Cipro, Congress was steering public policy in a very different direction. Lawmakers voted to extend the monopoly patents on Cipro and dozens of other top selling drugs for six months. To qualify all drug companies have to do is test these drugs for safety and efficacy in children – something that Public Citizen feels should be required as part of the U.S. Food and Drug Administration (FDA) drug approval process.

In fact, the FDA adopted a regulation in 1998 (the so-called "pediatric rule") that gives the agency authority to require drug companies to conduct such tests. The problem is that the drug companies are able to get a six-month monopoly patent extension in return for conducting the tests.

The patent extensions granted for conducting pediatric tests will give drug companies an added \$29.6 billion in sales over the next 20 years, according to the FDA, and hand drug companies \$592 million more in profits each year.¹ (Because access to cheaper generic alternatives will be delayed, the added costs to consumers will be \$14 billion.)

In the case of Cipro, the six-month patent extension will generate \$358 million in added revenue for Bayer.² The pediatric tests for Cipro will cost Bayer approximately \$4 million.³

How could this be? Why would Congress want to so heavily pad the profits of Bayer and other pharmaceutical companies?

It's all explained in an overlooked story of desperate advocates for children, unbending drug companies and compliant lawmakers.

I. "There is No Choice" – Children's Groups Boxed In By the Drug Industry

Drug companies use many legal techniques to protect and extend the monopoly patents of lucrative drugs. One of them is a provision in federal law known by the mind-numbing name of "pediatric exclusivity." It was created as part of the Food and Drug Administration Modernization Act of 1997.⁴

The pediatric patent extension works this way: Drug companies have historically refused to test their products for safety and efficacy in children because the children's market for prescription drugs is not as big and rewarding as the adult market. Pediatric tests cost only \$3.87 million per drug, according to the Tufts Center for the Study of Drug Development, a research group with ties to the drug industry.⁵ But “[b]ecause of the small market for pediatric formulations, a pharmaceutical manufacturer has no incentive to invest resources in such trials,” according to the drug industry's trade association, the Pharmaceutical Research and Manufacturers of America (PhRMA).⁶

Obviously, this creates a public health problem. Children are not miniature adults. Children react differently to medicines than adults do. Without information on how children will respond, pediatricians have to rely on guesswork when prescribing some drugs – or not prescribe some drugs at all.

So, for decades, children's health advocates implored drug companies to conduct pediatric tests. And, for decades, drug companies resisted. “For years we could not get results on this crucial issue,” said Paul Glaser, chairman of the Elizabeth Glaser Pediatric AIDS Foundation, in testimony to the Senate earlier this year.⁷ (Glaser lost his wife and daughter to AIDS and discovered, as his daughter struggled to survive, that life-prolonging AIDS drugs had not been tested for children.)

In some cases, the drug companies went so far as to break promises to test certain drugs in kids. According to an FDA report released earlier this year, the industry actually renege on 60 out of 71 pediatric tests it had promised to complete between 1991 and 1996.⁸

Desperate to get drugs tested in kids, children's health advocates resorted to a bribe – they supported a financial incentive for pediatric tests. The incentive adopted by Congress in 1997 was six months of added market “exclusivity” – or monopoly patent protection. In effect, that meant monopoly patents of eligible drugs would be extended six months. (According to the FDA, the industry started out asking for an additional five years of monopoly protection in exchange for pediatric tests.)⁹

Children's health advocates acknowledge that this incentive is less than ideal. That's because it has lead companies to conduct pediatric tests on their most lucrative drugs and it hurts consumers, such as senior citizens, because it delays their access to cheaper generic alternatives. (See Table 1)

“This is an incentive that has become such a windfall for blockbuster drugs,” said Paul Glaser. “However, as I see it, that is all part and parcel of buying into our system that stresses money and power and where there is very little room for mandating a ‘moral imperative’...There is no choice.”¹⁰

Unsure of how well the pediatric incentive would work, Congress mandated in 1997 that the law would expire at the end of 2001. With the help of a few key lawmakers, lobbyists and advocates,

the bill elbowed its way into Congress’s busy post-September 11 agenda. And it faced its first major test on October 4 in a subcommittee of the House Energy and Commerce Committee.

Table 1: Billion-Dollar Drugs Headed for Pediatric Patent Extensions – Added Revenues and Costs to Consumers

Drug Names	Manufacturer	2000 U.S. Sales	Added Revenues	Added Costs to Consumers
Prilosec	AstraZeneca	\$4,102,195,000	\$1,435,768,250	\$676,862,175
Lipitor	Pfizer	\$3,692,657,000	\$1,292,429,950	\$609,288,405
Prevacid	TAP	\$2,832,602,000	\$991,410,700	\$467,379,330
Prozac	Eli Lilly	\$2,567,107,000	\$898,487,450	\$423,572,655
Zocor	Merck	\$2,207,042,000	\$772,464,700	\$364,161,930
Celebrex	Pharmacia	\$2,015,508,000	\$705,427,800	\$332,558,820
Zoloft	Pfizer	\$1,890,416,000	\$661,645,600	\$311,918,640
Paxil	GlaxoSmithKline	\$1,807,955,000	\$632,784,250	\$298,312,575
Claritin	Schering-Plough	\$1,667,347,000	\$583,571,450	\$275,112,255
Glucophage	Bristol-Myers Squibb	\$1,629,157,000	\$570,204,950	\$268,810,905
Norvasc	Pfizer	\$1,597,091,000	\$558,981,850	\$263,520,015
Pravachol	Bristol-Myers Squibb	\$1,203,474,000	\$421,215,900	\$198,573,210
Neurontin	Pfizer	\$1,131,678,000	\$396,087,300	\$186,726,870
Oxycontin	Purdue Pharma	\$1,052,771,000	\$368,469,850	\$173,707,215
Cipro	Bayer	\$1,023,657,000	\$358,279,950	\$168,903,405
Total		\$30,420,657,000	\$10,647,229,950	\$5,019,408,405

Sources: Sales data for year 2000 comes from www.drugtopics.com. Public Citizen calculated added revenues and added costs to consumers based on a formula used by the U.S. Food and Drug Administration in a January 2001 report to Congress. (“The Pediatric Exclusivity Provision: Status Report to Congress”) The FDA formula multiplies peak year annual sales by .5 (to account for the six-month patent extension) and by .7 (to reflect the patent-holders’ “avoided lost market share” – in other words the market share they avoided losing to generic competitors). Public Citizen’s calculations may understate the added revenues and costs for some drugs because 2000 sales are less than sales when the drug’s patent expires; and it may overstate the added revenues and costs for other drugs because 2000 sales may be higher than sales when the drug’s patent expires.

II. Reps. Tauzin and Eshoo to the Industry’s Rescue

Rep. Henry Waxman (D-Calif.) expected to be the leading Democratic sponsor of the patent extension legislation. That’s the role he played in 1997 when the legislation was created and adopted. This time, though, Waxman wanted to overhaul the law so it dangled in front of drug companies something more like a carrot than a carat. He explained why at an October 4 subcommittee markup of the bill, when he uttered something rarely heard from members of Congress: “We were mistaken.”¹¹

As Waxman went on to say, the pediatric incentive had turned out to be too generous to drug companies and too onerous to consumers. “The cost of exclusivity has exploded beyond any relation to the cost of a drug company doing the pediatric studies,” Waxman said.

Indeed the ulcer medication Prilosec was giving consumers heartburn. Waxman noted that pediatric tests for Prilosec were estimated to cost between \$2 million and \$4 million, while the added patent protection was worth more than \$1.4 billion to Prilosec’s manufacturer, AstraZeneca.¹² That, Waxman noted, was a 36,000 percent return on the company’s investment.

Waxman and other Democrats offered several amendments aimed at curtailing the drug industry’s windfall from the pediatric patent extension.¹³ One amendment would have replaced the six-month patent extension with a program to pay drug companies twice the costs of any pediatric studies. Another amendment would have limited the extension to three months for drugs with annual sales above \$800 million (in other words, the 25 best-selling drugs). Yet another amendment would have prohibited the patent extension for a drug if consumers covered by federal programs, such as Medicaid, spent 100 times the cost of pediatric studies (or roughly \$400 million) on that drug.

All of the amendments were defeated, thanks to Republicans, who voted unanimously against them, and a handful of Democrats.¹⁴

Waxman and eight other Democrats who wanted to amend the law were outvoted again on the full Energy and Commerce Committee – although they were backed by the committee’s senior Democrat and former chairman, John Dingell of Michigan.

The Republican position against amendments reportedly came down from House and Energy Commerce Committee Chairman W.J. “Billy” Tauzin of Louisiana. First, Tauzin insisted that the law is “working now and we ought to keep it.”¹⁵ Then, “Chairman Tauzin gave marching orders that there would be no amendments – no way, no how – from Republicans.”¹⁶

Why would the GOP – ostensibly the party of fiscal discipline – want to hand the most profitable industry in the country an additional \$592 million in annual profits?

It might be because the drug industry contributed \$20.1 million to federal candidates and party committees in 1999-2000 and 76 percent of that money went to Republicans. (Tauzin himself has collected \$110,647 in drug industry contributions since 1990, with his receipts increasing every election cycle as he rose to the committee chairmanship.)¹⁷

Indeed, it seems more than coincidence that the Health Subcommittee members who voted against the amendments received far more in drug industry contributions (an average of \$64,691 since 1990) than the subcommittee members who voted for amendments (\$25,493 on average since 1990).¹⁸

No doubt those contributions helped drug industry lobbyists (the industry employed 625 Washington D.C. lobbyists last year¹⁹) get in to see House Energy and Commerce Committee members and staffers. And when the lobbyists got face time with members and staffers, their

message was clear: “They were pretty pointed in saying, in effect, ‘We’ll walk away [if Congress trims the pediatric incentive]. We want our bill.’”²⁰

That message was reinforced by children’s health advocates, who also called for passage of the bill without any reductions in the industry’s financial rewards. Leading the push for children’s advocates was the American Academy of Pediatricians (AAP). “For 40 years we’ve tried to get these tests,” AAP lobbyist Elaine Vining explained, “and now we have a bill that’s working for kids. Nobody could guarantee us that paying the companies two times the cost of the studies would get us the studies. The only solid information we have now is that the [current incentive] is working.”²¹

Of course the pediatric incentive was working – and a 10-year patent extension would probably work even better. The question was whether the incentive, in current form, was too generous.

“Is there a better way so consumers pay less? Possibly,” added Vining. “Will we lose something that way? Maybe.”

Together, lobbying by the industry and children’s groups such as AAP and the Coalition for Children’s Health, was potent – and the children’s groups gave Congress a convenient excuse for supporting the bill. “If it was a straightforward debate with pharmaceutical companies against consumers that would be one thing. But AAP was giving members of Congress who wanted to vote with PhRMA (the Pharmaceutical Research and Manufacturers of America) a fig leaf.”²²

That’s an understatement. Imagine being able to help children’s advocates and big drug companies at the same time. It’s a politician’s dream: kiss a baby, get a fat campaign contribution.

It wasn’t just Republicans taking the industry’s side. The Democratic sponsor of the bill and chief Democratic opponent of pro-consumer amendments was Rep. Anna Eshoo (D-Calif.). Eshoo, who has received \$131,544 in drug industry campaign contributions since 1992 when she was first elected, ranks sixth among all House members in drug industry contributions received in that period.²³

The drug industry lobbied the House Energy and Commerce Committee in strategic fashion.

Consider the efforts of Merck, the most profitable drug company in America. Merck has a lot riding on the pediatric monopoly patent bill – the company has 12 drugs eligible for the pediatric incentive and those drugs had combined sales of \$3.9 billion last year. To get the patent extension bill passed, Merck knew it needed to win friends among Democrats in the House Energy and Commerce Committee, which has jurisdiction over the pediatric patent extension.

So Merck hired two former Democratic House staffers with close ties to the committee to lobby on the bill.²⁴ One is Kay Holcombe, who worked on the Energy and Commerce Committee from 1993 to 1997. The other is Stacey Rampy, who until this summer was a health care aide to Rep. Eshoo, who only recently emerged as the chief Democratic sponsor of the pediatric patent

extension legislation. (In all, Merck had five lobbyists working on the pediatric bill, and the company spent \$2.8 million on all lobbying in the first half of 2001.)²⁵

PhRMA employed another former Energy and Commerce Committee staffer, Howard Cohen (committee counsel 1988-1999), to lobby for the pediatric incentive. (Cohen also lobbies for Merck and several other drug companies).²⁶

III. Senate Takes Path of Least Resistance

In theory, there was a better chance of amending the pediatric patent extension in the Senate, which is controlled by Democrats. But the amendment effort fared even worse – the bill was unanimously approved without significant changes on October 18 – for the following reasons, according to Senate sources:²⁷

- Drug companies made it clear they did not want to negotiate on this issue. “The message was always ‘it’s good for kids, it’s good for innovation, don’t screw with it or it could go away.’”²⁸
- Influential advocates for children’s health, such as the AAP, stood along with the drug industry against any reductions in the incentive. “AAP did a lot...unions and seniors’ groups never kicked up a fuss. So it was not the best of dynamics.”²⁹
- Drug companies employed lobbyists with key connections to Democrats such as Steve Ricchetti, who was deputy chief of staff for President Clinton and former executive director of the Democratic Senatorial Campaign Committee.³⁰ Ricchetti’s firm (Ricchetti Inc.) lobbied for the pediatric bill on behalf of Eli Lilly and Pharmacia in the first half of 2001 and earned \$180,000 from the two drug companies in that period.³¹

Still, the same politics were at play in the House. And House Democrats put up some fight, at least, forcing roll call votes on amendments to curtail the patent extensions. Why didn’t that happen in the Senate?

- Chris Dodd (D-Conn.), the Democratic sponsor of the Senate bill (and the original sponsor of the 1997 law), did not share Waxman’s desire to cut the costs of the pediatric patent extension to consumers. Dodd reportedly told colleagues that profit-limiting amendments would cause the drug industry to walk away from the pediatric tests. Dodd “twisted everybody’s arms and picked off senators one-by-one.”³² Furthermore, Dodd comes from a state with strong ties to the drug industry. Nearly 11,000 Connecticut residents work for 20 drug companies that have offices or laboratories in the Nutmeg State (including Pfizer, which recently completed construction of its global headquarters in New London, and Bayer, which has its U.S. headquarters in West Haven.) And these jobs pay handsomely – an average of \$63,000 per year.³³ Connecticut also accounts for 11 percent of all the research and development dollars spent by U.S. drug companies.³⁴ Not surprisingly, Dodd has received \$165,698 in drug industry campaign contributions since 1990. The Republican co-sponsor, Mike DeWine of Ohio, has collected \$132,800 in that time. Among the Senate’s leading

recipients of drug industry campaign contributions since 1990, Dodd ranks third and DeWine ranks seventh.³⁵

- Sen. Edward Kennedy (D-Mass.), who chairs the committee with jurisdiction over the bill, also refused to fight – for reasons that remain less clear. (“I think he wanted to work with, not against Sen. Dodd, who’s a close personal friend and a big children’s advocate,” explained one source.³⁶) And when the committee chairman doesn’t want to take up the fight, there’s not much of a forum for critics. That makes it difficult for senators who were inclined to do battle, such as Hillary Clinton (D-N.Y.),³⁷ to follow through. As one source observed: “Members of the Senate felt that if they were going to have a knock-down, drag-out fight with the pharmaceutical industry this was not the issue for it. You’ve got to pick and choose your spots and Sen. Clinton has already become a good vote counter.”³⁸
- Throw in the September 11 attacks, subsequent anthrax contamination of the Senate Hart Office Building, and the fact that many senators didn’t look closely at the bill, and the drug industry found itself with an easy win. “The Senate was distracted. Lawmakers were not focused on this bill. There was also a sense that the Senate was just reauthorizing something already on the books.”³⁹

Also lost in the post-September 11 tumult was the idea that there is a better, cheaper way to help both children and consumers. Congress could pass a law requiring that pharmaceutical companies test their products in children as a condition of gaining new drug approval by the FDA. That way, pediatricians could get the information they want, kids could get the drugs they need, and consumers could get price relief.

It’s almost surreal that drug companies can demand financial rewards for testing the safety of their products in one population group. Just substitute “gender” or “race” for the “pediatric” population. Imagine a law that said we need to give the drug companies a multi-billion dollar incentive or else they would refuse to test the safety and efficacy of their products in women or African-Americans.

IV. Stakes High for Drug Companies, Their Lobbyists

The pharmaceutical industry shelled out \$262 million for lobbying, campaign contributions and so-called “issue ads” in 1999-2000 – more than any other industry. (For details about the industry’s army of 625 lobbyists, see Public Citizen’s report, “The Other Drug War,” <http://www.citizen.org/documents/pharma.pdf>)

Drug companies have continued to spend heavily on lobbying – and the pediatric patent extension legislation – in 2001.⁴⁰

Bayer, for instance, spent \$875,000 in the first half of 2001 on lobbying, and the pediatric bill was one of the key issues the company lobbied on. (Lobbyists are required to disclose their activities and expenditures twice a year.) And Bayer was practically a minor leaguer compared to other drug companies and industry groups.

PhRMA spent a total of \$5.8 million lobbying in the first half of 2001 and had six lobbyists advocating for the pediatric patent legislation. Eli Lilly's lobbying bill for the first six months of 2001 was \$3.3 million and it lobbied for the pediatric patent extension bill. Bristol-Myers Squibb spent \$2.5 million and had four lobbyists working on the pediatric bill. Novartis reported lobbying expenditures of \$1.4 million and employed seven lobbyists on the issues.

The list goes on: Schering-Plough's lobbying expenses were \$980,000 for the first six months of 2001 and the company pushed for the pediatric bill; Pharmacia reported spending \$719,000 on lobbying and had five lobbyists on the bill. Merck, as noted earlier, had five lobbyists buttonholing lawmakers on the pediatric bill and the company spent a total of \$2.8 million on lobbying in the first half of 2001.

That's just a glimpse of the industry's lobbying campaign for pediatric patent extensions. The expenditures are likely to be even larger for the second half of 2001, when the issue heated up in Congress. But lobbying reports covering that period won't become public until early 2002.

The pharmaceutical industry also continued its aggressive campaign contributions throughout the pediatric testing debate – including large soft money donations to the party committees. Pharmaceutical manufacturers have given \$2,099,837 in soft money contributions, with 74 percent going to Republicans, since January 2001 when activity on the bill began.⁴¹

Since June, four of the companies which stand to reap windfall profits from the monopoly extension and the industry's trade group have given \$427,000 to the party committees. The Democratic Senatorial Campaign Committee during that time took in \$25,000 from Eli Lilly and \$100,000 from Pharmacia Corp., which also gave \$105,447 to Republicans.

Bristol-Myers Squibb has contributed \$351,397 in soft money this year, and in August gave the Republican National Committee \$100,000. In June, the GOP's senatorial committee received \$125,000 from PhRMA, which has given \$230,290 in soft money this year.

V. Don't Get Fooled Again

Lobbyists, children's advocates and members of Congress have stressed several seemingly persuasive arguments for pediatric patent extensions. But those arguments have flaws that haven't been reported. For instance:

1. Children's advocates funded by the drug industry

Perhaps the most compelling argument for the pediatric incentive comes from the children's health advocates. Their pleas for pediatric tests – at any cost – serve two functions. First, they convince members of Congress to put the need for pediatric tests ahead of concerns about increased costs to consumers. Second, they give cover to members of Congress who support the patent extensions for less altruistic reasons – such as their cozy relationship with the drug industry, fueled, in part, by sizable campaign contributions.

Amendments proposed by Rep. Waxman and other Democrats on the House Energy and Commerce Committee could well have resulted in more testing and better information about the safety and efficacy of drugs for children without forcing seniors and other consumers to pay higher drug prices resulting from the patent extensions.

But children's groups refused to budge. Their ostensible reason was a fear that if they opposed the drug industry's position the program would not be renewed. But another reason may come from a close relationship that exists between the drug industry and some of these organizations.

One of the leading groups advocating for children's health has financial ties to the drug industry and an apparent conflict of interest. The Coalition for Children's Health has made advocating for the pediatric incentive one of its top priorities.⁴² The group held a press conference with the bill's Senate sponsors, put out press releases and lobbied members of Congress. But few members of Congress know that the Coalition – which describes itself as “the leading coalition in Washington on children's health policy” – received \$70,000 this past summer from PhRMA after the Coalition made supporting the pediatric patent extension one of its top priorities.⁴³

In addition, the chairwoman of the coalition, Audrey Spolarich, was a paid lobbyist for one drug company, Schering-Plough, last year.⁴⁴ (The firm at which Spolarich worked was paid \$720,000 in lobbying fees by Schering-Plough in 1999 and 2000.)

Using Schering-Plough's money, Spolarich helped create the group Veterans Aimed Toward Awareness to promote awareness of Hepatitis C – a disease that can be treated with Schering-Plough's drug Rebetrone,⁴⁵ which costs \$18,000 per year.⁴⁶ Spolarich then created an ad hoc spin-off group, Veterans Aimed Toward Children, that has advocated for the pediatric patent extension legislation – which will benefit Schering-Plough drugs such as Claritin and Rebetrone.

Does Spolarich think it's a conflict of interest for the Coalition for Children's Health (and Veterans Aimed Toward Children) to take drug industry money and push legislation that would enrich drug companies? Spolarich says her daughter, who suffers from Hepatitis C, motivates her, not drug companies. “I don't think my background is a problem. I still don't feel it is a conflict,” she says.⁴⁷

Some of the groups in the coalition – such as the Arthritis Foundation – also receive significant funding from drug companies.⁴⁸ These groups include the Hep C Connection, which – according to a story in *The Washington Post* – was supported by drug company Schering-Plough to help promote the company's products.⁴⁹

A final note: the Coalition for Children's Health doesn't even have its own office. It operates out of the Washington, D.C. offices of Sagamore Associates, a lobbying firm that created a consulting company (Aventor) whose stated purpose is to help drug companies with grassroots lobbying.⁵⁰

2. FDA downplays cost to consumers

The FDA estimates that the pediatric incentive will cost consumers \$695 million per year because it delays access to lower-priced generic drugs.⁵¹ The FDA says that \$695 million will, in turn, increase national spending on drugs by one-half of one percent (Americans spent an estimated \$117 billion on prescription drugs in the year 2000). But don't try telling a senior who's taking three very popular drugs – like Glucophage, Vasotec and Prilosec – that their own bills will increase by only one-half of 1 percent. They won't – their bills will increase much more because of six-month patent extensions.

By citing the one-half of one percent figure, an aggregate statistic, the FDA greatly downplays the impact of pediatric patent extensions on individual consumers. For instance, a senior who takes Glucophage (diabetes), Vasotec (high blood pressure) and Prilosec (heartburn) could see their prescription drug bill increase by \$425 because of the added patent protection given to those three drugs. That \$425 increase represents a 45 percent hike in such a senior's drug bill, which is a far cry from one-half of one percent.⁵²

The increase occurs because consumer access to lower-priced generic drugs is delayed by six months. If a senior takes Glucophage, Vasotec and Prilosec – a very plausible scenario as they are the leading drugs in their respective therapeutic categories – then that senior will pay approximately \$291 more for Prilosec because that drug obtained six months of added monopoly patent protection; plus, \$134 more for Glucophage and Vasotec because of their patent extensions.

3. GAO downplays the pediatric windfall

The usually reliable General Accounting Office (GAO), the investigative arm of Congress, has also downplayed the economic impacts of the pediatric incentive. In testimony to the Senate in May, Janet Heinrich, GAO's health care issues director, addressed concerns that the pediatric incentive may be sought and granted primarily for drugs that are the top-sellers – not the drugs most needed for children.

Heinrich, however, used questionable logic in minimizing these concerns. The FDA has requested pediatric tests for 155 existing drugs (and 33 that have not yet been approved). Of those 155 drugs already on the market, Heinrich noted that *only* 46.5 percent of those drugs had sales of \$120 million or more in 1999.⁵³

What Heinrich *didn't mention* is that drugs with sales above \$120 million are in the top 2 percent of best-selling drugs. Therefore, roughly half of the drugs destined for the pediatric incentive are among an elite group of best selling drugs.

She also stressed that only 7.7 percent of the 155 drugs had sales of more than \$1 billion in 1999. There are several problems with that analysis. First, Heinrich relied on 1999 sales data. If sales data for the year 2000 are used, we see that 15 drugs with at least \$1 billion in sales, or 10 percent, are headed for the pediatric patent extension.⁵⁴ More important is the fact that the vast majority (15 of 19) of the drugs with sales over \$1 billion in 2000 were likely to receive monopoly patent protection from the pediatric incentive. That's the real concern from

a consumer perspective – the pediatric patent extension is being disproportionately sought for, and granted to, the biggest selling drugs.

4. FDA threatened with lawsuit brought by bogus consumer groups

A lawsuit was filed in December 2000 to stop the FDA rule requiring drug companies to conduct pediatric testing. The lawsuit was filed by Dan Troy, a conservative pro-business lawyer who was recently appointed chief counsel of the FDA.⁵⁵

The lawsuit was brought on behalf of three conservative groups: Consumer Alert, the Competitive Enterprise Institute, and The Association of American Physicians and Surgeons (AAPS). The first two of these groups are financially supported by the drug industry. The third is a right wing group of doctors who oppose Medicare and in written statements have said things such as the following: “Give us liberated pharmacy companies or give us death!” and have compared President Clinton’s tobacco policies to “Third Reich measures against corporations engaged in a legal business.”

5. Pediatric tests cost a pittance

As mentioned earlier, the Tufts Center for the Study of Drug Development surveyed drug companies and found that pediatric tests cost \$3.87 million, on average, for a drug. The FDA wants pediatric tests for 155 existing drugs and another 33 that are still in the approval process.⁵⁶

That means all the pediatric tests sought by the government will cost the drug industry \$727 million.⁵⁷ At the same time, the FDA estimates that pediatric patent extensions will generate \$29.6 billion in added sales for patent-holding drug companies.⁵⁸ That means the drug industry will receive a return 40 times its investment.

This is a conservative estimate because the FDA calculated added sales based on a study of only 119 drugs which the FDA had requested tests for as of March 2000. The FDA’s estimate of \$29.6 billion in added sales would increase if it accounted for the 188 drugs the FDA has requested tests for. No doubt, the FDA will seek pediatric tests for even more new drugs in future years, which will only drive up the added sales figure.

VI. Why Stop At Six Months? Drug Companies Seek Six Times More

Ironically, at least one drug company thinks the six-month monopoly patent extension isn’t enough and is trying to get more by adding a special interest provision to the pediatric bill.

Bristol-Myers Squibb is asserting a novel legal argument that would have the effect of giving the company three and one-half years of patent protection for testing their blockbuster diabetes drug, Glucophage, in children.

Here is what Bristol-Myers Squibb is arguing.

Under the 1984 Hatch-Waxman Act a company can get three years of market exclusivity (the exclusive rights to certain information) when they use data from a clinical trial to supplement a drug's label with new information. However, this exclusive right applies only to that new information. It has always been assumed that this exclusivity does not prevent generic drug companies from producing and marketing a drug; it only blocks generics from using the new protected information on their labels. So generics could come on the market as soon as the patent on the active ingredient in a drug had expired. They simply could not include the new protected information in their labeling.

What's different here is Bristol-Myers Squibb's novel argument that in the case of Glucophage, the FDA should not allow generics to come to market – at all, in any way – without the new information that Bristol-Myers Squibb discovered through testing in children. And only Bristol-Myers Squibb has rights to that information. If Bristol succeeds in this argument, they would block generic competition for an additional three years on top of the six months for testing in children. In effect, they would get an extension of their monopoly patent.

Moreover, a precedent would be set for any pharmaceutical company to use a pediatric study to keep generic drugs off the market, for all uses, for three and one-half years.

Right now, the FDA is delaying approval of generic versions of Glucophage until the Bristol-Myers Squibb claim is resolved. Meanwhile, Bristol-Myers Squibb has been lobbying Congress to ensure its three and one-half year patent extension is protected by wording in the pediatric bill.

Lawmakers seem committed to keeping that from happening. Rep. Anna Eshoo, a chief sponsor of the House pediatric bill, said that the bill's intention is not to allow companies such as Bristol-Myers Squibb to use pediatric testing to further game the system. "We should close that loophole. That really is a mockery of what the law is about," Eshoo said.⁵⁹

As this report goes to press, it's not clear if Bristol-Myers Squibb will prevail. If it does, the cost to consumers of pediatric tests will mushroom far beyond the \$14 billion price tag calculated by the FDA.

Endnotes

¹ U.S. Food and Drug Administration, “The Pediatric Exclusivity Provision: Status Report to Congress,” January 2001. <http://www.fda.gov/cder/pediatric/reportcong01.pdf>

² Public Citizen calculation based on methodology used by U.S. Food and Drug Administration (FDA) in “The Pediatric Exclusivity Provision: Status Report to Congress,” January 2001. FDA uses the following formula in Appendix C of report to calculate additional sales revenue generated by six-month patent extension: annual sales of drug x 70 percent (avoided lost market) x .5 year.

³ Christopher-Paul Milne, “The Pediatric Studies Incentive: Equal Medicines For All,” Tufts Center for the Study of Drug Development, April 2001. Milne’s survey of drug companies concludes that pediatric tests cost an average of \$3.87 million per drug.

⁴ Food and Drug Administration Modernization Act (FDAMA), Public Law 105-115, enacted November 1997.

⁵ Christopher-Paul Milne, “The Pediatric Studies Incentive: Equal Medicines For All,” Tufts Center for the Study of Drug Development, April 2001.

⁶ Pharmaceutical Research and Manufacturers of America (PhRMA), “Pediatric Incentive for Pharmaceutical Products, November 1997 to February 2001.”

⁷ Paul Glaser, chairman of the board, Elizabeth Glaser Pediatric AIDS Foundation, testimony before the Senate Committee on Health, Education, Labor and Pensions, May 8, 2001.

⁸ U.S. Food and Drug Administration, “The Pediatric Exclusivity Provision: Status Report to Congress,” January 2001.

⁹ Ibid.

¹⁰ Paul Glaser, chairman of the board, Elizabeth Glaser Pediatric AIDS Foundation, testimony before the Senate Committee on Health, Education, Labor and Pensions, May 8, 2001.

¹¹ Rep. Henry A. Waxman, “Statement at the Markup on Pediatric Exclusivity,” House Subcommittee on Health, Committee on Energy and Commerce, October 4, 2001.

¹² Ibid.

¹³ *Congressional Quarterly Monitor*, House Subcommittee on Health, Committee on Energy and Commerce, votes on HR 2887, October 4, 2001.

¹⁴ Ibid. Health Subcommittee Democrats who voted consistently against the amendments were Reps. Anna Eshoo of California, Ted Strickland of Ohio, Edolphus Towns of New York, and Albert Wynn of Maryland.

¹⁵ Ibid.

¹⁶ Public Citizen interview with House staff member, October 29, 2001.

¹⁷ Center for Responsive Politics. www.opensecrets.org

¹⁸ Public Citizen analysis of data from the Center for Responsive Politics.

¹⁹ Public Citizen, “The Other Drug War: Big Pharma’s 625 Washington Lobbyists,” July 2001.

²⁰ Public Citizen interview with House staff member, September 17, 2001.

²¹ Public Citizen interview with Elaine (Holland) Vining, October 31, 2001.

²² Public Citizen interview with House staff member, October 29, 2001.

²³ Center for Responsive Politics. www.opensecrets.org

²⁴ Public Citizen analysis of Lobby Disclosure reports filed with the Secretary of the Senate and Clerk of the House pursuant to the Lobby Disclosure Act of 1995.

²⁵ Ibid.

²⁶ Ibid.

²⁷ Public Citizen interviews with Senate staff members on September 17, 2001 and October 26 and 29, 2001.

²⁸ Public Citizen interviews with Senate staff member, September 17, 2001.

²⁹ Public Citizen interview with Senate staff member, October 26, 2001.

³⁰ Public Citizen analysis of Lobby Disclosure reports filed with the Secretary of the Senate and Clerk of the House pursuant to the Lobby Disclosure Act of 1995 and Public Citizen interview with Senate staff member on September 17, 2001.

³¹ Public Citizen analysis of Lobby Disclosure reports filed with the Secretary of the Senate and Clerk of the House pursuant to the Lobby Disclosure Act of 1995.

³² Public Citizen interview with Senate staff member, October 26, 2001.

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- ³³ Connecticut United for Research Excellence, Annual Report, 2001.
- ³⁴ Pharmaceutical Research and Manufacturers of America, Annual Survey 2000.
- ³⁵ Public Citizen analysis of data from the Center for Responsive Politics, www.opensecrets.org
- ³⁶ Public Citizen interview with drug industry consultant, November 1, 2001.
- ³⁷ Rachel Smolkin, "Pros, Cons of Pediatric Drug-Testing Are Debated," *Pittsburgh Post-Gazette*, August 5, 2001. Story reported that Clinton said she might try to amend the bill when it reached the Senate floor because of the excessive returns some companies received for conducting pediatric tests. The story quoted Clinton as saying: "Tests that may have cost sometimes less than a million dollars, no more than \$8 million at the high end, are awarded a windfall exceeding \$1 billion dollars."
- ³⁸ Public Citizen interview with drug industry of consultant, Nov. 1, 2001.
- ³⁹ Public Citizen interview with Senate staff member, October 26, 2001.
- ⁴⁰ Public Citizen analysis of Lobby Disclosure reports filed with the Secretary of the Senate and Clerk of the House pursuant to the Lobby Disclosure Act of 1995.
- ⁴¹ Center for Responsive Politics, www.opensecrets.org
- ⁴² Public Citizen interviews with Senate and House staff members on September 17, 2001 and review of Coalition for Children's Health documents.
- ⁴³ Coalition for Children's Health stationery, October 2, 2001, states that the Coalition receives financial support from PhRMA. Coalition Chairwoman Audrey Spolarich told Public Citizen in an October 26, 2001 interview that PhRMA gave CCH "around \$70,000" this summer. Spolarich said the unrestricted grant from PhRMA came after the coalition adopted its position on the pediatric exclusivity legislation.
- ⁴⁴ Public Citizen analysis of Lobby Disclosure reports filed with the Secretary of the Senate and Clerk of the House pursuant to the Lobby Disclosure Act of 1995. Spolarich was listed by her employer, Health Policy Analysts, as a paid lobbyist for Schering-Plough in 2000. Health Policy Analysts was paid \$400,000 by Schering-Plough last year.
- ⁴⁵ Public Citizen interview with Audrey Spolarich, October 26, 2001.
- ⁴⁶ Robert O'Harrow Jr., "Grass Roots Seeded by Drugmaker; Schering-Plough Uses 'Coalitions' to Sell Costly Treatment, *The Washington Post*, September 12, 2000.
- ⁴⁷ Public Citizen interview with Audrey Spolarich, October 26, 2001.

⁴⁸ According to the Arthritis Foundation, it received contributions of \$100,000 or more from 10 different drug companies. <http://www.arthritis.org/resources/sponsors/sponsorlist.asp>

⁴⁹ Robert O'Harrow Jr., "Grass Roots Seeded by Drugmaker; Schering-Plough Uses 'Coalitions' to Sell Costly Treatment," *The Washington Post*, September 12, 2000.

⁵⁰ According to Aventor's website, the company helps its clients, including drug companies: "Aventor organizes sophisticated coalitions and grassroots networks, then deploys them to support legislative and policy goals." http://www.aventor.com/serv_grass.htm

⁵¹ U.S. Food and Drug Administration, "The Pediatric Exclusivity Provision: Status Report to Congress," January 2001.

⁵² Public Citizen calculation developed with the assistance of Larry Sasich, Pharm. D, M.P.H., of Public Citizen's Health Research Group.

⁵³ Janet Heinrich, Director, Health Care-Public Health Issues, General Accounting Office, "Pediatric Drug Research: Testimony Before the Committee on Health, Education, Labor and Pensions," U.S. Senate, May 8, 2001.

⁵⁴ www.drugtopics.com

⁵⁵ U.S. District Court for the District of Columbia, *Association of American Physicians and Surgeons and Competitive Enterprise Institute and Consumer Alert v. U.S. Food and Drug Administration and U.S. Department of Health and Human Services*, December 4, 2000. Complaint for declaratory and injunctive relief filed by attorneys for plaintiffs: Bert W. Rein, Andrew Krulwich and Daniel E. Troy, Wiley, Rein & Fielding.

⁵⁶ Janet Heinrich, Director, Health Care-Public Health Issues, General Accounting Office, "Pediatric Drug Research: Testimony Before the Committee on Health, Education, Labor and Pensions," U.S. Senate, May 8, 2001.

⁵⁷ Public Citizen analysis of GAO and Tufts Center for the Study of Drug Development information. GAO reported that FDA is seeking pediatric tests for 188 drugs in all; 188 multiplied by \$3.87 million (The Tufts Center's estimated cost for pediatric tests per drug) equals \$727 million.

⁵⁸ U.S. Food and Drug Administration (FDA), "The Pediatric Exclusivity Provision: Status Report to Congress," January 2001.

⁵⁹ Lisa Richwine, U.S. House Committee Clears Pediatric Drug Test Bill," Reuters News Service, October 11, 2001.