

# **Schering-Plough Political Money Pushes Claritin Patent Extension and Distorts GAO Report**



**Congress Watch  
Originally Published August 2000  
Updated March 2001**

## **Schering-Plough Political Money Pushes Claritin Patent Extension and Distorts GAO Report**

### **Summary**

In 1996, the Schering-Plough Corporation began trying to persuade Congress to extend the company's monopoly patent on its billion-dollar allergy drug Claritin. Since that time, Schering-Plough has dramatically increased its soft money contributions and lobbying expenditures, and hired a "dream team" of lobbyists including Linda Daschle, wife of Senate Minority Leader Tom Daschle (D-S.D.), former House Appropriations Committee Chairman Bob Livingston (R-La.), and Peter Knight, manager of the 1996 Clinton-Gore campaign. The company also made its corporate jet available to presidential candidate Sen. Orrin Hatch (R-Utah), who chairs the Senate committee with jurisdiction over drug patents, in an apparent attempt to help win an extension of Claritin's monopoly patent.

It's understandable why Schering-Plough would go to such lengths. The company made \$2.3 billion in 1999 on Claritin sales in the U.S.<sup>1</sup> The patent extension it is seeking could cost consumers \$7.3 billion over 10 years because their access to cheaper generic alternatives would be delayed.<sup>2</sup>

For a company making that kind of money, spending \$28.1 million since the start of the 1996 election cycle on campaign contributions and lobbying is a small but smart investment.<sup>3</sup> Particularly when it's buying advice and influence from lobbyists such as Howard Baker, former Republican Senate majority leader, Richard Ben-Veniste, who defended the Clintons during the Senate Whitewater hearings, and Vic Fazio, former chairman of the House Democratic Caucus, as well as Daschle, Livingston and Knight.

This cast has used its considerable legislative cunning on behalf of Schering-Plough. For instance, after the Claritin patent extension bills (H.R. 1598/S. 1172) got stalled in the House and Senate in 1999, a Senate ally of the company tried this year to secretly attach a rider to the fiscal year 2001 Military Construction appropriations bill to achieve Schering-Plough's goal. Five separate times in 1999 Schering-Plough supplied its corporate jet to presidential candidate Hatch, who chairs the Senate Judiciary Committee, which oversees patents. And at a strategic point in the legislative process last year, the company gave \$50,000 in soft money to Sen. John Ashcroft's (R-Mo.) joint fundraising committee with the National Republican Senatorial Committee.<sup>4</sup> Ashcroft chairs the Senate subcommittee that oversees patents and was considering a presidential bid last year.

Now Schering-Plough is trying to distort the findings of an August 2000 General Accounting Office (GAO) report on patent extensions.<sup>5</sup> The company claims it deserves a monopoly patent for another three years because the Food and Drug Administration (FDA) took too long to approve Claritin.<sup>6</sup> In fact, the GAO found that the company's flawed application and the FDA's concern about cancer delayed the Claritin application for justifiable reasons. Don't be fooled by Schering-Plough – follow the money.

### **Findings**

## **Lobbying Expenditures**

- Schering-Plough spent \$17.2 million on lobbying during 1999-2000 election cycle – almost triple what Schering-Plough spent during the 1997-1998 election cycle. Overall, since 1996, Schering-Plough has spent \$26 million lobbying Congress and the administration. *[Figure 2]* Most of the spending has gone towards one goal – a Claritin patent extension – unlike that of other drug companies which lobby on a wide range of issues.<sup>7</sup>

## **Soft Money Contributions**

- Since the start of the 1996 election cycle, Schering-Plough has given \$1.5 million in soft money to Democratic and Republican party committees. During the 2000 cycle, the company's soft money contributions totaled \$847,000. Schering-Plough's soft money contributions during the last election cycle were more than twice as much as during the 1996 cycle and three times as much as during the 1998 cycle. *[Table 1]*
- Schering-Plough gave just 4 percent of its soft money to Democratic Party committees in the 1996 cycle. But that figure has jumped to 20 percent in the 2000 cycle as the company sought greater influence with key Democratic lawmakers – an effort that has paid dividends. Sen. Robert Torricelli (D-N.J.), who chairs the Democratic Senatorial Campaign Committee (DSCC), was the chief sponsor of a bill (S. 1172) to give Claritin a three-year patent extension (the current patent expires in 2002). Torricelli introduced the bill on May 27, 1999, the day after Schering-Plough made a \$50,000 contribution to the DSCC. Republican staff on the House Judiciary Committee told Schering-Plough lobbyists in 1998 that they “better get liberal Democrats on board this bill,” if it was going to succeed.<sup>8</sup> *[Table 1 and Table 4]*

## **PAC Candidate Contributions**

- Schering-Plough's campaign contributions to candidates show the same trend of increased giving to Democrats. Since the start of the 1996 election cycle, Schering-Plough's corporate PAC has contributed \$547,350 to members of Congress – \$395,850 to Republicans and \$151,500 to Democrats. In the 1996 election cycle, the ratio was 3.5-to-1 Republican over Democrat. In 2000, 66 percent went to Republicans and 34 percent went to Democrats – a ratio of only 2 to 1. *[Table 2]*

## **Contributions to Senate Judiciary Committee Members**

- Schering-Plough has strategically targeted members of the Senate Judiciary Committee, which has jurisdiction over patent extensions. The six current and one former member of the Senate Judiciary Committee who co-sponsored the patent extension bill, S. 1172, or have aggressively promoted a Claritin patent extension, collectively received \$136,762 in campaign contributions from the company over the past three election cycles. This is 12 times more than the company's contributions of \$11,300 to the committee's other 17 members over the same period. *[Table 3 and Figure 1]*
- Over the past three election cycles, Sen. Torricelli, the Claritin patent extension bill's chief proponent, was the leading recipient (\$36,800) of “hard money” from the corporation's PAC and executives. Torricelli was also vice chairman (1998) and chairman (1999-2000) of the Democratic Senatorial Campaign Committee, which has received \$190,000 from Schering-Plough since 1995.

[Table 3 and Table 1] Schering-Plough was also a “vice-chair” of Democratic Senatorial Campaign Committee events at the national party convention in Los Angeles this month.<sup>9</sup>

- Chairman Hatch was the Judiciary Committee's second-highest recipient of “hard money” from the Schering-Plough PAC and corporate executive contributions, taking in \$20,000 in the last three cycles. [Table 3]
- Hatch also used Schering-Plough's corporate jet for his presidential campaign on five occasions in July and August of 1999 within days of the Judiciary Committee's hearing on S. 1172 at which he spoke in support of the legislation. (The Iowa Republican presidential straw poll took place August 14, 1999. *The Washington Post* reported that at least one of the flights was to Iowa.) Hatch reimbursed the company a total of \$18,961 in five separate payments, which represents the price of a first-class air ticket for each passenger.<sup>10</sup> These payments cover just a fraction of the actual cost of operating Schering-Plough's corporate jet, a Gulfstream IV. A charter service operating at Reagan National Airport quotes a price of \$30,000 to fly 2-3 people round-trip from Washington to Des Moines. [Table 4]

### 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 drug giant hired several key Democrats with strong ties to both the Clinton Administration and liberal leaders in Congress, especially on the Judiciary Committees. In June 1999, 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 Sen. Richard Shelby (R-Ala.) joined the team. For good measure, Schering-Plough recently hired former House Appropriations Committee Chairman Bob Livingston. Below are some of Schering-Plough's lobbyists, their firms and recent earnings. (All data comes from lobby disclosure reports filed with the Clerk of the House and Secretary of the Senate pursuant to the Lobby Disclosure Act of 1995.)

- **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 in February 1999. The former Assistant Special Prosecutor and Chief of the Watergate Task Force and Democratic Minority Counsel for the Senate Whitewater hearings helped earn a total of \$240,000 from Schering-Plough for his firm in 1999 and 2000.
- **Linda Daschle** of Baker, Donelson, Bearman & Caldwell, P.C., registered last year to lobby on H.R. 1598 and S. 1172, joining such power players as former Republican Senate Majority Leader Howard Baker on the Claritin team. Her firm received a total of \$470,000 from Schering-Plough in 1999 and 2000 for lobbying the House and Senate. Daschle, wife of Senate Minority Leader Tom Daschle, reported that she “voluntarily will not lobby U.S. Senate.”
- **Vic Fazio**, former California representative and Chair of the House Democratic Caucus, is now a

partner in the firm of Clark & Weinstock. Fazio has also registered to lobby on H.R. 1598 and S. 1172. His firm reported making a combined total of \$640,000 from Schering-Plough in 1999 and 2000.

- **Hall, Green & Associates** bring strong ties to the Senate Republican Leadership and the Appropriations process to the Claritin team. The firm registered to lobby the House and Senate on H.R. 1598 and S. 1172 on June 1, 1999 and received a total of \$140,000 from Schering-Plough in 1999 and 2000. John Green was formerly the executive director of Senate Majority Leader Trent Lott's political action committee as well as Deputy Chief of Staff for Sen. Lott. Stewart Hall was Sen. Richard Shelby's Legislative Director from 1992 to 1996, acting as the Senator's liaison to the powerful 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 reported lobbying the Patent and Trademark Office – the agency to which H.R. 1598/S. 1172 would have given 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 forms:

- **Clark & Weinstock** – The firm's new partner, former Rep. Vic Fazio (D-Calif.) lists the Executive Branch as his sole lobbying target.<sup>11</sup>
- **Wunder, Knight, Thelen, Forscey & DeVierno** – Partner Peter Knight was a top fundraiser for Clinton-Gore and campaign manager for the 1996 Clinton-Gore campaign. His firm reported receiving \$160,000 from Schering-Plough in 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 & Trademark Office, on H.R. 1598/S. 1172.
- **Swidler, Berlin, Shereff, Friedman** – Also listed the Patent and Trademark Office on their disclosure form. The firm received a total of \$340,000 during 1999 and 2000.
- **Parry, Romani & DeConcini, Inc.** – The firm's partners include former Sen. Dennis DeConcini (D-Ariz.) and Thomas Parry, former Chief Counsel to Senate Judiciary Committee Chairman Hatch. The firm also employs Sen. Hatch's son Scott as research director. It received a total of \$240,000 from Schering-Plough in 1999 and 2000.

## **The Stakes Are High for Consumers**

H.R. 1598/S.1172 would have allowed, in all likelihood, a three-year patent extension 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. The stealth legislation that surfaced this summer (see Chronology section below for details) would have also allowed a three-year patent extension for Claritin – although it would have transferred the review process from the Patent and Trademark Office to a federal Court of Claims. In either case, consumers would pay through the nose. A three-year patent extension for all seven "pipeline" drugs would cost \$11 billion over 10 years, with Claritin accounting for two-thirds of that total, according to a University of Minnesota study.<sup>12</sup>

The real impact of the legislation on U.S. health care costs could be much worse. Waiting in the wings to see if the Claritin patent extension bill becomes law 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.<sup>13</sup> If some form of a Claritin patent extension gets signed into law, Congress likely would be bombarded by other 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)?

## **Chronology of Legislative Events/Soft Money Contributions**

A chronology of key legislative events on the Claritin patent extension effort and notable soft money contributions by Schering-Plough is contained in Table 4. It shows the suspicious relation between legislative action and Schering-Plough's contributions. For instance, the chronology shows Torricelli's introduction of S. 1172 a day after the company's \$50,000 contribution to the DSCC; the timing of Hatch's flights on the corporation's jet relative to his Judiciary Committee hearing on S. 1172; the \$50,000 given to the Ashcroft Committee on September 30, 1999, at the height of Senate Judiciary Committee deliberation over S. 1172; and how Sen. Arlen Specter (R-Penn.) tried to attach a Claritin patent extension to the Agriculture Department appropriations bill during the same time period that Schering-Plough gave \$200,000 in soft money to Republican campaign committees.

The chronology also tracks the Claritin patent extension bill as it moved in strange and surreptitious ways through the legislative process in late 1999 and the summer of 2000. First, the Senate Judiciary Committee held a hearing on Torricelli's bill in August 1999. Sen. Hatch did all he could to ram the bill through his Judiciary Committee in October and November in an end-of-the-year rush. But the bill was indefinitely postponed after intense media scrutiny, protests from committee Democrats and signals from several Republican Senators up for re-election that they would not support Hatch's efforts.

The patent extension resurfaced in June 2000 amid even more controversy. This time it was in legislation written by an anonymous senator. The new proposal was considered even more costly to consumers

than S. 1172 because it would automatically extend the Claritin patent while a Federal judge studied the company's request for an extension. There also was reportedly an attempt to attach the Claritin patent extension to a Military Construction Appropriations bill. That tactic was considered so sneaky that a nonprofit group, The Seniors Coalition, offered a \$1,000 reward to anyone who could identify "senator anonymous." Sen. Hatch admitted he was responsible for the text of the bill, but insisted he personally did not try to slip the pro-Claritin language into an appropriations bill.<sup>14</sup>

Eventually, appropriators rejected the idea of adding controversial patent provisions to spending bills. Schering-Plough lobbyist Bob Livingston has reportedly advised the company that any Claritin patent extension must win approval in the Senate Judiciary Committee before it can be considered by all of Congress.<sup>15</sup>

## The GAO Report

With the release of the General Accounting Office (GAO) report on August 10, 2000, came signs that Schering-Plough was preparing for another attempt at a patent extension. Schering-Plough's lobbyists claim the new GAO report supports the company's argument for extending Claritin's patent. The company contends that the federal Food and Drug Administration needlessly delayed the approval process for Claritin. At one point, Schering-Plough said an FDA reorganization "resulted in inefficiencies and delay when new reviewers rereviewed data that had been accepted by the first reviewers."<sup>16</sup>

While it's true that the FDA took longer than the average time to approve Claritin (77 months compared to the average of 42.5 months for similarly classified pipeline drugs), it wasn't because of "inefficiencies" or needless delays by the government. GAO found that the FDA took 77 months to approve Claritin because of concerns about cancer (carcinogenicity) and the company's flawed application data. More specifically, the FDA focused on tumors found in mice and rats tested with Claritin, and the question of whether the tablet and capsule forms of Claritin are absorbed into the body in equivalent ways. (This is known as "bioequivalence.")

Here are some facts that Public Citizen has gleaned from the GAO report about safety and efficacy issues that concerned the FDA:

- The company claims that an FDA reorganization caused inefficiency and delays at the agency, but the GAO says "we have *no evidence* that the reorganization affected the approval of Claritin." (italics added)
- Schering-Plough submitted 37 major amendments to the FDA during Claritin's New Drug Application (NDA). (Major amendments may be submitted either at the sponsor's own initiative or in response to an issue raised by the FDA.) In contrast, 97 percent of the NDAs submitted to the FDA between 1987 and 1992 required just 10 or fewer amendments.
- Of these 37 major amendments, 18 dealt with animal carcinogenic studies or establishing the bioequivalence of Claritin capsules and tablets.

- The FDA became concerned that Schering-Plough's carcinogenicity testing was inadequate after the agency initially found Claritin approvable. That's because laboratory animals were not given the maximum tolerated dose (MTD) of Claritin during tests. At the time, MTD was the "gold standard" for cancer tests.
- A mouse cancer study was done at one-fourth to one-third of the MTD, doses that the FDA was concerned might be too low to properly evaluate the cancer-causing potential of Claritin. Even at the inappropriately lower doses there were findings of increased tumors in the mouse study.
- With respect to bioequivalency, Schering-Plough conducted clinical tests with a capsule form of Claritin rather than the tablet the company intended to market. The data submitted to the FDA by Schering-Plough did not support the bioequivalence of capsule and tablet forms of Claritin, according to GAO. "After FDA biopharmaceutics experts reviewed the 13 studies Schering-Plough submitted to establish the bioequivalence of the tablet and capsule, they concluded that the data did not support that they were equivalent."
- In addition, the FDA initially gave the drug a low priority in the approval process because FDA questioned the need for Claritin. "[T]here was little or no therapeutic gain from the drug compared with already manufactured drugs," the FDA reported.

In conclusion, it's important to stress that the FDA's first responsibility is to the American public and the FDA alone has the sole responsibility for deeming a drug safe and effective. Schering-Plough should not get an extended monopoly for three years – at a cost of \$7.3 billion to consumers over 10 years – because it submitted flawed reports.

**Table 1: Schering-Plough's Soft Money Contributions  
to Party Committees, 1995 – 2000**

Democrat			Republican		
Democratic Congressional Campaign Committee	11/3/00	\$10,000	National Republican Senatorial Committee	10/6/00	\$50,000
Democratic Senatorial Campaign Committee	9/21/00	\$10,000	National Republican Congressional Committee	9/5/00	\$100,000
Democratic Senatorial Campaign Committee	9/13/00	\$50,000	Republican National Committee	8/9/00	\$100,000
Democratic Congressional Campaign Committee	5/28/99	\$25,000	Republican National Committee	7/20/00	\$100,000
Democratic Senatorial Campaign Committee	5/26/99	\$50,000	2000 Republican Senate/House Dinner Committee	5/3/00	\$20,000
Democratic Congressional Campaign Committee	3/25/99	\$25,000	Republican National Committee	4/28/00	\$15,000
			Ashcroft Victory Committee - Joint Fund	9/30/99	\$50,000
			National Republican Senatorial Committee	9/15/99	\$50,000
			National Republican Congressional Committee	7/16/99	\$50,000
			1999 Republican Senate/House Dinner Committee	6/3/99	\$20,000
			Republican National Committee	5/5/99	\$15,000
			Republican National Committee	3/31/99	\$2,000
			National Republican Congressional Committee	3/22/99	\$25,000
			National Republican Congressional Committee	3/22/99	\$75,000
			National Republican Congressional Committee	3/10/99	\$5,000
<b>Total (1999-2000)</b>		<b>\$170,000 (20%)</b>	<b>Total (1999-2000)</b>		<b>\$677,000 (80%)</b>
Democratic National Committee	11/3/98	\$1,000	National Republican Congressional Committee	10/9/98	\$5,000
Democratic Senatorial Campaign Committee	3/12/98	\$50,000	National Republican Senatorial Committee	9/30/98	\$50,000
Democratic Senatorial Campaign Committee	5/19/97	\$15,000	National Republican Congressional Committee	9/17/98	\$100,000
			National Republican Congressional Committee	9/16/98	\$1,021
			Republican National Committee	3/11/98	\$15,000
			1997 Republican Senate/House Dinner Committee	6/11/97	\$20,000
			Republican National Committee	5/21/97	\$15,000
			Republican National Committee	5/15/97	\$15,000
<b>Total (1997-1998)</b>		<b>\$66,000 (23%)</b>	<b>Total (1997-1998)</b>		<b>\$221,021 (77%)</b>
Democratic Senatorial Campaign Committee	6/19/96	\$15,000	National Republican Senatorial Committee	10/25/96	\$50,000
			National Republican Congressional Committee	9/17/96	\$100,000
			Republican National Committee	8/28/96	\$15,000
			National Republican Congressional Committee	8/11/96	\$585
			National Republican Senatorial Committee	8/7/96	\$585
			1996 Republican Senate/House Dinner Committee	7/19/96	\$10,000
			National Republican Senatorial Committee	7/15/96	\$5,000
			Republican National Committee	6/28/96	\$3,000
			National Republican Senatorial Committee	6/27/96	\$2,000
			1996 Republican Senate/House Dinner Committee	6/26/96	\$10,000
			Republican National Committee	6/6/96	\$100,000
			National Republican Senatorial Committee	6/5/96	\$10,000
			National Republican Senatorial Committee	11/6/95	\$25,000
			Republican National Committee	5/24/95	\$15,000
			1995 Republican Senate/House Dinner Committee	3/15/95	\$20,000
			National Republican Congressional Committee	3/1/95	\$15,000
<b>Total (1995-1996)</b>		<b>\$15,000 (4%)</b>	<b>Total (1995-1996)</b>		<b>\$381,170 (96%)</b>
<b>Total (1995-2000)</b>		<b>\$251,000 (16%)</b>	<b>Total (1995-2000)</b>		<b>\$1,279,191 (84%)</b>

Note: The National Republican Senate-House Dinner Committee is an annual, joint event to raise funds for the NRCC and NRSC.

Source: Figures compiled by Public Citizen from FECInfo ([www.tray.com](http://www.tray.com)).

**Table 2: Schering-Plough's PAC Contributions to Congressional Candidates, 1995 – 2000**

<b>Cycle</b>	<b>Democrats</b>		<b>Republicans</b>		<b>Total</b>
<b>1999-2000</b>	\$80,500	34%	\$154,850	66%	<b>\$235,350</b>
<b>1997-1998</b>	\$39,000	23%	\$130,500	77%	<b>\$169,500</b>
<b>1995-1996</b>	\$32,000	22%	\$110,500	76%	<b>\$142,500</b>
<b>Total</b>	<b>\$151,500</b>	<b>28%</b>	<b>\$395,850</b>	<b>72%</b>	<b>\$547,350</b>

Source: FECInfo ([www.tray.com](http://www.tray.com)).

**Table 3: Contributions to U.S. Senate Judiciary Committee Members by Schering-Plough's PAC or Executive Employees 1995 – 2000**

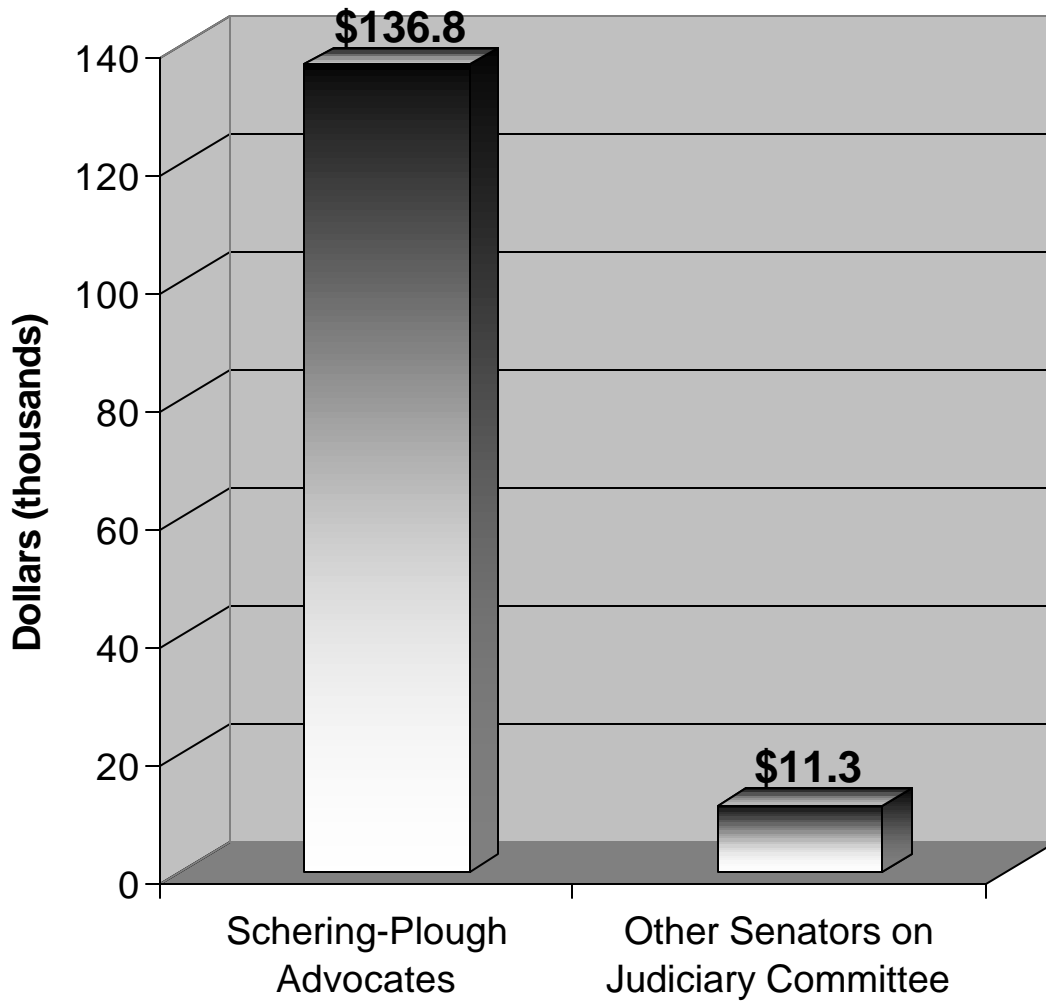
Senators For	Party	Amount	Position on Claritin Patent Extension	Congressional Terms on this Committee**
Ashcroft (Mo.)	R	\$52,000*	co-sponsor of S. 1172	105 <sup>th</sup> -106 <sup>th</sup>
Torricelli (N.J.)	D	\$36,800	lead sponsor of S. 1172	106 <sup>th</sup>
Hatch (Utah)	R	\$20,000	publicly endorsed S. 1172	104 <sup>th</sup> -106 <sup>th</sup>
Thompson (Tenn.)	R	\$11,514	sponsor of 1997 attempt	104 <sup>th</sup> -105 <sup>th</sup>
Sessions (Ala.)	R	\$10,448	co-sponsor of S. 1172	105 <sup>th</sup> -106 <sup>th</sup>
Specter (Penn.)	R	\$6,000	sponsor of 1996 attempt	104 <sup>th</sup> -106 <sup>th</sup>
Thurmond (S.C.)	R	\$0	co-sponsor of S. 1172	104 <sup>th</sup> -106 <sup>th</sup>
<b>Total</b>		<b>\$136,762</b>		
<b>Senators Against or Undeclared</b>				
DeWine (Ohio)	R	\$7,000	not a co-sponsor	104 <sup>th</sup> -106 <sup>th</sup>
Abraham (Mich.)	R	\$1,000	not a co-sponsor	104 <sup>th</sup> -106 <sup>th</sup>
Kyl (Ariz.)	R	\$1,000	not a co-sponsor	104 <sup>th</sup> -106 <sup>th</sup>
Grassley (Iowa)	R	\$1,000	not a co-sponsor	104 <sup>th</sup> -106 <sup>th</sup>
Simpson (Wyo.)	R	\$1,000	not a co-sponsor	104 <sup>th</sup>
Smith (N.H.)	R	\$300	not a co-sponsor	106 <sup>th</sup>
Biden (Del.)	D	\$0	not a co-sponsor	105 <sup>th</sup> -106 <sup>th</sup>
Brown (Colo.)	R	\$0	not a co-sponsor	104 <sup>th</sup>
Durbin (Ill.)	D	\$0	not a co-sponsor	105 <sup>th</sup>
Feingold (Wis.)	D	\$0	not a co-sponsor	104 <sup>th</sup> -106 <sup>th</sup>
Feinstein (Calif.)	D	\$0	not a co-sponsor	104 <sup>th</sup> -106 <sup>th</sup>
Heflin (Ala.)	D	\$0	not a co-sponsor	104 <sup>th</sup>
Kennedy (Mass.)	D	\$0	not a co-sponsor	104 <sup>th</sup> -106 <sup>th</sup>
Kohl (Wis.)	D	\$0	not a co-sponsor	104 <sup>th</sup> -106 <sup>th</sup>
Leahy (Vt.)	D	\$0	not a co-sponsor	104 <sup>th</sup> -106 <sup>th</sup>
Schumer (N.Y.)	D	\$0	not a co-sponsor	106 <sup>th</sup>
Simon (Ill.)	D	\$0	not a co-sponsor	104 <sup>th</sup>
<b>Total</b>		<b>\$11,300</b>		

Source: Figures compiled by Public Citizen from Center for Responsive Politics ([www.opensecrets.org](http://www.opensecrets.org)) data.

\*Includes a \$50,000 soft money contribution to the Ashcroft Victory Committee, a joint fund-raising account set up by Ashcroft and the National Republican Senatorial Committee.

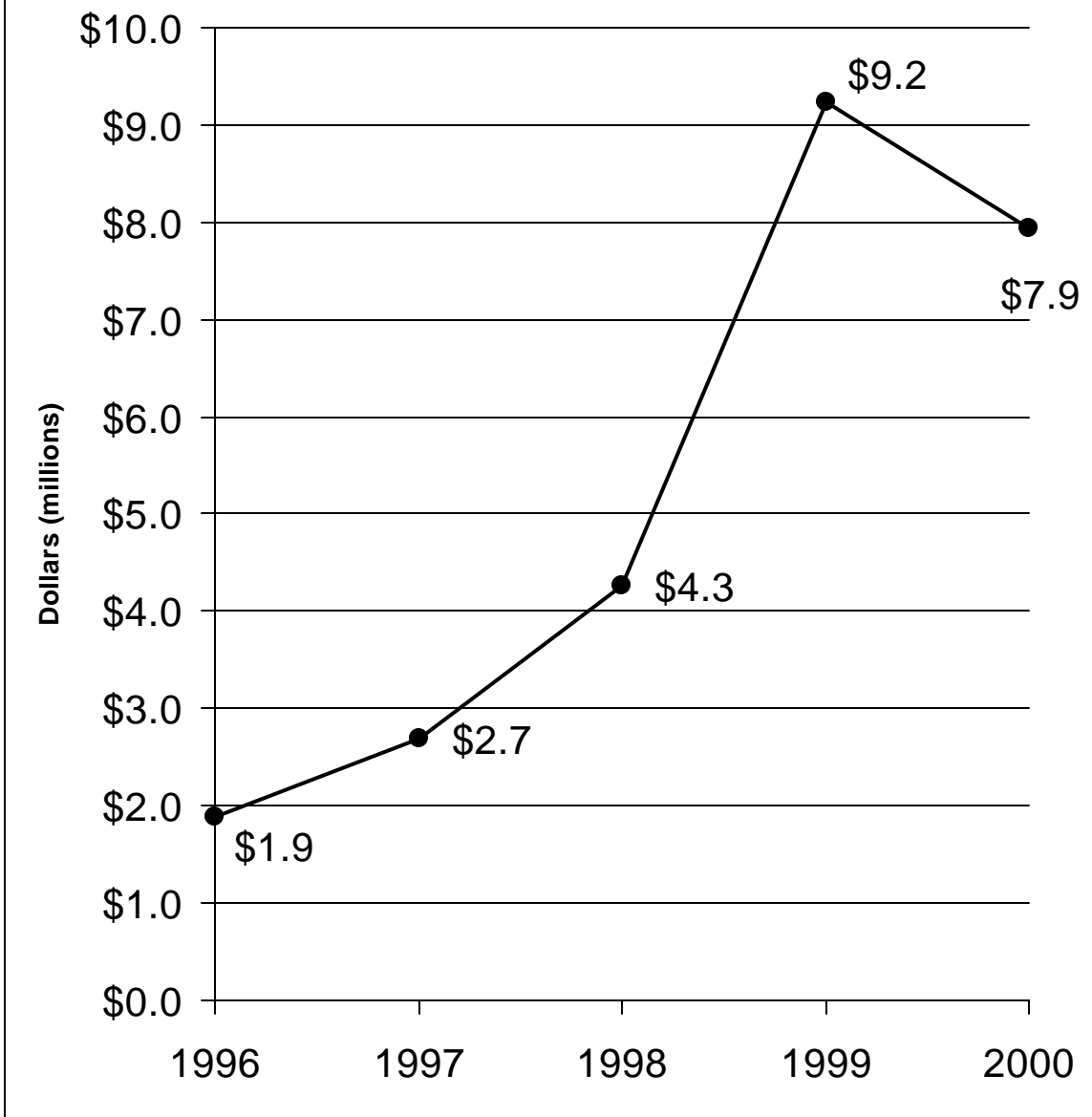
\*\* Refers only to Congressional terms that coincide with Schering-Plough's patent extension effort. In other words, only the Congressional terms since 1995.

**Figure 1: Total Contributions to Senate Judiciary Committee Members Who Have Supported Claritin Patent Legislation vs. Those Committee Members Who Are Opposed Or Undeclared (1995 – 2000)**



Source: Figures compiled by Public Citizen from Center for Responsive Politics ([www.opensecrets.org](http://www.opensecrets.org)) data.

**Figure 2: Schering-Plough Lobbying Expenditures (1996 – 2000)**



Source: Lobby disclosure reports filed with the Clerk of the House and Secretary of the Senate pursuant to the Lobby Disclosure Act of 1995.

**Table 4: Legislative Events on Claritin Patent Extension and Notable Soft Money Contributions and Expenditures by Schering-Plough**

Legislative Activity	Contributions and Expenditures
<p><b>Spring 1996</b> Schering-Plough's appeal to Congress began in the spring of 1996, not long after Searle &amp; Co. received a patent extension for its arthritis drug.</p> <p><b>Summer 1996</b> Sen. Arlen Specter (R-Penn.) tries unsuccessfully to attach two-year Claritin patent extension to the Agriculture Department appropriations bill.</p> <p><b>Early 1997</b> Schering-Plough begins to court Senators to support legislation to create a stacked-deck patent review process for Claritin and six other pipeline drugs.</p> <p><b>May 1998</b> Rep. Ed Bryant's (R-Tenn.) effort to insert Claritin patent extension proposal into unrelated patent legislation in House Judiciary Subcommittee on Courts and Intellectual Property fails.</p> <p><b>October 1998</b> Sen. Frank Lautenberg (D-N.J.) tries to attach Claritin's pipeline drug proposal to omnibus appropriations bill.</p>	<p><b>1995-1996</b> Schering-Plough gives a total of only \$15,000 in soft money to Democratic Party committees while giving \$381,170 to Republican Party committees.</p> <p><b>June 6, 1996</b> Schering-Plough contributes \$100,000 in soft money to the RNC.</p> <p><b>September 17, 1996</b> \$100,000 in soft money to the NRCC.</p> <p><b>October 25, 1996</b> \$50,000 in soft money to the NRSC.</p> <p><b>1997-1998</b> Schering-Plough gives a total of \$66,000 in soft money to Democratic Party committees and \$220,000 to Republican Party committees.</p> <p><b>March 12, 1998</b> \$50,000 in soft money to the DSCC (first-time ever contribution), which was vice-chaired by Sen. Robert Torricelli (D-N.J.).</p> <p><b>September 17, 1998</b> \$100,000 in soft money to the NRCC.</p> <p><b>September 30, 1998</b> \$50,000 in soft money to the NRSC.</p>

<p><b>April 28, 1999</b> Rep. Bryant introduces Claritin's pipeline drug patent extension proposal (H.R. 1598).</p> <p><b>May 27, 1999</b> Sen. Torricelli introduces Claritin's pipeline drug patent extension proposal (S. 1172).</p> <p><b>July 1, 1999</b> House Judiciary Subcommittee on Courts and Intellectual Property holds hearing on H.R. 1598.</p> <p><b>August 4, 1999</b> Sen. Orrin Hatch (R-Utah), chair of the Judiciary Committee, holds hearing on S. 1172.</p>	<p><b>1999- July 2000</b> Schering-Plough gives a total of \$100,000 in soft money to Democratic Party committees and \$428,500 to Republican Party committees.</p> <p><b>March 22, 1999</b> \$100,000 in soft money to the NRCC.</p> <p><b>March 25, 1999</b> \$25,000 in soft money to the DCCC.</p> <p><b>May 26, 1999</b> \$50,000 in soft money to the DSCC, which is chaired by Sen. Torricelli.</p> <p><b>May 28, 1999</b> Another \$25,000 to the DCCC brings Schering-Plough's soft money donations to the Democrats to \$100,000 for 1999. In just the first nine months of 1999, Claritin's makers have given more than the total it gave to Democrats in the preceding four years.</p> <p><b>July 22 - August 21, 1999</b> Sen. Hatch's presidential campaign committee makes five reimbursements totaling \$18,961.50 to Schering-Plough for use of its corporate jet. At least one trip was to Iowa where a Republican Party straw poll for the presidency was held on August 14.</p> <p><b>September 15, 1999</b> \$50,000 in soft money to the NRSC.</p>
---	--

**November 4, 1999**

Sen. Torricelli raises prospect of amending S. 1172 into unrelated legislation during Senate Judiciary Committee mark up.

**November 10, 1999**

Sen. Hatch schedules Senate Judiciary Committee mark-up of S. 1172.

**November 17, 1999**

Consideration of S. 1172 indefinitely postponed by Senate Judiciary Committee. Senators cite Democratic opposition and hectic end-of-year schedule as reasons for inaction.

**May 26, 2000**

Sen. Judd Gregg (R-N.H.) slips patent extension for his alma mater Columbia University into Agriculture Department appropriations bill.

**June 16, 2000**

ABC News reports that an anonymous senator tried to attach a Claritin patent extension amendment to a Military Construction appropriations bill during a closed-door House-Senate conference.

**September 30, 1999**

\$50,000 to Ashcroft Victory Committee, a nonfederal joint fundraising committee set up with the NRSC. Sen. John Ashcroft (R-Mo.) chairs a key Judiciary subcommittee with drug patent oversight.

**February 14, 2000**

Schering-Plough reports lobbying expenses of \$7 million in second half of 1999, bringing year's total lobbying bill to \$9.2 million – more than double 1998 expenditures.

**April 28, 2000**

\$15,000 in soft money to Republican National Committee.

**May-June 2000**

Schering-Plough's PAC contributes \$31,000 in "hard" money to candidates, including \$5,000 each to H.R. 1598 co-sponsors Rep. Jim Gibbons (R-Nev.) and Rep. Jim McDermott (D-Wash.). Company also gives \$5,000 each to U.S. Senate candidate Rick Lazio (R-N.Y.) and Rep. Bill Thomas (R-Calif.), sponsor of pro-drug company bill that would offer

**June 21, 2000**

The Seniors Coalition offers a \$1,000 reward to anyone who can identify “senator anonymous.”

**June 25, 2000**

Sen. Hatch says, “I’m ‘Mr. Anonymous,’” but qualifies his confession. While his staff did author the language, Hatch says he did not try to sneak it into the appropriations bill.

**June 26, 2000**

ABC News says other leading suspects – Senators Gregg, Torricelli and Conrad Burns (R-Mont.) – deny that they tried to sneak Claritin’s patent extension into the military appropriations bill.

**July 2000**

Appropriators reject Claritin proposal because they don’t want their bills cluttered with controversial provisions.

**August 10, 2000**

*Roll Call* says Livingston has advised Schering-Plough that patent extension can’t be slipped into an appropriations bill; the Senate Judiciary Committee must first pass it.

senior citizens prescription drug coverage through private insurers instead of Medicare.

**June 2000**

Former House Appropriations Committee Chairman Bob Livingston hired by Schering-Plough to lobby for patent extension.

**July 20, 2000**

\$100,000 in soft money to RNC.

**August 9, 2000**

\$100,000 in soft money to RNC.

**September 5, 2000**

\$100,000 in soft money to the NRCC.

**September 13, 2000**

\$50,000 in soft money to DSCC

**October 6, 2000**

\$50,000 in soft money to the NRSC.

--	--

## Endnotes

1. Chris Adams, "Delays Disclosed in FDA Process to Approve Claritin, Other Drugs," *Wall Street Journal*, August 14, 2000, page B8. Claritin's worldwide sales totaled \$2.7 billion in 1999, with U.S. sales accounting for \$2.3 billion.
2. Prof. Steven Schondelmeyer, "Patent Extension of Pipeline Drugs: Impact on US Health Care Expenditures," PRIME Institute, University of Minnesota, July 28, 1999. Schondelmeyer asserts that a patent extension for Claritin would keep generic alternatives out of the market entirely for three years, then it would effectively slow consumers' purchases of generic alternatives over the next seven years, as the generic drugs struggled to market themselves on a par with Claritin.
3. Campaign contributions, including soft money, from the 1996 election cycle through July 2000 and lobbying expenditures from 1996 through 1999, tallied by Public Citizen. In that time, Schering-Plough spent \$18.2 million on lobbying, \$1.2 million in soft money and \$509,500 on "hard" money contributions to candidates.
4. Center for Responsive Politics and FECInfo soft money databases show the Sept. 30, 1999 \$50,000 contribution to the Ashcroft Victory Committee. The *St. Louis Post-Dispatch* also cited the contribution in an editorial, "The Senator from Claritin," July 5, 2000.
5. GAO Health, Education and Human Services Division, "Prescription Drugs: Many Factors Affected FDA's Approval of Selected 'Pipeline' Drugs," August 10, 2000.
6. Paul Kane, "Report Restarts Claritin Battle," *Roll Call*, August 10, 2000, page 1 and Chris Adams, "Delays Disclosed in FDA Process to Approve Claritin, Other Drugs," *Wall Street Journal*, August 14, 2000, page B8. Kane's article said: "Claritin lobbyists now say a GAO report, a draft of which is due out today, will vindicate the drug maker's claim that the Food and Drug Administration took too long to approve the patent for the drug." The story by Adams reported that Schering-Plough "said the report's conclusions bolster its case, which it will continue to press in Washington."
7. Based on Public Citizen's review of lobby disclosure reports filed by Schering-Plough and other drug companies with the Clerk of the House and Secretary of the Senate pursuant to the Lobby Disclosure Act of 1995.
8. Interview with Republican committee staff member (name withheld).
9. Ruth Marcus and Juliet Eilperin, "Party's Targets Among Sponsors of Social Events," *Washington Post*, August 17, page A13. Story reports that while Democrats assail drug companies on the campaign trail, Bristol-Myers Squibb Co. and Merck & Co. were "gold sponsors" of Sen. John Breaux's Mardi Gras party at the Democratic convention in Los

Angeles and Schering-Plough was a “vice chair” of DSCC events at the convention.

10. Charles R. Babcock, “Patent Fight Tests Drug Firm’s Clout; Claritin Maker Goes All Out in Congress,” *Washington Post*, Oct. 30, 1999, page 1. Babcock reported that federal campaign rules allow a candidate to use a corporate jet for the price of first-class airline ticket. Hatch’s spending report showed that one payment was made the day after the hearing on S. 1172 for a trip to Iowa.
11. Clark & Weinstock lobby disclosure reports filed with the Clerk of the House and Secretary of the Senate pursuant to the Lobby Disclosure Act of 1995. Reports for 1999 show that while the firm lobbied the House, Senate and White House, Fazio only lobbied the Executive Branch.
12. Schondelmeyer, see n. 2.
13. Generic Pharmaceutical Industry Association, “Top 20 Rx Drugs Coming Off Patent by December 31, 2005.”
14. Jackie Judd, ABC NEWS, “Mystery Senator Pushes Bill,” *World News Tonight*, June 16, 2000 and ““Senator Anonymous Revealed,”” *World News Tonight*, June 24, 2000. In the first story, Judd reported that an anonymous senator had written patent extension legislation and was reportedly trying to attach it to a military appropriations bill. In the second story, Sen. Hatch admitted he was responsible for the legislation but denied that he tried to attach it to the military spending bill during a closed-door House-Senate conference. However, Hatch did say someone on his staff might “have easily explored” the stealth strategy.
15. Kane, see n. 6.
16. Adams, see n. 1.

---

<sup>1</sup> \$2.3 billion in Claritin sales in 1999.

<sup>2</sup> July 1999 study by Prof. Steven Schondelmeyer, University of Minnesota PRIME Institute.

<sup>3</sup> \$19.8 million.

<sup>4</sup> Ashcroft.

<sup>5</sup> Gao title

<sup>6</sup> FDA.

<sup>7</sup> Lobbying since 1996.

<sup>8</sup> Conversation with Repub staff.

<sup>9</sup> DSCC Convention party.

<sup>10</sup> Hatch to Iowa.

<sup>11</sup> while the firm lobbies the House, Senate and White House, Fazio's disclosure form is noted "Executive Branch only.

<sup>12</sup> \$11 billion cost to consumers.

<sup>13</sup> 20 blockbuster drugs await

<sup>14</sup> hatch, abc

<sup>15</sup> Bob Livingston advises SP.

<sup>16</sup> WSJ 8.14.00 article.