

A Record Year for the Pharmaceutical Lobby in '07 Washington's largest lobby racks up another banner year on Capitol Hill

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Data analysis by Helena Bengtsson

Washington, June 24, 2008 – Washington's largest lobby, the pharmaceutical industry, racked up another banner year on Capitol Hill in 2007, backed by a record \$168 million lobbying effort, according to a Center for Public Integrity analysis of federal lobbying data. Among the industry's successes: getting two controversial laws extended and thwarting congressional efforts to restrict media ads for prescription drugs.

The spending represents a 32 percent jump over 2006. Driven in part by a busy legislative calendar dominated by issues critical to the industry, the effort raised the amount spent by drug interests on federal lobbying in the past decade to more than \$1 billion. Pharmaceutical, medical device, and other health product manufacturers, together, spent more than \$189 million on lobbying last year, another record and nearly three times the \$67 million they spent in 1998, the first full year for which complete records and totals are available.

More than 90 percent of the total was spent by 40 companies and three trade groups: the Pharmaceutical Research and Manufacturers of America ([PhRMA](#)), the [Biotechnology Industry Organization](#), and the Advanced Medical Technology Association.

The spending binge last year may have also been fueled by the previous November's Democratic takeover of Congress. After the Democratic sweep of the House of Representatives, several long-standing critics of the industry, such as Representative Henry Waxman of California, assumed leadership roles of powerful committees. Intent on closer oversight of the industry, they conducted a series of hearings on issues such as drug safety, pharmaceutical pricing, and availability of generic medicines. Waxman and some fellow Democrats also tried to give more regulatory power to the Food and Drug Administration and revisit the Medicare Prescription Drug, Improvement, and Modernization Act, a law that came into being in 2003 after heavy industry lobbying. The legislation, which resulted in the largest overhaul of Medicare in its history, provides prescription drug coverage through the program.

"After the Democratic victory in November 2006, [the industry] had to scramble," says Ira Loss, a pharmaceutical analyst with Washington Analysis Corporation. "They had to hire more Democratic lobbyists." Ken Johnson, senior vice president of communications at PhRMA, acknowledged that the industry faced "a difficult political environment." But he maintained that PhRMA doesn't see having a Democratic Congress as a disadvantage. "We don't look at it through the prism of Democrats and Republicans. We look at it in terms of those who support free market policies and those who don't."

A review of campaign contributions reveals that the industry has dramatically increased donations to the Democrats since their victory in November 2006. In the current election cycle so far, for the first time on record, the pharmaceutical and health products industry has given slightly more money to Democrats than Republicans, according to the Center for Responsive Politics. In the 2006 cycle, Democrats received only 31 percent of the contributions from the industry, while the Republicans received 67 percent.

More than \$6.8 million of the \$14.4 million the pharmaceutical and health product industry gave in contributions went to members of three committees that regulate the industry: the House Committee on Energy and Commerce, House Committee on Ways and Means, and Senate Committee on Health, Education, and Labor.

As in previous years, the trade group PhRMA led the drug industry in lobbying, spending close to \$23 million in 2007, a 26 percent jump over 2006. Among drug companies, Amgen Inc., a biomedical firm based in Thousand Oaks, California, led by spending more than \$16.2 million, and [Pfizer](#), the world's largest pharmaceutical company, notched second with \$13.8 million. Other big spenders last year included Roche Holding AG (\$9 million), [Sanofi-Aventis](#) (\$8.4 million), [GlaxoSmithKline](#) (\$8.2 million), Johnson & Johnson Inc. (\$7.7 million) and the trade group Biotechnology Industry Organization (\$7.2 million).

The Industry Agenda

Lobbying disclosure reports filed with Congress reveal that pharmaceutical interests lobbied on an array of issues. Among the industry's top achievements:

- blocking the importation of inexpensive drugs from other countries;
- protecting pharmaceutical patents both within the United States and abroad; and
- ensuring greater market access for pharmaceutical companies in international free trade agreements.

Apart from these subjects, which have become "bread and butter" issues for the industry in recent years, lobbyists focused on a handful of legislation. One law they pushed forcefully was the reauthorization and expansion of the State Children's Health Insurance Program, or SCHIP, a federal plan that provides insurance to children. "They lobbied very hard for SCHIP," says analyst Loss. "More children insured means using more drugs." The industry had pressed to reauthorize the program for five years and expand it to cover an additional 4 million children — at a cost of \$35 billion in new funding. In a rare defeat for the industry, the measures were vetoed by President Bush, who in December extended the current program for 18 months.

The industry had better luck with two other laws it lobbied robustly to extend, the Prescription Drug User Fee Act and the Best Pharmaceuticals for Children Act. Both were reauthorized in the Food and Drug Administration Amendment Act of 2007, which became law last September. The User Fee Act was enacted in 1992 in response to complaints from drug companies and patients rights advocates about long lags in drug approval. It allows the FDA to collect funds — so-called "user fees" — from the industry to employ additional drug reviewers and bring medicines faster to the market.

The law's supporters point out that, since it was enacted, the average drug review time has considerably shortened. "In my opinion, that law has worked very well," says Washington Analysis's Loss. A September 2002 study by the U.S. General Accounting Office (now the Government Accountability Office) stated that "the median approval time for new drug applications for standard drugs dropped from 27 months to 14 months" from 1993 to 2001.

But critics contend that the emphasis on faster approval time has resulted in a watering down of safety issues. The same GAO study also found that "a higher percentage of drugs has been withdrawn from the market for safety-related reasons since PDUFA's enactment than prior to the law's enactment." The FDA disagreed with that conclusion, but critics argue that the User Fee Act creates a built-in conflict-of-interest by making the FDA dependent on the industry it regulates for budgetary resources. "The FDA should be "completely funded by the taxpayers," says Melody Petersen, author of the book *Our Daily Meds*. "With the user fee, the FDA has two customers — us and the drug industry."

This much is clear: The FDA's reliance on user fees has increased markedly over the years, rising 17-fold since 1993. According to the 2009 budget request, the agency is slated to collect \$628 million in user fees, an increase of \$79 million from this year and more than a quarter of the agency's overall budget of \$2.4 billion.

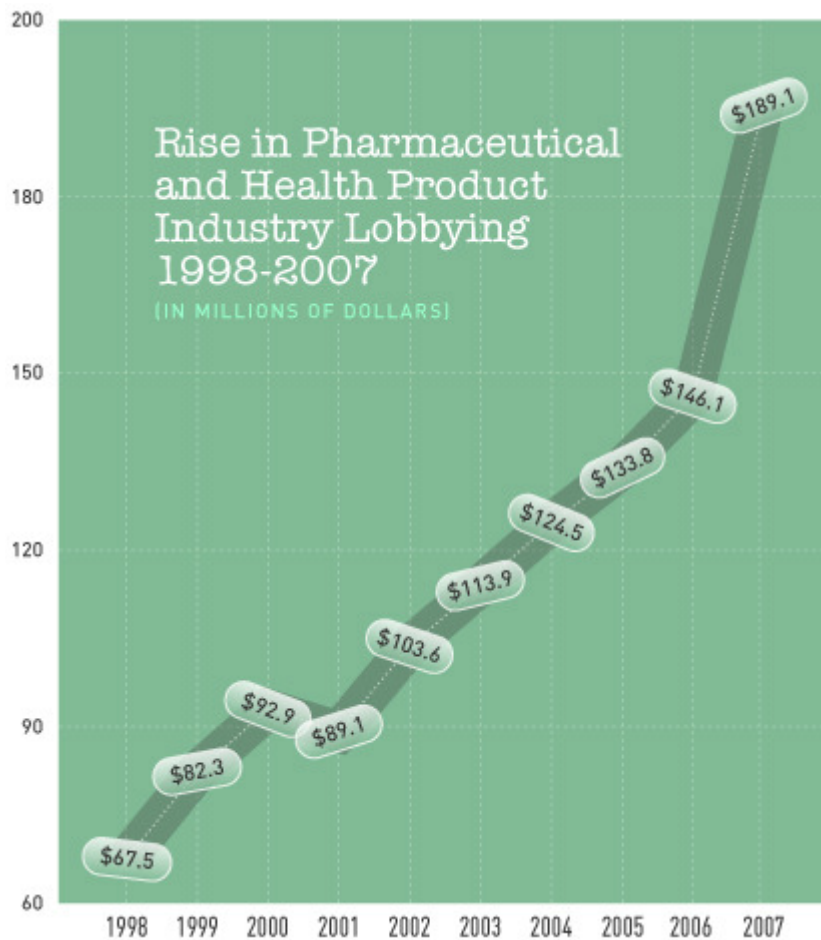
Another lobbying target was extension of the Best Pharmaceuticals for Children Act, a law designed to give the

Top Pharmaceutical Lobby Spenders in 2007

(IN MILLIONS OF DOLLARS)

COMPANY/ORGANIZATION	AMOUNT
Pharmaceutical Research & Manufacturers of America	\$22.7
Amgen Inc.	\$16.3
Pfizer Inc.	\$13.8
Roche Holding AG	\$9.0
Sanofi-Aventis	\$8.4
GlaxoSmithKline	\$8.2
Johnson & Johnson Inc.	\$7.7
Biotechnology Industry Organization	\$7.2
Novartis AG	\$6.6
Merck & Co.	\$6.6
Bristol-Myers Squibb Co.	\$6.0
Abbott Laboratories	\$4.6
Eli Lilly and Co.	\$4.3
Boehringer Ingelheim	\$4.1
AstraZeneca Pharmaceuticals	\$4.1
Bayer Corp.	\$4.1
Genzyme Corp.	\$2.7
Wyeth	\$2.5
Teva Pharmaceuticals	\$2.3
Baxter Healthcare Corp.	\$2.2

SOURCE: SENATE OFFICE OF PUBLIC RECORDS
DATA ANALYSIS: THE CENTER FOR PUBLIC INTEGRITY



with the User Fee legislation.

Drug companies also fought to keep Congress from limiting advertising aimed directly at the public. Consumers are hit with a daily barrage of ads for prescription drugs, targeting every condition from depression to erectile dysfunction. Industry spending on these so-called direct-to-consumer ads has jumped more than 20-fold in the past decade, helping push prescription drug sales to a record \$286.5 billion last year, according to IMS Health, a consulting firm. Consumer groups have long complained that the ads have led to widespread over-prescribing of drugs.

Last June, Representative Pete Stark, an industry critic, tried to reign in the direct ads, but ran into the pharmaceutical industry's powerful lobby. The law he introduced, the Fair Balance Prescription Drug Advertisement Act of 2007, never came out of committee. The industry argued that the ads help inform patients of potential diseases and encourage people to seek treatment at an early stage. But critics were not appeased. "All you have to do is watch the ads," says author Petersen. "It is not about educating the public. It is about selling drugs."

Michael Pell, Tuan Le and Mary Beth Lombardo contributed to the story. Funding for this report was provided by the Nathan Cummings Foundation.

industry incentive for testing medicines in children by granting additional patent protection for six months. According to the agency's website, labels of 148 drugs have been changed to include the findings of pediatric tests. First enacted in 1997, the law has allowed companies to reap windfall profits while delaying the entry of low-cost generic drugs. A joint investigation by the Center and HDNet's *Dan Rather Reports* last year found that half of the top 20 blockbuster drugs in 2006 were given six month extensions under this law. Included were drugs not usually associated with children's health, among them two top-selling anti-cholesterol drugs, Pfizer's Lipitor and Merck's Zocor, and Sanofi-Aventis's popular sleep inducer Ambien.

Last year, some lawmakers tried to trim the windfall. Three Senate bills would have capped the additional time given to protect a company's patent, depending on how lucrative the drug was. Drugs projected to earn more than \$1 billion per year would get three months — not six — of market exclusivity. The Senate passed one of these bills, but the House took no action on it. When another bill did clear both houses, the industry managed to get the exclusivity provision reauthorized without significant changes, just as it had