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The New York Times

Drug Lobby Got a Victory in Trade Pact Vote

By STEPHANIE SAUL

The sidewalk between the drug industry's headquarters in Washington and the United States trade representative's office has been taking a pounding from the wingtips of industry lobbyists.

The work of these drug industry courtiers, who represent what is arguably Washington's biggest and wealthiest lobby, appears to have succeeded in the Central American Free Trade Agreement. The agreement would extend the monopolies of drug makers and, critics say, lead to higher drug prices for the mostly impoverished people of the six Latin American countries it covers.

The accord cleared the Senate on Thursday but faces a difficult floor vote in the House of Representatives this month. The agreement's pharmaceutical provisions are a sideshow in the Congressional debate, eclipsed by concerns of the textile and sugar industries and the labor unions that their interests would not be protected.

In contrast, the agreement's pharmaceutical provisions, which provide five years of market exclusivity to brand-name drugs, have been front and center in Guatemala, where poor AIDS patients have marched in the streets to protest.

Orlando Sierra/Agence France-Presse — Getty Images

A protest in March over the trade pact's drug provisions led to clashes with the police in Guatemala.

The six countries affected by the pact "understand that the net effect of these pharmaceutical provisions will be to raise the price of medicine," said Frederick M. Abbott, a professor of international law at Florida State University. "The way they have to view it is that they're getting something out of the agreement that will give them a net trade benefit."

The problem with such an analysis, Professor Abbott said, is that the textile employers and agricultural producers gain, but the economic benefits may never flow down to the

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Drug Lobby Scored a Victory in Vote on the Central American Trade Accord

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people who cannot afford medicines.

According to Representative Sherrod Brown, Democrat of Ohio, the trade agreement is an example of how the pharmaceutical lobby rarely loses on trade issues, often by quietly working behind the scenes.

"A voter walking down the street would never think of the pharmaceutical industry's influence in another country through the U.S. trade representative," said Mr. Brown, who has criticized how the industry and other corporate interests shaped the trade accord.

The Pharmaceutical Research and Manufacturers of America, the drug industry association, is the single biggest influence group at the trade office, according to a new analysis by the Center for Public Integrity, a government watchdog group. The analysis is based on the sheer number of reports, 59, filed by lobbyists for the group since 1998.

The reports do not have to disclose how many individual contacts the lobbyists made.

The industry's primary interest at the trade office is protecting its intellectual property, which Peter R. Dolan, the chief executive of Bristol-Myers Squibb, recently called the "lifeblood" of the industry.

Like movies and software, pharmaceuticals require a lot of time, money and creativity to develop, yet they are fairly simple to replicate. The industry association estimates that intellectual property infringement in 21 countries costs its members $7 billion a year. Therein lies the problem for drug makers, and the reason they are fighting a global war to protect their patents.

In defending their efforts to extend intellectual property protection abroad, industry officials point out that pharmaceutical companies subsidize treatment for millions of people in developing countries. Bristol-Myers, for example, has invested $150 million to set up AIDS clinics and other charitable programs in Africa, a figure that does not include the low-cost drugs the company distributes there.

The industry association also argues that extending its patent protections worldwide will result in greater access to medications by encouraging drug makers to enter those markets.

"It provides certainty for companies to be able to market and sell their medicines in those particular markets," said Mark Grayson, a spokesman for the trade association.

The certainty, according to Professor Abbott of Florida State, results from the agreement's "highly restrictive market exclusivity rules which allow the originator companies to block any registration."

One of the most contentious provisions in the trade pact is a requirement that gives brand-name manufacturers market exclusivity for five years after a drug is registered in the countries, even if the 20-year patent has expired. A similar five-year period exists in the United States, but the trade agreement would require countries to enforce the five-year period even if the exclusivity period in the United States has already expired.

During that period, manufacturers who ultimately wanted to register a generic equivalent to the drug in that country would be barred from using the animal and human test data submitted for the drug's approval, a provision that critics say could delay the approval of generics beyond the five-year period.

By protecting marketing exclusivity, the industry says, the trade agreement would also spur innovation and encourage pharmaceutical companies to register drugs in the small countries, ultimately helping deliver those drugs to the needy.

It is a philosophical argument that the United States trade representative's office has embraced.

"Trade rules that protect innovation and research foster a system that produces the types of medicines American health consumers and health consumers around the world use and need to fight diseases," said Richard Mills, a spokesman for the trade office. Former Representative Rob Portman, an Ohio Republican, was sworn in to the cabinet-level trade post that runs the trade office in May.

The issue of intellectual property protection for pharmaceuticals has been highlighted in the last week with the Brazilian government's threat to break Abbott Laboratories' patent for the AIDS drug Kaletra by authorizing one of its domestic drug manufacturers to make a copy at roughly half the cost.

The Brazilian government currently buys Kaletra for about 180,000 citizens with AIDS. Abbott Laboratories charges Brazil $2,500 a patient annually. That represents a special price break from the company, which charges $6,000 to $7,000 for the drug in other developed countries, according to figures supplied by the company. Despite the special deal his government is getting, Brazil's president, Luiz Inácio Lula da Silva, wants the drug cheaper.

If President Lula goes through with his threat, he would invoke rarely used "compulsory licensing" provisions of a 1994 World Trade Organization agreement on intellectual property. The agreement forced countries to adopt American-style patent rules for pharmaceuticals, but allowed flexibility in cases of overriding public health issues by giving countries the right to order compulsory licenses.

Citing the Brazilian example, Representative Pete Stark, a California Democrat, referring to the industry trade group, said, "My guess is that Pharma's worry is that one of these countries will say, ' To hell with you,' and start making their own drugs."

Critics of the trade agreement say it sets up barriers to compulsory licensing in the countries it covers — the Dominican Republic as well as Nicaragua, Guatemala, El Salvador, Honduras and Costa Rica. The combined gross domestic product of the six countries amounts to a third of the annual revenues of major drug makers.

The pharmaceutical industry has also been successful in influencing trade "priority lists" and "watch lists" issued by the trade representative in recent years, according to the Center for Public Integrity analysis, released this week. Inclusion on the trade watch lists constitutes the first salvo in a trade war.

Last year, the pharmaceutical trade group requested action against 38 countries for infringing on American patents, producing counterfeit drugs and releasing confidential test data. Of those, 31 found their way onto some level of the trade watch list, according to the center's analysis.

The report for 2005, released in May, again showed the extent of the industry's influence. Of 41 companies recommended for inclusion by the industry, 32 made it onto one of the trade lists, the center said.

The trade representative's office disputes the analysis, however, saying the office complies with exact pharmaceutical industry requests involving the priority and watch lists only about half the time.

The 59 reports filed by lobbyists for the pharmaceutical association do not count dozens of reports filed by individual companies. The analysis revealed that Pfizer lobbyists had filed reports about lobbying the trade office 32 times during the same period; Bristol-Myers, 27 times; and Wyeth, 19 times.

Over all, the various representatives of the pharmaceutical association and its individual companies filed 289 reports of lobbying at the trade representative's office since 1998, making pharmaceuticals the fourth-largest lobbying interest group, behind miscellaneous manufacturing, business associations and agriculture, according to the center's analysis.

Mr. Grayson said extensive lobbying efforts by his industry were a good sign.

"If we're not doing a lot, we're not doing our job," Mr. Grayson said.

Senate Leader Calls for Limits on Drug Ads

By STEPHANIE SAUL

The Senate majority leader, Bill Frist, called yesterday on the pharmaceutical industry to limit drug advertising directed at consumers, increasing the pressure on companies to curb such marketing.

Senator Frist, a Tennessee Republican, embraced an increasingly popular idea, a delay in advertising after a drug is introduced. He called for a two-year restriction.

Proponents of a delay say it will give doctors time to understand how drugs work before patients begin asking for them, sometimes based on inflated claims.

"This advertising can lead to inappropriate prescribing and fuel prescription drug spending," Senator Frist said. "It can also oversell benefits and minimize risks."

He also said he would ask the Government Accountability Office to examine whether the Food and Drug Administration should review drug advertising before its publication or broadcast.

The senator's remarks, delivered yesterday on the Senate floor and posted on his Web site, add a politically powerful voice to the growing support for some limits on the quality and quantity of drug ads aimed at consumers.

Such advertising has grown to a $3.8 billion industry since 1997, when the F.D.A. lifted limits on it.

Consumer drug advertising has prompted a reaction in recent months. Some critics say it contributed to an excessive, unnecessary use of cox-2 painkillers, which were later shown to cause serious cardiovascular problems in some patients. Others criticized the drug industry for prime-time erectile dysfunction drug ads that are laden with sexual innuendo.

The Pharmaceutical Research and Manufacturers of America, a trade association, is formulating guidelines for advertising and is likely to adopt them this month. It is unlikely that the guidelines will require a moratorium on advertising new drugs, said Ken Johnson, a spokesman for the association.

"We believe as an industry that there should be an appropriate way to educate doctors and health care providers before advertising begins," Mr. Johnson said. "But we also believe strongly that patients have a right to know about new drugs that could save and improve the quality of their lives."

Last month, Bristol-Myers Squibb became the first company to embrace a self-imposed lag time — 12 months — between the introduction of a drug and consumer advertising. Also last month, the American Medical Association decided to conduct a study of consumer drug advertising after several medical groups proposed that the association recommend limits on ads.