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Trade Agreement May Undercut Importing of Inexpensive Drugs

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WASHINGTON, July 11 — Congress is poised to approve an international trade agreement that could have the effect of thwarting a goal pursued by many lawmakers of both parties: the import of inexpensive prescription drugs to help millions of Americans without health insurance.

The agreement, negotiated with Australia by the Bush administration, would allow pharmaceutical companies to prevent imports of drugs to the United States and also to challenge decisions by Australia about what drugs should be covered by the country's health plan, the prices paid for them and how they can be used.

It represents the administration's model for strengthening the protection of expensive brand-name drugs in wealthy countries, where the biggest profits can be made.

In negotiating the pact, the United States, for the first time, challenged how a foreign industrialized country operates its national health program to provide inexpensive drugs to its own citizens. Americans without insurance pay some of the world's highest prices for brand-name prescription drugs, in part because the United States does not have such a plan.

Only in the last few weeks have lawmakers realized that the proposed Australia trade agreement — the Bush administration's first free trade agreement with a developed country — could have major implications for health policy and programs in the United States.

The debate over drug imports, an issue with immense political appeal, has been raging for four years, with little reference to the arcane details of trade policy. Most trade agreements are so complex that lawmakers rarely investigate all the provisions, which typically cover such diverse areas as manufacturing, tourism, insurance, agriculture and, increasingly, pharmaceuticals.

Bush administration officials oppose legalizing imports of inexpensive prescription drugs, citing safety concerns. Instead, with strong backing from the pharmaceutical industry, they have said they want to raise the price of drugs overseas to spread the burden of research and development that is borne disproportionately by the United States.

Many Democrats, with the support of AARP, consumer groups and a substantial number of Republicans, are promoting legislation to lower drug costs by importing less expensive medicines from Europe, Canada, Australia, Japan and other countries where prices are regulated through public health programs.

These two competing approaches represent very different ways of helping Americans who typically pay much more for brand-name prescription drugs than people in the rest of the industrialized world.

Leaders in both houses of Congress hope to approve the free trade agreement in the next week or two. Last Thursday, the House Ways and Means Committee endorsed the pact, which promises to increase American manufacturing exports by as much as \$2 billion a year and preserve jobs here.

Health advocates and officials in developing countries have intensely debated the effects of trade deals on the ability of poor nations to provide inexpensive generic drugs to their citizens, especially those with AIDS.

But in Congress, the significance of the agreement for health policy has generally been lost in the trade debate.

The chief sponsor of the Senate bill, Senator Byron L. Dorgan, Democrat of North Dakota, said: "This administration opposes re-importation even to the extent of writing barriers to it into its trade agreements. I don't understand why our trade ambassador is inserting this prohibition into trade agreements before Congress settles the issue."

Senator John McCain, an author of the drug-import bill, sees the agreement with Australia as hampering consumers' access to drugs from other countries. His spokesman said the senator worried that "it only protects powerful special interests."

Gary C. Hufbauer, a senior analyst at the Institute for International Economics, said "the Australia free trade agreement is a skirmish in a larger war" over how to reduce the huge difference in prices paid for drugs in the United States and the rest of the industrialized world.

Kevin Outterson, an associate law professor at West Virginia University, agreed.

"The United States has put a marker down and is now using trade agreements to tell countries how they can reimburse their own citizens for prescription drugs," he said.

The United States does not import any significant amount of low-cost prescription drugs from Australia, in part because federal laws effectively prohibit such imports. But a number of states are considering imports from Australia and Canada, as a way to save money, and American officials have made clear that the Australia agreement sets a precedent they hope to follow in negotiations with other countries.

Trade experts and the pharmaceutical industry offer no assurance that drug prices will fall in the United States if they rise abroad.

Representative Sander M. Levin of Michigan, the senior Democrat on the panel's trade subcommittee, voted for the agreement, which could help industries in his state. But Mr. Levin said the trade pact would give a potent weapon to opponents of the drug-import bill, who could argue that "passing it would violate our international obligations."

Such violations could lead to trade sanctions costing the United States and its exporters millions of dollars.

One provision of the trade agreement with Australia protects the right of patent owners, like drug companies, to "prevent importation" of products on which they own the patents. Mr. Dorgan's bill would eliminate this right.

The trade pact is "almost completely inconsistent with drug-import bills" that have broad support in Congress, Mr. Levin said.

But Representative Bill Thomas, the California Republican who is chairman of the Ways and Means Committee, said, "The only workable procedure is to write trade agreements according to current law."

For years, drug companies have objected to Australia's Pharmaceutical Benefits Scheme, under which government officials decide which drugs to cover and how much to pay for them. Before the government decides whether to cover a drug, experts analyze its clinical benefits, safety and "cost-effectiveness," compared with other treatments.

The trade pact would allow drug companies to challenge decisions on coverage and payment.

Joseph M. Damond, an associate vice president of the Pharmaceutical Research and Manufacturers of America, said Australia's drug benefit system amounted to an unfair trade practice.

"The solution is to get rid of these artificial price controls in other developed countries and create real marketplace incentives for innovation," Mr. Damond said.

While the trade pact has barely been noticed here, it has touched off an impassioned national debate in Australia, where the Parliament is also close to approving it.

The Australian trade minister, Mark Vaile, promised that "there is nothing in the free trade agreement that would increase drug prices in Australia."

But a recent report from a committee of the Australian Parliament saw a serious possibility that "Australians would pay more for certain medicines," and that drug companies would gain more leverage over government decisions there.

Bush administration officials noted that the Trade Act of 2002 said its negotiators should try to eliminate price controls and other regulations that limit access to foreign markets.

Dr. Mark B. McClellan, the former commissioner of food and drugs now in charge of Medicare and Medicaid, said last year that foreign price controls left American consumers paying most of the cost of pharmaceutical research and development, and that, he said, was unacceptable.