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## House Approves Bill Easing Imports of Less Expensive Drugs

By **SHERYL GAY STOLBERG**

**W**ASHINGTON, July 25 -- In a major defeat for the pharmaceutical industry, the House voted by a wide margin early this morning to approve a measure that would make it easier for Americans to import inexpensive prescription medicines from Canada and Europe.

The vote, 243-186, came shortly before 3 a.m., after a fiery hour-long debate that capped a long and stressful day for lawmakers, who are rushing to finish their business by tonight so they can leave the Capitol to start their month-long summer recess.

The outcome was a surprise. Until the last minute, lawmakers on both sides were saying the vote would be too close to call. Even as the votes were being cast, some lawmakers held back, to see which way their colleagues were voting.

"I think this is the Congress saying, 'We hear you, drug prices are too high,'" said Representative Jo Ann H. Emerson, Republican of Missouri, who forced the vote by extracting a promise from the House leadership in exchange for favoring a broader Medicare prescription drug benefit that is a high priority of the White House. She added, "It's time we stopped subsidizing the world and bring fairness and fair prices to Americans."

The measure now becomes the official position of the House in its negotiations with the Senate to reconcile differences in their two versions of the prescription drug legislation. But its fate is uncertain; on Thursday, 53 senators released a letter saying they oppose the provision. And it is unclear how hard the House representatives in the Medicare negotiations will fight for it.

The Republican leadership of the House worked vigorously against the bill, as did the drug manufacturers--who stand to lose millions if it becomes law--and the Food and Drug Administration, whose officials argued the measure would jeopardize safety. The vote did not fall along party lines; rather, the debate turned on whether lawmakers were willing to accept the drug makers' argument that the measure would harm patients and defy free trade by allow the importation of not only drugs, but price controls.

"This is an interesting debate, because its not between the Democrats and the Republicans" said Representative Ted Strickland, Democrat of Ohio, who supported the measure. He added, "It's between the people and the pharmaceutical companies."

At times, the debate grew dramatic. Toward the end, Representative Billy Tauzin, Republican of Louisiana and the lead opponent of the bill, produced medicines that he said had been purchased from web sites purporting to sell drugs made in Canada. Instead, he said, the pills were from India, and, tossing them aside, declared they contained "nothing but pond water."

The pharmaceutical industry has long argued that it could not guarantee the safety of imported medicines, and drug makers have also said higher prices in the United States are necessary so that they can funnel the profits back into research and development. But many Americans are already buying their drugs from overseas, either through the mail or over the Internet, and consumers--as well as some lawmakers--are outraged by cheaper prices in nations whose governments control prices.

As a result, the importation bill had been picking up steam in recent weeks. The bill called for the F.D.A. to create a program to enable consumers, pharmacists and wholesalers to import agency-approved medicines from agency-approved facilities overseas.

"The issue is not safety, my friends," said Representative Rosa DeLauro, Democrat of Connecticut. "The issue is price. It is time that this Congress stop acting as a wholly-owned subsidiary of the pharmaceutical companies and step up to its responsibility to the consumers of this nation."

But Representative James C. Greenwood, Republican of Pennsylvania, said he had witnessed airport inspections of imported drugs, and "what we saw would turn your stomach--drugs coming in from countries all over the world, where there is no regulation. Drugs of incalculable content, of unknowable safety."

Under the terms of Mrs. Emerson's deal, the House leaders had promised not to work against the bill. But earlier this week, as it became clear that the measure was gaining in the House, Representative Tom Delay, the majority leader, told reporters he would fight against it.

"I think it's horrible policy," Mr. Delay said then, adding, "From a free-market perspective, I'm not interested in importing price controls."

Others insisted the measure was not impeding free trade, but rather injecting it into the pharmaceutical marketplace. "People from around the world come to America for their medical care, yet Americans travel around the world for affordable medications," said Representative Rahm Emanuel, Democrat of Illinois, adding, "The legislation we are debating today is about inserting competition and the free market into the pricing of medication."

After the vote, Mr. Emanuel said, "I think the people took back their House."

This morning was not the first time Congress has tackled the importation issue. A similar bill was passed in 2000 and signed into law by President Clinton, and both the House and the Senate included drug importation provisions in their Medicare prescription drug bills.

But each of those measures contained what Mrs. Emerson has called a "poison pill" -- a requirement that the secretary of health and human services certify that the imported medicines "pose no additional risk" to consumers. Both the Clinton and Bush administrations have refused to do so, preventing the program from taking effect. The bill the House approved today eliminates the certification requirement, which is one reason the drug manufacturers fought so hard against it.

"In the past this was seen as simply a political vote to lower drug prices, and that it was never going to be implemented, so it was a free vote," Ian Spatz, an executive with Merck & Co., said Thursday, before the vote. He added, "I think this is really the first time that it is being seriously debated and that member are taking a close look at the issues."

While the drug industry ran advertisements and sent armies of lobbyists to Capitol Hill, the Food and

Drug Administration also made an intense effort to persuade lawmakers to reject the bill. That prompted an outcry from measure's backers, who accused the agency of potentially violating, or at least bumping up against, a ban on lobbying by federal agencies.

Some suggested the F.D.A. was bowing to the industry it regulates.

"The F.D.A. is doing something I've never seen," said Representative Sherrod Brown, Democrat of Ohio and a co-sponsor of the importation measure. "The call we got from F.D.A. illustrates the way the pharmaceutical industry has co-opted the Food and Drug Administration."

A spokesman for the agency, Peter Pitts, characterized the contacts as a "very aggressive and appropriate effort to educate members on Capitol Hill." Insisting they were "strictly appropriate," he added, "I should also say that we have not received any complaints from any members of Congress, or otherwise."

Yet at least one congressional expert, Norm Ornstein, a resident scholar at the American Enterprise Institute, questioned the F.D.A.'s actions. Ordinarily, Mr. Ornstein said, federal agency officials are passive in approaching members of Congress, doing so only when they are requested to.

"There is a line," he said. "To be calling lawmakers in that way is at least pushing up to that line."