

Central America Trade Deal Hits Snag on Guatemala Law

By Mark Drajem

Jan. 7 (Bloomberg) -- The U.S. Trade Representative's office said Guatemala violated the terms of a pending Central American trade agreement with a new pharmaceutical data law the U.S. objects to, and said the move could delay the trade pact.

Guatemala repealed a law in late December that keeps pharmaceutical companies' testing data under seal for five years. That five-year protection is mandated by the U.S.-Central American free trade agreement, an accord reached in late 2003 and still awaiting congressional approval.

Guatemalan President Oscar Berger pledged to reinstate the data protections, which were requested by companies such as Pfizer Inc., Eli Lilly & Co., and Merck & Co., the U.S. trade office said today. The U.S. pharmaceutical industry pressed to include those measures in the trade agreement, saying they clarify global rules protecting patents.

"Congress has voiced concerns to us that for Cafta to proceed all participants need to be in compliance with its provisions," said Neena Moorjani, a spokeswoman for the U.S. trade office. "We're very disappointed that Guatemala has taken a step that violates its commitments under Cafta." The trade accord with Costa Rica, the Dominican Republic, El Salvador, Guatemala, Honduras and Nicaragua would immediately end duties on as much as 80 percent of the \$15 billion in U.S. exports to the region. It would help U.S. companies sell more products at lower cost in Central America and protect investments of U.S. businesses with assets in the region.

Setting Precedent

The data protection ensures that makers of generic drugs can't use the trial data of the originators of the drug for a certain period of time. Allowing use of that data can speed the introduction of cheaper generic drugs by giving them access to safety and efficacy studies, and also make it easier for countries facing a health crisis to overturn patent protections and use cheaper generics, said Jennifer Brant, a trade and copyright analyst at Oxfam in Geneva.

"They want these legal protections in Cafta as precedents for other trade agreements that may follow," Brant said. The U.S. pharmaceutical industry would "definitely" oppose moving ahead with congressional consideration of Cafta as long as the Guatemalan measure is in force, said Mark Grayson, a spokesman for the Pharmaceutical Research and Manufacturers of America, an industry trade group. The data provisions "basically protect the information that companies have put together," Grayson said.

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