New complication for D.R.-Cafta

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Twelve members of the U.S. Congress are voicing strong opposition to the Bush administration's proposal to include provisions in several free-trade agreements (FTAs) pending, on the grounds they would restrict access to generic drugs.

The FTAs cited are those with the Dominican Republic (D.R.), five Central American countries (Cafta), four Andean countries, and Panama. The efforts to link the D.R. and Cafta accords are being challenged by some members of Congress and industry associations from corn-producing states that are upset with the D.R. Congress' decision to impose a 25% duty on corn syrup imports from the U.S. (CB Sept. 30). The dispute over generic drugs adds yet another serious obstacle to the pact.

"We believe provisions in these agreements or under consideration for inclusion violate the requirement of the Trade Promotion Authority Act of 2002 to uphold the 2001 World Trade Organization [WTO] on Trade Related Aspects of Intellectual Property Rights Agreement & Public Health and additional protocols on its implementation," wrote the 12 members of Congress in their letter to the president. The WTO statement has become known as the Doha Declaration and is being vociferously opposed by most of the pharmaceutical industry.

"The fundamental purpose of the Doha Declaration was to clarify that trade rules on intellectual property don't interfere with the ability of developing countries to take 'measures to protect public health,'" the members of Congress told the president. "The flexibility to use such measures can be extremely important for countries struggling with HIV/AIDS and other serious diseases where new brand-name medications may be priced out of the reach of those suffering."

The lawmakers noted the consensus reflected in the Doha Declaration. Yet, they told the president, "Your administration appears to be seeking bilateral and multilateral agreements that undermine its important protections. We are specifically concerned about the inclusion of intellectual property restrictions in U.S. bilateral free-trade negotiations with developing countries in Latin America and elsewhere that would grant five to eight years of exclusivity for brand-name pharmaceutical products, even where patent barriers no longer exist."

The members of Congress added, "During that time, governments wouldn't be able to rely upon clinical test data submitted by the brand-name products to grant marketing approval for generic copies, even in situations of urgency."