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## States' Governors, FDA Face off Over Drug Imports

By Julie Rovner

WASHINGTON (Reuters Health) Feb 24 - The war of words between the U.S. Food and Drug Administration and the nation's governors over whether to allow Americans to buy cheaper prescription drugs from other countries escalated Tuesday.

The regulatory agency urged one state to shut down a website to facilitate the purchase of drugs from Canada, while another state vowed to go ahead with its own Canadian drug buying plan.

In a letter to Minnesota Republican Gov. Tim Pawlenty, Associate FDA Commissioner William K. Hubbard called the state's "endorsement of foreign internet pharmacies ... unsafe, unsound, and ill-considered," and urged him to work with the FDA on legal approaches to helping consumers buy cheaper drugs.

"We can do better than simply giving Minnesotans a foreign fax number and wishing them luck," Hubbard wrote.

But Pawlenty, in Washington to attend the annual meeting of the nation's governors and for a special "prescription drug reimportation summit" on Capitol Hill, said he has no intention of backing away from his program. "We're going ahead," he said. "We just don't agree with the FDA's conclusions" that the program is unsafe.

Other governors attending the summit agreed with Pawlenty. Wisconsin Democratic Gov. Jim Doyle announced he would be expanding his state's website, which also facilitates drug purchases from Canada, on Wednesday. "It's time to give our citizens the same prescription drugs at the same prices" as Canadians can get, Doyle said.

Both governors and members of Congress lambasted the FDA, which they said was doing the bidding of the drug industry, which fears Canadian drug purchasing because it would cut into their profits. "The FDA is supposed to regulate, not represent, the drug industry," said Sen. Byron Dorgan, D-N.D.

Agreed Sen. John McCain, R-Ariz., "The FDA has frightened our citizens into believing that even drugs made in the U.S. that go to Canada and come back are somehow hazardous to our health."

Dorgan even threatened to hold up the nomination of FDA Commissioner Mark McClellan to head the agency that runs Medicare, until McClellan explains "what's going on at the FDA" on the reimportation issue.

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"That nomination is going to spend a while," said Dorgan, referring to the ability of any senator to block - at least temporarily - Senate confirmation to posts such as the Medicare administrator.

Governors and members of Congress at the summit were also angry that the FDA declined an invitation to attend. FDA Associate Commissioner for External Relations Peter Pitt, however, did attend an earlier meeting across town held by reimportation opponents.

At that session, sponsored by the Institute for Policy Innovation, Pitts said the FDA understands American consumers' frustration with high drug prices, but that "Americans do not deserve a buyer-beware policy that trades safety for lower prices." Pitts said that drugs physically purchased in Canadian pharmacies are safe, but that purchasing over the Internet from sites that purport to be Canadian is not.

Pitts said that a recent ruling by a U.S. Federal judge shutting down a U.S. storefront service that was facilitating the purchase of drugs from Canada should "send a message to public officials that it is illegal and unsafe."

Canadians at the session also said that safety considerations aside, drug-buying from Canada cannot continue indefinitely. If just California and Illinois were to begin large-scale purchasing from Canada, which both are considering, said Sally Pipes of the Pacific Research Institute, "it would take the total Canadian market for drugs."

Lothar Dueck, President of the Coalition for Manitoba Pharmacy, said that the increasing purchases from the United States "are damaging the Canadian health care system" by "buying up finite quantities of drugs."

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