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Vermont Will Sue U.S. for the Right to Import Drugs

By PAM BELLUCK

BOSTON, Aug. 10 - Vermont will become the first state to sue the federal Food and Drug Administration for rejecting a plan to import prescription drugs from Canada, the state's governor and attorney general said Tuesday.

Reacting to intense pressure to help make prescription drugs more affordable, Vermont officials had asked the drug agency in November to approve a pilot program under which the state would contract with a Canadian company that would take orders from Vermont residents and distribute the drugs by mail.

On Monday, state officials received a letter from the drug agency denying the request, saying the government could not ensure the safety of drugs from Canada.

Other states, including Illinois, have received similar denials, but no other state has sued the F.D.A.

"The claims on which they've based this denial are, in our view, unsubstantiated, and we have no choice but to pursue any and all legal remedies available," said Gov. Jim Douglas, a Republican, in a statement late Tuesday.

The state's attorney general, William H. Sorrell, said: "Vermont's petition was carefully crafted and reasonable. I am amazed that the F.D.A. rejected it, but I am

looking forward to getting this in front of a federal judge."

States across the country have been trying to figure out ways to allow their citizens access to lower-priced Canadian drugs. Two dozen legislatures have passed or are considering bills to allow such programs, said Richard Cauchi, a health program director with the National Conference of State Legislatures.

But while a few cities, like Springfield, Mass.; Montgomery, Ala.; and Burlington, Vt., have started programs that import Canadian drugs, most state governments, faced with warnings from the F.D.A., are treading carefully. Minnesota, New Hampshire, North Dakota and Wisconsin have set up Web sites that link consumers in their states with Canadian pharmacies so consumers can buy drugs on their own.

New Hampshire's governor, Craig Benson, a Republican, said late last year that his state would import Canadian drugs for prison inmates, retired state employees and Medicaid recipients, but the program has not yet begun. And Illinois's governor, Rod R. Blagojevich, a Democrat, who has projected that his state could save \$91 million by buying Canadian drugs, has said he will not act without federal approval.

In February, an Illinois couple filed a federal lawsuit against the drug agency and the secretary of health and human services, but Vermont, which expects to file its lawsuit within a week, will be the first state to take the federal government to court on the issue.

Jason Gibbs, a spokesman, said Governor Douglas was determined to "work within the system and within the limits of current law to implement a program."

Vermont's proposal would have initially allowed the state to import Canadian drugs for current and retired state employees and their dependents, with a goal of expanding the plan to cover other Vermonters, Mr. Gibbs said.

He said the pilot program was projected to save the state about 5 percent of the

\$18 million it spends on prescriptions for state employees and retirees.

Mr. Gibbs said the Vermont proposal should have satisfied the safety issues because it "called specifically for the F.D.A. to work with us to address safety concerns."

But in denying Vermont's petition, William K. Hubbard, the agency's associate commissioner for policy and planning, wrote that "it would be extremely unlikely that the State of Vermont could ensure that all the Canadian drugs" would be "in full compliance with all laws and regulations applicable to F.D.A.-approved drug products and were safe and effective."

A spokeswoman for the drug agency, Kathleen Quinn, said it was "a little premature for us to be commenting on a lawsuit that hasn't been filed, but as always F.D.A. is concerned about the safety of drugs coming into the United States."

Mr. Gibbs said that while the lawsuit was pending, Vermont officials would meet with New Hampshire officials and consider adopting that state's proposal to start importing Canadian drugs for some beneficiaries of state health care coverage.

And in a letter Tuesday to the drug agency, Michael K. Smith, the Vermont secretary of administration, wrote that the state would be "forced to consider development of a reimportation program that conforms to our interpretation of the current laws, independent of your agency."

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