

David A. Kessler, M.D.

September 13, 2000

Honorable Byron Dorgan
719 Hart Senate Office Building
Washington, DC 20510

Dear Senator Dorgan:

Thank you very much for your letter of Sept. 12, 2000. I very much applaud the effort that you and your colleagues are making to assure that the American people have access to the highest quality medicines. As you know, my concerns about the re-importation of prescription drugs center around the issues of assuring quality products. The Senate Bill which allows only the importation of FDA approved drugs, manufactured in approved FDA facilities, and for which the chain of custody has been maintained, addresses my fundamental concerns. The requirement that the importer maintain a written record of the chain of custody and batch testing to assure the product is both authentic and unadulterated provides an important safety net for consumers.

Let me address your specific questions. First, I believe U.S. licensed pharmacists and wholesalers - who know how drugs need to be stored and handled and who would be importing them under the strict oversight of the FDA are well positioned to safely import quality products rather than having American consumers do this on their own. Second, if the FDA is given the resources necessary to ensure that imported, FDA-approved prescription drugs are the authentic product, made in an FDA-approved manufacturing facility, I believe the importation of these products could be done without causing a greater health risk to American consumers that currently exists. Finally, as a nation we have the best medical armamentarium in the world. Over the years FDA and the Congress have worked hard to assure that the American public has access to important medicine as soon as possible. But developing life saving medications doesn't do any good unless Americans can afford to buy the drugs their doctors prescribe. The price of prescription drugs poses a major public health challenge. While we should do nothing that compromises the safety and quality of our medicine it is important to take steps to make prescription drugs more affordable.

I applaud your efforts to provide American consumers with both safe and affordable medicine.

Sincerely,



David A. Kessler, M.D.