

# United States Senate

WASHINGTON, DC 20510

November 4, 2003

Mark B. McClellan  
Commissioner  
United States Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Dear Commissioner McClellan,

We are writing in response to the escalation in enforcement actions taken by FDA in recent months against Americans seeking to purchase their prescription drugs more affordably through Canada.

Nearly thirty percent of American seniors cannot afford to purchase the medicine their doctors prescribe. Some of those seniors and their families have turned to legitimate Canadian pharmacies to remedy this serious access problem; as you know, millions of Americans now fill their doctor-prescribed medications in this manner. The Governors of Illinois, Iowa, Michigan, and Minnesota have announced plans for their States to examine ways to buy medicine from Canada for the benefit of their public employees and low-income citizens, and many other organizations and individuals are currently helping American seniors to safely obtain their prescriptions from Canada. Considering the scope of activity in this area, what enforcement guidelines are governing your decision to seek injunctions against some facilitating importation but not others? For the people who are benefiting from their ability to access safe and affordable medicine from Canada – especially those who now take their medicine when they otherwise could not – the answer to this question has significant implications for their compliance with their doctors' treatment plans and their continued health.

Unfortunately, as illustrated in a recent series of articles featured in the *Washington Post*, there are criminals who seek to take advantage of the demand in this country for lower priced pharmaceuticals by diverting, adulterating, weakening or counterfeiting products. We are especially concerned about the trafficking of narcotics and highly addictive controlled substances. What action is FDA currently taking to stop such domestic operations? We believe these fraudulent activities highlight the need for FDA to work with Congress to improve the integrity of our nation's drug distribution system. In part, these illicit activities could be reduced by increasing the availability of legitimate, FDA-approved pharmaceuticals through a tightly controlled regulatory process that follows the pharmaceutical product from development and manufacturer through its distribution.

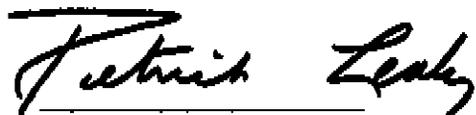
Commissioner Mark B. McClellan

November 4, 2003

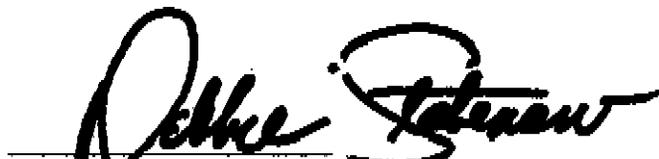
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We suggest that FDA's resources would best be targeted at shutting down fraudulent pharmaceutical distribution operations – regardless of the importation status of the drugs at issue – rather than selectively targeting cross-border transactions that are safely helping individuals access affordable medicine. We are eager to work with you to address these problems and look forward to your response.

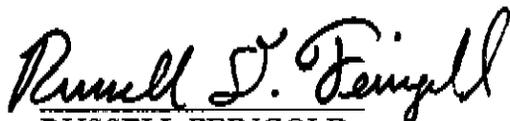
Sincerely,



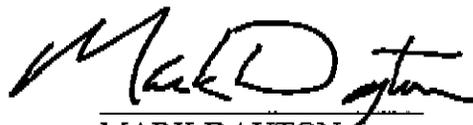
PATRICK LEAHY  
United States Senator



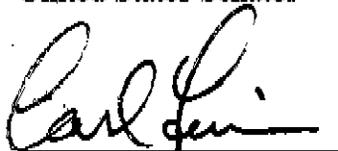
DEBBIE STABENOW  
United States Senator



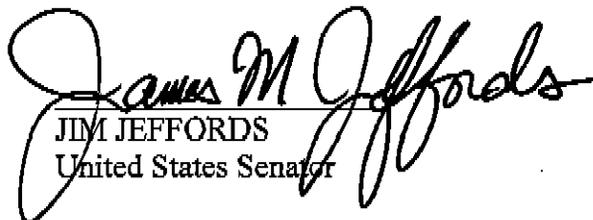
RUSSELL FEINGOLD  
United States Senator



MARK DAYTON  
United States Senator



CARL LEVIN  
United States Senator



JIM JEFFORDS  
United States Senator