THE CITY OF SPRINGFIELD, MASSACHUSETTS

MAYOR MICHAEL J. ALBANO

Tuesday, October 7, 2003

Dockets Management Branch,
Food and Drug Administration,
Department of Health and Human Services,
5630 Fishers Lane, rm. 1061,
Rockville, MD 20852

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Citizen Petition

The undersigned submits this petition under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR 5.10 to request the Commissioner of Food and Drugs to waive, change or cancel FDA's interpretation of statutes and regulations which are restricting competition in the pharmaceutical industry and negatively impacting the American people by hindering and, in some cases, preventing chronically ill American citizens from obtaining effective, low cost, safe prescription medications from Canada.

A. Action requested

This petition requests FDA to use its enforcement discretion to allow importation of Canadian versions of drugs that are approved in the United States.

This petition asks FDA to provide petitioner with a complete copy of all documents between FDA and Health Canada's Therapeutic Products Directorate regarding FDA's review of

Health Canada's Therapeutic Products Directorate to assess the safety, efficacy and quality of prescription medications before being authorized for sale in Canada

This petition requests FDA to verify that all pharmaceutical drugs which are regulated by Health Canada's Therapeutic Products Directorate pose no additional risk to the public's health and safety.

This petition requests FDA to immediately promulgate regulations as required in the Medicine Equity and Drug Safety Act of 2000, Pub.L. 106-387, § 1(a); 21 U.S.C.A. § 384(a) which in relevant part, states: "The Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting pharmacists and wholesalers to import into the United States covered products."

This petition requests FDA to amend, suspend, revoke or waive it's interpretation of the following statutory and regulatory provisions which have resulted or which may result in any administrative or legal action being taken pursuant to one or more of the following: 21 U.S.C. § 381(d)(1); 21 U.S.C. § 355; 21 U.S.C. § 353(b)(2); 21 U.S.C. § 353(b)(1); 21 U.S.C. § 331(a), (d), (t); and 21 U.S.C. § 331(t); 21 C.F.R. § 314.50; 21 C.F.R. § 201.100(c)(2).

This petition requests FDA to dismiss, suspend or revoke all current legal and administrative actions which inhibit implementation of the Medicine Equity and Drug Safety Act of 2000, Pub.L. 106-387; 21 U.S.C.A. § 384.

B. Statement of grounds

The factual and legal grounds for this petition are that the FDA has taken administrative and legal action to intimidate, coerce and threaten companies and/or individuals who attempt to assist United States citizens in obtaining effective, low cost, safe prescription medications from Canada which are prescribed by licensed American physicians. Example of this include, but are not limited to: FDA warning letters to various officers and employees of Rx Depot, Inc. dated March 21, 2003 whom FDA learned were assisting United States consumers in obtaining prescription drugs from Canada; an FDA letter to Mr. Gregory Gonot, Deputy Attorney General, State of California, dated August 25, 2003 regarding the importation of prescription drugs from Canada into the State of California; and FDA warning letters to various officers and employees of CanaRx Services, Inc. whom FDA learned were assisting United States consumers in obtaining prescription drugs from Canada; and FDA press releases concerning this topic.

In addition, FDA has not fulfilled its legal obligation under the Medicine Equity and Drug Safety Act of 2000, Pub.L. 106-387, § 1(a); 21 U.S.C.A. § 384(a) which states: "The Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting pharmacists and wholesalers to import into the United States covered products." FDA's failure to follow this federal law has cost American consumers millions of dollars. FDA's inaction has prevented many chronically ill American citizens from obtaining effective, low cost, safe prescription medications from Canada resulting in a diminished state of health and sometimes a premature death for those citizens who are dependent upon access to affordable medication. All the relevant information and views on which the petitioner relies for this petition with respect to the safety, efficacy and quality of prescription medications authorized for sale in Canada is available from Health Canada's Therapeutic Products Directorate which is the Canadian federal authority that regulates pharmaceutical drugs and medical devices for human use. All the relevant information and views on which the petitioner relies for this petition with respect to the pricing information is too extensive to be summarily quantified in this petition but, it includes, among other things, the information pertaining to the price of prescription medicine which is available at pharmacies in the United States and Canada and referenced in numerous web sites which are publicly accessible. All the relevant information and views on which the petitioner relies for this petition with respect to the impact of high cost prescription drugs on American citizens is too vast to be readily quantified in this petition but, it includes, among other things, the following:

- A CBS news report quoting Earl Turow as explaining the "very hard choices" people have to make such as "whether to pay their rent on time or at all or take their medicine - whether to eat full meals or cut their pills in half."
- Bernard Sanders, a Member of Congress from Vermont, stated: "Given the fact that the price of drugs in this state and country are outrageously high, it is not possible to determine how many seniors and others might die or suffer because they are now unable to afford the medicine that their doctors have prescribed."
- "A study by the U.S. Government Reform and Oversight Committee showed that older Americans and others who pay for their own drugs are charged far more for their prescription drugs than are the drug companies' most favorite customers, such as large insurance companies

and health maintenance organizations (HMO's). This study, requested by US Representative Tom Allen (1st district of Maine), compared the prices paid by pharmaceutical companies' most favored customers to prices paid by seniors for the 10 brand name drugs most commonly used by seniors. The results of the study showed that a senior citizen (in 1st district of Maine - where study was conducted) pay, on average, over twice as much as the drug companies' favored customers. The price differential is approximately five times greater than the average price differential of other consumer goods."

- "The absence of pharmaceutical price containment in the United States leaves consumers paying two to three times as much as consumers in other countries, including neighbors Canada and Mexico. The end result: those without insurance cannot afford prescribed medicines and the insured are paying higher premiums or co-pays so their insurance provider will continue to offer coverage as drug prices escalate. The burden of inflated drug costs rests heavily on the country's elderly and people with disabilities, for whom monthly drug costs may exceed $500. A Families USA report illustrated it as follows: A widow living on $12,525 a year (150% of the poverty level) who has acid reflux disease would spend about $1,455 or 12% of her income on medicine."
- "Lack of drug coverage among chronically ill lower income Medicare beneficiaries increases the risk of nursing home admission and hospitalization."

There is no information known to the petitioner that may be unfavorable to the petitioner's position except for information contained in the above referenced FDA letters and published reports. Petitioner believes that it is in the public interest to make reasonably priced, safe, prescription medicine available for the benefit of the American people.

C. Environmental impact

This petition does not require the preparation of an EA or an EIS because it is entitled to categorical exclusion under 21 CFR § 25.30 or other relevant provisions of that chapter.

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Very truly yours,

Michael J. Albano
Mayor
City of Springfield
36 Court Street
Springfield, MA 01103
(413) 787-6100

cc: Mark B. McClellan, M.D., Ph.D.,
Commissioner of Food and Drugs.
U. S. Food and Drug Administration
5600 Fishers Lane,
Rockville MD 20857-0001

Peter P. Fenton, Esq.
City Solicitor
Springfield Law Department
36 Court Street
Springfield, MA 01103

Harry P. Carroll, Esq.
Deputy City Solicitor
Springfield Law Department
36 Court Street
Springfield, MA 01103

Mayors waiver letter.3finaLwpd