

Strambler, Karen



A Reason for Hope

The Amyotrophic
Lateral Sclerosis
Association

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Stevan Gibson
*Vice President,
Government Relations
& Public Affairs*

March 30, 2004

Karen Strambler
Office of Policy
Office of the Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Karen:

This letter serves as a request to present at the public meeting on Prescription Drug Importation to be held on April 14, 2004 [Docket No. 2004N-0115].

I serve as Vice-President of Government Relations and Public Affairs of the nation's only voluntary health association dedicated solely to amyotrophic lateral sclerosis (ALS), better known as Lou Gehrig's disease.

The ALS community has large stake in the outcome of the drug importation debate. Because ALS is always fatal, its patients are often tempted by fraudulent claims of miracle drugs that will cure their disease. A weakening of the current drug importation regulation regime would open the floodgates to deceptive schemes that ALS patients may fall victim too. Moreover, the quest for a real treatment and cure for ALS is dependent upon continued investment in pharmaceutical research and development. Allowing drug reimportation will greatly diminish the amount of money that will be available for such research investment.

I have attached a summary of points that I will be making in my presentation. I will need 8-12 minutes to make my presentation.

Thank you for your consideration in this matter; I look forward to hearing from you. Please feel free to contact me if you have any questions.

Sincerely,

Steve Gibson,
Vice-President, Government Relations and Public Affairs

The ALS Association is the only
national not-for-profit voluntary
health organization whose sole
mission is to find a cure for and

3/31/2004

SUMMARY OF PRESENTATION

Submitted by Steve Gibson, The ALS Association

Position: For the past five years, on behalf of the ALS community, we have advocated against relaxing the rules on drug re-importation for two main reasons: concerns about fraudulent claims made to patients with a fatal disease; and concern about the availability of capital for investment in research and development of new drug therapies. Relaxing the rules on reimportation would adversely affect the ALS community on both of these fronts.

Summary: Some legislators are considering contaminating the prescription drug market with foreign drugs in a misguided drive to save a few health care dollars.

We find no fault with those who examine all options for treatment. When afflicted with a rare disease anyone would do the same. But we do find fault with proposals to re-open the floodgates for foreign-made drugs in America again. It is not just ALS-drug scams that this proposal will foster. Counterfeit medicines, for instance, have already infiltrated our medicine supply, though on a limited basis. Allowing the importation of prescription drugs will threaten the integrity of our medicine supply, because counterfeiting outside our borders is reaching a horrific scale.

The cost of prescription drugs in the United States also is a big concern for orphan diseases like ALS that need "research and development funds" from a drug company to develop a therapy or find a cure for a smaller community that is most likely to produce a "blockbuster" profit for the drug company. Drug companies often shy away from spending funds on such profitable ventures, thus limiting the amount of available drugs on the market.

The opportunity to access drugs through reimportation will have a limited impact, if any, on the many patients with rare diseases. Not every patient of every disease has access to a long list of available drugs. In fact, many patients only have one or two prescription drugs available to them and such drugs are only manufactured and sold in the United States, creating a less equitable system of drug availability for patients of all diseases.