

People's Medical Society®

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June 25, 2007

Dockets Management Branch (HFA-305)
FDA
5630 Fisher's Lane
Room 1061
Rockville, MD 20852

REFERENCE DOCUMENT NUMBER 2006p-0405

Dear Sir/Madam:

I write in support of the above noted document, a Citizen Petition to ensure the safe and effective use of antiepileptic drugs.

The petition calls upon the FDA to take three very important actions that would ensure that physicians and pharmacists successfully treating patients with epilepsy with existing medications be warned of the potential dangers of switching medications, unless medically warranted, and that patients and physicians are advised of such possible switches well in advance.

The petition also calls upon the FDA to add a discussion in the Orange Book highlighting the particular risks associated with substitution of these drugs. It also requests that the FDA limit the bioequivalence range.

Over the past 25 years, the People's Medical Society has become quite familiar with problems associated with changing antiepileptic medications in persons whose seizures were previously under control with an earlier medication. Our familiarity comes from hundreds of letters, emails and telephone calls from consumers across the country whose medications were switched for any number of non-medical reasons. Chief among the reasons for such switches, it appears, are employers or drug plans finding less expensive drugs that claimed to treat epileptic seizures equally effectively as drugs previously on the formulary. In all of these instances, and we acknowledge these were self-reported, problems occurred after the switch.

In addition, I would like to relate additional experience I have had that would further support the actions requested in the petition. Between 1971 and 1983, I led national efforts to deinstitutionalize mentally retarded and other developmentally disabled persons including thousands of persons who suffered from epilepsy. In filing federal and state lawsuits to achieve these ends, we learned in the discovery process that tens of thousands of otherwise healthy persons were placed in institutions for the mentally retarded simply because they were epileptic

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(not mentally retarded) with seizures that medications available were ineffective in controlling. As newer and more effective medications came into existence, we were able to extricate these individuals from these state facilities and place them into the community with great success. Over the years, however, we discovered that a number of persons in this category were readmitted to facilities because their seizures returned. Upon further examination of these cases, under federal court orders, we discovered the vast majority of these returnees had had their successful medications switched by unsuspecting physicians or clinicians often at the demand of health plans. Returning these patients to their successful medications allowed them to return to the community and be fully functioning members of society.

On the basis of the above, we want to reiterate our strong support of this Citizen Petition. It calls for nothing more than giving physicians, pharmacists and patients fair and proper warning of the need to carefully consider the well documented potential negative outcomes that the non-medical switching of anti-epileptic medications may cause in the lives of people whose seizure problems are effectively under control.

Thank you for the opportunity for us to comment on this most important request.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles B. Inlander". The signature is fluid and cursive, with a long horizontal stroke at the end.

Charles B. Inlander
President