EPILEPSY
ASSOCIATION
OF THE BIG BEND

June 25, 2019

Crystal Demott
Procurement Director
Agency for Health Care Administration
2727 Mahan Drive
Tallahassee, FL 32308

Dear Ms. Demott,

We are writing in regards to the Agency for Health Care Administration (AHCA) Request for Information 003-18/19 around the Canadian Drug Importation Proposal.

Epilepsy patients face many challenges, but one of the biggest barriers to quality of life is ensuring the right medication consistently at the most appropriate time in partnership with their physician. Patients with epilepsy can be particularly susceptible to adverse reactions from medications that differ from the treatments their doctors prescribe resulting in serious issues from additional seizures to lengthy hospital stays with massive costs to both the patient and system as a whole.

More than 360,000 Florida patients suffer from epilepsy, a neurological disorder that can cause fainting, painful seizures and even temporary paralysis. Fortunately, as many as 85 percent of epileptics can control their seizures and other symptoms through proper drug treatment. However, any minor change in prescribed treatments, even if just a difference in the filler between a brand vs. generic medication, will produce a high risk of experiencing sudden seizures and other complications.

It is unconscionable for Florida to force their most vulnerable patients to participate in a program that the FDA has concerns over. The last four FDA commissioners have said there is no effective way to ensure drugs coming from Canada really are coming from Canada, rather than being routed from a counterfeit factory in China.

Former FDA Commissioner Dr. Robert Califf said, “FDA would not be able to make safety and quality determinations for prescription drugs offered for import into the United States that have not gone through the U.S. regulatory process. FDA evaluation of non-FDA-approved imported drugs revealed that while nearly half of imported drugs claimed to be Canadian or from Canadian pharmacies, 85 percent of such drugs were actually from different countries.

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Authorizing importation would compromise the closed drug distribution system in the United States and undermine these laws, thus making it easier for unapproved drugs, which may include counterfeit or other substandard drugs, to reach American patients putting their treatment at risk. FDA is concerned that the risks of unapproved products from foreign sources outweigh any potential cost savings. We are also concerned that adverse events flowing from importation of such unapproved products could lead to diminished confidence in FDA- approved products."

The United States has the safest regulatory system in the world. The last thing we need is open borders for unsafe drugs in search of savings that cannot be safely achieved, and a vendor will not be able to create a system that the FDA has deemed impossible.

Importation proposals put our patients at risk for counterfeit or mislabeled drugs with no guarantee of any potential cost-savings to the patient. We must address costs with alternative solutions that directly lower out-of-pocket costs for patients. Please consider these points while reviewing vendors for this program.

Sincerely,

Mandy Bianchi

Mandy Bianchi, Executive Director

Submitted via email: Solicitation.questions@ahca.myflorida.com

United Way of the Big Bend | United Partners for Human Services | Florida Department of Health | United Way of Northwest Florida

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