EPILEPSY PATIENTS GET HELP WITH MARIJUANA EXTRACT BILL

Posted: March 9, 2016 By SALLY VOTH *The Winchester Star*



Dr. Paul D. Lyons, of Winchester Neurological Consultants, is excited about the prospect of being able to prescribe pharmaceutical drugs based on marijuana extracts for his epilepsy patients if a bill in the state senate becomes law. (Photo by Jeff Taylor/The Winchester Star)

WINCHESTER — A path for more patients in Virginia to alleviate their intractable epilepsy with marijuana extracts gained some clarity Tuesday with a vote by the state Senate.

The body unanimously passed one of its bills that was slightly tweaked by the House of Delegates, which unanimously passed it Monday. It now goes before Gov. Terry McAuliffe, a Democrat.

The legislation would allow a physician to write a prescription for cannabidiol oil or THC-A oil to alleviate the symptoms of treatment-resistant epilepsy, and lay the framework for pharmaceutical processors to set up shop — something that wouldn't happen before next year.

The bill would limit the number of pharmaceutical processors who can get a permit from the state Board of Pharmacy, which would adopt regulations for the processors.

Processors, prescribing physicians, patients and their caregivers would all have to register with the board.

The bill comes a year after the General Assembly passed a law providing a defense for marijuana possession if it is cannabidiol oil or THC-A oil that someone has on doctor's orders for intractable epilepsy.

Tuesday's vote was welcomed by Dr. Paul Lyons, a neurologist and epileptologist with Winchester Neurological Consultants and the medical director of the Virginia Comprehensive Epilepsy Program.

"It's going to make things a lot easier for me and other clinicians," Lyons said. "And also... it will increase [their] confidence that the commonwealth of Virginia, through the Board of Pharmacy, who will be responsible for controlling the quality of the substances we're prescribing."

The Board of Pharmacy regulations will make obtaining the oil more like getting a prescription, Lyons said.

"The legislation that was previously passed was the first step," he said. "This is the step that actually makes it practical."

Under current law, parents and doctors are in an "awkward position," Lyons said. Parents or patients need to obtain the drug by illegal means, such as having it shipped across state lines, and its quality isn't assured, he said.

Lyons and registered nurse Jennifer Stanford, the director of the Valley Health Clinical Research Department, have worked together on clinical trials using Epidiolex, pure cannabidiol made from the cannabis plant. In a 2015 interview, Lyons said Epidiolex is made by England-based GW Pharmaceuticals, and is the only pharmaceutical-grade cannabinoid drug for epilepsy approved by the U.S. Food and Drug Administration.

Patients with a form of epilepsy called Lennox-Gastaut syndrome have completed a trial of the drug, and are now in a long-term follow-up, Stanford said Tuesday.

"In the first phase of the study, it was blinded and randomized, so half got it and half didn't, but you didn't know which ones," she said.

Now that the first phase is done, all of the patients are getting the drug as an open-label trial, Stanford said. She said data isn't available yet on the first trial, but Stanford and Lyons are pleased with how it went.

"The results have been very, very compelling," Lyons said. "They've been really almost astounding in some cases. It's gone exceptionally well."

Four children are being studied and are receiving the drug in a compassionate-use trial, Stanford said.

Another trial is looking for epileptics with the more rare Dravet syndrome, she said. Those interested in that study can call Stanford at 540-536-8978, or visit <u>clinicaltrials.gov</u>.