One Hundred Fifth Legislature - First Session - 2017

Introducer's Statement of Intent

LB167

Chairperson: Senator Laura Ebke

Committee: Judiciary

Date of Hearing: January 25, 2017

The following constitutes the reasons for this bill and the purposes which are sought to be accomplished thereby:

LB167 reschedules cannabidiol in a drug product approved by the United States Food and Drug Administration into Schedule V of the Nebraska Controlled Substances Act. Currently, cannabidiol in any form is a Schedule I Controlled Substance with no approved medical use and possession, distribution and sale of cannabidiol is a criminal act in Nebraska.

Later this year, cannabidiol in a pharmaceutical formulation will be submitted to the FDA for approval. The drug is called Epidiolex® and it is a pure cannabidiol (CBD) investigational product that is being studied as a potential anti-convulsive treatment for children with certain types of childhood-onset, medication-resistant epilepsies, including Dravet Syndrome and Lennox Gastaut Syndrome (LGS).

These types of epilepsies are severe and highly resistant to treatment with existing medications. With uncontrolled seizures, most patients will develop moderate to severe intellectual and development disabilities in childhood and require lifelong supervision and care. They face a significant risk of early death. They urgently need new treatment options. Currently, there are no approved treatments for Dravet Syndrome and the FDA has granted Epidiolex® Fast Track and Orphan Drug designations, meaning FDA approval could come as soon as eight months after submission.

LB167 seeks to address the problem a cannabidiol based pharmaceutical has as a Schedule I substance both federal and state la. Upon FDA approval, rescheduling by the DEA will take place and take care of federal law, but Epidiolex® must be rescheduled in each state, including Nebraska. This bill allows our legislature to proactively reschedule cannbidiol in an FDA approved product, ensuring Epidiolex® will be available to patients in Nebraska as soon as federal approval and rescheduling is complete. Without this proactive legislation, Nebraska children with these devastating types of epilepsy might not be able to obtain rapid access to an exciting new treatment option, especially if the federal approvals occur when our legislature is out of session. There is no reason why these children and their families should suffer a day longer than is necessary if there is an FDA approved treatment that might alleviate the burdens of uncontrolled seizures.

Principal Introducer: _____

Senator Laura Ebke