DRM Downs Rachlin Martin PLLC
Business Sense · Legal Ingenuity

TO: House Health Care Committee

FROM: Lucie Garand

DATE: April 30, 2019

RE: FDA-Approved Prescription Drugs Containing Cannabinoids

Section 20b of S.54 adds language to 18 V.S.A. § 4474 regarding the use of US Food and Drug Administration approved drugs containing one or more cannabinoids. The existing language passed in 2017 is in session law and is specific to cannabidiol. The suggested amendment would codify and broaden the 2017 language so that patients would have access to future FDA approved products that contain other cannabinoids found in the marijuana plant. Rather than "prescription drugs containing cannabidiol" the new language is for "prescription drugs containing one or more cannabinoids".

The amendment language is necessary for the following reasons:

- If the FDA approves a new prescription medicine and the Drug Enforcement Administration designates that product as a controlled substance, then prior to patient use in Vermont, the product would need to be added to the state's Regulated Drug Rule. Because this regulatory process takes 6-7 months, patients would not have access to a federally lawful prescription medication during that time. Language enacted in 2017 clarifies that it would be lawful to prescribe, dispense, possess and use such a product in Vermont. The state will still go through the normal regulatory process of adding the product to the Regulated Drug Rule, but the language allows for patient access during that time.

- For example, in June 2018, the FDA approved Epidiolex oral solution to treat children with two rare treatment-resistant seizure syndromes: Dravet syndrome and Lennox Gastaut syndrome. The DEA placed Epidiolex in Schedule V of the federal Controlled Substances Act on September 27, 2018, and the product became available by prescription on November 1, 2018. The existing 2017 language allowed children with Dravet or Lennox Gastaut syndrome to immediately access Epidiolex if prescribed by a licensed physician. Without the 2017 language, children with these severe, life-threatening epilepsies would have been denied access for many months until the Rule process was complete.