Whereas, Almost 500,000 children in the United States suffer from epilepsy and approximately thirty percent of those children’s seizures are not adequately controlled by current anti-convulsant medications; and

Whereas, Childhood-onset, encephalopathic epilepsies, such as Dravet syndrome and Lennox-Gastaut syndrome, are even more treatment resistant, with as many as 80-90% of children’s seizures resistant to available anti-convulsant medications; and

Whereas, There is an urgent need for new U.S. Food and Drug Administration (FDA)-approved treatment options for these childhood encephalopathies; and

Whereas, Cannabidiol has no effect on the receptors that produce euphoria with THC (tetrahydrocannabinol); and

Whereas, Recent controlled clinical trials with cannabidiol (CBD) suggest that CBD may be a promising treatment option for these encephalopathies; and

Whereas, In the absence of an FDA-approved CBD medication, desperate families are turning to these unapproved cannabis and CBD products in an effort to reduce their child’s seizures; and

Whereas, Many manufacturers of unapproved CBD products sold online make unsupported medical claims of safety and efficacy, including that their products will treat epilepsy and cancer, and in 2015, 2016, and 2017, the FDA sent Warning Letters to a number of these manufacturers, requiring them to cease making such claims; and

Whereas, CBD is classified in Schedule I or is defined as marijuana under virtually all of the states’ laws and, therefore, upon FDA approval and U.S. Drug Enforcement Administration rescheduling, each state must make changes to state law in order for pharmacies and prescribers to sell and dispense CBD containing medication; and

Whereas, The need to make such changes to state law to allow a CBD medication, once it is FDA approved, to be dispensed may result in a delay in access for children suffering from such encephalopathies; and

Whereas, If state laws are not corrected to allow medical dispensing, the only option for obtaining FDA-approved medication may require registration on special state patient registries, may require distribution through cannabis dispensaries, and may impose labeling requirements that are not consistent with FDA-approved labeling; therefore be it
RESOLVED, That our American Medical Association encourage state controlled substance authorities, boards of pharmacy, and legislative bodies to take the necessary steps including regulation and legislation to reschedule U.S. Food and Drug Administration (FDA)-approved cannabidiol products, or make any other necessary regulatory or legislative change, as expeditiously as possible so that they will be available to patients immediately after approval by the FDA and rescheduling by the U.S. Drug Enforcement Administration (New HOD Policy); and be it further

RESOLVED, That our AMA advocate that an FDA-approved cannabidiol medication should be governed only by the federal and state regulatory provisions that apply to other prescription-only products, such as dispensing through pharmacies, rather than by these various state laws applicable to unapproved cannabis products. (New HOD Policy)

Fiscal Note: Not yet determined

Received: 04/25/18