AES Position Statement on Cannabis as a Treatment for Patients with Epileptic Seizures

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More than three million Americans live with epilepsy, one-third of whom have seizures that are not controlled by medications. As the leading organization of clinical and research professionals specializing in the treatment of epilepsy, the American Epilepsy Society (AES) supports all well-controlled research studies that will lead to a better understanding of the disease and the development of safe and effective treatments.

The term “medical marijuana” is a legal definition that refers to the use of substances derived from the cannabis plant on the recommendation of a healthcare provider in certain U.S. states. Currently, United States Pharmacopeia (USP) standards do not exist to give either providers or patients information about the identity, purity, or quality of any cannabis product obtained in this way. There are two classes of compounds in cannabis: phytocannabinoids and terpenoids. There are over 100 phytocannabinoids and over 200 terpenoids in cannabis. Most phytocannabinoids, and all terpenoids, are present in tiny amounts. Terpenoids are mainly responsible for the smell associated with cannabis, and we do not clearly understand their benefits or adverse effects, if any. There are seven phytocannabinoids present in large enough quantities to have significant pharmacologic effects, including tetrahydrocannabinol (THC) which has psychoactive effects and cannabidiol (CBD) which does not have psychoactive effects. It is important that an evidence-based approach be taken to the discovery, development, and clinical application of these compounds.

There has been great interest in the medical and scientific communities to explore the potential of CBD to treat patients with difficult–to-control (refractory) epilepsy. In the past, only anecdotal reports existed to support the use of CBD to treat persons with epilepsy. Recently, there have been several scientifically rigorous, double-blind, placebo-controlled randomized clinical trials of one specific pharmaceutical-grade, purified, highly concentrated CBD for patients with refractory epilepsy that have been published. Studies evaluating the pharmacokinetics and potential drug-drug interactions with this formulation have also been published or presented at epilepsy

congresses. These trials demonstrated that this one pharmaceutical-grade CBD is moderately effective in the treatment of patients with seizures in both Lennox-Gastaut syndrome (LGS) and Dravet syndrome. However, these studies also showed that CBD has more side effects than placebo and revealed previously unrecognized drug-drug interactions.
The results of the pivotal clinical trials led to FDA approval on June 25, 2018 of a pharmaceutical formulation of purified CBD to treat persons with epilepsy. Currently, the only FDA approved drug product is cannabidiol oral solution (Epidiolex®). This drug is a Schedule V product available by prescription only and is currently provided by specialty pharmacies. Patients, caregivers and clinicians are encouraged to consult the product information regarding dosing, adverse effects and potential drug interactions. Of note, similar levels of scientific evidence do not currently exist in the medical literature for other artisanal formulations of CBD.

Persons with epilepsy must use caution because there is a vast array of other cannabis products, and availability is dependent on individual state laws. Of importance, this new prescription product (Epidiolex) cannot be obtained from a cannabis dispensary. When patients purchase cannabis-based products from a dispensary, it is extremely important to understand that the product they select may not contain just CBD, but also other phytocannabinoids such as THC, pesticides, and other dangerous impurities, of which the concentrations are unknown. In some U.S. states, CBD is manufactured only in state-licensed facilities. Facilities in some states are monitored to ensure products have appropriate content and purity, and no contaminants. This is not true in other states. Independent laboratory testing of samples of cannabis products in states lacking strict regulation have shown that the product labels provided by dispensaries in the latter states can be inaccurate. Currently, no United States Pharmacopia (USP) standards exist regarding CBD formulations.

The AES calls on government, private funders, and manufacturers to support and develop well-designed, controlled, scientifically rigorous research for any cannabis-based products that have potential positive effects in the treatment of resistant epilepsy. The standard of this type of research is necessary to optimally evaluate the safety, efficacy, and drug-drug interactions of any potential anti-seizure drug (ASD). To increase clinical research, the AES urges that the cannabis status, as a Federal DEA Schedule 1 controlled substance, should be reviewed. The AES call for rescheduling is not an endorsement of the legalization of cannabis but is recognition that the

current restrictions on the use of cannabis products for research continue to stand in the way of scientifically rigorous research for the development of cannabis-based treatments. We also encourage the USP to continue its efforts to provide quality and purity standards for therapeutically promising cannabinoids.

The AES is very sympathetic to the needs of people with severe, treatment-resistant epilepsy. Our members work with these families daily and are very aware of the need for compassionate use of promising new therapies in appropriate and controlled circumstances. The AES urges all people touched by epilepsy to consult with an epilepsy specialist and explore the many existing treatment options, so they can make informed decisions with their specialist that weigh the risks and benefits of the various treatment options.

About the American Epilepsy Society

The American Epilepsy Society is a medical and scientific society whose members are engaged in research and clinical care for people with epilepsy. For more than 75 years, AES has provided a dynamic global forum where professionals from academia, private practice, not-for-profit, government and industry can learn, share and grow.