



AMERICAN
EPILEPSY
SOCIETY

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Supplemental Appendix A. *American Epilepsy Society Position Statement on Cannabis as a Treatment for Patients with Epileptic Seizures.* Revised February 19, 2019.

American Epilepsy Society (AES)

**Written Comments to Norman E. "Ned" Sharpless, MD
Acting Commissioner of Food and Drugs
U.S. Food and Drug Administration (FDA)
Department of Health and Human Services (HHS)**

on Docket ID# FDA-2019-N-1482

***Scientific Data and Information about
Products Containing Cannabis or Cannabis-Derived Compounds;
Public Hearing; Request for Comments***

Submitted on: July 16, 2019

Appendix A. American Epilepsy Society Position Statement on Cannabis as a Treatment for Patients with Epileptic Seizures. Revised February 19, 2019

https://www.aesnet.org/about_aes/position_statements/AES%20Position%20on%20Medical%20Marijuana

Over three million Americans live with epilepsy, of whom one-third 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 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 cannabis on the recommendation of a healthcare provider in certain 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. Given that over 80 active compounds derived from the cannabis plant (called phytocannabinoids) have been isolated, many with various pharmacologic actions (including psychoactive ones producing a “high”), it is important that an evidence-based approach be taken to the discovery, development, and clinical application of these compounds.

Over the last several years, there has been great interest in the medical and scientific communities to explore the potential of cannabidiol (CBD), a non-psychoactive phytocannabinoid, to treat difficult-to-control epilepsy. Until recently, only anecdotal reports existed to support CBD’s use in treating epilepsy. Recently, important research data have emerged in the form of scientifically rigorous, double-blind randomized clinical trials on the use of a pharmaceutical formulation of purified, highly concentrated CBD for refractory epilepsy. These trials demonstrated that purified CBD is moderately more effective than placebo in the treatment of seizures in both Lennox-Gastaut syndrome (LGS) and Dravet syndrome. However, these trials showed that CBD has more side effects than placebo, and revealed previously unrecognized drug-drug interactions.

The results of these scientifically rigorous randomized clinical trials led to the FDA approval of a pharmaceutical formulation of purified CBD to treat persons with epilepsy (Epidiolex®). This drug is a Schedule V product available by prescription only, and provided by specialty pharmacies. 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, the purified, pharmaceutical formulation of CBD described above cannot be obtained from a marijuana 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 (which is psychoactive), pesticides, and other dangerous impurities, of which the concentrations are unknown. Independent laboratory testing of samples of cannabis products have shown that the labels on products in the dispensaries claiming to have a certain percentage of CBD or THC are often incorrect.

While there are anecdotal reports of positive effects of cannabis and/or other CBD products on seizures, it is imperative that we remember that anecdotal reports alone are not sufficient to support treatment decisions. Robust scientific evidence for the use of cannabis itself in the treatment of epilepsy is limited. The lack of information does not mean that cannabis is ineffective for epilepsy, but it just means that providers do not have the required data needed to adequately inform rational clinical decisions for our patients with epilepsy.

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 to have 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-epileptic drug. To increase clinical research in this regard, AES urges that cannabis' status as a Federal DEA Schedule 1 controlled substance be reviewed. AES's call for rescheduling is not an endorsement of the legalization of cannabis, but is a recognition that the current restrictions on the use of cannabis products for research continue to stand in the way of scientifically rigorous research into the development of cannabis-based treatments. We also encourage USP to continue its efforts to establish recognized guidance for cannabis as well as individual, therapeutically promising cannabinoids.

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. AES urges all people touched by epilepsy to consult with an epilepsy specialist and explore the many existing treatment options, so that they can make informed decisions with their specialist that weighs the risks and benefits of the different 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.