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February 22, 2018

Governor Butch Otter
State of Idaho
Office of the Governor
P.O. Box 83720
Boise, ID 83720

Dear Governor Otter,

As Idaho reconsiders enacting new legislation regarding access to cannabidiol oil, I write to offer the perspective of the American Epilepsy Society (AES), the leading U.S. organization of clinical and research professionals specializing in the treatment and care of people with epilepsy.

Epilepsy is the most common and potentially devastating neurological disease, affecting people across the lifespan. In America, one in 26 people will be diagnosed with epilepsy at some time during their life. More will experience an isolated seizure. Epilepsy is associated with significant morbidity and mortality and with many co-morbidities including depression, cognitive dysfunction, and autism. Approximately 3 million Americans, including almost 400,000 children, live with epilepsy, with one third living with treatment-resistant seizures that do not respond to current medications.

The American Epilepsy Society [position](#) on marijuana and its derivatives as a treatment option for people with epilepsy is informed by the current research and supported by position statements from the American Academy of Neurology, the American Academy of Pediatrics and the American Medical Association.

Specifically, AES has called for acceleration of research, for the rescheduling of marijuana by the DEA to ease access for clinical studies, and has supported compassionate use programs where a purified and uniform preparation of cannabidiol (CBD) is administered under the guidance and close monitoring of an appropriate medical professional. AES has also been highly supportive of the double-blind clinical trials conducted over the past several years, several of which were [recently reported out](#) on at the AES Annual Meeting in December. These are finding both promise for use in specific types of intractable epilepsies, but also caution related to adverse events.

These clinical trials utilize a vastly different substance than the artisanal cannabis products that are being considered for use in Idaho. Currently, United States Pharmacopia (USP) standards do not exist to guide either clinicians or patients regarding identity, purity or quality of cannabis sativa or any other cannabis varietal or derivative. Given that over 100 active phytocannabinoids have been isolated from the cannabis plant, many with varying pharmacological

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properties (including both psychoactive and non-psychoactive actions), it is prudent that an evidenced-based approach be taken to the discovery, development, and clinical application of these molecules.

As noted above, in the last year some positive scientific data have emerged in the form of scientifically-valid randomized control trials (RCTs) for the use of a *pharmaceutical formulations* of purified, highly-concentrated CBD for refractory epilepsy. These trials demonstrated that purified CBD's is significantly more effective than placebo in the treatment of seizures in Lennox-Gastaut Syndrome (LGS) and Dravet Syndrome. However, these trials also showed that CBD has more side effects than placebo.

These data are promising due to the scientifically rigorous and controlled nature of studies performed. Data from these controlled studies also provided evidence of significant pharmacokinetic and possibly pharmacodynamics drug-drug interactions that were previously unrecognized.

AES is sympathetic to the desperation felt by parents of children with severe, treatment-resistant epilepsy, and understand the need for compassionate or promising new therapies in appropriate and controlled circumstances. We are however opposed to the use of artisanal preparations of unregulated compounds of cannabis that contain unverified content, may contain impurities and typically are not produced using best pharmaceutical practices.

The products currently available do not meet the [FDA definition](#) of expanded or compassionate use. The FDA requires compassionate use therapies to meet the same criteria as an investigational new drug which require standard purity, content and content uniformity testing of the product. None of these criteria are met in the products available, and yet these and other similar products are being considered for use in Idaho.

In sum, there simply is **no clinical, controlled research to support the adoption of new cannabidiol oil legislation such as your state is considering**. The rush by states to pass CBD legislation has created an unusual situation where people with epilepsy and their families are demanding access to a highly variable artisanal substance that may or may not be beneficial, may have side effects including cognitive impairment or liver toxicity, and may trigger drug-drug interactions.

We strongly urge you to wait what may be the relatively short time for the FDA to act on the most recent submissions for approval of *pharmaceutical formulations* of purified CBD to treat epilepsy. Affording the medical and scientific community with the necessary efficacy and safety data to make good treatment decisions regarding cannabis for people with epilepsy, especially in children, is imperative.

We urge you to delay adoption of new CBD legislation and to continue to support and encourage new research and efforts to speed development and approval of all new medications and treatments. If we can be of additional help please contact our Executive Director, Eileen Murray, at emurray@aesnet.org. Thank you for your consideration of our position.

Sincerely,



Shlomo Shinnar, MD, PhD
President
American Epilepsy Society

Cc: Eileen M. Murray, MM, CAE - Executive Director

