AMERICAN EPILEPSY SOCIETY

www.AESnet.org

135 SOUTH LASALLE STREET, SUITE 2850
CHICAGO, IL 60603
OFFICE 312.883.3800
FAX 312.896.5784
EMAIL info@aesnet.org

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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 cannabis legislation, 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 that affects people across the lifespan. In America, one in 26 people will be diagnosed with epilepsy at some time in the course of their life - more will experience an isolated seizure. Epilepsy is associated with significant morbidity and mortality and is associated with many co-morbidities including depression, cognitive dysfunction, and autism. Today between 2.2 and 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 medical marijuana as a treatment option for people with epilepsy is informed by the current research and supported by the position statements from the American Academy of Neurology, the American Academy of Pediatrics and the American Medical Association. Additionally, a 2014 survey of practitioners published in the journal Epilepsy Currents found that the majority of epilepsy practitioners agreed with and supported the AES position.

Specifically, AES has called for more research, for the rescheduling of marijuana by the DEA to ease access for clinical studies, and has supported the compassionate use program of GW Pharmaceuticals, where a purified and uniform preparation of cannabidiol (CBD) called Epidiolex is being administered under the guidance and close monitoring of an appropriate medical professional. AES has also been highly supportive of the double-blind clinical trial now underway by GW Pharmaceuticals and of the forthcoming clinical trial by INSYS Therapeutics.

These clinical trials utilize a vastly different substance than the artisanal cannabis products that are being considered for use in Idaho, and that have been used in Colorado. As you likely know, medical marijuana and its derivatives are legal in Colorado, but you may not realize that the content of these products is not regulated for purity or uniformity. A study by a team from Children's Hospital Colorado that was presented during the AES Annual Meeting in December 2014 and has recently been accepted for publication in the journal *Epilepsy & Behavior*, found that artisanal "high CBD" oils resulted in no significant reduction in seizures in the majority of patients

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and in those for whom the parents reported improvements, these improvements were not associated with improvement in electroencephalograms (EEGs), the gold standard monitoring test for people with epilepsy.

Additionally, in 13% of cases reviewed seizures worsened with use of cannabis and in some patients there were significant adverse events. These are not the stories that you have likely heard in your public hearings, but they are the reality of practitioners at Children's Hospital Colorado who have cared for the largest number of cases of children with epilepsy treated with cannabis in the U.S.

The families and children coming to Colorado are receiving unregulated, highly variable artisanal preparations of cannabis oil prescribed, in most cases, by physicians with no training in pediatrics, neurology or epilepsy. As a result, the epilepsy specialists in Colorado have been at the bedside of children having severe dystonic reactions and other movement disorders, developmental regression, intractable vomiting and worsening seizures that can be so severe they have to put the child into a coma to get the seizures to stop. Because these products are unregulated, it is impossible to know if these dangerous adverse reactions are due to the CBD or because of contaminants found in these artisanal preparations. The Colorado team has also seen families who have gone into significant debt, paying hundreds of dollars a month for oils that do not appear to work for the vast majority. For all these reasons not a single pediatric neurologist in Colorado recommends the use of artisanal cannabis preparations. Possibly of most concern is that some families are now opting out of proven treatments, such as surgery or the ketogenic diet, or newer antiseizure medications because they have put all their hope in CBD oils.

AES is sympathetic to the desperation parents of children with severe, treatment-resistant epilepsy feel, and understand the need for compassionate or promising new therapies in in appropriate and controlled circumstances. We are however opposed to the use of artisanal preparations of unregulated compounds of cannabis that contain unverified content and are produced by people with no experience in pharmaceutical production. That is what is currently happening in Colorado and may soon be happening in multiple states across the country as they legalize the use of medical marijuana products.

The products currently provided in Colorado 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 being given to people with epilepsy in Colorado and we are seeing the distressing results noted above. And yet, these and other similar products are being considered for use in Idaho.

It is also worth noting that in late February 2015, the FDA issued several warning letters to firms that claim that their products contain CBD. The FDA has tested those products and, in some of them, did not detect any CBD as claimed on the label. Because there is no standard for these products, the market is increasingly flooded with a wide variation of products and states which

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approve access to these preparations will bear the burden of monitoring for quality and controlling for the continuity of supply.

In sum, there simply is **no clinical, controlled research to support the adoption of new CBD legislation for epilepsy such as your state is considering**. The anecdotal results of a few families in Colorado, shared in the media, should not be the basis for law making. 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 homegrown substance that may or may not be beneficial and the medical and scientific community lacks the necessary efficacy and safety data to make good treatment decisions regarding cannabis for people with epilepsy, especially in children.

The new legislation in most states places epilepsy practitioners in an untenable situation where they are expected, or in some states directed by law, to respond to requests for these highly variable artisanal products with no protocols, no research and no clinical guidelines regarding dosing or side-effects, and no assurance that the cannabis products that are to be recommended are pure, safe or uniform, making it nearly impossible to know if we are truly "Doing No Harm." We need to accelerate the clinical research and wait to act until we have results to support decisions. If there are components of cannabis with specific therapeutic values we need to know this and we need to develop pharmacy grade compounds that utilize these components to help the nearly one million people living with drug resistant epilepsy. And if the harmful aspects of cannabis outweigh the therapeutic benefits, we need to find out now, before more medically fragile children have been exposed to cannabis products that are not effective and may risk damage to vital organs, brain development, or worse.

We urge you and your fellow committee members to delay adoption of new cannabis legislation and to continue to support and encourage new research. 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,

Amy Brooks-Kayal, MD
President, American Epilepsy Society
Chief and Ponzio Family Chair, Children's Hospital Colorado
Professor of Pediatrics and Neurology, University of Colorado School of Medicine