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## Policy Statement on Cannabidiol

The Governor's Office of Drug Policy opposes legalization of marijuana in any form, other than specific marijuana-based medications that have received FDA approval. As the state's lead on substance abuse policy and prevention, ODP evaluates credible scientific research to inform public policy decisions. In response to proposed legislation and ballot initiatives aimed at marijuana legalization, ODP finds it necessary, based on the current evidence, to advise against the legalization of marijuana as a public health and safety measure.

Regarding the medical use of marijuana, including cannabidiol, ODP's position is that components of the marijuana plant should be evaluated by the same rigorous, scientific FDA process through which every legal medication in the United States is tested.

Pharmaceutical grade CBD products have shown promise. Research on Epidiolex®, a highly purified CBD oil derived from the marijuana plant showed 43 percent of Dravet syndrome patients taking Epidiolex® experienced a 50 percent or greater reduction in convulsive seizures<sup>1</sup>. Another study conducted with Lennox Gastaut syndrome showed that 44.2 percent of patients taking Epidiolex had 50 percent or greater reduction in seizures<sup>2</sup>.

Idaho's Expanded Access Program provided access to Epidiolex® to qualifying pediatric patients suffering from intractable seizures. Twenty-five of the 39 patients enrolled in the EAP reported some form of subjective seizure improvement for either seizure frequency or seizure severity<sup>3</sup>. Overall, results from the study showed that Epidiolex® appears to be safe and well tolerated by most patients.

The FDA accepted the new drug application for Epidiolex® in October, 2017 with Priority Review and approved Epidiolex® in June 2018. The DEA subsequently scheduled Epidiolex® as a Schedule V drug. Epidiolex® is now available with a physician's prescription and will be covered under most Medicaid and insurance plans. The manufacturer's Patient Assistance Program will provide Epidiolex® free of charge to financially eligible patients who cannot afford their medication or don't have sufficient prescription drug coverage. Therefore, CBD is available as a clean, regulated product, prescribed by a doctor, and covered by insurance.

Artisanal CBD products are not regulated by the Food and Drug Administration and research has shown that such products contain inconsistent levels of CBD and THC<sup>4,5</sup>.

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<sup>1</sup> Cross, H.J., Devinsky, O., Laux, L., Marsh, E., Miller, I., Nabbut, R., Scheffer, I.E., Thiele, E.A., Wright, S. (2016). Proceedings from The National Epilepsy Society Annual Meeting: *Cannabidiol (CBD) significantly reduces convulsive seizure frequency in Dravet Syndrome: Results of a multi-center, randomized, double-blind, placebo-controlled trial (GWPCARE1)*. Houston, TX

<sup>2</sup> Thiele, E.A., Mazurkiewicz-Beldzinska, M., Benbadis, S., Marsh, E.D., Joshi, C., French, J.A., Roberts, C., Taylor, A., Sommerville, K. (2016). Proceedings from The National Epilepsy Society Annual Meeting: *Cannabidiol (CBD) significantly reduces drop seizure frequency in Lennox-Gastaut Syndrome (LGS): Results of a multi-center, randomized, double-blind, placebo-controlled trial (GWPCARE4)*. Houston, TX

<sup>3</sup> Bishop, J.A., Wechsler, R.T., Pape, D.A., Gravett, L.L. (2017, December). *Cannabidiol (CBD, Epidiolex) for Severe, Treatment-Resistant Epilepsy: Continued Experience in Idaho Expanded Access Program*. Poster session presented at the American Epilepsy Society Annual Meeting, Washington, D.C.

<sup>4</sup> Vandrey, R., Raber, J.C., Raber, M.E., Douglass, B., Miller, C., Bonn-Miller, M.O. (2015). Cannabinoid dose and label accuracy in edible medical cannabis products. *Journal of the American Medical Association*, 313 (24). Pp 2491-2493.

Many major medical organizations also oppose the use of medical marijuana outside of the FDA process. The American Medical Association has stated, “(1) cannabis is a dangerous drug and as such is a public health concern<sup>6</sup>”.

Likewise, the American Academy of Pediatrics opposes “medical marijuana” outside the regulatory process of the FDA due to potential harms to children and adolescents<sup>7</sup>.

In a letter to Governor C.L. “Butch” Otter in 2015, the American Epilepsy Society wrote, “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.” The AES also noted, “Not a single pediatric neurologist in Colorado recommends the use of artisanal cannabis preparations.”

Maintaining drug policy that promotes prevention is paramount to the Office of Drug Policy. Idaho ranked 24<sup>th</sup> among the states and District of Columbia for the percentage of individuals 12 to 17 reporting marijuana use in the past month<sup>8</sup>. The top 22 states all have either legal retail or medical marijuana.

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<sup>5</sup> Bonn-Miller, M., Loflin, M., Thomas, B., et al (2017) Labeling accuracy of Cannabidiol extracts sold online. *JAMA*, 318(17). Retrieved from <https://jamanetwork.com/journals/jama/article-abstract/2661569?redirect=true>

<sup>6</sup> American Medical Association House of Delegates (1-13), Council on Science and Public Health Report 2. “AMA Policy Statement on Cannabis, H-95.998.” November 19, 2013. P. 6

<sup>7</sup> American Academy of Pediatrics, Committee on Substance Abuse, Committee on Adolescence. (2015) The impact of marijuana policies on youth: Clinical, research, and legal update. Retrieved from: <http://pediatrics.aappublications.org/content/135/3/584>

<sup>8</sup> SAMHSA, Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, 2016-2017.