Cannabidiol Research Expansion Act (S 1276, 115th Congress)

Requires the Departments of Justice and Health and Human Services to reassess the appropriate drug schedule of cannabidiol and reduces barriers for cannabidiol medical research.

Updated last **August 17, 2017**
for the 05/25/2017 version of S 1276.

WHAT IT DOES

The Cannabidiol Research Expansion Act (S 1276) focuses on the regulation of and research on cannabidiol (CBD), defined in the bill as a nonpsychoactive substance derived either from marijuana or synthetically. The bill gives the Department of Justice (DOJ) and the Department of Health and Human Services (HHS) a one year deadline to complete an assessment of CBD in the manner specified by the Controlled Substances Act (21 U.S.C. 801 *et seq.*; specifically 21 U.S.C. 811(b)); determine whether CBD should be a scheduled drug under the Controlled Substances Act; and, based on the results of that review and determination, initiate the process of control, transfer, or removal for CBD per the Controlled Substances Act (21 U.S.C. 811(a)).

The Cannabidiol Research Expansion Act also encourages research on the medical uses of CBD and amends regulations currently applying to CBD research. More specifically, the bill:

- Requires the DOJ to amend the Code of Federal Regulations (21 CFR 1301.18) to eliminate the requirement that the Food and Drug Administration review requests from authorized researchers seeking to increase the quantities of controlled substances needed for research protocols; and to give the Drug Enforcement Agency (DEA) up to 30 days to deny a supplemental research protocol involving controlled substances before such protocol is automatically approved;
- Allows appropriately registered entities to manufacture, distribute, dispense, and possess marijuana and CBD for authorized medical research;
- In the event that CBD is listed as a schedule I drug, allows appropriately registered entities to continue performing CBD research if they were already performing that research when the schedule determination was reached, and if they were authorized to perform research with any schedule II drug;
- Requires the DOJ to create registration processes for entities manufacturing or distributing CBD or marijuana for the purpose of commercially producing a drug containing or derived from marijuana;
- Creates a timely process for DOJ approval of manufacturing, distributing, dispensing, or possessing controlled substances under the Controlled Substances Act, requiring a decision within 60 days of the application or within 90 days if supplemental information is requested by DOJ; and
- Amends the Controlled Substances Import and Export Act (21 U.S.C. 951 *et seq.*) to allow for the importation of certain quantities of CBD and marijuana for authorized research purposes or for manufacturing approved drugs; and removes registration requirements for importing or exporting CBD and marijuana for those same purposes.

The bill further allows for the possession and transport of CBD and other nonpsychoactive components of marijuana for the treatment of intractable epilepsy, defined in the bill as a form of epileptic seizure disorder for which standard medical treatment does not prevent or ameliorate recurring seizures or that results in harmful side effects, if the epileptic patient:

- Has had intractable epilepsy for at least six months;
- Has not benefitted from other forms of treatment;
- Has discussed with their neurologist the potential harms and benefits of treating epilepsy with CBD or nonpsychoactive components of marijuana; and
- Receives an agreement from their neurologist that they will monitor the patient for adverse conditions.

Lastly, the bill requires HHS to increase the scale of research initiatives on CBD and other nonpsychoactive components of marijuana as undertaken by the National Institutes of Health (NIH). Such research will focus on potential therapeutic applications of those substances, including the treatment of intractable epilepsy.

RELEVANT SCIENCE

Cannabidiol

Cannabidiol is one of the cannabinoids, the class of chemical compounds synthesized by the *Cannabis* plant. According to the NIH, cannabinoids interact with the brain and the body during *Cannabis* usage. Cannabinoids exert varying effects on the brain and the body through the endocannabinoid system (ECS). The ECS consists of cannabinoid receptors, endogenous cannabinoids (endocannabinoids), and the enzymes that synthesize and degrade the endocannabinoids. Endocannabinoids engage cannabinoid receptor sites on neurons in a way that influences the activity of those cells and regulates many normal cellular functions. In this way, the ECS is naturally regulated in the body by endocannabinoids. However, externally introduced cannabinoids derived from *Cannabis* can interfere with the function of endocannabinoids and the physiological regulation of this system.

Cannabinoids affect the brain and body differently; some cannabinoids are psychoactive, allowing them can alter the brain and the body, and some are nonpsychoactive. According to the National Institute on Drug Abuse (NIDA), CBD is not psychoactive and does not induce euphoria, due to its lack of binding affinity for the Cannabinoid 1 receptor (CB1) on neurons. Activation of the CB1 receptor induces euphoric effects. Psychoactive cannabinoids, such as THC, have a high binding affinity for the CB1 receptor site and activate CB1; nonpsychoactive cannabinoids, such as CBD, have a low binding affinity for CB1 and do not active CB1.

NIDA further explains that although CBD cannot produce psychoactive effects by activating CB1 cannabinoid receptor sites, CBD can produce other therapeutic effects by interacting with other cannabinoid receptors and proteins. Through activation of various cannabinoid receptors and ion channels, CBD has been found to have potential anti-inflammatory, anti-pain, anti-tumor, anti-psychotic, and anti-anxiety effects.

Epilepsy

Epilepsy is a brain disorder that causes recurring seizures. Approximately 1.2% of individuals in the United States had active epilepsy in 2015. During a seizure, neurons miscommunicate and send the wrong signals, causing involuntary movements, sensations, and emotions. Often, the underlying cause of epileptic neuron miscommunication is unknown, but various potential causes include genetic disorders, stroke, brain tumors, traumatic brain injury, infections, and Alzheimer's disease.

Different types of epilepsy are categorized based on the extent of neuron miscommunication during the seizure. Individuals with generalized epilepsy have seizures that affect neurons on both sides of the brain whereas those with focal epilepsy have seizures that affect neurons in one side of the brain. Individuals could also have both forms of epilepsy, or an unclassified form in the absence of a diagnosis.

Due to differences in types of epilepsy and co-occurring medical conditions, those with epilepsy can experience seizures of different types and severities. Seizure effects may include involuntary body movements, impaired consciousness, and intense changes in physical or emotional feelings. The Centers for Disease Control and Prevention explains that all seizures may reduce the quality of life in those with epilepsy. Physically, the involuntary body movements occurring during seizures can result in injury or death. Psychologically, the toll of recurring seizures can cause feelings of depression and anxiety.

While no cure exists for epilepsy, antiepileptic medications exist to reduce the frequency and severity of epilepsy-induced seizures. Around 70% of patients with epilepsy will gain more control over their seizures with medication, but 30% will not adequately respond to traditional medication. In response, researchers have considered administering CBD to treat seizures. Various studies of children and young adults with specific epileptic syndromes suggest that CBD can deliver a statistically significant reduction in seizure frequency. Other research suggests similar outcomes for adults, but researchers point out that more clinical studies are

needed to best evaluate CBD's therapeutic use for seizures.

RELEVANT EXPERTS

William Herman Wilson, PhD, is a Professor Emeritus of Psychiatry and Behavioral Sciences at Duke University. His research focuses on the effects of marijuana and other substances on blood, metabolism, and the brain in general.

Relevant publications:

- Mathew, R.J., W.H. Wilson, and R. Davis. 2003. "Postural Syncope After Marijuana: A Transcranial Doppler Study of the JHemodynamics." *Pharmacology Biochemistry and Behavior* 75(2): 309–318. doi:10.1016/S0091-3057(03)00086-8
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- Mathew, R.J., and W.H. Wilson.1993. "Acute Changes in Cerebral Blood Flow After Smoking Marijuana." *Life Sciences* 52(8): 757–767. doi:10.1016/0024-3205(93)90239-Y

Madeline Meier, PhD, is an Assistant Professor of Psychology at Arizona State University. Her research focuses on sociological risk factors for substance dependence and the neurology behind adolescent substance abuse.

Relevant publications:

- Meier, M.H., W. Hall, A. Caspi, W. Belsky, M. Cerdá, H.L. Harrington, R. Houts, R. Poulton, and T.E. Moffitt. 2016. "Which Adolescents Develop Persistent Substance Dependence in Adulthood? Using Population-Representative Longitudinal Data to Inform Universal Risk Assessment." *Psychological Medicine* 46(4): 877–889. doi:10.1017/S0033291715002482

- Volkow, N.D., J.M. Swanson, A.E. Evins, L.E. DeLisi, M.H. Meier, R. Gonzalez, M.A. Bloomfield, H.V. Curran, and R. Baler. 2016. "Effects of Cannabis Use on Human Behavior, Including Cognition, Motivation, and Psychosis: A Review." *JAMA Psychiatry* 73(3): 292–297. doi:10.1001/jamapsychiatry.2015.3278
- Cerdá, M., T.E. Moffitt, M.H. Meier, H.L. Harrington, R. Houts, S. Ramrakha, S. Hogan, R. Poulton, and A. Caspi. 2016. "Persistent Cannabis Dependence and Alcohol Dependence Represent Risks for Midlife Economic and Social Problems: A Longitudinal Cohort Study." *Clinical Psychological Science* 4(6): 1028–1046. doi:10.1177/2167702616630958
- Meier, M.H., M.L. Hill, P.S. Small, and S.S. Luthar. 2015. "Associations of Adolescent Cannabis Use with Academic Performance and Mental Health: A Longitudinal Study of Upper Middle-Class Youth." *Drug and Alcohol Dependence* 156: 207–212. doi:10.1016/j.drugalcdep.2015.09.010
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BACKGROUND

Marijuana and marijuana extracts, including CBD, are currently classified as schedule I drugs under the Controlled Substances Act. The DEA specifies that this classification is reserved for substances which have "no currently accepted medical use and a high potential for abuse". Of note, in the final rule classifying marijuana extracts under the Controlled Substances Act (81 FR 90194), the DEA emphasized that CBD counts as a marijuana extract because it is a cannabinoid.

As of August 2017, eighteen states have a statute recognizing the legality of CBD for medical use and 25 states plus D.C. and Guam have legalized the dispensing of medical marijuana.

ENDORSEMENTS & OPPOSITION

Endorsements:

- Senator Chuck Grassley (R-IA), press release, May 25, 2017: "The parents of children with severe epilepsy and other conditions are interested in cannabidiol to try to ease their children's symptoms. I understand their interest. Research is necessary to determine the potential medical value of cannabidiol, and wherever possible, the government should help facilitate the scientific research needed to give these parents the answers they need."
- Senator Dianne Feinstein (D-CA), press release, May 25, 2017: "Cumbersome research regulations have made it difficult to conduct research on the potential medical benefits of marijuana. I strongly believe such research is necessary, especially for cannabidiol, a non-psychoactive component of marijuana. This bill paves the way for new research to be conducted with greater ease to determine if cannabidiol can be an effective medication for serious illnesses such as intractable epilepsy."

Opposition:

At present, there has not been any publicly reported opposition to this bill. However, there was expressed opposition to a previous version of the bill introduced in the 114th Congress (S 3269).

- Americans For Safe Access (advocacy group advocating for legal access to marijuana for therapeutics uses), blog post, July 15, 2016: "While we are encouraged that Senators Grassley and Feinstein have asserted that exemptions to federal law are good policy, we are concerned about the millions of patients this proposal currently leaves out. We look forward to working with the bill sponsors on how we can make sure that every patient who relies on physician-recommended medical cannabis has safe and legal access to treat their condition."

STATUS

S 1276 was introduced in the Senate on May 25, 2017.

POLICY HISTORY

S 1276 is the second version of the Cannabidiol Research Expansion Act. The bill was originally introduced in the Senate on July 14, 2016 as the Cannabidiol Research Expansion Act (S 3269). Senator Dianne Feinstein (D-CA) introduced both versions of the bill.

SPONSORS

Sponsor: Senator Dianne Feinstein (D-CA)

Cosponsors:

- Senator Chuck Grassley (R-IA)

- Senator Patrick Leahy (D-VT)
- Senator Thom Tillis (R-NC)

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