Resolution #10 (18) –2018 Annual Leadership Forum

TITLE: Changing the Drug Enforcement Administration (DEA) Schedule of Tetrahydrocannabinol (THC), Cannabidiol and Combinations to Promote Research

SPONSORED BY: District I

DATE: October 30, 2017

DISPOSITION: ADOPTED AS AMENDED

Whereas, the federal government regulates the availability of medical treatments through the FDA and the DEA to ensure the treatments are safe and effective, assigning treatments to a scheduled set of restrictions; and

Whereas, marijuana is a Schedule I category substance with no federally recognized medical value, making it difficult for researchers to obtain and study cannabidiol and other cannabinoids found in the marijuana plant; and

Whereas, many states have passed statutes allowing for the prescription of marijuana to treat medical conditions in infants, children, and teens and they are primarily prescribed the liquid extract, edible form; and

Whereas physicians and other medical professional prescribers in these states have limited knowledge of the chemical content or dosing schedule of the substances they are prescribing to children because of a lack of research and data on the substance’s safety, efficacy, product testing, and quality, therefore be it

RESOLVED, that the Academy work with the federal government to reschedule tetrahydrocannabinol (THC), cannabidiol and combinations thereof to Schedule II to ensure product content and quality control and to ensure its safety and efficacy when used to treat ailments in infants, children, and teens.

FISCAL NOTE: None

REFER TO: 2018 Annual Leadership Forum

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Background Information from the Author

“Anecdotal reports continue to emerge of children with intractable epilepsy and severe autism who show symptomatic improvement after being administered cannabinoids. The call from the public for research on cannabinoids is growing louder and many families are already using marijuana for childhood conditions—this despite very little evidence on efficacy and in the face of known long-term harms. The medical community has an urgent duty to respond. As we face a tide of rapidly changing attitudes and policies on marijuana in the US and elsewhere, it is urgent that we prioritize carefully conducted RCTs to close the current knowledge gap.” J Dev Behav Pediatr. 2015 Nov-Dec; 36(9): 767–768.

“Despite the availability of more than 20 different antiseizure drugs and the provision of appropriate medical therapy, 30% of people with epilepsy continue to have seizures.” “Cannabis-based treatment for epilepsy has recently received prominent attention in the lay press and in social media, with reports of dramatic improvements in seizure control in children with severe epilepsy. In response, many states have legalized cannabis for the treatment of epilepsy (and other medical conditions) in children and adults.” (For a list of medical marijuana laws according to state, see www.ncsl.org/research/health/state-medical-marijuana-laws.aspx).

“The Schedule I category limits the availability of pure cannabidiol, Δ⁹-THC, and other cannabinoids derived from cannabis while placing a high regulatory burden on investigators who want to study these agents in cell cultures, animal models, or patients.” “If randomized clinical trials show that specific cannabinoids are unsafe or ineffective, those preparations should not be available. If studies show that specific cannabinoids are safe and effective, those preparations should be approved and made readily available.” N Engl J Med 2015; 373:1048-1058/toc/nejm/373/11/

“The regular use of marijuana during adolescence is of particular concern, since use by this group is associated with an increased likelihood of deleterious consequences. Although multiple studies have reported detrimental effects, others have not and the question of whether marijuana is harmful remains the subject of heated
debate.” “Despite some contentious discussions regarding the addictiveness of marijuana, the evidence clearly indicates that long-term marijuana use can lead to addiction.” The number goes up to 1/6 among those who start using marijuana as teenagers and to 25% to 50% among those who smoke marijuana daily.” N Engl J Med 2014;370:2219-27.

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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

21 CFR Chapter II

[Docket No. DEA–426]

**Denial of Petition To Initiate Proceedings To Reschedule Marijuana**

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Denial of petition to initiate proceedings to reschedule marijuana.

**SUMMARY:** By letter dated July 19, 2016 the Drug Enforcement Administration (DEA) denied a petition to initiate rulemaking proceedings to reschedule marijuana. Based on the HHS evaluation and all other relevant data, the DEA has concluded that there is no substantial evidence that Marijuana should be removed from Schedule I. A document prepared by the DEA addressing these materials in detail also is enclosed. In short, marijuana continues to meet the criteria for Schedule I control under the CSA because:

(1) *Marijuana has a high potential for abuse.* The HHS evaluation and the additional data gathered by the DEA show that marijuana has a high potential for abuse.

(2) *Marijuana has no currently accepted medical use in treatment in the United States.* Based on the established five-part test for making such determination, marijuana has no “currently accepted medical use” because: As detailed in the HHS evaluation, the drug’s chemistry is not known and reproducible; there are no adequate safety studies; there are no adequate and well controlled studies proving efficacy; the drug is not accepted by qualified experts; and the scientific evidence is not widely available.
Marijuana lacks accepted safety for use under medical supervision. At present, there are no marijuana products approved by the U.S. Food and Drug Administration (FDA), nor is marijuana under a New Drug Application (NDA) evaluation at the FDA for any indication. The HHS evaluation states that marijuana does not have a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions. At this time, the known risks of marijuana use have not been shown to be outweighed by specific benefits in well-controlled clinical trials that scientifically evaluate safety and efficacy.

Background Information from the Committee on Substance Use and Prevention

This resolution has already been addressed. The Committee on Substance Use and Prevention has addressed this in their 2015 policy statement “The Impact of Marijuana Policies on Youth: Clinical, Research, and Legal Update.” Recommendation #5 reads “The AAP strongly supports research and development of pharmaceutical cannabinoids and supports a review of policies promoting research on the medical use of these compounds. The AAP recommends changing marijuana from a Drug Enforcement Administration schedule I to a schedule II drug to facilitate this research.”

Background Information from the Committee on Drugs

At this time, the Committee on Drugs is not addressing the issue(s) raised in the resolved portion(s) of this resolution. The Committee on Substance Use and Prevention provides leadership for policy related to the use of marijuana. The following is current information related to the topic:

From the Food and Drug Administration:
The FDA has not approved marijuana as a safe and effective drug for any indication. The agency has, however, approved two drugs containing a synthetic version of a substance that is present in the marijuana plant and one other drug containing a synthetic substance that acts similarly to compounds from marijuana but is not present in marijuana. Although the FDA has not approved any drug product containing or derived from botanical marijuana, the FDA is aware that there is considerable interest in its use to attempt to treat a number of medical conditions, including, for example, glaucoma, AIDS wasting syndrome, neuropathic pain,
cancer, multiple sclerosis, chemotherapy-induced nausea, and certain seizure disorders.

Before conducting testing in humans of a drug that has not been approved by the FDA, an investigator submits an investigational new drug (IND) application, which is reviewed by the FDA. An IND includes protocols describing proposed studies, the qualifications of the investigators who will conduct the clinical studies, and assurances of informed consent and protection of the rights, safety, and welfare of the human subjects. The FDA reviews the IND to ensure that the proposed studies, generally referred to as clinical trials, do not place human subjects at unreasonable risk of harm. The FDA also verifies that there are adequate assurances of informed consent and human subject protection.

The FDA’s role in the regulation of drugs, including marijuana and marijuana-derived products, also includes review of applications to market drugs to determine whether proposed drug products are safe and effective for their intended indications. The FDA’s drug approval process requires that clinical trials be designed and conducted in a way that provide the agency with the necessary scientific data upon which the FDA can make its approval decisions. Without this review, the FDA cannot determine whether a drug product is safe and effective. It also cannot ensure that a drug product meets appropriate quality standards. For certain drugs that have not been approved by the FDA, such as marijuana, the lack of FDA approval and oversight means that the purity and potency of the drug may vary considerably.

As with other drugs that are not approved by the FDA, the agency works closely with the medical and patient communities, and our federal partners when necessary, to allow access to experimental treatments through the expanded access provisions described in the FDA’s statute and regulations. The FDA’s expanded access provisions are designed to facilitate the availability of investigational products to patients with serious diseases or conditions when there is no comparable or satisfactory alternative therapy available, either because the patients have exhausted treatment with or are intolerant of approved therapies, or when the patients are not eligible for an ongoing clinical trial.

From the Drug Enforcement Agency:
Marijuana is currently a Schedule I substance under the Controlled Substances Act. Schedule I drugs are classified as having a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use of the drug or other substance under medical supervision. Marinol, a synthetic version of THC, the active ingredient found in the marijuana plant, can be prescribed for the control of nausea and vomiting caused by chemotherapeutic agents used in the treatment of cancer and to stimulate appetite in AIDS patients. Marinol is a Schedule III substance under the Controlled Substances Act. Schedule III drugs are classified as having less potential for abuse than the drugs or substances in Schedules I and II, and have a currently accepted medical use in treatment in the U.S., and abuse of the drug may lead to moderate or low physical dependence or psychological dependence.

**Other:**

Some media outlets have reported that despite repeated attempts by advocates requesting that marijuana be moved to Schedule II, the DEA has pointed to the FDA's guidance that says it does not have medical value.

Former Acting DEA Chief Chuck Rosenberg had been quoted as saying that DEA takes recommendations about how to classify the drug from the FDA. He also acknowledged that some marijuana studies show promise for children with epilepsy.

**Background Information from Federal Advocacy**

The Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA) can work together to reschedule substances, provided that the substances are approved through the FDA New Drug Application (NDA) process. Following FDA’s determination that a scheduled drug or derivative is approved through the NDA process, it must then submit its scientific and medical evaluation, including an analysis of abuse potential for the drug, to the DEA. Following a DEA review of the drug for its abuse potential, the DEA can accept an FDA recommendation for rescheduling. As such, marijuana-derived therapies can seek approval through FDA. The cannabidiol-based pharmaceutical Epidiolex, a seizure treatment for individuals with certain forms of epilepsy, is currently seeking FDA approval; it is the first drug derived from cannabis to do so. The company that produces Epidiolex is submitting extensive research on the
therapeutic benefits of the product based on preclinical and clinical research as part of its New Drug Application. A decision from FDA is expected in 2018.

The AAP has supported legislation to encourage research into the potential medical benefits of marijuana and marijuana derivatives to ensure that any approved treatments are grounded in medical knowledge and prioritize the needs of children. The AAP has endorsed the Marijuana Effective Drug Studies (MEDS) Act, introduced by Sens. Brian Schatz (D-HI) and Orrin Hatch (R-Utah), which seeks to increase research on marijuana-derived therapies. The MEDS Act would encourage valid scientific and clinical research into marijuana’s therapeutic potential, expand sources of research-grade marijuana, and allow the commercial production of FDA-approved drugs derived from marijuana that may be developed. The legislation does not change marijuana’s classification as a Schedule I substance under the Controlled Substances Act. The AAP has opposed legislative proposals such as the Compassionate Access, Research Expansion, and Respect States (CARERS) Act, which would essentially grant federal approval of state “medical marijuana” laws that circumvent the research-based process overseen by the FDA for the review and approval of new drugs.