OpJAGAF 2019-23, 30 April 2019, Use of Cannabidiol

TOPIC

Use of Marijuana Extract – Cannabidiol

TEXT OF THE DECISION

We were asked whether Airmen are permitted to use cannabidiol (CBD) products. We conclude that with a proper prescription, Airmen are permitted to use the Food and Drug Administration-approved drug Epidiolex®, which contains CBD. Absent such a prescription, Airmen are advised against using CBD products. Depending on the source of the CBD and the member's intent, Airmen may be subject to punitive action under Article 92, Uniform Code of Military Justice (UCMJ) or Article 112a, UCMJ, as discussed below.

BACKGROUND

Cannabidiol. CBD is derived from the plant cannabis sativa L. (commonly referred to as marijuana).[1] CBD is non-psychotropic, meaning it does not produce the high associated with tetrahydrocannabinol (THC), the primary psychoactive component of marijuana.[2] Likewise, CBD does not exhibit a significant potential for abuse or dependence.[3] In June 2018, following a rigorous vetting process, the U.S. Food and Drug Administration (FDA) approved the CBD oral solution Epidiolex® for the treatment of seizures associated with two rare and severe forms of epilepsy.[4] Subsequently, the Drug Enforcement Administration (DEA) placed the FDA-approved drug formulation in Schedule V, the least restrictive schedule of the Controlled Substances Act.[5] Except for this specific drug formulation, CBD remains a Schedule I controlled substance.

CBD products are available in numerous forms including but not limited to oils, e-cigarette liquids, and extracts and can be administered via many routes.[6] CBD products available without a prescription (e.g., at health food stores, smoke shops, or online) are not FDA-approved.[7] Such products may contain appreciable levels of THC and those same products may either (1) omit any

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[1] U.S. Food and Drug Administration, *FDA Approves First Drug Comprised of an Active Ingredient Derived from Marijuana to Treat Rare, Severe Forms of Epilepsy*, June 25, 2018, https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm611046.htm.
[2] *See* Randall C. Baselt, *Disposition of Toxic Drugs and Chemicals in Man* 2063 (Biomedical Publications 2017) (1978).
[3] World Health Organization Expert Committee on Drug Dependence: Thirty-ninth Meeting, Geneva, Switz., Nov. 6–10, 2017, *Agenda Item 5.2: Cannabidiol (CBD)*, 5.
[4] *Id.*
[5] U.S. Department of Justice Drug Enforcement Administration, *FDA-approved Drug Epidiolex Placed in Schedule V of Controlled Substance Act*, Sept. 27, 2018, https://www.dea.gov/press-releases/2018/09/27/fda-approved-drug-epidiolex-placed-schedule-v-controlled-substance-act.
[6] *See Agenda Item 5.2: Cannabidiol (CBD), supra* note 3.
[7] U.S. Food and Drug Administration, *Statement from FDA Commissioner Scott Gottlieb, M.D., on Signing of the Agriculture Improvement Act and the Agency's Regulation of Products Containing Cannabis and Cannabis-derived Compounds*, Dec. 20, 2018, https://www.fda.gov/newsevents/newsroom/pressAnnouncements/ucm628988.htm.

reference to THC on the label; or, (2) list an inaccurate THC content.[8] In a 2017 study of eighty-four CBD products sold online, only thirty-one percent of the products listed an accurate CBD content (within plus or minus ten percent of the listed amount), and about twenty-one percent of the products contained THC.[9] Additionally, products labeled as CBD are sometimes adulterated with synthetic cannabinoids, as discussed below.[10] The FDA has issued warnings to numerous CBD producers for claiming their products were effective in the treatment of specific diseases.[11] Only FDA-approved drugs can make such claims.

Department of Defense Drug Testing Capabilities. The military service laboratories are bound by the technical requirements and drug concentration cutoffs established in Department of Defense (DoD) Instruction 1010.16.[12] Urine specimens tested at these laboratories are subjected to a minimum of two rounds of testing before a positive result may be reported. The two tests include screen testing using immunoassay and confirmation testing using gas chromatography/mass spectrometry (GC/MS) or liquid chromatography-tandem mass spectrometry (LC-MS/MS).[13] GC/MS confirmation testing for THC is sufficiently specific to differentiate between CBD and THC. However, given that their ingredients are not consistently regulated, use of non-FDA-approved CBD products could cause a positive result for THC using the DoD cutoff of 15 ng/mL.

LAW AND ANALYSIS

Marijuana and its extracts, hemp, synthetic cannabinoids, and FDA-approved products containing THC or CBD are all legally distinguishable, as discussed below.

Marijuana and Marijuana Extracts. Marijuana and its extracts are controlled not based upon their THC content, but rather, based upon the material comprising the end product. 'Marijuana' means "all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin."[14] In 2016, the DEA added to the Controlled Substances Act a new drug code for 'marijuana extract,' which is defined as extract containing one or more cannabinoids derived from any plant of the genus cannabis, other than the separated resin.[15] CBD is one such derivative.[16]

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[8] Marcel O. Bonn-Miller, et al., *Labeling Accuracy of Cannabidiol Extracts Sold Online*, JAMA, 1708–1709 (2017), https://jamanetwork.com/journals/jama/fullarticle/2661569.
[9] *Id.*
[10] U.S. Army Public Health Center, *Health Effects of Vape Oils Containing Unknown Substances,* Apr. 25, 2018, https://phc.amedd.army.mil/topics/healthyliving/tfl/Pages/VapeOils.aspx (About sixty patients hospitalized after vaping spice or CBD, with symptoms ranging from nausea to psychosis).
[11] U.S. Food and Drug Administration, *Warning Letters and Test Results for Cannabidiol-related Products*, Nov. 2, 2017, https://www.fda.gov/newsevents/publichealthfocus/ucm484109.htm.
[12] Department of Defense Instruction 1010.16, *Technical Procedures for the Military Personnel Drug Abuse Testing Program*, Oct. 10, 2012 (Incorporating Change 1, Feb. 27, 2017), Enclosure 4, para. 9.
[13] *Id.*
[14] Title 21, United States Code (U.S.C.) § 802(16) (2019).
[15] Title 21, Code of Federal Regulations (C.F.R.) § 1308.11(d) (2019).
[16] U.S. Department of Justice Drug Enforcement Administration, *Clarification of the New Drug Code (7350) for Marijuana Extract*, https://www.deadiversion.usdoj.gov/schedules/marijuana/m_extract_7350.html.

The Controlled Substances Act places drugs regulated under federal law in one of five schedules based upon an eight-factor analysis; such factors include consideration of the drug's potential for abuse and its physiological dependence liability.[17] Marijuana and its extracts, including CBD, are Schedule I controlled substances.[18] Military personnel are subject to prosecution under Article 112a, UCMJ for offenses involving marijuana and marijuana extracts. Federal law preempts state and local laws that legalize use of marijuana or CBD.[19]

Hemp. The Agriculture Improvement Act of 2018 (hereinafter "Farm Bill"), which the President signed into law in December 2018, excludes hemp from the Controlled Substances Act definitions of 'marijuana' and 'tetrahydrocannabinol.'[20] In accordance with the Farm Bill, 'hemp' is defined as the plant Cannabis sativa L. and any part of the plant with a THC content of not more than 0.3 percent on a dry weight basis.[21] In other words, products that would otherwise constitute the Schedule I controlled substance marijuana now qualify as hemp under the Farm Bill (and thus are not controlled) so long as those products contain 0.3 percent THC or less. In spite of the Farm Bill, an exception applies to hemp products containing CBD. On 20 December 2018, the FDA Commissioner made the following statement regarding CBD products:

> [T]he FDA requires a cannabis product (hemp-derived or otherwise) that is marketed with a claim of therapeutic benefit, or with any other disease claim, to be approved by the FDA for its intended use before it may be introduced into interstate commerce . . . [c]annabis and cannabis derived products claiming in their marketing and promotional materials that they're intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases . . . are considered new drugs . . . and must go through the FDA drug approval process for human or animal use before they are marketed in the U.S.[22]

(emphasis added). Due to their potential for adulteration and given that said products have not been recognized as safe or effective, using non-FDA-approved CBD puts Airmen at risk.[23]

Air Force Instruction (AFI) 90-507, Military Drug Demand Reduction Program, prohibits Airmen from knowingly using intoxicating substances (other than alcohol or tobacco) with the intent to alter mood or function.[24] AFI 90-507 also contains a punitive provision specifically barring ingestion of food products containing or derived from hemp seed or hemp seed oil.[25] In United States v. Pugh, the Court of Appeals for the Armed Forces considered whether this latter prohibition was overly broad.[26] The food product in question – Strong and KIND® bars – did not contain sufficient THC to interfere with the military drug testing program; further, the Court ruled

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[17] 21 U.S.C. § 811 (2019).
[18] 21 C.F.R. § 1308.11(d) (2019).
[19] Memorandum from the Undersecretary of Defense for Personnel and Readiness, *Prohibition on the Use of Marijuana or its Chemical Components by Military Service Members and Department of Defense Civilian Employees*, Feb. 27, 2018 ("The provisions of the UMCJ apply regardless of State, District, or Territorial laws permitting the use of marijuana . . . [t]his prohibition includes chemical components and extracts of marijuana listed as Schedule I illicit drugs . . .).
[20] Agriculture Improvement Act of 2018, Pub. L. No. 115–334, 132 Stat. 4490 (2018).
[21] *Id.*
[22] *Statement from the FDA Commissioner Scott Gottlieb, supra* note 7.
[23] *See id.*
[24] AFI 90-507 at para. 1.1.7.
[25] *Id.* at para. 1.1.6.
[26] 77 M.J. 1, 3 (C.A.A.F. 2017).

the use of hemp in food products marketed and sold in the United States is heavily regulated.[27] The Pugh Court found:

> [T]he Air Force has a legitimate concern in prohibiting hemp food products that contain enough THC to trigger a positive drug test. However, banning legal, properly labeled food products well regulated by the United States government under the guise of protecting airmen from unlabeled, unregulated, illegal food products is well beyond the Government's stated purpose for the ban. The regulation is therefore overbroad because Appellant's act of consuming Strong & KIND bars cannot interfere with the . . . Drug Testing Program.[28]

(emphasis added) (citation omitted). The United States market has been flooded with CBD products that the FDA construes as illegal and unreliable. Although the FDA has issued warnings to companies that misrepresent the effects of CBD, the vast scope and availability of CBD products precludes consistent federal oversight, contributing to a caveat emptor scenario where the buyer assumes the risk that the product contains THC or is otherwise mislabeled. Additionally, the Director of the Office of Drug Demand Reduction for the DoD ("the Director") has concluded that consuming (e.g., orally, intravenously, through smoking/vaporization, or any other route that results in delivery into the bloodstream) a relatively small amount of hemp products with a 0.3 percent THC content could cause THC positive urinalysis results on military drug tests. In order to protect Airmen and to preserve the Department's ability to identify illicit THC use, the Director is currently considering whether the services should enact punitive regulations prohibiting the consumption of products made or derived from hemp.

Synthetic cannabinoids. Synthetic cannabinoids, known as "spice," are often marketed as herbal blends and labeled as not for human consumption.[29] Numerous synthetic cannabinoids are Schedule I controlled substances.[30] In a 2019 study published in Forensic Science International, analysis of nine e-cigarette liquids labeled as CBD resulted in the unexpected detection of a spice analyte.[31] Given that manufacturers of spice consistently develop new variants to avoid federal regulation, some blends available are not controlled.[32] However, even those synthetic cannabinoids not controlled remain dangerous for consumption.[33] Airmen are prohibited by regulation from using spice products not listed on the schedule because of their intoxicating nature.

FDA-approved Drugs Containing THC or CBD. In addition to Epidiolex, the FDA has approved other prescription medications containing marijuana-derived substances that would otherwise be Schedule I controlled substances. Dronabinol (trade names Marinol® and Syndros®) and nabilone (trade name Cesamet®) are FDA-approved drugs containing synthetic THC. Because these drugs contain THC, their use is detectable at the service laboratories. If an Airman is lawfully prescribed dronabinol or nabilone, commanders are cautioned against pursuing judicial or administrative

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[27] *Id.* at 7–9.
[28] *Id.* at 9.
[29] *Disposition of Toxic Drugs and Chemicals in Man*, 2007.
[30] U.S. Department of Justice Drug Enforcement Administration, *Drugs of Abuse: A DEA Resource Guide* 88–89 (2017).
[31] Poklis, J.L, et al., *The Unexpected Identification of the Cannabimimetic, 5F-ADB, and Dextromethorphan in Commercially Available Cannabidiol E-liquids,* Forensic Science International, Jan. 2019, https://www.sciencedirect.com/science/article/pii/S037907381830704 7?via%3Dihub.
[32] *See Drugs of Abuse: A DEA Resource Guide, supra* note 30.
[33] *Id.*

action under Article 112a, UCMJ following a THC positive result. However, if the individual's command suspects the member is concurrently abusing marijuana, the command may request the urine be tested for the plant product tetrahydrocannabivarin (THCV), which is not present in the three drugs containing synthetic THC. The presence of THCV in the urine of an individual prescribed dronabinol or nabilone would suggest marijuana use. Commanders should consult with a DoD forensic toxicologist in the event of a THCV positive result.

The U.S. Federal Food, Drug, and Cosmetic Act (FD&C Act) grants authority to the FDA to regulate food and drugs, among other products.[34] Dietary supplements are excluded from the FD&C Act definitions of food and drugs, respectively,[35] and the FDA does not regulate dietary supplements in the same manner as drugs.[36] Although numerous products labeled as containing CBD tout their health and medical benefits, because CBD is an active ingredient in a drug product that the FDA has approved, CBD may no longer be considered a dietary supplement.[37] Additionally, the FDA has "concluded that it is a prohibited act to introduce or deliver for introduction into interstate commerce any food . . . to which THC or CBD has been added."[38]

Ultimately, the commercial availability of CBD products should not contribute to an inference that such products comply with federal law and/or the UCMJ. The DEA has determined that CBD constitutes marijuana extract, a Schedule I controlled substance. Because the FDA has approved Epidiolex, other products containing CBD (regardless of whether the product stems from hemp) may not be marketed under the guise of a dietary supplement or sold as a food product. Furthermore, the hemp-based food product under consideration in United States v. Pugh is distinguishable from CBD products because the FDA has explicitly recognized that non-FDA-approved CBD is illegal and has not been proven safe or effective. Further, use of such products could cause a positive THC result on a service laboratory drug test. In determining whether to pursue punitive or adverse action for an offense involving CBD, commanders should focus on the source of the CBD and the member's intent.

CONCLUSION

The exception to AFI 90-507's prohibition on ingesting hemp products, established in United States v. Pugh, is not applicable to CBD products. CBD available in the United States market and online is not well regulated and can trigger a positive THC result at service drug testing laboratories. Use of CBD is generally permissible only when an Airman has a valid prescription for Epidiolex.

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[34] 21 U.S.C. §§ 301–392 (2019).
[35] 21 U.S.C. § 321 (2019).
[36] U.S. Food and Drug Administration, *Dietary Supplements*, Nov. 16, 2018, https://www.fda.gov/food/dietarysupplements/.
[37] *Id.*
[38] *Id.*