DAZED AND CONFUSED: MAKING SENSE OF EMPLOYERS' RISKS FROM MANDATED COVERAGE OF NON-FDA-APPROVED CANNABIS PRODUCTS

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I. Introduction

In recent years, cannabis products that have not received approval from the U.S. Food and Drug Administration (FDA) have become increasingly popular. Non-FDA-approved products containing delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD), such as tinctures, gummies and other edibles, lotions, pills, and vaping oils and inhalation products, are sold everywhere from high-end beauty stores to local gas stations. The growing availability of these products is largely due to states' concerted efforts to enact laws legalizing non-FDA-approved cannabis products.[1] These laws create unique challenges for employers, including workplace safety issues and personnel decisions, including hiring, firing, and disciplinary actions. Employers must also wrestle with the fact that their employees may use cannabis for medical reasons, even though the cannabis products that their employees use have not undergone the FDA's rigorous review and approval process, and therefore, have unknown safety and efficacy profiles, as well as unpredictable composition and quality.

Despite the recent passage of the Agriculture Improvement Act of 2018 ("the Farm Bill"), which was intended to carve out hemp-derived products from the definition of "marijuana" under the federal Controlled Substances Act (CSA),[2] most non-FDA-approved cannabis products remain illegal under the CSA and the Food, Drug, and Cosmetics Act (FDCA).[3] Marijuana is still a Schedule I substance under the CSA, meaning that it has no currently accepted medical use and has a high potential for abuse.[4] Additionally, non-FDA-approved cannabis products, including CBD products, are often marketed for therapeutic purposes in violation of the FDCA.[5] The FDCA only permits

[1] *See State Medical Marijuana Laws*, NAT'L CONFERENCE OF STATE LEGISLATURES, (Oct. 12, 2020), https://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx.

[2] The Agriculture Improvement Act of 2018 defines "hemp" as "the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." 7 U.S.C. § 1639o(1).

[3] 21 U.S.C. § 812 Schedule 1 (c)(17) (setting forth Schedule 1 controlled substances); 21 C.F.R. §§ 1308.11(d)(23), (58); 21 U.S.C. § 331(a) (stating that an unapproved new drug cannot be sold in interstate commerce under the FDCA). Illegality under the FDCA stems from two different theories. Non-hemp products are illegal *per se* in foods, dietary supplements, and drugs. All cannabis, including hemp products, that make therapeutic claims are illegal unless they are FDA-approved drugs.

[4] 21 U.S.C. § 812(b)(1).

[5] 21 U.S.C. §§ 321(g)(1), 331 (a), 352(a); *see, e.g.*, *FDA Warns 15 Companies for Illegal Selling Various Products Containing Cannabidiol as Agency Details Safety Concerns*,

manufacturers of FDA-approved drugs to make therapeutic claims about their products.[6] Currently, the FDA has only approved four prescription drugs containing cannabis – one cannabis-derived and three cannabis-related drugs.[7] These drugs include one product containing cannabis plant-derived CBD as its active ingredient, two products that include the active ingredient dronabinol (i.e., a synthetic THC), and one product containing the active ingredient nabilone (i.e., a synthetic product with a chemical structure similar to THC).[8] The FDA-approved CBD product is specifically indicated for the treatment of seizures associated with three rare and severe forms of epilepsy, Lennox-Gastaut Syndrome, Dravet Syndrome, and Tuberous Sclerosis Complex; dronabinol is indicated for the treatment of anorexia associated with weight loss in patients with AIDS; and both dronabinol and nabilone are indicated for nausea and vomiting associated with cancer chemotherapy.[9] Yet, manufacturers of non-FDA-approved cannabis products have made unsubstantiated claims that their products can be used to prevent, diagnose, mitigate, treat, or cure several medical conditions, including: Alzheimer's Disease, autism, cancer, diabetes, heart disease, kidney disease, liver disease, opioid use disorder, Parkinson's Disease, and most recently, COVID-19.[10]

Additionally, manufacturers of non-FDA-approved cannabis products have marketed their products as dietary supplements or

FDA (Nov. 25, 2019), https://www.fda.gov/news-events/press-announcements/fda-warns-15-companies-illegally-selling-various-products-containing-cannabidiol-agency-details [hereinafter *FDA Warns 15 Companies*].

[6] 21 U.S.C. §§ 321(g)(1), 331 (a), 352(a).

[7] *FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)*, FDA (Oct. 1, 2020), https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd#farmbill [hereinafter *FDA Regulation of CBD*].

[8] *Epidiolex Label*, Greenwich Biosciences, https://www.epidiolex.com/sites/default/files/pdfs/1120/EPX-03645-1120_EPIDIOLEX_(cannabidiol)_USPI.pdf#page=9; *Marinol Label*, FDA (Revised Aug. 2017), https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/018651s029lbl.pdf; *Syndros Label*, FDA (Revised July 2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/205525s000lbl.pdf; *Cesamet NDA*, FDA (Revised May 2006) https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/018677s011lbl.pdf.

[9] *Id.*

[10] *See Warning Letter: Homero Corp DBA Natures CBD Oil Distribution*, FDA (Apr. 20, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/homero-corp-dba-natures-cbd-oil-distribution-605222-04202020; *Warning Letter: CBD Gaze*, FDA (May 26, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/cbd-gaze-607299-05262020.

food.[11] Yet, the FDA has clearly stated that it is illegal to market such non-FDA approved cannabis products by adding them to food or labeling them as dietary supplements.[12] Nonetheless, FDA is "concerned at the proliferation of such products."[13] In light of the lack of regulatory oversight and enforcement against illegal drug products, employees who use such products could be at risk of ingesting high concentrations of THC or contaminated and unsafe substances, including undisclosed pesticides, heavy metals, and controlled substances, such as K2/spice.[14] Use of these products creates particularly unique challenges for employers given that THC can cause impairment.[15]

Arguably there are minimal differences between medical and recreational cannabis beyond their "intent of use" and cost. Yet, at least six states have introduced legislation to require health plans and workers' compensation programs to cover non-FDA-approved cannabis products for medical purposes, despite the lack of safety and efficacy requirements.[16] Such legislation directly conflicts with federal laws, such as the CSA and the FDCA, poses health risks to employees, and increases risk of liability for employers. As such, states should not enact these mandates.

Part II of this Article defines key terminology and provides an overview of relevant federal laws, such as the Farm Bill of 2018, the CSA,

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[11] *FDA Regulation of Dietary Supplement & Conventional Food Products Containing Cannabis and Cannabis-Derived Compounds*, FDA, https://www.fda.gov/media/131878/download (last visited Nov. 3, 2020).

[12] *What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-Derived Compounds, Including CBD*, FDA, https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis#:~:text=The%20FDA%20has%20approved%20only,it%20as%20a%20dietary%20supplement (last updated Mar. 5, 2020) [hereinafter *What You Need to Know (And What We're Working to Find Out)*]. But note that the FDA considers certain foods containing hemp and hemp seed-derived food ingredients to be "generally recognized as safe" or GRAS. *FDA Responds to Three GRAS Notices for Hemp Seed-Derived Ingredients for Use in Human Food*, FDA, (Dec. 20, 2018), https://www.fda.gov/food/cfsan-constituent-updates/fda-responds-three-gras-notices-hemp-seed-derived-ingredients-use-human-food.

[13] *FDA Regulation of CBD, supra note 7.*

[14] Lisa Fletcher, *The Risk of Contaminants and False Labeling in the Exploding CBD Industry,* WJLA (May 15, 2019), https://wjla.com/features/7-on-your-side/the-risk-of-contaminants-and-false-labeling-in-the-exploding-cbd-industry.

[15] *See Report to the U.S. House Committee on Appropriations and the U.S. Senate Committee on Appropriations, Sampling Study of the Current Cannabidiol Marketplace to Determine the Extent that Products Are Mislabeled or Adulterated*, FDA (2020), https://hempindustrydaily.com/wp-content/uploads/2020/07/CBD-Marketplace-Sampling_RTC_FY20_Final.pdf.

[16] *See infra* Part III.A.

FDCA, and state laws governing the use of cannabis products. Part III analyzes proposed legislation that would mandate coverage of non-FDA-approved cannabis products and how that legislation may directly conflict with various federal laws, creating the potential for employer liability. Part IV provides recommendations for state legislators and employers.

II. Background

The federal and some state governments have enacted legislation with the intent to legalize non-FDA-approved cannabis products, including CBD products. There are, however, other federal laws that directly conflict with these state legalization efforts. Additionally, products currently sold to the public oftentimes do not comply with the federal or state laws that intended to legalize such products. This section defines key terminology and summarizes those relevant laws.

A. TERMINOLOGY

The terms "cannabis" and "marijuana" are often used interchangeably, however, they do not have the same meaning. [17] "Cannabis" refers to "a plant of the Cannabaceae family and contains more than eighty biologically active chemical compounds," with the most commonly known compounds being THC and CBD. [18] Under federal law, the term "marijuana" (or "marihuana") refers to "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." [19] Additionally, according to a recent interim final rule from the U.S. Drug Enforcement Administration ("DEA"), "marihuana extract" is defined as "an extract containing one or more cannabinoids that has been derived from any plant of the genus Cannabis, containing *greater than 0.3 percent* delta-9-tetrahydrocannabinol on a dry weight basis, other than the separated resin (whether crude or purified) obtained from the plant."[20] "Marihuana" does not include "hemp" as that term is defined or:

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[17] *Cannabis (Marijuana) and Cannabinoids: What You Need To Know*, NIH NAT'L CTR. FOR COMPLEMENTARY & INTEGRATIVE HEALTH, https://www.nccih.nih.gov/health/cannabis-marijuana-and-cannabinoids-what-you-need-to-know (last updated Nov. 2019).

[18] *FDA Regulation of CBD*, *supra* note 7.

[19] 21 U.S.C. § 802(16)(A).

[20] Implementation of the Agriculture Improvement Act of 2018, 85 Fed. Reg. 51639, 51641–42 (Aug. 21, 2020) (interim final rule) (emphasis added); *but see*, Brief of

> the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.[21]

"Hemp" is defined as "the plant *Cannabis sativa L.* and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of *not more than 0.3 percent* on a dry weight basis."[22] Hemp is an industrial plant once cultivated exclusively for its fiber and edible seeds.[23] While hemp is a variety of the cannabis plant, hemp varieties are lower in THC content than marijuana plants, as required by U.S. law.[24]

THC is the main psychoactive constituent of marijuana and is primarily responsible for the intoxicating and impairing effects that marijuana has on a person's mental state.[25] Cannabinoids are "[a]ny of the various naturally occurring, biologically active chemical constituents of hemp or cannabis, including some that possess psychoactive properties," such as THC.[26] CBD is a non-psychogenic cannabinoid derived from marijuana or synthesized.[27]

In this Article, the term "non-FDA-approved cannabis products" is used as a catchall term. It includes all products that are illegal under the CSA (i.e., marijuana, marijuana extract, and THC) and illegal under the FDCA (i.e., non-FDA-approved products regardless of whether they are derived from hemp or marijuana, or in other words, regardless of whether they contain less than 0.3 percent THC). The term does not

Petitioner at 5, Hemp Indus. Ass'n v. DEA, No. 20-1376 (D.C. Cir. Sept. 18, 2020) (challenging the legality of the Interim Final Rule).

21 21 U.S.C. § 802(16)(B).

22 7 U.S.C. § 1639o(1) (emphasis added).

23 Dana Sullivan Kilroy, *Speaking the Endocannabinoid System: A Glossary of Terms Used to Describe Marijuana, Cannabidiol, the Endocannabinoid System, and Cannabis*, EVERYDAY HEALTH (Nov. 6, 2019), https://www.everydayhealth.com/marijuana/cbd-oil/glossary/.

24 *Id*.

25 *Cannabis (Marijuana) and Cannabinoids: What You Need To Know*, *supra* note 17.

26 Kilroy, *supra* note 24.

27 *Common Terminology & Glossary*, THE COLLABORATIVE FOR CBD SCI. & SAFETY, https://a2890a0f-5011-4a6c-a93d-804dc45494d5.usrfiles.com/ugd/a2890a_b3d21d5fcebb49669a5191ef4dcf0a2a.pdf (last visited Nov. 3, 2020).

include food products containing hemp that the FDA has deemed legal (i.e., certain foods containing hemp and hemp seed-derived food ingredients that the FDA consider to be "generally recognized as safe" or "GRAS").[28] The term also does not include CBD-containing cosmetics, which the FDA does not prohibit outright, unless such products make improper therapeutic claims.[29]

B. THE CSA

Enacted in 1970, the CSA provides the DEA with regulatory authority over controlled substances, including the authority over the manner in which controlled substances are imported, manufactured, distributed, possessed, and used.[30] Controlled substances are drugs or other substances with abuse potential.[31] The DEA categorizes a controlled substance within five schedules based on their medical effectiveness and abuse potential.[32]

Schedule I is reserved for substances with (1) the highest potential for abuse, (2) no currently accepted medical use in the U.S., and (3) a lack of accepted safe use under medical supervision.[33] Under the CSA, it is a crime to "knowingly or intentionally . . . possess" and to "knowingly or intentionally . . . manufacture, distribute, or dispense, or possess with the intent to manufacture, distribute, or dispense" a Schedule I substance.[34] Marijuana is regulated as a Schedule I substance.[35] THC (except for THC in hemp) is also a Schedule I substance.[36] The CSA prohibits possession and distribution of non-FDA-approved marijuana even for medical use, regardless of whether a state has enacted a law to allow such use.[37] The CSA, however, does permit marijuana to be used in research by properly-licensed researchers.[38]

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[28] *FDA Responds to Three GRAS Notices for Hemp Seed-Derived Ingredients for Use in Human Food*, *supra* note 12.

[29] *FDA Regulation of CBD*, *supra* note 7.

[30] *See* 21 U.S.C. §§ 801, 811.

[31] 21 U.S.C. §§ 802(6), 811(c).

[32] *See* 21 U.S.C. §§ 811, 812.

[33] 21 U.S.C. § 812(b)(1).

[34] 21 U.S.C. § 841(a)(1).

[35] 21 U.S.C. § 812(c)(10); 21 C.F.R. §§ 1308.11(d)(23), (58).

[36] 21 U.S.C. § 812 Schedule 1(c)(17).

[37] *See* Gonzales v. Raich, 545 U.S. 1, 29 (2005).

[38] 21 U.S.C. § 822(b); Controls to Enhance the Cultivation of Marihuana for Research in the United States, 85 Fed. Reg. 82333, 82338 (Dec. 18, 2020) (Final Rule).

C. THE FARM BILL

In December 2018, Congress passed the Farm Bill, which among other things, made changes related to the production and marketing of hemp.[39] As noted above, the Farm Bill defined "hemp" as "the *plant Cannabis sativa L.* and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis."[40] It also amended the CSA by removing hemp from the CSA's definition of marijuana and the Schedule I listing of THC.[41] As a result, hemp-derived products (including hemp-derived CBD products) containing less than 0.3 percent THC that were produced with less than 0.3 percent THC extract are no longer considered controlled substances under federal law.[42] Conversely, any marijuana products with levels of THC above the 0.3 percent cut-off are not considered to be "hemp products" and are, therefore, still regulated as Schedule I controlled substances under the CSA.[43]

On August 26, 2019, the DEA announced that it would no longer require registration to grow, research, or manufacture hemp because hemp was "not a controlled substance."[44] On August 21, 2020, the DEA issued an interim final rule ("IFR"), which was intended to codify regulations required by the Farm Bill.[45] The DEA stated that the IFR

[39] *FDA Regulation of CBD*, *supra* note 7.

[40] *FDA Regulation of CBD*, *supra* note 7 (emphasis added); *cf.* Agricultural Act of 2014, Pub. L. No. 113-79, § 7606(b)(2), 128 Stat. 912-13 (2014). Congress enacted the Agricultural Act of 2014 (2014 Farm Bill), which initially defined "industrial hemp" as "the plant Cannabis sativa L. and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." The 2014 Farm Bill allowed institutes of higher education and state departments of agriculture to grow and cultivate industrial hemp for research in limited circumstances. The 2014 Farm Bill did not, however, remove hemp from the schedules of controlled substances under the CSA.

[41] CONGRESSIONAL RESEARCH SERVICE, R44742, *Defining Hemp: A Fact Sheet*, https://fas.org/sgp/crs/misc/R44742.pdf (updated Mar. 22, 2019).

[42] *FDA Regulation of CBD*, *supra* note 7.

[43] *FDA Regulation of CBD*, *supra* note 7.

[44] *DEA Announces Steps Necessary to Improve Access to Marijuana Research*, DEA (Aug. 26, 2019), https://www.dea.gov/press-releases/2019/08/26/dea-announces-steps-necessary-improve-access-marijuana-research.

[45] The regulations state that the definition of THC does not include "any material, compound, mixture, or preparation that falls within the definition of hemp," and it stated that the definition of "marihuana extract" is limited to extracts "containing greater than 0.3 percent delta-9-tetrahydrocannabinol on a dry weight basis." The IFR also removed FDA-approved products containing CBD from schedule V, among other changes. Implementation of the Agriculture Improvement Act of 2018, 85 Fed. Reg. 51639–40 (Aug. 21, 2020) (interim final rule).

"merely conforms DEA's regulations to the statutory amendments to the CSA that have already taken effect."[46] But, the IFR defined "marihuana extract" as extracts "containing greater than 0.3 percent delta-9-tetrahydrocannabinol on a dry weight basis."[47] This means that if a hemp product contains intermediate extracts of 0.3 percent THC at some point during the manufacturing process, then it is still considered a Schedule I controlled substance, even if the finished product has less than 0.3 percent THC.[48] In response, Hemp Industries Association and RE Botanicals Association filed suit against the DEA in the U.S. Court of Appeals for the D.C. Circuit to challenge the rule.[49] The case is still pending. The DEA, for now, will not regulate hemp-derived products containing less than 0.3 percent THC of a dry weight basis and that were produced using intermediate extracts containing less than 0.3 percent THC. The DEA will, however, continue to regulate marijuana and marijuana extract products containing more than 0.3 percent THC on a dry weight basis as illicit Schedule I substances, at least while the IFR remains in place.

At the same time, the Farm Bill "explicitly preserved FDA's authority to regulate products containing cannabis or cannabis-derived compounds under the [FDCA] and section 351 of the Public Health Service Act (PHS Act)."[50] According to the FDA, all cannabis and cannabis-derived products are "subject to the same authorities and requirements as any other FDA-regulated products[.]"[51]

D. THE FOOD, DRUG, AND COSMETICS ACT

Originally enacted in 1938, the FDCA provides the FDA with the authority to regulate food, drug, and cosmetic products, by, among other things, creating regulatory pathways for products and enforcing consumer protection provisions.[52] Under the act, the FDA defines a prescription drug as "a substance intended for use in the diagnosis, cure,

46 *Id.*

47 *Id.*

48 *Id.* at 51640–41.

49 Brief of Petitioner at 5, Hemp Indus. Ass'n v. DEA, No. 20-1376 (D.C. Cir. Sept. 18, 2020). Petitioners argue that 1) the DEA promulgated the IRF without complying with the proper procedure required by law; 2) the rule exceeds statutory jurisdiction, authority, or limitations; and 3) the IFR is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law in violation of the Administrative Procedures Act. *Id.*

50 *FDA Regulation of CBD*, *supra* note 7.

51 *FDA Regulation of CBD*, *supra* note 7.

52 *How Did the Federal Food, Drug, and Cosmetic Act Come About?*, FDA, https://www.fda.gov/about-fda/fda-basics/how-did-federal-food-drug-and-cosmetic-act-come-about (last updated Mar. 28, 2018).

mitigation, treatment, or prevention of disease" that is prescribed by a health care practitioner and regulated by the FDA.[53] Prior to marketing, a prescription drug must meet the FDA's standards for safety and efficacy.[54] Drugs must also uniformly meet standards regarding quality, purity, and dosage.[55] The FDA applies rigorous standards and requires substantial scientific evidence to prove a product meets the safety and efficacy requirements for its intended use before it is approved as a drug.[56] A drug without the FDA's prior approval is deemed a "new drug" under the FDCA, and it cannot be introduced, distributed, or sold in interstate commerce.[57]

In contrast, the FDCA defines a dietary supplement as a product that is intended to supplement a diet, contains one or more dietary ingredient (*e.g.*, vitamins, minerals, herbs), and is intended to be taken orally.[58] The FDA does not review dietary supplements for safety or efficacy before they are marketed in the U.S. unless they contain new dietary ingredients.[59] Additionally, while the FDA has established good manufacturing practices (GMPs) that manufacturers must comply with to help ensure the identity, purity, strength, and composition of their products, the FDA does not have a regulatory pathway ensuring the safety and efficacy of dietary supplements in the U.S. through a pre-approval process as is applicable to drugs.[60]

Moreover, dietary supplements are intended to support a consumer's diet rather than treat a patient's medical condition.[61] If a

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[53] 21 U.S.C.S. § 321(g)(1)(B); *Prescription Drugs and Over-the-Counter (OTC) Drugs: Questions and Answers*, FDA, https://www.fda.gov/drugs/questions-answers/prescription-drugs-and-over-counter-otc-drugs-questions-and-answers (last updated Nov. 13, 2017).

[54] 21 U.S.C.S. § 321(p)(1).

[55] 21 C.F.R. § 211.22(c).

[56] 21 U.S.C. § 355(d) (defining "substantial evidence" as that which generally consists of data from "adequate and well-controlled" clinical trials); 21 C.F.R. § 314.126; *see also* 21 U.S.C. § 393(b)(2)(B); FDA v. Brown & Williamson Tobacco Corp.*,* 529 U.S. 120, 133 (2000).

[57] 21 U.S.C. § 331.

[58] *Questions and Answers on Dietary Supplements*, FDA, https://www.fda.gov/food/information-consumers-using-dietary-supplements/questions-and-answers-dietary-supplements (last updated July 22, 2019).

[59] *What You Need to Know (And What We're Working to Find Out)*, *supra* note 12; 21 U.S.C. § 350b(d). The FDCA defines a "new dietary ingredient" as "a dietary ingredient that was not marketed in the United States before October 15, 1994 and does not include any dietary ingredient which was marketed in the United States before October 15, 1994." 21 U.S.C. § 350b(d).

[60] *What You Need to Know (And What We're Working to Find Out)*, *supra* note 12; *Questions and Answers on Dietary Supplements*, *supra* note 58.

[61] 21 U.S.C. § 321(ff).

dietary supplement manufacturer makes therapeutic claims about its product, then the product would be an illegal new and misbranded drug, in violation of the FDCA.[62] Such products would be considered "drugs" rather than "supplements" under the FDCA because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, or intended to affect the structure or any function of the body.[63] Yet, given that supplements are not FDA-approved, supplements with therapeutic claims are not generally recognized as safe and effective for the claimed uses.[64] Such supplements, therefore, are new drugs under the FDCA which cannot be introduced into interstate commerce until they receive FDA approval.[65]

These provisions notwithstanding, marketers frequently claim that their cannabis and cannabis-derived products treat serious medical conditions even though they have not been approved by the FDA and there is no substantial evidence of effectiveness or safety.[66] Yet, the FDA has not approved marijuana as a "drug" for therapeutic use under the FDCA. As mentioned, the agency has only approved one cannabis-derived and three cannabis-related products. The FDA has also stated that irrespective of claims, CBD and THC are only permissible in FDA-approved drugs and are not permissible ingredients in foods or dietary supplements.[67]

In other words, the FDA authorized the study of, and approved the use of, a prescription drug containing CBD or THC prior to the marketing of CBD and THC as a dietary supplement or an ingredient in food.[68]

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62 21 U.S.C. § 352(f)(1).

63 21 U.S.C. § 321(g).

64 21 U.S.C. § 321(ff)(3)(B).

65 21 U.S.C. § 331.

66 *FDA Regulation of CBD*, *supra* note 7.

67 *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*, FDA (Dec. 20, 2018), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-signing-agriculture-improvement-act-and-agencys ("It is unlawful under the [FDCA] to introduce food containing added CBD or THC into interstate commerce, or to market CBD or THC products as, or in, dietary supplements, regardless of whether the substances are hemp-derived. This is because both CBD and THC are active ingredients in FDA-approved drugs and were the subject of substantial clinical investigations before they were marketed as foods or dietary supplements. Under the [FDCA], it's illegal to introduce drug ingredients like these into the food supply, or to market them as dietary supplements.") [hereinafter *Statement from FDA Commissioner Gottlieb*].

68 As of November 11, 2020, the FDA has approved one CBD drug product (Epidiolex). *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, FDA, https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm (last visited March 13, 2021) (search "cannabidiol").

Therefore, no food or dietary supplement may contain CBD or THC; they are excluded from the FDCA's definition of dietary supplement,[69] and they are not permissible in foods because they are not GRAS or an approved additive.[70] CBD and THC cannot, therefore, be introduced into interstate commerce.[71]

The FDA has stated that it has the authority to issue a regulation allowing the use of a pharmaceutical ingredient in a food or dietary supplement, and the agency is currently in the process of evaluating what such a regulatory pathway might look like.[72] Until it creates one, however, the FDA will continue to deem the marketing of such products to be illegal.[73]

E. STATE LAW

While marijuana remains an illegal Schedule I substance under federal law, as of the end of 2019, forty-eight states have laws that decriminalize or allow the use of non-FDA-approved cannabis products under some circumstances.[74] States have also enacted their own laws governing the manufacture and sale of non-FDA-approved cannabis products. These laws vary significantly from state to state. For example, eleven states and Washington, DC have legalized adult use of cannabis products, and fifteen states have decriminalized it.[75] "Legalization" refers to removing legal prohibitions against the use of cannabis so that it is available to the general adult population for purchase and use at will, similar to the regulation of tobacco and alcohol products.[76] In these states, the laws still contain certain limitations, however, such as possession limits.[77] "Decriminalization" means that cannabis would remain illegal, but the individual possessing less than a certain amount of cannabis would not be prosecuted.[78] The individual may receive no

[69] 21 U.S.C. § 321(ff).

[70] 21 U.S.C. § 331 (ll)(3)(C).

[71] 21 U.S.C. § 331.

[72] *Statement from FDA Commissioner Gottlieb*, *supra* note 67.

[73] *Statement from FDA Commissioner Gottlieb*, *supra* note 67.

[74] Taylor Miller Thomas & Beatrice Jin, *The Dis-United States of Cannabis*, POLITICO (Oct. 1, 2019), https://www.politico.com/interactives/2019/where-is-cannabis-legal-illegal-by-state/.

[75] *Id.*

[76] Dragan M. Svrakic, et. al, *Legalization, Decriminalization & Medicinal Use of Cannabis: A Scientific and Public Health Perspective*, 109:2 MO. MED. 90 (Mar./Apr. 2012).

[77] *See, e.g.*, AK. CODE ANN. § 17.38.020; CAL. HEALTH & SAFETY CODE § 11357; COLO. CONST. ART. XVIII § 16(3).

[78] Svrakic, *supra* note 76.

penalty at all, civil fines, or may be required to obtain drug education or treatment.[79]

Some states permit the use of non-FDA-approved cannabis products for "medical" purposes. For example, the Maine Medical Use of Marijuana Act authorizes qualifying patients to obtain or receive cannabis for a medical use.[80] Under this law, a qualified patient is defined as a "person who has been a resident of the State for at least 30 days and who possesses a valid written certification regarding medical use of marijuana[.]"[81] A medical provider provides the written certificate for medical use of cannabis, establishing the provider's professional opinion that the patient is likely to receive therapeutic or palliative benefit from cannabis.[82]

Other states permit limited use of such cannabis products if they have low levels of THC or if they contain CBD.[83] For example, Iowa's Medical Cannabidiol Act of 2014 allows consumers to possess or use FDA-approved CBD products or CBD products containing no more than three percent THC and "that is delivered in a form recommended by the medical cannabidiol board, approved by the board of medicine, and adopted by the [Department of Public Health]" provided that they receive certification from a health care provider of medical necessity of such products.[84] In other states, such as Idaho, all forms and uses of cannabis, except for any drugs approved by the FDA, are illegal.[85]

III. Analysis

In some states, courts have interpreted state medical marijuana laws as requiring employers to reimburse employees for non-FDA-approved cannabis products as a workers' compensation benefit,[86] and other states may soon pass legislation requiring health plans to provide

79 Svrakic, *supra* note 76.

80 22 ME. REV. STAT. TIT. 22 § 2423-A (2020).

81 22 ME. REV. STAT. TIT. 22 § 2422(9) (2020).

82 22 ME. REV. STAT. TIT. 22 § 2423-B (2020).

83 *State Medical Marijuana Laws*, *supra* note 1.

84 IOWA CODE ANN. §§ 124E.2(6) (2020). "In a prosecution for the unlawful possession of marijuana . . . for the possession of medical cannabidiol, . . . it is an affirmative and complete defense to the prosecution that the patient has been diagnosed with a debilitating medical condition, used or possessed medical cannabidiol pursuant to a certification by a health care practitioner . . ., and, for a patient eighteen years of age or older, is in possession of a valid medical cannabidiol registration card[.]" *Id.* at § 124E.12(4)(a).

85 Thomas & Jin, *supra* note 74.

86 *See* Hager v. M&K Const., 225 A.3d 137, 140-41 (N.J. Super. Ct. App. Div. 2020).

coverage for medical use of non-FDA-approved cannabis products. But, state laws mandating coverage of non-FDA-approved cannabis products are in direct conflict with and preempted by certain federal laws. Additionally, such laws open employers up for both criminal and tort liability.

A. PROPOSED LEGISLATION

In recent years, lawmakers in several states have introduced legislation to mandate that insurance cover non-FDA-approved cannabis products as a health benefit.[87] These laws would require health plans to provide payment for such products if used by insured individuals or employers to reimburse for those products as a workers' compensation benefit through their workers' compensation insurance carrier.[88] In January 2020, the New Jersey Assembly introduced A1708, which requires workers' compensation and health insurance coverage for medical use of marijuana.[89] In January 2020, Hawaii introduced SB 2586, which requires state-regulated health plans, health maintenance organizations, and workers' compensation programs to reimburse qualifying patients up to a certain monthly and annual dollar amount for "medical cannabis or manufactured cannabis products."[90] A "qualifying

[87] In addition to the bills described in this section, Maine introduced LD942 and Wisconsin introduced SB377 in 2019, both of which would have required certain health plans to cover marijuana for medical use. But, both bills died. *See, e.g.*, H.P., 697, 129th Leg., 1st Sess. (Me. 2019); WI SB 377, 2019-20 Reg. Sess. (Wis.2019).

[88] *See* A. 1708, 219th Leg. (N.J. 2020); S.B. 2054, 2019-20 Reg. Sess. (N.Y. 2020); H. 3875, 191 Gen. Ct. Leg. (Ma. 2019); H.P., 697, 129th Leg., 1st Sess. (Me. 2019); WI S.B. 377, 2019-20 Reg. Session (Wis. 2019).

[89] A. 1708, 219th Leg. (N.J. 2020). This bill amends Section 16 of P.L. 2009, which adopts the definition of marijuana from the New Jersey Controlled Dangerous Substances Act. "Marijuana" is defined as "all parts of the plant genus Cannabis, whether growing or not; the seeds thereof; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds, except those containing resin extracted from the plant; but shall not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks, fiber, oil, or cake, or the sterilized seed of the plant which is incapable of germination." The definition excludes "industrial hemp cultivated pursuant to the New Jersey Industrial Hemp Pilot Program." *Id.*; N.J. STAT. ANN. §§ 24:21-2.

[90] S.B. 2586 , 30th Leg. S.D. 1 (Haw. 2020). Pursuant to this bill, "medical cannabis" has the same meaning as "marijuana" and "marijuana concentrate." *Id.*; HAW. REV. STAT. 329-121. "Marijuana" is defined as "all parts of the plant (genus) Cannabis whether growing or not; the seeds thereof, the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or resin. It does not include the mature stalks of the plant, fiber produced from the stalks, oil, or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of the plant which is

patient" is defined as "a person who has been diagnosed by a physician or advanced practice registered nurse as having a debilitating medical condition."[91] In January 2019, New York introduced SB 2054, which requires that certain state-regulated health plans (e.g., exchange plans, Medicaid, and the Children's Health Insurance Program (CHIP) and workers' compensation) cover marijuana.[92] Massachusetts also introduced a bill that would require state employee health plans, Medicaid managed care organizations, and other state-regulated plans to cover "medical use marijuana."[93] All of these bills would mandate coverage of non-FDA-approved cannabis products.

B. HEALTH COVERAGE & BENEFITS

1. Small Business Group Health Plans

Under the Patient Protection and Affordable Care Act (ACA), states have regulatory authority over some employer health plans, such as group plans offered to employers through the Small Business Health Options Program (SHOP).[94]

SHOP plans are likely prohibited from covering non-FDA-approved cannabis products. The ACA contains requirements for exchange plans' formulary drug lists (i.e., the list of drugs that a particular health plan has decided to cover).[95] For example, the ACA requires pharmacy and therapeutic committees to base their decisions to include a medication

incapable of germination." *Id.* at § 329-1. "Marijuana concentrate" means hashish, tetrahydrocannabinol, or any alkaloid, salt, derivative, preparation, compound, or mixture, whether natural or synthesized, of tetrahydrocannabinol. HAW. REV. STAT. § 712-1240 (2020).

91 HAW. REV. STAT. § 329-121 (2020).

92 S.B. 2054, 2019-20 Reg. Sess. (N.Y. 2020). New York Public Health Law defines "marijuana" as "all parts of the plant of the genus Cannabis, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin. It does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of the plant which is incapable of germination," and also includes tetrahydrocannabinols or a chemical derivative of tetrahydrocannabinol. N.Y. PUB. HEALTH LAW §§ 3302, 3397-b.

93 H. 3875, 191 Gen. Ct. Leg. (Ma. 2019). "Medical use marijuana" is defined as marijuana that is cultivated, processed, transferred, tested, or sold in compliance with Massachusetts's Act to Ensure Safe Access to Marijuana. 935 CMR. § 501.002.

94 42 U.S.C. § 300gg-22(a)(1); 45 C.F.R. § 150.101(b)(2); *Blueprint for Approval of State-Based Health Insurance Exchanges*: *Coverage Years Beginning On or After 2019*, CMS,https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/CMS-Blueprint-Application.pdf (last visited Mar. 24, 2021).

95 45 C.F.R. § 156.122.

on an exchange plan's formulary on the "strength of scientific evidence and standards of practice," and "the therapeutic advantages of drug in terms of safety and efficacy." [96] Non-FDA-approved cannabis products are Schedule I substances, meaning they lack scientific evidence establishing their therapeutic value.[97] Additionally, given that such substances have not received FDA approval, their safety and efficacy has not been demonstrated and cannot be assured. Thus, an exchange plan, including small business plans offered through the SHOP, would likely violate the ACA if such substances were included on the plan's formulary. Moreover, the ACA contains preemption language, which notes that states are allowed to adopt and enforce laws that provide greater consumer protections, but not weaker protections.[98] A state law requiring exchange plans to cover non-FDA-approved cannabis products would, therefore, likely be preempted by the ACA because it would weaken consumer protections in the federal law aimed at ensuring consumers receive safe and effective medications.

2. ERISA

The Employee Retirement Income Security Act of 1974 (ERISA) is a federal law that establishes minimum standards for employer-sponsored health plans in the private industry (other than churches).[99] ERISA requires plans to: (1) provide participants with plan information; (2) imposes fiduciary duties upon those who manage and control the health plan; (3) requires the plan to implement a grievance and appeals process for participants to access their plan benefits; and (4) provides participants with the right of action to sue for benefits and breaches of a fiduciary duty.[100] ERISA states that a plan shall "specify the basis on which payments are made to and from the plan[]" and that the fiduciary shall administer the plan "in accordance with the documents and instruments governing the plan[.]"[101]

[96] 45 C.F.R. § 156.122(a)(3)(iii)(B-C).

[97] 21 U.S.C. § 812(b)(1).

[98] 42 U.S.C. § 1804(d) ("Nothing in this title shall be construed to preempt any State law that does not prevent the application of the provisions of this title.").

[99] 29 U.S.C. § 1001; *ERISA*, U.S. DOJ, https://www.dol.gov/general/topic/health-plans/erisa (last visited Feb.. 26, 2021).

[100] *ERISA*, U.S. DOJ, https://www.dol.gov/general/topic/health-plans/erisa (last visited Feb. 26, 2021).

[101] 29 U.S.C. §§ 1l02(b)(4), 1l04(a)(1)(D); Egelhoff v. Egelhoff, 532 U.S. 141, 148 (2001) (*quoting* Fort Halifax Packing Co. v. Coyne, 482 U.S. 1, 9 (1987)).

ERISA preempts all state laws as they "relate to" employer-sponsored health plans.[102] Based on Supreme Court precedent, ERISA's preemption clause should be interpreted broadly to allow for national uniformity of rules that apply to employee benefit programs.[103] In particular, ERISA preempts state laws that: (1) refer specifically to ERISA plans (i.e., all private employer-sponsored health plans), (2) mandate employee benefit structures or their administration, (3) offer different enforcement mechanisms, or (4) constrain employers or plan fiduciaries to certain choices or prevent uniform administrative practice.[104] As such, unless a provision of ERISA explicitly provides states with the authority to regulate a particular aspect of an employer-sponsored plan,[105] ERISA preempts state laws that either directly regulate employer-sponsored plans (e.g., requiring a plan to offer all employees health insurance) or that indirectly impact the plans (e.g., regulating a plan's formulary).[106] Additionally, the Supreme Court has held that "if an individual, at some point in time, could have brought his claim under ERISA [to recover benefits due to him, enforce his rights, or clarify his rights under the terms of the plan], and where there is no other independent legal duty that is implicated by a defendant's actions, then the individual's cause of action is completely preempted by ERISA[.]"[107]

ERISA's "savings clause" creates an important exception from preemption, thereby allowing states to regulate "the business of insurance."[108] The savings clause permits states to "regulate traditional insurance carriers conducting traditional insurance business."[109] In other words, it allows states to regulate the terms and conditions of health insurance (e.g., the benefits in a health plan or the rules under which the health insurance market must operate). But, the Supreme

102 29 U.S.C. § 1144(a) (stating "the provisions of [ERISA] shall supersede any and all State laws insofar as they may now or hereafter related to any employee benefit plan[.]").

103 Shaw v. Delta Air Lines, 463 U.S. 85, 98 (1983); Metro. Life Ins. Co. v. Mass., 471 U.S. 724, 732 (1985); Alessi v. Raybestos-Manhattan, Inc. 451 U.S. 504, 524 (1981).

104 *Egelhoff*, 532 U.S. at 148; NY State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 658 (1995); Ingersoll-Rand Co. v. McClendon, 498 U.S. 133, 142 (1990); Fort Halifax Packing Co. v. Coyne, 482 U.S. 1, 14 (1987).

105 *See, e.g.*, 42 U.S.C. § 300gg-22(a)(1).

106 *ERISA Preemption Primer*, THE AUTISM CMTY. IN ACTION, http://tacanow.org/wp-content/uploads/2011/03/erisa-preemption-primer.pdf (last visited Feb. 26, 2021).

107 Aetna Health Inc. v. Davila, 542 U.S. 200, 210 (2004); *see also* Conn. State Dental Ass'n v. Anthem Health Plans, Inc., 591 F.3d 1337, 1345 (11th Cir. 2009) ("The *Davila* test thus requires two inquiries: (1) whether the plaintiff could have brought its claim under § 502(a); and (2) whether no other legal duty supports the plaintiff's claim.").

108 29 U.S.C. § 1144(b)(2)(A).

109 *ERISA Preemption Primer*, *supra* note 106.

Court has ruled that ERISA would preempt state law if the state law "govern[ed] … a central matter of plan administration … [or] interfere[d] with nationally uniform plan administration."[110]

The savings clause is subject to an exception known as ERISA's "deemer clause." The deemer clause provides that employer-sponsored self-insured plans (i.e., plans for which the employer provides all of the funding and coverage without the assistance of an insurance company) are not deemed to be insurance and thus not subject to state regulation.[111] The deemer clause does not, however, apply to employer-sponsored fully-insured plans (i.e., plans for which an insurance company provides funding).[112] As such, while both self-insured and fully-funded plans are both subject to ERISA, only fully funded plans may be subject to state regulation.

ERISA would likely prohibit a health plan from providing coverage of non-FDA-approved cannabis products. ERISA imposes a fiduciary duty on plan administrators to comply with all federal laws.[113] For example, in *Durand v. Hanover Insurance Group*,[114] a plan administrator brought suit against the sponsor of an employee pension plan for using a methodology to calculate lump-sum distributions that did not comply with the law.[115] The Sixth Circuit held that ERISA requires that the plan administrator act "in accordance with the documents and instruments governing the plan insofar as such documents and instruments are consistent with [ERISA]."[116] The court also noted that the plan administrator's authority to "disregard unlawful plan provisions" was "derived from [her] own duty to comply with the law."[117] As previously discussed, all non-FDA-approved cannabis products are illicit under the CSA and FDCA.[118] ERISA would therefore prohibit plan administrators from offering payment for or coverage of such products because, in doing so, plan administrators would be breaching their fiduciary duty to comply with federal laws.

ERISA also would likely preempt any state law mandating that non-FDA-approved cannabis products be a covered benefit for both self-funded plans and fully insured plans. Pursuant to the deemer clause,

110 Egelhoff v. Egelhoff, 532 U.S. 141, 148 (2001).

111 29 U.S.C. § 1144(b)(2)(B).

112 Metro. Life Ins. Co. v. Mass., 471 U.S. 724, 732 (1985).

113 *See* Durand v. Hanover Ins. Grp., Inc., 560 F.3d 436, 442 (6th Cir. 2009).

114 *Id.* at 436.

115 *Id.* at 437.

116 *Durand*, 560 F.3d at 442.

117 *Id.*

118 21 U.S.C. § 812 Schedule 1 (c)(17) (2018); 21 C.F.R. §§ 1308.11(d)(23), (58) (2020); 21 U.S.C. § 355(a) (2021); *FDA Regulation of CBD*, *supra* note 7.

states may not regulate self-funded employer plans. Thus, any state law mandating coverage of non-FDA-approved cannabis products would automatically be invalid as it pertains to self-funded plans. Additionally, such state laws would likely interfere with the nationally uniform plan administration of fully insured plans.[119] State laws legalizing the use of cannabis vary from state-to-state, and at this point, only a handful of states have introduced legislation that would mandate health plans to cover non-FDA-approved cannabis products as a health benefit. Plan administrators would have to create varying formularies from state-to-state wherein claims for cannabis coverage or reimbursement would be approved in some states but not others. As such, laws mandating coverage would interfere with plan administrators' ability to administer uniform plans nationally.

3. Workers' Compensation

Workers' compensation programs provide benefits to workers who are injured while working, or whose health conditions or disabilities were caused or worsened by workplace conditions.[120] Benefits are offered without regard to fault and are often the exclusive remedy offered for workplace injuries and illnesses.[121] Workers' compensation is usually provided through a network of state programs.[122] Employers purchase insurance to provide for workers' compensation benefits.[123] Federal workers' compensation laws cover federal civilian employees and their dependents, persons engaged in maritime employment, seamen, coal miners who develop black lung or pneumoconiosis, veterans, and railroad workers.[124] State workers' compensation statutes govern most, if not all, other workers.[125] Further, state workers' compensation laws and the protections provided vary on a state-by-state basis..[126] Workers' compensation typically covers the

119 *Gobeille v. Liberty Mut. Ins. Co.,* 136 S. Ct. 936, 943 (2016).

120 CONG. RESEARCH SERV., R44580, WORKERS' COMPENSATION: OVERVIEW AND ISSUES 1, 13 (2020), https://fas.org/sgp/crs/misc/R44580.pdf.

121 *Id.* at 1.

122 *Id.*

123 *Id.*

124 *See* Federal Employees' Compensation Act, 5 U.S.C. §§ 8101-8193 (2016); Longshore and Harbor Workers' Compensation Act, 33 U.S.C. §§ 901-950 (2020) ; Federal Coal Mine Health and Safety Act of 1969, 30 U.S.C. §§ 901-945 (2020); Federal Employers' Liability Act, 45 U.S.C. §§ 51-60 (2020); Veterans' Benefits Act, 38 U.S.C. § 1151 (2020).

125 CONG. RESEARCH SERV., *supra* note 120, at 1 ("The federal government has only a limited role in the provision of workers' compensation because most workers are covered by state laws.").

126 *See* CONG. RESEARCH SERV., *supra* note 120, at 5-6.

cost of clinical visits, laboratory tests, exams, and medications that are prescribed to treat an injured or ill employee.[127]

Coverage of medical marijuana, in particular, differs from state to state, with courts weighing in on whether reimbursement can be compelled, given that non-FDA-approved cannabis products are illegal under the CSA and FDCA.[128] For example, medical marijuana laws exempt certain entities, such as health insurers, from reimbursement mandates.[129] Colorado law provides that "[n]o governmental, private, or any other health insurance provider shall be required to be liable for any claim for reimbursement for the medical use of marijuana."[130] These exemptions could also include workers' compensation plans. Additionally, Arizona law explicitly states that nothing in its marijuana laws mandates that "a government medical assistance program, a private health insurer or a workers compensation carrier or self-insured employer providing workers compensation benefits to reimburse a person for costs associated with the medical use of marijuana."[131] Ohio's Bureau of Workers' Compensation goes one step further and states that it will only cover medications that are FDA approved, dispensed from a pharmacy, and on a pharmaceutical formulary.[132]

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[127] *See, e.g.*, CAL. LAB. CODE § 4600(a) (2021); *Medical & Pharmacy Benefits*, NY STATE INS. FUND, https://ww3.nysif.com/Home/Claimant/WCClaimant/ProviderNetworks (last visited Feb. 28, 2021); *Florida Workers' Compensation Health Care Provider Reimbursement Manual*, 45-46 (2016), https://www.myfloridacfo.com/Division/WC/PublicationsFormsManualsReports/Manuals/Final%20Draft%2069L-7.020%20Post%20Hearing%202016HCPRM%2011_30_2016.pdf.

[128] *See, e.g.*, Bourgoin v. Twin Rivers Paper Co., 187 A.3d 10, 17 (Me. 2018) (finding that employers were not required to cover medical marijuana under workers' compensation); Appeal of Panaggio, 205 A.3d 1099, 1103 (N.H. 2019) (finding that the insurer was required to cover medical marijuana); Vialpando v. Ben's Auto. Servs., 331 P.3d 975, 980 (N.M. Ct. App. 2014) (finding that the employer was required to cover medical marijuana).

[129] James Lynch & Lucian McMahon, *Haze of Confusion: How Employers and Insurers Are Affected by a Patchwork of State Marijuana Laws*, INS. INFO. INST., 13 (June 2019), https://www.iii.org/sites/default/files/docs/pdf/marijuanaandemploy_wp_062019.pdf.

[130] COLO. CONST. art. XVIII, § 14, (10)(a) (2020); Lynch & McMahon, *supra* note 129, at 13.

[131] ARIZ. REV. STAT. ANN. § 36-2814 (2020); Lynch & McMahon, *supra* note 129, at 13.

[132] Lynch & McMahon, *supra* note 129; *Medical Marijuana and Its Impact on BWC*, OHIO BUREAU OF WORKERS' COMPENSATION, 1 (Aug. 2018), https://www.bwc.ohio.gov/downloads/blankpdf/MedMarijuanaImpact.pdf.

Other states permit coverage of cannabis products. For example, in *Petrini v. Marcus Dairy, Inc.*,[133] Connecticut's Workers Compensation Commission found that medical marijuana is a "reasonable and necessary medical treatment" that is reimbursable.[134] Additionally, in 2015, the Minnesota Department of Labor and Industry promulgated a rule that excluded "medical cannabis" from its definition of illegal substance so that it could be reimbursed as a medical treatment.[135] But, laws that would mandate coverage would likely be preempted by federal law, as discussed below.

C. FEDERAL PREEMPTION AND THE CSA

State laws mandating that health plans or workers' compensation plans cover non-FDA-approved cannabis products will likely be preempted by federal laws, such as the CSA, to the extent that such state laws conflict with the federal law. The Supremacy Clause of the U.S. Constitution "unambiguously provides that if there is any conflict between federal and state law, federal law shall prevail."[136] Federal law can preempt state law in three ways: (1) "express preemption, where Congress expressly states that the federal law preempts the state law;" (2) "field preemption where Congress explicitly or implicitly leaves 'no room' for state law, or where federal law is 'so dominant' that it 'will be assumed to preclude enforcement' of state law"; and (3) "by conflict preemption, where the state law 'actually conflicts with the federal law.'"[137] Conflict preemption occurs if "compliance with both federal and state [law] is a physical impossibility" because federal and state law "irreconcilabl[y] conflict" or if "state law stands as an obstacle to the accomplishment and execution of the fully purposes and objectives of Congress."[138]

The CSA contains specific conflict preemption language. It states:

> No provision of this title shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the

133 Petrini v. Marcus Dairy, Inc., 2016 WL 6659149 (Conn. Work. Comp. May 12, 2016).

134 *Id*. at ¶ H.

135 MINN. R. § 5221.6040(7a); Lynch & McMahon, *supra* note 129.

136 Gonzales v. Raich, 545 U.S. 1, 29 (2005); *see* U.S. CONST. art. VI, cl. 2 ("This Constitution, and the Laws of the United States . . . shall be the supreme Law of the Land.").

137 Bourgoin v. Twin Rivers Paper Co., 187 A.3d 10, 14 (Me. 2018).

138 *Id*.

> exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this title and that State law so that the two cannot consistently stand together.[139]

In short, the CSA preempts any state law if (1) a conflict exists between the CSA and the state law; and (2) compliance with the requirements of both is impossible.[140] In practice, the CSA likely would not preempt state laws that simply allow for (but do not mandate) the distribution and possession of marijuana because such laws do not require an entity to violate a federal law. But, the CSA would preempt a state law mandating that an entity violates the CSA because the state law and the CSA would not be able to "consistently stand together," as established in *Bourgoin v. Twin Rivers*.[141]

1. Case Law Supporting Preemption

In *Bourgoin*, the Maine Supreme Court held that covering the cost of injured workers' marijuana qualified as aiding and abetting unlawful possession and use of marijuana.[142] In that case, the plaintiff sustained a work-related injury and was initially prescribed opioids.[143] The opioids resulted in severe adverse side effects.[144] The plaintiff's physician then issued him a certification to use medical marijuana for chronic back pain.[145] The plaintiff successfully petitioned the workers' compensation board for an order requiring his former employer, the defendant, to reimburse him for medical marijuana.[146] The court was called upon to determine the relationship between the federal CSA and the Maine Medical Use of Marijuana Act (MMUMA).[147] The court concluded that, where an employer is subject to an order that would require it to subsidize an employee's acquisition of medical marijuana, there is a positive conflict between federal and state law, and as a result, the CSA preempts the MMUMA.[148] The court noted that marijuana is a Schedule I drug, and therefore, it is illegal to knowingly or intentionally

139 *Id.* (citing 21 U.S.C. 903).
140 *Id*. at 15.
141 *Id.* at 20.
142 *Id*.
143 *Bourgoin*, 187 A.3d at 13.
144 *Id*.
145 *Id.*
146 *Id*.
147 *Id.*
148 *Id*.

"manufacture, distribute, or dispense, or possess with the intent to manufacture, distribute, or dispense" marijuana.[149] The MMUMA allows a "qualifying patient" to possess a limited amount of marijuana for medical use.[150] Under the MMUMA, a patient is "qualified" if he or she receives a written certification from a professional that he or she "is likely to receive therapeutic benefit" from the medical marijuana and the medical marijuana used "to treat or alleviate the patient's debilitating medical condition."[151] The CSA and MMUMA conflict because under the CSA marijuana has no legitimate medical purposes, unlike under the MMUMA, which states that it does.[152] As such, the court found that it would be impossible to comply with both the CSA and the state order to cover medical marijuana as a workers' compensation benefit because complying with the order requires aiding and abetting the illegal possession of marijuana; therefore, observing the CSA requires violating the MMUMA.[153] The court further noted that MMUMA does not create a "state right to commit a federal crime" and that "a person's right to use medical marijuana cannot be converted into a sword that would require another party, such as [the defendant], to engage in conduct that would violate the CSA."[154]

In discussing the employer's risk of criminal liability, the court stated that a federal prosecution can be initiated against a "principal," which is defined as any individual who, among other things, aids or abets a crime.[155] A party can be liable for aiding and abetting a crime if it: (1) took "an affirmative act in furtherance of that offense", and (2) acted "with the intent of facilitating the offense's commission."[156] Ultimately, the court found that marijuana is a Schedule I substance under the CSA for which it is illegal to "manufacture, distribute, or dispense, or possess."[157] Thus, if the defendant were to comply with the administrative order and subsidize the plaintiff's use of medical marijuana, the defendant would be engaging in conduct that meets the elements of criminal aiding and abetting despite state law allowing medical marijuana use.[158] The court stated "[a]s invoked against [the

149 Bourgoin, 187 A.3d at 16.

150 *Id.* at 18; 22 M.R.S. §§ 2422(9), 2423-A(1) (authorizing the possession of marijuana).

151 *Bourgoin*, 187 A.3d at 18.

152 *See id.* at 18-19.

153 *Id.* at 19.

154 *Id*. at 19-20.

155 *Id.* at 17 (citing 18 U.S.C. 2(a)).

156 *Id.* (citing Rosemond v. United States, 134 S. Ct. 1240, 1245 (2014)).

157 *Bourgoin*, 187 A.3d at 16 (quoting 21 U.S.C.S. § 841(a)(1)).

158 *Id.* at 17.

defendant], the MMUMA requires what federal law forbids, and the authority ostensibly provided by the Maine law is 'without effect.'"[159] The court ultimately held that employers are not required to reimburse employees for the cost of medical marijuana through workers' compensation programs.[160]

Likewise, in *In re Daniel Wright*,[161] the Massachusetts Supreme Judicial Court was asked to determine whether an insurance company can be required to reimburse an employee for medical marijuana expenses.[162] The claimant sought reimbursement for medical marijuana to treat chronic pain resulting from a work-related injury.[163] The court ruled that marijuana's status as a federally illicit substance preempted the state from ordering a workers' compensation insurer to cover medical marijuana expenses.[164] Massachusetts law expressly states that "[n]othing in the law requires any health insurer, or any government agency or authority, to reimburse any person for the expenses of the medical use of marijuana."[165] The court stated "[i]f insurers were required to make such payments, the size and scope of the legalization of medical marijuana would be substantially expanded, raising concerns about federal enforcement and preemption."[166] The court went on to state that unlike patients and providers covered by Massachusetts's medical marijuana laws, insurers would "not be participating in the patient's use of a federally proscribed substance voluntarily."[167] The risk of federal prosecution for aiding and abetting in the possession and distribution of marijuana would involuntarily be imposed upon insurers.[168] The court noted that insurers are commonly engaged in interstate commerce, which increases federal regulators' concerns of CSA violations, and that "[r]equiring interstate insurers to participate in the Massachusetts medical marijuana scheme would extend the reach of the Massachusetts act well beyond the Commonwealth's borders."[169]

159 *Id.* at 22 (quoting *Mut. Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 486-87 (2013)).
160 *Id.*
161 *In re Daniel Wright*, 486 Mass. 98 (2020).
162 *Id.* at 98-99.
163 *Id.* at 99.
164 *Id*.
165 *Id.* (quoiting St. 2012, c. 369, §7 (B)).
166 *Wright's Case*, 486 Mass at 109.
167 *Id.*
168 *Id.* at *21.
169 *Id.*

2. Improper Findings of No Preemption

There are several cases that stand in direct contrast with *Bourgoin* and *Wright*. The courts' rationale in each of these cases was flawed, however. For example, in *McNeary v. Freehold Township*,[170] a New Jersey workers' compensation judge (WCJ) ruled that the defendant, a self-insured township, was required to pay for a worker's medical marijuana.[171] In that case, the defendant refused to cover the medical marijuana treatment for the worker who had muscular spasticity, arguing that marijuana was illegal under the CSA and that the CSA preempts state law.[172] The insurer cited *Bourgoin* for the basis of its argument.[173] But, the WCJ ruled that the CSA did not preempt the state's medical marijuana law.[174] He noted that the CSA and the New Jersey Medical Marijuana Act were both intended to deter the distribution and use of illicit substances for the purposes of the overall general public health.[175] The WCJ did not personally believe that deterring the use of marijuana for medical purposes achieves the goal of improving general public health, however.[176] Making his own medical judgement, the WCJ stated that medical marijuana "is safer," "less addictive," and "better for the treatment of pain" than currently marketed opioid analgesics.[177] The WCJ also stated that an insurance carrier could not possess, distribute, or intend to distribute marijuana in violation of the CSA by providing coverage of the substance.[178]

The WCJ in *McNeary* erred because the ruling stands in direct conflict with the CSA. As noted in *Bourgoin*, the CSA contains no

170 Order, McNeary v. Freehold Twp., 2008-8094, *1 (N.J. Workers' Comp. Div., June 28, 2018).

171 *Id.*

172 *McNeary*, 2008-8094 at *4, 10, 12.

173 *Id.* at *6.

174 *Id.* at *10.

175 *Id.*

176 *Id.* at *11–12 ("I honestly don't feel in my heart of hearts that this is a conflict. . . . What else is important to note here is in this, Mr. McNeary's case, there is a documented medical need and the concern is that Mr. McNeary is going to become addicted to opioids, [P]ercocet and others. And, quite frankly, this Court is very aware of the tremendously, the explosion of these narcotics on the streets in the United States in the last decade, the tremendous amounts of death and addiction that are associated with these opioids. If there's anything criminal here, it's how these drugs have been force fed to injured people creating addicts. I believe, and I think the science supports this, is that medical marijuana is safer, it's less addictive, it is better for the treatment of pain.").

177 *Id.* at *11.

178 *McNeary*, 2008-8094 at *11 ("Certainly I don't understand how a carrier, who will never possess, never distribute, never intend to distribute these products, who will nearly sign a check into an attorney's trust account is in any way complicit with the distribution of illicit narcotics.").

exception for medical uses of marijuana.[179] Instead, the CSA places marijuana in Schedule I, which is reserved for substances with "high potential for abuse" and with "no currently accepted medical use in treatment in the U.S."[180] Had Congress or the DEA determined that marijuana contained accepted medical uses, it would have removed it from Schedule I. As such, any conflict between state law and the CSA should be resolved in favor of the CSA.[181] Moreover, while an insurer is not directly possessing, distributing, or intending to distribute marijuana, the WCJ failed to consider whether the insurer could be considered aiding and abetting such actions. Many courts have held that defendants can be convicted of aiding and abetting drug transactions because they "contribute to" or "further" such transactions by providing the "purchase money" for the illicit substances at issue.[182]

Like the WCJ in *McNeary*, the Court of Appeals of the State of New Mexico in *Vialpando v. Ben's Automotive Services*[183] upheld an order requiring an employer to reimburse an employee for medical marijuana treatment.[184] In this case, an employee sustained a low back injury.[185] He filed for workers' compensation to cover medical marijuana after his health care provider certified that his severe chronic pain was debilitating.[186] The WCJ granted his order pursuant to the state's Compassionate Use Act (CUA).[187] On appeal, the employer argued that it would be illegal and unenforceable under federal law to reimburse for medical marijuana.[188] The employer further argued that the CUA did not require reimbursement for medical marijuana.[189] The court held that the CUA *did* authorize reimbursement for medical marijuana, noting that the CUA required employers to provide injured workers with "reasonable and necessary health care services from a health care provider."[190] The court agreed with the WCJ's determination that the employee's "participation in a course of cannabis in the New Mexico [M]edical Cannabis Program would constitute reasonable and necessary

179 Bourgoin v. Twin Rivers Paper Co., 187 A.3d 10, 15 (Me. Sup. Jud. Ct. 2018); *see also* Gonzales v. Raich, 545 U.S. 1, 27–28 (2005).

180 21 U.S.C. § 812(b)(1).

181 *See Gonzales*, 545 U.S. at 29.

182 *See, e.g.*, United States v. Garcia-Benites, 702 F. App'x 818, 822 (11th Cir. 2017); United States v. Tenorio, 360 F.3d 491, 495 (5th Cir. 2004).

183 Vialpando v. Ben's Auto. Serv., 331 P.3d 975 (N.M. App. Ct. 2014).

184 *Id.*at 976.

185 *Id.*

186 *Id.* at 977.

187 *Id.*

188 *Id.* at 976.

189 *Vialpando*, 331 P.3d at 976.

190 *Id.* at 977.

services," as established by employee's medical necessity certification form from his health care provider.[191]

The employer argued that the WCJ's order was illegal because it was contrary to the CSA.[192] The court acknowledged that the CSA classifies marijuana as a Schedule I controlled substance and that any conflict between the CSA and the CUA should be resolved in favor of the CSA.[193] The court found, however, that in this case, the employer was not attempting to challenge the legality of the CUA.[194] While the employer asserted that the order to reimburse the employee's medical marijuana "essentially requires" the employer to commit a federal crime, the court also stated that the employer failed to cite to any federal statute it would be forced to violate.[195] The *McNeary* court therefore ruled in favor of the plaintiff based on failure to plead proper arguments, like the arguments made in *Bourgoin* and *Wright*.[196]

In *Lewis v. American General Media*,[197] New Mexico's CUA was challenged.[198] In that case, another worker who was certified to receive treatment with medical marijuana sought and received reimbursement through workers' compensation.[199] The employer challenged a WCJ's finding that there was sufficient evidence to support reimbursement for the marijuana.[200] Among other things, the employer argued that the CUA conflicted with the CSA.[201] While the court acknowledged that the CSA conflicted with the CUA in that the CSA did not except marijuana use for medical purposes, it still declined to reverse the WCJ's order.[202] The court noted that then Deputy Attorney General James M. Cole had issued a federal memorandum (referred to as the "Cole Memo") with the U.S. Department of Justice's (DOJ) position on marijuana enforcement.[203] The Cole Memo affirmed that marijuana is illegal under the CSA but did not identify enforcement against medical marijuana users as a priority.[204] Instead, the Cole Memo noted that the DOJ "would generally

191 *Id.* at 977-78.
192 *Id.* at 979.
193 *Id.*
194 *Id.* at 979-980.
195 *Vialpando*, 331 P.3d at 980.
196 *See id.*
197 Lewis v. Am. Gen. Media, 355 P.3d 850 (N.M. App. Ct. 2015).
198 *Id.* at 851.
199 *Id.* at 852.
200 *Id.*
201 *Id.*
202 *Id.*
203 *Lewis*, 355 P.3d at 857.
204 *Id.*

defer to state and local authorities."[205] While the employer argued that it would be aiding and abetting in a violation of the CSA, the court ruled that the employer would likely not face liability based on the DOJ's position laid out in the Cole Memo.[206]

The court in *Lewis* also erred. While the Cole Memo allowed for discretionary enforcement of the federal law, a conflict between state and federal law, nevertheless, still exists. Preemption is based upon the black letter of the law rather than the likelihood of whether that law will be enforced.[207] The Cole memo did not challenge the existence of the CSA, but merely instituted an internal policy regarding enforcement.[208] As stated in *Bourgoin*, "[p]rosecuted or not, the fact remains that [the insurer] would be forced to commit a federal crime if it complied with the directive of" a state law mandate of medical marijuana coverage; the "magnitude of the *risk* of criminal prosecution is immaterial."[209] As noted in *Wright*, reliance on an internal federal policy is misplaced because such policies are transitory.[210] For example, the current Administration revoked the Cole Memo in its entirety.[211]

In *Hager v. M&K Construction*,[212] the Appellate Division of the Superior Court of New Jersey also held that a WCJ "can order an employer to reimburse its employee for the employee's use of medical marijuana prescribed for chronic pain following a work-related accident."[213] Similar to *Bourgoin*, the employer argued that the New Jersey Compassionate Use Medical Marijuana Act (MMA) was preempted by the CSA and that the employer would be aiding and abetting in a violation of the CSA by reimbursing the employee for his marijuana use.[214] Here, as in *McNeary*, the court determined that the

205 *Id.*

206 *Id.* at 859.

207 *See* Bourgoin v. Twin Rivers Paper Co., 187 A.3d 10, 21 (Me. Sup. Jud. Ct. 2018) (referring to the "Ogden Memo," a predecessor to the Cole Memo).

208 *See id.*

209 *See id.*

210 *In re Daniel Wright*, SJC-12873 at *12-13 (["T]he Department of Justice has reversed its own stance toward the prosecution of medical marijuana cases multiple times. The Department of Justice issued a series of memoranda during the administration of President Barack Obama advising Federal prosecutors not to prioritize the prosecution of individuals engaged in marijuana-related activities pursuant to a State medical marijuana law. . . . This guidance was later rescinded under the administration of President Donald Trump.").

211 Memorandum from the Attorney General on Marijuana Enforcement (Jan. 4, 2018), *available at* https://www.justice.gov/opa/press-release/file/1022196/download.

212 Hager v. M&K Const., 462 N.J. Super. 146 (App. Div. 2020).

213 *Id.* at 152.

214 *Id.*

WCJ's order does not require the employer to possess, manufacture, or distribute marijuana, and therefore, there is no conflict between the MMA and the CSA.[215] The court further held that the employer lacked the specific intent required to aid and abet in an offense under federal law, and that "one cannot aid and abet a completed crime."[216] The court reasoned that the employer was simply paying for the employee's medical expense and not purchasing or distributing marijuana on the employee's behalf, and that the employee obtained the drug prior to the reimbursement.[217] The court further held that the employer was not an active participant in the commission of a crime but rather merely complying with state law.[218]

The arguments in *Hager* are flawed. First, as established, while the employer is not directly possessing, manufacturing, or distributing marijuana, it is aiding and abetting in the possession of marijuana if it reimburses for such products. The court is incorrect in reasoning that the employer lacks "intent" to aid and abet. As set forth in *Rosemond v. United States*,[219] "for purposes of aiding and abetting law, a person who actively participates in a criminal scheme *knowing* its extent and character *intends* that scheme's commission," and on that basis, is criminally liable.[220] An employer knowingly violates the CSA by reimbursing for marijuana because the employer is required to submit all workers' compensation claims for processing. Thus, the employer is not just paying for expenses in a black box; the employer is fully aware that the employee is seeking to possess marijuana in violation of the CSA. As such, in reimbursing for the marijuana, the employer is aiding in the commission of the crime. Moreover, it cannot be a defense to a federal law that a party complied with a state law; otherwise, the preemption doctrine would be reversed, and states could completely disregard federal criminal law. Finally, it is inaccurate to state that an insurer or employer would not aid and abet by reimbursing the cost of marijuana after it has been purchased because it is impossible to aid and abet a completed crime. By offering coverage of marijuana as a workers' compensation or health benefit, an insurer is making a future promise to reimburse marijuana costs. Because courts have held that a promise of future payment is equivalent to payment before the fact, the payment

215 *Id.* at 153.
216 *Id.* at 166.
217 *Id.*
218 *Hager*, 462 N.J. Super. at 166.
219 Rosemond v. United States, 572 U.S. 65 (2014).
220 *Id.* at 77.

itself furthers the crime's commission.[221] The promise of payment for marijuana expenses, therefore, encourages the crime of marijuana possession.

Other courts have danced around the issue of federal preemption. For example, in *In re WDF Inc.*,[222] New York Workers' Compensation Board determined that medical marijuana is reimbursable if certain criteria are met.[223] It noted that the state's Public Health Law ("Medical Use of Marijuana") permits marijuana to be "prescribed" to treat several medical conditions and that the state law is not preempted merely because the law had not yet been invalidated by the Second Circuit or the New York Court of Appeals under federal preemption doctrine.[224] Likewise, in *Appeal of Andrew Panaggio*,[225] the New Hampshire Supreme Court determined that the lower court erred when it held that the state's workers' compensation law prohibited an insurer from reimbursing for medical marijuana because marijuana treatment was "reasonable, medically necessary and causally related to [the] work injury."[226] The court remanded the case so the lower court could determine whether reimbursement would violate federal laws.[227]

One could argue that state laws requiring coverage of marijuana products, including cannabis-derived CBD containing more than 0.3 percent THC, similar to the ones proposed in New Jersey, New York, and Hawaii, would violate the CSA for the reasons discussed in *Bourgoin* and *Wright*. The CSA would preempt those laws because they require insurers and employers to take an action in violation of the CSA. The state law and the CSA "cannot consistently stand together."[228] Moreover, such laws would require insurers or employers to commit the federal crime of aiding and abetting marijuana possession.

D. FDCA

State laws mandating the coverage of non-FDA-approved cannabis products undermine the purpose and intent of the FDCA, thereby posing a risk to public health and safety.

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221 *See, e.g.*, United States. v. Camargo-Vergara, 57 F.3d 993, 1001 (11th Cir. 1995); United States. v. Mitchell, 944 F.3d 116, 120 (3d Cir. 2019).

222 2017 NY Wrk Comp G1403803 (N.Y. Workers' Comp. Bd. June 6, 2017).

223 *Id.*

224 *Id.*

225 *In Re* Panaggio, 205 A.3d 1099 (N.H. Sup. Ct. 2019).

226 *Id.* at 1103.

227 *Id.* at 1105. A subsequent opinion from the remand is not available at the time of writing.

228 *Bourgoin,* 187 A.3d at 20 (citing 21 U.S.C. 903)

1. Unapproved New Drugs and Misbranded Drugs

State laws mandating the coverage of non-FDA-approved cannabis products promote the violation of the FDCA. As explained above, when intended for use as a "drug" (i.e., to diagnose, cure, mitigate, treat, or prevent disease),[229] cannabis products must obtain FDA approval before they can be marketed or distributed in interstate commerce.[230] To date, the FDA has approved one cannabis-derived product and three synthetic cannabis-related drug products.[231] To the extent that they are used, or intended for use, to treat a medical condition, all other non-FDA-approved cannabis products are considered unapproved new drugs and are illegal under the FDCA.[232] Unapproved new drugs create significant risks to patients because the FDA has not reviewed such substances for safety, effectiveness, or quality.[233]

In recent years, the FDA has engaged in enforcement actions against parties that manufacture, distribute, market, or sell non-FDA-approved cannabis products.[234] State medical marijuana laws that allow for the distribution, sale, and possession of non-FDA-approved cannabis products are in direct conflict with the FDCA because they permit parties to introduce, or cause to be introduced, non-FDA-approved and misbranded products into interstate commerce if a health care provider certifies that a patient has a legitimate medical need for such products.

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229 21 U.S.C. § 321 (g)(1)(B).

230 *See* 21 U.S.C. § 321(g)(1).

231 Those products are Epidiolex (cannabidiol), Marinol (dronabinol), Syndros (dronabinol), and Cesamet (nabilone). *FDA and Cannabis: Research and Drug Approval Process*, FDA, https://www.fda.gov/news-events/public-health-focus/fda-and-cannabis-research-and-drug-approval-process (last updated Oct. 1, 2020).

232 *What You Need to Know (And What We're Working to Find Out)*, *supra* note 12. The FDA "permits some unapproved drugs to be marketed if:

The drug is subject to an open drug efficacy study implementation (DESI) program proceeding,

1) Health care professionals rely on the drug to treat serious medical conditions when there is no FDA-approved drug to treat the condition,
2) There is insufficient supply of an FDA-approved drug.
3) The law allows some unapproved prescription drugs to be lawfully marketed if they meet the criteria of generally recognized as safe and effective (GRASE) or grandfathered. But, the agency is not aware of any human prescription drug that is lawfully marketed as grandfathered." *Unapproved Drugs*, FDA, (Oct. 26, 2020), https://www.fda.gov/drugs/enforcement-activities-fda/unapproved-drugs.

233 21 U.S.C. § 393(b)(2); *Unapproved Drugs*, *supra* note 232.

234 *FDA Warns 15 Companies*, *supra* note 5.

Under the FDCA, the FDA has sole authority over drug approval and labeling.[235] Yet, state medical marijuana laws effectively allow states to make their own judgments about a drug's safety and efficacy. Some states even have a list of medical conditions for which the law is applicable.[236] These laws thereby stand in conflict with the FDCA.[237] State law cannot "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[238] For example, in *Zogenix, Inc. v. Patrick*,[239] the United States District Court for the District of Massachusetts found that the FDCA preempted a state order banning an FDA-approved drug.[240] In that case, the court noted that while a state's police powers permit it to regulate the administration of drugs by the health professionals, the state may not exercise those powers in a way that is inconsistent with federal law, including the FDCA's objective that safe and effective drugs be available to the public.[241]

Likewise, in *Ouellette v. Mills*,[242] the U.S. District Court for the District of Maine held that the FDCA preempted a state law permitting the importation of foreign drugs that the FDA had not approved.[243] The state had passed a law to allow Maine residents to import prescription drugs from international mail order pharmacies.[244] The court noted, however, that the FDCA "prohibits the importation or introduction into interstate commerce of any 'new drug' that has not received FDA approval."[245] Similarly, states that permit distribution and possession of non-FDA-approved cannabis products directly conflict with the FDCA by promoting the distribution of products that the FDA has not deemed to be safe and effective.

State laws mandating coverage of non-FDA-approved cannabis products further the notion that these products are safe and effective to

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235 Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 486 (2013); *see, e.g.*, Zogenix, Inc. v. Patrick, 2014 WL 1454696, at *1 (D. Mass. Apr. 15, 2014) (holding state order banning drugs which FDA had approved was preempted); Ouellette v. Mills, 91 F. Supp. 3d 1, 4 (D. Me. 2015) (holding state law permitting importation of foreign drugs FDA had not approved was preempted).

236 *State Medical Marijuana Laws*, *supra* note 1.

237 Bartlett, 570 U.S. at 486; *see, e.g.*, *Zogenix*, 2014 WL 1454696 at *1; *Ouellette*, 91 F. Supp. 3d at 4.

238 Arizona v. United States, 567 U.S. 387, 399 (2012).

239 Zogenix, Inc. v. Patrick, 2014 WL 1454696, at *1 (D. Mass. Apr. 15, 2014).

240 *Id*. at *1.

241 *Id.* at *4.

242 Ouellette v. Mills, 91 F. Supp. 3d 1, 4 (D. Me. 2015).

243 *Id.*

244 *Id.*

245 *Id.* at 5.

treat medical conditions, despite the lack of approval. The FDA has stated that more clinical trials are needed to study and assess the safety and efficacy of cannabis products to treat medical conditions.[246] Yet, state coverage mandates authorize health plans to reimburse patients who use such products for treatment purposes. In doing so, these coverage mandates create and promote a market for unapproved and unlawful drugs. Health care practitioners may direct their patients to purchase non-FDA-approved cannabis products, knowing that such products will be covered. These patients may not have otherwise purchased such products, and instead, may have been prescribed FDA-approved drugs proven to be safe and effective in treating their conditions. As such, these state mandates would create an incentive for patients to purchase and use unregulated substances that are potentially unsafe and ineffective and that are sold by entities who violate the FDCA.

Additionally, these state laws would incentivize the purchase of drugs that are often deceptively marketed, given that many manufacturers of cannabis products have misleadingly advertised their products with therapeutic claims, stating that such products can treat, mitigate, or even cure certain health conditions. Making such misleading claims is a violation of the FDCA.[247] Currently, rigorous scientific data does not exist to establish that these non-FDA-approved cannabis products are effective in treating the medical conditions that they claim to treat.[248] For example, in April 2020, the FDA issued a warning letter to Homero Corp. for marketing its CBD products as dietary supplements in violation of the FDCA.[249] The FDCA states that if a product contains an active ingredient in a drug product that has been FDA-approved, then it does not meet the definition of dietary supplement.[250] Additionally, Homero made claims that their non-FDA-approved CBD products could be used to diagnose, cure, mitigate, treat, or prevent a disease.[251] In particular, Homero's website stated that its CBD products could "alleviat[e] severe withdrawal symptoms associated with opiate dependency," and could be used to treat AIDS,

246 *FDA Regulation of CBD*, *supra* note 7.

247 *FDA Warns 15 Companies*, *supra* note 5.

248 *FDA and Cannabis: Research and Drug Approval Process*, *supra* note 231.

249 *Warning Letter: Homero Corp DBA Natures CBD Oil Distribution*, FDA (Apr. 20, 2020),https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/homero-corp-dba-natures-cbd-oil-distribution-605222-04202020.

250 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 321(ff)(3)(B)(i), (ii); *Warning Letter: Homero Corp DBA Natures CBD Oil Distribution*, *supra* note 249.

251 *Warning Letter: Homero Corp DBA Natures CBD Oil Distribution*, *supra* note 249.

Alzheimer's Disease, autism, cancer, diabetes, heart disease, kidney disease, Parkinson's disease, and others.[252] Yet, the FDA noted that Homero's CBD products were not generally recognized as safe and effective for the aforementioned uses, and therefore, the products were considered "new drugs."[253] New drugs may not be legally introduced into interstate commerce without prior approval from the FDA.[254] These deceptive marketing activities provide consumers with a false sense of security that the products they are taking are safe and beneficial to their health.

2. General Safety and Efficacy Concerns

The FDA has stated that non-FDA-approved cannabis products "can have unpredictable and unintended consequences, including serious safety risks" and that "there has been no FDA review of data from rigorous clinical trials to support that . . . unapproved products are safe and efficacious."[255] Recent studies support the FDA's statements. Given that non-FDA-approved cannabis products are not required to go through rigorous safety and efficacy protocols and lack standards for quality, purity, and dosage, many have been found to be adulterated with undisclosed substances, including high levels of THC, heavy metals, toxins, and mold. For example, one study found synthetic, psychoactive adulterants, such as "spice" / "K2," and other dangerous illicit substances in one third of the CBD vape oils that it tested.[256] Another study from 2019 showed that 70 percent of the CBD products tested were "highly contaminated" with heavy metals, such as lead and arsenic, herbicides, and pesticides.[257] Additionally, an FDA study published in July 2020 found that 49 percent of tested CBD products had THC levels above the Limit of Quantification.[258] A different study published in 2020

252 *Warning Letter: Homero Corp DBA Natures CBD Oil Distribution*, *supra* note 249.

253 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 331(d), 355(a); *Warning Letter: Homero Corp DBA Natures CBD Oil Distribution*, *supra* note 249.

254 21 U.S.C. § 355(a).

255 *FDA and Cannabis: Research and Drug Approval Process*, *supra* note 249.

256 Holbrook Mohr, *Some CBD Vapes Contain Street Drug Instead of the Real Thing*, AP NEWS (Sept. 16, 2019), https://apnews.com/article/7b452f4af90b4 620ab0ff0eb 2cca62cc.

257 Fletcher, *supra* note 14.

258 *Sampling Study of the Current Cannabidiol Marketplace to Determine the Extent that Products are Mislabeled or Adulterated*, U.S Food and Drug Administration, 6 (2020), https://aimedalliance.org/wp-content/uploads/2020/07/CBD-Marketplace-Sampling_RTC_FY20_Final.pdf.

showed that 27 percent of the leading CBD brand products contain dosages that differ from what is indicated on their labels.[259]

A recent survey highlighting consumer confusion about CBD products is also concerning. It found that 21 percent of respondents said they continue to take more of their CBD product of choice until they "feel something," 15 percent said they "estimated" their dosages, and 15 percent said they were not sure of how much they took.[260] Only half of respondents said they referred to the product labels on dosage.[261] If these products contain high levels of THC or other harmful adulterants and consumers are taking more than the recommended dose, they could experience harmful side effects. For example, the FDA recently stated that CBD toxicity could result in such adverse events as liver injury, interactions with other drugs, drowsiness, diarrhea, and changes in mood.[262] Additionally, the United States Army issued a public health warning in 2018 after approximately sixty people over the course of a few months presented health issues linked to adulterated CBD products at medical centers at two bases in North Carolina.[263] Symptoms included headaches, nausea, vomiting, disorientation, agitation, and seizures.[264] A few months later, North Carolina health officials issued their own warning after approximately thirty people presented in the emergency departments with hallucinations, loss of consciousness, and heart irregularities linked to adulterated CBD.[265]

Similarly, the Nevada Department of Taxation recently issued a public health and safety advisory because it identified several non-FDA-approved cannabis products (i.e., raw cannabis buds and raw cannabis in pre-rolled cigarettes) that contained yeast, mold, bacteria, and fungi, which are particularly dangerous to consumers with suppressed

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259 Maria Loreto, *Leading CBD Brands Still Have Some Inaccurate Dosages, Even If Their Numbers Have Improved*, CHICAGO TRIBUNE (June 17, 2020), https://www.chicagotribune.com/marijuana/sns-tft-cbd-inaccurate-dosages-20200617-vizdcxchijbqbpf5ofqvbvjtcm-story.html.

260 Hank Schultz, *Research Confirming Consumers' Confusion Points to Yawning Gap in CBD Market Surveillance*, NUTRA (May 21, 2020), https://www.nutraingredients-usa.com/Article/2020/05/21/Research-confirming-consumers-confusion-points-to-yawning-gap-in-CBD-market-surveillance.

261 *Id.*

262 *FDA Warns 15 Companies*, *supra* note 5.

263 Mark Hay, *Everything We Know About the Health Risks of Vaping CBD,* VICE, Aug. 27, 2018, https://tonic.vice.com/en_us/article/zmk55a/everything-we-know-about-the-health-risks-of-vaping-cbd; *Public Health Alert: Health Effects of Vape Oils Containing Unknown Substances*, ARMY PUB. HEALTH CTR., Aug. 31, 2020, https://phc.amedd.army.mil/topics/healthyliving/tfl/Pages/VapeOils.aspx.

264 Hay, *supra* note 263.

265 Hay, *supra* note 263.

immune systems.[266] These products had been sold legally at thirty dispensaries within the state.[267] Likewise, a Hawaii Department of Health whistleblower identified a lack of proper controls over Hawaii's marijuana dispensaries.[268] The whistleblower, a board-certified cannabis physician in the state, noted that at least a third of his patients reported safety concerns with vaping cartridges containing THC oils purchased from state-regulated shops.[269] Tests of the oils showed dangerously high concentrations of ethanoyl (e.g., ten times the ethanol allowed in Colorado), which can cause eye, lung, nose, and throat irritation among other harms.[270]

E. DRUG-FREE WORKPLACE ACT

Non-FDA-approved cannabis products also pose a risk for employers because they could result in impairment in the workplace. According to the National Alliance of Healthcare Purchasers Coalition, "THC in cannabis has an intoxicating effect that can affect an individual's motor skills, reaction time, and coordination at low levels (as little as 2.5 milligrams to 5 milligrams)."[271]

If an employee is impaired in the workplace, the employer may face liability, including loss of federal contracts, under the Drug-Free Workplace Act of 1988 (DFWA).[272] Under the DFWA, employers that have entered into federal contracts, or who have received federal grants, must make good faith efforts to maintain a drug-free workplace.[273] If they receive more than $25,000, then they must also provide

266 *Public Health and Safety Advisory 2020-05*, STATE OF NEV., DEP'T OF TAXATION, Feb. 21, 2020, https://tax.nv.gov/uploadedFiles/tax.nv.gov/ Content/MME/ Public% 20Health%20and%20Safety%20Advisory%20Cannex%202020-05%20(006).pdf; Jenny Kane, *Another Marijuana Health Advisory Issued for Products Sold at 30 Dispensaries in Nevada*, RENO GAZETTE JOURNAL, Feb. 24, 2020, https://www.rgj.com/story/news/marijuana/2020/02/24/nevada-dispensaries-sold-tainted-marijuana-pot-health-advisory-issued/4857545002/.

267 *Id.*

268 Allyson Blair, *State-Regulated Marijuana Vape Cartridges Aren't Safe, Doctor and Whistleblower Say*, HAWAII NEWS NOW, June 3, 2020, https://www.hawaiinewsnow.com/2020/06/03/state-regulated-marijuana-vape-cartridges-arent-safe-doctor-whistleblower-say/.

269 *Id.*

270 *Id.*

271 *Clinical Brief: Medicinal Uses of Cannabis-Derived Products*, NAT'L ALLIANCE OF HEALTHCARE PURCHASER COALITIONS, https://www.nationalalliancehealth.org/resources-new (last visited March 13, 2021).

272 George Fitting, *Careless Conflicts: Medical Marijuana Implications for Employer Liability in the Wake of Vialpando v. Ben's Automotive Services*, 102 IOWA L. REV. 259, 269 (2016).

273 41 U.S.C. §§ 8102–8103.

certification of such efforts.[274] If the employer is unable to make such good faith efforts, it is considered to be in material breach of its contract; payments may be suspended, the contract may be terminated, and the contractor can be suspended or debarred as a government contractor.[275] If the employer makes a false certification regarding its good faith efforts, it may be subject to federal prosecution.[276] "Drug-free workplace" is defined as "a site of an entity (A) for the performance of work done in connection with a specific contract or grant . . .; and (B) at which employees of the entity are prohibited from engaging in the unlawful manufacture, distribution, dispensation, possession, or use of a controlled substance."[277]

Given that non-FDA-approved cannabis products are illegal under the CSA, use of such products would be considered unlawful under the DFWA, triggering certain remediation steps by the employer (e.g., encouraging drug counseling, rehabilitation, or use of employee assistance program, or imposing penalties on the employee for drug abuse violations).[278] If the employer is required to cover such products through a health plan or workers' compensation, however, it is unlikely the employer could certify that it is making a good faith effort to maintain a drug-free workplace. While employers could require employees to only use such substances while they are not working, the substances may still remain in the employees' systems even when they are working.[279] Consequently, a drug test may not be able to distinguish between on-site and off-site drug use. Additionally, a recent study showed that drug testing methodology often cannot distinguish between CBD and THC even if THC levels within the CBD product are no more than 0.3 percent – the cutoff concentration for a product to become illegal marijuana rather than legal hemp.[280] Furthermore, in *University of Hawai'i Professional Assembly v. Tomasu*[281] the Supreme Court of the State of Hawaii found that to comply with the DFWA employers must both have a policy against drug use and implement that

274 18 C.F.R. § 1316.7.

275 18 C.F.R. § 1316.7.

276 18 C.F.R. § 1316.7.

277 41 U.S.C. § 8101(a)(5).

278 41 U.S.C. §§ 8101(a)(1), 8102(a)(1), 8104.

279 Priyamvada Sharma, et. al., *Chemistry, Metabolism, and Toxicology of Cannabis: Clinical Implications*, 7(4) IRAN J. PSYCHIATRY 149, 153 (2012) ("The half-life of [THC] for an infrequent user is 1.3 days and for frequent users 5-13 days.").

280 Amanda Chicago Lewis, *CBD or THC? Common Drug Test Can't Tell the Difference*, N.Y. TIMES (Oct. 15, 2019), https://www.nytimes.com/2019/10/15/science/cbd-thc-cannabis-cannabidiol.html.

281 Univ. of Haw. Prof'l Assembly v. Tomasu, 900 P.2d 161 (Haw. 1995).

policy by engaging in affirmative disciplinary action against an employee who fails a drug test.[282] The DFWA does not contain any exceptions for employers bound by state law.[283]

F. OCCUPATIONAL SAFETY AND HEALTH ACT

State laws mandating coverage of non-FDA-approved cannabis products could also expose employers to liability under the Occupational Safety and Health Act of 1970 (OSH Act) if employees are impaired. The OSH Act imposes a general duty on employers to "furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees" ("General Duty Clause").[284] The Occupational Safety and Health Administration (OSHA) has strongly supported "measures that contribute to a drug-free environment and reasonable programs of drug testing within a comprehensive workplace program for certain workplace environments, such as those involving safety-sensitive duties like operating machinery."[285]

While the OSH Act and its implementing regulations do not explicitly require a drug-free workplace, OSHA has stated that, in some situations, OSHA's General Duty Clause may be applicable "where a particular hazard is not address by any OSHA standard."[286] OSHA has stated that the four components of the General Duty Clause are:

> (1) the employer failed to keep its workplace free of a "hazard;" (2) the hazard was "recognized" either by the cited employer individually or by the employer's industry generally; (3) the recognized hazard was causing or was likely to cause death or serious physical harm; and (4) there was a feasible means available that would eliminate or materially reduce the hazard.[287]

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[282] *Id.* at 169–70 ("[M]ere promulgation of a policy that proclaims compliance with a federal statute will not constitute compliance with that statute . . . . [T]he DFWA inherently mandates implementation[.]"); Fitting, *supra* note 272, at 269.

[283] Fitting, *supra* note 272, at 269.

[284] 29 U.S.C. § 654(a)(1).

[285] Letter from John B. Miles, Director of Enforcement Programs, Occupational Health and Safety Administration to Patrick J. Robinson, Safety Coordinator, Starline Manufacturing Co., Inc., (May 2, 1998), OSHA ARCHIVE, https://www.osha.gov/laws-regs/standardinterpretations/1998-05-02.

[286] 29 U.S.C. § 654(a)(1); Letter from John B. Miles to Patrick J. Robinson, *supra* note 285.

[287] Letter from John B. Miles to Patrick J. Robinson, *supra* note 285.

The duty only arises if all four elements are present.[288] Violations of the OSH Act may include a civil penalty ranging from $5,000 to $70,000 and imprisonment.[289]

If an employer must cover non-FDA-approved cannabis products and employees are impaired while in the workplace, then the workplace may not be free of hazard. The risk of impairment from marijuana use is generally recognized in industries with safety-sensitive positions. For example, a 2019 survey from the National Safety Council (NSC) showed that 81 percent of employers were concerned about marijuana having a negative impact on their workforce.[290] As a result, the NCS has stated that no amount of marijuana or other THC products should be allowed for employees working in safety-sensitive positions given the impact of cannabis on the worker's psychomotor skills and cognitive ability.[291] Additionally, serious physical harm or death is foreseeable when an impaired employee completes safety-sensitive duties, such as operating heavy machinery or dealing with hazardous chemicals. For example, according to the National Institute on Drug Abuse, employees who tested positive for marijuana had 55 percent more industrial accidents and 85 percent more injuries than those who tested negative for marijuana use.[292] While the adoption of a drug-free workplace policy would be a feasible means of eliminating or materially reducing the hazard, state laws mandating coverage of medical marijuana interfere with employers' ability to successfully implement such a policy.

G. TORT LIABILITY

Finally, an employer could be liable for the acts of an impaired employee if such employee injures a third party or causes damage to the third party's property while acting within the scope of their employment.[293] The third party could sue under common law tort

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288 Letter from John B. Miles to Patrick J. Robinson, *supra* note 285..

289 29 U.S.C. § 666.

290 *NSC to Employers: Allow NO Cannabis Use Among Workers in Safety Sensitive Positions*, INDUS. SAFETY & HYGIENE NEWS (Oct. 22, 2019), https://www.ishn.com/articles/111721-nsc-to-employers-allow-no-cannabis-use-among-workers-in-safety-sensitive-positions.

291 *Id.*

292 *Marijuana Research Report: How Does Marijuana Use Affect School, Work, and Social Life?*, NAT'L INST. ON DRUG ABUSE (July 2020), https://www.drugabuse.gov/publications/research-reports/marijuana/how-does-marijuana-use-affect-school-work-social-life.

293 *See, e.g.*, Otis Eng'g Corp. v. Clark, 668 S.W.2d 307, 311 (Tex. 1984) (holding that an employer has a duty to exercise reasonable prudence to prevent an employee from "causing an unreasonable risk of harm to others" after the employer permitted a visibly

doctrine of vicarious liability, including respondeat superior.[294] Respondeat superior has been used to hold employers liable in situations in which employees injured or assaulted others as a result of intoxication or drug use.[295] Under the theory of respondeat superior, employers are vicariously liable for the actions of their employees.[296] To hold an employer liable under respondeat superior, plaintiffs usually must satisfy the scope-of-employment test.[297] The scope-of-employment test requires that an employee "be acting, at least in part, with the motivation to be about the employer's business" and the employee's action must be foreseeable.[298]

For example, in *Ira S. Bushey & Sons, Inc. v. United States*,[299] a drydock owner sued the United States after a member of the U.S. Coast Guard returned to his ship under the influence of alcohol and turned the drydock's water flow control valves, causing the drydock's tanks to flood.[300] As a result, the ship listed, slid off its blocks, and fell against the wall, partially sinking the ship and the drydock.[301] The defendant argued that it should not be held liable for the actions of its employee because the employee was not acting "within the scope of employment."[302] The Second Circuit Court of Appeals noted that vicarious liability is based on foreseeability.[303] It stated that the Coast Guard member's conduct "was not so 'unforeseeable' as to make it unfair to charge the government with responsibility . . . . The employer should be held to expect risks . . . which arise 'out of and in the course of' his employment of labor."[304] The court noted that "it was foreseeable that crew members crossing the drydock may negligently or even intentionally damage it."[305] Additionally, the court noted that it was foreseeable that a seaman would "find solace for solitude by copious

intoxicated employee to drive home, resulting in a fatal automobile accident). Fitting, *supra* note 272, at 271–72.

294 Laura L. Hirschfield, *Legal Drugs? Not Without Legal Reform: The Impact of Drug Legalization on Employers Under Current Theories of Enterprise Liability*, 7 CORNELL J. L & PUB. POL'Y 757, 760 (1998).

295 Fitting, *supra* note 272, at 271–72.

296 Fitting, *supra* note 272, at 271–72.

297 Fitting, *supra* note 272, at 271.

298 Fitting, *supra* note 272, at 271-72.

299 Ira S. Bushey & Sons, Inc. v. United States, 398 F.2d 167 (2d Cir. 1968).

300 *Id.* at 168.

301 *Id.*

302 *Id.* at 170.

303 *Id.* at 172.

304 Bushey & Sons, Inc. v. United States, 398 F.2d 167, 171-72; Hirschfield, *supra* note 294, at 796.

305 *Bushey & Sons*, 398 F.2d at 172.

resort to the bottle while ashore."[306] The court therefore ruled that the U.S. was vicariously liable for the Coast Guard member's actions.[307]

Likewise, under the proposed state laws, an employer may be required to cover non-FDA-approved cannabis products as part of workers' compensation benefits, or an employee may have a health plan that covers such products. It would be foreseeable that an employee under the influence of THC while acting within his or her scope of work, could cause injury or property damage, resulting in vicarious liability for the employer.

H. OTHER DISINCENTIVES TO COVER MARIJUANA PRODUCTS

Currently, many health plans only cover FDA-approved drugs with limited exceptions.[308] Health plans generally do not cover non-FDA-approved products because they have not undergone the FDA's rigorous safety and efficacy process, and as such, there is no way to guarantee such products' potency, dosage, or purity. In addition, non-FDA-approved products are not required to comply with good manufacturing practices.[309]

Moreover, employers may be hesitant to cover non-FDA-approved products through workers' compensation or health plans because doing so could be seen as condoning the use of such products at work. Yet, if an employee is under the influence in the workplace, the employee could face negative repercussions and the employer could be subject to liability. For example, the U.S. Department of Transportation (DOT) has a zero-tolerance policy for marijuana use and has announced that state initiatives have no bearing on the DOT's regulated drug testing program.[310] The policy states that the DOT "will not verify a drug test as negative based upon information that a physician recommended that the employee use 'medical marijuana' when states have passed 'medical marijuana' initiatives" because the DOT "want[s] to assure the traveling

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306 *Id.* at 171-72; Hirschfield, *supra* note 294, at 796.

307 *See* Bushey & Sons, 398 F.2d at 172.

308 *See, e.g.*, *Commercial Claim Payment Bulletin – Pharmacy Benefit: Non-FDA Approved Products* (Jan. 1, 2021), INDEPENDENCE BLUE CROSS, https://www.ibx.com/documents/35221/56638/non-fda-approved-medication.pdf/2b052ab2-2194-3502-f044-f3ecd5082a1f?t=1593556692733; *Drugs Never Covered by Medicare*, PRIORITY HEALTH, https://www.priorityhealth.com/medicare/drug-coverage/covered-drugs/never-covered (last visited Feb. 28, 2021) (noting that nonprescription drugs and non-FDA-approved products are excluded from coverage).

309 *DOT "Recreational Marijuana" Notice*, U.S. DEP'T TRANSP. (Feb. 1, 2017), https://www.transportation.gov/odapc/dot-recreational-marijuana-notice.

310 *Id.*; *DOT "CBD" Notice*, U.S. DOT (Feb. 18, 2020), https://www.transportation.gov/odapc/cbd-notice.

public that [the] transportation system is the safest it can possibly be."[311] Additionally, the DOT issued a policy on hemp-derived CBD products containing less than 0.3 percent of THC.[312] The DOT notes that many CBD products purporting to comply with the Farm Bill may in fact contain more than 0.3 percent of THC, and therefore, may produce unexpected positive drug test results.[313] As such, the agency has warned that "CBD use is not a legitimate medical explanation for a laboratory-confirmed marijuana positive result" and "consumers should beware purchasing and using" such products.[314] Thus, if state law required DOT-governed employers to cover marijuana through workers' compensation or health plans and an employee uses marijuana products, the employee could face negative ramifications, including termination of employment.[315]

IV. Recommendations

To protect residents' health and safety, states should not enact laws mandating that health plans and workers' compensation cover marijuana. Such laws cannot exist legally until Congress or the FDA removes marijuana from Schedule I and the FDA creates a new regulatory pathway for non-FDA-approved cannabis products used for the treatment of specific conditions. While both Congress and the DEA have considered de-scheduling marijuana several times over the years, both have declined to do so.

To the extent that ERISA preempts state law, employers should voluntarily choose not to cover non-FDA-approved cannabis products due to the risk of criminal and tort liability, and the various employee safety and efficacy concerns addressed above. Instead, employers should only cover FDA-approved products so that their employees have access to safe and effective drugs. If states pass laws requiring coverage of non-FDA-approved products, employers could deny coverage and challenge those laws in court by applying similar legal arguments as those presented in *Bourgoin*. Additionally, it is important for employers to educate their employees on the risks of non-FDA-approved cannabis

311 *DOT "Recreational Marijuana" Notice*, *supra note* 309.

312 *DOT "CBD" Notice*, *supra* note 310.

313 *DOT "CBD" Notice*, *supra* note 310.

314 *DOT "CBD" Notice*, *supra* note 310.

315 DOT employees likely to face discipline include: school bus drivers, truck drivers, train engineers, subway operators, aircraft maintenance personnel, transit fire-armed security personnel, ship captains, and pipeline emergency response personnel, among others. *DOT "Recreational Marijuana" Notice*, *supra note* 309.

products so that they are less likely to seek coverage or reimbursement for such products.

V. Conclusion

Non-FDA-approved cannabis products pose health and safety risks to employees and liability risks for employers. Moreover, state laws that would require employers to cover such products through health plans or workers' compensation benefits conflict with, and are preempted by, federal laws such as the CSA. As such, states should not enact such mandates.