How FDA Could Use Its Existing Authorities to Make State Legalization of Cannabis More Safe and Effective

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ABSTRACT

FDA has been giving state-legalized cannabis products a free pass. Although the federal government has chosen not to enforce its strong anti-drug laws against state-legalized cannabis products, many of those cannabis products are being labeled, advertised, or otherwise marketed and used in ways that make them medical drugs that have failed to secure legally required FDA drug approvals. In addition, any state-legalized cannabis products that were not unapproved medical drugs would likely qualify as supplements, foods, cosmetics, or tobacco products that have largely failed to comply with related Federal Food, Drug, and Cosmetic Act provisions and FDA regulations. Consistent with the current federal policy of tolerance (despite federal laws making cannabis distribution and sale illegal), FDA could use its existing authorities to make state cannabis legalization less harmful and risky to the public health without interfering with any states' ability to achieve its legalization policy goals. By thoughtfully exercising its enforcement discretion, FDA could make the labeling and marketing of state-legalized cannabis products more accurate, less misleading, and less troublesome for the public health. Going further, FDA could stop state-legalized cannabis from being offered in forms that are more harmful, addictive, or attractive to youth than the cannabis products typically offered in illicit markets. Through such an approach, FDA would be honoring its public health mission and protecting the integrity of our federal systems for regulating drugs, tobacco products, supplements, foods, and cosmetics. It would also do far more than current federal policies and practices to reduce some of the most serious and unnecessary public health risks from state cannabis legalization, which both supporters and opponents of cannabis legalization should welcome.

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INTRODUCTION

To date, thirty-three states and the District of Columbia have legalized cannabis products for medical use under state law, with ten of those states and D.C. also legalizing cannabis for broader purposes, such as recreational use.[1] In addition, thirteen states have legalized products containing the most well-known non-intoxicating constituent of cannabis, cannabidiol (CBD).[2] Cannabis is a psychoactive plant that typically contains intoxicating amounts of delta-9-tetrahydrocannabinol (Δ9-THC).[3] Even cannabis that has non-active levels of Δ9-THC still affects the brain through other psychoactive cannabinoids and cannabis constituents, including CBD.[4]

Under the Federal Food, Drug, and Cosmetic Act (FDCA), the Food and Drug Administration (FDA) has extensive authorities to regulate drugs. The FDCA defines "drug" to include, inter alia, any product "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals."[5] That part of the definition, alone, would likely reach any cannabis products legalized under state law explicitly for medical use. The Act also includes as a drug any product "intended to affect the structure or any function of the body,"[6] which would likely reach any

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[1] *See*, *e.g.*, *State Marijuana Laws in 2018, Map*, GOVERNING, http://www.governing.com/gov-data/safety-justice/state-marijuana-laws-map-medical-recreational.html [https://perma.cc/9QBJ-KQYK].

[2] *State Medical Marijuana Laws,* NAT'L CONF. STATE LEGISLATURES (Jan. 23, 2019), http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx [https://perma.cc/ZD84-F8N4]. In addition, the recently passed Agriculture Approval Act of 2018 has removed hemp, from which CBD can be derived, from Schedule I of the U.S. Controlled Substances Act and legalized its cultivation, marketing, and sale—which has fueled the emergence of a wide-range of new products containing CBD, both in states that have legalized them and in states that have not. But the new law did not curtail any of FDA's authorities over CBD-containing products. *See, e.g.*, *2018 Farm Bill Legalizes Hemp*, NAT'L L. REV. (Dec. 26, 2018), https://www.natlawreview.com/article/2018-farm-bill-legalizes-industrial-hemp [https://perma.cc/9FFY-269W]; Steven Petrow, *Is the Hype About CBD, or Cannabidiol, Real?*, WASH. Post (Jan. 5, 2019), https://www.washingtonpost.com/national/health-science/is-the-hype-about-cbd-or-cannabidiol-real/2019/01/04/bb824280-ed09-11e8-96d4-0d23f2aaad09_story.html?noredirect=on&utm_term=.f8bdff78809c [https://perma.cc/9PXC-S4DX].

[3] *See, e.g.*, NAT'L ACADS. SCI. ENG'G & MED., THE HEALTH EFFECTS OF CANNABIS AND CANNABINOIDS: CURRENT STATE OF EVIDENCE AND RECOMMENDATIONS FOR RESEARCH 46, 53 (2017), (Most of the health harms and risks associated with cannabis use appear to come from Δ9-THC via its intoxicating qualities and its effects on the brain.); Tista S. Ghosh, et al., *Medical Marijuana's Public Health Lessons — Implications for Retail Marijuana in Colorado*, 372 NEW ENG. J. MED. 991 (Mar. 12, 2015) (Although some cannabis and cannabis-derived products available in state-legalized cannabis markets are not intoxicating because they contain little or no Δ9-THC, most contain Δ9-THC, sometimes at extraordinarily high levels.); Justin T. Fischedick, *Identification of Terpenoid Chemotypes Among High (-)-trans-Δ9-Tetrahydrocannabinol-Producing Cannabis sativa L. Cultivars*, 2 CANNABIS & CANNABINOID RES. 34 (2017).

[4] *See, e.g.*, NAT'L ACADS. SCI. ENG'G & MED., *supra* note 3, at 45, 47; C. Casajuana Kogel et al., *Psychoactive Constituents of Cannabis and Their Clinical Implications: A Systematic Review*, 30 ADDICIONES 140 (2017); Danilo A. Nader & Zila M. Sanchez, *Effects of Regular Cannabis Use on Neurocognition, Brain Structure, and Function: A Systematic Review of Findings in Adults*, 44 AM. J. DRUG & ALCOHOL ABUSE 4 (2017).

[5] 21 U.S.C. § 321(g)(1).

[6] *Id.*; *see also*, E.R. Squibb & Sons v. Bowen, 870 F.2d 678, 682-683 (D.C. Cir. 1989) (stating that "the 'structure or . . . function' definition, unlike the 'disease in man' definition, is relatively narrow, and was not intended to encompass all articles that might have some remote physical effect upon the body" and finding that a product that affected only non-human organisms residing within the intestinal tract did not affect the structure or function of the human body, itself). *But see* U.S. v. Undetermined Quantities of Bottles of an Article of Veterinary Drug, 22 F.3d 235, 240 (10th Cir. 1994) (noting that E.R. Squibb defined

cannabis products legalized by a state for broader uses (unless "intended to" is interpreted much more narrowly).[7] Indeed, the primary reasons people consume cannabis products (legal or illegal) are to get high or intoxicated, relax or reduce anxiety, or otherwise affect their thoughts or brains, or for medical purposes.[8] As a result, it is unlikely that any state-legalized cannabis products that contain psychoactive amounts of cannabis, Δ9-THC, CBD, or certain other cannabis constituents would not qualify as drugs under the FDCA definitions.[9]

FDA's regulatory authorities over drugs empower the Agency to remove from the market any cannabis products in interstate commerce that fit under the FDCA definition of drug and are being distributed or sold in interstate commerce without prior FDA approval.[10] Yet no state-legalized cannabis products have yet sought or received such FDA approval, not even any of those sold expressly for medical use.[11]

"structure or function" rather narrowly, and finding that a product that affected resident organisms in the gastrointestinal tract did affect "structure or function" because they affected the body's digestion). It also appears that judicial interpretations of what products affect the structure or function of the body has been expanding. For example, an earlier case cited in the E.R. Squibb ruling found that nicotine did not affect structure or function. Action on Smoking & Health v. Harris, 655 F.2d 236, 238 (D.C. Cir. 1980). But the Supreme Court later found that products that deliver nicotine actually do affect structure or function. Food & Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 131-132 (2000).

[7] *See Brown & Williamson*, 529 U.S. at 132, 162-174 (with the 5-4 majority leaving open the question as to whether a product can be "intended to affect the structure or any function of the body" absent express claims of therapeutic or medical benefit by the manufacturer or vendor, and the four-justice dissent finding no such express claims necessary)*; see also* U.S. v. Caronia, 703 F.2d 149, 170-72 (2d Cir. 2012) (Livingston, J., dissenting); 21 CFR 201.128 (defining "intended uses"); and Food & Drug Admin., *Statement from FDA Commissioner Scott Gottlieb, M.D., on FDA Decision to Seek Additional Time to Reassess Rule that Would Have Changed Longstanding Practices for how the Agency Determined the 'Intended Use' of Medical Products* (Jan. 12, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592358.htm [https://perma.cc/5CAV-XB8U].

[8] *See, e.g., Yahoo News/Marist Poll: Weed & The American Family*, MARIST POLL, http://maristpoll.marist.edu/yahoo-newsmarist-poll/#sthash.fyLKU73q.dpbs [https://perma.cc/FLR6-P643]; Kristen C. Ciombi et al., *Consumers' Perceptions of Edible Marijuana Products for Recreational Use: Likes, Dislikes, and Reasons for Use*, 53 SUBSTANCE USE & MISUSE 541 (2018); Ji-Yeun Park & Li-Tzy Wu, *Prevalence, Reasons, Perceived Effects, and Correlates of Medical Marijuana Use: A Review*, 177 DRUG & ALCOHOL DEPENDENCE 1 (2017).

[9] A product can also qualify as an FDA-regulated drug under the Act if it is "recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them." *See* Park & Wu, *supra* note 8. Cannabis was included in the United States Pharmacopoeia from 1850 to 1942 (then removed pursuant to efforts against recreational use by the Federal Bureau of Narcotics). But the Pharmacopoeia currently includes listings for dronabinol (an FDA-approved drug containing synthetic Δ9-THC), and other cannabis-related listings are under consideration. Gabriel I. Giancaspro, et al., *The Advisability and Feasibility of Developing USP Standards for Medical Cannabis*, 42 PHARMACOPEIAL FORUM 1 (2016).

[10] 21 U.S.C. § 355(a). How state-legalized cannabis products qualify as being in interstate commerce is discussed below. *See infra* notes 35–40 and accompanying text. If a state-legalized cannabis product qualified not as just an FDCA drug but as a combination product that is also either a FDCA device or a biologic product it would still be on the market illegally if it did not have a formal FDA approval. The FDCA gives FDA authority to regulate such combination products, and they would basically be subject to the same requirements that apply to non-combination drugs that require prior FDA approval before being legally marketed. 21 U.S.C. § 353(g). *See also* 21 U.S.C. §§ 360c(a)(1)(C), 360e (devices); 42 U.S.C. § 262 (biologics); *About Combination Products*, FOOD & DRUG ADMIN., www.fda.gov/CombinationProducts/AboutCombinationProducts [https://perma.cc/8ME4-5LSE].

[11] 21 U.S.C. §§ 355, 331(d), 331(ll). So far, the only cannabis-derived product FDA has approved as a medical drug is Epidiolex, a prescription drug containing the non-intoxicating cannabis constituent CDB for the treatment of certain forms of epilepsy in patients two years of age or older. Food & Drug Admin.,

In addition, FDA has authority to pull off the market any cannabis or cannabis-derived product that qualifies as an FDA-regulated drug (or, instead, as an FDA-regulated food, supplement, cosmetic, or tobacco product or combination product) if they are adulterated,[12] their labeling is false or misleading in any particular, they are otherwise misbranded,[13] or they violate any of the many other requirements and restrictions in the FDCA and related FDA regulations that apply to drugs (or to foods, supplements, cosmetics, tobacco products, or combination products).[14]

To date, however, FDA has rarely used its extensive authorities to ensure that state-legalized cannabis products subject to its jurisdiction comply with the FDCA.[15] Indeed, strictly enforcing the applicable statutory provisions and related rules would likely require removing the vast majority of currently available state-legalized cannabis products from their respective state markets (e.g., as non-FDA-approved drugs), contradicting the current federal policy of forbearance.[16]

FDA Approves First Drug Comprised of an Active Ingredient Derived from Marijuana to Treat Rare, Severe Forms of Epilepsy (June 25, 2018), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm611046.htm [https://perma.cc/M5PJ-QSYJ]. FDA drug approval is contingent on FDA finding the product is safe and effective for its intended use. *See, e.g.*, *Brown & Williamson*, 529 U.S. at 133.

12 21 U.S.C. § 331; *id.* § 351 (drugs); *id.* § 342 (food, supplements). *See also id.* § 321(ff) ("Except for purposes of paragraph (g) and section 350f of this title, a dietary supplement shall be deemed to be a food within the meaning of this chapter.").

13 21 U.S.C. § 352(a) (drugs); *id.* § 343(a) (foods and supplements).

14 *See, e.g.,* 21 U.S.C. § 331 (Prohibited Acts); Searchable Database of Food & Drug Admin. Regulations, FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm [https://perma.cc/85A4-QC4S]. FDA's authorities over foods includes foods for pets and other animals; and there are numerous reports of pet foods having cannabis or cannabinoids (especially CBD) added into them. *See, e.g.*, 21 U.S.C. § 321(f); Rachel Rabkin Peachman, *Should You Try CBD for Your Pet?* CONSUMER REPORTS (2019), https://www.consumerreports.org/cbd/should-you-try-cbd-for-your-pet [https://perma.cc/A5UR-ZRMH].

15 It appears that the only thing FDA has done recently in terms of substantive regulatory action and enforcement is send warning letters to a handful to companies (three so far in 2019, one in 2018) regarding their marketing of products claiming to contain CBD that were non-FDA-approved drugs because related therapeutic claims made it clear they were articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. *Warning Letters and Test Results for Cannabidiol-Related Products*, FOOD & DRUG ADMIN., https://www.fda.gov/newsevents/publichealthfocus/ucm484109.htm [https://perma.cc/4LUF-5TA5]. Moreover, in a hearing before the U.S. Senate Committee on Appropriations, FDA Commissioner Gottlieb stated that FDA "is using enforcement discretion now" and "will take enforcement action against CBD products that are on the market if manufacturers are making what I consider 'over-the-line' claims." Josh Long, *Gottlieb: FDA targeting CBD marketers of 'over-the-line claims,'* NAT'L PRODUCTS INSIDER (Mar. 28, 2019), https://www.naturalproductsinsider.com/ingredients/gottlieb-fda-targeting-cbd-marketers-over-line-claims [https://perma.cc/NJ5B-GPRD]. At the same time, FDA clearly recognizes that it has regulatory jurisdiction over a range of cannabis and cannabis-derived products and has an important public health role with respect to those products. *See, e.g.*, Statement, Food & Drug Admin., *Statement from FDA Commissioner Scott Gottlieb, M.D., on Signing of the Agriculture Improvement Act and the Agency's Regulation of Products Containing Cannabis and Cannabis-Derived Compounds* (Dec. 20, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm628988.htm [https://perma.cc/W54S-A85S] [hereinafter *Gottlieb Statement* (Dec. 20, 2018)]; Food & Drug Admin., *Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to advance agency's continued evaluation of potential regulatory pathways for cannabis-containing and cannabis-derived products* (Apr. 2, 2019), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-advance-agencys-continued-evaluation [https://perma.cc/3EQ7-3RN5] [hereinafter *Gottlieb Statement* (Apr. 2, 2019)].

16 As discussed more fully below, the only solid defense against strict FDA enforcement would be for state-legalized cannabis products to establish that they were not in interstate commerce but were purely

THE FEDERAL GOVERNMENT'S TOLERATION OF STATE CANNABIS LEGALIZATION

The federal government's forbearance policy has been in place since 1996, when state cannabis legalization for medical use first began, and it continued when states began legalizing cannabis for broader purposes in 2012.[17] Most notably, United States Attorneys and other federal enforcement officials have exercised their discretion not to enforce federal anti-drug laws against states that have legalized cannabis products for either medical or broader use or against any state-legalized cannabis businesses or cannabis-using customers.[18] Going further, a series of amendments to congressional appropriations acts, starting in December 2014, have prohibited the Department of Justice (DOJ) from using any of its funding to prevent certain specified states from implementing their own laws that legalize cannabis for medical purposes.[19]

From 2009 through 2017, the DOJ also had formal, nationwide enforcement discretion polices that all United States Attorneys were required to follow, which were outlined in a series of memoranda.[20] The most comprehensive and recent of those

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produced, marketed, and sold in-state with only in-state ingredients. *Infra*, notes 35–40 and accompanying text.

[17] *See, e.g.*, *Timeline of Cannabis Laws in the United States*, WIKIPEDIA, https://en.wikipedia.org/wiki/Timeline_of_cannabis_laws_in_the_United_States [https://perma.cc/QG2Q-UKJH]; *supra* notes 1–2 and accompanying text.

[18] It also appears that no other federal agencies that appear to have jurisdiction over certain aspects of state-legalized cannabis products, such as the Federal Trade Commission or Consumer Product Safety Commission, have taken any significant action against them. But the sellers of both legal or illegal cannabis products do have to comply with federal income tax laws. *See, e.g.,* Justin Rohrlich, *Cannabis Companies Are Paying Federal Taxes in Cash and It's Giving the IRS a Headache*, QUARTZ (Nov. 14, 2018), https://qz.com/1461947/the-irs-cant-handle-cannabis-companies-all-cash-tax-payments [https://perma.cc/QT8T-QS9H].

[19] Consolidated and Further Continuing Appropriations Act, 2015, Pub. L. No. 113–235, § 538 (2014); *s*ee *also* United States v. McIntosh 833 F.2d 1163, 1176-1178 (9th Cir. 2016) (interpreting the appropriations act rider prohibiting DOJ from spending funds to prevent state implementation of their laws legalizing cannabis for medical purposes as prohibiting DOJ from enforcing against individuals taking actions legal under those state laws). The most recent of these appropriations amendments or riders, which has passed the House and Senate Appropriations Committees, states:

> None of the funds made available under this Act to the Department of Justice may be used, with respect to any of the States of Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming, or with respect to the District of Columbia, Guam, or Puerto Rico, to prevent any of them from implementing their own laws that authorize the use, distribution, possession, or cultivation of medical marijuana.

Commerce, Justice, Science, and Related Agencies Appropriations Act, 2019 (S. 3072 & H.R. 5952).

[20] *See* Memorandum from David Ogden, Deputy Att'y Gen., to Selected U.S. Attorneys, Investigations and Prosecutions in States Attorneys Authorizing Medical Use of Marijuana (Oct. 19, 2009), https://www.justice.gov/opa/press-release/file/1022196/download [https://perma.cc/K8AJ-EU2W]; Memorandum from James M. Cole, Deputy Att'y Gen., to all U.S. Attorneys, Guidance Regarding the Ogden Memo in Jurisdictions Seeking to Authorize Marijuana for Medical Use (June 29, 2011), https://www.justice.gov/sites/default/files/oip/legacy/2014/07/23/dag-guidance-2011-for-medical-marijuana-use.pdf [https://perma.cc/4KU9-YMHP]; Memorandum from James M. Cole, Deputy Att'y Gen., to all U.S. Attorneys, Guidance Regarding Marijuana Enforcement (Aug. 29, 2013), https://www.

memoranda stated that, despite the federal laws making cannabis illegal, DOJ law enforcement officials would basically allow cannabis-legalizing states to run their own regulatory systems for making cannabis legally available under state law if the legalization states implemented and enforced "strong and effective regulatory and enforcement systems that will address the threat those state [legalization] laws could pose to public safety, public health, and other law enforcement interests" (including certain federal cannabis-enforcement priorities listed in the memoranda).[21] Although these DOJ memoranda did not apply to FDA's use of its own enforcement discretion, they presented a clear Administration policy of leaving cannabis-legalizing states largely free of federal interference, unless the state systems failed to prevent new threats to public safety and the public health (or other serious new problems).

In January 2018, Attorney General Sessions issued a Memorandum for All United States Attorneys that rescinded the prior DOJ cannabis-enforcement memoranda.[22] But the Sessions Memorandum does not specifically mention state cannabis legalization, much less direct any United States Attorneys to take enforcement action against any state-legalized cannabis businesses or customers. Instead, it says that the "memorandum is intended solely as a guide to the exercise of investigative and prosecutorial discretion," and directs federal prosecutors to "weigh all relevant considerations," including well-established principles governing all federal prosecutions, when "deciding which marijuana activities to prosecute under [federal] laws with the Department's finite resources."[23] Following the Sessions Memorandum, U.S. Attorneys and other DOJ enforcement officials appear still to be operating as they were under the now-rescinded DOJ memoranda or are otherwise exercising their discretion to allow state-legalized markets for cannabis to operate basically free from federal enforcement.[24]

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justice.gov/iso/opa/resources/305201382913275685746 7.pdf [https://perma.cc/EK67-XDDS] [hereinafter *Cole Memorandum* (Aug. 29, 2013)]; Memorandum from James M. Cole, Deputy Att'y Gen., to all U.S. Attorneys, Guidance Regarding Marijuana Related Financial Crimes (Feb. 14, 2014), http://www.dfi.wa.gov/documents/banks/dept-of-justice-memo.pdf [https://perma.cc/Q48T-AVFQ]; Memorandum from Monty Wilkinson, Director at Executive Office for U.S. Attorneys to all U.S. Attorneys, First Assistant U.S. Attorneys, Criminal Chiefs, Appellate Chiefs, OCDETF Coordinators, and Tribal Liaisons, Policy Statement Regarding Marijuana Issues in Indian Country (Oct. 28, 2014), https://www.justice.gov/sites/default/files/tribal/pages/attachments/2014/12/11/policystatementregardingmarijuanaissuesinindiancountry2.pdf [https://perma.cc/K2ME-JJDD].

[21] *Cole Memorandum* (Aug. 29, 2013), *supra* note 20. That Cole Memorandum stated that DOJ's cannabis-related enforcement priorities were to prevent: distribution to youth, drugged driving and the exacerbation of other adverse public health consequences from cannabis use, the cultivation or use of cannabis on federal property, cannabis revenue going to criminal organizations, state-authorized cannabis activity being used as a cover or pretext for trafficking in other illegal drugs or other illegal activities, the diversion of cannabis from legalization states to other states, and violence and firearms use in the cultivation or distribution of cannabis. For federal laws making illegal the production, distribution, dispensing, or possession of cannabis or "marihuana" (broadly defined to include any state-legalized cannabis products), see 21 U.S.C. §§ 802(16), 812(c), Schedule I(c)(10), 841(a).

[22] Memorandum from Jefferson B. Sessions, Attorney General, to all U.S. Attorneys, Marijuana Enforcement (Jan. 4, 2018), https://www.justice.gov/opa/press-release/file/1022196/download [https://perma.cc/C74J-5MHG].

[23] *Id*.

[24] *See, e.g.*, Press Release, Dept. of Justice, U.S. Attorney's Office, Western District of Washington, U.S. Attorney Annette L. Hayes Statement on Federal Marijuana Prosecutions in the Western District of Washington (Jan. 4, 2018), https://www.justice.gov/usao-wdwa/pr/us-attorney-annette-l-hayes-statement-federal-marijuana-prosecutions-western-district [https://perma.cc/2TNP-D38G]; Press Release, Dept. of Justice, U.S. Attorney's Office, Eastern District of Washington, Federal Marijuana Enforcement Policy (Jan.

Although unintended, the primary impact of the rescission of the earlier DOJ memoranda by Attorney General Sessions appears to be that legalization states, to prevent federal enforcement, are no longer explicitly subject to any formal DOJ policy requiring them to have "strong and effective regulatory and enforcement systems that will address the threat those state [legalization] laws could pose to public safety, public health, and other law enforcement interests."[25] Yet the federal government still has a general goal of promoting public safety and protecting the public health, and FDA, in particular, has protecting the public health as its overriding guiding purpose. Accordingly, it would be fully consistent with its own mission and with the current federal policy of tolerating state cannabis legalization for FDA to exercise its own enforcement discretion, under its existing powers and authorities, to reduce some of the most serious and unnecessary risks to public safety and the public health from state-legalized markets.

As detailed below, FDA could exercise its core authorities in its role as the nation's regulator of medical drugs to stop state-legalized cannabis products from being marketed or sold as medical drugs or with therapeutic claims, and FDA could use its authorities over drugs, tobacco products, foods, supplements, and cosmetics to prevent state-legalized cannabis products from being made even more harmful, addictive, or attractive to adults or youth than those cannabis products typically available from illicit markets. Doing that would not put FDA in the position of having to ban or regulate all state-legalized cannabis products and markets. Instead, FDA would protect and promote the public health by subjecting state-legalized cannabis products and their labeling and marketing only to responsible FDA limits that would not interfere with the states' ability to achieve the core policy goals behind their decisions to legalize. At

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4, 2018), https://www.justice.gov/usao-edwa/pr/federal-marijuana-enforcement-policy [https://perma.cc/J4Y6-UMHW] (Washington had previously legalized cannabis for medical and broader purposes under state law.); Press Release, Dept. of Justice, U.S. Attorney's Office, District of Oregon, U.S. Attorney Statement on Marijuana Enforcement in the District of Oregon (Jan. 4, 2018), https://www.justice.gov/usao-or/pr/us-attorney-statement-marijuana-enforcement-district-oregon [https://perma.cc/8DYT-44YT] (Oregon had previously legalized cannabis for medical and broader purposes.); Press Release, Dept. of Justice, U.S. Attorney's Office, District of Maine, Statement by U.S. Attorney Halsey B. Frank Regarding Federal Marijuana Enforcement (Jan. 9, 2018), https://www.justice.gov/usao-me/pr/statement-us-attorney-halsey-b-frank-regarding-federal-marijuana-enforcement [https://perma.cc/7VZ5-R7N7] (Maine had previously legalized cannabis for medical purposes.); Press Release, Dept. of Justice, U.S. Attorney's Office, District of Colorado, U.S. Attorney Bob Troyer Issues Statement Regarding Marijuana Prosecutions in Colorado (Jan. 4, 2018), https://www.justice.gov/usao-co/pr/us-attorney-bob-troyer-issues-statement-regarding-marijuana-prosecutions-colorado [https://perma.cc/7C2W-LYK4] (Colorado had previously legalized cannabis for medical and broader purposes.); Press Release, Dept. of Justice, U.S. Attorney's Office, District of Montana, U.S. Attorney Kurt Alme Issues Statement Regarding Marijuana Prosecutions in Montana (Jan. 5, 2018), https://www.justice.gov/usao-mt/pr/us-attorney-kurt-alme-issues-statement-regarding-marijuana-prosecutions-montana [https://perma.cc/X5GB-KNMJ] (Montana had previously legalized cannabis for medical purposes.); Press Release, Dept. of Justice, U.S. Attorney's Office, District of Massachusetts, Statement from U.S. Attorney Andrew Lelling Regarding the Legalization of Recreational Marijuana in Massachusetts (July 10, 2018), https://www.justice.gov/usao-ma/pr/statement-us-attorney-andrew-lelling-regarding-legalization-recreational-marijuana [https://perma.cc/V22F-A6M8]. The currently pending nominee to become U.S. Attorney General, William Barr, while personally opposed to state legalization, has also said that the Justice Department would not enforce federal anti-drug laws against cannabis companies operating legally under legalization-state laws, especially if they have been following the guidelines in the Sessions-rescinded Cole memorandum. *See* Glenn Fleishman, *States Hold Breath as Trump's Attorney General Nominee Says He Won't Prosecute Pot in Marijuana-Legal States*, Fortune (Jan. 15, 2019), http://fortune.com/2019/01/15/barr-marijuana-pot-cole-memo-legal-states [https://perma.cc/TG7F-6EX9].

[25] *Cole Memorandum* (Aug. 29, 2013), *supra* note 20.

the same time, FDA's use of its enforcement discretion in this way would protect the integrity of FDA's existing authorities and the regulatory systems it operates for medical drugs, tobacco products, foods, including dietary supplements, and cosmetics.

HOW FDA COULD STOP STATE-LEGALIZED CANNABIS FROM BEING MARKETED WITH FALSE, MISLEADING, OR UNVERIFIED MEDICAL LABELING AND THERAPEUTIC CLAIMS

One might think that the states would effectively regulate the production, distribution, marketing, and sale of any cannabis products they legalized for medical use, which would make FDA action less necessary. But the range of state approaches is quite broad, and none provides the kind of regulation necessary to protect and promote the public health most effectively.[26] For example, one careful research evaluation of different state medical-legalization systems in 2016 did not find any that were doing a very good job based on basic principles of medical practice, also concluding that fourteen were "nonmedical" medical-legalization systems.[27]

One major problem for the public health and FDA occurs where cannabis products are not only explicitly legalized for medical use but also labeled as medical products, sold from medical dispensaries, promoted by sales staff for certain medical uses, or otherwise marketed with therapeutic claims—all of which confers a medical status or legitimacy that they either do not deserve or have not yet earned or had verified.[28] In states legalizing cannabis products for broader recreational or discretionary purposes, lax laws or enforcement can also allow the marketing of the cannabis product with explicit or implicit therapeutic claims. In the worst cases, the therapeutic claims for certain state-legalized cannabis products (including those made by untrained "budtenders" at medical cannabis dispensaries or other state-legalized sales outlets) are not just unsupported, but misleading or false in serious ways.[29]

Such labeling and claims can confuse consumers about the medical safety and effectiveness of cannabis products, misleading many into thinking that cannabis

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[26] *See, e.g.*, ERIC N. LINDBLOM, A PUBLIC HEALTH APPROACH TO MAKING CANNABIS LEGALLY AVAILABLE FOR MEDICAL USE (forthcoming) (presenting recommendations for how states and countries that choose to make legalized cannabis available for medical use could, consistently with the core policy goals for medical or broader legalization, regulate the products and their production, distribution, marketing, and sale to protect and promote the public health more effectively).

[27] Arthur R. Williams et al., *Older, Less Regulated Medical Marijuana Programs Have Much Greater Enrollment Rates Than Newer 'Medicalized' Programs*, 35 HEALTH AFF. 480 (2016). *See also* Sarah B. Klieger et al., *Mapping Medical Marijuana: State Laws Regulating Patients, Product Safety, Supply Chains and Dispensaries*, 2017, 112 ADDICTION 2206 (2017).

[28] *See, e.g.*, Katelyn D. Boatwright & Morgan L. Sperry, *Accuracy of Medical Marijuana Claims Made by Popular Websites*, J. PHARMACY PRACTICE (Dec. 30, 2018); Patricia A. Cavazos-Rehg et al., *Marijuana Promotion Online: An Investigation of Dispensary Practices*, 20 PREVENTION SCI. 280 (2018); LIVEGREEN, www.livegreencannabis.com [https://perma.cc/6LDE-XCE7] (recreational and medical cannabis seller in Colorado); *Can Cannabis Treat Cancer?*, LIVEGREEN (Dec. 7, 2016), https://www.livegreencannabis.com/cannabis-cancer-treatment [https://perma.cc/8XGN-GNW5]; *Common Medical Conditions That Sativas Can Help Manage*, LIVEGREEN (Apr. 4, 2016), https://www.livegreencannabis.com/common-health-conditions-that-sativas-can-help-manage [https://perma.cc/F8UT-RQGS].

[29] *See, e.g.*, Nicholas C. Peiper, et al., *Medical Decision-Making Processes and Online Behaviors Among Cannabis Dispensary Staff*, 11 SUBSTANCE ABUSE 1 (2017); *supra* note 27 and accompanying text.

products (whether purchased from medical or non-medical legal markets or from illicit sellers) are less risky and more beneficial than they actually are for both medical or recreational use. Such misunderstandings could increase medical and non-medical use of both state-legalized and illicit-market cannabis, and could prompt patients to use cannabis products to treat certain medical conditions when there is either no evidence they will do any good or clear evidence that they will do more harm than good, or when conventional medicines or treatments would be safer or more effective.[30]

By giving cannabis and cannabis-derived products undeserved medical legitimacy, such medical labeling and therapeutic claims—without any related FDA preventive efforts or enforcement—could also threaten the perceived legitimacy of the formal FDA procedures for evaluating, approving, and regulating medical drugs and other medical products. If FDA is going to allow state-legalized cannabis products to present themselves as medical drugs and otherwise make therapeutic claims without any remedial or regulatory action by FDA, why should other products—such as alcoholic beverages, foods, supplements, and cosmetics—have to obtain FDA approval as drugs before being marketed with therapeutic claims?[31] Or why should states not legalize other illicit drugs for FDA-free marketing and sale for medical use?[32]

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[30] *See, e.g.*, NAT'L ACADS. SCI. ENG'G & MED., *supra* note 3, *passim*.

[31] The integrity of the FDA drug-approval process may also be threatened by some people seeing state cannabis legalization for medical use as a necessary, direct consequence of the FDA drug-approval system failing to make medically beneficial cannabis products (or other equally or more effective medicines) readily available to patients who cannot currently find or access adequate treatments for their medical problems. But there might not be much FDA could do to address that problem. FDA cannot approve drugs unless manufacturers submit applications seeking approval, and the ability of applicants to do the underlying research necessary to secure approval for cannabis or cannabis-derived drugs is significantly constrained by federal anti-drug laws and international illicit-drug treaty requirements, which also impede FDA's ability to approve and regulate them. The Single Convention on Narcotic Drugs, for example, requires full governmental control of the stock of any cannabis being researched or used for medical purposes, with required governmental mechanisms to control, license, supervise, document, and report on the cultivation of the cannabis and the manufacture of any related medical drugs. UNITED NATIONS OFFICE ON DRUGS & CRIME, THE INTERNATIONAL DRUG CONTROL CONVENTIONS (2013), https://www.unodc.org/documents/commissions/CND/Int_Drug_Control_Conventions/Ebook/The_International_Drug_Control_Conventions_E.pdf [https://perma.cc/4ZDJ-98P7]. In addition, the U.S. Controlled Substances Act designates all parts of the cannabis plant as a Schedule I drug that has no currently accepted medical use in treatment in the United States with a lack of accepted safety for the use of the drug under medical supervision, and otherwise impedes medical research and FDA approvals. *See* 21 U.S. C. § 812 (2018). *See also* David Nutt, *Illegal Drug Laws: Clearing a 50-Year Old Obstacle to Research*, PLOS BIOLOGY, (Jan. 27, 2015), at 2, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4307971/pdf/pbio.1002047.pdf [https://perma.cc/7L6L-WP8C]; David J. Nutt et al., *Effects of Schedule I Drug Laws on Neuroscience Research and Treatment Innovation*, 14 NATURE REV. NEUROSCIENCE 577 (2013). Although FDA approved Epidiolex, the first prescription drug containing a cannabis constituent (non-intoxicating CBD), that FDA approval could not go into effect until the Drug Enforcement Agency provided its additional stamp of approval, which required taking CBD off of Schedule I of the Controlled Substances Act. *See, e.g.*, Linda Bentley, *Epidiolex Approval Suggests the Way Forward for Marijuana-Derived Products*, UPDATE, (Oct.–Nov. 2018), https://www.fdli.org/2018/10/epidiolex-approval-suggests-the-way-forward-for-marijuana-derived-products [https://perma.cc/8JE3-Y94A]; *supra* note 11. Whether an FDA-approved drug containing the intoxicant Δ9-THC could, under existing law, secure the required DEA approval and reclassification of Δ9-THC is not clear—but FDA has been able to approve some drugs containing synthetic Δ9-THC (Marinol, Syndros, and Cesamet), which did not require DEA approval. *See, e.g.*, *Researching the Potential Medical Benefits and Risks of Marijuana: Hearing before the Subcomm. on Crime and Terrorism of the S. Comm. on the Judiciary*, 114th Cong. (2016) (statement of Douglas Throckmorton, M.D., Deputy Director for Regulatory Programs Center for Drug Evaluation and Research, Food and Drug Administration, Department of Health & Human Services).

[32] Efforts along these lines have already begun. *See, e.g.*, Esther Honig, *In Close vote, Denver Becomes 1st U.S. City to Decriminalize Psychedelic Mushrooms*, NAT'L PUB. RADIO (May 9, 2019),

FDA could eliminate these problems by strictly enforcing the provision in the FDCA that makes it illegal for any new drug product to be in interstate commerce unless it has first been formally evaluated and approved by FDA as a safe and effective medical drug.[33] But that would threaten to remove all state-legalized cannabis products from the market. To be much more flexible (and fully compatible with federal forbearance), FDA could, instead, take enforcement action against only those state-legalized cannabis products that explicitly hold themselves out as being medical drugs by being: (a) distributed or sold from stores labeled as medical outlets; (b) packaged or labeled as medical products; (c) marketed with explicit or clearly implied therapeutic claims; or (d) otherwise specifically presented or promoted for therapeutic purposes.[34]

Announcing and carrying out such an enforcement policy would sharply reduce the number of state-legalized cannabis products being labeled or marketed with false, misleading, or unsupported medical-type labeling or therapeutic claims. But it would not reduce the availability of state-legalized cannabis products for possible medical use nor otherwise interfere with state legalization systems. Any medical labeling or medical marketing done by businesses that would directly profit from increasing the cannabis products' sales and use would be stopped. But patients could still get information about possible medical uses of non-FDA-approved cannabis products from their health care providers, or from publicly accessible websites and other sources.

Some manufacturers or sellers would likely try to evade such FDA enforcement by claiming that their state-legalized cannabis-related products were exclusively being produced, marketed, and sold in a single state and, therefore, were not subject to FDCA or FDA enforcement as products "introduced or delivered for introduction into interstate commerce."[35] However, the FDCA definition of "interstate commerce" is an "expansive and unrestricted definition,[36] reaching any product that has crossed any U.S. international, state or territory border, or is destined to do so, on its way to reaching the consumer;[37] and also reaches drugs marketed only in intrastate commerce that include any components or ingredients shipped interstate.[38] Going further, the U.S. Supreme Court has ruled that the federal government's clear authority to regulate interstate cannabis markets must include the right to ensnare some purely intrastate activity so as to avoid substantially undercutting the federal efforts to regulate the

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https://www.npr.org/sections/health-shots/2019/05/09/721660053/in-close-vote-denver-becomes-first-u-s-city-to-decriminalize-psychedelic-mushroo [https://perma.cc/8AFF-XCHP].

33 *See* 21 U.S.C. §§ 355, 331(d), 331(ll) (2018); *see also* 21 U.S.C. §§ 321(g)(1), (p) (2016).

34 As noted above, FDA has already done such enforcement to an extremely limited extent, sending warning letters in 2017 to four companies based in legalization states regarding their marketing of products claiming to contain CBD, which FDA stated were illegal non-FDA-approved drugs. *See supra* note 15.

35 21 U.S.C. §§ 355, 331(d), (ll) (2018).

36 21 U.S.C. § 321(b) (2016); *see* United States v. Food, 2,998 Cases, 64 F.3d 984, 989 (5th Cir. 1995).

37 *Id.*; *see* United States v. Themy-Kotronakis, 140 F.3d 858, 862-63 (10th Cir. 1998); United States v. Regenerative Sciences, LLC, 741 F.3d 1314, 1320 (D.C. Cir. 2014).

38 *See* Impro Prods., Inc. v. Herrick, 715 F.2d 1267, 1269 (8th Cir. 1983) (citing Grand Laboratories, Inc. v. Harris, 660 F.2d 1288, 1289 (8th Cir.1981), *cert. denied,* 456 U.S. 927 (1982)).

interstate market.[39] In addition, the diversion of a state's legalized cannabis or cannabis-derived products into other states' illicit cannabis markets—and possibly the purchase of state-legalized cannabis products by buyers from out of state for subsequent out-of-state use—also puts them into interstate commerce.[40]

Another way that producers or sellers might try to evade FDA enforcement against certain state-legalized cannabis or cannabis-derived products as non-FDA-approved drugs would be to claim that they are not drugs but supplements, which the FDCA defines as including products intended to supplement the diet that bear or contain "an herb or other botanical" or "a concentrate, metabolite, constituent, extract, or combination of any [herb or other botanical]."[41] However, FDA has concluded that products containing either Δ9-THC or CBD cannot qualify as dietary supplements under the FDCA because CBD is the active ingredient in an FDA-approved drug and both Δ9-THC and CBD are active ingredients in products that have been "authorized for investigation as a new drug.[42] For the same reason, products containing Δ9-THC or CBD could not qualify as FDCA-compliant cosmetics or foods, either.[43]

Even if any products containing cannabis or cannabis derivatives were able to qualify as supplements, they would, by definition, have to be labeled as dietary

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[39] *See* Gonzales v. Raich, 545 U.S. 1, 15-33 (2005); Nat'l Fed'n of Indep. Bus. v. Sebelius, 567 U.S. 519, 560 (2012); *see also* United States v. Article of Drug . . . Bacto-Unidisk . . . , 394 U.S. 784, 798 (1969) ("The historical expansion of the definition of drug, and the creation of a parallel concept of devices, clearly show, we think, that Congress fully intended that the Act's coverage be as broad as its literal language indicates—and equally clearly, broader than any strict medical definition might otherwise allow . . . . [R]emedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health . . . .").

[40] *See Gonzales*, 545 U.S. at 2-3 (2005). Even if some purely intrastate production, marketing, and sale of state-legalized cannabis products could not be reached by FDA's authority to regulate medical drugs in interstate commerce, such insulated products would still be subject to regulation by the state, which might choose to prohibit or restrict any intrastate products able to evade FDA's health-directed enforcement efforts.

[41] 21 U.S.C. § 321(ff); *id.* § 321(g)(1).

[42] *FDA Regulation of Cannabis and Cannabis Derived Products: Ques*tions *and Answers*, FOOD & DRUG ADMIN., https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421168.htm#dietary_supplements [https://perma.cc/JV9L-87F2]. *See* Letter from Steve E. Porter, Jr., Dir., Div. of Pharm. Quality Operations IV, to That's Natural! Marketing & Consulting (Oct. 31, 2017), https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm583197.htm [https://perma.cc/4K3R-AMYZ] ("Although you market 'CBD All-Natural Hemp Oil' as a dietary supplement, FDA has concluded based on available evidence that CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B)(ii) of the Act" [21 U.S.C. (321(ff))]. That definition states that "dietary supplement" does not include "an article that is approved as a new drug under section 355 of this title" or "an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public.").

[43] *See, e.g.*, *Gottlieb Statement* (Dec. 20, 2018), *supra* note 15. The Commissioner's statement raises the possibility of FDA issuing a new rule to allow CBD in certain foods or supplements, but only if FDA determines that such a rulemaking could be done consistently with all of the FDCA's requirements for drugs, foods, and supplements (which might be quite difficult). U.S. Senators Ron Wyden and Jeff Merkley, among others, have urged FDA to be more permissive regarding the use of hemp-derived CBD, in food, beverage and dietary supplements. *See, e.g.*, Letter from Sens. Ron Wyden & Jeffrey A. Merkley to Food & Drug Admin. Comm'r Scott Gottlieb (Jan. 15, 2019), https://www.wyden.senate.gov/imo/media/doc/011519%20FDA%20CBD%20Hemp%20Letter.pdf [https://perma.cc/M45L-5XMM]. FDA subsequently noted that it is continuing to consider all of these issues and scheduled a public hearing to obtain additional information. *Gottlieb Statement* (Apr. 2, 2019), *supra* note 15*; Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing; Request for Comments*, U.S. FOOD & DRUG ADMIN., 84 FED. REGISTER 12969.

supplements[44]—and they would still become subject to FDA regulation as drugs if their labeling or marketing claimed that the products could diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases.[45] Accordingly, any cannabis or cannabis-derived products that were able to escape FDA regulation as drugs by qualifying as non-drug supplements still could not be labeled as medical products or make any significant therapeutic claims in their labeling or advertising.[46] Moreover, while supplements may make certain truthful and not misleading statements on their labeling relating to the health impacts of the nutrients or dietary ingredients they contain without qualifying as drugs, any such statements must be accompanied by a prominent disclaimer that statements have not been evaluated by FDA and the products are not intended to diagnose, treat, cure, or prevent any disease.[47]

This analysis indicates that an FDA enforcement strategy to take only those state-legalized cannabis products off the market that qualify as non-FDA-approved drugs specifically because of their labeling, advertising, or other marketing could largely eliminate a number of problems for FDA and the public health that could be caused by such products being labeled or advertised with false, misleading, or unapproved therapeutic claims. But such an FDA enforcement strategy would not make state-legalized cannabis products any less available for medical or other legalized use (unless FDA suddenly enforced it strictly with no prior warning, which is hardly FDA's way). Nor would it interfere with the ability of patients to obtain cannabis-related information, advice, or authorizations from their health care providers. But it would clean up the way the state-legalized cannabis products are being labeled, advertised, and otherwise promoted by commercial manufacturers and sellers with powerful profit motives to maximize use.

HOW FDA COULD STOP ADDITIVES AND COMBINATIONS (AND RELATED MISLABELING) THAT MAKE STATE-LEGALIZED CANNABIS PRODUCTS EVEN MORE HARMFUL, ADDICTIVE, OR ATTRACTIVE

In some of the medical-legalization states, especially those with commercial retail dispensaries, and many of the broader legalization states, the available state-legalized cannabis products include a remarkable array of new types of cannabis products not typically found in illicit cannabis markets, such as cannabis edibles (including cookies and candies), lozenges, beverages, including cannabis beers and wines, and vaporized

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[44] 21 U.S.C. § 321(ff)(2)(C). To qualify as a supplement, the product must also: (i) be intended for ingestion in tablet, capsule, powder, softgel, gelcap, or liquid form, or (ii) not be represented as conventional food or as a sole item of a meal or the diet. 21 U.S.C. § 321(ff)(2)(A), referencing 21 U.S.C. §§ 350(c)(1)(B)(i), (ii), 321(ff)(2)(B).

[45] 21 U.S.C. § 321(g)(1).

[46] The only apparent advantage from qualifying as a non-drug supplement, instead of a drug, is that there would be no requirement of *prior* FDA review and approval of the product or its labeling before it could legally be marketed and sold. If FDA determined that a state-legalized cannabis product qualified as a drug, it could pull it off the market immediately for failing to obtain the required prior FDA approval. 21 U.S.C. § 321(p). But if FDA determined that the cannabis product was a non-drug supplement, it could pull it off the market only after also determining that it was mislabeled, adulterated, or otherwise violating the FDCA.

[47] 21 U.S.C. § 343(6).

or vaped cannabis or Δ9-THC products[48]—including highly-Δ9-THC-concentrated "dabs" (which are sometimes vaporized with a blow torch).[49] Transdermal patches to deliver Δ9-THC and/or CBD (much like nicotine patches for smoking cessation) are also available,[50] as are CBD-only liquids for vaping.[51] There are also references in the research literature to cannabis-derived lipstick, creams, and sunscreen;[52] as well as reports of state dispensaries selling medical-cannabis pizza, mac-and-cheese, pies, and lemonade;[53] and medical-cannabis gummy bear candies (including some brought to school by a nine year old to share with friends).[54]

So far, there is no research or other evidence finding that any of these new types of cannabis products that deliver Δ9-THC offer more safe and effective ways to use cannabis for medical purposes compared to smoking natural cannabis. The vast majority of research into potential medical benefits from the types of cannabis products available in state-legalized markets looks only at smoked cannabis.[55] Nor is there any clear evidence that the wide array of new types of cannabis products makes non-medical use of cannabis less harmful or risky, as opposed to making it more harmful. For example, while smoking cannabis likely causes some smoking-related health harms and risks for users and exposed nonusers, they are much less serious than

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[48] *See, e.g.*, Jacob T. Borodovsky et al., *Smoking, Vaping, Eating: Is Legalization Impacting the Way People Use Cannabis*?," 36 INT'L J. ON DRUG POL'Y 141 (2016); Stephen E. Lankenau et al., *Marijuana Practices and Patterns of use Among Young Adult Medical Marijuana Patients and Non-Patient Marijuana Users,* 170 DRUG & ALCOHOL DEPENDENCE 181 (2017); Gosh et al., *supra* note 3. In regard to cannabis beers and wines (some with alcohol, some without), see, e.g., Joshua M. Bernstein, *For a Buck and Sometimes a Buzz, Brewers Are Putting Cannabis Into Cans*, N.Y. TIMES (Nov. 15, 2018), https://www.nytimes.com/2018/11/15/dining/drinks/beer-cbd-marijuana-breweries.html [https://perma.cc/9LKF-D8P2]; Andre Borque, *Cannabis Beer And Wine Are Here, But Are They Here To Stay?*, FORBES (Nov. 6, 2018), https://www.forbes.com/sites/andrebourque/2018/11/06/cannabis-beer-and-wine-are-here-but-are-they-here-to-stay/#7c0dd489224d [https://perma.cc/Z6QB-GVQK]; Craig Giammona, *The Next Big Thing is Weed Beer*, BLOOMBERG BUSINESSWEEK (Oct. 10, 2018), https://www.bloomberg.com/news/articles/2018-10-10/the-next-big-thing-is-weed-beer [https://perma.cc/WRU5-4KTB].

[49] *See, e.g.*, John M. Stogner & Bryan Lee Miller, *Assessing the Dangers of "Dabbing": Mere Marijuana or Harmful New Trend?*," 136 PEDIATRICS 136, 1 (2015); Mallory Loflin & Mitch Earleywine, *A New Method of Cannabis Ingestion: The Dangers of Dabs?*, 39 ADDICTIVE BEHAV. 1430 (2014) ("The use of butane hash oil [dabs] has spread outside of the medical marijuana community.").

[50] Joseph Misolunas, *Why Marijuana Patches Could Be the Future for Cannabis*, CIVILIZED (Jan. 22, 2018), https://www.civilized.life/articles/marijuana-patches-future-for-cannabis [https://perma.cc/VHU4-25SQ].

[51] *See, e.g.*, Michelle Peace et al., *Evaluation of Two Commercially Available Cannabidiol Formulations for Use in Electronic Cigarettes*, FRONTIERS PHARMACOLOGY, (Aug. 29, 2016).

[52] *See* Brian F. Thomas & Gerald T. Pollard, *Preparation and Distribution of Cannabis and Cannabis-Derived Dosage Formulations for Investigational and Therapeutic Use in the United States*, FRONTIERS PHARMACOLOGY, (Aug. 31, 2017).

[53] *See* Lisa Creamer, *Medical Marijuana Patients Get A New Way To Score A Slice — With Pot Pizza*, WBUR (June 7, 2017), https://www.wbur.org/news/2017/06/07/medical-marijuana-pizza-quincy [https://perma.cc/77SY-5B37].

[54] *See* Jamie Ducharme, *A 9-Year-Old Accidentally Shared Her Grandpa's Marijuana Gummies With Her Fifth-Grade Class*, TIME (Jan. 23, 2018), http://time.com/5114582/thc-edibles-new-mexico. [https://perma.cc/7MMN-CXJJ].

[55] *See, e.g.*, Kristen Rømer Thomsen et al., *Recommendation to Reconsider Examining Cannabis Subtypes Together Due to Opposing Effects on Brain, Cognition and Behavior,* 80 NEUROSCIENCE & BIOBEHAVIORAL REV. 156 (2017); NAT'L ACADS. SCI. ENG'G & MED., *supra* note 3, at 6, 39.

those from daily tobacco smoking.[56] On the other hand, the most well-documented health harms and risks from cannabis consumption come from its intoxicating effects and its effects on the brain; and eating or drinking products containing cannabis or Δ9-THC causes much longer-lasting, often stronger intoxication effects, compared to smoking.[57]

In addition, studies have found increased hospitalizations in states that have legalized cannabis because of some adults experiencing unexpectedly strong effects from using edible cannabis products, and, to a lesser extent, other new types of cannabis products (e.g., extremely high potency "dabs" or other extracts).[58] Similar problems arise when legal consumers eat a single cannabis cookie or candy without realizing that it actually contains multiple servings or doses and much larger amounts of Δ9-THC than should be consumed by one person at one time.[59] The availability of legal edible medical cannabis products in some states has also been linked with increased calls to poison control centers and visits to emergency rooms because of young children consuming edible cannabis products meant for others.[60] There are also reports of youth and young adults using non-smoked cannabis or Δ9-THC to circumvent laws or rules prohibiting public consumption (e.g., at school or work) or while driving.[61]

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[56] *See, e.g.*, Donald P. Tashkin, *How Beneficial is Vaping Cannabis to Respiratory Health Compared to Smoking?,* 110 ADDICTION 1706 (2015). Besides the fact that cannabis smoking is less harmful than tobacco smoking, even regular cannabis smokers tend to spend considerably less time smoking than addicted tobacco smokers.

[57] *See, e.g.*, NAT'L ACADS. SCI. ENG'G & MED., *supra* note 3, at 51; Ryan Vandrey et al., *Pharmacokinetic Profile of Oral Cannabis in Humans: Blood and Oral Fluid Disposition and Relation to Pharmacodynamic Outcomes,* 41 J. ANALYTICAL TOXICOLOGY 83 (2017); Borodovsky et al., *supra* note 48; Stéphanie Baggio et al., *Routes of Administration of Cannabis Used for Non-Medical Purposes and Associations with Patterns of Drug Use*, 54 J. ADOLESCENT HEALTH 235 (2014); Edward J. Cone et al., *Marijuana-Laced Brownies: Behavioral Effects, Physiological Effects, and Urinalysis in Humans Following Ingestion*, 12 J. ANALYTICAL TOXICOLOGY 169 (1988); *see also* David M. Benjamin & Michael J. Fossler, *Edible Cannabis Products: It is Time for FDA Oversight*, 56 J. CLINICAL PHARMACOLOGY 1045 (2016).

[58] *See* Jane A. Allen et al., *New Product Trial, Use of Edibles, and Unexpected Highs Among Marijuana and Hashish Users in Colorado*, 176 DRUG & ALCOHOL DEPENDENCE: 44 (2017) (Most adults experiencing unexpected high simply slept it off, but 13% had unintended sex and 8% went to hospital or emergency room.); Dazhe Cao et al., *Characterization of Edible Marijuana Product Exposures Reported to United States Poison Centers*, 54 CLINICAL TOXICOLOGY 840 (2016).

[59] *See* Borodovsky et al., *supra* note 48. *See also* Daniel G. Barrus et al., *Tasty THC: Promises and Challenges of Cannabis Edibles* (RTI Press 2016).

[60] *See* Cao et al., *supra* note 58; Bridget Onders et al., *Marijuana Exposure Among Children Younger Than Six Years in the United States*, 55 CLINICAL PEDIATRICS 428 (2016); George S. Wang et al., *Association of Unintentional Pediatric Exposures with Decriminalization of Marijuana in the United States*, 63 ANNALS EMERGENCY MED. 684 (2014); George S. Wang et al., *Pediatric Marijuana Exposures in a Medical Marijuana State*, 167 JAMA PEDIATRICS 630 (2013) (Colorado study); Kathy T. Vo et al., *Cannabis Intoxication Case Series: The Dangers of Edibles Containing Tetrahydrocannabinol*," 71 ANNALS EMERGENCY MED. 306 (2018) (San Francisco, California study). Commentators have noted that the commercial packaging and sale of some of the new edible cannabis products "brings to mind the tort-law concept of the "attractive nuisance": a hazardous condition that is foreseeably likely to attract children who are unable to appreciate the risk involved." Robert J. MacCoun & Michelle M. Mello*, Half-Baked — The Retail Promotion of Marijuana Edibles*, 372 NEW ENG. J. MED. 989 (2015).

[61] *See, e.g.*, Emily Anne McDonald et al., *Traversing the Triangulum: The Intersection of Tobacco, Legalised Marijuana and Electronic Vaporisers in Denver, Colorado*, 25 TOBACCO CONTROL (Supp. 2016).

FDA could help to address the many health harms and threats to the public health caused by the increasingly broad array of new types of cannabis products appearing in legalization states—and from related failures to prevent adulteration and minimize contamination or provide accurate labeling and clear warnings and instructions for use—by exercising its enforcement discretion to remove from the market only those FDCA-violating cannabis products that do not meet certain related FDA-established minimum requirements.

If too strict, detailed, or comprehensive, however, enforcing those minimum standards could seriously strain FDA's resources, diverting them from other important FDA priorities. Such FDA action could also improperly shift actual or perceived responsibility for prudently regulating the quality and harm-related characteristics of state-legalized cannabis products from the specific states that choose to legalize to FDA. Moreover, neither Congress nor the Administration has specifically directed FDA to implement and enforce such an extensive regulatory scheme, much less provided any related guidance, resources, or new authorities. Nevertheless, FDA's core mission is to protect and promote the public health through its authorities relating to drugs, foods, supplements, cosmetics, tobacco products, and other products.[62]

To act consistently with that mission—while taking account of its own limitations, the legalizing states' responsibilities, and other concerns—FDA should at least take those actions relating to state-legalized cannabis products that would not only protect and promote the public health without straining FDA's resources, but also work directly to protect the actual or perceived integrity and legitimacy of FDA's existing regulatory authorities over drugs and over tobacco products, supplements, cosmetics, and foods.

FDA's Tobacco Control Authorities and Cannabis

State-legalized cannabis products that contain tobacco or nicotine do not yet appear to be a significant problem. But many cannabis users already combine tobacco with cannabis, suggesting a ready market;[63] and mixing nicotine into an e-cigarette liquid or other product that delivers either Δ9-THC or cannabis would be an easy way to make the intoxicating cannabis product highly addictive, thereby increasing sales, use, profits, and harms. To prevent such hybrid products from appearing, and to act consistently with its authorities over tobacco products, FDA should make it very clear to all legalization states, manufacturers, and sellers that the agency will aggressively enforce against any state-legalized cannabis products that also contain tobacco or nicotine. If not illegal as an unapproved drug, any such hybrid cannabis product would

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[62] *See, e.g.,* U.S. FOOD & DRUG ADMIN., OFFICE OF REGULATORY AFFAIRS, OFFICE OF OPERATIONS, INVESTIGATIONS OPERATING MANUAL 2018 (2018), https://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM607759.pdf [https://perma.cc/S49P-XF8J] (listing agency's public health mission as "Protecting consumers and enhancing public health by maximizing compliance of FDA regulated products and minimizing risk associated with those products"); U.S. v. Article of Drug . . . Bacto-Unidisk . . . 394 U.S. 784, 798 (1969) (referring to Food, Drug, and Cosmetic Act's "overriding purpose to protect the public health"). *See also What We Do*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/aboutfda/whatwedo/default.htm [https://perma.cc/HT2C-4MAY]; *FDA Launches New Campaign to Advance Ongoing Efforts to Recruit and Retain a World-class Workforce Dedicated to Protecting and Promoting the Public Health*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm614567.htm [https://perma.cc/V792-G7WU].

[63] *See, e.g.*, McDonald et al., *supra* note 61; Gillian L. Schauer et al., *Marijuana and Tobacco Co-Administration in Blunts, Spliffs, and Mulled Cigarettes*, 64 ADDICTIVE BEHAVIOR 200 (2017).

be subject to FDA's tobacco control authorities as a "tobacco product" illegally on the market without the permissive FDA new tobacco product order required under the Tobacco Control Act.[64] Such a product would also directly violate the Act's provision that specifically prohibits the marketing of any product that combines a tobacco product with any other product regulated by FDA, including any drugs, foods, biologics, cosmetics, or supplements.[65]

Because consuming products that combine nicotine or tobacco with cannabis or Δ9-THC is remarkably more harmful and addictive than consuming cannabis or Δ9-THC alone, FDA action to prevent any such hybrid products from appearing in the legalization states would work directly to protect the public health and otherwise follow the dictates of the Tobacco Control Act—without interfering with the legalization states' ability to make unadulterated cannabis available to their residents for medical or broader uses.

FDA's Authorities Over Dietary Supplements and Cannabis

FDA could also make it clear that it will exercise its authorities over foods and dietary supplements to pull off the market any state-legalized cannabis product that: (a) is combined with any dietary supplement (e.g., any vitamin, mineral, other herb or botanical, amino acid, or dietary substance used by humans to supplement the diet);[66] or (b) presents itself as being a dietary supplement, but fails to fully comply with all related requirements and restrictions in the FDCA and related FDA regulations. As noted above, FDA has already determined that any product containing Δ9-THC or CBD cannot qualify as a supplement,[67] and it is unlikely that any products containing whole cannabis or other psychoactive cannabis constituents could qualify as a supplement, either, much less also comply with all the related requirements in the FDCA and related rules.[68]

Such an enforcement policy would, among other things, help to stop state-legalized cannabis products from being fortified with caffeine to make them more addictive, and prevent the addition of vitamins or other healthy-sounding supplements into cannabis products, which could mislead consumers into thinking the cannabis products were less harmful or more therapeutically beneficial than they actually are. It would also prevent any state-legalized cannabis or cannabis-derived products from being labeled or marketed as dietary supplements (which could also mislead consumers to think the cannabis products were less harmful or more beneficial). But this supplement-based FDA enforcement policy would not make state-legalized cannabis products without dietary-supplement additives or claims any less available to authorized state users.[69]

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[64] 21 U.S.C. § 321(rr); Section 910 of the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (21 U.S.C. § 387j).

[65] 21 U.S.C. § 321(rr)(4).

[66] 21 U.S.C. § 321(ff).

[67] *See supra* notes 42, 43.

[68] *See* 21 U.S.C. § 321(ff); *Dietary Supplements Proposed and Final Rules*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm2006896.htm [https://perma.cc/XB67-PVHW].

[69] For example, this approach would stop non-FDA-approved products containing CBD from being sold mixed with bona fide supplements or being labeled or marketed as supplements. But they could still be sold, without any FDA interference, if they did not have any such ingredients, labeling, or marketing.

FDA's Authorities Over Cosmetics and Cannabis

FDA could also take a parallel approach to stop the marketing and sale of products that contain cannabis or certain cannabis constituents that are labeled or promoted as cosmetics, which the FDCA defines as articles, other than soap, "intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance."[70] The FDA policy could be simple and clear: If you contain cannabis, Δ9-THC, or certain other cannabis constituents and either claim to be a cosmetic or are clearly packaged and marketed as one, FDA will pull you off the market unless the product complies with all FDCA requirements that apply to cosmetics (e.g., is not misbranded or adulterated, which includes not containing any approved or unapproved drugs).[71] This policy would stop state-legalized cannabis products from being labeled or marketed as cosmetics and would protect the integrity of FDA's authorities over cosmetics. But, like the other proposed enforcement policies, it would not interfere with the states' ability to make cannabis products legally available to authorized adults within their borders for medical or broader use, including their possible use by buyers as cosmetics.

FDA's Authorities Over Food and Cannabis

Along the same lines, FDA could also adopt and publicize an enforcement policy of pulling off the market any state-legalized product containing cannabis or Δ9-THC, or other cannabis constituents that claims to be a food or otherwise qualifies as a food under the FDCA ("articles used for food or drink" for humans or animals).[72] Moving in that direction, FDA's website already states that it is not legal, in interstate commerce, to sell a food to which Δ9-THC or CBD have been added.[73]

Actually implementing that enforcement policy would have the most powerful impact on existing markets for state-legalized cannabis products because it would eliminate the wide range of edible and drinkable products that contain cannabis or cannabis constituents that are already being offered for sale and, in some cases, are quite popular with legal users (as well as youth).[74] Such a dramatic impact could be worthwhile given the many health harms and risks created by making intoxicating cannabis or Δ9-THC available in attractive foods and drinks, by adding cannabis or Δ9-THC into alcoholic beverages, or by mixing cannabis or cannabis derivatives with other harmful ingredients for consumption in a food or beverage. There is also no clear

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[70] 21 U.S.C. § 321(i).

[71] 21 U.S.C. §§ 361, 362.

[72] 21 U.S.C. § 321(f). See, also, Paul J. Larkin Jr., *Marijuana Edibles and "Gummy Bears"*, 66 BUFF. L. REV. 313 (2018).

[73] *See FDA Regulation of Cannabis and Cannabis Derived Products: Questions and Answers*, *supra* note 42 at questions 13 and 14. FDA recently determined that certain hemp seed and hemp seed ingredients (which do not contain psychoactive levels of Δ9-THC, CBD, or any other cannabis constituent) are generally recognized as safe as food ingredients; but the agency also stated that those GRAS conclusions do not affect its position that adding CBD or Δ9-THC to foods is a prohibited act under the FDCA. *FDA Responds to Three GRAS Notices for Hemp Seed-Derived Ingredients for Use in Human Food*, U.S. FOOD & DRUG ADMIN., (Dec. 20, 2018), https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm628910.htm [https://perma.cc/C4FF-MG6W].

[74] *See, e.g.,* Borodovsky et al., *supra* note 48; Lankenau et al., *supra* note 48; Ghosh et al., *supra* note 3.

evidence to date that providing cannabis or any of its constituents through foods or drinks makes them any less harmful to users or any more effective for medical purposes. Moreover, this enforcement policy would not interfere with state-legalized sales of cannabis in its natural form, in non-food products delivering Δ9-THC or other cannabis constituents without smoking (e.g., via an e-cigarette device or pill), or in conventional concentrates, such as hash or hash oil, or in new, highly concentrated "dabs" (which should be restricted separately).[75] In addition, those that purchased the state-legalized cannabis products which would still be available after FDA implemented such a food-based enforcement policy could, if desired, still consume the cannabis products through converting them into foods or drinks, themselves.

If pulling all state-legalized foods containing cannabis off the market were seen as too extreme, FDA should still, at a minimum, use its authorities over food to implement and publicize an enforcement policy of pulling off the market any state-legalized cannabis beverage that includes alcohol, such as cannabis or cannabinoid-infused beer, wine, or spirits.[76] Such FDA action would be entirely consistent with the announcement by the Alcohol and Tobacco Tax and Trade Bureau (TTB) that it will not approve any formulas or labels for alcohol beverage products that contain a controlled substance under Federal law, including cannabis and its derivatives, such as Δ9-THC and CBD.[77]

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[75] New, highly concentrated pure cannabis products, such as "dabs," can deliver incredibly strong doses of Δ9-THC very rapidly (often through the use of a blowtorch), creating much larger health risks than other cannabis products; and there is no evidence that they offer a more effective way to consume cannabis for any medical uses. *See, e.g.,* Stogner & Miller, *supra* note 49; Loflin & Earleywine, *supra* note 49. To address the additional new health risks from these extreme cannabis products, FDA might want to move beyond the main enforcement strategies proposed in this article and take some additional special action just to take certain state-legalized highly concentrated and unnecessarily risky cannabis concentrates off the market. FDA could do that simply by announcing that it will be removing from the market (as unapproved drugs) any state-legalized cannabis product that contains more than, say, 50% Δ9-THC or delivers more than a certain amount of Δ9-THC in any one dose or use. Cannabis in its natural plant or flower form typically has less than 25% Δ9-THC, even after post-legalization potency increases (while dabs can have more than 90%). *See, e.g*., Ghosh et al., *supra* note 3. Prior to 2008, the average levels of Δ9-THC in conventional hash and hash oil products annually confiscated by federal and state law enforcement officials never exceeded 35% and were usually much lower (with cannabis leaf or flower never exceeding 15%). Zlatko Mehmedic et al., *Potency Trends of Δ9-THC and Other Cannabinoids in Confiscated Cannabis Preparations from 1993 to 2008*, 5 *J. FORENSIC SCI.* 1209 (2010).

[76] FDA does not have primary regulatory authority over alcoholic beverages, which is managed by the Treasury Department pursuant to the Federal Alcohol Administration Act. 27 U.S.C. § 201 et seq. *See also* 21 U.S.C. § 350*l*(e). But FDA does have primary authority to regulate non-beverage foods that contain alcohol. *See, e.g.,* 21 U.S.C. § 342 (a confectionary containing more than trivial amounts of alcohol is an adulterated food). FDA can also regulate alcoholic beverages (as "foods," which includes foods and drinks) to some extent. *See, e.g*., *Guidance for Industry: Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration*, U.S. FOOD & DRUG ADMIN. (Dec. 2014), https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm166239.htm [https://perma.cc/JU3D-LQ36]; *Memorandum of Understanding Between the Food and Drug Administration and the Bureau of Alcohol, Tobacco and Firearms*, U.S. FOOD & DRUG ADMIN (Nov. 20, 1987), https://www.ttb.gov/main_pages/memo-understanding.shtml [https://perma.cc/8PUS-AFHA]. Any alcoholic beverages labeled or marketed with therapeutic claims would also be subject to FDA's regulatory authority over drugs. *Id.*

[77] *Frequently Asked Question (FAQ): Alcohol Beverage Formulas and Labels*, U.S. DEP'T TREASURY, ALCOHOL & TOBACCO TAX & TRADE BUREAU (May 23, 2018), https://www.ttb.gov/faqs/a29.shtml# [https://perma.cc/2X58-98MH] (noting that "TTB may require formula applicants to obtain documentation from FDA indicating that the proposed use of an ingredient in an alcohol beverage would not violate the Federal Food, Drug and Cosmetic Act").

Preventing cannabis-alcohol product combinations, especially those mixing Δ9-THC with alcohol, is critically important for protecting the public health because the combined effects of alcohol and cannabis can sharply increase the intoxicating and debilitating effects on users well beyond the impact from consuming either product alone, thereby increasing the risk of vehicle crashes and other intoxication-caused harms.[78] In addition, there is moderate evidence that cannabis use is associated with the development of alcohol substance use disorders,[79] and consuming cannabis already mixed with alcohol could only increase that risk.[80]

As another alternative to a more comprehensive food-based enforcement policy, FDA could announce and enforce a policy of removing from the market any state-legalized cannabis products that qualify as FDA-regulated foods if they contain any ingredients (other than cannabis or cannabis derivatives) not generally recognized as safe (GRAS), which foods are not allowed to contain as additives or ingredients without prior review and approval by FDA.[81]

But these less comprehensive food-based approaches would not support the integrity of FDA's regulatory system for foods and drugs as well as an enforcement policy to prevent any foods from containing or delivering actionable levels of a non-FDA-approved drug or, without prior FDA approval, containing or delivering actionable levels of an FDA-approved drug.

CONCLUSION

By announcing and implementing all or some of these proposed enforcement strategies, FDA would not be creating or enforcing its own regulatory scheme for state-

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[78] *See, e.g.*, Christina M. Lee et al., *Differences in Reporting of Perceived Acute Effects of Alcohol Use, Marijuana Use, and Simultaneous Alcohol and Marijuana Use*, 180 DRUG & ALCOHOL DEPENDENCE 391 (2017); Percy Bondallaz et al., *Cannabis and its Effects on Driving Skills*, 268 FORENSIC SCI. INT'L 92 (2016); Guohua Li et al., *Role of Alcohol and Marijuana Use in the Initiation of Fatal Two-Vehicle Crashes*, 27 ANNALS EPIDEMIOLOGY 342 (2017).

[79] NAT'L ACADS. SCI. ENG'G & MED., *supra* note 3, at 357-73.

[80] Conversely, if FDA implemented a policy of removing from the market any state-legalized cannabis products that qualified as an FDA-regulated "food," it might want to exercise its enforcement discretion to exclude those cannabis or cannabis-infused "beers," "wines," or "spirits" that can produce a cannabis "high" but either do not have any alcohol or include only trace amounts of alcohol that could not case inebriation even if consumed in large quantities. Such beverages have already been developed, and they might serve as less-harmful direct substitutes for alcoholic beverages. *See, e.g.,* Thomas Pellechia, *A New Cannabis Infusion Bubbles Its Way Into The Non-Alcohol Wine Category,* FORBES (Sept. 27, 2018), https://www.forbes.com/sites/thomaspellechia/2018/09/27/a-new-cannabis-infusion-bubbles-its-way-into-the-non-alcohol-wine-category/#71bdf4c263b1 [https://perma.cc/TC8Y-HWU8]; Kari Sonde, *Pot-Infused Beer Has Hit Shelves. Is It Legal?,* MOTHER JONES (Aug. 2, 2018), https://www.motherjones.com/food/2018/08/pot-infused-beer-has-hit-shelves-is-it-legal [https://perma.cc/2WVN-GP8A]. If consumed instead of alcoholic beverages, these cannabis beverages would likely reduce (but not eliminate) intoxication vehicle crash risks. *See, e.g.*, Lee et al., *supra* note 78; Li et al., *supra* note 78. In addition, consuming cannabis instead of alcohol generally appears to produce less serious health harms and risks. *See, e.g.*, Meenakshi Sabina Subbaraman, *Can Cannabis be Considered a Substitute Medication for Alcohol*, 49 ALCOHOL & ALCOHOLISM 292 (2014); Dirk W. Lachenmeier & Jurgen Rehm, *Comparative Risk Assessment of Alcohol, Tobacco, Cannabis and Other Illicit Drugs Using the Margin of Exposure Approach*, 5 SCI. REP. 8126 (2015). *But see*, David A. Gorelick, *The Relative Harms of Marijuana and Alcohol*, 40 AM. J. DRUG & ALCOHOL ABUSE 419 (2014).

[81] *See, e.g.,* U.S. FOOD & DRUG ADMIN., REGULATORY FRAMEWORK FOR SUBSTANCES INTENDED FOR USE IN HUMAN FOOD OR ANIMAL FOOD ON THE BASIS OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) PROVISION OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT: GUIDANCE FOR INDUSTRY (2017).

legalized cannabis products or taking on the task states should be shouldering to responsibly regulate the cannabis products they legalize. Instead, FDA would simply be announcing new enforcement policies, which should work quickly to improve the quality and characteristics of state-legalized cannabis products and the ways they are being labeled and marketed, while also helping to guide the development of future state legalization laws and regulations. To the extent that state-legalized cannabis products and businesses did not comply with the new enforcement policies, FDA would take enforcement action only to stop the marketing and sale of those state-legalized cannabis products that have characteristics, labeling, or marketing that most directly and flagrantly violated the FDCA requirements that apply to all FDA-regulated medical drugs, tobacco products, dietary supplements, cosmetics, and foods. In this way, FDA would protect the legitimacy and integrity of the FDCA's regulatory frameworks for those products, while working directly to promote the agency's core mission of protecting the public health. Yet FDA would not be straining its own resources nor interfering with the states' ability to make all of the major types of cannabis products previously offered only by illicit markets legally available for medical or broader uses to adult buyers within their borders.

Following these enforcement strategies would also be entirely consistent with the existing federal policy of generally tolerating state cannabis legalization through exercising enforcement discretion—and only interfering when fundamental federal priorities and goals are at serious risk.

It is likely, however, that FDA could not implement all of these enforcement strategies, especially those that would have the most dramatic impacts on existing state-legalized markets, without first securing approval from the White House, which might require approvals from the Department of Justice and other federal agencies, as well. If the White House seriously wanted to protect the public health more effectively it would not only approve any such proposals made by FDA but would direct FDA to take these kinds of actions if the agency did not propose them itself. Such FDA enforcement strategies might also be an effective way for the Administration to balance its respect for states' rights with the need to address some of the most serious concerns many in the Administration and elsewhere still have about allowing states to make an intoxicating, long-standing illicit drug legally available and commercially marketed for medical or broader use.

These FDA enforcement strategies would stop the development and sale of state-legalized cannabis products that are more harmful, addictive, or attractive than conventional illicit cannabis products and would prevent state-legalized cannabis from being marketed in ways that mislead consumers in harmful ways. They would sharply reduce the ability of state legalization to normalize cannabis use, increase recreational use, or increase related harms. But simply continuing the current Administration policy of discretionary tolerance by DOJ, with little or no action by other federal agencies directly related to state-legalized cannabis, would not.

Proponents of cannabis legalization for medical or broader purposes should also support these proposed new FDA enforcement practices to reduce the likelihood that the legalization system in any state will produce such serious unintended and undesirable consequences that the federal government might either terminate its current policy of forbearance or place much tighter controls and restrictions on all the legalizing states. At the same time, these FDA actions would not interfere with the legitimate policy goals being pursued by states that choose to legalize cannabis for either medical or broader purposes. Even if the proposed FDA enforcement practices

proposed were entirely successful, patients in medical-legalization states would still be able to obtain state-legalized cannabis for medical use, with guidance from their health care providers, and would be able to consume the cannabis in a variety of ways other than just smoking. In states with broader legalization, the FDA enforcement efforts would not in any way recriminalize cannabis use nor would it impede state efforts to put illicit markets out of business through direct market competition. But these new FDA policies would limit the kind of new commercial cannabis-product development and marketing most likely to attract brand new youth and adult users to both legal and illicit markets and increase overall cannabis-related harms.[82]

[82] After this article was submitted for publication, the following paper appeared that looks at some of the same issues from a somewhat different perspective (and with more historical and other background information): Sean M. O'Connor & Erika Lietzan, *The Surprising Reach of FDA Regulation of Cannabis, Even After Descheduling*, 68 AM. UNIV. L. REV. 823 (2019).