Cannabis Cannibalism: How Federal Rescheduling Could Consume the State-Licensed Industry Without Safe Harbors Under the Federal Food, Drug and Cosmetic Act

by Khurshid Khoja[*]

Rescheduling cannabis and THC to Schedule III of the federal controlled substances act ("CSA") seem like well-intended efforts to support medical research, while also eliminating exposure to Internal Revenue Code Section 280E ("280E") by removing cannabis and THC from Schedule I. But whether we reschedule cannabis to Schedule III or lower (or deschedule cannabis altogether), current state-licensed businesses will need a carve-out for non-pharmaceutical "whole plant" cannabis products[1] in order to keep these products from being swept into the federal Food, Drug and Cosmetic Act ("FDCA") definition of what constitutes a drug product regulated solely by the Food and Drug Administration ("FDA"). Earnest efforts to meaningfully roll back federal cannabis prohibition should not cannibalize hard-fought wins in states where we've already defeated failed prohibitionist policies.

Even a well-intended measure may have lasting and irreversible repercussions. Would rescheduling make a material difference in support for medical research over *other policy options*—specifically, descheduling or the status quo? And would it lead to existing state-licensed cannabis operators being treated like all other lawful businesses in the United States? Or would it foreclose their access to certain markets, introduce well-capitalized competitors from the pharmaceutical space, and continue to block their access to banking? Could it also spur the pharmaceutical industry to leverage its resources to oppose descheduling cannabis, once they've been granted an effective monopoly over federally-lawful cannabis products regulated under Schedule III?

As cannabis industry advocates, we owe it to ourselves to examine proposals for rescheduling cannabis and THC closely and carefully to assess all potential benefits and drawbacks, and perform a sober cost-benefit analysis. Fortunately, there is extensive peer-reviewed legal and academic scholarship that thoughtfully examines the potential consequences of removing cannabis and THC from Schedule I. These assessments recognize the limited impact of administrative rescheduling. They also suggest the need for pairing rescheduling with additional legislative relief and statutory safeguards to protect the state-licensed cannabis industry from the unintended consequences of rescheduling:

> While rescheduling has been popular among advocates, the press, and some members of Congress, it offers-at best-limited hope for reform. Such a move would not automatically bestow legal status on existing medical marijuana enterprises, and marijuana would still have to go through the lengthy process of FDA approval before being legally marketable. *For tax purposes, placing marijuana in Schedule III would be the biggest boom to business, but beyond that,*

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[*] *Khurshid Khoja is CEO of Greenbridge Corporate Counsel, P.C., a business and regulatory law boutique serving enterprises in the cannabis, hemp and biosynthetic cannabinoid industries since 2012. He currently serves as Chair Emeritus of the National Cannabis Industry Association's Board of Directors, and Co-Chair of its Policy Council.*

> *rescheduling would have limited effects on criminal penalties, banking services, and state-level recreational programs. The most notable effect of rescheduling would be to remove some research barriers for medical marijuana, but would lack the comprehensive effects many supports seek. (Emphasis added, and all internal citations removed from sources quoted herein.)*[2]

Some of these assessments highlight the grave potential risks of shifting primary responsibility for the enforcement of federal laws applicable to cannabis from the Drug Enforcement Administration ("DEA") to the FDA, with the latter shoe-horning "whole plant" cannabis products into existing regulatory categories under the FDCA:

> The end result [of removing cannabis from Schedule I] may be the FDA cracking down hard--perhaps in conjunction with state governments--on medical claims and any positioning of cannabis products as medical without successful completion of the arduous and expensive new drug application (NDA) process…. While proponents of medical cannabis may assume that the flower could simply be marketed as a dietary supplement outside the new drug framework, dietary supplement options are quite limited. Nor is marketing of medical cannabis in food an easy alternative, given the FDA's complex framework for food regulation and its interaction with the new drug framework.[3]

With that, I offer the following assessment of the potential benefits, limitations and drawbacks of rescheduling "whole plant" cannabis products to Schedule III, citing existing peer-reviewed legal scholarship for support.

A. BENEFITS OF RESCHEDULING TO SCHEDULE III

1. Medical Research: Rescheduling cannabis from Schedule I to Schedule III, IV, or V would undoubtedly facilitate medical research, relaxing the researcher certification and licensure requirements currently imposed on cannabis research.[4] It's important to note however that rescheduling isn't a necessary prerequisite for developing much-needed cannabis derived pharmaceutical drugs[5] — though rescheduling cannabis to Schedule III would make it considerably easier and cheaper[6] to do so compared to the current pathway for developing these drugs, which requires both a DEA Schedule I license and compliance with cannabis-specific hurdles codified in state and federal law.

2. Fair Taxation: Section 280E of the Internal Revenue Code prohibits existing cannabis businesses from deducting standard business expenses because their "trade or business . . . consists of trafficking in controlled substances (within the meaning of schedule I and II of the Controlled Substances Act)." *Rescheduling cannabis to Schedule III would allow cannabis businesses to claim the same federal tax deductions that all other lawful businesses take.*[7]

B. LIMITATIONS OF RESCHEDULING TO SCHEDULE III

1. No Impact on Banking Access: While rescheduling would provide relief from IRC 280E, it offers very limited financial relief otherwise, having no positive impact on access to capital and/or financial services—basic business banking would continue to elude most of the

industry.[8] As such, any effort to reschedule "whole plant" cannabis should be combined with legislation to reform banking laws (ideally the SAFE Banking Act) in order to address this blind spot.

2. No Impact on Criminal Penalties: Rescheduling would also do little to address federal criminal penalties for cannabis, which President Biden has called on Congress to reform.[9]

> *Because rescheduling would not change the federal status of the marijuana grown, processed, and sold in state-legal enterprises, it would have very little impact on criminal penalties.* Generally, penalties for possessing drugs in lower schedules are less harsh than those in Schedule I or II. *However, Section 841 of the Controlled Substances Act outlines minimum and maximum penalties for marijuana specifically*, as enacted at various times in the 1980s. *It is unlikely that rescheduling would have any impact on these mandatory penalties, and therefore congressional action amending the CSA would be necessary to reduce them.*[10]

As such, proposals for rescheduling should ideally incorporate the repeal of criminal penalties under the CSA that are specific to cannabis. It should be noted that the proposed carve-out discussed below for "whole plant" cannabis products would preclude criminal penalties under the FDCA for delivering unapproved new "drugs" into interstate commerce,[11] introducing or receiving adulterated or misbranded foods into interstate commerce (or adulterating or misbranding foods already in interstate commerce),[12] as well as other violations of the FDCA that would be premised on "whole plant" cannabis products being deemed "drugs" under the FDCA.[13] That said, it should also be acknowledged that the vast majority of criminal penalties for cannabis offenses are currently imposed at the state level.

C. POTENTIAL RISKS OF RESCHEDULING TO SCHEDULE III

1. Overview of Potential Risks: Rescheduling cannabis from Schedule I to Schedule III would be a long overdue reversal of the federal government's position that cannabis (like other Schedule I controlled substances) has no accepted medical use. While such a reversal would be a welcome admission, it also permits the FDA to acknowledge the accepted medical use of "whole plant" cannabis and cannabis products (as well as any accompanying health claims, as an enforcement priority) for the first time — as opposed to just individual cannabinoids used as active ingredients in "small molecule" cannabis-derived drugs previously approved through the FDA's existing new drug application (NDA) process.[14] As discussed below, rescheduling would largely remove the DEA from cannabis enforcement and enable the FDA to effectively occupy the field of regulating interstate cannabis commerce almost exclusively under the rubric of its small molecule[15] and botanical "drug" paradigms under the FDCA[16] — unless additional statutory protections are enacted concurrently. The sad irony of opening up the regulated interstate market to medical cannabis through rescheduling is that the resulting application of the FDCA could lead to foreclosing access to the interstate market for the vast majority of state-licensed cannabis industry operators.

Entrenching the FDA's NDA path as the only legal route to the interstate and international cannabis markets, would effectively preventing current industry participants from accessing these markets as the capital costs of complying with the FDA's drug regime would put them out of reach[17], and non-compliance would lead to federal criminal and civil penalties—hardly an improvement on the status quo and incentive enough to continue limiting operations to *intrastate* markets. As noted below, rescheduling doesn't need to result in limiting the industry to the NDA pathway alone.

2. FDA Regulation of Whole-Plant Cannabis Products as "Drugs". The FDA exercises near-exclusive jurisdiction over the production, labeling, packaging, marketing, distribution and sale of "drugs" in the US (as the term is defined under the FDCA).[18] *"Explicit or implicit claims that a product containing cannabis (or a cannabis constituent) could treat disease, or even simply affect the functioning of the body, would turn that product into a 'new drug' that requires premarket approval from the FDA."* [19]

Upon rescheduling cannabis to Schedule III or lower (or descheduling), the FDA could no longer simply defer to the DEA as the primary federal enforcement agency (as it has historically done with respect to Schedule I substances[20]) and would likely exercise its authority over "drugs" on its own initiative,[21] triggered by the cannabis industry's own widely-publicized claims about the potential health and wellness benefits of medicinal cannabis:[22]

> [I]f the seller (in interstate commerce) made claims about treating a disease or about affecting the structure or functioning of the body, the FDA would deem the cannabis a drug. *Thus, claims that smoking the cannabis would promote relaxation, mitigate insomnia, reduce anxiety, or maintain the appetite would turn the cannabis into a regulated drug. In the absence of these claims, the agency might try to assert its drug authorities on the theory that the product's design or the circumstances surrounding its use demonstrated its intended use as a drug.*[23]

Given the foregoing (and without any statutory amendments) it is all but assured that all existing medicinal cannabis products available in state markets would be deemed "drugs" under the FDCA as a matter of law:

> *Any product containing or made from cannabis would be deemed a "drug" by the FDA if it were associated with medical claims.* Section 201 of the FDCA defines a "drug" as any article (item) "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man." The term "drug" also includes any article "intended to affect the structure or function of the body of man" (unless it is a food). Finally, anything intended as a "component" of a drug is also a drug.[24]

However, it is also true that the FDA could apply the "drug" definition to adult use products too, based on established medicinal uses among consumers:

> [While t]here is a solid argument that *interstate* transactions of cannabis only for recreational smoking also would not trigger the FDA's jurisdiction…. It is also possible the agency would find

> an intended drug use even without claims—based on the [purveyor]'s knowledge of actual use in the market or perhaps its design.[25]

3. Regulation of Cannabis as a "Drug" Would Foreclose Access to Interstate Commerce. In contrast with the CSA, which imposes jurisdiction over acts ***affecting*** interstate commerce,

> the FDCA is drafted even more narrowly. It is not sufficient for the agency to find a connection with interstate commerce; it generally must also find that a product or component of the product traveled in interstate commerce.[26]

That said, "the interstate commerce requirement generally does not meaningfully constrain the FDA's authority."[27]

Put differently, the FDCA imposes FDA jurisdiction over any finished medicinal cannabis product delivered into the stream of interstate commerce, but also extends the FDA's reach much further.[28] As such, rescheduling to Schedule III, shifting primary enforcement responsibility from the DEA to the FDA, and applying the FDCA's existing "drug" provisions could permanently freeze access to interstate and international markets for current state-licensed cannabis businesses, reserving those markets for well-capitalized pharmaceutical companies capable of navigating the NDA process.

While rescheduling to Schedule III, and concurrently limiting current medical cannabis providers to purely intrastate operations might arguably preserve "the traditional medical cannabis industry — sale of whole plant-based products, by small operations, to locally-based consumers," that outcome is not assured.[29]

> *Cannabis that is grown, sold, and used entirely within the borders of one state will not fall within the FDA's jurisdiction.* This is true even if the seller makes medical claims about the product and if those claims are made in media, such as on the internet, that are accessible outside the state….
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> *But there are reasons to be cautious about this pathway. To begin with, if the FDA is concerned about the claims made or about the safety of the product, it will strain to find a component that traveled in interstate commerce. Any inactive ingredient will qualify. In addition, the agency takes the position that sale of a product in one state for consumer use in another state constitutes introduction of that product into interstate commerce. This will include not only online sales to residents of other states but in-person sales if the purchasers cross state lines. Moreover, violation of the FDCA is a strict liability offense; a seller's ignorance of the purchaser's out-of-state status would presumably be irrelevant. This effectively places the burden on the [existing] medical cannabis business to ensure that transactions are purely intrastate.*[30]

4. Exclusive FDA Oversight Would Impose Insurmountable Compliance Costs for Existing Operators. Small businesses, MWBEs and social equity licensees are already struggling with access to capital and financial services. Compliance with the FDCA and FDA oversight would not be possible for most:

> *The new drug research and development process is notoriously expensive and risky. For a new chemical entity, it can take ten to twelve years and cost more than $1 billion.* Prior and longstanding use of cannabis for medical and non-medical purposes may reduce some of the risk, for instance, by identifying promising uses and suggesting the appropriate dosing. Also, *the agency's flexibility with botanical NDAs may reduce some of the cost, where it applies. Pursuing new drug approval for medical cannabis after descheduling [or rescheduling] could, however, still cost hundreds of millions of dollars. This will put the process out of reach for most entities currently providing medical cannabis.* Yet avoiding the new drug approval process is not an option; *medical claims on any product in interstate commerce will trigger the FDA's new drug authorities and require an approved NDA.*[31]

Additionally, the NDA-related costs triggered by the assertive application of the FDCA's "drug" definition would be just the beginning. Such costs would also include compliance with "current good manufacturing practices" (cGMP) as well as drug packaging and labeling requirements:

> *"Drug" status under the FDA framework would trigger a variety of regulatory requirements. For instance the manufacturer would be required to comply with "current good manufacturing practices" (cGMP).* The FDA's cGMP regulations impose requirements relating to the creation and training of a quality control unit, design and features of any buildings and facilities used, design and maintenance of equipment used, production and process controls, and recordkeeping, among other things. *Failure to comply with current cGMP would render the product adulterated and could expose the company to enforcement action, including criminal prosecution.*
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> *Also, the FDA would have jurisdiction over the product's "labeling," meaning any "written, printed, or graphic materials" associated with the product….* The agency could also take enforcement action if any labeling--written, printed, or graphic materials--were "false or misleading in any particular." This would include taking action if the labeling omitted material information, such as the consequences from customary or usual use of the product. Again, these rules would apply simply because the product bore a medical claim and therefore became a "drug"--no matter what form the product took.[32]

5. Unfair Competition from the Pharmaceutical Industry. To date, Schedule I and II penalties have operated as formidable (though not insurmountable)[33] barriers to entry for pharmaceutical companies exploring the development of cannabis-derived drugs.[34] Even without the benefit of rescheduling the FDA has already approved one CBD-derived drug and two synthetic THC drugs.[35] Removing those penalties could open the floodgates to new drug applications for much needed cannabis-derived drugs, but also rampant attempts to use new drug applications to fence-in and squat on specific cannabis constituents. Such attempts could prevent state-license cannabis operators from the interstate production and sale of whole plant products (on the grounds that they are unapproved "drugs"), and also foreclose alternate regulatory pathways to the interstate market such as the FDA's "dietary supplement" designation.[36]

6. Ban on Interstate Sale of Cannabis-Infused Edibles. As stated above pharmaceutical companies could make novel medical claims about various cannabis constituents, invoking the FDCA's new drug approval process and the FDA's sole authority over "drugs," making it potentially unlawful for a state licensed cannabis operator to sell their wares outside of their state. For example, once a cannabis constituent is deemed a "drug" under the Food Drug and Cosmetic Act, it may no longer be used as an ingredient in a food or beverage,[37] and even without the "drug" designation, alternate regulatory pathways provided by the FDCA may not be readily available to cannabis-infused "edible" products:

> [T]here are also substantial impediments to simply adding cannabis, or an extract from cannabis, to a conventional food such as a cookie, candy, or beverage. These impediments include the rule that foods cannot contain new drugs (the drug exclusion rule) and the fact that, as a single ingredient among many, cannabis (and a cannabis constituent) would probably be deemed a "food additive" requiring premarket approval.[38]

This would effectively block cannabis-infused edibles in the interstate market by preventing the introduction of goods from currently state licensed cannabis operators into the stream of interstate commerce.

D. RESCHEDULING TO SCHEDULE III WITH GUARDRAILS: Carving "Whole Plant" Cannabis Products Out of the FDCA Definition of "Drug"

Given the limited benefits and potentially lasting repercussions, we should not consider rescheduling in isolation, without also evaluating guardrails for protecting the existing state-licensed cannabis enterprises. Specifically, existing operators would need (at a minimum) a carve-out for "whole plant" cannabis products so that they (and the naturally occurring cannabinoids and other components of them) cannot be deemed "drugs" under the FDCA.

1. Existing FDCA Categories Are Inadequate to Capture "Whole Plant" Cannabis. This is not only warranted given the potentially dire industry consequences outlined above, but also as a matter of regulatory clarity and consistency. "Whole plant" cannabis products require their own category because, even if the FDA deems them to be "drugs" under the FDCA, they would still fail to meet the requirements for FDA approval of either a small molecule drug or a botanical drug—potentially leading to the eventual exclusion of such "whole plant" cannabis products from lawful interstate markets:

> *[G]iven the high degree of reproductive variability of cannabis… it is unlikely that the psychoactive part of cannabis in its natural state, and the way in which it is traditionally rolled and smoked, would give anywhere near the predictable and quantifiable product and clinical test results needed to satisfy the FDA under the NDA process.*[39]

> *[T]he botanical NDA framework does not apply to drugs containing highly-purified substances simply derived from naturally occurring sources. Many commonly-used drugs contain active ingredients derived from plant sources and subsequently are highly processed and purified.* The FDA gives the example of paclitaxel, originally derived from an extract of the yew tree. The

> agency does not consider these botanical drugs…. *Likewise, a highly processed and purified drug derived from an extract of the cannabis plant does not enjoy the same flexibility that attaches to drugs the FDA deems botanical.*[40]

Furthermore, we need this "whole plant" carve-out from the definition of "drugs" not only to permit existing state-licensed medical cannabis providers' access to interstate and international cannabis markets, but also to assure this access for state-licensed adult-use cannabis businesses as well. Without it, access to markets could be threatened by the FDA's potential inference of drug claims from widespread customary use of cannabis for every-day maintenance of mental health and wellness:

> *Cannabis flower might simply be sold for recreational smoking. Purely intrastate transactions (in which the cannabis is grown, sold, and smoked within one state) would not trigger the FDA's jurisdiction. This is true even if the seller made claims about using the cannabis to treat a disease or other health conditions.* There is a solid argument that *interstate* transactions of cannabis only for recreational smoking also would not trigger the FDA's jurisdiction…. It is also possible the agency would find an intended drug use even without claims--based on the company's knowledge of actual use in the market or perhaps its design.[41]

2. A Carve-out for "Whole Plant" Cannabis Products Improves Previous Industry Proposals Premised on Descheduling. Note that the proposed carve-out from the FDCA definition of "drug" is consistent with the position taken in the National Cannabis Industry Association Policy Council's October 2019 white paper "Adapting a Regulatory Framework for the Emerging Cannabis Industry,"[42] but offers a more comprehensive solution than the narrow carve-out proposed suggested in the white paper. The authors of the white paper prescribe a federal regulatory structure in the event cannabis is descheduled and removed from the DEA's review entirely. The white paper thus suggests a carve-out permitting existing state regulatory agencies to police structure/function claims made by high-THC cannabis products (i.e., claims that make such products "drug" claims) and permitting such products to make dietary supplement-type claims for medicinal cannabis products, but would not exempt any "whole plant" cannabis products entirely from the category of "drugs" under the FDCA. The expanded carve-out proposed herein has more beneficial downstream effects, including obviating criminal prosecutions for the violations of the FDCA discussed above, and would apply to both medicinal and adult-use cannabis products.

Additionally, in order to make the carve-out proposed herein optimally effective, it should also explicitly assign the primary role for regulatory enforcement to existing state cannabis regulatory agencies. This would be another departure from industry recommendations in the white paper, which prescribe the primary regulatory role to the FDA and TTB (but only after descheduling) while relegating state regulators to overseeing the retail market alone. Importantly, adopting the proposed carve-out from the FDCA definition of "drugs" would not preclude transitioning to the more robust federal regulatory framework envisioned in the white paper post-descheduling.

The carve-out proposed here would essentially freeze the status quo in that respect, leaving state cannabis regulators free to continue police structure/function claims and prohibit (or permit) other health-related claims. This would provide much needed breathing room and the time for both Congress and the states to determine whether to adopt a framework similar to that suggested in the white paper (which presumed descheduling), or a state-lead regulatory regime (not unlike that currently observed in the insurance market[43]) wherein federal regulators merely set a "floor" for cannabis warning symbols, minimum labelling and packaging standards and other consumer protection standards. In either case, uniform national standards would still need to be promulgated and adopted in order to smooth the transition to interstate commerce while protecting public health and consumer safety. Adopting the proposed carve-out would make that outcome more likely than rescheduling without the carve-out from the FDCA definition of "drugs".

3. A Carve-out for "Whole Plant" Cannabis Products Doesn't Preclude Pursuing Complementary Protective Measures. Some argue that the FDA is not actually interested in regulating "whole plant" cannabis products, and that this is much ado about nothing. If that is the case, one would expect the FDA to support the proposed statutory carve-out, so that the industry has the assurances of FDA non-intervention *in writing* which carries the force of law. Others argue that such a carve-out might prevent FDA from authorizing studies using "whole plant" cannabis, which is a legitimate concern; but this concern can likely be accommodated within the language of the carve-out itself. Still others, while acknowledging the potentially looming issues with FDA jurisdiction and enforcement, argue that obtaining executive agency guarantees of non-enforcement (*ala* the Cole Memo) may be sufficient on its own, or when combined with Congressional action to tie the purse strings on enforcing the FDCA against "whole plant" cannabis (*ala* the Rohrabacher Amendment). This is a viable alternative in the short term; however, executive agency forbearance does not offer a permanent solution, as Attorney General Sessions demonstrated when rescinding the Cole Memo.

Adopting a statutory carve-out from the FDCA definition of "drug" for "whole plant" cannabis would protect the state-sanctioned industry while still allowing more research to flourish if cannabis were rescheduled to Schedule III. Absent the addition of explicit safe harbors for "whole plant" cannabis goods sold by existing state-licensed cannabis businesses, rescheduling could inadvertently facilitate the pharmaceutical industry's monopoly over the interstate and international cannabis markets.

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[1] By "whole plant" cannabis products, I'm referring to "marihuana," "marihuana" products and THC products derived from "marihuana" as those terms are defined under the CSA.

[2] Grace Wallack & John Hudak, Marijuana Rescheduling: A Partial Prescription for Policy Change, 14 Ohio St. J. Crim. L. 207, 216 (2016).

[3] Sean M. O'Connor & Erika Lietzan, The Surprising Reach of FDA Regulation of Cannabis, Even After Descheduling, 68 Am. U. L. Rev. 823, 832 (2019).

[4] "**The biggest policy impact of rescheduling marijuana from Schedule I to Schedule II, III, IV or V would be in the area of medical research, particularly with regard to researcher certification and licensure….**

Researchers hoping to conduct research with Schedule I drugs undergo a multi-agency review and registration process. First, researchers must submit the FDA's Investigational New Drug (IND) application, and NIH-funded projects also undergo an additional, three-step NIH review. Researchers then obtain a DEA registration for possessing the substance for research. Researchers then submit their proposal and request for study drugs to the National Institute on Drug Abuse (NIDA) for review and to approve the supply of the drugs they need…. [The] **DEA registration represent[s] hurdles to research that would not be present if marijuana were [rescheduled]."** (Emphasis added, and all internal citations removed from sources cited in this and all other endnotes.) Wallack & Hudak, *supra* note 2, at 211.

"Tetrahydrocannabinol is the only Schedule I substance that has been used in an approved drug, but there is a growing interest in marketing drugs containing other Schedule I substances. **When comparing the current regulatory approval processes needed to bring CBD (not a controlled substance) and THC drugs (a Schedule I substance) to market, the primary difference lies in the IND processes. Unlike CBD-derived drugs, THC-derived drugs must obtain CMC and BRM information from a DEA-registered source, approval from the DEA to use cannabis from said source, protocol registration from the DEA, and ultimately cannabis from a DEA-registered source. THC-derived and synthetic THC drugs must also obtain study site and investigator Schedule I licenses from the DEA, requiring submission and review of clinical and nonclinical protocols, as well as a determination of the qualifications and competency of study researchers."** Gabrielle Feliciani, Cannabis Drug Development and the Controlled Substances Act, 18 Duke J. Const. L. & Pub. Pol'y Sidebar 153, 171 (2023).

[5] Even absent rescheduling, the CSA currently allows "small molecule drug development for a product containing a cannabis constituent or a synthetic cannabinoid. Indeed, the FDA has already approved several new drugs containing synthetic cannabinoids as well as one new drug containing CBD." O'Connor & Lietzan, *supra* note 3, at 909.

[6] "**The cost of bringing a drug to market has been estimated in the range of $985 million to $2.6 billion, and these estimates do not account for the cost of complying with DEA regulations for Schedule I drugs.** The NIH is one of the main public cannabis research funders, providing $111.3 million for 285 projects in 2015 and $189 million for 408 projects in 2019. But, these investments make up only 0.5 percent of NIH's overall research budget. In addition, NIDA has prioritized funding studies on the negative health effects and behavioral consequences of cannabis, rather than health benefits. In 2015, NIDA made up 59.3 percent of NIH cannabis research spending, but only 16.5 percent of this spending went to research investigating cannabis's therapeutic properties. The Center for Medicinal Cannabis Research at the University of California, San Diego also provides grants for cannabis research, funded by sales of state recreational cannabis, but grants are competitive at a 12 percent funding rate.

As a result of the limited public support and funding available for cannabis research, pharmaceutical and biotech companies have taken the lead on cannabis drug research and development. Private funding for cannabis research remains available, although companies selling cannabis cannot trade on the New York Stock Exchange due to its federal illegality. Still, big pharmaceutical companies have begun to dedicate funds to cannabis-derived drug development, and many smaller biotech companies raise funds through venture capital, mergers and acquisitions activity, real estate investment trusts, and from tech and celebrity investors." Feliciani, *supra* note 4, at 175-76.

[7] "**[R]escheduling marijuana to Schedule III, IV, or V could have tax relief implications sought out by the cannabis industry and <u>minor</u> benefits for criminal justice advocates, <u>but only under additional, specific circumstances</u>.** Only removal from the CSA's schedules entirely would facilitate full legalization in the U.S.…. Under section 280E of the Internal Revenue Code, '[n]o deduction or credit shall be allowed . . . in carrying on any trade or business if such trade or business . . . consists of trafficking in controlled substances (within the meaning of schedule I and II of the Controlled Substances Act)'…. **Rescheduling marijuana to Schedule III would mean that marijuana enterprises**

would be eligible for the same federal tax deductions that traditional businesses are eligible for." Wallack & Hudak, *supra* note 2, at 212-213.

[8] "**Aside from 280E, the impact of rescheduling on financial matters related to marijuana is limited. All banks, national or state-based, must comply with all federal laws in order to maintain their charter and federal deposit insurance and avoid criminal and civil sanctions.** Providing services to marijuana businesses put banks in violation of federal anti-money laundering statutes, the Banking Secrecy Act (BSA), and federal regulations. The BSA requires banks to file suspicious activity reports (SARs) on any depositor whose behavior they suspect may violate federal law. In practice, this means banks must file an SAR on all activity involving a marijuana-related business because all financial transactions from that business produce funds derived from federally-illegal activity. In addition, anti-money laundering statues (18 U.S.C. sections 1956 and 1957) make clear that all financial and monetary transactions using proceeds from "specified unlawful activities" are considered money laundering. Failure to comply with any of these laws could form the basis of prosecution against a bank, even if the underlying activity (i.e., a marijuana business) is state-legal. **Because rescheduling marijuana would not automatically legalize marijuana for medical (or recreational) use, it would have virtually no impact on the status of banking services for marijuana enterprises."** Wallack & Hudak, *supra* note 2, at 213-14.

"Moving marijuana to Schedule III or lower would ease the tax burden on businesses under IRC section 280E, but full banking access would likely require additional congressional action." Wallack & Hudak, *supra* note 2, at 215.

[9] "Under federal law, possession of small amounts of marijuana on first offense is punishable by prison time, and penalties escalate dramatically based on the amount, related criminal activities (sale, cultivation, etc.) and the number of offenses…. Unfortunately, marijuana rescheduling would do very little to solve this issue.

Because rescheduling would not change the federal status of the marijuana grown, processed, and sold in state-legal enterprises, it would have very little impact on criminal penalties. Generally, penalties for possessing drugs in lower schedules are less harsh than those in Schedule I or II. **However, Section 841 of the Controlled Substances Act outlines minimum and maximum penalties for marijuana specifically**, as enacted at various times in the 1980s. **It is unlikely that rescheduling would have any impact on these mandatory penalties, and therefore congressional action amending the CSA would be necessary to reduce them."** Wallack & Hudak, *supra* note 2, at 214.

[10] Wallack & Hudak, *supra* note 2, at 214.

[11] *See* 21 U.S.C. § 331(d).

[12] *See* 21 U.S.C. § 331(a), (b) and (c).

[13] *See generally* 21 U.S.C. § 331.

[14] "Dronabinol (brand names Marinol, Syndros) and nabilone (brand name Cesamet) are synthetic forms of THC that were developed in the 1980s. Marinol was approved by the FDA in 1985 to mitigate the side effects of chemotherapy. The DEA placed Marinol in Schedule II during its approval process but has since rescheduled it to Schedule III. Marinol later received seven years of exclusivity under the Orphan Drug Act in December 1992 for the treatment of anorexia in HIV/AIDS patients. Marinol's sponsor, Unimed, has held a patent for use in patients with dementia since 1998, but this indication has not yet gained FDA approval. Four companies currently market generic dronabinol, with SVC Pharma first receiving generic approval in 2008. The FDA granted marketing approval to Syndros, an oral solution form of dronabinol, in 2016, and the DEA placed it in Schedule II.

Eli Lilly received original approval to market Cesamet in 1985 but took it off the market in 1989 for 'commercial reasons.' Valeant acquired Cesamet from Eli Lilly in 2004 and received FDA approval for use in treating

chemotherapy effects and to stimulate appetite in patients with cachexia in 2005. The DEA has categorized Cesamet as a Schedule II controlled substance. There is currently no generic version available in the United States.

A THC and CBD-derived drug, Sativex, was developed by GW to treat spasticity associated with multiple sclerosis. Although the drug has been approved for use in Canada and the EU, it has not been approved in the US. But, its sponsor is currently working with the FDA on its approval for cancer pain and multiple sclerosis spasticity indications." Feliciani, *supra* note 4, at 168-69.

[15] "Small molecule drugs are '[synthetic] compounds with low molecular weight that are capable of modulating biochemical processes to diagnose, treat, or prevent diseases.' Small molecule drugs make up about 90 percent of the pharmaceutical drug market. Due to their prevalence, the standards for researching and developing small molecule drugs are clear, and there are 'established methods for manufacturing, testing, and quality control from start to finish.' **Small molecule drugs--as opposed to the 'heterogeneous mixture' in botanical drug products--are more attractive to drug developers because of their ease of testing and manufacturing, predictability, and shelf stability."** Feliciani, *supra* note 4, at 160.

[16] Once the DEA has ceded its enforcement authority over cannabis through rescheduling, the FDA becomes the sole remaining enforcement authority. *See generally*, Taleed El-Sabawi, Why the DEA, Not the FDA? Revisiting the Regulation of Potentially-Addictive Substances, 16 N.Y.U. J.L. & Bus. 317 (2020).

[17] **"**The research required to support [FDA] premarket approval of a new drug is expensive and time consuming, and some cannabis-based products could present novel scientific and regulatory questions for the agency, potentially slowing the process and adding risk. The agency has signaled its support for cannabis-based drugs and may be flexible with regulatory requirements in some situations, **but there is no escaping the fact that the cost of taking a cannabis-based product through the FDA's new drug approval paradigm could place this pathway out of reach for most entities providing medical cannabis today…."** O'Connor & Lietzan, *supra* note 3, at 861.

[18] "**The [FDA]'s authority to regulate an item is triggered when that item satisfies a definition in the primary statute implemented by the agency, the FDCA. For instance, if an item meets the definition of 'drug' in § 201(g) the FDCA, the FDA has jurisdiction over the item and applies its rules and policies relating to drugs."** O'Connor & Lietzan, *supra* note 3, at 858.

[19] O'Connor & Lietzan, *supra* note 3, at 861. "Under this definition, the **FDA's authority is triggered by the 'intended use' of an item…."** *Id.*

[20] Note that the FDA has not yet taken any enforcement action — nary a warning letter has been issued — against state-licensed cannabis providers in any state; not so with purveyors of hemp-derived CBD —the enforcement of which was absent before the 2014 Farm Bill. The 2014 Farm Bill began the process of legally excepting hemp from the DEA's enforcement purview and culminating in the descheduling of all hemp-cannabinoids under the 2018 Farm Bill. As the FDA website shows, the earliest publicly disclosed enforcement efforts against CBD-product manufacturers (based on "drug" claims) dates back to 2015. *See* "Warning Letters and Test Results for Cannabidiol-Related Products" on the FDA website at https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products accessed on May 26, 2023.

"[T]he DEA, a criminal justice agency, continues to retain the power to make key decisions on the classification of potentially-addictive substances, thereby affecting their manufacture, distribution, and overall availability. While the DEA is statutorily required to defer to the Food and Drug Administration ('FDA'), a public health agency, at junctions of the decision-making process, the current 'split enforcement' scheme laid out in the statutes has not actualized the legislative intent of balancing the medical and scientific considerations with those of law enforcement, tilting the weight of determinations instead to law enforcement criteria and a criminal justice approach to its regulation and enforcement." El-Sabawi, *supra* note 16, at 319–20.

See also, Paul J. Larkin, Jr., Marijuana Edibles and "Gummy Bears", 66 Buff. L. Rev. 313, 349-366 (2018) (proffering a number explanations as to why the FDA not taken any steps to halt the distribution of cannabis-infused foods since California enacted Prop 215 in 1996).

"This distribution of regulatory authority, between a traditional law enforcement agency and one that focuses on patient health, can generate incongruities. In some instances, the DEA's desire to facilitate prosecution of drug abusers by placing a substance into Schedule I or II conflicts with the FDA's effort to promote the development of a drug potentially valuable in the treatment of a legitimate class of users. In other instances, at least where it has not already approved a drug proposed for inclusion in Schedule I, the FDA has done little more than 'rubber stamp' DEA scheduling recommendations." Lars Noah, Challenges in the Federal Regulation of Pain Management Technologies, 31 J.L. Med. & Ethics 55, 60–61 (2003)

[21] "**The FDA's regulations state that a product's intended use is determined by the expressions of the person legally responsible for its labeling, but it may also be shown 'by the circumstances surrounding the distribution of the article.' These include the circumstance that the item is, with this person's knowledge, 'offered and used for a purpose for which it is neither labeled nor advertised.'"** O'Connor & Lietzan, *supra* note 3, at 894.

[22] "**Drug claims need not be explicit. If a company implies its product can be used to treat disease, the FDA may conclude that the product is a drug.** And the term 'disease' should be understood broadly. Any claim relating to treatment of a medical condition--for instance, easing the symptoms (such as muscle spasms) of multiple sclerosis, reducing nausea associated with chemotherapy, increasing appetite in patients with chronic illness such as HIV, or relieving pain and inflammation of arthritis--will be viewed as a drug claim by the FDA.…

Any item is a 'drug' for purposes of the FDA's authority if it has the requisite intended use. The agency's drug authority will apply whether the product is composed of dried cannabis flower, derived from a cannabinoid (or terpenoid or flavonoid), extracted from the plant, or composed of synthetic compounds identical to (or similar to) these botanically-derived alternatives. FDA authority will apply no matter what form the product takes--whether it is sold in a tin like chewing tobacco, sold dried for smoking, sold in an oil form for use with a diffuser, or baked into a cookie…. **Drug claims will establish a drug's intended use and turn the item into a drug, for FDA purposes."** O'Connor & Lietzan, *supra* note 3, at 861-863.

[23] O'Connor & Lietzan, *supra* note 3, at 902-03.

[24] O'Connor & Lietzan, *supra* note 3, at 861.

[25] O'Connor & Lietzan, *supra* note 3, at 902-04.

[26] O'Connor & Lietzan, *supra* note 3, at 907-08.

[27] "Most medical treatments and consumer products travel in interstate commerce, so the interstate commerce requirement generally does not meaningfully constrain the FDA's authority. After descheduling, however, **some cannabis-based products could be made, sold, and used only within the borders of one state, without any component that traveled in interstate commerce. In these cases, the FDA would have no jurisdiction."** O'Connor & Lietzan, *supra* note 3, at 859-60.

[28] "The FDA derives its jurisdiction from statutory provisions, however, that **expressly require the movement of products in interstate commerce**. This means the agency will not regulate cannabis grown, sold, and consumed entirely within the borders of a single state, even if that cannabis is sold with claims about treatment of disease. So, too, with conventional foods and dietary supplements. But if any ingredient (such as the gelatin used to make a capsule for a dietary supplement) travels in interstate commerce, the agency could--and likely would--assert its authority." O'Connor & Lietzan, *supra* note 3, at 906.

[29] O'Connor & Lietzan, *supra* note 3, at 907-08.

[30] O'Connor & Lietzan, *supra* note 3, at 907-08.

[31] O'Connor & Lietzan, *supra* note 3, at 884-85.

[32] O'Connor & Lietzan, *supra* note 3, at 863-64.

[33] "**Schedule I status is <u>not</u> an absolute barrier to [new drug] development, <u>and if FDA drug approval requirements are met, the DEA will likely reschedule [the resulting new drug]</u>. But, a drug sponsor that includes a Schedule I substance in its proposed drug must seek approval from the FDA and the DEA to even begin clinical studies. Adding requirements to the drug development process adds significant time, money, and uncertainty to an already complex and expensive process….** Nevertheless, drug and biotech companies remain interested in developing drugs containing Schedule I substances, and this increased activity will likely pave the way for the approval of other drugs containing Schedule I substances." Feliciani, *supra* note 4, at 172.

[34] "The specific effects of the CSA on cannabis drug supply and demand are mixed and nuanced. Although the CSA does not have a notable effect on consumer demand for cannabis drugs or available exclusivities, it does create barriers to research and development. The law restricts the supply of cannabis plant material and requires drug sponsors to obtain Schedule I licenses before conducting clinical studies, limits public sector support for research, and impedes patient access to approved cannabis drugs. On the whole, the CSA disincentivizes cannabis drug production, so lawmakers and agencies must make changes to the drug development process if they wish to incentivize innovation in this space." Feliciani, *supra* note 4, at 180.

[35] ***"*The FDA has [already] approved one CBD-derived drug and two synthetic THC drugs to date. The FDA granted approval to GW Pharmaceuticals (GW) for Epidiolex on June 25, 2018.** Epidiolex is an oral solution derived from CBD indicated for the treatment of seizures associated with Lennox-Gastaut syndrome and Dravet syndrome. GW received Fast Track designation for Epidiolex, as Lennox-Gastaut and Dravet syndromes are rare conditions with no available, comparable treatments. GW submitted three randomized, double-blind, and placebo-controlled clinical trials in its NDA to demonstrate effectiveness. Epidiolex's approval caused the DEA to reschedule it and any future generic versions to Schedule V. The DEA later descheduled Epidiolex but did not make a general scheduling determination about future approved CBD-derived drugs." Feliciani, *supra* note 4, at 166-67.

[36] "**The prospects for marketing medical cannabis in dietary supplement form are more complex, and the pathway is riskier. It is a misimpression that dietary supplements are mostly unregulated and that labeling a product as a 'supplement' is enough to mostly bypass the FDA framework. The most important restriction is that no dietary supplement may contain a constituent of cannabis that already appears in an approved drug or in a drug that is the subject of clinical trials.** Although it is theoretically possible to avoid this by proving the substance was marketed (overtly) in dietary supplements or food earlier, the FDA takes such a conservative approach to this exception that, in our view, pursuing the exception is unlikely to be productive…. **The catch, however, is that time is of the essence; once a clinical trial of the same constituent has begun and is made public, the dietary supplement route is legally foreclosed** — even if the supplement company is in the middle of its safety tests or waiting for the FDA's response. Once the seventy-five days lapse or the agency issues a no objection letter, the company could market the dietary supplement nationally, including with structure/function claims. But the agency polices structure/function claims vigorously, and we believe it would be especially vigilant with respect to cannabis-derived dietary supplements. Finally, the full scope of the drug exclusion may be the subject of some dispute with the agency. That CBD is excluded is clear, but whether the FDA would attempt to treat all THCs as the same for purposes of drug exclusion remains to be seen. The dietary supplement pathway would be much less expensive than the new drug pathway, but its availability is much less clear." O'Connor & Lietzan, *supra* note 3, at 923.

[37] "**Under the drug exclusion rule of § 301(ll) of the FDCA, a food containing a substance that is an active ingredient of an <u>approved</u> drug product--or an active ingredient of a product in <u>clinical trials that have been</u>**

made public--cannot be shipped in interstate commerce. Although there are ways to avoid the drug exclusion rule, these are not promising for cannabis-based foods.

First, § 301(ll) contains an exception for a substance marketed in food *before* the drug in question was approved or the trials started. But the agency requires that the substance be overtly marketed in the food, for instance with references in the label. The FDA would probably refuse to consider marketing in violation of federal law, including the CSA. Moreover, the FDA has already concluded that 'THC' and CBD must be excluded from foods in interstate commerce. That said, it has invited evidence and arguments to the contrary. In addition, its claim about 'THC' may be overbroad. The agency has approved products containing dronabinol, which is a synthetic Δ^9-THC, but cannabis also contains several variants of Δ^8-THC. These are also referred to as 'THC' but may not be barred by the drug exclusion rule." O'Connor & Lietzan, *supra* note 3, at 887-88.

"[A] company might be able to 'avoid the drug exclusion rule by manufacturing and selling conventional food products with dronabinol or CBD purely within the confines of a single state.' To be sure, the FDA has asserted jurisdiction over medical treatments involving substances prepared purely on premises or within a state when it can identify a component (raw material) that had been shipped in interstate commerce. But doing so rests on the phrasing of an enforcement provision that would not apply here. The FDA generally proceeds under § 301(k) of the statute, which prohibits misbranding or adulteration after an item has been shipped in interstate commerce. But § 301(ll) is drafted differently, prohibiting interstate shipment of a food after addition of a new drug. **It is not clear that the FDA could act under § 301(ll) with respect to a food made with dronabinol or CBD and sold within the same state, even if it contained a component (which is also a 'food')--such as flour--that had been shipped in interstate commerce."** O'Connor & Lietzan, *supra* note 3, at 889.

"Even if a company avoided the drug exclusion rule (for instance, by adding a new cannabinoid, terpenoid, or flavonoid to its food), it would still need to grapple with the FDA's food additive rules. Generally speaking, every ingredient in a food sold in interstate commerce is a food additive, subject to preapproval requirements, unless an exception applies. The FDCA defines 'food additive' as 'any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food.' **Even food itself becomes a food additive if it is used as a component in another food.**

A company wishing to add a non-excluded cannabis constituent (other than dronabinol or CBD) to a conventional food would need to obtain approval of a food additive petition unless it determined that an exception applied. A petition, in turn, must contain information about the additive itself (its 'chemical identity and composition'), information about the manufacturing process and facility, and the controls used to ensure that the additive's composition is consistent. It must also contain data on the technical effects of the food additive, as well as data from safety studies. **Generating these data and securing the FDA's approval of a food additive petition can take six years or longer.**

The key exception carves out a substance 'generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown ... to be safe under the conditions of its intended use.' Put another way, **if the cannabis constituent were generally recognized as safe (GRAS) under the specific conditions of use intended, meaning safe at a particular level in a particular type of food, it would not be considered a food additive.** A company could determine on its own that a particular cannabis constituent was GRAS for use in the particular food the company marketed. **Federal law does not require a company to seek the FDA's approval, or even the agency's agreement, that the product is GRAS. But if the agency disagreed with the company's judgment call, the ingredient would be an unapproved food additive, which would mean the conventional food containing this ingredient was adulterated under § 402(a) of the FDCA. A company that shipped or received the food in interstate commerce could face enforcement action, up to and including criminal prosecution. Even if the food itself was not shipped in interstate commerce, the FDA could take enforcement action if another ingredient was shipped in interstate commerce."** O'Connor & Lietzan, *supra* note 3, at 889-91.

"The path forward for a food containing a cannabis constituent requires solving the drug exclusion issue (for instance, by ensuring the food contains only constituents that have not been studied or approved in new drugs,

which excludes at least dronabinol and CBD), avoiding § 402(a) (through approval of a food additive petition or a GRAS determination), and making no claims relating to the *medical* benefits of cannabis in the food (though perhaps making health claims tied to *nutritive* benefits, with the agency's permission). **But there would still be a non-trivial risk that the FDA would classify the product as a drug."** O'Connor & Lietzan, *supra* note 3, at 894.

[38] O'Connor & Lietzan, *supra* note 3, at 887.

[39] O'Connor & Lietzan, *supra* note 3, at 832.

[40] O'Connor & Lietzan, *supra* note 3, at 870.

"Epidiolex's approval marked the first FDA approval of a new drug derived directly from the cannabis plant and attracted attention in the popular press. **Although approving a drug derived from cannabis was unprecedented, it is important to understand what the approval does and does not represent. Because the FDA had already approved a drug containing synthetic Δ^9-THC and a drug containing a THC-like ingredient, the primary significance of Epidiolex's approval was the natural, rather than synthetic, origins of the ingredients. Nor was it new for the FDA to approve a drug with botanical origins. The agency had approved numerous new drugs with highly-processed active ingredients that derived from natural sources, as well as two botanical NDAs made from less-processed botanical raw materials. The active ingredient of Epidiolex is a highly purified extract produced from the cannabis plant. The FDA did not deem this drug substance a botanical.** Consequently, it did not treat the application as a botanical NDA, nor did it exercise the flexibility with respect to chemistry, manufacturing, and controls that botanical drugs have needed in the past. Thus, the precedent is not as significant as it might seem at the surface." O'Connor & Lietzan, *supra* note 3, at 914-15.

"The FDA regulates botanicals and defines a botanical drug product as 'plant materials, algae, macroscopic fungi, and combinations thereof ... intended for use in diagnosing, curing, mitigating, or treating disease.' The FDA has published guidance on botanical drug development, identifying **unique challenges associated with botanical research that affect the information required in a botanical drug's IND application. For one, botanical drugs must 'fully characterize, define, and demonstrate consistency in chemical composition,' but heterogeneous mixtures in plant materials are not well defined, their active constituents are not always identified, and their biological activities are not well characterized.** For this reason, the FDA has approved only two botanical drug applications despite receiving more than five hundred botanical drug INDs since 1999. **A cannabis-derived botanical drug would be formulated using extracts from the actual cannabis plant, and its heterogeneous mixture would likely contain 'phytocannabinoids THC and/or CBD, and possibly additional cannabis constituents such as other phytocannabinoids, terpenoids, and flavonoids.'"** Feliciani, *supra* note 4, at 159-60.

"The FDA indicated it would consider cannabis-derived drugs to be botanical drugs in its cannabis drug development guidance. But, it has so far considered all synthetic and cannabis-derived drugs as small molecule drugs. This is most likely because **the FDA's definition of botanical drugs excludes 'highly purified drug substances' and 'materials derived from genetically modified botanical species.' A cannabis-derived drug would fall into this exclusion for two reasons. First, 'medical or therapeutic applications require [cannabis] products to be ultra-pure (beyond 99 percent purity).' This purification process would remove a resulting drug from the botanical designation. Second, the number of genetically modified cannabis plants is growing, with biotech and drug companies snapping up patents for novel isolated genes and genetically modified plant cells taken from naturally occurring cannabis strains.** And, as synthetic compounds contain no plant material, drugs containing synthetic cannabis would also surely be considered small molecule drugs by the FDA." Feliciani, *supra* note 4, at 161-62.

[41] O'Connor & Lietzan, *supra* note 3, at 902-04.

[42] Available at https://thecannabisindustry.org/reports/adapting-a-regulatory-framework-for-the-emerging-cannabis-industry/

[43] Insurance is regulated at the state level by state insurance commissioners. These state insurance regulators coordinate their actions through the National Association of Insurance Commissioners (NAIC) which promulgates uniform and model laws and regulations that are adopted by NAIC member states. Similarly, state cannabis regulators coordinate their actions via an analogous association called the Cannabis Regulators Association ("CannRA")—though CannRA has not yet promulgated any uniform laws for adoption by its member states. *See generally,* CANNRA's website at https://www.cann-ra.org/our-work accessed on May 28, 2023.