Neutral Testimony HB2152
Nick Reinecker
03/15/2017 House Health and Human Services
Rep. Dan Hawkins Chairman

Thank you Mr. Chairman and members of the committee for allowing me to speak today on House Bill 2152 pertaining to cannabis and healthcare. I am Nick Reinecker and I am an advocate of cannabis legalization. Kansas does not have a citizen initiative process and although to some of you, I may have become a nuisance, it is my right and duty to be involved in individual and collective actions designed to identify and address issues of public concern. I stand before you today in a neutral capacity asking this committee to decide if you are going to oblige the nearly 70 percent of Kansans that support bills like HB2152 or continue to support the status quo of draconian cannabis laws that invoke state use of force and punishment against those you serve. I am neutral to this bill because it does not go near far enough to help those who could be helped by this plant, including self-cultivation and comprehensive cannabinoid access, however, I do believe in the rule of law, with part of me thinking if you do not legalize, tax and regulate this commodity then enact law that would make anything to do with cannabis, felonious activity. I do not appreciate the piecemeal approach this legislature is taking with this botanical.

I have attempted many routes to effect change regarding cannabis laws. My Federal Senator has told me in a town hall that he supports medical cannabis, yet has done nothing. My other Federal Senator, Chairman of the Agriculture, Nutrition and Forestry committee has told me he supports state's rights, yet has done nothing. Our current President campaigned on state's rights and the only thing he has done is produce terror in the hearts of the suffering and vulnerable citizens currently using cannabis for non-FDA approved uses and otherwise. I am a Republican and I feel I am being hoodwinked by those I have helped elect into this democratic-Republic, who appear to be addicted to special interests and that other green, the dollar.

It could be argued that this bill violates Federal law as it pertains to the DEA's recent establishment of a new drug code making "marihuana" extracts, including cannabidiol, schedule 1 substances. It could be argued under the Cole memo and state's rights, that cannabis in all forms could be legalized in the laboratory of democracy that we call home, the agricultural state of Kansas. Either way, no matter what you do, you have a choice to make. A choice that promotes withering and death or a choice that promotes growth and life.

Thank You

FDA performs to monitor third-party certification bodies that are accredited by a recognized accreditation body under § 1.662.

§ 1.710 How will FDA notify the public about the fee schedule?

FDA will notify the public of the fee schedule annually. The fee notice will be made publicly available prior to the beginning of the fiscal year for which the fees apply, except for the first fiscal year in which this regulation is effective. Each new fee schedule will be adjusted for inflation and improvements in the estimates of the cost to FDA of performing relevant work for the upcoming year.

§ 1.715 When must a user fee required by this subpart be submitted?

(a) Accreditation bodies applying for recognition and third-party certification bodies applying for direct accreditation must submit a fee concurrently with submitting an application or a renewal application.

(b) Accreditation bodies and third-party certification bodies subject to an annual fee must submit payment within 30 days of receiving billing for the fee.

§ 1.720 Are user fees under this subpart refundable?

User fees accompanying completed applications and annual fees under this subpart are not refundable.

§ 1.725 What are the consequences of not paying a user fee under this subpart on time?

(a) An application for recognition or renewal of recognition will not be considered complete for the purposes of § 1.631(a) until the date that FDA receives the application fee. An application for direct accreditation or for renewal of direct accreditation will not be considered complete for the purposes of § 1.671(a) until FDA receives the application fee.

(b) A recognized accreditation body that fails to submit its annual user fee within 30 days of the due date will have its recognition suspended.

(1) FDA will notify the accreditation body electronically that its recognition is suspended. FDA will notify the public of the suspension on the Web site described in § 1.690.

(2) While an accreditation body's recognition is suspended, the accreditation body will not be able to accredit additional third-party certification bodies. The accreditation of third-party certification bodies that occurred prior to an accreditation body's suspension, as well as food or facility certifications issued by such third-party certification bodies, would remain in effect.

(3) If payment is not received within 90 days of the payment due date, FDA will revoke the accreditation body's recognition under § 1.634(a)(4)(iii), and provide notice of such revocation in accordance with § 1.634.

(c) An accredited third-party certification body that fails to submit its annual fee within 30 days of the due date will have its accreditation suspended.

(1) FDA will notify the third-party certification body that its accreditation is suspended, electronically and in English. FDA will notify a recognized accreditation body, electronically and in English, if the accreditation of one if its third-party certification bodies is suspended. FDA will notify the public of the suspension on the Web site described in § 1.690.

(2) While a third-party certification body's accreditation is suspended, the third-party certification body will not be able to issue food or facility certifications. A food or facility certification issued by a third-party certification body prior to the suspension of the auditor/certification body accreditation will remain in effect.

(3) If payment is not received within 90 days of the payment due date, FDA will withdraw the third-party certification body's accreditation under § 1.664(a)(4), and provide notice of such withdrawal in accordance with § 1.664.

Dated: December 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–30033 Filed 12–13–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–342]

RIN 1117–AB33

Establishment of a New Drug Code for Marihuana Extract

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration is creating a new Administration Controlled Substances Code Number for "Marihuana Extract." This code number will allow DEA and DEA-registered entities to track quantities of this material separately from quantities of marihuana. This, in turn, will aid in complying with relevant treaty provisions.

Under international drug control treaties administered by the United Nations, some differences exist between the regulatory controls pertaining to marihuana extract versus those for marihuana and tetrahydrocannabinols. The DEA has previously established separate code numbers for marihuana and for tetrahydrocannabinols, but not for marihuana extract. To better track these materials and comply with treaty provisions, DEA is creating a separate code number for marihuana extract with the following definition: "Meaning an extract containing one or more cannabinoids that has been derived from any plant of the genus Cannabis, other than the separated resin (whether crude or purified) obtained from the plant." Extracts of marihuana will continue to be treated as Schedule I controlled substances.

DATES: *Effective:* January 13, 2017.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Background

As provided in 21 CFR 1308.03, each controlled substance or basic class thereof is assigned a four digit Administration Controlled Substance Code Number ("Code number" or "drug code") that is used to track quantities of the controlled substance imported and exported to and from the United States. Additionally, the DEA uses these code numbers in establishing aggregate production quotas for basic classes of controlled substances listed in Schedules I and II as required by 21 U.S.C. 826.

Consistent with the Controlled Substances Act (CSA), the schedules contained in DEA regulations include marihuana (drug code 7360) in Schedule I. 21 CFR 1308.11(d)(23). This listing includes (unless specifically excepted or unless listed in another schedule) any material, compound, mixture, or preparation, which contains any quantity of the substance, or which contains any of its salts, isomers, and salts of isomers that are possible within the specific chemical designation. Because the definition of marihuana in 21 U.S.C. 802(16) includes both derivatives and preparations of marihuana, the DEA until now has used drug code 7360 for extracts of marihuana. This final rule finalizes a

July 5, 2011, Notice of Proposed Rulemaking (76 FR 39039) in which the DEA proposed that a new drug code 7350 be used for extracts of marihuana.

Why a New Code Number Is Needed

The United Nations Conventions on international drug control treats extracts from the cannabis plant somewhat differently than marihuana or tetrahydrocannabinols. The creation of a new drug code in the DEA regulations for marihuana extracts will allow for more appropriate accounting of such materials consistent with treaty provisions.

The Single Convention on Narcotic Drugs, 1961 ("Single Convention") and the 1971 Convention on Psychotropic Substances ("Psychotropic Convention") provide for the international control of marihuana constituents. Many of the CSA's provisions were drafted to comply with these Conventions. The CSA includes schemes of drug scheduling and procedures for adding, removing, and transferring drugs among the schedules that are similar, in some ways, to those in the Single Convention. With respect to those drugs that are subject to control under the Single Convention, the CSA mandates that DEA control such drugs in a manner that will ensure the United States meets its obligations under the Single Convention. 21 U.S.C. 811(d)(1).

Somewhat similar to the CSA, the Single Convention lists substances in four schedules. However, under the Single Convention, the drugs that are subject to the most stringent controls are in Schedule IV. Another difference between the CSA and the Single Convention is that, under the latter, a drug can be listed in more than one schedule. Cannabis and cannabis resin are listed in both Schedule IV and Schedule I of the Single Convention. Schedule I controls under the Single Convention include: Requirements for import and export authorization, licensing of manufacturers/distributors, recordkeeping requirements, a requirement for prescriptions for medical use, annual estimate of needs, quotas, annual statistical reporting, and a requirement that use be limited to medical and scientific purposes. Schedule II of the Single Convention is similar in controls to Schedule I with a few exceptions, and Schedule III is less restrictive. All substances listed in Schedule IV are also listed in Schedule I under the Single Convention in order to encompass the requirements mentioned above. In addition, as indicated, the Single Convention imposes certain heightened measures of control with respect to Schedule IV drugs. The placing of a drug into both Schedule I and Schedule IV, therefore imposes the most stringent controls under the Single Convention. Although cannabis and cannabis resin are listed in Schedules I and IV of the Single Convention, cannabis extracts are listed only in Schedule I.

Comments

In response to the July 5, 2011, Notice of Proposed Rulemaking (76 FR 39039), the DEA received six submissions from five commenters. Three of the comments raised issues relating to the medical use or legality of marihuana/cannabis; these comments were not germane to the issues addressed by this rulemaking. A fourth comment was merely a clarification of a comment previously submitted.

One comment requested clarification of whether the new drug code will be applicable to cannabidiol (CBD), if it is not combined with cannabinols.

DEA response: For practical purposes, all extracts that contain CBD will also contain at least small amounts of other cannabinoids.[1] However, if it were possible to produce from the cannabis plant an extract that contained only CBD and no other cannabinoids, such an extract would fall within the new drug code 7350. In view of this comment, the regulatory text accompanying new drug code 7350 has been modified slightly to make clear that it includes cannabis extracts that contain only one cannabinoid.

Another comment from a pharmaceutical firm currently involved in cannabinoid research and product development praised DEA's efforts to establish a new drug code for marihuana extracts as a means to more accurately reflect the activities of scientific research and provide more consistent adherence to the requirements of the Single Convention. However, the comment expressed concerns that the proposed definition for the new drug code (*i.e.* "meaning extracts that have been derived from any plant of the genus Cannabis and which contain cannabinols and cannabidiols") is too narrow. The comment suggested that the broader term "cannabinoids" be substituted for "cannabinols and cannabidiols." The comment pointed out that other constituents of the marihuana plant may have therapeutic potential. The comment further clarified that the broader term "cannabinoid" includes both cannabinol-type compounds and cannabidiol-type compounds, as well as cannabichromene-type compounds, cannabigerol-type compounds, and other categories of compounds.

DEA response: DEA agrees with the commenter that the term "cannabinoid" would provide for a broader definition of marihuana extract; however, use of the term "cannabinoid" necessitates that the DEA clarify that the new marihuana extract category (drug code 7350) is not intended to include "cannabis resin" as defined in the U.N. Single Convention.

As discussed in the NPRM, a new drug code is necessary in order to better account for these materials in accordance with treaty obligations. The Single Convention placed "cannabis" and "cannabis resin" under both Schedule I and IV of the Convention, the most stringent level of control under the Convention. While "cannabis resin" is extracted from "cannabis," the Single Convention specifically controls "extracts" separately. Extracts of cannabis are controlled only under Schedule I of the Convention, which is a lower level of control than "cannabis resin."

Accordingly, it is the DEA's intent to define the term "marihuana extract" so as to exclude material referenced as "cannabis resin" under the Single Convention on Narcotics. "Cannabis resin" (regulated under the CSA as a resin of marihuana) contains a variety of "cannabinoids" and will continue to be regulated as marihuana under drug code 7360. The new drug code for marihuana extracts under 21 CFR 1308.11(d)(58) will exclude the resin. Cannabis resin and marihuana resin remain captured under the drug code for marihuana (drug code 7360), thus differentiating this material from marihuana extracts (new drug code 7350). This will maintain compliance with the Single Convention.

Final Action

After careful consideration of all comments, the DEA is hereby amending 21 CFR 1308.11(d) to include a new subparagraph (58) which creates a new code number in Schedule I as follows:

"(58) Marihuana Extract—7350

"Meaning an extract containing one or more cannabinoids that has been derived from any plant of the genus Cannabis, other than the separated resin (whether crude or purified) obtained from the plant."

The creation of this new drug code in the DEA regulations for marihuana extracts allows for more appropriate accounting of such materials consistent with treaty provisions. Such marihuana

[1] Although it might be theoretically possible to produce a CBD extract that contains absolutely no amounts of other cannabinoids, the DEA is not aware of any industrially-utilized methods that have achieved this result.

extracts remain in Schedule I. Entities registered to handle marihuana (under drug code 7360) that also handle marihuana extracts, will need to apply to modify their registrations to add the new drug code 7350 to their existing DEA registrations and procure quotas specifically for drug code 7350 each year.

Regulatory Analyses

Executive Orders 12866 and 13563, Regulatory Planning and Review, and 13563, Improving Regulation and Regulatory Review

This regulation has been drafted and reviewed in accordance with the principles of Executive Orders 12866 and 13563. This rule is not a significant regulatory action under Executive Order 12866.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of Executive Order 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–602, has reviewed this rule and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities. This rule establishes a new drug code for marihuana extracts. DEA already registers persons handling marihuana extracts but within another already-established drug code. Thus, persons who handle these marihuana extracts have already met DEA's registration, security, and other statutory and regulatory requirements. The only direct effect to registrants who handle marihuana extracts will be the requirement to add the new drug code to their registration. Therefore, DEA has concluded that this rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the "Regulatory Flexibility Act" section above, DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, that this action would not result in any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted for inflation) in any one year. Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of the UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act (CRA)). This rule will not result in: An annual effect on the economy of $100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based companies to compete with foreign based companies in domestic and export markets. However, pursuant to the CRA, the DEA has submitted a copy of this final rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Drug traffic control, Controlled substances.

For the reasons set out above, 21 CFR part 1308 is amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

■ 2. Section 1308.11 is amended by adding paragraph (d)(58) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(58) Marihuana Extract—(7350)

Meaning an extract containing one or more cannabinoids that has been derived from any plant of the genus Cannabis, other than the separated resin (whether crude or purified) obtained from the plant.

* * * * *

Dated: December 7, 2016.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2016–29941 Filed 12–13–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1988

[Docket Number: OSHA–2015–0021]

RIN 1218–AC88

Procedures for Handling Retaliation Complaints Under Section 31307 of the Moving Ahead for Progress in the 21st Century Act (MAP–21)

AGENCY: Occupational Safety and Health Administration, Labor.

ACTION: Final rule.

SUMMARY: On March 16, 2016, the Occupational Safety and Health Administration (OSHA) of the U.S. Department of Labor (Department) issued an interim final rule (IFR) that provided procedures for the Department's processing of complaints under the employee protection (retaliation or whistleblower) provisions of Section 31307 of the Moving Ahead for Progress in the 21st Century Act (MAP–21). The IFR established procedures and time frames for the

U.S. Department of Justice

Office of the Deputy Attorney General

The Deputy Attorney General

Washington, D.C. 20530

August 29, 2013

MEMORANDUM FOR ALL UNITED STATES ATTORNEYS

FROM: James M. Cole
Deputy Attorney General

SUBJECT: Guidance Regarding Marijuana Enforcement

In October 2009 and June 2011, the Department issued guidance to federal prosecutors concerning marijuana enforcement under the Controlled Substances Act (CSA). This memorandum updates that guidance in light of state ballot initiatives that legalize under state law the possession of small amounts of marijuana and provide for the regulation of marijuana production, processing, and sale. The guidance set forth herein applies to all federal enforcement activity, including civil enforcement and criminal investigations and prosecutions, concerning marijuana in all states.

As the Department noted in its previous guidance, Congress has determined that marijuana is a dangerous drug and that the illegal distribution and sale of marijuana is a serious crime that provides a significant source of revenue to large-scale criminal enterprises, gangs, and cartels. The Department of Justice is committed to enforcement of the CSA consistent with those determinations. The Department is also committed to using its limited investigative and prosecutorial resources to address the most significant threats in the most effective, consistent, and rational way. In furtherance of those objectives, as several states enacted laws relating to the use of marijuana for medical purposes, the Department in recent years has focused its efforts on certain enforcement priorities that are particularly important to the federal government:

- Preventing the distribution of marijuana to minors;
- Preventing revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels;
- Preventing the diversion of marijuana from states where it is legal under state law in some form to other states;
- Preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity;

- Preventing violence and the use of firearms in the cultivation and distribution of marijuana;
- Preventing drugged driving and the exacerbation of other adverse public health consequences associated with marijuana use;
- Preventing the growing of marijuana on public lands and the attendant public safety and environmental dangers posed by marijuana production on public lands; and
- Preventing marijuana possession or use on federal property.

These priorities will continue to guide the Department's enforcement of the CSA against marijuana-related conduct. Thus, this memorandum serves as guidance to Department attorneys and law enforcement to focus their enforcement resources and efforts, including prosecution, on persons or organizations whose conduct interferes with any one or more of these priorities, regardless of state law.[1]

Outside of these enforcement priorities, the federal government has traditionally relied on states and local law enforcement agencies to address marijuana activity through enforcement of their own narcotics laws. For example, the Department of Justice has not historically devoted resources to prosecuting individuals whose conduct is limited to possession of small amounts of marijuana for personal use on private property. Instead, the Department has left such lower-level or localized activity to state and local authorities and has stepped in to enforce the CSA only when the use, possession, cultivation, or distribution of marijuana has threatened to cause one of the harms identified above.

The enactment of state laws that endeavor to authorize marijuana production, distribution, and possession by establishing a regulatory scheme for these purposes affects this traditional joint federal-state approach to narcotics enforcement. The Department's guidance in this memorandum rests on its expectation that states and local governments that have enacted laws authorizing marijuana-related conduct will implement strong and effective regulatory and enforcement systems that will address the threat those state laws could pose to public safety, public health, and other law enforcement interests. A system adequate to that task must not only contain robust controls and procedures on paper; it must also be effective in practice. Jurisdictions that have implemented systems that provide for regulation of marijuana activity

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[1] These enforcement priorities are listed in general terms; each encompasses a variety of conduct that may merit civil or criminal enforcement of the CSA. By way of example only, the Department's interest in preventing the distribution of marijuana to minors would call for enforcement not just when an individual or entity sells or transfers marijuana to a minor, but also when marijuana trafficking takes place near an area associated with minors; when marijuana or marijuana-infused products are marketed in a manner to appeal to minors; or when marijuana is being diverted, directly or indirectly, and purposefully or otherwise, to minors.

must provide the necessary resources and demonstrate the willingness to enforce their laws and regulations in a manner that ensures they do not undermine federal enforcement priorities.

In jurisdictions that have enacted laws legalizing marijuana in some form and that have also implemented strong and effective regulatory and enforcement systems to control the cultivation, distribution, sale, and possession of marijuana, conduct in compliance with those laws and regulations is less likely to threaten the federal priorities set forth above. Indeed, a robust system may affirmatively address those priorities by, for example, implementing effective measures to prevent diversion of marijuana outside of the regulated system and to other states, prohibiting access to marijuana by minors, and replacing an illicit marijuana trade that funds criminal enterprises with a tightly regulated market in which revenues are tracked and accounted for. In those circumstances, consistent with the traditional allocation of federal-state efforts in this area, enforcement of state law by state and local law enforcement and regulatory bodies should remain the primary means of addressing marijuana-related activity. If state enforcement efforts are not sufficiently robust to protect against the harms set forth above, the federal government may seek to challenge the regulatory structure itself in addition to continuing to bring individual enforcement actions, including criminal prosecutions, focused on those harms.

The Department's previous memoranda specifically addressed the exercise of prosecutorial discretion in states with laws authorizing marijuana cultivation and distribution for medical use. In those contexts, the Department advised that it likely was not an efficient use of federal resources to focus enforcement efforts on seriously ill individuals, or on their individual caregivers. In doing so, the previous guidance drew a distinction between the seriously ill and their caregivers, on the one hand, and large-scale, for-profit commercial enterprises, on the other, and advised that the latter continued to be appropriate targets for federal enforcement and prosecution. In drawing this distinction, the Department relied on the common-sense judgment that the size of a marijuana operation was a reasonable proxy for assessing whether marijuana trafficking implicates the federal enforcement priorities set forth above.

As explained above, however, both the existence of a strong and effective state regulatory system, and an operation's compliance with such a system, may allay the threat that an operation's size poses to federal enforcement interests. Accordingly, in exercising prosecutorial discretion, prosecutors should not consider the size or commercial nature of a marijuana operation alone as a proxy for assessing whether marijuana trafficking implicates the Department's enforcement priorities listed above. Rather, prosecutors should continue to review marijuana cases on a case-by-case basis and weigh all available information and evidence, including, but not limited to, whether the operation is demonstrably in compliance with a strong and effective state regulatory system. A marijuana operation's large scale or for-profit nature may be a relevant consideration for assessing the extent to which it undermines a particular federal enforcement priority. The primary question in all cases – and in all jurisdictions – should be whether the conduct at issue implicates one or more of the enforcement priorities listed above.

As with the Department's previous statements on this subject, this memorandum is intended solely as a guide to the exercise of investigative and prosecutorial discretion. This memorandum does not alter in any way the Department's authority to enforce federal law, including federal laws relating to marijuana, regardless of state law. Neither the guidance herein nor any state or local law provides a legal defense to a violation of federal law, including any civil or criminal violation of the CSA. Even in jurisdictions with strong and effective regulatory systems, evidence that particular conduct threatens federal priorities will subject that person or entity to federal enforcement action, based on the circumstances. This memorandum is not intended to, does not, and may not be relied upon to create any rights, substantive or procedural, enforceable at law by any party in any matter civil or criminal. It applies prospectively to the exercise of prosecutorial discretion in future cases and does not provide defendants or subjects of enforcement action with a basis for reconsideration of any pending civil action or criminal prosecution. Finally, nothing herein precludes investigation or prosecution, even in the absence of any one of the factors listed above, in particular circumstances where investigation and prosecution otherwise serves an important federal interest.

cc: Mythili Raman
Acting Assistant Attorney General, Criminal Division

Loretta E. Lynch
United States Attorney
Eastern District of New York
Chair, Attorney General's Advisory Committee

Michele M. Leonhart
Administrator
Drug Enforcement Administration

H. Marshall Jarrett
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Ronald T. Hosko
Assistant Director
Criminal Investigative Division
Federal Bureau of Investigation

http://www.cannabisindustryinstitute.com/news/flavonoids-add-entourage-effect/How

Flavonoids Add to the Entourage Effect

November 30, 2016

Just when we were starting to get a grasp on cannabinoids and terpenes, cannabis enthusiasts threw at us a new class of chemicals: flavonoids. To date, chemists have identified about two dozen flavonoids in the plant, enriching our perception of the chemical makeup of cannabis.

Flavonoids are another group of phytochemicals that are found in other plants. For example, many of the beneficial compounds found in tea are flavonoids. And wines, cocoa and berries all contain them. Flavonoids typically give plants their unique pigments, particularly in the yellow and bluish hues. By themselves, flavonoids don't confer any special sensory characteristics, such as aroma or flavor.

Health benefits of flavonoids

The body's CB receptors evolved to bind with cannabinoids—such as THC in cannabis or the body's own endocannabinoid known as anandamide—as well as terpenes. But flavonoids, which work together with cannabinoids and terpenes, can interact with CB receptors, too. And just like those other two chemicals, flavonoids act as antioxidants and anti-inflammatories and serve as anti-cancer, anti-aging, anti-bacterial and pro-cardiovascular agents.

Because flavonoids also bind to these CB receptors, they're another member of the "entourage effect." This is a model for explaining why certain cannabis strains produce different psychoactive or medicinal effects. Essentially, CB receptors don't bind only to THC; rather, they bind to *all* of the cannabinoids, terpenes and flavonoids that we ingest, whether we're smoking flower or eating cannabutter. The different ratios of these plant-based compounds trigger different kinds of chemical cascades in our nervous system, which may be the reason why some cannabis strains give us an uplifting effect and why some strains are better than others for controlling chronic pain.

One way to think about the entourage effect is to imagine you have only five CB receptors in your body (in reality, you have billions of them). If you inhaled pure THC, five THC molecules would bind to all five of your CB receptors. However, if you inhaled smoked cannabis flower, you would take in not only THC, but also CBD, other cannabinoids (like CBN), terpenes and flavonoids. In other words, each of your five CB receptors would have something different bound to them: one with THC, one with CBD, another with CBN, another with a terpene, and the last with a flavonoid. Your nervous system will generate a different kind of high with this whole-plant entourage effect than if you consume pure THC.

In addition to CB receptors, flavonoids can also bind directly to our opioid receptors. These are the same sites that activate after binding with painkillers like Vicodin, Percocet or morphine. Some cannabinoids like THC can indirectly bind to opioid receptors, which stimulates but doesn't truly activate the receptor. So, flavonoids provide a painkilling effect that you can't get from terpenes and cannabinoids alone. Best of all, flavonoids aren't addictive like most opioids.

Eating cannabis is the most sure-fire way to get the most flavonoids out of your buds. If you prefer smoking, combustion will likely activate some flavonoids while completely burning up others. If vaping flower is more to your liking, try experimenting with some different temperatures to target specific flavonoids. Tinctures may also deliver a hefty dose of flavonoids, but tincture prep may not activate all of them.

Making more flavonoids

How can you Increase flavonoid levels in your plants? Well, we don't really know. Flavonoids became a topic of interest within the industry only recently, and even most consumers aren't aware of them. It's likely that, given time, more research will be done on the cultivation side.

However, we can probably assume many of the same strategies for increasing cannabinoid or terpene counts could work for flavonoids, too. But just like those other chemicals, we can't target specific flavonoids when growing; it's either all or nothing.

Growing in rich, organic soil appears to be an easy path to higher flavonoid counts. Certain nutrient products may also encourage production. In addition, try fertilizing toward the end of flowering. Finally, maintaining proper humidity and temperature levels in the grow and cure rooms will keep flavonoids from evaporating.

By Randy Robinson

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http://www.foxnews.com/health/2016/12/20/now-schedule-1-drug-cbd-hemp-oil.print.html

Now a Schedule 1 drug: CBD hemp oil

Published December 20, 2016

Newser

A cannabidiol hemp oil that Leafly says is used by "hundreds of thousands of patients" in the US for a variety of medical purposes, including to help relieve seizures, has been designated a Schedule 1 drug by the DEA, 7NEWS reports.

Schedule 1 drugs (which are illegal and include LSD and heroin) are said to have "no currently accepted medical use and a high potential for abuse." The announcement published in the *Federal Register* last week details the new ruling for CBD, which sets aside a new code number for "marihuana extract" and pertains to any "extract containing one or more cannabinoids ... derived from any plant of the genus Cannabis." This decision came despite the fact that CBD from hemp—cannabis with no more than between 0.3% and 1% of the active ingredient THC—has been widely available up till now via mail order and the internet.

Companies selling it have been operating under assumed legality because of CBD's low THC levels, Leafly notes—an apparently murky area. The DEA made a similar move in 2001 when it failed in an attempt to ban all hemp products.

Leafly lays out the legalese surrounding CBD products and how it thinks patients could avoid prosecution in the 28 medical marijuana states and DC. "The DEA cannot create a statute," a lawyer specializing in cannabis law tells Leafly.

- "That can only be done by Congress." The DEA notes it created the regulation to comply with international drug treaties, per the Marijuana Resources blog.

•"This is a misguided and, frankly, ignorant move by the DEA," says Jeffrey Zucker, co-founder of a strategy firm for the cannabis industry. "CBD does nothing but help people, and to put it on a level with heroin is absurd." (Why hemp is "poorly understood.")

•This article originally appeared on Newser: Now a Schedule 1 Drug: CBD Hemp Oil

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www.pbs.org/newshour/updates/scientists-say-governments-pot-farm-moldy-samples-no-guidelines/

Scientists say the government's only pot farm has moldy samples — and no federal testing standards

BY Caleb Hellerman *March 8, 2017 at 3:55 PM EDT*

A researcher in Dr. Sue Sisley's lab pours out a sample of marijuana produced by the federal facility responsible for growing cannabis for clinical research. When she received marijuana for a PTSD trial last year, Sisley says the packages contained mold and weren't as potent as she requested. Photo courtesy of MAPS.

Sue Sisley, a primary care physician in Scottsdale, Arizona, recalls the moment she picked up the carefully wrapped package fresh from the delivery truck. Nearly two years after Sisley and her colleagues were awarded a grant to study marijuana as a treatment for 76 military veterans suffering from chronic post-traumatic stress disorder, her shipment of the drug was finally in hand.

But minutes later, as she opened the packets to weigh the drug – as required by the federal Drug Enforcement Administration – her enthusiasm turned to dismay. It didn't look like marijuana. Most of it looked like green talcum powder.

"It didn't resemble cannabis. It didn't smell like cannabis," Sisley says. What's more, laboratory testing found that some of the samples were contaminated with mold, while others didn't match the chemical potency Sisley had requested for the study.

There's only one source of marijuana for clinical research in the United States. And "they weren't able to produce what we were asking for," Sisley says.

It's unclear whether mold, lead or discrepancies in potency has been a problem in prior cannabis

studies, because until now, it appears that no one looked.

In January — four months and three rounds of testing after that first delivery — Sisley and researchers working with the Multidisciplinary Association for Psychedelic Studies (MAPS) were finally able to enroll their first subjects. But the delay and the reasons behind it have raised questions about the reliability of the facility responsible for supplying marijuana to every clinical study in the country.

The marijuana came from a 12-acre farm at the University of Mississippi, run by the National Institute on Drug Abuse (NIDA). Since 1968, it has been the only facility licensed by the DEA to produce the plant for clinical research. While eight states and the District of Columbia have legalized marijuana — and all but a handful allow at least some medical cannabis — growing the plant in large quantities remains forbidden under federal law. For all practical purposes, that means that any medical study that wants to use marijuana on human subjects must go through the University of Mississippi.

Rick Doblin, MAPS' director, says this recent episode "shows that NIDA is completely inadequate as a source of marijuana for drug development research."

"They're in no way capable of assuming the rights and responsibilities for handling a drug that we're hoping to be approved by the FDA as prescription medicine," he says.

The demand for the facility's product has surged in the past year, mirroring interest from medical researchers. Through mid-October 2016, the agency says it had fulfilled 39 requests for marijuana, from 10 different researchers. That's a jump from the 23 requests it filled in 2015, the most recent numbers available, according to an April letter from the DEA to Sen. Elizabeth Warren (D-Mass).

A video from the University of Mississippi shows its cannabis garden.

It's unclear whether mold, lead or discrepancies in potency has been a problem in prior cannabis studies, because until now, it appears that no one looked.

NIDA says this is the first time researchers have expressed concern about mold or potency testing. Neither the agency nor the University of Mississippi tests samples for mold before they're shipped.

Sisley says researchers have taken too much for granted. "There's no telling how many subjects in past studies were exposed," she says.

The uncertainty highlights a broader challenge in the growing field of cannabis research: there's little consensus on what testing is appropriate or on what findings constitute a hazard.

The uncertainty highlights a broader challenge in the growing field of cannabis research: there's little consensus on what testing is appropriate or on what findings constitute a hazard. Scientists and officials say they would love to have more guidance.

"Our biggest concern is patient safety," says Mike Van Dyke, chief of toxicology with the Colorado Department of Public Health and Environment, which is funding the MAPS-sponsored

study on PTSD. "The lack of a federal regulatory structure makes it a huge challenge. We don't have all the information we'd like to have."

Mixed signals on standards

A researcher in Dr. Sue Sisley's lab prepares to weigh a sample of marijuana received from the federal facility responsible for growing marijuana for clinical research. Photo courtesy of MAPS.

As part of the original study protocol, the marijuana that Sisley received was tested at an independent laboratory in Colorado, which found a high level of total yeast and mold (TYM) in several samples. The tests also found that the potency of some samples didn't match what study organizers had ordered, or what it says on the certificate of analysis from the federal supplier.

One sample, billed as having a 13 percent level of THC — the main psychoactive compound in marijuana — had just 8 percent when tested at the independent facility in Colorado. Other samples were off by lesser amounts. Subsequent testing at the University of Illinois-Chicago confirmed the presence of total yeast and mold.

The Chicago tests also found all four samples contained trace amounts of lead, though well below the levels generally considered to be hazardous, at least for adults.

Amsterdam cafe owner Michael Veling explains pot potency to PBS NewsHour by comparing it to liquor.

On the state level, testing requirements for recreational and medical marijuana vary widely. Most states require some testing for heavy metals such as lead, but not for pesticide residue. Yeast and mold testing is required in most states where cannabis is sold legally. The failure rate – frequently defined as a total mold and yeast count higher than 10,000 "colony-forming units" per gram (CFU/g) — is not officially tracked in Colorado. But state records show that approximately 7 percent of samples tested last year did not pass "microbial" standards, a category that includes bacterial contamination as well as TYM. Colorado only requires microbial testing for marijuana sold on the recreational market, not for medicinal use.

The Chicago tests found total yeast and mold (TYM) counts in Sisley and team's samples ranging from 23,000 to 64,000 CFU/g.

NIDA says it suspects the mold problem was introduced on the receiving end, when the Colorado lab accidentally left samples in a refrigerator for two days, instead of keeping them frozen at -10 to -25 degrees Celsius, as called for by handling instructions.

But Rebecca Matthews, who oversees clinical trials for MAPS, says the elevated TYM counts were found in samples that never left the freezer before testing. In the samples that were inadvertently defrosted, TYM counts were even higher, as much as 110,000 CFU/g.

Nevertheless, Sisley and the team ultimately concluded after months of research that it was safe to proceed with the study. They began in January. In an internal memo that outlines their reasons for moving forward, they wrote that there's no agreement on whether tests for TYM should be required, and no guidance from NIDA or the FDA.

One reason for that is a high TYM count does not always constitute a health risk, says Kevin McKernan, an entrepreneur and geneticist who is looking to improve the quality of testing in the realm of cannabis research. Certain types of fungus, notably a group of species known as aspergillus, can cause a variety of health problems when smoked, especially in people with compromised immune systems. But, many other mold varieties are considered harmless, McKernan says. Testing found the samples in question were not a harmful variety.

MORE: Until research unlocks medical understanding of marijuana, patients experiment

Immunocompromised patients were already excluded from Sisley's MAPS-sponsored study.

NIDA says its own tests show THC levels closer to what was expected – in the 10 to 12 percent range, instead of the 8 percent that MAPS found. It says it's reviewing MAPS' results and protocols to try to understand the discrepancy. NIDA also says it tested for heavy metals before shipping the material, and found nothing above acceptable levels.

Tighter control, broader playing field

Dr. Sue Sisley points to marijuana samples she received as part of a study that's testing whether marijuana can have a positive effect on veterans with PTSD. Photo courtesy of MAPS.

NIDA is also taking some steps to tighten oversight. In January, it announced a grant to McKernan's two Massachusetts-based companies, Medicinal Genomics and Courtagen, to develop a DNA-based test that would identify specific types of harmful mold and bacteria in marijuana.

Beyond quality control issues, some critics say the Mississippi farm doesn't provide researchers with enough options. For example, the potency of marijuana in NIDA's collection tops out at 13 percent THC. That's less than half the level in the most potent strains sold in states where the drug is legal and regularly tested.

That means "if you're trying to do a study where you imitate what patients do in the real world, you can't," Sisley says.

"If you're trying to do a study where you imitate what patients do in the real world, you can't." – Dr. Sue Sisley

Van Dyke echoes her concern. "It's an important issue. The products in Colorado are different from the products produced by NIDA, and there's untapped demand to study those products that people are really using."

In an email to NewsHour, the agency says it's growing new material that will likely contain higher THC levels. NIDA officials insist they're keeping up with demand, and in 2014, increased its production and diversified the strains of marijuana it grows.

Another criticism stems from NIDA's practice of achieving higher THC concentrations by mixing different strains together, rather than growing new plants.

In its April 2016 letter, the agency told Warren the Mississippi facility has "approximately 185" batches of cannabis, at varying concentrations of THC and CBD. Different varieties, the letter

says, "may be blended to achieve specific cannabinoid concentrations of interest to researchers."

Critics, including Sisley, say that mixing strains is a lost opportunity. Every cannabis plant contains several hundred unique compounds, which some believe may significantly alter the drug's effects. If different plants are mixed together, scientists have a harder time tracking those effects.

READ MORE: Meet the federal government's pot dealer

Many scientists were heartened this summer when the Drug Enforcement Agency (DEA) announced that it would license additional bulk growers, ending NIDA's monopoly.

According to the DEA, 16 organizations have submitted the paperwork to launch the application process, which comes with a $3,047 fee. None of those applications have been approved, however, and the agency says there is no set timeline to take action.

The delays in Sisley's study are energizing those who say the federal government needs to speed things up.

Frustrated by her experience, Sisley is hoping to take a more hands-on approach. One of the DEA applicants is the Scottsdale Research Institute (SRI), where she is the principal investigator. SRI has submitted a proposal to grow cannabis from tissue culture rather than seedlings, a more sterile method of producing the plant.

She doesn't mince words about the setback.

"We waited 20 months to get going, and then we got this sub-optimal study drug," she says. "The longer we allow this monopoly to continue, the more efficacy [of the] research will continue to be thwarted."