

The Explosive Growth of Cannabis: What Are FDA's and DEA's Roles?

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SAUL EWING ARNSTEIN & LEHR LLP

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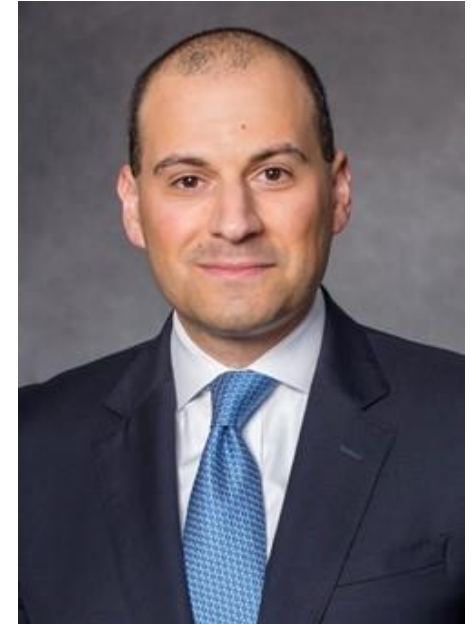
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Jonathan A. Havens

Jonathan Havens is Co-Chair of Saul Ewing Arnstein & Lehr's Cannabis Law Practice and Vice Chair of the Firm's Food and Beverage Practice. Jonathan's unique perspective on cannabis regulation is informed by his congressional, federal agency, and national and international law firm experience.

He advises prospective growers, processors, and dispensaries on how to obtain state agency licensure, including with regard to applicable requirements, application content and strategies, post-licensing compliance considerations, and relevant federal law. In addition to having represented entities that applied for state medical cannabis licensure and advised ancillary service and product providers, Jonathan follows existing and prospective cannabis regulations throughout the country, as well as federal policy developments affecting the cannabis industry.

Before entering private practice, Jonathan served as a regulatory counsel with the U.S. Food and Drug Administration (FDA), where he focused on compliance and enforcement related to promotion, advertising, and labeling. Prior to law school, Jonathan held legislative and government affairs positions in which he facilitated the development and execution of strategic communications to members of Congress and their staff aides, and managed several areas of policy and drafted legislative proposals.



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What is the regulatory status of cannabis?

- More than 50 percent of states have medical cannabis laws on the books.
- Nine states with medical cannabis laws have also legalized recreational or “adult use” cannabis.
 - Alaska, California, Colorado, Maine, Massachusetts, Nevada, Oregon, Vermont, and Washington.
 - Possession of up to two ounces of recreational marijuana is legal in Washington, D.C., but *sales* are not legal.
- Other states are considering establishing such programs.
- However, marijuana is still illegal under federal law.
 - It is a Schedule I drug under the Controlled Substances Act (21 U.S.C. § 812(b)(1)).

What ~~is~~ was the Cole Memo?

The U.S. Department of Justice (DOJ) issued a memorandum in 2013 (Cole Memo), which:

- Said that state laws do not change marijuana's illegal status under federal law; and
- Directed U.S. Attorneys to utilize their resources prudently, and to use discretion before prosecuting those using medical marijuana in compliance with their state's laws.

The Cole Memo represented a major shift in drug enforcement, and after its issuance, federal marijuana prosecutions declined in states that had authorized certain marijuana activity.

Rescission of Obama-Era Marijuana Enforcement Policies

- On January 4, 2018, Attorney General Jeff Sessions issued a memorandum to all U.S. Attorneys in which he rescinded, effective immediately, several previous U.S. Department of Justice (DOJ) guidance documents related to marijuana enforcement, including the Cole Memo.
- He also rescinded:
 - David W. Ogden, Deputy Att'y Gen., Memorandum for Selected United States Attorneys: Investigations and Prosecutions in States Authorizing the Medical Use of Marijuana (Oct. 19, 2009);
 - James M. Cole, Deputy Att'y Gen., Memorandum for United States Attorneys: Guidance Regarding the Ogden Memo in Jurisdictions Seeking to Authorize Marijuana for Medical Use (June 29, 2011);
 - James M. Cole, Deputy Att'y Gen., Memorandum for All United States Attorneys: Guidance Regarding Marijuana Related Financial Crimes (Feb. 14, 2014); and
 - Monty Wilkinson, Director of the Executive Office for U.S. Att'ys, Policy Statement Regarding Marijuana Issues in Indian Country (Oct. 28, 2014).

President Trump on Marijuana

- Not much is known about President Trump’s stance on marijuana regulation. A few clues:
 - Omnibus Bill signing statement: “Division B, section 537 provides that the Department of Justice may not use any funds to prevent implementation of medical marijuana laws by various States and territories. I will treat this provision consistently with my constitutional responsibility to take care that the laws be faithfully executed.” <http://www.whitehouse.gov/the-press-office/2017/05/05/statement-president-donald-j-trump-signing-hr-244-law>.
 - Tom Angell, the founder of Marijuana Majority and publisher of Marijuana Moment, on the signing statement: “[M]y read is it's basically saying they reserve the right to do whatever they want and enforce prohibition regardless of the statutory prohibition on doing so.” <http://www.businessinsider.com/medical-marijuana-trump-administration-2017-first-statement-2017-5>.

President Trump on Marijuana (cont'd)

- Another indication of Trump's potential thoughts on marijuana:
 - On the campaign trail, he said he was “in favor of medical marijuana 100 percent,” that he was skeptical of legalizing it more broadly, and marijuana policy should basically be left to the states.
<http://www.nytimes.com/2017/02/27/opinion/as-trump-said-in-the-campaign-leave-pot-to-the-states.html>.
- A recent development:
 - Sen. Cory Gardner (R-Colo.), who had been blocking Department of Justice (DOJ) nominees following Jeff Sessions's rescission of the Cole Memo, agreed to lift his holds in exchange for President Trump's assurance that he would support comprehensive legislation that protects state-authorized marijuana activity from federal interference.
<https://www.thecannabist.co/2018/04/13/cory-gardner-marijuana-protections-trump/103576/>.

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Was Sessions's Move Surprising? Not Exactly.

- Despite acknowledging the existence of the Cole Memo (before he rescinded it), Attorney General Jeff Sessions in 2017 issued a memo of his own, directing federal prosecutors to charge and pursue the most serious, readily-provable drug offenses.
- Under Sessions's program, which rolls back Obama-era policies, if prosecutors want to pursue lesser charges for low-level drug crimes, they must first obtain multiple layers of approvals.
 - <http://www.justice.gov/opa/press-release/file/965896/download>.

More on Sessions

- At a November 13, 2017 House Judiciary Committee hearing, Sessions, in responding to a question about DOJ’s marijuana enforcement policy, said:
 - “Our policy is the same really, fundamentally, as the Holder-Lynch policy, which is that the federal law remains in effect and a state can legalize marijuana for its law enforcement purposes, but it still remains illegal with regard to federal purposes.”
 - A federal court ruled last year that the Rohrabacher-Blumenauer amendment (more on that later) prohibits prosecution of patients and providers who are acting in accordance with state cannabis laws.
<http://cdn.ca9.uscourts.gov/datastore/opinions/2016/08/16/15-10117.pdf>.

Sessions (cont'd)

- Attorney General Jeff Sessions has said that:
 - “Good people don’t smoke marijuana;”
 - He is “dubious” about the benefits of the drug;
 - He is “surprised” that Americans are not overwhelmingly embracing his anti-cannabis stance; and
 - He is willing to re-write the Cole Memo.
- More actions taken by Sessions:
 - Asked congressional leaders not to renew Rohrabacher-Blumenauer protections:
<http://www.massroots.com/news/exclusive-sessions-asks-congress-to-undo-medical-marijuana-protections/>.
 - The Senate and House both rejected Sessions’s request:
<http://thehill.com/homenews/senate/344204-senate-panel-advances-measure-to-protect-medical-marijuana-states>.
 - Issued a memo that prohibits DOJ from issuing guidance documents that have the effect of adopting new regulatory requirements or amending the law:
<http://www.justice.gov/opa/press-release/file/1012271/download>.

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Sessions (cont'd)

- More actions taken by Sessions:
 - Sent letters to the governors of Colorado, Oregon, and Washington, about those states' cannabis programs and potential DOJ crackdowns:
 - CO and OR: <http://www.thecannabist.co/2017/08/04/jeff-sessions-colorado-marijuana-letter-hickenlooper/85404/>.
 - WA: http://www.huffingtonpost.com/entry/legal-weed-jeff-sessions_us_59834257e4b06d488874a716.
 - “What is interesting here, however, is that Sessions’s accusations (are) that states are not complying with the Cole Memo, perhaps suggesting he is fine with the Cole Memo just not the previous administration’s enforcement of it,” said John Hudak, a drug policy expert and senior fellow with the Brookings Institution.

Sessions (cont'd)

- A headscratcher:
 - Sessions said it would be “healthy” to have “more competition” among medical marijuana growers for research (“I think it would be healthy to have some more competition in the supply but I’m sure we don’t need 26 new suppliers.”). <http://www.businessinsider.com/jeff-sessions-more-medical-marijuana-growers-for-research-2017-10>.
- No permission? No problem:
 - Sessions asked a DOJ task force to review the Cole Memo and recommend changes. However, the task force gave him “no ammunition.”
<http://www.forbes.com/sites/tomangell/2017/09/20/jeff-sessions-slams-marijuana-legalization-again/#32466da027d1> and <http://apnews.com/ad37624fcb8e485a8d57a013d48a227c>.

Sessions – Takeaways and Considerations

- Before rescinding it, Sessions said that the Cole Memo was “truly valuable in evaluating cases” (*i.e.*, he believed it offered flexibility to more aggressively enforce federal drug laws). <http://www.newsweek.com/sessions-looks-set-back-his-marijuana-crackdown-652462>.
 - Why? The Memo identified several enforcement priorities that could justify DOJ taking action even in states that have cannabis laws on the books. Some of these were:
 - Preventing the distribution of marijuana to minors;
 - Preventing the diversion of marijuana from states where it is legal under state law in some form to other states;
 - Preventing drugged driving and the exacerbation of other adverse public health consequences associated with marijuana use; and
 - Preventing marijuana possession or use on public property.
 - *See* Sessions’s letters to CO, OR, and WA on certain of these broad issues, which are admittedly difficult, if not impossible to achieve.
- Sessions: (a) serves at the pleasure of the President; and (b) could be distracted by the Senate’s investigation into the Trump campaign’s alleged contact with Russians during the election (but don’t count on it: http://www.washingtonpost.com/world/national-security/while-eyes-are-on-russia-sessions-dramatically-reshapes-the-justice-department/2017/11/24/dd52d66a-b8dd-11e7-9e58-e6288544af98_story.html).

Sessions – Takeaways and Considerations

- Ironically, Sessions’s rescission of the Cole Memo might result in laws and/or policies that are more favorable to the cannabis industry. *See* <http://www.politico.com/magazine/story/2018/01/06/jeff-sessions-marijuana-legalization-congress-216251>.
- Sen. Cory Gardner (R-Colo.) has been joined by a large, bipartisan group of members of Congress, senators, and governors who are also pushing back against Sessions. *See* <http://www.marijuanamoment.net/lawmakers-react-sessions-anti-marijuana-move/>.
- Despite his well-known and longstanding opposition to marijuana, Sessions’s move is a bit surprising given public opinion polling data around marijuana and the fact that 2018 is an election year.

Sessions – Takeaways and Considerations

- How have U.S. Attorneys reacted to the rescission of the Cole Memo?
 - U.S. Attorney Andrew Lelling (District of MA) said he “cannot provide assurances that certain categories of participants in the state-level marijuana trade will be immune from federal prosecution.” <http://www.boston.com/news/local-news/2018/01/08/read-us-attorney-for-massachusetts-statement-on-federal-marijuana-enforcement>.
 - U.S. Attorney Bob Troyer (District of CO) said his office will continue to focus on “identifying and prosecuting those who create the greatest safety threats to our communities around the state.” <http://www.thecannabist.co/2018/01/05/prosecutors-pot-friendly-states-will-decide-crackdown/96164/>.
 - Interim U.S. Attorney Adam Braverman (S. District of CA) said Sessions’s move “returns trust and local control to federal prosecutors,” but also said his office would “continue to utilize long-established prosecutorial priorities to carry out our mission to combat violent crime, disrupt and dismantle transnational criminal organizations, and stem the rising tide of the drug crisis.” <http://www.washingtonexaminer.com/will-a-us-attorney-bust-up-pot-businesses-after-jeff-sessions-policy-change/article/2645166> (responses from other U.S. Attorneys are also discussed in this article).

Public Opinion

- An August 2017 Quinnipiac poll reported that 94 percent of Americans support “allowing adults to legally use marijuana for medical purposes if their doctor prescribes it,” up from 93 percent five months earlier, and up 5 points in the last year.
- The same poll showed that 61 percent of Americans agree that “the use of marijuana should be made legal in the United States,” up from 59 percent in February 2017, and up 10 points since December 2012.
 - <http://www.thecannabist.co/2017/08/08/marijuana-legalization-opinion-poll-americans/85562/>.
- In October 2017, Gallup reported that 64 percent of Americans were in favor of marijuana legalization, the highest level of support recorded in nearly 50 years.
- Per Gallup, while “Democrats and independents have historically been much more likely than Republicans to say marijuana should be legalized...[in 2017] for the first time, a majority of Republicans express[ed] support for legalizing marijuana.” During the October 2017 polling period, 51 percent of Republicans polled said that marijuana should be legalized, up nine percentage points from 2016.
 - <http://news.gallup.com/poll/221018/record-high-support-legalizing-marijuana.aspx>.

Marijuana at the Ballot Box

- Election 2017- Legalization Candidates and Measures Win Big: <http://www.leafly.com/news/politics/election-day-2017-these-are-the-states-marijuana-races-were-watching-closely>.
 - “New Jersey’s pro-legalization gubernatorial candidate, Phil Murphy, won handily, and will take over for the nation’s most notorious prohibitionist, Chris Christie.”
 - “In Detroit, two medical marijuana reform ordinances passed easily, with about 60% of the vote.”
 - “And in Athens, Ohio, voters overwhelmingly approved a measure to de-penalize cannabis possession, with a whopping 77% of voters approving the measure.”

Cannabis: It's Complicated

- **Banking**: Money earned from the production or sale of cannabis is federally illegal. Banks can provide cannabis businesses with accounts but under federal laws, banks must disclose cannabis-related transactions as suspicious activity. The U.S. Treasury Department allows banks to work with legal cannabis entities under limited circumstances but most lenders still hesitate.
- **Intellectual Property**: Businesses cannot get a federal trademark on goods and services that cannot be legally sold in commerce (*e.g.*, cannabis). State-level protection might be available, and use of the Lanham Act to protect an unregistered trademark could be a possibility.
- **Real Estate**: Lack of commercial lending, zoning restrictions, finding a willing landlord, and finding existing facilities that can be outfitted to comply with strict state laws and regulations are but a few of the myriad real estate challenges for cannabis businesses.

Cannabis: It's Complicated (continued)

- **Tax Deductions**: Cannabis businesses pay hefty taxes, state and federal. However, under 26 U.S. Code § 280E, businesses that engage in illegal drug trafficking generally cannot get certain tax credits or deduct operational expenses from federal returns.
- **Discrimination**: The Americans with Disabilities Act (“ADA”), and its state analogues, require that an employer reasonably accommodate disabled employees, absent a showing of undue hardship by the employer. Under the ADA, current illegal drug users are not “individuals with disabilities.” To date, no state or federal court has required an employer to accommodate medical marijuana use under the ADA. While no court at the federal level has caused an employer to violate the ADA by forcing an employer to accommodate use of a drug that remains illegal at the federal level, two recent decisions —one from the Supreme Judicial Court of Massachusetts and one from District of Connecticut — have cast doubt on whether reliance on federal law under the ADA is sufficient to dismiss a state law discrimination claim.
- **Drug Testing**: With the proliferation of medical cannabis across the country, will private employers scrap pre-hiring drug testing? Will such employers opt for more advanced testing that has the ability to detect usage within a much shorter time frame in favor of traditional urine testing?

A Look at State Licensing (PA Application)

PART A – Applicant Identification and Facility Information
1 – Applicant Name, Address and Contact Information
2 – Facility Information
PART B – Diversity Plan
3 – Diversity Plan
PART C – Applicant Background Information
4 – Principals, Financial Backers, Operators and Employees
5 – Moral Affirmation
6 – Compliance with Applicable Laws and Regulations
7 – Civil and Administrative Action
PART D – Plan of Operation
8 – Operational Timetable
9 – Employee Qualifications, Description of Duties and Training
10 – Security and Surveillance
11 – Transportation of Medical Marijuana
12 – Storage of Medical Marijuana
13 – Packaging and Labeling of Medical Marijuana

14 – Inventory Management
15 – Management and Disposal of Medical Marijuana Waste
18 – Nutrient and Additive Practices
19 – Processing and Extraction
20 – Sanitation and Safety
21 – Quality Control and Testing for Potential Contamination
22 – Recordkeeping
PART E – Applicant Organization, Ownership, Capital and Tax Status
23 – Organizational Structure
24 – Business History and Capacity to Operate
25 – Current Officers
26 – Ownership
27 – Capital Requirements
PART F – Community Impact
28 – Community Impact

ATTACHMENTS:
Attachment A: Signature Page
Attachment B: Organizational Documents
Attachment C: Property Title, Lease, or Option to Acquire Property Location
Attachment D: Site and Facility Plan
Attachment E: Personal Identification
Attachment F: Affidavit of Business History
Attachment G: Affidavit of Criminal Offense
Attachment H: Tax Clearance Certificates
Attachment I: Affidavit of Capital Sufficiency
Attachment J: Sample Medical Marijuana Product Label
Attachment K: Release Authorization
Attachment L –Applicant Priorities for Multiple Applications

Federal Legislation

- Rohrabacher-Blumenauer:
 - What is it: Formerly known as Rohrabacher-Farr, it is an amendment, most recently to the omnibus bill, that prohibits DOJ from using federal funds to interfere with state medical marijuana laws.
 - Is it permanent?: No. The omnibus bill funds the federal government through September 2018. In order for its protections to extend past that date, Rohrabacher-Blumenauer will have to be offered as an amendment to the next funding vehicle or a permanent solution will need to be advanced.

How Do We Read Rohrabacher-Blumenauer and Sessions's Actions Together?

- It is unclear how enforcement of federal drug laws in states that have authorized certain cannabis activity will occur given the current prohibition on the expenditure of DOJ funds to prevent states from implementing medical marijuana laws.
- As discussed in the Politico article referenced earlier, some in Congress, including House Minority Leader Nancy Pelosi, are now pushing for Rohrabacher-Blumenauer protections for recreational marijuana, whereas before such protections applied to medical marijuana only.

The U.S. Food and Drug Administration (FDA)

- Although it has not been well publicized, FDA has said quite a bit about cannabis:
 - FDA and Marijuana: Questions and Answers:
<http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421168.htm#enforcement>.
 - Marijuana Research with Human Subjects:
<http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421173.htm>.
 - FDA and Marijuana:
<http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421163.htm>.
 - CBD Warning Letters:
<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm549298.htm> (2017);
<http://www.fda.gov/newsevents/publichealthfocus/ucm484109.htm> (2016).

FDA (cont'd)

- Some highlights:
 - “The FDA has not approved marijuana as a safe and effective drug for any indication.”
 - “The agency has, however, approved two drugs containing a synthetic version of a substance that is present in the marijuana plant.”
 - “Is marijuana safe for medical use?...FDA has not found any...product [containing or derived from botanical marijuana] to be safe or effective for the treatment of any disease or condition.”
 - “Can products that contain cannabidiol [CBD] be sold as dietary supplements?...No.”

FDA (cont'd)

- Highlights (continued):
 - “Is it legal, in interstate commerce, to sell a food to which cannabidiol has been added?...No.”
 - “FDA Supports Sound Scientific Research...The FDA also has an important role to play in supporting scientific research into the medical uses of marijuana and its constituents in scientifically valid investigations as part of the agency’s drug review and approval process. As a part of this role, the FDA supports those in the medical research community who intend to study marijuana.”
- CBD NDA:
 - FDA is currently reviewing GW Pharmaceuticals’ New Drug Application (NDA) for Epidiolex (cannabidiol). Goal date for completion of review is June 27, 2018. See http://www.biospace.com/article/releases/fda-accepts-gw-pharma-s-epidiolex-nda-with-priority-review-for-lennox-gastaut-syndrome-and-dravet-syndrome/?utm_source=dlvr.it&utm_medium=twitter.

FDA (cont'd)

- CBD NDA (cont'd):
 - On April 19, 2018, FDA's Peripheral and Central Nervous System (PCNS) Drugs Advisory Committee met to discuss the Epidiolex application.
 - FDA Briefing Information:
<https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PeripheralandCentralNervousSystemDrugsAdvisoryCommittee/UCM604736.pdf>
 - "In general, the risks associated with [CBD] appeared to be acceptable. Although the risk of liver injury has the potential to be serious, the observed risk can be appropriately managed."
 - "Although the review is still ongoing, the risk-benefit profile established by the data in the application appears to support approval of cannabidiol for the treatment of seizures associated with [Lennox-Gastaut syndrome] and [Dravet syndrome]."
 - GW Pharmaceuticals Briefing Information:
<https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PeripheralandCentralNervousSystemDrugsAdvisoryCommittee/UCM604738.pdf>

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U.S. Drug Enforcement Administration (DEA)

- DEA is a federal agency under the Department of Justice (DOJ) that enforces the Controlled Substances Act (CSA).
- Marijuana is a Schedule I substance under the CSA.
 - Schedule I drugs are classified as having a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use of the drug or other substance under medical supervision.
 - Marinol, a synthetic version of THC (delta-9-tetrahydrocannabinol), the active ingredient found in the marijuana plant, can be prescribed for the control of nausea and vomiting caused by chemotherapeutic agents used in the treatment of cancer and to stimulate appetite in AIDS patients. Marinol is a Schedule III substance under the Controlled Substances Act.

DEA (cont'd)

- Think back to the discussion of the Epidiolex® NDA filing.
- If FDA approves the NDA, the drug would be subject to U.S. Drug Enforcement Administration (DEA) scheduling, a decision which industry will follow closely.
- It will be interesting to see how DEA schedules Epidiolex®, particularly in light of GW Pharmaceuticals' completion of a clinical trial assessing the abuse potential of CBD in October 2017.
- If DEA believes Epidiolex® has a low potential for abuse and low risk of dependence, it could schedule the drug as Schedule IV.

DEA (cont'd)

- In August 2016, DEA declined to reschedule marijuana.
- In February 2017, DEA removed from its website factually inaccurate information about cannabis. Americans for Safe Access (“ASA”), a nonprofit focused on ensuring access to medical cannabis for therapeutic use and research, filed with the U.S. Department of Justice (“DOJ”) last year a legal request demanding such action, and started a change.org petition related to the same (which has over 104,000 signatures).
- In March 2017, DEA approved Syndros, a synthetic formulation of THC, the main psychoactive component in the cannabis plant. FDA approved the drug in 2016 to treat nausea, vomiting, and weight loss in cancer and AIDS patients.

My Predictions

- States will continue to authorize cannabis medically and recreationally.
- The Trump administration will not directly impede such state efforts.
 - I do not expect changes to scheduling of cannabis or easing of federal banking restrictions, at least not during the Trump administration.
 - Despite repeated indications from President Trump on the campaign trail that his administration would not interfere with state-authorized cannabis activity, White House Press Secretary Sarah Huckabee Sanders said of Sessions's move that "The president believes in enforcing federal law -- that's his top priority -- regardless of what the topic is, whether it's marijuana or immigration."
- FDA will approve Epidiolex (unless they don't).

Questions?

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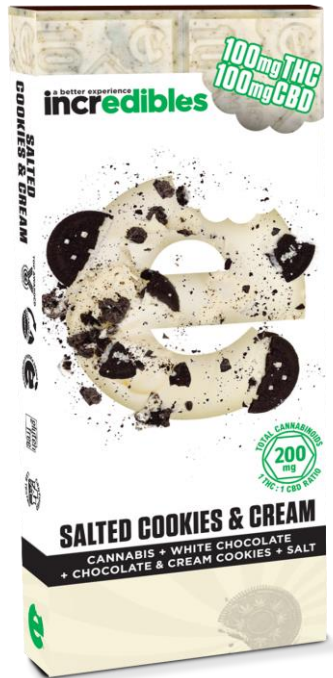
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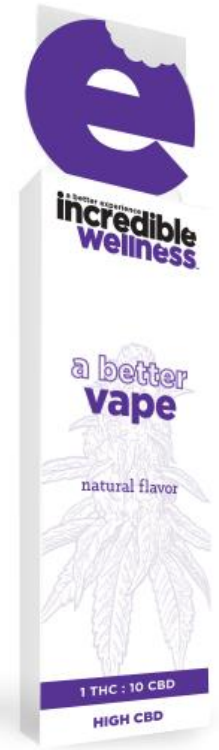
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2017

Kitchen made 1,000,000 products

Garden grew 5,000 pounds

Machine shop sold 20 units

Laboratory made 200,000 grams hash and
5,000,000 milligrams of food grade oil

Office printed/**Drivers** delivered 20,000 invoices



Frustrating, I know



Banking I have a bank account but...



Local AHJ Your facility's authority having jurisdiction, or **AHJ**, is the organization responsible for enforcing the codes and standards set by the NFPA. Often a fire marshal, AHJs vary in their strict adherence to code and their level of enforcement or just simply make things up.



DEA Yes, there's a local Denver office of **DEA agents** and I have met them.



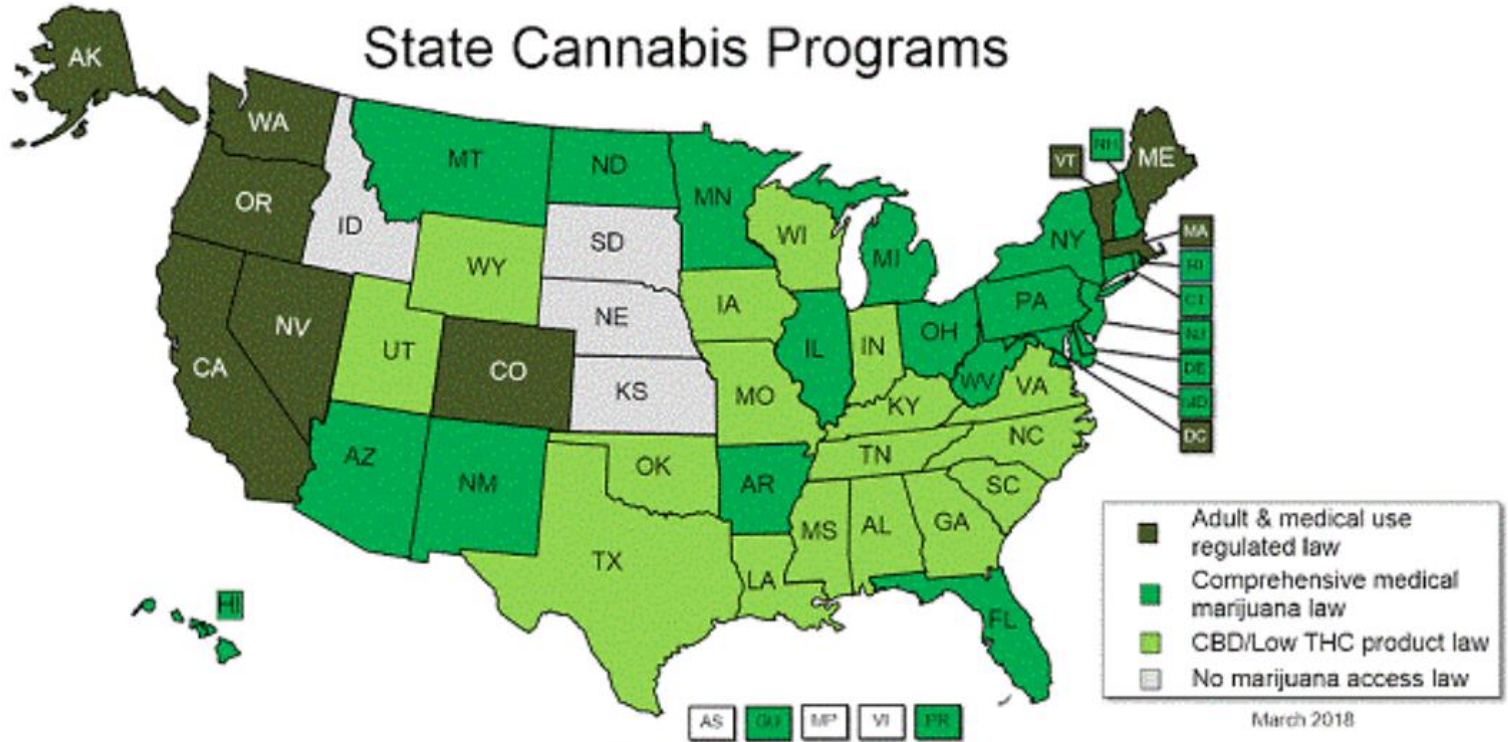
Rules we follow are just like Colorado weather, if you don't like it right now, wait around for a bit and it will change. **Get involved!**



Cannabis: FDA's Role in Regulation

Sara Beth Watson
Steptoe & Johnson LLP
May 4, 2018

State Cannabis Programs



Vermont adult use law signed Jan. 22, 2018. Effective July 1, 2018
 Limited adult possession and growing allowed, no regulated production or sales: DC, VT

Federal Status

- Marijuana is a Schedule I drug under the federal Controlled Substances Act, administered by the Drug Enforcement Administration
 - Schedule I drugs or substances are drugs with no currently accepted medical use and a high potential for abuse
 - The Hemp Industries Association sued DEA regarding a rule establishing a new drug code for marijuana extract
 - 9th Circuit denied the petition April 30, 2018. *Hemp Industries Association v. U.S. DEA*, Case No. 17-70162

Rescission of the “Cole Memo”



Office of the Attorney General
Washington, D. C. 20530

January 4, 2018

MEMORANDUM FOR ALL UNITED STATES ATTORNEYS

FROM: Jefferson B. Sessions, III
Attorney General

SUBJECT: Marijuana Enforcement

In the Controlled Substances Act, Congress has generally prohibited the cultivation, distribution, and possession of marijuana. 21 U.S.C. § 801 *et seq.* It has established significant penalties for these crimes. 21 U.S.C. § 841 *et seq.* These activities also may serve as the basis for the prosecution of other crimes, such as those prohibited by the money laundering statutes, the unlicensed money transmitter statute, and the Bank Secrecy Act. 18 U.S.C. §§ 1956-57, 1960; 31 U.S.C. § 5318. These statutes reflect Congress’s determination that marijuana is a dangerous drug and that marijuana activity is a serious crime.

In deciding which marijuana activities to prosecute under these laws with the Department’s finite resources, prosecutors should follow the well-established principles that govern all federal prosecutions. Attorney General Benjamin Civiletti originally set forth these principles in 1980, and they have been refined over time, as reflected in chapter 9-27.000 of the U.S. Attorneys’ Manual. These principles require federal prosecutors deciding which cases to prosecute to weigh all relevant considerations, including federal law enforcement priorities set by the Attorney General, the seriousness of the crime, the deterrent effect of criminal prosecution, and the cumulative impact of particular crimes on the community.

- Former U.S. Attorney General James Cole issued a memo in 2013 directing federal prosecutors to focus only on high priority cannabis operations, such as preventing distribution to minors.
- On January 4, AG Sessions withdrew the Cole memo and several other similar enforcement discretion memos re cannabis.

Reclassification

- DEA denied petition to reschedule marijuana in 2016
 - Stated FDA drug approval process is appropriate way to assess safe and effective medical use
- DEA and FDA both have a role to play in reclassification of marijuana
 - FDA consider factors (e.g.as addictive effects, current scientific knowledge related to the drug) and makes a recommendation
 - DEA may reclassify once it has scientific and medical evaluation of the drug and a recommendation from FDA

FDA Drug Status

- Botanical Marijuana
 - The FDA has not approved any product containing or derived from botanical marijuana for any indication. FDA has not found any such product to be safe or effective for the treatment of any disease or condition.
- Synthetic Products
 - The FDA has approved Marinol and Syndros for therapeutic uses. Marinol and Syndros include the active ingredient dronabinol, a synthetic delta-9-tetrahydrocannabinol (THC) which is considered the psychoactive component of marijuana.
 - Another FDA-approved drug, Cesamet, contains the active ingredient nabilone, which has a chemical structure similar to THC and is synthetically derived.

Dietary Supplements and Food

- FDA has concluded that THC and CBD products are excluded from the dietary supplement definition of the FD&C Act.
- FDA takes the position that the FD&C prohibits the introduction or delivery for introduction into interstate commerce any food (including any animal food or feed) to which THC or CBD has been added.

FDA: Enforcement Activity re CBD

- Over the past several years, FDA has issued several warning letters to firms marketing CBD products.
- In November 2017, FDA issued warning letters to four companies for unsubstantiated claims on product webpages, such as:
 - “CBD makes cancer cells commit ‘suicide’ without killing other cells;”
 - “Non-psychoactive cannabinoids like CBD (cannabidiol) may be effective in treating tumors from cancer – including breast cancer.”
- FDA required “prompt action to correct the violations” and noted that failure to do so could result in legal action, “including, without limitation, seizure and injunction.”
- FDA Warning Letters, see <https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm484109.htm>

Questions



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