



**2017 FDLI Annual Conference**

*Exploring Advanced Topics in Food and Drug Law*

**FDLI**  
Food and Drug Law Institute

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# **Regulation of Cannabis in FDA Regulated Products**

Douglas Throckmorton, Deputy Center Director for Regulatory Programs, CDER, FDA

# Regulating Cannabis: Federal and State Perspectives

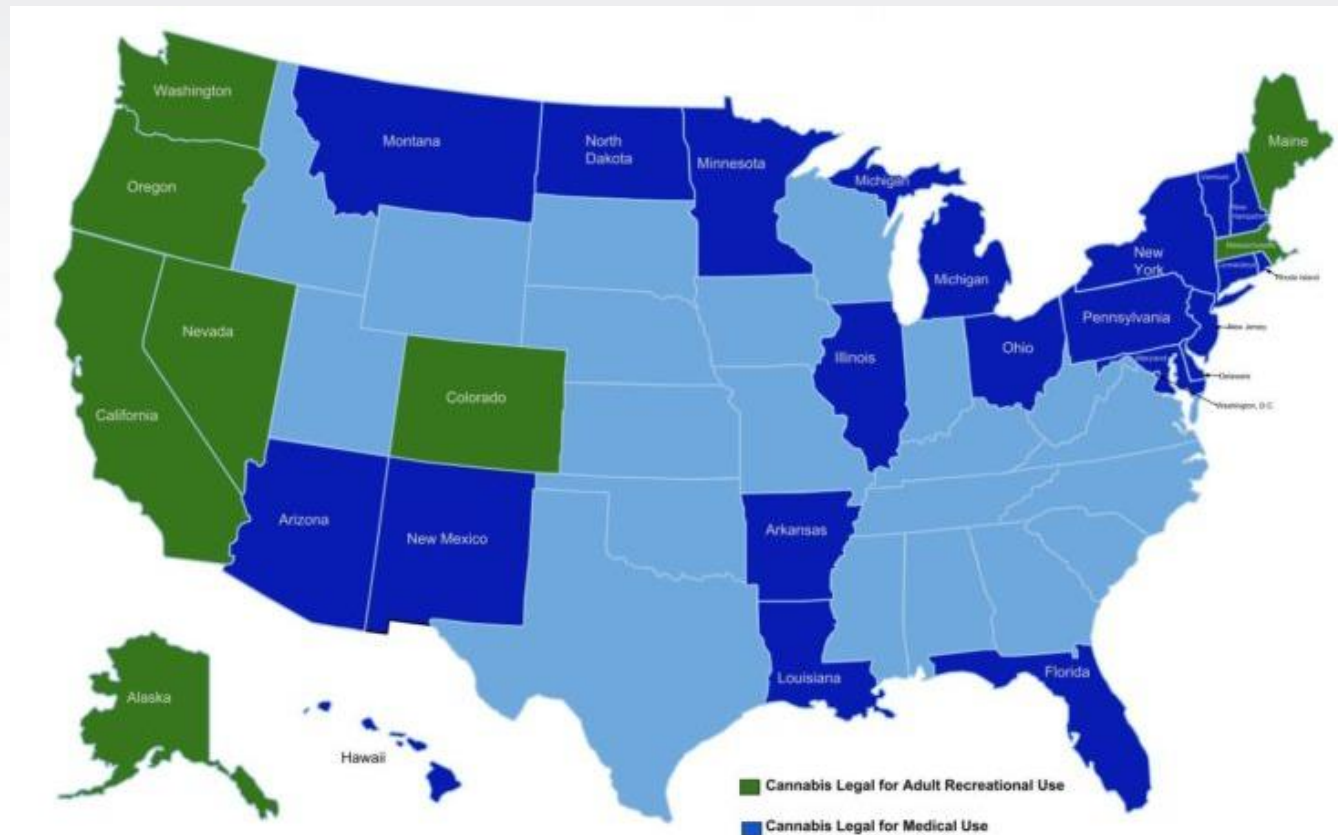
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**Jonathan A. Havens**  
**SAUL EWING LLP**  
FDLI Annual Conference  
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Washington, D.C.

# What is the regulatory status of cannabis?

- More than 50 percent of states have medical cannabis laws on the books.
- Eight states with medical cannabis laws have also legalized recreational cannabis.
- 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)).
  - The U.S. Department of Justice (DOJ) issued a memorandum in 2009 (Cole Memo), which:
    - Says that state laws do not change marijuana's illegal status under federal law; and
    - Directs 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.

# States Where Cannabis is Legal



Source: NM In Depth; [WV legalized medical marijuana on 4/19/17]

# Where Cannabis is Decriminalized

- The following states have passed laws decriminalizing certain marijuana possession offenses. Typically, decriminalization means no arrest, prison time, or criminal record for the first-time possession of a small amount of marijuana for personal consumption. In most decriminalized states, these offenses are treated like a minor traffic violation.

- Alaska \*
- California\*
- Colorado \*
- Connecticut
- Delaware
- District of Columbia \*
- Illinois
- Maine\*
- Maryland
- Massachusetts\*
- Minnesota \*\*
- Mississippi
- Missouri \*\*
- Nebraska
- Nevada \*
- New York
- North Carolina \*\*
- Ohio \*\*
- Oregon \*
- Rhode Island
- Vermont

\* Voters in each of these jurisdictions have subsequently approved legislation legalizing the adult use and personal cultivation of cannabis

\*\* These states still classify certain marijuana possession offenses as criminal misdemeanors, but such offenses do not result in jail time.

Source: NORML

# FDA's Statements on Cannabis and CBD

- 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's Statements on Cannabis (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.”
- “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.”

## Recent DEA Actions

- In August 2016, the Drug Enforcement Administration (“DEA”) declined to reschedule marijuana. It remains a Schedule I controlled substance, which by definition means it has “no currently accepted medical use and a high potential for abuse.”
- 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.



# Trump Administration

- Attorney General Jeff Sessions has said that: “good people don’t smoke marijuana;” he is “dubious” about the benefits of the drug; and he is “surprised” that Americans are not overwhelmingly embracing his anti-cannabis stance. He has also indicated a willingness to re-write the Cole Memo.
  - Close to 60 percent of Americans favor legalizing marijuana, and 71 percent think the federal government should not crack down on states with legalization laws on the books.
- Despite White House Press Secretary Sean Spicer’s remarks in February 2017 that “I do believe that you’ll see greater enforcement of [federal drug laws],” President Trump has indicated that it “should be a state issue.”
- Trump’s pick for drug czar, Rep. Tom Marino (R-Pa.), has a strong “no” vote record on cannabis, including CBD oil.
- Homeland Security Secretary John Kelly said cannabis is “not a factor in the drug war,” but has also said it is a “gateway drug” that could be grounds for deportation of undocumented immigrants.
- Despite this information, my personal prediction is that states will continue to legalize cannabis, at least medically, if not also recreationally, and that the Trump Administration will neither support nor hamper such efforts (*i.e.*, I do not expect changes to DEA scheduling of cannabis or easing of federal banking restrictions).

# 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.
- **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

# Questions?

**Jonathan A. Havens | SAUL EWING LLP**

Lockwood Place | 500 East Pratt Street,

9th Floor | Baltimore, MD 21202

1919 Pennsylvania Ave., NW, Suite 550 |

Washington, D.C. 20006

**T:** (410) 332-8757 | **F:** (410) 332-8179

[jhavens@saul.com](mailto:jhavens@saul.com) | [www.saul.com](http://www.saul.com)

## **Baltimore**

Lockwood Place • 500 East Pratt Street, Suite 900 • Baltimore, MD 21202-3171 • (tel) 410.332.8600 • (fax) 410.332.8862

## **Boston**

131 Dartmouth Street, Suite 501 • Boston, MA 02116 • (tel) 617.723.3300 • (fax) 617.723.4151

## **Chesterbrook**

1200 Liberty Ridge Drive, Suite 200 • Wayne, PA 19087-5569 • (tel) 610.251.5050 • (fax) 610.651.5930

## **Harrisburg**

Penn National Insurance Plaza • 2 North Second Street, 7th Floor • Harrisburg, PA 17101-1619 • (tel) 717.257.7500 • (fax) 717.238.4622

## **New York**

245 Park Avenue, 24th Floor • New York, NY 10167 • (tel) 212.672.1995 • (fax) 212.372.8798

## **Newark**

One Riverfront Plaza • Newark, NJ 07102 • (tel) 973.286.6700 • (fax) 973.286.6800

## **Philadelphia**

Centre Square West • 1500 Market Street, 38th Floor • Philadelphia, PA 19102-2186 • (tel) 215.972.7777 • (fax) 215.972.7725

## **Pittsburgh**

One PPG Place • 30th Floor • Pittsburgh, PA 15222 • (tel) 412.209.2500 • (fax) 412.209.2570

## **Princeton**

650 College Road East, Suite 4000 • Princeton, NJ 08540-6603 • (tel) 609.452.3100 • (fax) 609.452.3122

## **Washington**

1919 Pennsylvania Avenue, N.W. Suite 550 • Washington, DC 20006-3434 (tel) 202.333.8800 • (fax) 202.337.6065

## **Wilmington**

1201 North Market Street • Suite 2300 P.O. Box 1266 • Wilmington, DE 19899 • (tel) 302.421.6800 • (fax) 302.421.6813

# Addressing the State vs. Federal Dilemma



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# Testing, Testing and more Testing

## ANALYTICAL REPORT

Manifest#: 0001235158  
 Receive Date: 02/22/2017  
 Test Date: 02/23/2017  
 Report Date: 02/24/2017

Sample Type: Concentrate & Infused Edible  
 Prepared By: Jon Person  
 Reported By: Steven Glade  
 Reviewed By: Julia Bramante

Medically Correct, LLC – License# 404-00057

### CANNABINOID CONTENT

#### SCOPE

The content of ten cannabinoids was determined by solvent extraction followed by High Performance Liquid Chromatography with Diode Array Detection.

#### SUMMARY OF RESULTS

METRC ID	Product	Percent Cannabinoid									
		CBDV	CBDA	CBGA	CBG	CBG	THCV	CBN	Δ9-THC	CBG	THCA
1A4000500268748900033373	M420047A Black Label Harlo Shatter	0.00	<b>33.96</b>	0.00	0.00	<b>0.00</b>	0.00	<b>0.00</b>	<b>2.04</b>	0.00	<b>44.93</b>
1A4000500268748900033379	M420047B Black Label Harlo Shatter	0.00	<b>31.19</b>	0.00	0.00	<b>1.28</b>	0.00	<b>0.00</b>	<b>3.90</b>	0.00	<b>43.96</b>
1A4000500268748900034170	M420048A Black Label Sour Soda Shatter	0.00	<b>0.00</b>	2.57	0.00	<b>0.00</b>	0.00	<b>0.00</b>	<b>1.72</b>	0.00	<b>76.69</b>

0.00 – not detected; T – trace

## ANALYTICAL REPORT

### RESIDUAL SOLVENTS

#### SCOPE

The content of seven residual solvents was determined by Headspace-Gas Chromatography with Flame Ionization Detection.

#### SUMMARY OF RESULTS

METRC ID	Product	ppm Solvent						
		iso-Butane	n-Butane	Hexane	Benzene	Heptane	Toluene	Xylenes
1A4000500268748900033374	M420047A Black Label Harlo Shatter	0.00	0.00	0.00	0.00	0.00	0.00	0.00
1A4000500268748900033380	M420047B Black Label Harlo Shatter	0.00	T	0.00	0.00	0.00	0.00	0.00
1A4000500268748900034171	M420048A Black Label Sour Soda Shatter	0.00	T	0.00	0.00	0.00	0.00	0.00

0.00 – not detected; T – less than limit of quantitation

**Thank You! Colin@MedicallyCorrect.com**

