Part I: What is the Current Federal Oversight of Cannabis-Derived Products?

Larry K. Houck, Attorney, Hyman, Phelps & McNamara, PC
Keith Matthews, Of Counsel, Wiley Rein LLP
Kristi L. Wolff, Partner, Kelley Drye & Warren LLP
Moderated by **William A. Garvin**, Shareholder, Buchanan Ingersoll & Rooney PC

FDLI

DEA and Marijuana: Not Cannabis(ness) As Usual

Legal and Practical Issues in the Evolving World of Cannabis Regulation

FDLI Conference
November 18, 2019

Larry K. Houck
Hyman, Phelps & McNamara, P.C.
lhouck@hpm.com
www.hpm.com

FDLI

Larry Houck, Director, Hyman, Phelps & McNamara, P.C.

- Larry Houck counsels on DEA regulatory and enforcement actions. His career encompasses over 30 years focusing on controlled substances, prescription drugs, and regulated chemicals, helping clients navigate federal and state licensing, registration, and compliance issues.
- Mr. Houck counsels clients throughout the registrant supply chain on administrative, civil, and criminal proceedings. He advises on DEA inspections and audits. He works with clients to create the infrastructure to ensure compliant reporting, recordkeeping, and security.
- Before joining Hyman, Phelps & McNamara in 2001, Mr. Houck served as a DEA diversion investigator in the field and staff coordinator with DEA's Office of Diversion Control's Liaison and Policy Section.

Overview

- The Drug Enforcement Administration (“DEA”)
- The Controlled Substances Act (“CSA”)
- Scheduling
- Cannabis Scheduling
- DEA/DOJ Enforcement
- Manufacturer Registrations

DEA

- Regulates 1.8 million controlled substance manufacturers, distributors, pharmacies, practitioners, hospitals, importers and exporters.
- The primary federal agency responsible for enforcing the Comprehensive Drug Abuse Prevention and Control Act of 1970, the Controlled Substances Act (“CSA”).
- Enforces the CSA and regulations governing illicit street-type drugs and legal controlled pharmaceuticals and regulated chemicals.
- Mission is to eliminate illicit controlled substances and prevent, detect and eliminate diversion of controlled pharmaceuticals from legal channels while ensuring their availability for legitimate purposes.

The CSA

- Congress, through the CSA, established a closed system of controlled substance distribution requiring each entity in the chain-manufacturers, distributors, importers, exporters, practitioners and hospitals, etc., to account for the drugs they handle.
- This is achieved through a classification system of drugs based on potential for abuse relative to their legitimate use.
- The classification, or drug scheduling, triggers specific registration, quota, recordkeeping, reporting and security requirements.

Scheduling

- CSA requires analysis of 8 statutory factors:
  - Actual or relative potential for abuse.
  - Scientific evidence of its pharmacological effect, if known.
  - State of current scientific knowledge regarding the substance.
  - History and current pattern of abuse.
  - Scope, duration, and significance of abuse.
  - Risk to the public health.
  - Psychic or physiological dependence liability.
  - Immediate precursor of a substance already controlled.

Scheduling

- FDA conducts the 8 Factor Analysis and recommends scheduling.
- CDER's Controlled Substances Staff conducts analysis and makes recommendations.
- FDA Commissioner, with concurrence by NIDA, provides it to HHS Assistant Secretary for Health.
- HHS forwards the analysis and recommendation to DEA.
- DEA completes its own analysis and scheduling determination.
- If FDA/HHS recommends substance not be controlled, DEA cannot control it.
- Under CSA, HHS recommendation is binding as to "scientific and medical matters."
- DEA, with HHS/FDA, classifies controlled substances into 1 of 5 schedules.

Cannabis Scheduling

Schedule I:

- No currently accepted medical use in treatment in the U.S.;
- High potential for abuse; and
- Lack accepted safety for use under medical supervision.

- **Includes:**
  - Marijuana and any substance from parts of the *Cannabis sativa L.* plant within the CSA definition of “marihuana” (Drug Code 7360).
  - Tetrahydrocannabinols (“THC”)(Drug Code 7370).
  - Marijuana extract including CBD (Drug Code 7350).
  - Synthetic CBD (Drug Code 7360).
- **Also includes:** Heroin, LSD, Peyote, Ecstasy

Cannabis Scheduling

Schedule II

- Currently accepted medical use in treatment in the U.S.,
- High potential for abuse; and
- Abuse may lead to severe psychological or physical dependence.

- **Includes:**
  - Syndros (Synthetic THC, Drug Code 7365).
- **Also includes:** Oxycodone, Hydrocodone, Cocaine, Methamphetamine

Cannabis Scheduling

Schedule III:

- Currently accepted medical use in treatment in the U.S.;
- Potential for abuse less than drugs in schedules I and II; and
- Abuse may lead to moderate or low physical dependence or high psychological dependence.

- **Includes:**
  - Marinol (Synthetic THC, Drug Code 7369).
- **Also includes:** Tylenol with Codeine, Testosterone, Anabolic Steroids

Cannabis Scheduling

Schedule IV:

- Currently accepted medical use in treatment in the U.S.;
- Low potential for abuse relative to drugs in schedule III; and
- Abuse may lead to limited physical dependence or psychological dependence relative to the drugs in schedule III.

- **Includes:**
  - No cannabis.
- **Also includes:** Valium, Ambien, Xanax, Tramadol

Cannabis Scheduling

Schedule V:

- Currently accepted medical use in treatment in the U.S.;
- Has low potential for abuse relative to drugs in schedule IV; and
- Abuse may lead to limited physical dependence or psychological dependence relative to the drugs in schedule IV.

- **Includes:**
  - FDA-approved drugs in finished form containing CBD derived from cannabis with no more than 0.1% THC.
    - Epidiolex (Cannabis-derived, Drug Code 7367).
- **Also includes:** Lyrica, Lomotil

Cannabis Scheduling

Not Scheduled, Not Controlled:

- Hemp and hemp-derived products
  (THC not more than 0.3 percent on dry weight basis).
- CBD and products derived from parts of the *Cannabis sativa L.* plant excluded from definition of “marihuana.”
- Excluded parts: Mature stalks, fiber from stalks, oil or cake made from seeds, any other compound, manufacture, salt, derivative, mixture, or preparation from mature stalks (except the resin therefrom), fiber, oil, or cake, or sterilized seed incapable of germination.
- Excluded parts not controlled until 2003 when DEA amended regulations “clarifying” naturally-occurring THC, including products made from hemp, were within definition of “marihuana” and schedule I substances.

Cannabis Scheduling

Not Scheduled (Continued):

- DEA exempted processed plant material and animal feed mixtures derived from excluded parts of plant not intended for human consumption.
- Court of Appeals for Ninth Circuit enjoined DEA from enforcing regulation, concluding DEA cannot regulate *naturally-occurring* THC *not* contained within or derived from marijuana.
- On May 22, 2018, DEA conceded products derived from parts of plant excluded from definition of “marihuana” are not controlled and can be sold, distributed, imported or exported without restriction.

Cannabis Scheduling

Marijuana Rescheduling Denials (August 12, 2016):

- DEA denied 2 citizen petitions seeking to initiate proceedings to reschedule marijuana out of schedule I.
- Petitions asserted that marijuana has accepted medical use in treatment in U.S., is safe for use under medical supervision and has a low potential for abuse.
- DEA found that rescheduling turned on whether marijuana has currently accepted medical use for treatment in U.S.
- DEA requested scientific and medical recommendation from HHS as required by CSA, which is binding on DEA.
- HHS found marijuana had no accepted medical use in U.S.

Cannabis Scheduling

Marijuana Rescheduling Denials (Continued):

- Without finding that marijuana has accepted medical use in U.S., DEA was required to deny the petitions.
- But DEA advised future petitions:
- To limit rescheduling to particular strain to allow processing of standardized doses for specific disorders.
- Specific strain should be subject to safety and efficacy studies for recognized medical conditions.
- Petitions should provide data sufficiently addressing chemistry, toxicology and effectiveness of the strain.

Cannabis Scheduling

FDA-Approved CBD Drugs/Epidiolex (September 28, 2018):

- FDA approved Epidiolex, an oral CBD solution derived from cannabis, for treatment of seizures associated with Lennox-Gastaut and Dravet syndromes on June 25, 2018.
- DEA rescheduled FDA-approved drugs that contain CBD derived from cannabis with no more than 0.1% THC in schedule V.
- The U.S., as a signatory to Single Convention on Narcotic Drugs, 1961, requires comportment with treaty requirements, otherwise Epidiolex might have been descheduled due to lack of abuse potential.

Cannabis Scheduling

Agricultural Improvement Act of 2018 ("Farm Bill") (December 20, 2018):

- Removed hemp from CSA definition of marihuana and excludes THC in hemp from control under CSA.
- Defined hemp as *Cannabis sativa L.* plant and any part of the plant, including the seeds, and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with THC concentration of not more than 0.3% on dry weight basis.
- Established general requirements of U.S. Department of Agriculture ("USDA") and state/Indian tribal regulatory plans for oversight of hemp producers.
- Directed USDA to issue regulations and guidance "as expeditiously as practicable."
- Hemp production in a state or tribal territory that does not have a USDA-approved plan is unlawful unless producer has USDA license.

Farm Bill Interim Final Rule

2018 Farm Bill Interim Final Rule (October 31, 2019):

- Establishes USDA hemp production requirements for itself and state and Indian Tribes.
- USDA consulted with Attorney General in establishing rule.
- CSA and DEA will continue to play a role with noncontrolled hemp under USDA, and state and Tribal plans.
- Plans must require representative hemp samples be tested by labs registered with DEA to conduct chemical analysis of schedule I substances because they could potentially be testing cannabis with THC concentration above 0.3% on a dry weight basis.
- If cannabis exceeds 0.3% THC concentration, disposal must comply with CSA and cannabis must be destroyed by DEA-registered reverse distributor or federal, state or local law enforcement officer.

DOJ/DEA Enforcement

The Cole Memo (August 29, 2013):

- In response to states authorizing and legalizing cannabis while it remained a schedule I substance federally, DOJ established it was unlikely to take enforcement action against marijuana-related businesses operating in compliance with state law unless they implicated any of 8 enforcement priorities.
- Encouraged strong and effective regulatory and enforcement systems in states to control cultivation, distribution, sale and possession of marijuana.

DOJ/DEA Enforcement

The Cole Memo (Continued):

- Those priorities include:
  - Preventing distribution of marijuana to minors;
  - Preventing revenue from sale of marijuana to criminal enterprises, gangs and cartels;
  - Preventing 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 trafficking other illegal drugs or other illegal activity;

DOJ/DEA Enforcement

The Cole Memo (Continued):

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

DOJ/DEA Enforcement

Attorney General Sessions Memo (January 4, 2018):

- Rescinded prior DOJ guidance on marijuana enforcement, including Cole Memo.
- Directed federal prosecutors to weigh all relevant considerations, including federal enforcement priorities set by Attorney General, seriousness of crime, deterrent effect of criminal prosecution and cumulative impact of particular crimes on the community.

Attorney General Barr (January 2019):

- Stated during nomination that he disagreed with efforts by states to legalize marijuana, but consistent with Cole Memo, would not “go after” marijuana businesses states where activity is legal.

Manufacturer Registrations

DEA Policy Statement (August 12, 2016):

- DEA announced it was changing limiting marijuana cultivation for research to single grower.
- For 50 years, DEA granted 1 manufacturer registration for cultivating marijuana, restricting marijuana production for research to single grower.
- DEA believed that limiting cultivation to single grower decreased likelihood of diversion while meeting the limited demand for research-grade marijuana.
- DEA stated that along with NIDA and FDA, it "fully supports expanding research into the potential utility of marijuana and its chemical constituents."
- DEA recognized interest in research of certain cannabinoids, including CBD, and based on discussions with NIDA and FDA, concluded it must increase the number of authorized marijuana growers to satisfy current researcher demand.

Manufacturer Registrations

DEA Policy Statement (Continued):

- Approach fosters private sector commercial endeavors for product development rather than limitation to federally-funded and academic research.
- DEA has received 33 applications for registration to grow and cultivate marijuana for research.
- Many legitimate entities have applied that would be operated by established business and scientific professionals in compliance with DEA recordkeeping, reporting and security requirements.
- DEA has requested routine background information from some applicants, but has otherwise not acted on applications, despite number of requests from Congress.
- Additional registered marijuana manufacturers are more important given that 2019 marijuana aggregate production quotas are more than double 2018 quotas.

Manufacturer Registrations

DEA Press Release (August 26, 2019):

- DEA is still not ready to evaluate applications and needs to propose additional regulations to address process.
- DEA states before it can complete application evaluation and registration process, it “intends to propose regulations in the near future” governing applicants growing marijuana for research.
- DEA will evaluate applications, and of applicants it finds are compliant with “relevant laws, regulations and treaties,” will register number necessary to ensure adequate and uninterrupted supply under competitive conditions.
- Have researchers have been able to obtain necessary material to conduct their research.

Questions?

Thank You.

Larry K. Houck
Hyman, Phelps & McNamara, P.C.
(202) 737-9629
lhouck@hpm.com

Visit our blog: http://www.fdalawblog.net/

The Federal Trade Commission

KRISTI WOLFF
Partner
Advertising, Food + Drug
Chair, Cannabis Law Practice Group
Kelley Drye + Warren, LLP

Tel. (202) 342-8805
kwolff@kelleydrye.com

FDLI

FTC Leadership

Joseph J. Simons
Chairman
Sworn in: May 1, 2018

Noah Joshua Phillips
Commissioner
Sworn in: May 2, 2018

Rohit Chopra
Commissioner
Sworn in: May 2, 2018

Christine Wilson
Commissioner
Sworn in: Sept. 2018

Rebecca Kelly Slaughter
Commissioner
Sworn in: May 2, 2018

Section 5 of the FTC Act

Deception

- Material statement or omission
- Would tend to mislead a reasonable consumer

Unfairness

- Act or practice that causes substantial injury to consumers
- Consumers cannot reasonably avoid
- Not offset by benefits to consumers or competition

Deception

FTC Sends Warning Letters to Companies Advertising Their CBD-Infused Products as Treatments for Serious Diseases, Including Cancer, Alzheimer's, and Multiple Sclerosis

- FTC urged companies to review claims, including testimonials, and determine whether they were supported by competent and reliable scientific evidence
- FTC updated influencer guidance

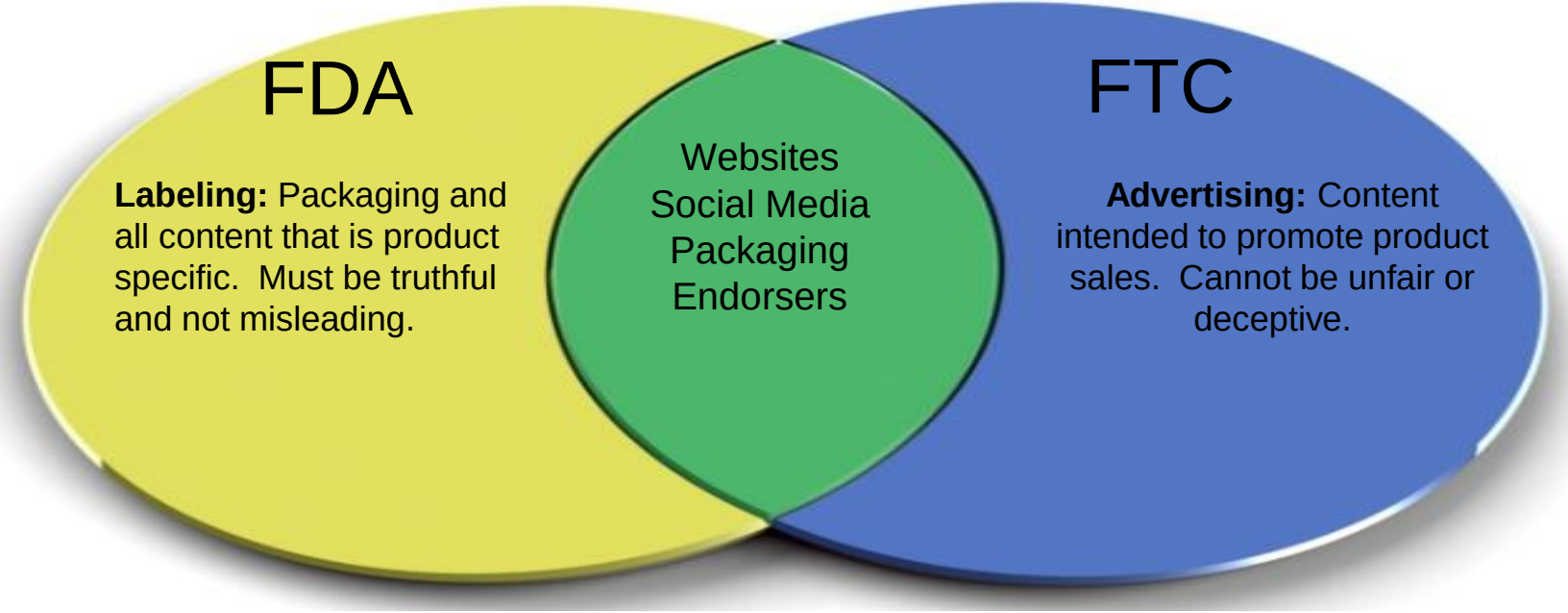
32

Health Claims: "Competent and Reliable Scientific Evidence"

unless the representation is non-misleading, including that, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. For purposes of this Provision, "competent and reliable scientific evidence" means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results.

Translation: Evidence sufficient in terms of quality and quantity such that experts in the field would say that it's enough to substantiate the claim.

Regulatory Overlap



Unfairness

Civil Penalty Authority

FTC + Cannabis

- CBD Warning Letters
- 21 U.S.C. § 843(c)(1) prohibits advertising of Schedule I controlled substances
- Rohrbacher-Blumenauer Amendment
- Scope of advertising is key consideration

Thank you!

Follow Us:
www.cannabislawupdate.com
www.adlawaccess.com
www.fooddruglaw.com

Legal and Practical Issues in the Evolving World of Cannabis Regulation

Federal Regulatory Oversight of Cannabis – EPA

Keith Matthews
202-719-4462
kmatthews@wileyrein.com

FDLI

Regulatory Perspectives on Cannabis/Hemp Agriculture

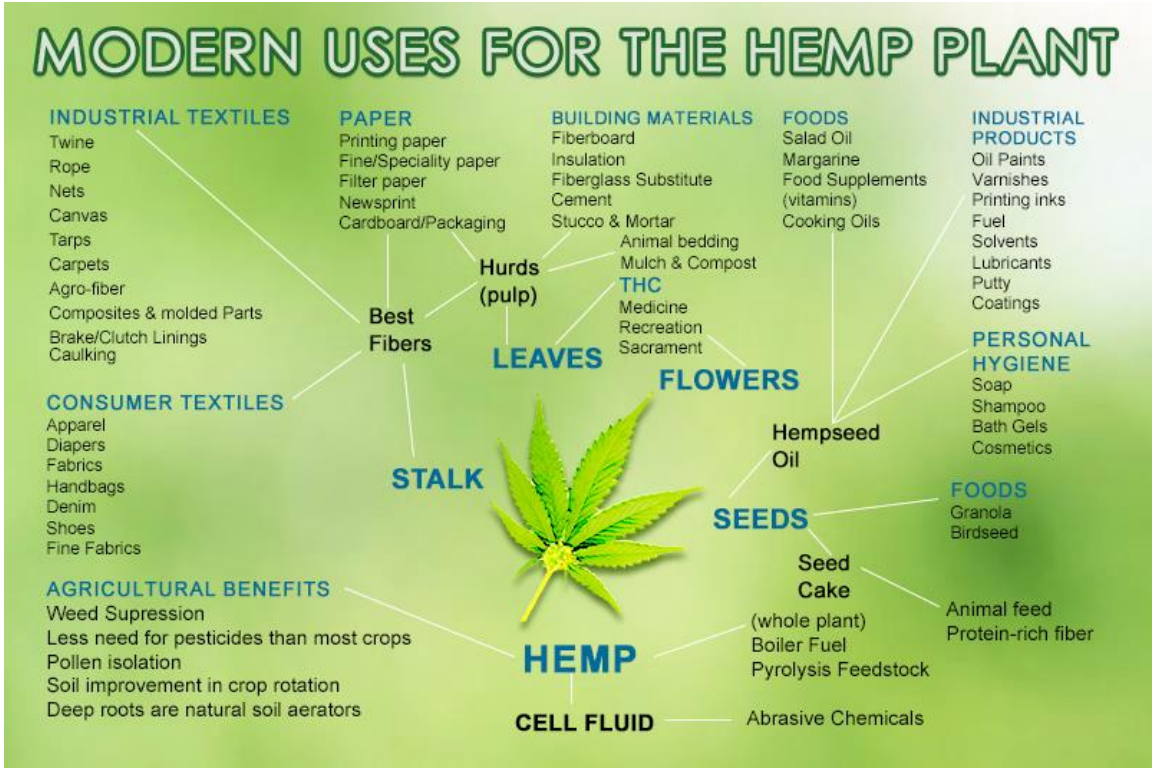
A Brief History

- Cultivation of hemp is one of the oldest industries in the world
- Hemp was a major crop during the Colonial Era and Early Republic
- Marihuana Tax Act (1937)
  - Effectively begins era of hemp prohibition
  - Tax and licensing regulations make hemp cultivation difficult
- Brief period of revitalization during WWII
- Controlled Substances Act (1970) blurs distinction between hemp and marijuana, therefore affecting hemp production

Hemp or Marijuana

Type	Cannabis?	Chemical Makeup	Psychoactive Properties?	Cultivation	Applications
Hemp	Yes	Low THC (less than 0.3%)	No	Grown as an agricultural crop	Automobiles, Body care, Clothing, Construction, Food, Plastic, others
Marijuana	Yes	High THC (5%-25%)	Yes	Grown as an agricultural crop	Medicinal and recreational use

Uses for Industrial Hemp



Source: Canada Health Services

2018 Farm Bill – Hemp Provisions

2018 Farm Bill provisions re hemp:

- Hemp is defined as a cannabis plant that contains no more than 0.3 percent THC; cannabis with a higher THC content remains classified as a controlled substance under Federal law.
- Hemp cultivation will be subject to joint Federal/State regulatory control.
- Hemp-derived cannabidiol (CBD) derived from legally produced hemp (i.e., in compliance with State and Federal regulations) is legal.

Federal Regulation – EPA

- Currently processing pesticide registrations for use on hemp under FIFRA
  - some pesticides currently registered for industrial hemp, but these do not have tolerances

- EPA is not giving consideration to pesticide registrations for use on marijuana

Cannabis Pests and Diseases

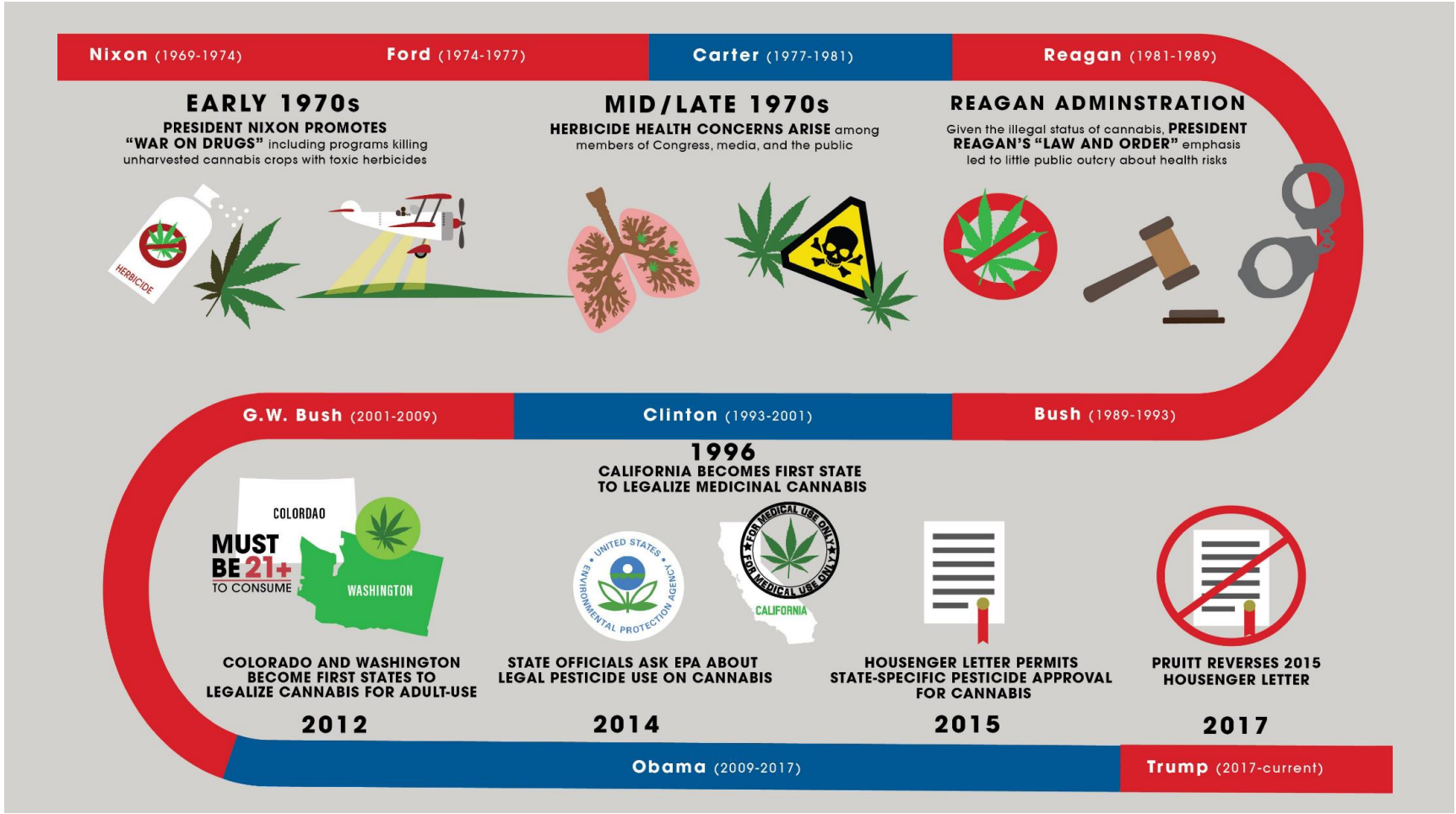
- Cottony Cushion Scale
- Mildew
- Whitefly
- Fungi or Virus
- Spider Mite
- Rust
- Black / Greenfly
- Bud / Toprot
- (Black) spot disease






Current Situation – Hemp

- There are only 6 EPA registered pesticides that list hemp on the label
- There are no existing food tolerances or exemptions for hemp – thus, as a matter of law, the currently registered pesticides cannot be used on hemp that is being grown for consumption
- EPA has announced the receipt of applications to amend 10 existing pesticide registrations to add hemp as a new use.
  https://www.govinfo.gov/content/pkg/FR-2019-08-23/pdf/2019-18151.pdf



Source: Environmental Law Institute

Current Situation – Cannabis/Marijuana

- There are no EPA-registered pesticide products approved for use on cannabis
  - EPA has not established food tolerances or exemptions for cannabis grown for consumption
- EPA does not regulate section 152.25(f) products, therefore, these products are not prohibited from use on cannabis

Concerns with Using Registered Pesticides on Hemp and Marijuana

- State “lists” are limited
- Most registrants of EPA-licensed pesticides do not want their products used on cannabis
- Efficacy, rate of application, and other elements normally determined as part of registration process are absent for cannabis use right now
- Lack of tolerances creates risk for cannabis grown for consumption; no risk assessment to establish tolerances; states are creating their own residue standards/action levels and enforcing standards on registrants for active ingredient contaminants

Concerns with Using Registered Pesticides on Hemp and Marijuana

- State specific information regarding cannabis pesticides:

- https://drive.google.com/file/d/1GLuckQPE4bNTPi_EitrEGMPkyfxf8YPG/view
- https://drive.google.com/file/d/1upPu4MArl5Wcdy0eOgP7fkgFDTTSmQo0/view
- https://www.colorado.gov/pacific/agplants/cannabis-faq
- https://www.colorado.gov/pacific/agplants/pesticide-use-cannabis-production-information
- https://agr.wa.gov/departments/marijuana/pesticide-use
- https://cms.agr.wa.gov/getmedia/60b63394-9f65-4f58-9820-bf11dddf9658/398-WSDACriteriaForPesticideUseOnMarijuana.pdf

What is the Current Federal Oversight of Cannabis-Derived Products? DOJ and USDA

William A. Garvin
Co-Chair, Cannabis Group | Shareholder, FDA
Buchanan Ingersoll & Rooney PC
Food and Drug Law Institute
Legal and Practical Issues in the Evolving World of Cannabis Regulation
November 18, 2019

FDLI

William A. Garvin

William focuses his practice on issues related to the approval, regulation, promotion, sale and reimbursement of drugs, medical devices, biologics, excipients, dietary supplements, foods and cannabis-related products.

William assists clients in their interactions with various federal agencies including the following:

- Food and Drug Administration (FDA)
- Centers for Medicare & Medicaid Services (CMS)
- Drug Enforcement Administration (DEA)
- Federal Trade Commission (FTC)
- Health and Human Services (HHS)

William's experience includes reviewing and revising the labeling of drugs, medical devices, foods and dietary supplements to ensure compliance with the FDA law and regulations. He works with clients to petition the FDA to ensure the safety and effectiveness of drug products on the market. He also assists in providing input to members of Congress regarding proposed legislation and highlighting arbitrary enforcement actions by federal and state agencies.

William is also co-head of the firm's cannabis group, where he assists companies in navigating federal and state law issues related to the promotion and sale of cannabis-related products. William has helped companies work to bring FDA-approved cannabinoid drug products to market as well as helped clients navigate the sale of cannabis and hemp-related products.

Since 2013, William has been consecutively named to the Washington, D.C. *Super Lawyers Rising Stars* list. He is also recognized as a Nationwide Band 1 Cannabis Lawyer by *Chambers USA* in 2019.

Department of Justice

Change of enforcement under Obama administration

- Oct 19, 2009 - Ogden memorandum
  - Deputy Attorney General David W. Ogden
  - US attorneys should not focus enforcement on “individuals whose actions are in clear and unambiguous compliance with existing state laws providing for the medical use of marijuana”
  - But continue to prosecute of commercial enterprises and gave characteristics of issues that would prompt prosecution

Department of Justice (cont.)

Change of enforcement under Obama administration

- June 29, 2011 – Early Cole memorandum
  - Deputy Attorney General James M. Cole
  - Regarding DOJ's position on Controlled Substances Act in jurisdictions that have medical marijuana legislation.
  - DOJ states that again individuals that act in compliance with the law should not be enforcement priorities but that those large scale commercial operations can be the target. This memo was in response to growth in those commercial groups.
- November 6, 2012 – Colorado becomes first state to legalize recreational marijuana

Cole Memo

August 29, 2013 – Cole Memo

- Deputy Attorney General James M. Cole
- Expands on Ogden memo and focused on new recreational market
- DOJ is unlikely to take enforcement as long as the activity doesn't implicate one of 8 enforcement priorities:
  1. Preventing the distribution of marijuana to minors
  2. Preventing revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels
  3. Preventing the diversion of marijuana from states where it is legal under state law in some form to other states
  4. Preventing the state-authorized marijuana from activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activities
  5. Preventing violence and the use of firearms in the cultivation an distribution of marijuana
  6. Preventing drugged driving and the exacerbation of other adverse public health consequences associated with marijuana use
  7. Preventing the growing of marijuana on public lands
  8. Preventing marijuana possession or use on federal property.

Trump Administration

January 4, 2018 - Attorney General Sessions Memo

- Rescinded Cole Memo along with all Obama era guidances and stated they were going back to original priorities set by Attorney General Benjamin Civiletti in 1980
- New system would be to generally treat marijuana like all other drug related crimes and weigh all relevant considerations, including "federal enforcement priorities set by Attorney General, the seriousness of crime, the deterrent effect of criminal prosecution, and the cumulative impact of particular crimes on the community."
- So what would happen after this?

Trump Administration

April 11, 2018 – Cory Gardner (R-Colo.) receives assurances that Trump won't interfere with Colorado's marijuana industry

- Gardner had blocked Justice Department nominees until he received assurances from Trump that they would not interfere with Colorado marijuana market

November 7, 2018 – Attorney General Jeff Sessions resigned

February 14, 2019 – Bill Barr becomes new Attorney General

- During nomination hearings Barr stated that he disagreed with the legalization of marijuana but would not go after marijuana businesses that were in compliance with State law.
- Provided further support for this position in April 2019

Congress and DOJ

- **Rohrbacher-Farr amendment –** no money to DOJ shall be used for interfere with state medical cannabis laws. First passed in December 2014 budget. This needs to be renewed with every budget.
- **Blumenauer amendment –** would protect medical and recreational cannabis programs. Not adopted.

USDA

- **2014 Farm Bill** –(Agricultural Act of 2014, P.L. 113-79)
  - Allowed for hemp cultivation under certain narrowly prescribed circumstances for research purposes by research institutions and state departments of agriculture in states with laws allowing for hemp production.
- **2018 Farm Bill** –(Agriculture Improvement Act of 2018, P.L. 115-334)
  - Redefined the distinction between marijuana and hemp
    - Marijuana and hemp are separate categories of products
    - Determination is whether delta-9 tetrahydrocannabinol is more than 0.3 percent on a dry weight basis
  - Allowed for hemp cultivation and sale of all hemp extracts (CBD!)
  - Directed USDA to develop hemp regulations and approve State plans for oversight.
  - If State unwilling to create their own regulatory plans, USDA would conduct oversight.
  - USDA to approve or reject state plans 60 days after receipt.

USDA regulations

- **Interim New Rules -** 84 Fed. Reg. 58,522 (Oct. 31, 2019)
  - Effective October 31, 2019 through November 1, 2021
  - Comment period – December 30, 2019
  - Creates
    - Rule for USDA to approve plans submitted for State and Indian tribes
    - Rules for States and territories that don't have USDA-approved plans
    - Maintaining information on hemp land
    - Testing of THC levels
    - Disposing of plants
    - And other provisions

USDA regulations (cont.)

State and Tribal Plans

- Must include
  - Plan to collect, maintain and report information on hemp cultivators,
  - Report information on land where hemp is produced,
  - Keep track of number of licenses issued,
  - Procedure for testing hemp within 15 days of the anticipated harvest,
  - Ability to have unrestricted access to all land, building, and structures used for the cultivation, handling, and storage of hemp, and
  - Establish lab standards

USDA Plan for places without State or Tribal plan

- Can grow hemp in that state or Tribal area under a USDA hemp license, so long as "the production of hemp is not otherwise prohibited by the State or Indian Tribe." Apply to USDA directly for hemp producer license in these circumstances.

USDA regulations (cont.)

- **THC testing –**
  - Testing of THC can be within the margin of error
    - 0.35% tested but +/-0.06% is margin of error, then okay because 0.3% is within margin
    - THC levels must be tested at most 15 days before harvest
    - Samples are taken from the flowers
    - Testing will be conducted using post-decarboxylation “or other similar reliable methods approved by the Secretary”

USDA regulations (cont.)

- **Violative crops**
  - Must destroy crops with high THC levels because they are marijuana.
  - To destroy must be authorized to handle Schedule I substances
  - Producers have to notify USDA of intent to dispose of non-conforming plants
  - Won't be able to compost it in soil that is used for plants for animal or human consumption
  - May be able to add to soil that won't be used for plants for consumption according to Hemp Industry Association.

USDA regulations (cont.)

- **Seeds**
  - USDA did not include a seed certification program because different regions can get different plants outcomes (high THC)
  - Nevertheless, State certification programs for seeds exist.
- **Interstate shipment allowed**
  - Nothing in this rule prohibits interstate commerce of hemp.
  - No State or Indian Tribe may prohibit the transportation or shipment of hemp produced in accordance with the Farm Bill
  - So Idaho can't stop shipping

USDA regulations (cont.)

- **Other provisions**
  - Pilot programs under 2014 bill can continue through 2020. After new rules go into effect, those 2014 rules will expire a year after
  - Ban on anyone who has felony conviction in last 10 years from participating in hemp industry except for those already participating under 2014 Farm Bill
  - USDA will gather records of hemp production

Part I: What is the Current Federal Oversight of Cannabis-Derived Products?

Larry K. Houck, Attorney, Hyman, Phelps & McNamara, PC
Keith Matthews, Of Counsel, Wiley Rein LLP
Kristi L. Wolff, Partner, Kelley Drye & Warren LLP
Moderated by **William A. Garvin**, Shareholder, Buchanan Ingersoll & Rooney PC

FDLI