K&L GATES

The Durham Bar 2019 CLE Program

The Shifting Federal Regulation of Cannabis Products

Erica M. Jackson, FDA Partner K&L Gates

February 6, 2019

K&L GATES

OVERVIEW

- About 147 million people, 2.5% of the world population, consume cannabis (annual prevalence) compared with 0.2% consuming cocaine and 0.2% consuming opiates
- Marijuana is the most widely available and commonly used illegal drug in the U.S.
- Marijuana refers to the dried leaves, flowers, stems and seeds from the cannabis plant
- Marijuana contains the psychoactive or mind-altering chemical delta-9-tetrahydrocannabinol (THC), as well as over 100 other active chemical constituents (cannabinoids or extracts)
- According to the World Health Organization, cannabis use can impair cognitive development, lead to cannabis dependence syndrome, exacerbate schizophrenia in affected individuals, impair fetal development when used during pregnancy, cause chronic bronchitis among other acute and chronic health conditions
- Consumer attitudes regarding cannabis are becoming more favorable
- Patients are increasingly turning to cannabis and cannabis products in an attempt to treat diseases and conditions
- Increased use and investments in food, beverage, dietary supplement and cosmetic companies

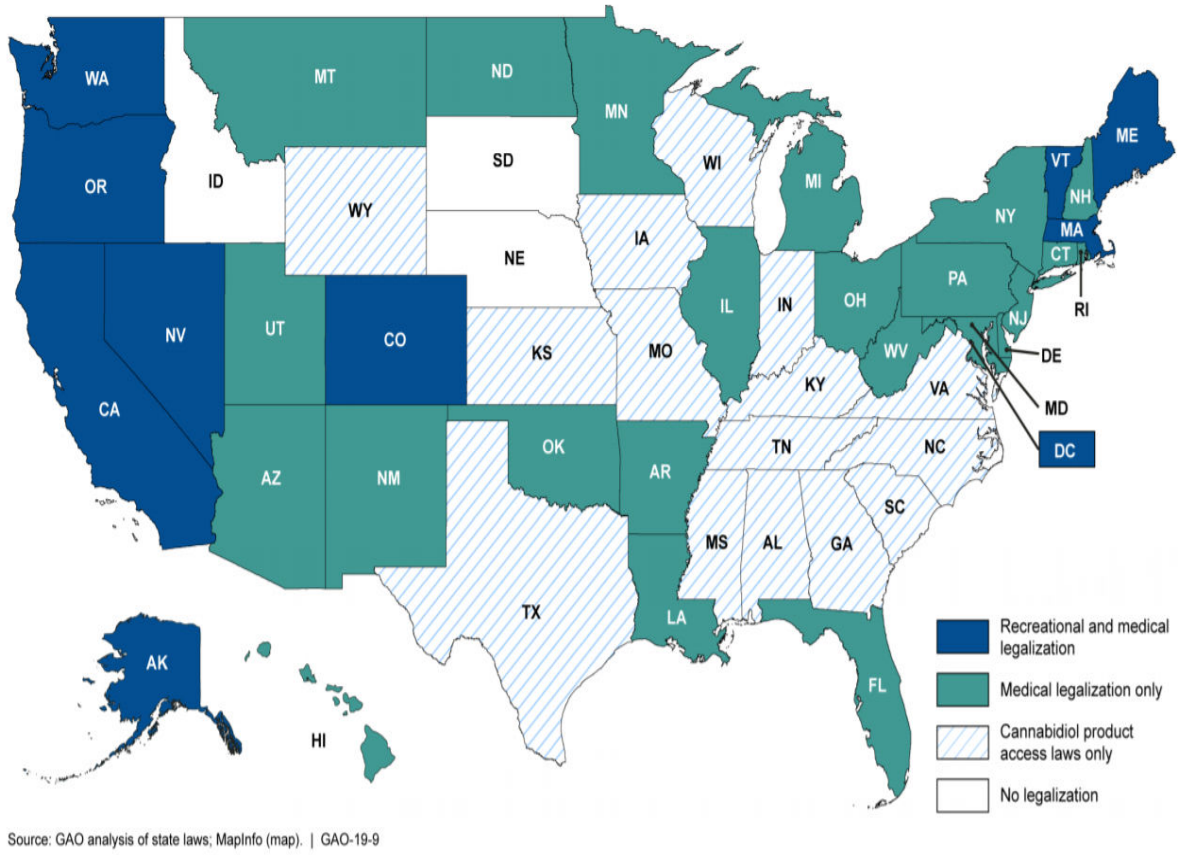
CONTROLLED SUBSTANCES ACT OF 1970

- Marijuana, marijuana extracts, and THC are classified as Schedule 1 drugs (most restrictive)
  - High potential for abuse
  - No currently accepted medical use
  - Lack of accepted safety for use under medical supervision
- Schedule 1 drugs cannot be dispensed with a prescription
- Federal government approved scientific research projects are permitted
- Imposes federal sanctions for the possession, manufacture, distribution, dispensing, or use of such drugs

K&L GATES

MARIJUANA STATE LAWS

Figure 1: Marijuana Legalization under State or Territorial Law, as of July 2018



Source: GAO analysis of state laws; MapInfo (map). | GAO-19-9

Note: The laws states and territories have passed legalizing medical or recreational marijuana or the use of products containing cannabidiol vary, as does the extent to which states and territories have established regulatory and enforcement systems to implement those laws.

- Increasing number of states have legalized medical or recreational marijuana under state law over the past 2 decades
- 32 states and the District of Columbia have legalized marijuana for medical purposes
- Of these, 9 states and the District of Columbia have legalized marijuana for recreational use
- Another 15 states have laws permitting the use of certain products containing cannabidiol (CBD), one of the non-psychoactive ingredients in cannabis

Figures are as of July 2018

AGRICULTURE IMPROVEMENT ACT OF 2018 (2018 FARM BILL)

- Signed into law on Dec. 20, 2018
- Removed hemp, defined as any portion of the cannabis plant with 0.3% THC, from the CSA
- Must be produced in accordance with USDA regulations and state/Indian tribe regulatory plans
- Does not preempt state/Indian tribe laws re hemp production that are more stringent
- Does not impact the U.S. Food and Drug Administration's (FDA's) regulatory authority

FDA-APPROVED CANNABIS DRUGS

- Growing public interest in the use of cannabis as potential treatments for certain medical conditions including AIDS, epilepsy, pain, multiple sclerosis, and cancer and chemotherapy-induced nausea
- The Federal Food, Drug, and Cosmetic Act (FDCA) requires that before a drug can enter the U.S. market, it must be demonstrated to be safe and effective for its intended use through adequate and well-controlled clinical trials
- The FDCA defines a drug in part as a substance intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease and a substance (other than food) intended to affect the structure or any function of the body

K&L GATES

FDA-APPROVED CANNABIS DRUGS (CONT.)

- Epidiolex (2018)
  - Contains purified drug substance CBD for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older
- Syndros (2017)
  - Contains active ingredient dronabinol, a synthetic THC
  - Approved uses include treatment of anorexia associated with weight loss in AIDS patients and nausea and vomiting associated with cancer chemo
- Cesamet (1985, 2006)
  - Contains the active ingredient nabilone, which has a chemical structure similar to THC and is synthetically derived
  - For the treatment of nausea and vomiting associated with cancer chemo
- Marinol (1985)
  - Contains active ingredient dronabinol, a synthetic THC
  - Approved uses include for treatment of anorexia associated with weight loss in AIDS patients and nausea and vomiting associated with cancer chemo

CANNABIS IN CLINICAL RESEARCH

- Regulated by FDA, DEA (researcher registration), and the National Institutes of Health (NIH)
- The National Institute on Drug Abuse (NIDA) within NIH provides research-grade marijuana and its cannabinoids
  - Has contracted with the University of Mississippi as sole grower of marijuana and cannabinoids for research for almost 50 years
- Historical one grower supply system was designed mainly to supply federally funded research, not for commercial product development
- Increased interest by academic researchers and the private sector and product quality complaints has impacted supply
- In 2016, DEA initiated a regulatory process to allow individuals and institutions to become registered growers under the CSA
  - At least 25 applications filed; no approvals to date

CANNABIS IN FOOD & DIETARY SUPPLEMENT PRODUCTS

- Under the FDCA, THC and CBD, whether marijuana or hemp-derived, ***cannot*** be sold as food (including animal feed) or dietary supplements
  - Active ingredients in approved drug products (THC and CBD)
  - Existence of substantial clinical investigations made public (CBD)
- The FDCA defines food in part as articles used for food or drink for humans and animals
  - Includes gummies, edibles, tinctures
- The FDCA defines dietary supplements in part as products taken by mouth that contain vitamins, minerals, amino acids, and herbs or botanicals that can be used to supplement the diet
  - Includes tablets, capsules, powders, energy bars, and liquids

CANNABIS IN FOOD & DIETARY SUPPLEMENT PRODUCTS (CONT.)

- FDA takes the position that food derived from parts of hemp that do not contain the active drug ingredients CBD or THC may be lawfully marketed if Generally Recognized as Safe (GRAS) under FDA requirements
- Dec. 20, 2018, FDA completed evaluations of three GRAS notices with no issues on the use of the following three hemp-seed derived ingredients in human food:
  - Dehulled hemp seed
  - Hemp seed protein powder
  - Hemp seed oil
- Use must be consistent with those specified in notices
- No therapeutic or disease claims
- FDA has authority to issue regulations to allow for use of CBD and THC in food and dietary supplements
- FDA plans to hold public meetings in 2019

CANNABIS IN COSMETIC PRODUCTS

- The FDCA defines cosmetic in part as an article intended to be rubbed, poured, sprinkled, or sprayed on, or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance
- FDCA does not expressly prohibit; products cannot make disease or therapeutic claims
- FDA has not issued express guidance on use in cosmetics
- DEA regulations (21 CFR 1308.35) allow for use in personal care products if made from portion of cannabis plant excluded from the definition of marijuana and not used, or intended for use, for human consumption
  - Can contain THC

Beauty

I Replaced My Entire Beauty Routine With Only CBD Products

FDA CANNABIS ENFORCEMENT ACTIONS

- FDA has prioritized enforcement actions against food and dietary supplement products marketed with disease or therapeutic claims
- Enforcement to date has focused on warning letters
- Includes CBD products and those derived from hemp
- Claims include the following diseases and conditions: pain, rheumatoid arthritis, cancer, diabetes, Crohn's disease, psychosis disorders
- FDA has performed analytic testing on products at issue and found many did not contain the level of CBD included on labeling

SUMMARY

- Shifting consumer attitudes, federal and state laws, and enhanced product availability are fueling the growing cannabis product market
- DEA, NIH, and FDA support the development of cannabis drugs that are safe, effective, and manufactured to a high quality
- For FDA, drug development, grounded in scientific research, is key to determining the appropriate uses of cannabis in the treatment of disease and conditions
- FDA is committed to taking enforcement actions related to the unlawful marketing of cannabis products
- FDA is actively evaluating its regulation of certain cannabis products

QUESTIONS?

Erica M. Jackson
FDA Partner
K&L Gates
Erica.Jackson@klgates.com
Office: 919.466.1127