

FDA Role in Marijuana Regulation

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Disclosure Statement

I have no financial relationships with proprietary entities that produce health care goods and services

The opinions and information in this presentation are my own and do not necessarily reflect the views and policies of the FDA



Central Messages

- FDA has clear role in supporting scientific and rigorous assessment of marijuana, including product development and regulation of marketing
- The promise of safety, efficacy and reliability is not good enough

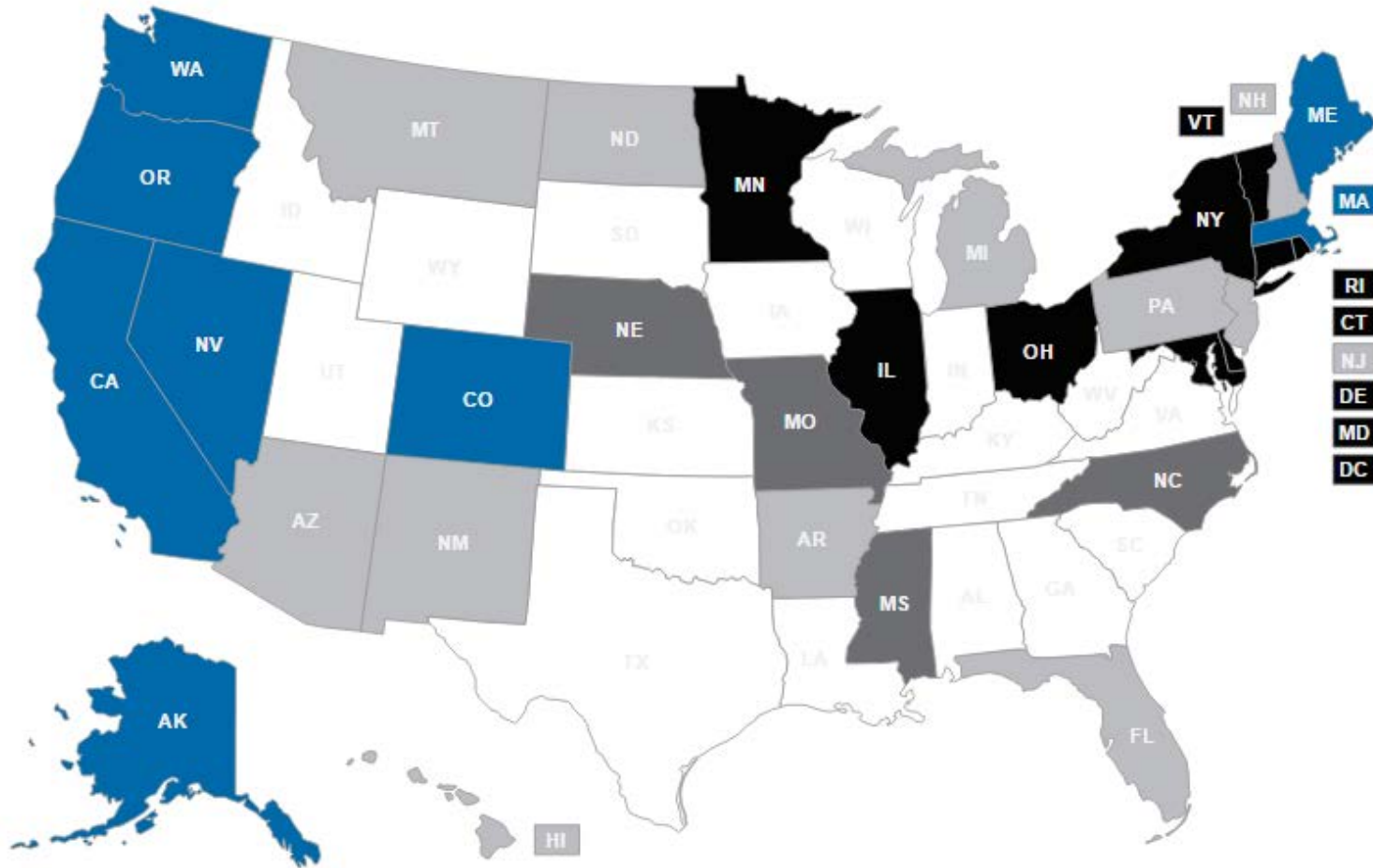
However

- FDA needs to do all it can to support the needed scientific research with marijuana to characterize its therapeutic promise

Status of MJ at the Federal Level

- Controlled Substance Act of 1970:
 - Marijuana regulated under **Schedule I**
 - High potential for abuse
 - No currently accepted medical use
 - Lack of accepted safety for use under medical supervision
 - In 2016 FDA completed review of published literature and recommended MJ remain in Schedule I

Status of Marijuana Laws in the US



- States with medical marijuana laws
- States that have removed jail time for possessing small amounts of marijuana
- States that have both a medical marijuana law and have removed jail time for possessing small amounts of marijuana
- Marijuana is legal for adults and is taxed and regulated similarly to alcohol; state also has a medical marijuana law

Source: Marijuana Policy Project



FDA Roles in MJ Regulation

- **Regulatory role:**

- FDA provides regulatory oversight for products containing compounds from marijuana to encourage drug development

- **Scientific role:**

- FDA provides scientific assessment on the appropriate controls ('schedule') for marijuana to HHS and DEA
- FDA supports rigorous scientific research on marijuana

- **Enforcement role:**

- Taking actions against products that present human health risks or that make egregious labeling claims

FDA Work with Marijuana



Office of the
Commissioner



Office of
Regulatory
Affairs



Center for
Food
Safety &
Applied
Nutrition

Center for
Drug
Evaluation
& Research



Center for
Biologics
Evaluation &
Research



Center for
Devices &
Radiological
Health

Center for
Veterinary
Medicine



National
Center for
Toxicological
Research



Center for
Tobacco



FDA, State and Federal Coordination

- FDA has worked with 12 states to date on MJ issues
- FDA cooperation with DEA and NIDA extensive
 - MOU between FDA and DEA facilitating data-sharing
 - FDA and NIDA cooperating to support study of abuse potential of CBD (trial ongoing)
- FDA interacts with multiple other Agencies across USG:
 - ONDCP, USDA, EPA, CBP, SAMHSA, NIDA

FDA Support for Drug Development from MJ

- Three products approved:
 - Marinol (dronabinol) (1985): nausea from cancer chemotherapy
 - Cesamet (nabilone) (1985 (2006)): nausea & neuropathic pain
 - Syndros (dronabinol) (2017)



FDA Support for Drug Development from MJ

- FDA work to provide guidance and speed review
 - Final Guidance on the use of botanicals (e.g., marijuana) as sources for drugs – 2016
 - Focus on measures to take to help assure quality manufacturing
 - Expediting drug development using available tools:
 - Orphan Disease designation, Priority Review, Fast Track Designation
 - Botanicals Team assistance
- <http://www.fda.gov/newsevents/publichealthfocus/ucm421168.htm>

FDA Support for Drug Development from MJ

- FDA work to provide guidance and speed review (cont):
 - FDA actively maintains a website with Q and A section addressing common issues
 - <https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421168.htm>
 - Extensive communication between FDA, investigators and public about MJ and product development
 - In the past 12 months, CDER has responded to over 450 calls, emails, and letters about marijuana/CBD

FDA Supports Early Access to Investigational Products MJ

- FDA supports early access to investigational drugs from MJ:
 - Expanded Access (EA) programs allow access to investigational drugs during development under IND
 - Set up by developer and investigator
 - Requires safety data collection and human subjects protection
 - Example: EA program for Epidiolex
 - Over 400 children have received Epidiolex through EA

<http://www.fda.gov/newsevents/publichealthfocus/ucm421168.htm>

FDA Enforcement Role in Regulating MJ



Cannabidiol Edibles





CBD Warning Letters

- FDA has enforcement role to target nationally marketed products making egregious health claims
 - Includes products that allege to contain CBD
- FDA has issued two sets (Feb 2015 & Feb 2016) of warning letters (14 total) to those marketing unapproved drugs for the diagnosis, cure, mitigation, treatment, or prevention of diseases
- Some of these firms claim that their products contain cannabidiol (CBD)

<http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421163.htm>

Examples of Claims

- “[S]tudies have found CBD to possess the following medical properties: ... Antipsychotic – combats psychosis disorders...combats neurodegenerative disorders ... Anti-tumoral – combats tumor and cancer cells ...combats...depression disorders”
- Treats rheumatoid arthritis
- CBD helps with cancer, multiple sclerosis ...diabetes, arthritis, dystonia, Crohn’s disease...

Results of Analytic Testing

- FDA has tested these products, and many were found to not contain the levels of CBD they claimed to contain. **Consumers should beware purchasing and using any such products.**

• <http://www.fda.gov/newsevents/publichealthfocus/ucm484109.htm>

Summary

- FDA has a clear role with multiple activities ongoing around the regulation of marijuana
- Ongoing FDA work includes:
 - Providing scientific advice on the risks of marijuana and its constituents
 - Supporting rigorous scientific research into therapeutic value of marijuana and its constituents
 - Taking appropriate actions related to the marketing of products containing marijuana or its constituents

Conclusions

- FDA will continue to support development of specific new drugs that are safe, effective, and manufactured to a high quality
- Drug development, grounded in rigorous scientific research is essential to determining the appropriate uses of marijuana and its constituents in the treatment of human disease
- FDA is committed to making this process as efficient as possible and looking for ways to speed the availability of new drugs from marijuana for the American public