



# Cannabis Forum for Certifying Providers

Cannabis Use During Pregnancy and While Nursing  
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Gary J. French, MD

UPDATE

# Rescheduling of Cannabis

# Background

- On August 29, 2023, the Department of Health and Human Services (HHS) recommended to the Drug Enforcement Agency (DEA) that cannabis be rescheduled from Schedule I to Schedule III under the Controlled Substances Act (CSA).
  - Schedule I – heroin, LSD, MDMA, peyote
  - Schedule III – ketamine, Tylenol with codeine, anabolic steroids
    - Schedule III substances have an accepted medical use and may lawfully be dispensed by prescription

*\*\*DEA enforces drug laws – FDA enforces drug standards\*\**

# Proposal – Schedule I to Schedule III



- Recognize the medical uses of cannabis.
- Acknowledge cannabis has less potential for abuse than some other substances.
  - Currently 38 states, three territories, and the District of Columbia allow the medical use of cannabis.\*
  - Currently 24 states, two territories, and the District of Columbia allow cannabis for adult recreational use.\*

*\*National Conference of State Legislatures – April 09, 2024\**  
*<https://www.ncsl.org/civil-and-criminal-justice/cannabis-overview>*

# Federal Implications

- Legal Status

- Rescheduling would not make all medical and recreational cannabis legal at the federal level.
- Products such as flower, edibles, vape products, suppositories, and topicals would still be illegal...until FDA approved.

- Production and Sales

- Those who manufacture, distribute, dispense and possess medical cannabis may now be able to do so lawfully under the CSA.
- Cannabis producers and retailers would be able to deduct the costs of selling their product for the purposes of federal income tax filing.
- Easier access to banking services for cannabis businesses.

# Federal Implications (continued)

- Agencies

- Will VA patients and IHS patients now have access to providers who will certify them to use medical cannabis?

- Research

- Less strict regulatory control as a Schedule III would promote greater research.
- Will improved access cause pharmaceutical companies to pursue the development of additional cannabis drugs that can pass FDA muster?
- Will FDA approved cannabis drugs be sold at pharmacies?

# State Implications

- Current “state-legal” cannabis markets are not designed for a Schedule III drug. State and federal laws would still be in conflict.
  - Currently over 1,000 dispensaries in New Mexico with a myriad of different products.
- Will the FDA fully enforce regulations on cannabis products as it does for all other Schedule III drugs?
  - Could the rescheduling actually be regressive for those states that currently have a medical and adult-use program?
  - Will there be a specific carve-out for cannabis products currently in the market?

# Patient Implications

- Those who use medical cannabis lawfully may benefit in the following ways:
  - Improved access to public housing
  - Obtain immigrant and nonimmigrant visas
  - Purchase and possess firearms
  - Face fewer barriers for federal employment
  - Eligible to serve in the military
  - Reduced penalties for federal cannabis crimes



# Provider Implications

- Will medical providers be required to “prescribe” only those cannabis products that have met FDA regulatory standards?
- Will medical providers have to write an actual prescription specific dose and administration details?
- Will the insurance industry compensate providers for the time and energy spent evaluating and educating patients about medical cannabis?

# Next Steps

- Proposal was reviewed by the White House Office of Management and Budget and moved forward.\*
- May 16, 2024\*
  - Notice of Proposed Rulemaking was submitted to the Federal Registrar by the Attorney General - initiating the formal rulemaking process.
- Public-comment period now open! – (ends July 22, 2024)\*
  - [Federal Register :: Schedules of Controlled Substances: Rescheduling of Marijuana](#)

# Next Steps

- Review from an administrative judge
- Likely some litigation!
- DEA would publish the final rule confirming the rescheduling  
*\*\*Expect at least 12 to 18 months for full rescheduling\*\**  
*HCPs - 9 years      Epidiolex - 3 months*

# PRESENTATION

## Cannabis Use During Pregnancy and While Nursing

# Background

- THC is lipid soluble
- THC can cross the placenta.<sup>1</sup>
- THC can diffuse into the blood stream of the fetus.<sup>2</sup>
- THC can cross the blood brain barrier and bind to endocannabinoid receptors in the fetal brain.<sup>3</sup>
  - (Receptors present as early as 5 to 6 weeks)<sup>4</sup>
- THC can accumulate in the breastmilk and be released slowly over days to weeks.<sup>5</sup>

# Trends

- Cannabis use amongst pregnant women is growing.<sup>6</sup>
  - (3.4% to 7%)
- Use is greatest in the first trimester.<sup>6</sup>
  - (5.7% to 12.1%)
- Use is greatest in the young<sup>6</sup>
  - (<18 y/o = 22%, 18 to 24 y/o = 19%)
- Use is typically misrepresented
  - Twice as likely to screen positive than what was self reported<sup>7</sup>
  - Self reported use = 7%<sup>6</sup> / Tested umbilical cords = 22.4%<sup>8</sup>

# Trends

- Women in states with legalized recreational were more likely to consume during preconception.<sup>9</sup>
  - Preconception = 1.52 times more likely to use
  - Pregnancy = 2.21 times more likely to use
  - Postpartum = 1.73 times more likely to use
- Met criteria for cannabis abuse and/or dependence (18.1%)<sup>10</sup>

# Mode of use<sup>11</sup>

- Smoking (91%)
- Eating (12.1%)
- Vaporizing (7.1%)
- Dabbing (4.5%)
- Drinking (0.5%)
- Other (0.5%)



# Reasons for use

- Nausea and vomiting of pregnancy (77.8%, 77%)<sup>11,12</sup>
- Stress/Anxiety (81.5%, 75%)<sup>11,12</sup>
- Pain (55.1%, 83%)<sup>11,12</sup>
- Sleep disorders (74%)<sup>12</sup>
- Improve appetite (70%)<sup>12</sup>
- Recreationally or for fun (45.7%)<sup>11</sup>

# Information Sources

- Family and friends<sup>13</sup>
- Internet and Social media<sup>14,15</sup>
- Dispensary/Budtenders<sup>16</sup>
- Labels<sup>17</sup>
- Healthcare providers

# Dispensary/Budtenders

- “Mystery Caller” study
  - 36% of budtenders blatantly stated cannabis use is safe in pregnancy
  - 69% recommended cannabis products specifically for morning sickness
  - 65% based their recommendations on personal or secondhand experiences rather than research or clinical recommendations
  - Often expressed animosity and distrust of physicians
  - “If cannabis is safe for cancer, it must be safe in pregnancy”

# Dispensary/Budtenders

- USA - no oversight board or regulation that holds budtenders accountable for spreading misinformation to customers.
- States - no individual state has requirements regarding what medical information budtenders are allowed to recommend.
  - Cannabis Regulatory Advisory Committee (C-RAC) –Cannabis Server
  - "A New Mexico public post-secondary educational institution may offer a practical or academic curriculum designed to prepare students for participation in the cannabis industry. The institution shall *register* its cannabis training and education program with the division, which shall include the information about the program on its website."

# Labels

- Cannabis Regulation Fact Sheet 2022<sup>17</sup>
  - 15/17 jurisdictions required labels on cannabis products to include a warning about the dangers of using the product while pregnant or breastfeeding.
  - Oregon and Washington had no such warning *on labels*
  - New Mexico does have a warning, but not required on principal display panel, only on information panel or accessed through QR code.

# Perceptions of use

- Perceive as low risk to fetus<sup>18</sup>
- Cannabis is not addictive<sup>18</sup>
- Aware of risks, but perceived cannabis use as safer than prescribed medications because it is a “natural plant”<sup>19</sup>
- Medical cannabis is safer than recreational marijuana
- A lack of communication by medical providers reinforced the idea that cannabis use may be harmless or risk insignificant.<sup>20</sup>

# What is the message we should give?

- ACOG recommends that anyone who is pregnant, planning to get pregnant, or breast feeding - not use cannabis.

## Marijuana and Pregnancy





If you use marijuana during pregnancy, you may be putting your health and your fetus's health at risk.



### Possible Effects on Your Fetus

-  Disruption of brain development before birth
-  Smaller size at birth  
Higher risk of stillbirth
-  Higher chance of being born too early, especially when you use both marijuana and cigarettes during pregnancy
-  Harm from secondhand marijuana smoke
-  Behavioral problems in childhood and trouble paying attention in school

### Possible Effects on You

-  Permanent lung injury from smoking marijuana
-  Dizziness, putting you at risk of falls
-  Impaired judgment, putting you at risk of injury
-  Lower levels of oxygen in the body, which can lead to breathing problems

### Did you know?

- Medical marijuana is not safer than recreational marijuana. Recreational and medical marijuana may be legal in some states, but both are illegal under federal law.
- There's no evidence that marijuana helps morning sickness. Ask your obstetrician-gynecologist (ob-gyn) about safer treatments.
- You should also avoid marijuana before pregnancy and while breastfeeding.

# Some hard numbers

- Mother using cannabis during pregnancy 2.6 times more likely to have baby with low birthrate.<sup>21</sup>
- 1.7 times more likely to spontaneously deliver their newborn prematurely.<sup>21</sup>
- Mother using cannabis during pregnancy 1.5 times more likely to have a child with autism.<sup>22</sup>
- Infants born to mothers were 2.5 times a likely to need to be admitted for intensive care.<sup>21</sup>



# Impact of Prenatal Cannabis Exposure (PCE) on growth parameters<sup>23</sup>



- Cannabis use through gestation resulted in significant deficits in birth weight and head circumference.
- The longer the exposure time resulted in a greater impact on the fetus.
- Recommendation: Cannabis use should be discontinued as early as possible during the pregnancy!

# Impact of Decreased Birth Weight & Head Circumference<sup>24-27</sup>



- Neurological issues
  - Cognitive delay
  - ADHD
- Psychological issues
  - Depression
  - Social dysfunction
  - Somatic symptoms
- Health Complications in childhood
  - Childhood hypertension
  - Obesity in Adolescence
- Non-communicable diseases in adulthood

# Prenatal Cannabis Exposure (PCE) and structural birth defects<sup>28</sup>



- Mixed and inconclusive association
- Lack of results should not be interpreted that cannabis use during pregnancy is safe
- Highlights the need for greater research

# Effects to Mother

- Lung injury if smoking
- Dizziness leading to falls risk
- Impaired judgement leading to injury
- Lower levels of oxygen leading to breathing problems

# Why are we seeing this data now?

- Increased number of users
- Increased number of states who have legalized use
- Increased potency of product
- Continued distribution of misinformation

# Recommendations<sup>29</sup>

- Follow ACOG Recommendations
- Ensure that women who use cannabis during pregnancy are treated in a neutral, non-stigmatizing way and are supported to make decisions based on evidence, rather than ideology.
- Women who are unable to abstain from cannabis use are advised not to breastfeed within 1 Hour of inhaling or consuming cannabis to reduce the infant's exposure to the highest concentration of cannabis in breast milk.
- Avoid pitting the rights of the mother and fetus against each other or threaten punitive measure in cases of substance misuse.

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# Any Questions?

- Website:  
[www.nmhealth.org/go/mcp](http://www.nmhealth.org/go/mcp)
- Email:  
[medical.cannabis@doh.nm.gov](mailto:medical.cannabis@doh.nm.gov)
- Phone: (505) 827-2321

