NATALIE M. LAPRADE

MMCC

MARYLAND MEDICAL CANNABIS COMMISSION

# MEDICAL CANNABIS INFUSED VAPE CARTRIDGES
## Product Testing Landscape

Lori Dodson, MS, MT(ASCP)

Deputy Director

January 09, 2020

# MMCC Mission

*The Maryland Medical Cannabis Commission (MMCC) develops policies, procedures, and regulations to implement programs that ensure medical cannabis is available to qualifying patients in a safe and effective manner. The MMCC oversees all* ***licensing, registration, inspection, and testing measures*** *pertaining to Maryland's medical cannabis program and provides relevant program information to patients, providers, caregivers, growers, processors, dispensaries and testing laboratories.*

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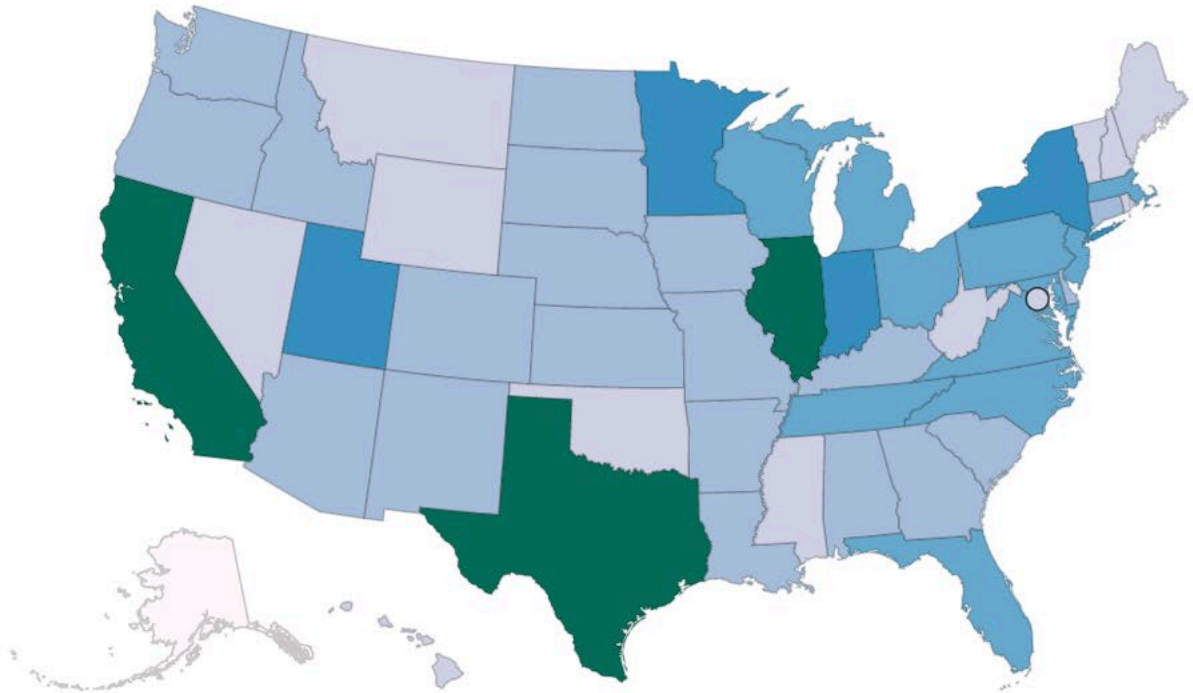
# Vape Lung Injury and Cannabis Regulation

Number of Lung Injury Cases Reported to CDC as of November 19, 2019



Legend

Number of lung injury cases per state

- 0 cases
- 1-9 cases
- 10-49 cases
- 50-99 cases
- 100-149 cases
- 150-199 cases

Territories AS GU MH FM PW PR VI

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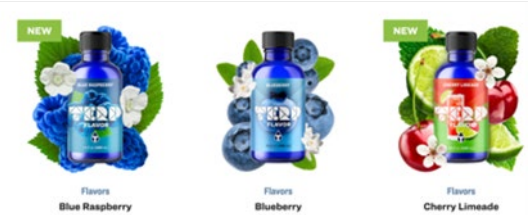
# Vape Lung Injury and Cannabis Regulation

## Potential Concerns

- **Excipients/Diluents**
  - Aerosol testing not performed routinely
  - Unregulated
- **Plant-derived terpenes**
  - Proprietary formulas; often including carrier oils
  - Unregulated
- **Vape cartridges and devices**
  - Heavy metals leaching
  - Heat variation
  - Unregulated

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# Vape Lung Injury and Cannabis Regulation

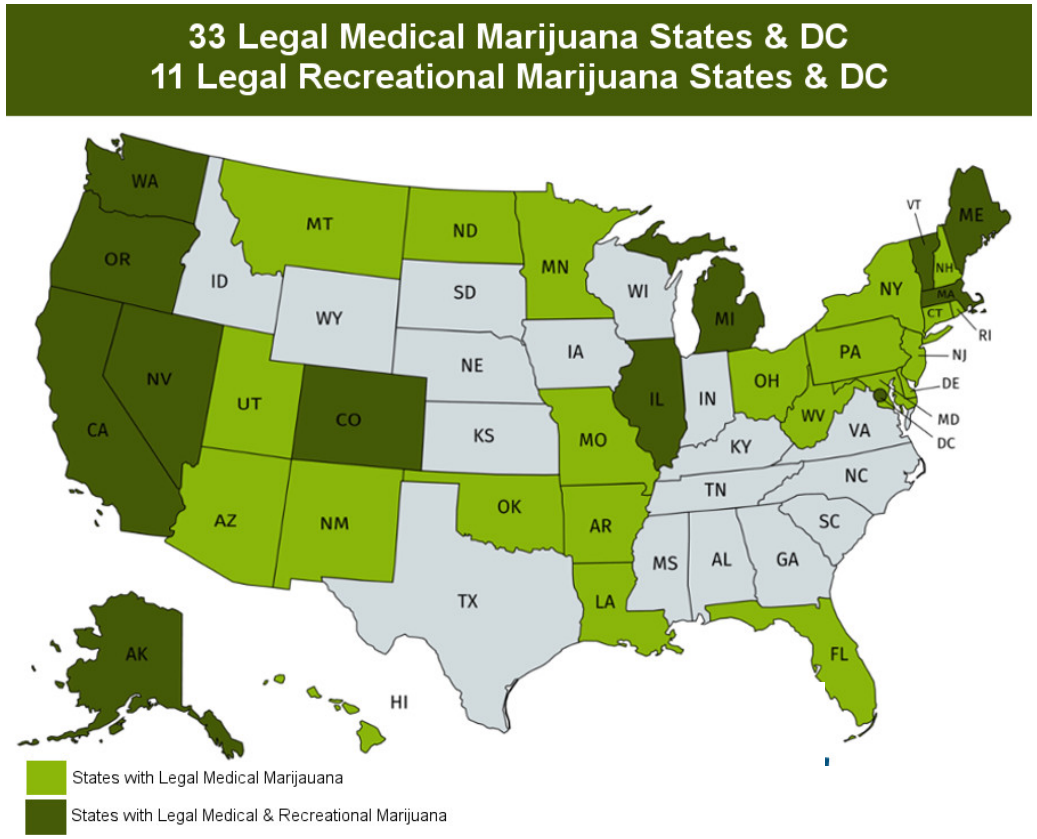
## Regulatory Approaches:

- Flavor bans/requirements

(CO, NY, HI, WA, OH, ND)

- Excipient restrictions

(CO, MD, MA, MI, OH, OR, WA)

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# Vape Lung Injury and Cannabis Regulation

**MMCC's Action Plan:**

- **Banned Vitamin E Acetate**
  - Bulletin 2019-013 "MMCC Expands Compliance Testing and Bans Vitamin E Acetate in Medical Cannabis Vape Products
  - Updated the Technical Authority for Medical Cannabis Testing
  - Required all vape cartridges to be tested for detection of Vitamin E Acetate before product hold was lifted

- **Performed landscape analysis of manufacturing facilities**
  - Survey sent to licensed processors regarding manufacturing protocols

- **Issued an RFP for expanded laboratory testing on vape cartridge retention samples**
  - Currently in the process of testing retention samples for additional excipients/diluents

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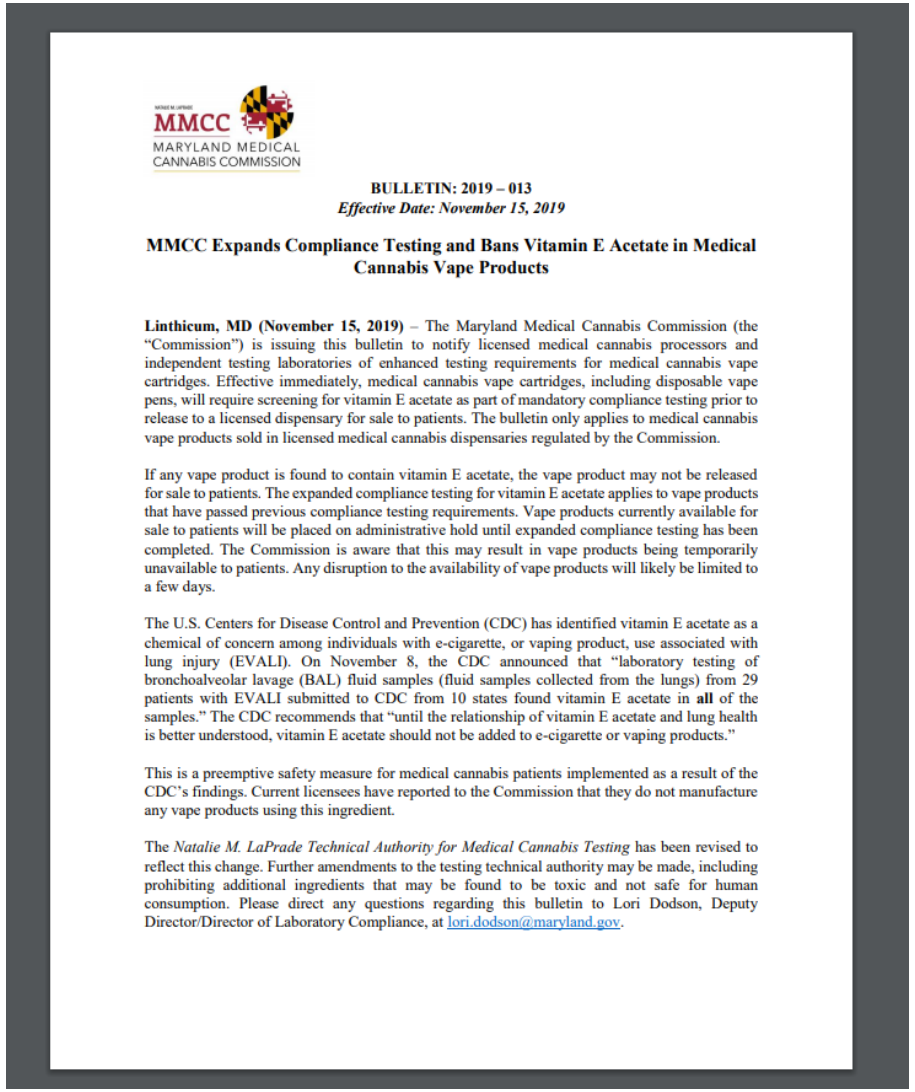
# Vape Lung Injury and Cannabis Regulation

- Banned Vitamin E Acetate
  - COMAR 10.62.23.04
    - Landscape analysis of licensed processors
    - Technical Authority for Medical Cannabis Testing
    - Temporary vape cartridge administrative hold



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**BULLETIN: 2019 – 013**
***Effective Date: November 15, 2019***

**MMCC Expands Compliance Testing and Bans Vitamin E Acetate in Medical Cannabis Vape Products**

**Linthicum, MD (November 15, 2019)** – The Maryland Medical Cannabis Commission (the "Commission") is issuing this bulletin to notify licensed medical cannabis processors and independent testing laboratories of enhanced testing requirements for medical cannabis vape cartridges. Effective immediately, medical cannabis vape cartridges, including disposable vape pens, will require screening for vitamin E acetate as part of mandatory compliance testing prior to release to a licensed dispensary for sale to patients. The bulletin only applies to medical cannabis vape products sold in licensed medical cannabis dispensaries regulated by the Commission.

If any vape product is found to contain vitamin E acetate, the vape product may not be released for sale to patients. The expanded compliance testing for vitamin E acetate applies to vape products that have passed previous compliance testing requirements. Vape products currently available for sale to patients will be placed on administrative hold until expanded compliance testing has been completed. The Commission is aware that this may result in vape products being temporarily unavailable to patients. Any disruption to the availability of vape products will likely be limited to a few days.

The U.S. Centers for Disease Control and Prevention (CDC) has identified vitamin E acetate as a chemical of concern among individuals with e-cigarette, or vaping product, use associated with lung injury (EVALI). On November 8, the CDC announced that "laboratory testing of bronchoalveolar lavage (BAL) fluid samples (fluid samples collected from the lungs) from 29 patients with EVALI submitted to CDC from 10 states found vitamin E acetate in **all** of the samples." The CDC recommends that "until the relationship of vitamin E acetate and lung health is better understood, vitamin E acetate should not be added to e-cigarette or vaping products."

This is a preemptive safety measure for medical cannabis patients implemented as a result of the CDC's findings. Current licensees have reported to the Commission that they do not manufacture any vape products using this ingredient.

The *Natalie M. LaPrade Technical Authority for Medical Cannabis Testing* has been revised to reflect this change. Further amendments to the testing technical authority may be made, including prohibiting additional ingredients that may be found to be toxic and not safe for human consumption. Please direct any questions regarding this bulletin to Lori Dodson, Deputy Director/Director of Laboratory Compliance, at lori.dodson@maryland.gov.

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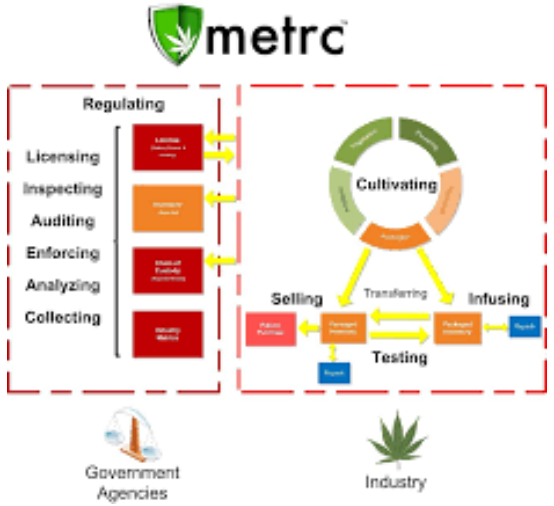
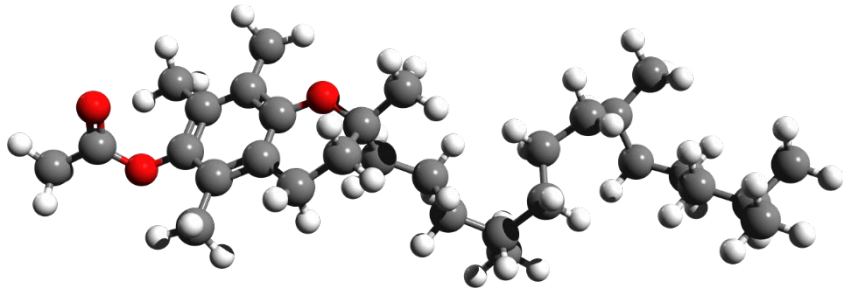
# Vape Lung Injury and Cannabis Regulation

- Product Testing
  - Administrative Hold
  - Sample Collection and Analysis (retention samples)
  - Product Release







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# Questions?

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