

Food, Cannabis, Dietary Supplements and ISO 17025





For food manufacturers, 17025 accredited testing is often the first requirement to bring product to market.

- Consumer safety!
- FSMA
- Lack of conformity in state/regulatory agencies



Ensure products are being tested using scientifically sound, validated test methods that are appropriate (fit for use) to the product being tested.

- Complications of sample matrix

Similarities between Food/Cannabis/Dietary Supplements testing

- Matrix concerns and challenges
- AOAC Guidelines (covers all 3)
- Regulatory/stakeholder involvement and enforcement. (States for Cannabis & food; FDA for food and/or dietary supplements)
- Consumer Safety!



Validity of Results – confidence in the marketplace

- Laboratory has a well-established quality system and practices.
- Method validations/verifications
- Equipment: qualification, verification, and calibration.
- Technical competency
- QA/QC
- Interlaboratory comparisons (PT)



In addition to ISO 17025, ABs offer specialized requirements to meet industry/regulatory needs.

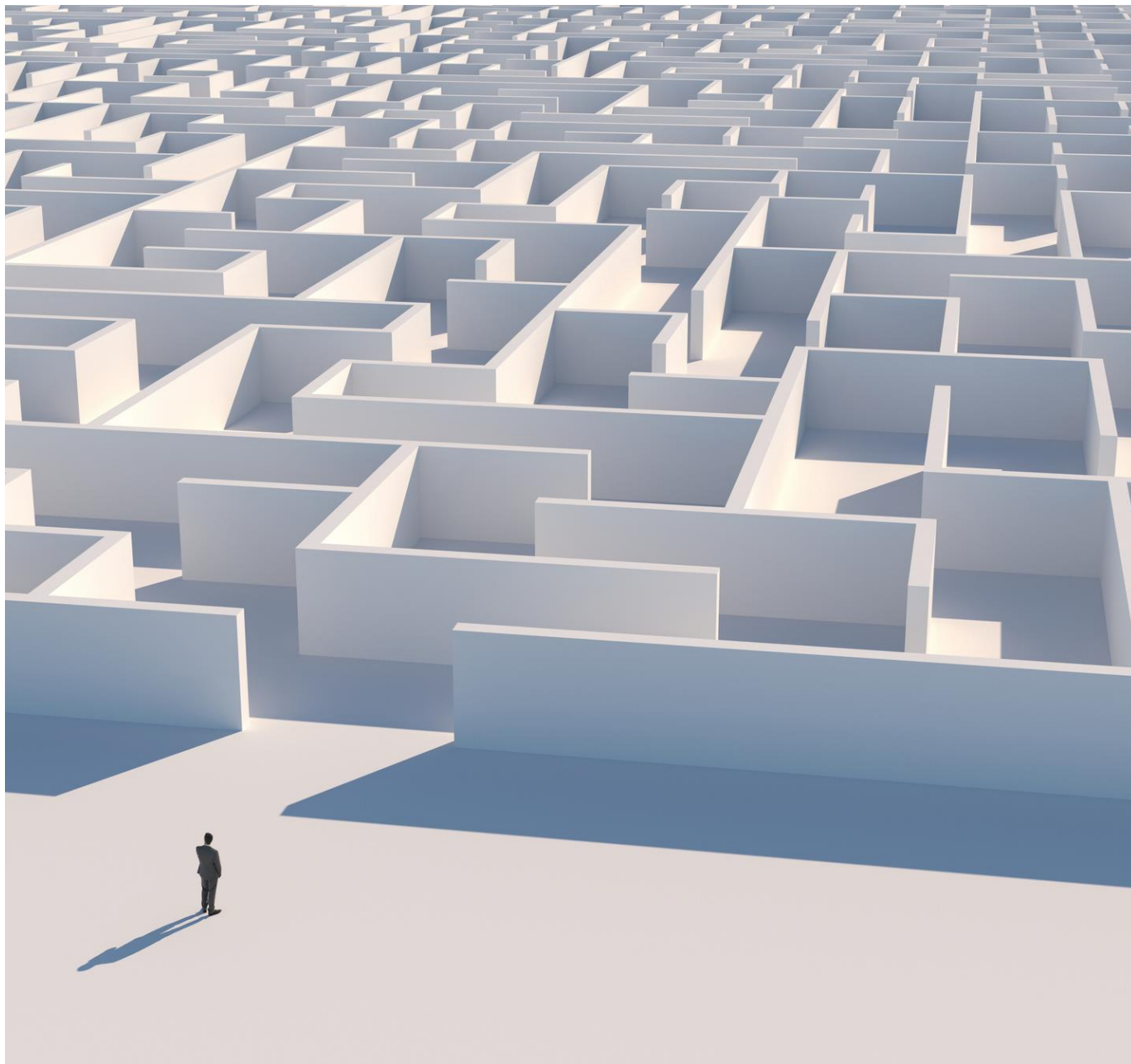
- AOAC (Food, Cannabis, Dietary Supplements and Pharmaceuticals) – MI CRA and Cannabis/Hemp program
- ACIL Guidelines for Cannabis Testing
- AAFCO (Animal and Pet feed)
- GRMA (Dietary Supplements)
- ACIL Guidelines for Dietary Supplements
- FDA LAAF (Laboratory Accreditation for the Analysis of Foods)





LAB SHOPPING

- Dangers to industry
- Food vs Cannabis



Future challenges

-Regulatory with cannabis market

The Cannabis Regulatory Landscape (From a Technical Perspective)

Lori Dodson, MS, MT(ASCP)

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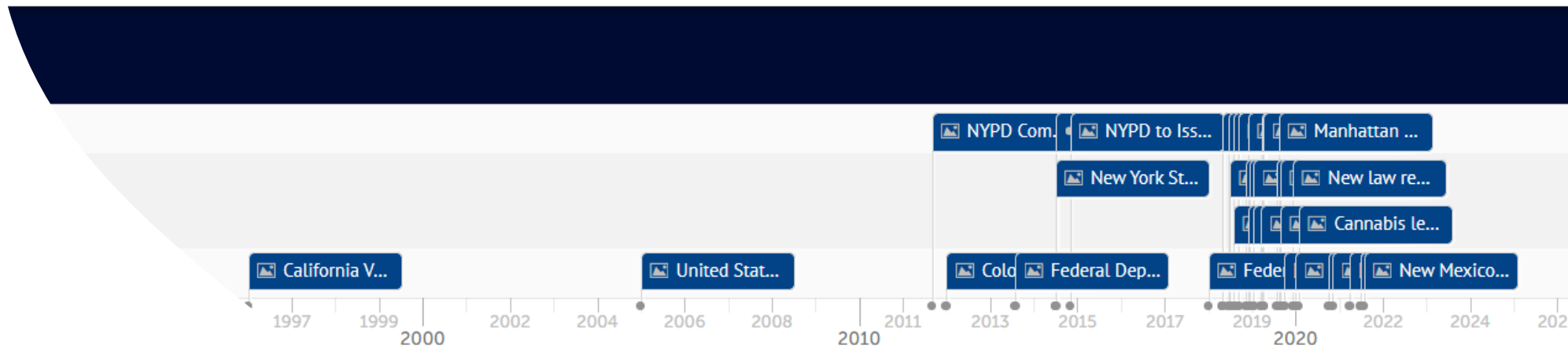
Heather Krug, MS

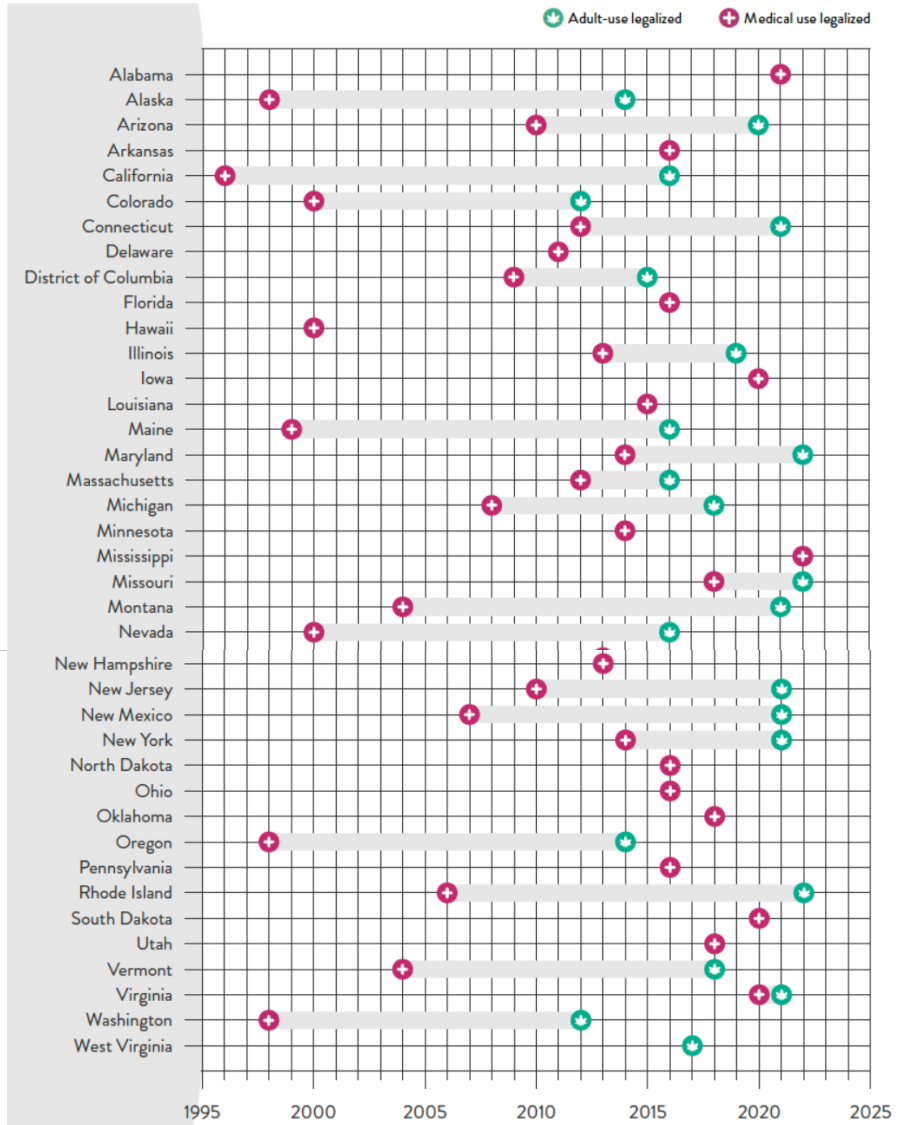
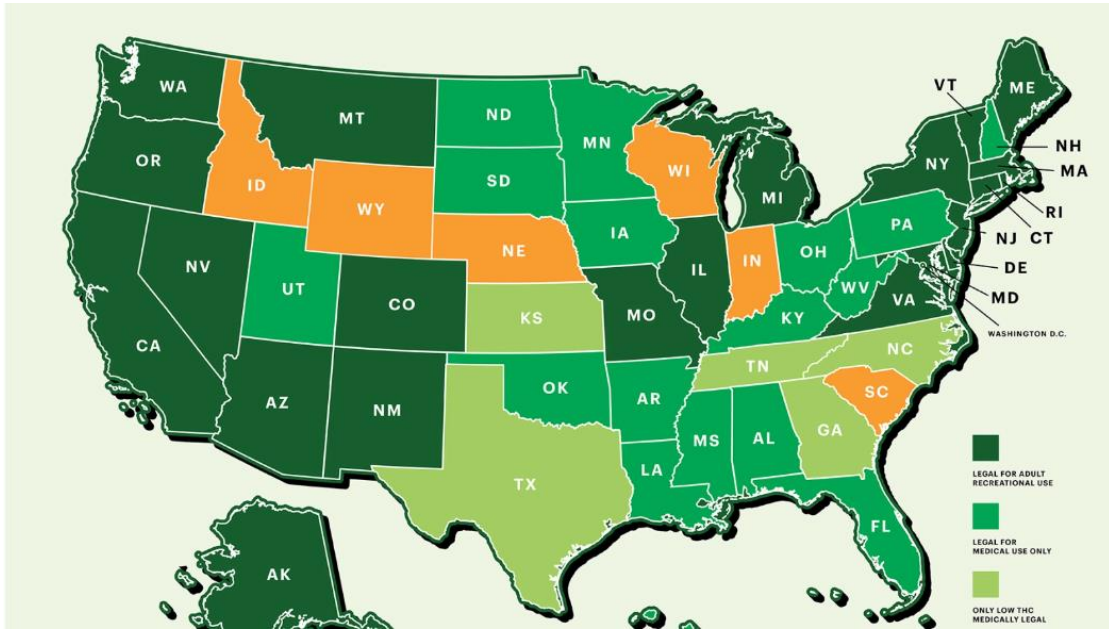
Regulatory Programs
Branch Chief, Colorado
State Public Health
Laboratory

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Cannabis Regulatory Landscape: A Snapshot in Time



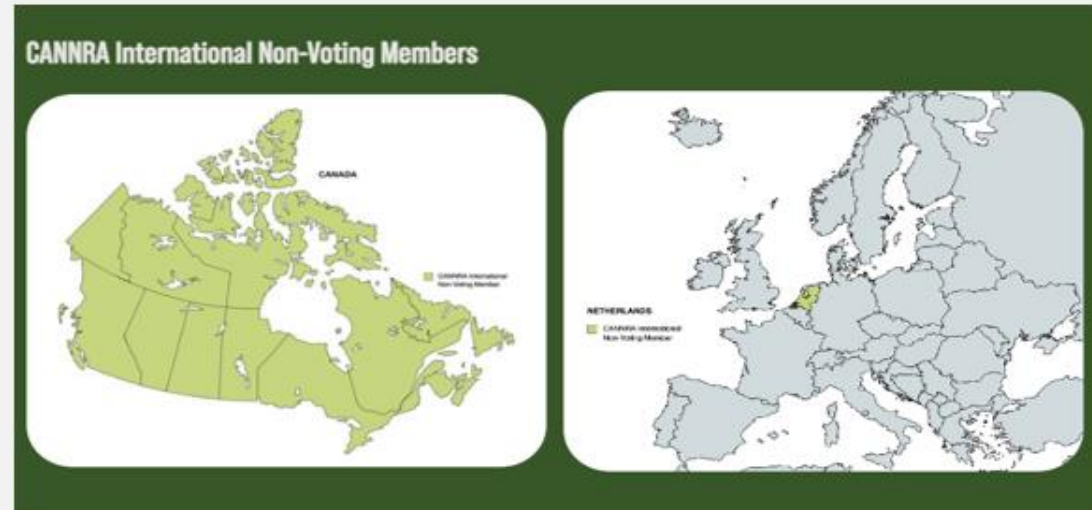


CANNABIS REGULATORS ASSOCIATION (CANNRA)

Our mission is to convene, educate, and support governmental jurisdictions responsible for implementing cannabis and cannabinoid policies and regulations. We do this by fostering collaboration and coordination to identify and share best practices that safeguard public health and consumer safety, promote equity, and create regulatory certainty for industry participants.

Members:

- 45 States and US Territories
- Canada
- The Netherlands



CANNRA'S WORK



POLICY
TRACKING



TOPICS BASED
COMMITTEES



REPORTS AND
FACTSHEETS



MONTHLY
WEBINARS



IN-PERSON
MEETINGS



**CANNRA Lab
Testing and
Product Safety
Subcommittee**

SUBCOMMITTEE MEMBERS:

127 MEMBERS

36 STATES, CANADA, THE NETHERLANDS

WORKING GROUPS:

TECHNICAL CALLS

WEBINARS

POLICY/TESTING TRACKER

TESTING STANDARDIZATION (LEGACY)

EXAMLES OF OUTREACH:

AOAC

USP

ASTM

ISO ACCREDITING BODIES

Additional Challenges to Cannabis Innovation

The Pace of the Industry

- Lab Testing Standardization remains a challenge, but states are effectively moving forward

Increased use of non-cannabis additives in products

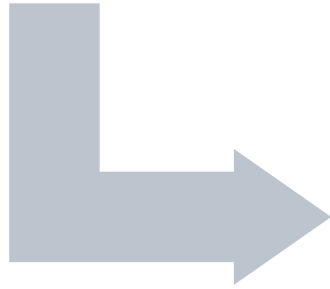
Lack of data

- Shelf stability and expiration dating
- Safety thresholds for contaminants based on modes of consumption

Inability for state regulators to test products in a reference lab environment

Pace of
industry
(slow)

- Lack of standard test methods
- ISO 17025 Accreditation
- State Certification/Accreditation



Development

- AOAC SMPRs & Test Methods
- ASTM test methods



Continued
Advances

- ALACC Guidelines
- ACIL Guide

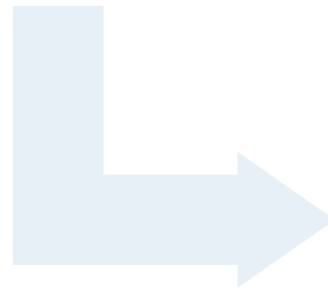
Pace of
industry
(fast)

- New product type, formulation, manufacturing process/practice



Regulatory
restrictions

- Limit solvents
- Limit decontamination or remediation techniques



Don't stifle
improvement!

- Process to modify restrictions

Good Manufacturing Practices

Food?

21 CFR 117

Hazard prevention &
Risk-based preventive
controls

- Prevent contamination and ensure food is safe to eat

Drug?

21 CFR 210 & 211

Master production & control
records
Batch production & control records
Laboratory records.
Process Validation

- Assure identity, strength, quality and purity of drug

Dietary Supplement?

21 CFR 111

Process controls:
Manufacturing
Packaging
Labeling

- Ensure quality (consistent outcome)
- Free from contamination
- Label accuracy

CAPA

- January 1, 2021
- All business types

Specific requirements for certain products

- Audited products
 - Master formulation records
 - Batch manufacturing records
 - Ingredient quality specifications
- Third-party audit

HACCP

- July 1, 2024
- RTA microbial testing – cultivation
- ASTM D8250-19

Additives

- Terpenes
- Vape diluents
- Herbal supplements

Monitor & Research

- No VEA/MCT oil
- Voluntary removal

Regulatory action

- Reg update
- Product recall
- Adverse health event reporting

- Shelf stability
- Expiration date

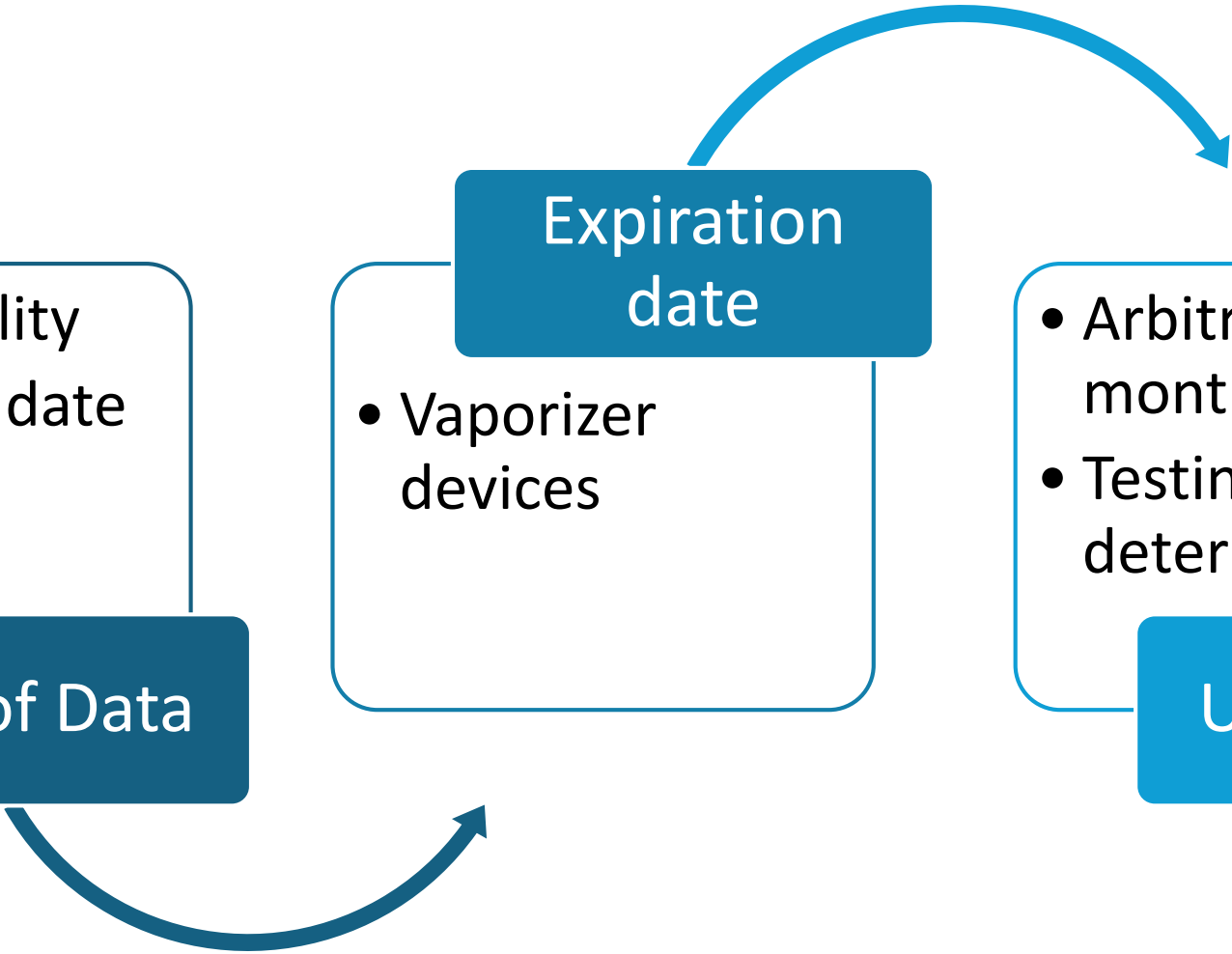
Lack of Data

- Vaporizer devices

Expiration date

- Arbitrary 9 months, or;
- Testing determined

Use by date



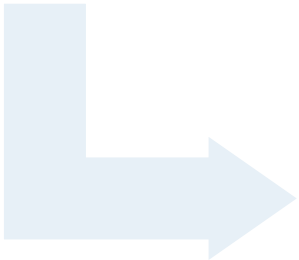
Lack of data

- Mode of administration



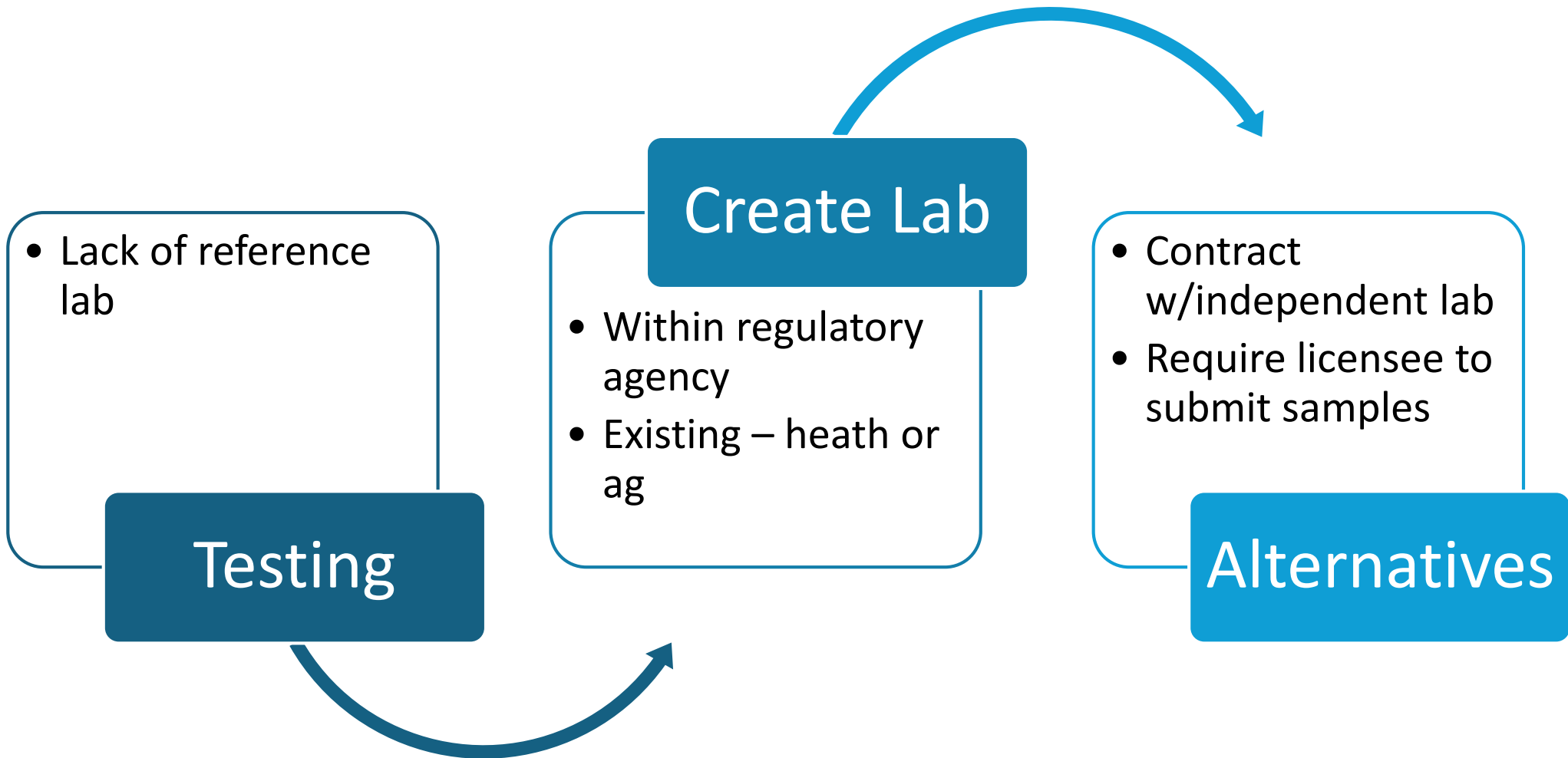
Oral
Inhaled
Skin & Body
Audited

- Consider risk created



Analogous
product

- USP
- Food





Industry Perspective

Kathy Knutson, Ph.D.

Kathy Knutson Food Safety Consulting LLC
Food Safety Summit 2024
Rosemont, IL

Working In the Cannabis Industry

- Personal journey as a food microbiologist and patient
 - There will always be opportunities in the cannabis industry.
- My field trips
 - Wisconsin product sold in a Missouri cannabis boutique
 - Georgia first state to allow cannabis sales in pharmacies
- Qualifying medical condition
 - Texas (2024), n = 9 + medical research
 - Florida, n = 10 + terminal condition + chronic nonmalignant pain
 - Oklahoma, no specific qualifying conditions

Professional Associations to Watch

CANNRA

National Cannabis Industry Association

ASTM International D37 Cannabis Committee

- 2023 International symbol
- 2024 Draft GMP standard
- 2024 Workshop on sensory analysis of cannabis
- 2024 Working group on sanitation

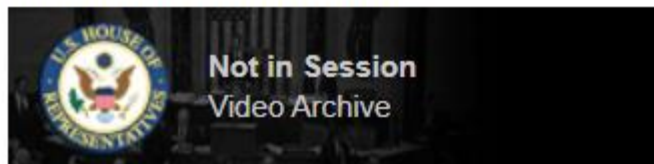


What is the FDA doing?

- Center for Drug Evaluation and Research (CDER)
 - Norman Birenbaum, Senior Public Health Advisor
 - Pathway for pharmaceutical drugs
- Center for Food Safety and Applied Nutrition (CFSAN)
 - CBD and THC are not dietary supplements
 - CBD and THC are not approved food additives
- An Act of Congress



House of Representatives



Senate



Hemp Derivatives and Isomers: Exploitation of an Unintended Loophole



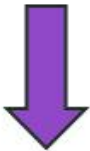
Christopher Hudalla PhD

ProVerde Laboratories – Milford, MA

Conversion of CBD into THC



Dissolve in solvent



Add Acid



Reflux

↑Temp



Neutralize Acid



Remove Solvent

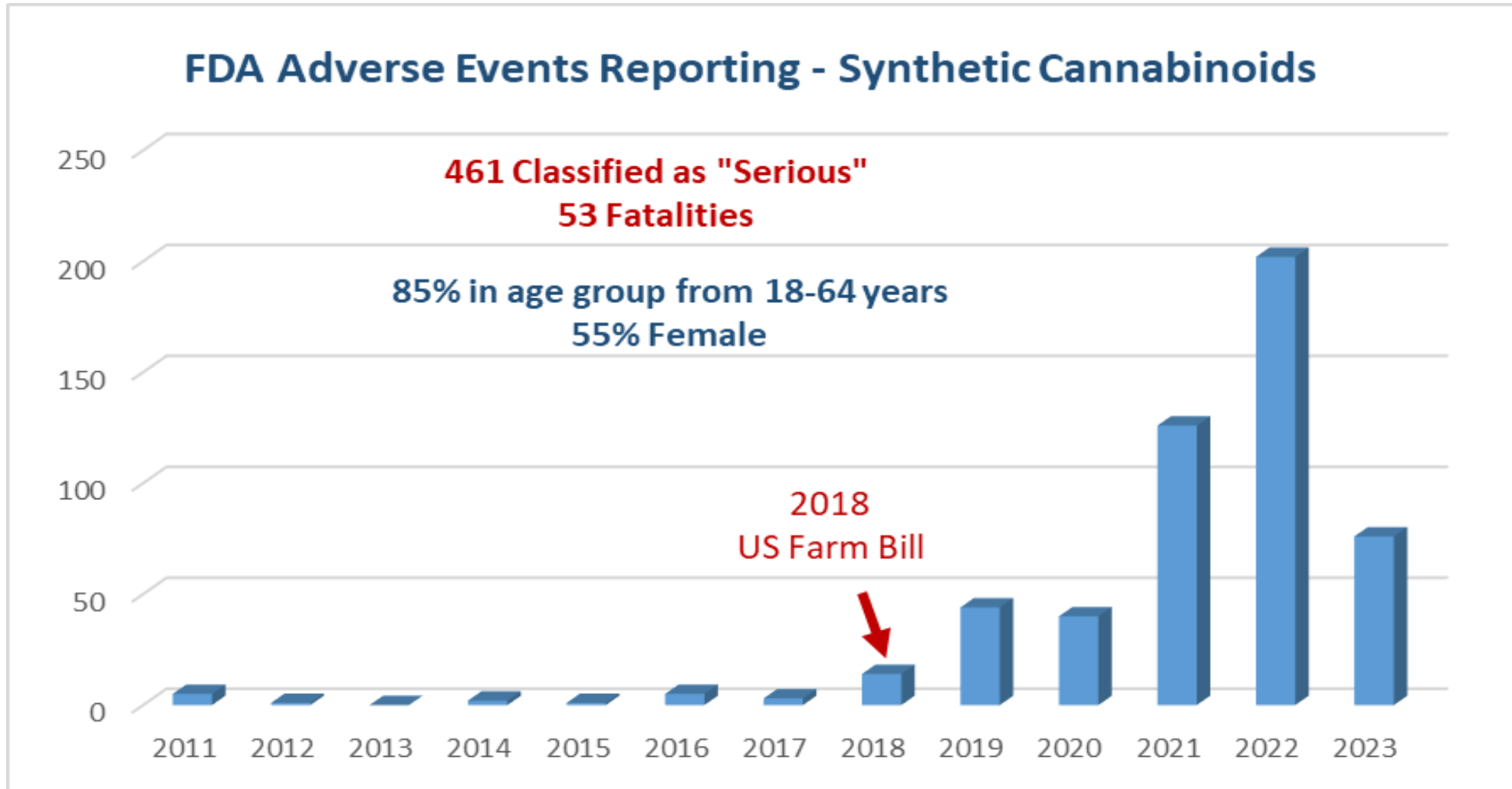


What Is the Safety of Cannabinoids?

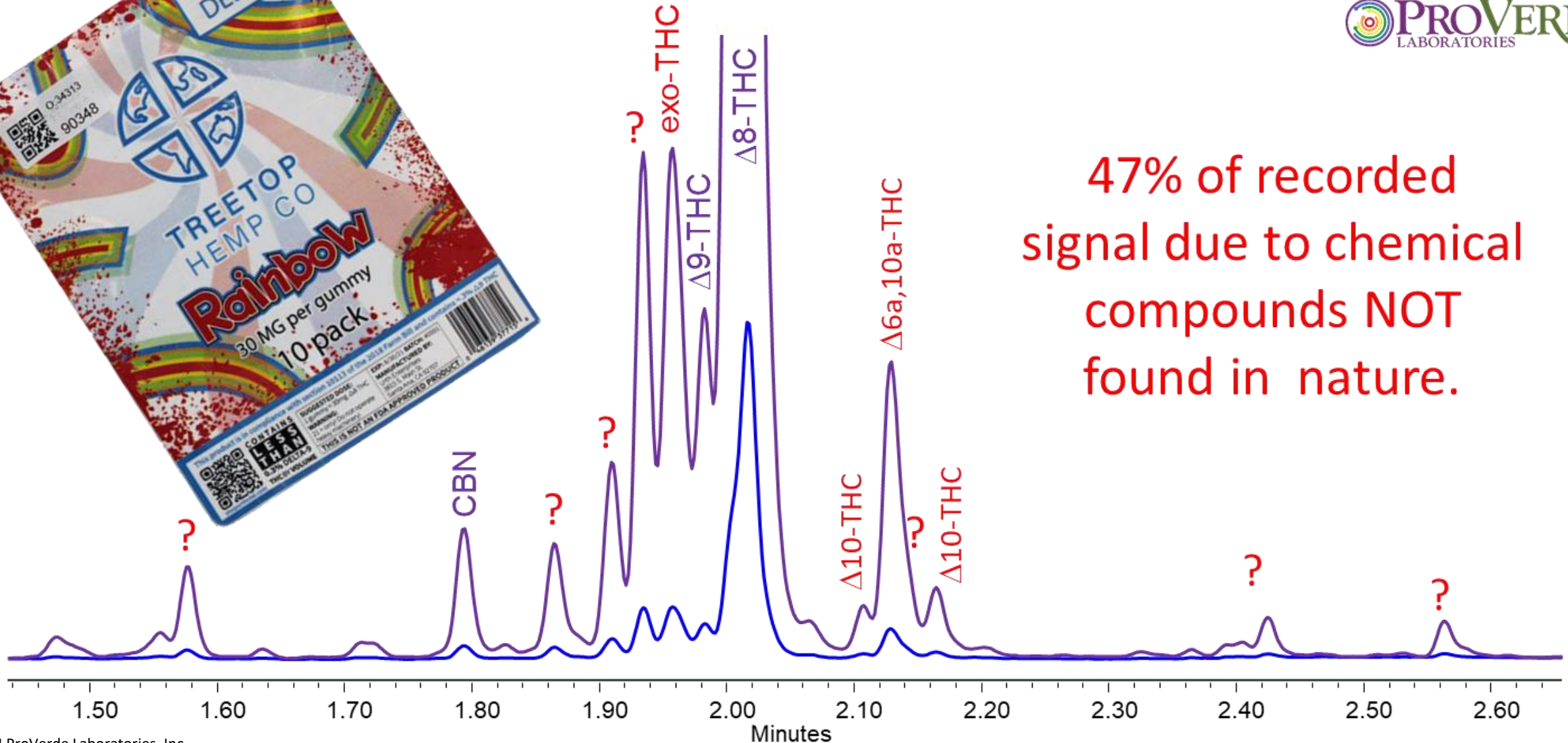
- Cannabis
 - Entourage effect
 - Isolates
- Hemp
 - 2018 USDA Farm bill
 - Hemp-derived compounds
- Unknown synthetic compounds



Regulatory and Consumer Safety Groups



Tree Top Gummies



47% of recorded signal due to chemical compounds NOT found in nature.

Positive Notes

- SOPs, GMPs, QMS, HACCP, PCQIs
- The majority of citizens want federal legalization.
 - The federal government must write and pass legislation.
- Lab method development
- Proficiency testing programs
- Sensory analysis and stability testing
- Creative, entrepreneurial spirit



What questions do you have?

Our Speakers:

- Lori Dodson
 - Lori.dodson1@maryland.gov
- Heather Krug
 - Heather.krug@state.co.us
- Roger Muse
 - Rmuse@anab.org
- Kathy Knutson
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Thanks Michael Wood for organizing this group again this year!



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