# A Tale of Two and a Half Laboratories: A Case Study

Thuy Vu, Thuy Vu Consulting LLC Kevin Armbrust, Louisiana State University

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## Thuy Vu Consulting LLC



## **Kevin Armbrust Lousiana State University**



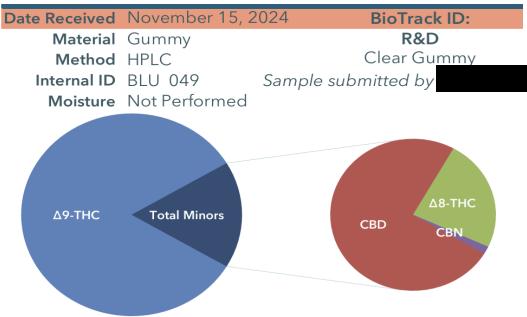
# A Tale of Two and a Half Laboratories: A Case Study

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### Case Background

- Multi-state cannabis testing laboratory: 3 States
- Provides full-panel cannabis testing
- Main lab:
  - A2LA accredited (ISO 17025)
  - ILAC-MRA
  - DEA registered to handle Schedule 1 substances (Hemp)



	Method	mg/g sample	Cannabinoid
Total THC	HPLC	3.1	Δ9-THC
0.308%	HPLC	<0.1	Δ9-THCa
	HPLC	0.15	Δ8-THC
Total CBD	HPLC	0.47	CBD
0.047%	HPLC	<0.1	CBDa
	HPLC	<0.1	CBG
	HPLC	<0.1	CBGa
	HPLC	0.01	CBN
Total Cannabinoids	HPLC	<0.1	CBC
0.372%	HPLC	<0.1	Δ6a,10a-THC
	HPLC	<0.1	Δ10-THC
	HPLC	<0.1	Δ9-THCP
	HPLC	<0.1	CBDV
mg/g sample		3.7	TOTAL

### The Investigation

- On November 15, 2024, the State Regulatory Agency was notified that samples were dropped off at a separate licensed lab for R&D residual solvent and terpene analysis, specifically requesting no potency testing of samples.
- On November 18, 2024, an annual inspection was conducted. It was determined that the Lab did not possess the necessary equipment at its licensed facility to conduct cannabis testing in the manner for which it was approved.
- On November 18, 2024, a referral was submitted for a Notice of Contemplated Action (NCA) against The Lab.
- On November 18, 2024, the Director issued a written Notice of Violation to the Lab, communicating that the knowing transfer of cannabis products across state lines was a violation of federal law and that The Lab should cease this violation of federal law.
- At that time, The Lab claimed they had been provided authorization to engage in cannabis sample testing at their DEA Schedule 1 Analytical Testing Laboratory in another state.

### The Violations

- Improper Storage of Cannabis Samples for Testing
- Improper Storage of Reagents and Solutions & Improper Equipment Record Keeping
- Failure to Maintain Testing Laboratory Premises
- Falsifying Required Data Reporting For The Testing Of Cannabis Products
- Improper Entry of Cannabis Samples for Testing into the State Mandated Track and Trace System
- Failure to Maintain the Results of Laboratory Tests
   Conducted on Cannabis Product for a Period of Two Years
   and Other Materials Required to be Maintained on the
   Premises
- Failure to Submit Initial Demonstration of Capabilities for Material Changes to Cannabis Testing Laboratory Testing Methods
- Failure to Establish Required Testing Laboratory Training Policies and Procedures
- Failure to Maintain Required Employee Training
- Failure to Maintain Digital Video Surveillance

#### Shipping

Thursday, August 31, 2023

12:03 PM

#### Packing

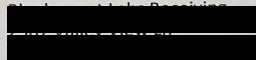
- Wrap top of vials and tubes with small piece of parafilm
- Group by test type and place in vacuum seal bag in order of sample
- Place open end in vacuum seal machine and press start
- Remove once seal strip has cooled
- Write sample IDs on outside of bag (on top of corresponding vial/to
- Write test type and sample ID range
- Place inside envelope or box with sufficient packing material

#### Paperwork

- Include copies of COCs associated with each sample. (fold in half)
- Print 1 vial label for each sample and attach to COC packet with pa
- Include copies of bench sheets for each test type (fold in half)

#### **Printing Shipping Labels**

- Go to Stamps.com <a href="https://print.stamps.com/SignIn/">https://print.stamps.com/SignIn/</a> and sign in
- Go to MAIL tab
- Ship to:



- Select USPS PME (Priority Mail Express) Flat Rate Envelope or Pa
- Select weight (estimate ok)
- Print label and tape to package or box

#### Notify TX lab

- Post sample IDs and tracking info on shipping channel on Slack

### **Administration Action**

- On January 9, 2025, a NCA was issued addressing the facts, evidence, alleged violations of law, and potential administrative penalties that may be imposed.
  - The State Regulatory Agency requested The Lab grant access to the State Regulatory Agency staff for an inspection of the sister facility where samples were sent on Wednesday, January 15, 2025.
  - The Lab indicated that the proposed date was generally acceptable but stated they would need to confirm with their business partner. Following this communication, travel arrangements were made to conduct the inspection of the sister facility.
- On January 14, 2025, The Lab indicated via phone they would not allow the State Regulatory Agency into their sister lab to review the testing equipment and procedures.
- On January 25, 2025, A Petition for Temporary Restraining Order and Preliminary Injunction was submitted.
- On February 12, 2025, A Temporary Restraining Order and Preliminary Injunction was granted.
  - The State Regulatory Agency made multiple attempts to coordinate with the Lab to conduct an inspection of the sister lab where The Lab asserts cannabis testing was performed.
- On March 6, 2025, Administrative Hearing scheduled.
- On March 27, 2025, Settlement Agreement reached.

# Temporary Restraining Order & Preliminary Injunction

- The Lab's actions pose a clear and immediate danger to public health and safety.
- Without failed test results, the State Regulatory Agency lacks an adequate administrative remedy to prevent the sale or distribution of cannabis products associated with potentially non-compliant testing, necessitating judicial intervention.
- The balance of hardships favors the issuance of a temporary restraining order and preliminary injunction, as the potential harm to consumers who may unknowingly purchase and consume untested, or unsafe cannabis products outweighs any financial or operational harm to The Lab.

# The Lab is hereby ORDERED to immediately cease all commercial cannabis activities

- Any cannabis product tested or certified by The Lab shall be placed on immediate administrative hold. No such products shall be sold, transferred, or otherwise introduced into the commercial cannabis market until:
  - a. The product's parent lot id or other representative samples undergoes a separate independent retesting by a state licensed cannabis testing laboratory, and is confirmed to meet applicable health and safety equipment; and
  - b. The Lab shall submit to an inspection conducted by the State Regulatory Agency at its testing lab facility located in another state within ten (10) days of the issuance of the Order.
- The State Regulatory Agency provided notice to all licensed cannabis producers, manufacturers, and retailers regarding this Order. Licensees in possession of cannabis products certified by The Labs must immediately cease sale or distribution of those products and take appropriate steps to comply with the directives regarding product verification.
- The State Regulatory Agency is authorized to take all necessary actions to enforce this Order, including administrative measures to suspend Track and Trace IDs for affected cannabis products and ensure compliance by licensees.

### Statutory Authority

- The State Regulatory Agency's statutory authority related to the control of cannabis products on the market is limited to a RECALL.
- Only applies when a tested batch of cannabis product has a result that indicates noncompliance with applicable health and safety standards.
- May only issue a recall order when a Certificate of Analysis (COA) indicates a failure to meet one or more of the required testing standards for the specific product type being sold.

### **Preliminary Injunction**

- For a preliminary injunction to issue, the Petitioner must show that
  - "(1) the [Petitioner] will suffer irreparable injury unless the injunction is granted;
  - (2) the threatened injury outweighs any damage the injunction might case the [Respondent];
  - (3) issuance of the injunction will not be adverse to the public's interest; and
  - (4) there is a substantial likelihood [Petitioner] will prevail on the merits."
- "When a board finds that evidence in its possession indicates that a licensee poses a clear and immediate danger to the public health and safety if the licensee continues to practice, the board may seek a preliminary injunction from the district court in the county in which the principal office is located.
- If the injunction is granted, the board shall hold an expedited hearing for the suspension of the license or probation of the licensee.



### Settlement Agreement

- Revocation of license
- Ineligibility to apply for or have controlling interest in cannabis license in this state for 3 years.
- \$70,000 penalty

# Legal Risks & Ethical Breakdown



- State licensing violations
- Violations of CSA (Controlled Substances Act)
- Potential federal enforcement

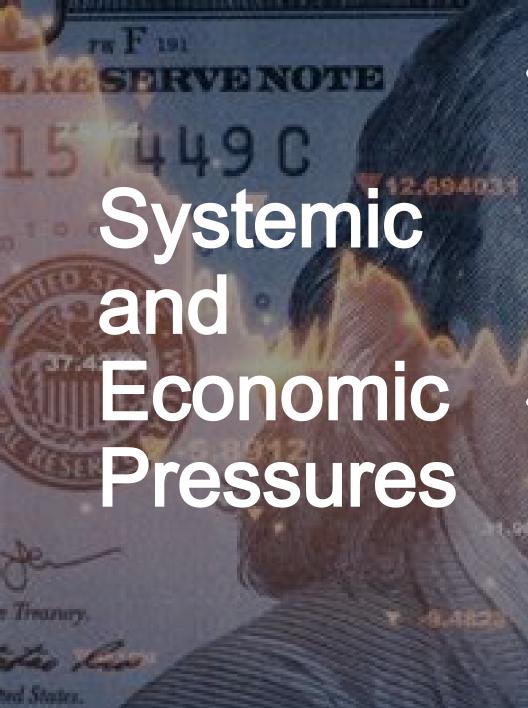
- Trust and transparency in lab results
- Professional responsibilities of lab directors and analysts
- Conflict between business viability and public protection



### Public Health Risks

- Risk of contaminated or mislabeled products reaching consumers
- Loss of consumer trust in state-legal cannabis markets



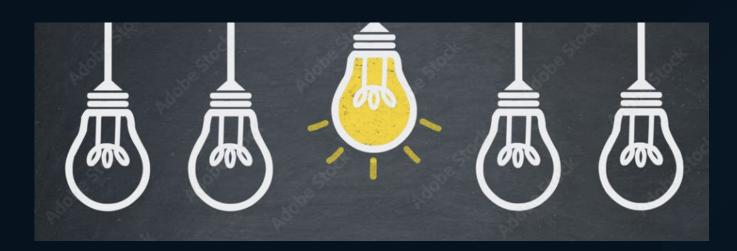


- Why Did This Happen?
  - Financial burden of operating multistate labs
  - Staffing shortages
  - High cost of validated methods, equipment, and certifications
- Regulatory Fragmentation
  - Patchwork state laws
  - No federal standard or oversight
  - Labs trying to survive within inconsistent frameworks

# The Bigger Picture

- Bigger Picture Questions
  - Can the current system protect consumers?
  - Are states equipped to handle these investigations on their own?
  - Should testing labs be federally regulated?
- A Case for Federal Legalization
  - Unified testing standards
  - Federal lab certifications
  - Improved enforcement and data sharing between states

# Lessons Learned & Policy Solutions



#### **Lessons Learned**

- Compliance is essential—even when it's inconvenient
- Regulators need tools, cooperation, and standards
- Consumers are the ultimate stakeholders

### Call to Action

- For industry: prioritize ethics and quality
- For regulators: push for federal standardization
- For policymakers: consider legalization as a public safety measure







## 2025 Rocky Mountain Food Safety Conference

WHEN: August 25-26, 2025

#### WHERE:

Adams County Government Center 4430 South Adams County Parkway Brighton, CO 80601

https://rmfoodsafety.org/

# THANK YOU! Please join AFDO's Cannabis Committee

Thuy Vu

Thuy Vu Consulting

thuy@thuyvuco.com

720-634-5534

Instagram: @thuyvuco

Kevin Armbrust

Louisiana State University

Armbrust@lsu.edu

office: (225)578-3030

Cell: (662)418-9458