

WEBINAR

Recent Developments in Cannabis Products and Laboratory Litigation

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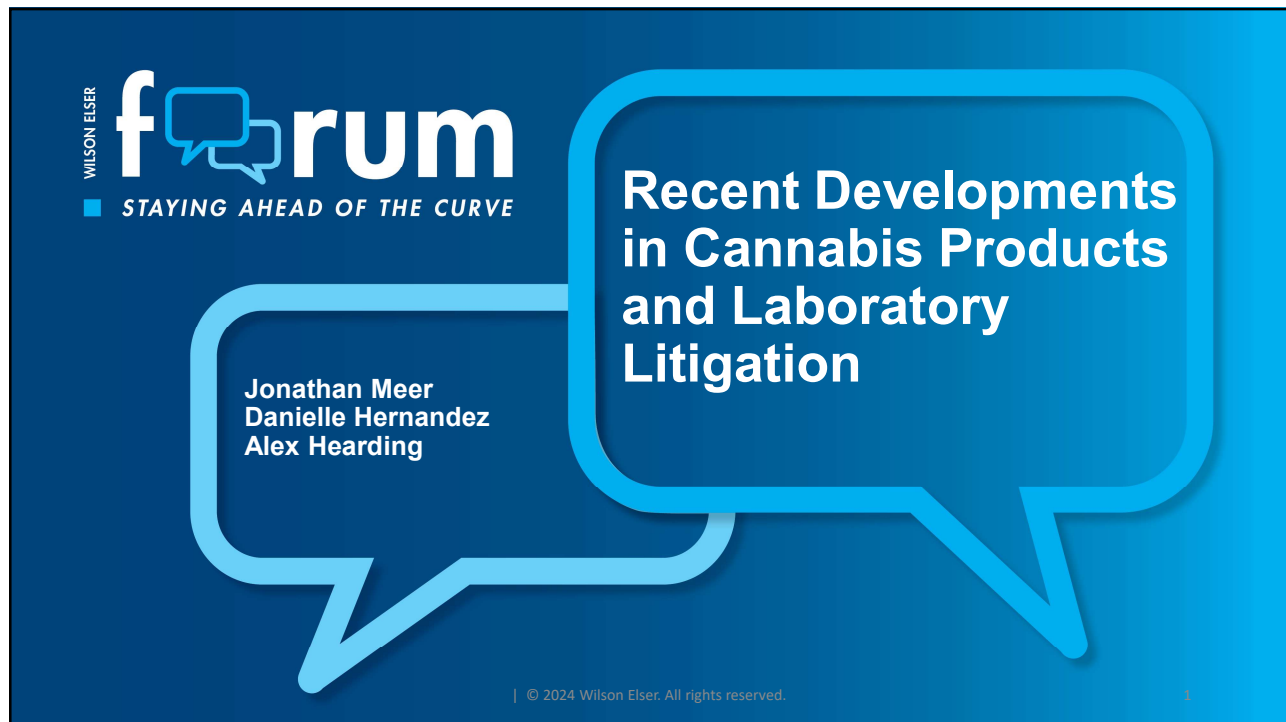
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**Recent Developments
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General Issues As To Claims Involving Cannabis Testing and Label Failures



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- The importance of uniform testing standards has been made more apparent by recent reports of negligence and even fraud committed by cannabis testing laboratories in multiple states.
- Issues as to Lab Shopping and Cherry-Picking the samples which can lead to biased and/or manipulated lab results.
- Varying Methods and Equipment
- Limit of Detection Problem
- Continued Concern on Label Inaccuracies

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Product Protection Pyramid

The diagram is a pyramid with four levels, each with a corresponding color and description. To the left of the pyramid is a vertical bar with a red arrow pointing upwards, indicating increasing complexity or importance. The levels are:

- Agency Level Program (Red):** Health Risks and Benefits
- Production Level Program (Orange):** Risk Analysis Product Testing and Health Surveillance
- Hazard Analysis and Critical Control Point (Yellow):**
- Most Common (Green):** Good Production Practices

Types of data collected, evaluated and combined in a risk assessment:

- Sources/Hazards (contaminants, pesticides, microbes or active ingredients)
- Health effects/consequences/adverse events associated with each hazard
- Exposure which involves sampling of products to determine concentrations of ingredients/contaminants and human exposure through use of the target product.

management system designed to ensure product quality from production to consumption.

growers and processors implement good practices (maintaining growing facilities, appropriate use of insecticides, etc).

Guidance for State Medical Cannabis Testing Programs – Association of Public Laboratories May 2016

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Dealing with THC

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- THC (and other cannabinoids) are metabolized to other compounds and how the native plant or extract is consumed alters the biochemistry and the biological result. THCA needs to be decarboxylated into $\Delta 9$ -THC before consumption to achieve certain biological effects.
- Though cannabis contains more than 150 cannabinoids, delta-9-tetrahydrocannabinol ($\Delta 9$ -THC) has received the most attention since it is the principal psychoactive component of the plant. Other analytes often required for analysis include cannabidiolic acid (CBD-A), cannabigerolic acid (CBGA), cannabidiol (CBD), cannibigerol (CBG), tetrahydrocannabinol acid (THCA), cannabinol (CBN) and delta-8-THC ($\Delta 8$ -THC).

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Example Testing for THC



- In Oregon, the rule requires testing for THC, THC-A, CBD, and CBD-A. Due to the potential of THC-A decarboxylizing into Δ 9-THC during sample processing and analysis, a total THC amount must be calculated,³⁶ where M is the mass or mass fraction of Δ 9-THC or Δ 9-THCA:
 - $M_{\text{total } \Delta 9\text{-THC}} = M_{\Delta 9\text{-THC}} + 0.877 \times M_{\Delta 9\text{-THCA}}$
- Total CBD must also be calculated, where M is the mass or mass fraction of CBD and CBDA:
 - $M_{\text{total CBD}} = M_{\text{CBD}} + 0.877 \times M_{\text{CBDA}}$
- Oregon acknowledged that as seen analytically, the mass ratio scenario is not perfect. They expect the equation for calculating Total THC to change after data is produced

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Type of Cannabis for Product Testing



- **Pill/Capsule** - Testing would be similar to other extracts, in addition to testing for any potentially harmful materials frequently tested for in the pharmaceutical industry
- **Tincture** - Testing would be similar to extract testing and possibly verifying alcohol content
- **Spray** - similar to tinctures above or extract oils below.
- **Creams / Oils/ extracts for vaporizing** - Extracts should commonly be tested for active ingredients; residual extraction solvents (hydrocarbons or other); mycotoxins; any pesticides not typically removed in the extraction process; any biological that might be introduced after extraction but before final packaging; and heavy metals (depending on the grow medium).
- **Plant for Smoking** - These products commonly tested in the same way as a raw plant product, ideally before and after homogenization

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Dealing with Schedule 1 Materials



- Marijuana is classified as a schedule I substance under the Controlled Substance Act (CSA) 21 U.S.C. § 801 et seq. This Act requires persons who handle controlled substances to register with the Drug Enforcement Agency (DEA) in the Department of Justice, which administers and enforces the Act.
- In New York for example, medical marijuana and related products produced by a registered organization must be examined in a laboratory located in New York State. The laboratory must be licensed by the DEA and approved for the analysis of medical marijuana by the department in accordance with New York law.

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Concerns Related to Cannabis Recalls



- There have been over 50 Cannabis Recalls in 2022 and 2023 combined. States with the most recalls occurred in California, Colorado, Oklahoma, Oregon, and Washington.
- Common contaminants have been Yeast, Mold, Aspergillus, Metals, and pesticides.
- Common reasons for recall include failed audit retesting, not properly tested, and labeling error

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Arkansas Lawsuit Over Medical Cannabis



- Jackie Hanan v. Overlook Partners, LLC d/b/a Steep Hill Arkansas, et al (60CV-23-1393) (Filed 2/23/23)
 - The suit alleges that Steep Hill inflates the amount of THC in the cultivators' cannabis products, and in return, the cultivators have an incentive to use Steep Hill's lab.
 - The third-party labs produced THC potency results within 10% of each other, according to the complaint. Meanwhile, Steep Hill's results averaged 25% or higher than the other labs.
 - Current Status – Matter was removed the ED Arkansas (23-CV-308), but remanded back to Arkansas State court on 9/5/23 with motions to dismiss pending.

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California Lawsuits Over Mislabeled THC



- Litigations against Lowell Farms, Stiizy, Jeeter, and Iron Works Collective
 - On the Buntarn Lun v. Lowell Farms, Inc. matter, California Superior Court, LA County (22STCV3886), the court on July 31, 2023 let six of the seven claims proceed in the lawsuit which alleges the cannabis companies overstated their prerolls' THC content.
 - Shanti Gallard v. Ironworks Collective Inc. and Stiizy LLC, California Superior Court, LA County (22STCV38021), alleges in part that testing by an independent laboratory reveals that the true THC content of the products is materially less than the amount listed on the label, and is far greater than the 10% margin of error that regulations permit. Defendants Demurrer currently pending.
 - Jasper Centeno v. Dreamfields Brands Inc. California Superior Court, LA County (22STCV33980) alleged that the company behind Jeeter joints have exaggerate the amount of THC in its products. The court on June 15, 2023 allowed most of the claims to go forward for alleged violations of the state unfair competition law and false advertising law claims to survive.
- Other litigations include *Argueta v. VO Leasing Corp.*, 22-STCV-38126 (Los Angeles County); *Willeford v. Greenfield Organix Inc., et al.*, No. 22-CV-003301 (Monterey County)

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Michigan Litigation Over A Cannabis Testing Lab



- **Viridis Laboratories v. Julie Kluytman, WD Michigan (22-cv-283)**
 - Lawsuit involved a testing lab suing the Michigan regulator after a major product recall and allegations of unreliable results. It is claimed that the recall violated its due process since the CRA blocked sales of marijuana without an opportunity to challenge the allegations.
 - July 31, 2023 decision from the court dismissed the lawsuit. The dismissal of the lawsuit, finding that because marijuana is still federally illegal, the industry isn't protected by the Constitution.
 - There are other complaints against Viridis' for rule violations are currently being contested in the Michigan administrative courts regarding Viridis lab results.

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Missouri Lab Testing Litigation



- **Matthew D. Wolf v. Daniel Altmann (US Dist Court, ED MO) (22-cv-397).** Complaint filed on April 4, 2022 seeking a declaratory judgment regarding a cannabis partnership for a license for a testing laboratory, which was granted by Missouri in December 2019. The license was later revoked on March 2, 2021.
- The dispute is over the parties business arrangement, but addresses in general issues as to testing for Cannabis in Missouri.
- Current Status – Various motions pending including (1) motion to compel settlement, (2) motion to dismiss counterclaims.

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New York Issues on Lab Results



- March 2023 NY Cannabis Insider Experiment found majority of cannabis products had lower THC than advertised
 - One strain showed 33.8% THC on the consumer-facing label, while testing said the actual number was 21.7%
 - The lab found another product contained 17.7% THC, while its label advertised 28.5% – a roughly 47% difference
 - Only three samples came within a 10% margin of error from their labeled potency, which is more or less the variance state regulators are proposing be allowed for the New York industry
 - Only one out of the five brands had gone through testing for state-certified potency, and its strength was almost exactly what the label stated.

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New York Issues on Lab Results



- Various explanations of proposed causes
 - After this Experiment, the NY OCM sent an email to all state-licensed cultivators and processors, which included addressing line testing.
 - Follow-up Investigation in September 2023 showed cannabis with heavy metals, bacteria, yeast and mold count above the medical limit.
- Jenny's Baked at Home Company, LLC v. New York State Office of Cannabis Management, (902522-24), filed on 3/13/24
 - Actions by OCM, including addressing testing of product.

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Pennsylvania Lawsuit Over Testing



- Green Analytics North, LLC d/b/a Steep Hill PA, et al. v. Pennsylvania Department of Health, Commonwealth Court of Pennsylvania (104 MD 2023).
 - On March 4, 2023, a group of cannabis growers and labs went to court to block the rule requiring cannabis growers to use different labs to test their products at the harvesting and final stages.
 - On June 29, 2023, the court held that Section 1171a.29(c)(1)-(2) of the Pennsylvania Department of Health's (Department) Regulations, 28 Pa.Code § 1171a.29(c)(1)-(2), was declared invalid and unenforceable. Court said that only one lab was required to do the testing

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Testing Concerns in Other States



- Massachusetts: MCR Labs raised concerns to the State's Joint Committee on Cannabis Policy in July 2023 about testing-lab conduct and that the state Cannabis Control Commission retaliated against MCR by investigating into his business.
- In Montana in September 2023, Stillwater Laboratories owners Ron and Kristine Brost said they're concerned that a software program the state uses may inadvertently approve large lots of marijuana without complying with the state's testing standards, leading to a market that has increased the volume of marijuana without a commensurate increase in testing.

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Testing Concerns in Other States



- In Washington in October 2023, True Northwest lab received an emergency suspension of its state certification because the lab failed to meet several accreditation requirements, including not having a lab director and not having its scales properly calibrated.

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Defense Issues in Testing Cases



- When there is a claim, it can be very significant
 - Equipment faulty, People errors, Validation concerns
 - Recall program can involve the lab's work for many companies,
 - Can hit policy limits real fast, may require interpleader with the court.
- Cannabis is unique with regulated product without any standard lab certifications, like a UL Certified Lab or a FDA Lab.

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Defense Issues in Testing Cases



- When defending most consumer products, the lab may be used as an informal partner and expert that has expertise needed to defend the case.
 - With Cannabis, labs are part of the chain of distribution of the product and the product does not go to consumer before green light from the testing lab.
 - This can result in a greater risk for finger-pointing and an adversarial relationship between lab and license-holder during litigation.
- Questions about testing validation, which can be a shield and sword
 - Look at Label on THC and CBD (it may have been accurate at time of batch testing, but cannabinoids are active compounds and can change over time).
 - Different labs use varying testing and validation methods, so even a retained sample can return different results by different labs

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Coverage Issues



- Given these litigations, there are concern on getting coverage for lab and testing companies for the alleged professional negligence.
 - Limited Insurers offering coverage
 - Lot of policies have lab exclusions and lab testing issues
- Other Type of Policies Typically Exclude Testing:
Based upon, arising out of, in consequence of or in any way involving the performance of, or failure to perform, professional services for others. This includes but is not limited to any financial, legal, accounting, consulting, compliance, medical, psychological, counseling, investing, testing or other services.

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Example Analytical/Environmental Testing Laboratories Policy



- Coverage for **Testing Laboratories Professional Services** means the performance of scientific analysis, examination, evaluation, sampling, investigation, identification, studies, consulting and expert witness testimony services for others, for a Fee.
- Understand what can be excluded
 - **Bodily Injury**, except mental anguish and emotional distress without physical manifestation of bodily harm, sickness or disease, shall not apply to any **Bodily Injury** sustained by an **Insured** or any employee of an **Insured**, except, this exclusion shall not apply in the performance of **Testing Laboratories Professional Services**;
 - **Property Damage**, except, this exclusion shall not apply in the performance of **Testing Laboratories Professional Services**;
 - any **Loss** arising out of **1.** any laboratory testing services for aircraft, parts or equipment; **2.** any goods or products manufactured, sold, or distributed by any **Insured**;
 - any **Testing Laboratories Professional Services** which can only be performed by a licensed or certified architect, engineer, medical practitioner or health care provider.

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What Are the Concerns Going Forward



- Adopting uniform standards for cultivation, manufacturing and testing should help to drive down future liability for contamination and label claims, so long as the standards are followed by cannabis operators.
- Several key practices should be embraced by the cannabis testing industry, including full accreditation, objective demonstration of proficiency, better investment in state-of-the-art equipment and the adoption – and enforcement – of ethical business practices.
- Of the 26 states that currently mandate cannabis testing, 18 require some form of accreditation. This usually means accreditation through the International Organization for Standardization (ISO).
- Consideration of Proficiency Testing

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Ideas for Best Practices



- Dealing with Recall Notices
 - How to address issues with Aspergillus
 - How to address pesticides being implicated
 - Idea of recall notice with a health warning
- Idea of modifying testing practices in these facilities versus defending these litigations or addressing the costs of the recalls.
- Avoid bodily injury claims

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