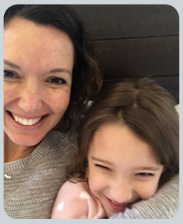
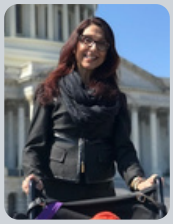
REGULATING CANNABIS MEDICINES

CANNABIS TESTING PROGRAMS & ENSURING PATIENT SAFETY

The federal prohibition of cannabis and the lack of a viable pathway for complex botanical medicines to achieve FDA approval has put the burden of regulating access to cannabis and cannabinoid products for patients on the states. Since 1996, the states and territories that have adopted access programs have found that the positive impacts are profound and far-reaching, enhancing patient outcomes for over 6 million registered patients as well as alleviating burdens to the healthcare systems that serve them.

Robust testing programs are crucial to protecting patient health by identifying contaminants & providing accurate labeling of cannabis products.


While cannabis in its natural form is inherently safe for most patients, Like all agricultural commodities, it is susceptible to contaminants during cultivation, manufacturing, handling & storage. However, due to the high value and demand of cannabis, it is not uncommon for unscrupulous producers to improperly use pesticides or to use additives or adulterants to add weight, fragrance, or even dilute their products. Product testing is the only way to ensure products intended for patients are free from contaminants, adulterants, and additives.

Unlike other medications that come in standardized formulations, cannabis is highly individualized in terms of its therapeutic effects. Patients rely on accurate and detailed labels to ensure they are obtaining the specific formulations and potencies that work best for their medical conditions. Medical cannabis patients and their healthcare providers depend on proper labeling of cannabis products to determine the best treatment outcomes.

CONSIDERATIONS FOR CANNABIS SAFETY

1. ROLE OF TESTING PROGRAMS IN MEDICAL CANNABIS MARKETS
2. TESTING & THERAPEUTIC EFFICACY
3. IMPACTS OF INACCURATE LABELING
4. ORIGIN OF CANNABIS CONTAMINANTS.
5. CONTAMINANTS & HEALTH IMPACTS
6. SPECIAL CONSIDERATIONS FOR CONTAMINANTS & PATIENTS
7. ACCEPTABLE THRESHOLDS LIMITS HAVE BEEN ESTABLISHED & IMPLEMENTED

1 ROLE OF TESTING PROGRAMS IN MEDICAL CANNABIS MARKETS

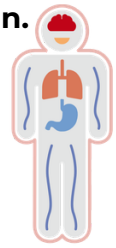
Testing programs serve two critical roles in the medical cannabis marketplace. First, like other agricultural commodities, product safety standards should encompass guidelines from seed to consumption, and testing programs act as oversight tools to ensure the enforcement of these protocols, alongside inspections and certifications. Second, unique to pharmaceutical agriculture and especially relevant to cannabis, testing programs inform patients and their medical professionals about the active therapeutic compounds, such as cannabinoid and terpene content. Medical cannabis treatments are highly personalized medications and require accurate information accurate dosage.

2 TESTING & THERAPEUTIC EFFICACY

Unlike other medications that come in standardized formulations, cannabis is highly individualized in terms of its therapeutic effects. Patients rely on accurate and detailed labels to ensure they are obtaining the specific formulations and potencies that work best for their medical conditions. Medical cannabis patients and their healthcare providers depend on proper labeling of cannabis products to determine the best treatment outcomes.

Cannabis provides a combination of cannabinoids, terpenes, & flavonoids that work synergistically. This enhances therapeutic effects –a concept known as the "entourage effect."

Chemical compounds found in the cannabis plant interact with receptors in the body's **endocannabinoid system** (ECS). The ECS is the body's mechanism for preserving homeostasis (keeping all body functions running smoothly) and consists of endocannabinoids, cannabinoid receptors, and enzymes. The ECS regulates various physiological processes including **movement, mood, memory, appetite and pain.**



To keep systems running smoothly, the body produces endocannabinoids as needed; these are similar to phytocannabinoids, the cannabinoids found in the cannabis plant. They bind with cannabinoid receptors (**CB1** & **CB2**) that are found in central and peripheral nervous systems and immune cells. The effects depend on a variety of factors.

EXAMPLE OF DESCRIPTION OF CANNABIS PRODUCTS

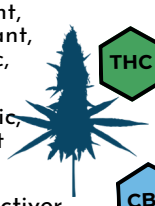
Cannabinoid Profile

Analyte	%	mg/g
THCa	19.29	192.9
Δ9-THC	0.24	2.4
Δ8-THC	ND	ND
THCV	0.13	1.3
CBDa	0.57	5.7
CBD	0.02	0.2

Terpene Profile

Analyte	%	mg/g
β-Myrcene	0.30352	3.0352
β-Caryophyllene	0.19738	1.9738
β-Pinene	0.14000	1.4000
δ-Limonene	0.13865	1.3865
α-Pinene	0.12000	1.2000
α-Bisabolol	0.05061	0.5061
Linalool	0.03189	0.3189
(-)-Guaiol	0.02884	0.2884
α-Humulene	0.02672	0.2672
Terpinolene	0.01752	0.1752

CANNABINOIDS & TERPENOIDS



CBD — Non-intoxicating, anti-depressant, anti-inflammatory, anti-convulsant, anti-emetic, anxiolytic, analgesic, muscle relaxant

THC — Psychotropic, analgesic, anti-inflammatory, anti-microbial, muscle relaxant

CBC — Anti-inflammatory, analgesic, anti-anxiety, antidepressant

CBG — Muscle relaxant, anti- eurythmic, analgesic, digestive aid

THCA — Anti-inflammatory, immunomodulatory, neuroprotective

CBN — Sedative, topical analgesic for burns, may stimulate bone growth

LIMONENE
Potent immunostimulant via inhalation, anxiolytic, apoptosis of breast cancer cells and anti-bacteria

α-PINENE
Anti-inflammatory, bronchodilatory, acetylcholinesterase inhibitor

β-CARYOPHYLLENE
Gastric cytoprotective, anti-malarial, selective CB2 agonist, anti-inflammatory

β-MYRCENE
Blocks inflammation, analgesic, sedative, muscle relaxant, hypnotic, blocks hepatic carcinogenesis by aflatoxin

PHYTOL
GABA via SSADH inhibition

LINALOOL
Anti-anxiety, local anesthetic, analgesic, anticonvulsant/anti-glutamate

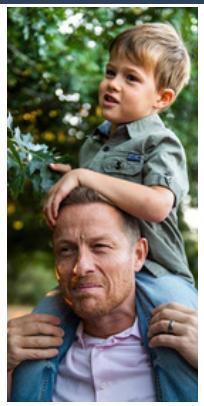
NEROLIDOL
Sedative

Living with cannabis as a medicine means that patients require their medication to control the symptoms of their diseases or conditions, enabling them to carry out essential life activities such as work, school, and childcare. Daily use of cannabis is often required to maintain symptom relief and overall well-being, and any interruption or inconsistency in their medication can have significant consequences for their treatment success and quality of life.

3 IMPACTS OF INACCURATE LABELING

Inaccurate labeling of cannabis products can have serious consequences for patients who depend on specific cannabinoid profiles and potency levels for therapeutic relief. When labels misrepresent contents, patients may unknowingly consume doses that are either too weak or too strong, leading to ineffective treatment or unintended side effects such as nausea, discomfort, rapid heartbeat, or even a dangerous drop in blood pressure.

These effects can be especially disruptive for individuals managing chronic conditions, potentially causing a regression in symptom control or a decline in their overall health and quality of life. Ingestible products like edibles, which metabolize differently and have delayed onset times, present further risk; patients may mistakenly consume additional doses too soon, leading to accidental intoxication that can last for hours. Such incidents not only cause distress but may also result in adverse events including falls, impairment, or failed drug tests.



Beyond the health implications, inaccurate labeling can significantly impact a patient's daily functioning and financial stability. Incorrect dosages or formulations can lead to missed work or school due to illness or impairment, interrupting routines and diminishing productivity. Furthermore, because most medical cannabis patients pay entirely out-of-pocket, inaccurate labels can result in wasted funds on ineffective or unsuitable products. This makes access to transparent, precise labeling essential not just for health outcomes, but for economic stability. Preventable harms—such as overconsumption, contamination-related reactions, or mislabeled multi-dose products—underscore the urgent need for robust testing programs and regulatory oversight to ensure label integrity and protect patient safety.

4 ORIGIN OF CANNABIS CONTAMINANTS

Like all agricultural commodities, cannabis is susceptible to contamination. A combination of unique properties in this plant means that producing products for human consumption requires special care.

CULTIVATION & PROCESSING

Cannabis and hemp are known as hyper-accumulators because of their ability to absorb chemicals & heavy metals from the soil and accumulate them in the flowers, stems & leaves.

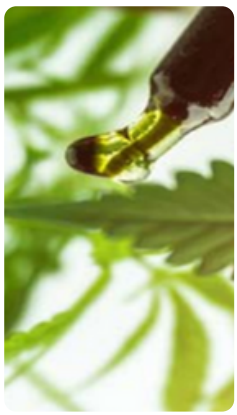
The cannabis plant grows best in warm, humid environments, the same conditions that many microbiological species and pests such as spider mites, aphids, and thrips thrive in. Agricultural products are also exposed to additional pests such as insects, rodents, and birds.

Farmers attempting to prevent the degradation of this highly valuable crops may improperly use pesticides to treat pests.

PESTICIDES **HEAVY METALS** **FOREIGN MATTER** **BACTERIA, VIRUSES & PARASITES** **MOLD, MILDEW, FUNGUS & YEASTS**

MANUFACTURING

Solvents are often used to extract cannabinoids and terpenes from cannabis to make products. If this process is done incorrectly, the residuals of these solvents can remain in the final products. Additionally, all extraction methods are creating concentrations of everything, even the contaminants.



Producers may use additives and adulterants to add weight or fragrance, or even to dilute their products. The 2019 vaping crisis exposed additives and adulterants, including vitamin E acetate, squalene, coconut oil, and food flavorings. Limonene, a naturally occurring terpene in cannabis, is often removed during the extraction process. Manufacturers often add food-grade Limonene to finished products to enhance the “cannabis fragrance,” which has not been evaluated for inhalation toxicity.

FOREIGN MATTER **ADDITIVES & ADULTERANTS** **RESIDUAL SOLVENTS**

STORAGE

Cannabis' high moisture content and improper storage promote mold, mildew, and fungal growth. Light, heat, and oxygen can also affect and degrade cannabinoids and terpenes.

Metals from old oil vaporizer devices (vapes) may leach into the product.

MOLD, MILDEW, FUNGUS & YEASTS **HEAVY METALS** **BACTERIA, VIRUSES & PARASITES**

5 CONTAMINANTS & HEALTH IMPACTS

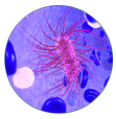
Most contaminants are invisible to the naked eye, making laboratory tests necessary to identify their presence. Contamination can have lasting health impacts. Symptoms might not manifest immediately and, in some cases, can take weeks, months, or even years to manifest. These health impacts can affect various body systems, increase the risk of cancer, and complicate underlying conditions. Symptoms are more severe in children, the elderly, & individuals with compromised immune systems. Also, certain prescription drugs can hinder the body's ability to eliminate these contaminants.

IMMEDIATE SYMPTOMS OF CONTAMINATION

- FEVER
- HEADACHE
- DIZZINESS
- TREMORS
- HIVES
- FATIGUE
- RAPID HEARTBEAT
- SLURRED SPEECH
- ABDOMINAL CRAMPING
- MUSCLE TWITCHING
- SINUS INFECTIONS
- LOSS OF CONSCIOUSNESS
- DIARRHEA
- VOMITING
- CONFUSION
- ALLERGIES
- SEIZURE
- CONVULSIONS

MICROBIOLOGICAL CONTAMINANTS

Microbiological contaminants include bacteria, fungi, yeasts, molds, and viruses. These species are ubiquitous in the environment; however, exposure to certain species has been shown to present severe health risks. The following is not representative of every species of bacteria, virus, fungi, or pest that could contaminate cannabis:



Escherichia coli (E. Coli) is a bile-tolerant bacteria that is commonly found in the intestines of humans and other warm-blooded animals and the environment. E. Coli contamination is most often linked to animal manure, which is commonly used in cultivation practices as a soil amendment to provide additional nutrients. E. Coli can also be found in water.

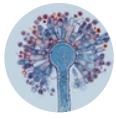
HEALTH IMPACTS: Haemolyticuraemic Syndrome (HUS), Stroke, & Coma

Salmonella is an infection of the gastrointestinal tract that is commonly known as food poisoning. In more severe cases, salmonellosis can cause enteric fever (typhoid fever). Use of antacids, recent use of antibiotics, or having irritable bowel syndrome (IBS) may increase a person's susceptibility to salmonellosis.

HEALTH IMPACTS: Typhoid Fever & Salmonellosis

Botrytis cinerea, gray mold, is an airborne fungus that can infect plants at any stage of growth. Botrytis can be found in greenhouses, nurseries, and outdoor growing environments, and can result in occupational exposure, "wine grower's lung."

HEALTH IMPACTS: Lung Inflammation, Lung Infections, & Sinus Infections



Aflatoxins and Ochratoxin A are mycotoxins produced by fungi found all over the world. According to the World Health Organization, over 25% of the world's food crops must be destroyed annually due to aflatoxins.

HEALTH IMPACTS: Immunosuppressant, Liver & Kidney Damage, Birth Defects, & Cancer

Aspergillus is a fungus (mold) with approximately 180 species. It can be found both indoors and outdoors, on surfaces and in the air. Cannabis is most often consumed via inhalation and as such, contaminated products may result in the direct administration of Aspergillus spores into the lungs.

HEALTH IMPACTS: Chronic Pulmonary Aspergillosis, Lung Infections, & Sinus Infections

other Molds & Yeasts-Apart from the mentioned species, cannabis is susceptible to various other yeasts, molds, and fungi. Comprehensive testing for each type isn't always feasible, so some states have instituted testing for Total Yeasts and Molds (TYM/TYMC). These contaminants pose risks to exposed workers and consumers with weakened immune systems.

HEALTH IMPACTS: Asthma, Pneumonia, & Sinus Infections

SOURCE: CULTIVATION & STORAGE

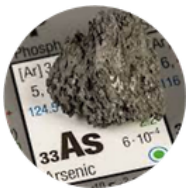
PESTICIDES

Pesticides are a broad class of chemicals that include herbicides, fungicides, insecticides, and rodenticides. They are crop-control agents used by cultivation operators to prevent infestation by pests and are generally highly regulated.

SOURCE: CULTIVATION

HEALTH IMPACTS: Endocrine Disruption, Neurological Disturbances, Reproduction & Development Issues, Cancer, Coma, & Death

HEAVY METALS



Heavy metals such as lead, cadmium, arsenic, and mercury are found in soil, water, fertilizers, and nutrients used during cultivation. These can be further concentrated during manufacturing. Metals can also come from the grinding, processing, and manufacturing equipment or leach into oils and extracts from the metal components of vape pens over time.

SOURCES: CULTIVATION STORAGE MANUFACTURING

HEALTH IMPACTS: Lower Intelligence, Reduced Brain Development, Learning Disabilities, Apoptosis (Cell Death), Cancer, & Death

RESIDUAL SOLVENTS

Solvent extraction refers to methods to extract cannabinoids and terpenes from the cannabis plant using a solvent such as ethanol, carbon dioxide (CO_2), or various hydrocarbons like butane and propane. After the extraction is completed, depending on the solvent, various processing steps must occur to remove any plant material or other matter that was co-extracted, along with any remaining residual solvents.

SOURCE: MANUFACTURING

HEALTH IMPACTS: Central Nervous System Disturbance, Fetal Abnormalities, Sever Brain Damage, Cardiac system Disruption, Coma, & Death

ADDITIVES & ADULTERANTS

Additives and adulterants may be used by producers to add weight, dilute, or add fragrance to their products. Limonene, a naturally occurring terpene in cannabis is often removed during extraction processes. Manufacturers often add food-grade Limonene to finished products to enhance the "cannabis fragrance, which has not been evaluated for inhalation toxicity.

HEALTH IMPACTS: Lung Infections, Death

SOURCE: CULTIVATION STORAGE MANUFACTURING

VAPE PENS

TERPENES/FLAVORING ADDITIVES

TERPENE "CONCENTRATES" Safety unknown at concentrations above 5%
FOOD GRADE TERPENES - Not approved for inhalation
ESSENTIAL OILS - Not approved for inhalation
ARTIFICIAL FLAVORS - None approved for inhalation

THINNING AGENTS/PROPELLANTS

PROPYLENE GLYCOL & POLYETHYLENE GLYCOL- Becomes carcinogenic formaldehyde, the health risk is as much as 15X that of chronic cigarette smoking
MCT (coconut oil) – Safer than glycols, but not approved for inhalation
VITAMIN E OIL - Deadly when inhaled
TERPENE "CONCENTRATES" - Safety unknown at concentrations above 5%
FOOD GRADE TERPENES - Not approved for inhalation

Contaminant, pesticide, cannabinoid, and terpene levels can ONLY be determined through laboratory testing.

6 — SPECIAL CONSIDERATIONS FOR CONTAMINANTS & PATIENTS

ORGAN TRANSPLANT RECIPIENTS:

Aspergillus, a contaminant frequently found in cannabis, can lead to complications resulting in organ transplant rejections and a heightened risk of tacrolimus toxicity.

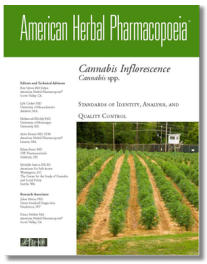
ANTACIDS, ANTIBIOTICS & IBS:

Individuals with gastrointestinal disorders such as IBS, as well as the use of antacids and antibiotics, increase a person's susceptibility to developing Salmonellosis, an unpleasant and potentially fatal illness caused by exposure to salmonella bacteria, a contaminant frequently found in cannabis.

PRESCRIPTION DRUGS, PESTICIDES & HEAVY METALS:

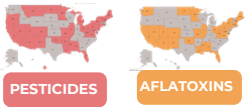
The liver and kidneys can typically break down and remove trace amounts of pesticides and heavy metals from the body. However, several types of prescription drugs impact the body's ability to properly eliminate these toxins creating intensified exposure from cannabis products.

7 — ACCEPTABLE THRESHOLDS HAVE BEEN ESTABLISHED & IMPLEMENTED

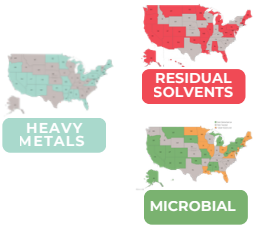


In 2013, the American Herbal Pharmacopoeia published the first cannabis monograph, Cannabis Inflorescence: Standards of Identity, Analysis, and Quality Control, to provide scientifically valid methods for cannabis and its preparations. Updated in 2014 version, this comprehensive description of the plant's botany, constituent components, analysis, and quality control. This monograph, was authored by the world's leading experts on the plant, provides scientifically valid methods of testing the identity, purity, potency, and quality of cannabis products.

AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION



Since it was published, every state witn a medical cannabis program with the exception of Maine has adopted product safety protocols. The AHP Monograph along with Recommendations for Regulators from the American Herbal Products Association (AHPA) are at the heart of all medical cannabis regulations ensuring safe products for patients.



"Over two-thirds (68.9%) of clinicians surveyed believe that cannabis has medicinal uses, and just over a quarter (26.6%) had ever recommended cannabis to a patient."

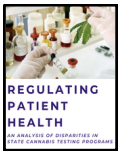
Schauer GL, Njai R, Grant AM. Clinician Beliefs and Practices Related to Cannabis. Cannabis Cannabinoid Res. 2022 Aug;7(4):508-515. doi: 10.1089/can.2020.0165. Epub 2021 Apr 26. PMID: 33998899; PMCID: PMC9418355.

Americans for Safe Access

Americans for Safe Access Foundation (ASA) is a 501(c)3, nonprofit organization. Founded in 2002, ASA is the largest national organization of patients, medical professionals, scientists, providers, and concerned citizens promoting safe and legal access to cannabis for therapeutic use and research. **www.SafeAccessNow.org**

References:

Regulating Patient Health:
An Analysis of Disparities in State Cannabis Testing Program



SafeAccessNow.org/ WhatsInYourCannabis

WHAT'S IN YOUR CANNABIS?
A Patient & Consumer Guide To Navigating Cannabis Safety