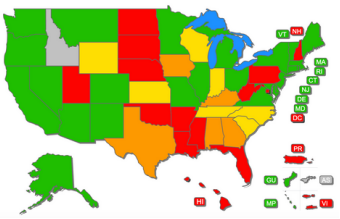
REGULATING CANNABIS MEDICINES

6 KEY CONSIDERATIONS FOR WHOLE-PLANT ACCESS

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.



Cannabis medicines provide relief to millions of Americans, often serving as a crucial alternative when conventional treatments have failed or as a safer option compared to pharmaceuticals.

Cannabis and cannabinoid medicines are unlike traditional pharmaceuticals and require a special approach to regulations. Cannabis can be manufactured into a variety of delivery methods and can be used immediately after being harvested. Whole-plant cannabis offers well-documented medical benefits, including through inhalation, which allows for rapid relief, high bioavailability, and patient-controlled dosing. Denying access limits patients' ability to manage their conditions effectively. As policymakers shape medical cannabis legislation and regulations, it is crucial to recognize the importance of whole-plant access as a cornerstone of patient-centered care.

CONSIDERATIONS FOR WHOLE PLANT ACCESS

1. LIMITING THERAPEUTIC POTENTIAL OF CANNABIS
2. PATIENTS & CAREGIVER AUTONOMY
3. INHALATION: FAST-ACTING, EFFECTIVE, FDA APPROVED.
4. MEDICAL DEVICES ARE AVAILABLE FOR CANNABIS INHALATION
5. POLYPHARMACY, DRUG INTERACTIONS & INHALATION
6. ADDITIVES & ADULTERANTS SENSITIVITY

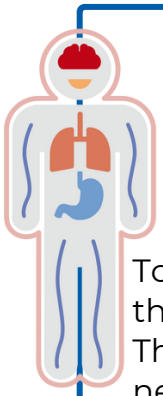
1 LIMITING THERAPEUTIC POTENTIAL OF CANNABIS TREATMENTS

The therapeutic threshold for cannabis is unique to each patient, so unlike most prescription medications, cannabis medicines do not come with a specific dose. Patients and their medical professionals choose preparations based on cannabinoid and terpene content, potency, and delivery methods (routes of administration) to determine optimal treatment protocols through a process of guided experimentation and self-titration.

Cannabis medicines are made from dried flowers and concentrates extracted through a variety of methods. Cannabis can be inhaled, ingested, and administered topically, or sublingually (buccally). Cannabis products affect individuals differently due to a variety of factors including their health, the contents of the product, and the delivery method. The therapeutic effects of cannabis are derived from variations of hundreds of cannabinoids, terpenes, and other compounds produced by the cannabis plant that interact with a complex system of receptors in the human body, the endocannabinoid system.

Humans have used the cannabis plant for thousands of years, but it wasn't until scientists isolated the cannabinoid THC in 1964 that we began to understand how cannabis works in the body. By 1984, researchers not only unlocked this mystery but, in doing so, revealed the potential for cannabis medicines.

CANNABIS & THE HUMAN BODY



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**) found in central and peripheral nervous systems and immune cells. The effects depend on a variety of factors.

CANNABINOIDS & TERPENOIDS

Cannabis sativa L.

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

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

THCA
BENEFIT
Anti-inflammatory, immunomodulatory, neuroprotectiver

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

CBN
BENEFIT
sedative, topical analgesic for burns, may stimulate bone growth

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

Whole-plant cannabis provides a combination of cannabinoids, terpenes, & flavonoids that work synergistically.

This enhances therapeutic effects –a concept known as the "entourage effect."

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

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

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

α-PINENE
Anti-inflammatory, bronchodilatory, acetylcholinesterase inhibitor

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

PHYTOL
GABA via SSADH inhibition

NEROLIDOL
Sedative

MODES OF ADMINISTRATION

WHOLE PLANT (FLOWER)

EXTRACTIONS
Extraction methods include solventless (water, heat & pressure, or dry sieve) & chemical (CO_2, butane, ethanol propane, hexane).

INHALATION
Product Types: whole plant, oils, waxes, concentrates, vaporizers
Expected onset: 0-10 min
Duration: 1-4 hours

INGESTION
Product Types: edible products, beverages, teas, capsules
Expected onset: 30-90 min
Duration: Up to 8 hours

TOPICALS
Product Types: lotions, salves, oils, patches
Expected onset: a few min
Duration: 1-4 hours

SUBLINGAL
Product Types: tinctures, lozenges
Expected onset: 0-60 min
Duration: 1-8 hours

2 – PATIENTS & CAREGIVER AUTONOMY

Patients and caregivers often prepare their own edibles and tinctures to control dosage, cost, and product safety. Denying access to whole-plant cannabis restricts their ability to customize treatments effectively, forcing them to rely on finished products available in dispensaries. Not only are these often a more expensive option for patients who must pay out of pocket for their treatments, but there is also no guarantee that dispensaries will always carry the specific products an individual needs. Whole-plant access ensures that patients retain the ability to tailor their treatment to their specific medical requirements.

"Advantages include more rapid absorption into the systemic circulation; avoidance of first-pass metabolism; lower incidence of systemic side effects; and higher bioavailability than other routes of administration."[1]

3 – INHALATION: FAST-ACTING, EFFECTIVE, FDA APPROVED.

Whole-plant cannabis offers critical, rapid-onset therapeutic benefits, particularly through inhalation. Inhalation is a drug delivery method that is a widely used, medically accepted, and highly effective route of administration. Inhaled medications are rapidly absorbed into the bloodstream, providing near-immediate effects. This is particularly beneficial for patients managing acute symptoms such as pain, nausea, muscle spasms, and respiratory conditions. Research underscores its advantages over other delivery methods.

KEY BENEFITS OF INHALATION:

- Avoids first-pass metabolism in the liver and kidneys
- Reduces systemic side effects
- Allows for rapid dose titration by patients

INHALATION IS AN FDA APPROVED MODALITY FOR DRUG DELIVERY

Many FDA-approved medications rely on inhalation for its superior bioavailability and rapid onset of action. Cannabis should be considered alongside these widely accepted treatments:

FDA-APPROVED INHALED MEDICATIONS:

Insulin: Afrezza
Antimicrobial Agents: Amikacin (Arikayce), Aztreonam (Cayston), Tobramycin (Bethkis, TOBI), Pentamidine (NebuPent), Ribavirin (Virazole)
Pulmonary Hypertension Agents: Iloprost (Ventavis), Treprostinil (Tyvaso)
Others: Dornase (Pulmozyme) – pulmonary function, Levodopa (Inbrija) – Parkinson's disease, Loxapine (Adasuve) – antipsychotic

4 – VAPORIZATION: SAFE, APPROVED MEDICAL DEVICE

Unlike common misconceptions that associate inhalation with smoking, this method is a widely used, medically accepted, and highly effective route of administration. It provides relief for various conditions with an established safety profile, supported by extensive research on whole plant cannabis.

MEDICAL DEVICES ARE AVAILABLE FOR CANNABIS INHALATION

The Volcano Vaporizer by STORZ & BICKEL is an internationally recognized medical-grade vaporization device, reinforcing the legitimacy of inhaled cannabis use. Unlike combustion methods, vaporization provides a cleaner, controlled way to inhale cannabinoids without harmful byproducts. The device is widely accepted in medical settings:

- **CE approval under the Medical Device Regulation (EU) 2017/745**
- **Approved for medical use in Canada, Europe, Australia, New Zealand, and Israel**

Vaporizers come in many sizes, from tabletop to pocket

5 POLYPHARMACY, DRUG INTERACTIONS & INHALATION

For patients who require a polypharmacy approach to treatment, inhalation is an optimal delivery system because it avoids first-pass metabolism in the liver and kidneys. This reduces the risk of drug interactions, making inhalation a safer option for many patients who rely on multiple medications.

DRUG INTERACTIONS & CANNABIS

WARNING: Warfarin, Buprenorphine, Tacrolimus

CAUTION: Clozapine, Methadone, Clobazam, Chlorpromazine, Hexobarbital, Rifampicin, Stiripentol, Theophylline, Valproate

MEDICATIONS THAT INCREASE CANNABIS EFFECTS: Amiodarone, Amlodipine, Azole, antifungals, Calcium antagonists, Doxycycline, Erythromycin, Fluoxetine, Ketoconazole, Proton pump inhibitors, Verapamil **[3]**

6 ADDITIVES & ADULTERANTS SENSITIVITY

Edibles, beverages, topicals and inhaled products other than flower are made by infusing cannabinoids and terpenes extracted from the cannabis plant. Manufacturers often add additives or adulterants to their products to enhance weight, dilute potency, or modify fragrance and taste. Many of these additives pose potential health risks, particularly when inhaled.

VAPE PENS: 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

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

Whole-plant cannabis is a well-researched, safe, and effective medicine that should be treated with the same legitimacy as other inhaled therapies. The rapid onset, predictable effects, and reduced risk of drug interactions make it an essential option for patients. Restricting access to this vital treatment limits patients' ability to manage their conditions effectively and deprives them of an approved medical approach used in numerous other therapies. As policymakers shape medical cannabis regulations, they must recognize the necessity of whole-plant access, particularly through inhalation, as a cornerstone of patient-centered care.

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**

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