# Seminar: "Implementing Product Safety Protocols in Cannabis Production and Distribution" offered by Americans for Safe Access in colaboration with Fundación CANNA"

PRESENTED BY AMERICANS FOR SAFE ACCESS:



IN COLLABORATION WITH FUNDACIÓN CANNA:



#### **PATIENT FOCUSED** CERTIFICATION

STANDARDS. EDUCATION. VERIFICATION.











# Implementing Product Safety Protocols in Cannabis Production and Distribution



#### Introduction

Steph Sherer is founder and Executive Director of Americans for Safe Access (ASA), the largest US member-based organization of patients, medical professionals, scientists, and concerned citizens promoting safe and legal access to cannabis for therapeutic use and research.

Her direct experience with the medical benefits of cannabis and her political organizing background led Steph to form ASA in 2002 with the purpose of building a strong grassroots movement to protect patients and their rights. As a powerful advocate, a skilled spokesperson, and an energetic initiator of campaigns, Steph has trained over 100,000 individuals across the country on civic engagement.

Steph has become the foremost international leader and expert on medical cannabis patient advocacy and, alongside American Herbal Products Association (AHPA), has created the first US industry standards in the areas of Cultivation and Processing; Manufacturing, Packaging, Labeling and Holding; Laboratory Analysis, and Distribution.



#### Introduction to ASA

Since its inception, ASA has successfully shifted the national debate around medical cannabis, which has focused solely on the legality and ethics of arresting and prosecuting patients for cannabis use, as well as the real concerns of patients, such as access and civil protections. ASA works with lawmakers across the US to adopt and improve medical cannabis legislation and regulatory policy in 40 states and the District of Columbia. In 2014, ASA passed federal legislation prohibiting the federal government from interfering with state laws which has created a "cease-fire" in the 19-year-old battle between state and federal governments.

In March 2015, ASA help co-found the International Medical Cannabis Patients Coalition (IMCPC), a coalition of medical cannabis patient organizations from 33 countries with the following mission:

Patient advocacy has been key in gaining rights for individuals to use cannabis under the care of a physician world-wide. Patient advocates must over come cultural fears of the cannabis plant, the illegal status of the use of cannabis as a medicine, and the gap in education for patients and medical professionals. While we may speak different languages and live under varying governmental structures; compassion, science and human health are the same in every language, in every country, and in every doctors office.

We are coming together not only to share our knowledge, experience, and resources but also to unite the patients' voices world-wide behind a declaration of human rights.





- > Founded in 2002
- > Largest organization of patients, medical professionals, scientists & concerned citizens, 50,000+ members
- Promoting safe and legal access to medical cannabis
   All 50 states and the District of Columbia



#### Americans for Safe Access' Goals

#### **Goals:**

- Resolve federal and state conflict on medical cannabis laws
- Ensure safe and legal access to medical cannabis (therapy and research) throughout the nation
- > End stigma and discrimination associated with medical cannabis use and research
- Regulate cannabis like a herbal medicine



#### Course Overview

- 1. Historia de los Protocolos de seguridad y Autorregulación en Mercados cannábicos:
- Una visión general de la evolución del mercado de cannabis medicinal comercial y la introducción en las leyes y reglamentos de los protocolos de seguridad de los productos Cannabicos.
- 2. ¿Cuáles son los protocolos de seguridad de los productos?: Una breve discusión sobre los componentes de los protocolos de seguridad del producto: normas, control de calidad y análisis de laboratorio.
- 3.Operaciones de los dispensarios: Un resumen de los tipos de dispensarios, los empleados, temas de seguridad y la compra de Cannabis y su calidad.



#### Course Overview

- 4. Normas para la industria del Cannabis Una visión general del AHP Cannabis Monografía y los estándares del American Herbal Products Association Standards cuales son estandardes mundiales reconocidos.
- 5. Seguridad de los productos y los consumidores Una discusión sobre adecuado embalaje, la manipulación y el etiquetado de los productos de cannabis (medicinal)
- 6. Certificación fijado en el paciente

Americans for Safe Access Foundation ha creado el Programa de la Certificación fijado en pacientes para tratar las cuestiones de control de calidad y seguridad de los productos en la industria del cannabis y para garantizar a los pacientes (consumidores) y sus mutuas, que pueden confiar en los productos y servicios de marihuana médica de alta calidad. ASA ha estado abogando por el acceso seguro y legal al cannabis para uso terapéutico durante más de una década. Fundada en 2002, ASA ha desarrollado una visión para el acceso seguro, que incluye un marco legal y regulatorio que ha dado forma a la industria médica del Cannabis.



#### **PATIENT FOCUSED** CERTIFICATION

STANDARDS. EDUCATION. VERIFICATION.











# History of Product Safety Protocols and Self-Regulation in Cannabis Markets



# Overview of US Cannabis Industry

#### LAWS:

- Still Illegal Federally
- 40 states plus District Of Columbia have medical cannabis laws
- 4 states plus District Of Columbia full legalization
- Over 2 million legal medical cannabis patients nation-wide

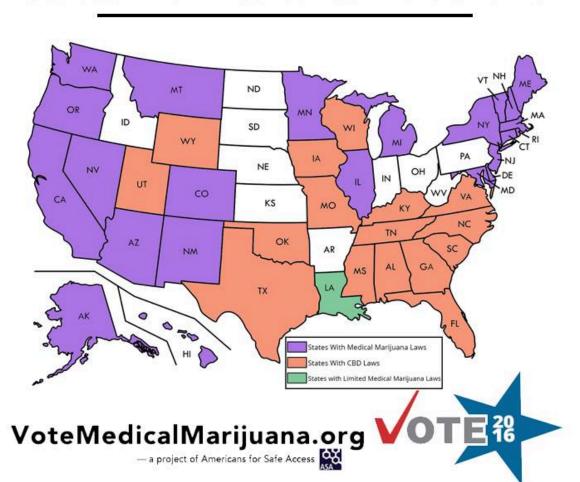
#### **Regulations:**

- 12 states have now adopted product safety protocols
- 8 states cite the AHP Cannabis monograph directly



# Overview of US Cannabis Industry

#### **States With Medical Cannabis Laws**





#### Evolution of laws: 1980's

- Individual patients pleading not guilty to marijuana charges and through exploring bureaucratic channels through federal government program in late 70s created the Investigation New Drug Program. In this program, the University of Mississippi distributed rolled marijuana cigarettes (an average of 4 lbs a year)
- In the mid-80's President Bush closed program in height of US Drug War.
- Several patients in the Investigation New Drug Program sued the federal government and won the right to continue to receive marijuana from the University of Mississippi (to date 4 of these patients still receive marijuana through this progam)
- With no means to legal access, individuals began breaking laws to distribute marijuana especially to patients with HIV/AIDS.



# Evolution of laws: 90s- early 2000s

- After several arrests and prosecutions in California of individuals distributing medical cannabis to patients, public outcry grew across the US. While most Americans did not want marijuana to be legal for everyone, they did not want to see patients going to jail.
- This lead to a series of laws passed in 8 states that created criminal exemptions to marijuana possession and cultivation laws if individuals had support from their doctors
- These laws did not include distribution programs or protections from civil discrimination



#### Evolution of laws: Mid 2000s

- In 2002, Americans for Safe Access was formed and began working with cities in CA to regulate medical cannabis distribution; and
- In 2003 ASA passed the first laws in the US allowing for distribution.
- These "dispensaries" were community-based access models (similar to social clubs in Spain)
- They consisted of patient members that sold the "excess" cannabis they grew back to the "dispensary". The dispensary would then package and sell the excess back to patient members.
- Regulations at this time consisted mostly of areas of the city where dispensaries could be located, hours of operation, limits on amounts to be sold, and restrictions for only verified patients to join.
- No product safety protocols
- Every new state law included distribution programs



# Evolution of laws: 2010s-present

- In 2010, Colorado passed the first "commercial" industry law creating licensing for all segments of the industry and for-profit businesses began to enter the market
- In 2011, the American Herbal Products Association (AHPA) created the Cannabis Committee, tasked with the creation of best business practices for product safety in the areas of cultivation, manufacturing, distribution, and laboratories.
- In 2013 the American Herbal Pharmacopoeia (AHP) published a Cannabis Monograph
- Every state that has passed medical cannabis laws after 2013 have included AHPA guidelines and the AHP monograph in the their laws and regulations
- Companies in the US are voluntarily signing up for ASA's Patient Focused Certification Program (PFC)



#### Patients' Role in Safe Access

- Courts
- Navigating Bureaucracy
- Media Strategies
- Civil Disobedience
- Direct Lobbying
- Development of Product Safety Protocols
- Medical Professional, Legal, Patient and Public Education



## Civil Disobedience











# Raid Response



# Direct Lobbying







### Highlighting Injustice



I just want to make sure Congress knows what's happening so they can fix the law & so there's no more money wasted on cases like mine."

> -- Larry Harvey, Kettle Falls Five Defendant

#peace4patients

7ET/PT





# Reports and Lawsuits from Data Gathered through Support

June 2013

#### What's the Cost?

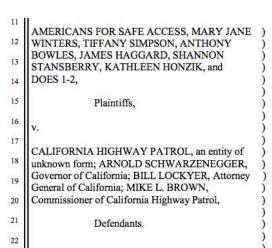
The Federal War on Patients

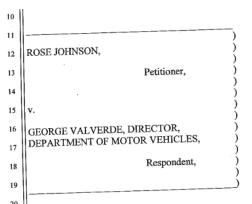




#### PATIENTS IN THE CROSSFIRE

Casualties in the War on Medical Marijuana





PETITION FOR ALTERNATIVE WRIT OF MANDAMUS; REQUEST FOR STAY OF PROCEEDINGS; MEMORANDUM OF POINTS AND AUTHORITIES (NON-DUI)

Civil Action No.

VERIFIED COMPLAINT FOR DECLARATORY RELIEF, PRELIMINARY INJUNCTION, AND PERMANENT INJUNCTION

1-888-929-4367 patientfocusedcertification.org

#### Public Education



Fund Size
Peace 4
Patients

IOO GRAND

Chew on This...President Obama Spends over \$100k per day
Fighting the War on Legal Medical Marijuana Patients





INGREDIENTS: 34% of Americans - more than 107 million people - live in states with medical cannabis laws. Over I million Americans are legally using medical cannabis under their state program. Nationwide support of state laws has remained between 70-80% for 2 decades. In last 17 years the DEA has conducted over 528 raids: 270 under Obama Administration. Cost of federal war on patients is nearly \$500 million. Obama Administration has spent nearly \$300 million on enforcement efforts in medical cannabis states. Obama Administration has outspent the Bush Administration by \$100 million in just 4.5 years.





#### COMING TO A COURTROOM NEAR YOU

John Ashcroft doesn't want anyone defending medical marijuana. Not you. Not your lawyer. Not even the judge.

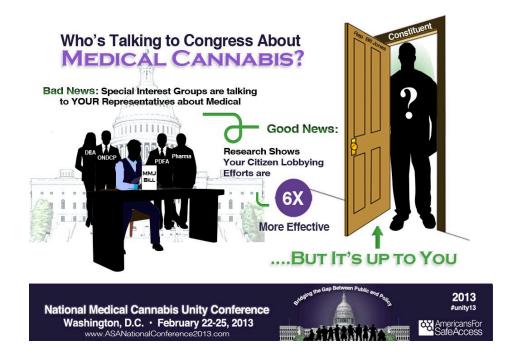
Despite impressive evidence that marijuana helps people with epilepsy, multiple sclerosis, AIDS wasting, and chemotherapy, Attenny General John Astrocti refuses to face the facts and he's willing to send you to prison to prove it. The U.S. Justice Dept. is putting care givers on trial for supplying medicine the sick and dying. They are not allowed to mention "medical marijuana" in their defense. They are tried as if they were drug kingpins. When a San Francisco jury realized they had convicted one of these good Samaritans, they were outraged. If feel like I made the biggest instake of my life, "said juror Marney Craig." We convicted a man who was not a criminal."

Help us stop the war on patients.

AMERICANS FOR SAFE ACCESS www.SafeAccessNow.org 888-929-4367



#### Organizing





# Who Controls the War on Medical Marijuana Patients?



Demand Congress resolve the conflict between federal & state laws!



1-888-929-4367 patientfocusedcertification.org

## Legal Education



#### HOW TO DEFEND A MEDICAL MARIJUANA PATIENT IN CALIFORNIA

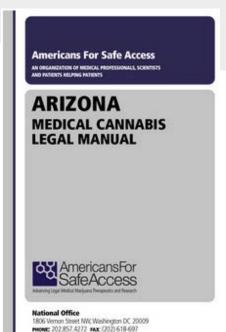
Published by Americans for Safe Access (Revised draft 2/22/13)



Many arrests for cannabis possession are due to traffic violations and noise complaints.

- Travel Safely: Do not smoke and drive. If you travel with cannabis, make sure your vehicle is up to code and your cannabis is concealed, preferably in your trunk.
- Be Prepared: Carry your recommendation and state-issued ID Card (if you have one) at all times, but do not present it to law enforcement unless accused of a marijuana-related crime.
- Be Discreet: Try not to smoke where others can see you and never leave cannabis items in plain view.

# There are three levels of police interactions and safe ways to handle each encounter 1. Casual conversation: Ask if you are being detained. If not, walk away. 2. Detention: If you are being detained, ask why! Make them cite the law (and remember what they say)! 3. Arrest: Say "I choose to remain silent and I want to see a lawyer." (Remember to remain silent.) 510-251-1856 AmericansForSafeAccess.org 888-929-4367



WEBSITE: www.AmericansForSafeAccess.org

**FACEBOOK:** Safeaccessnow TWITTEK: safeaccess



#### Medical Education



**CANCER MEDICAL CANNABIS** 















## **Product Safety Standards**









#### **PATIENT FOCUSED** CERTIFICATION

STANDARDS. EDUCATION. VERIFICATION.











What are Product Safety Protocols?



# "Quality is everyone's responsibility" -W. Edwards Deming

(Author of "Out of Crisis" and "14 Habits...")

#### Product Safety Statistics in the U.S.

Annual estimates show that contaminated food products in the U.S. are responsible for roughly:

- 47.8 million illnesses;
- 127,839 cases of hospitalization;
- 3,037 deaths; and
- Costs U.S. taxpayers \$14 billion in medical care, lost of productivity, and chronic health problems.



#### What are safe products?

- Expectations of all other products sold for human consumption
- Potency testing alone does not equal safe products
- Products can not be proven safe to consumer without recall strategies
- Making extractions from a safe product does not mean extraction is safe
- Safe food stuffs are not tested for combustion and inhalation
- Pesticides safe for food stuffs are not all tested for combustion and inhalation



#### Safe Products: proven safety profile

#### What is safe:

- Whole plant products
- Traditionally made hashes and kef
- Food products made with these
- Tinctures and/orally ingested made with known foodstuff (alcohol and glycerin glycol)

#### What do we NOT know is safe:

- Chemically produced concentrates and extractions (co2, butane)
- Excipients and food stuffs not tested for inhalation



#### Product Safety Testing

- Are you doing animal testing?
- Are you doing human testing with protections for human subjects?
- Are you doing human testing in your employees, friends and family?
- Or are you testing your products in your customers (patients)?



# Introduction to Product Safety

- Product safety protocols include 3 components:
- Standards: generally accepted requirements followed by the members of an industry
- Quality Control: a procedure or set of procedures intended to ensure that a cultivated product, manufactured product or performed service adheres to a defined set of quality criteria
- Quality Assurance: the verification that the quality control procedures are effective and working, includes the regular assessment and if necessary the updating of Quality Control in order to ensure that the products produced are of the purity, quality, and consistency claimed on the label. This includes lab testing.



#### Standards

- There are several types of standards that apply to the medical cannabis industry.
- Standards must be relevant.
- Standards are not tricks or illusions...





#### **Basic Elements of Standards**

- PERSONNEL: Personnel training, responsibilities, safety, and supervisor requirements
- FACILITIES: Design and construction, fire prevention, sanitation practices, electrical systems, ventilation system, disposal and waste practices, security provisions and equipment and utensils
- INVENTORY AND RECORDKEEPING: materials inventory, distributed materials, reconciliation and record retention
- WATER RESOURCE MANAGEMENT: Cultivation water management and potable water for employee use.
- PROCESS CONTROLS: manufacturing component control requirements, batch records, monitoring and controls, sampling requirements, in-process material specifications, sampling, and testing



#### Basic Elements of Standards

- PACKAGING AND LABELING PROCESS CONTROLS: general considerations for packaging components, including labels, packaging and/or labeling protocol, packaging and/or labeling batch record, and label content for cannabis and cannabis-derived products
- HOLDING CONTROLS: identification protocols, storage and handling, and withholding materials from use or distribution
- COMPLAINTS, RETURNS, AND RECALLS: complaint files, returned products and recall procedures
- COMPLIANT INDIVIDUALS: requirements for purchase, purchase limits, personal information, adverse event records, and rights and responsibilities of compliant individuals



## GMP Requirements

- Design facilities & product/manufacture in accordance with general worker safety requirements
- Ensure that the storage and transportation of products do not pose risk to the products quality, purity, consistency or compliance with product safety requirements, traceability systems, or laws and regulations
- Maintain all records necessary to provide wholesale and/or retail consumers with detailed explanation of product treatments, ingredients and handling protocols
- Develop and implement a product recall program that includes documentation of complaints received, investigation protocols and a communications plan designed to adequately notify consumers and companies that the product they have received is being recalled. The communications plan must include appropriate disposal procedures.



## Additional GMP Obligations and Requirements

#### **Consumer information, traceability and labeling requirements:**

- Products to include use by or expiration dates as well as lot, batch, control number or other identification allowing for both the forward and backward tracking of the product(s) and its source material(s)
- Products to indicate name, registered trade name or trademark and single point of contact address (except low risk products)
- Information must be provided on the product itself or, if not possible on packaging or accompanying document
- Products must be accompanied by instructions and safety information (except obvious products)
- When appropriate labels should include nutritional facts, ingredient list, and allergin warnings

#### **Post-marketing obligations:**

- When there is a reason to believe that a product on market is not safe or non-compliant, immediately take the necessary corrective action(s) to make achieve compliance or in the case of a serious and immediate health risk withdraw/recall
- When product is determined to ne unsafe for consumption, immediately inform market surveillance authorities of MS



# **Quality Control**

- Standard Operating Procedures (SOP): These should be in a written form and should include processes for each standard. For example: Procedures for packaging products, handling waste, handling customer complaints, batch records etc
- Staff Training: All staff should be trained and tested on the SOP's,
- Controls: systems to check each procedure including proper identification, tests, and limits for products, test methods, and sampling procedures



# Quality Assurance

- Internal/external audits:
- Lab testing:
- Review of controls



# QC/QA Fails





# QC/QA/GMP Failures

- 1969, Cape Town, South Africa: 7 Children die after receiving sedatives formulated with diethylene glycol
- 1990, Bangladesh: 236 children die from a diethylene glycol pharmaceutical poisoning
- 1990, Nigeria: 40 children die when a locally-prepared acetaminophen preparation is concocted using diethylene glycol instead of propylene glycol
- Challenger, Aspirin-Cyanide Poisoning (1982), Vioxx, Thalidomide, Ford Pinto, iPhone 4, Hubble...
- Can you name a cannabinoid QC/QA failure?



## Cannabis Product Safety Issues

- Cannabis is often extracted with polar solvents
- Many are flammable and potentially explosive
- THC (and contaminants) are highly concentrated by the process
- "Naptha" and butane are often contaminated and leave toxic residues
- Even dab users acknowledge greater tolerance and withdrawal (Loflin, 2014)

PATIENT FOCUSED CERTIFICATION

a project of Americans for Safe Access Foundation

How high does a patient need to be to have symptom relief?



Romano LL, Hazekamp A. Cannabis oil: chemical evaluation of an upcoming cannabis-based medicine. Cannabinoids. 2013;1:1-11.

1) NAPHTHA

5g

Nanhtha

(200 mL)

Extraction #1:

g cannabis + 100 ml

naphtha, agitate 20

min. (a)

Filtration with filter

Extraction #2

Same cannabis + 100

nl. naphtha, agitate 20

min. (a)

Filtration with filter

paper

Combine extracts

Evaporate solvent in

water bath ~98°C

under stream of

nitrogen gas

Reconstitute residue

with EtOH to 100 ml

Table 1: Detailed description of the five different protocols used for preparation of Cannabis oils.

2) PETROLEUM

ETHER

5e

Petroleum ether

(200 mL)

Extraction #1

g cannabis + 100 ml

petr. ether, agitate 20

Filtration with filter

Extraction #2

Same cannabis + 100

nll.petr. ether, agitate

20 min. (a)

Filtration with filter

Combine extracts

water bath ~98°C

under stream of

with EtOH to 100 mi

5 g/100 mt

2.5 mg/ml

3) ETHANOL

5g

Ethanol

Extraction #1:

g cannabis + 100 n

ethanol, agitate 20

min. (a)

Filtration with filter

Extraction #2

Same cannabis + 100

ml. ethanol, agitate 20

min. (a)

Filtration with filter paper

Combine extracts

extract over a column filled with activated charcoal

water bath ~98°C

under stream of

nitrogen gas

Reconstitute residu

with EtOH to 100 ml

2.5 mg/mL

4) OLIVE OIL

5g

Olive oil (20 mL)

5g cannabis + 20 mL

dive oil + 50 mL water.

Heat in water bath

~98°C for 60 min.

Before filtration, let it

stand to cool off.

material with 20 mL of hot water

filtrate by pressing (b)

Combine extracts

to separate water and

(-20°C) overnight

(oil) by pouring it off the frozen water lave

5 g/20 mL

100x

2.5 mg/mL

il. Put it in the freezer

5) OLIVE OIL II

10g

Olive oil

10 g cannabis + 100

mL olive oil. Heat in

water bath ~98°C for

120 min.

Before filtration, let it

stand to cool off

Collect the oil

10 g/100 mL

2.5 mg/mL

Filtrate by pressing (b) Filtrate by pressing (b)

			4
j	(8)		
1		0	
		ħ	

CANNABIS (q)

SOLVENT (mL)

EXTRACTION/

EXTRACT CLEAN-UP

EVAPORATION,

SEPARATION

EXTRACT

CONCENTRATION (cannabis/solvent) DILUTION FACTOR FOR

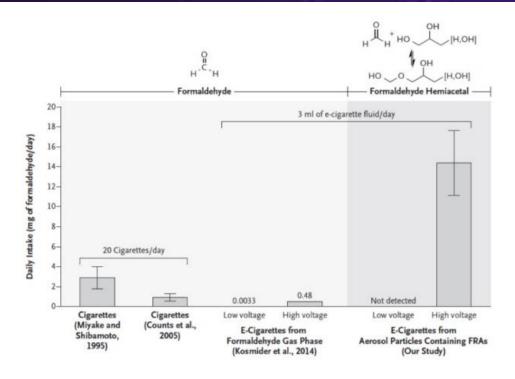
FILTRATION

2.5 mg/mL

CONCENTRATION (cannabis/solvent)

b): separate oil from plant material by using a French coffee press

# Product Safety with Vape Pens, Propylene Glycol & Formaldehyde



Jensen, R. P. et al. 2015. Hidden formaldehyde in e-cigarette aerosols. *NEJM* 372 (4):392-4.

E-cigarettes use propylene glycol and glycerol as propellants

Under heat, up to 2% of this mixture forms **formaldehyde**, a Group 1 carcinogen (International Agency for Research on Cancer-IARC)

Risk is as much as 15X that of chronic cigarette smoking.

Industry needs to verify their products are 100% compliant with safety standards.



# What does 99.9% conformance look like for other industries?

#### Would allow for:

- ◆Two unsafe landings at at Chicago O'Hare Airport each week
- ◆16,000 pieces of mail to be lost each hour
- ◆20,000 prescriptions to be incorrectly filled out each year



## Batch

- A batch...a finished product, manufactured according to regulations
- Standard processing unit
- If divided, it is nearly homogenous, uniform or the same



# Sampling

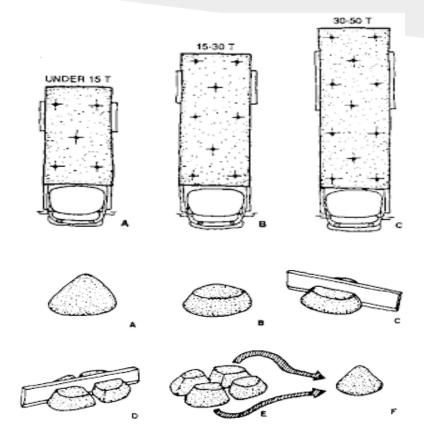
- Reduce bias in quantitative and qualitative analysis
- Samples are taken from the upper, middle, and lower sections of each container (USP561)
- Prepare sample by combining and mixing the individual samples taken from each opened container, without significantly affecting the material, i.e., the moisture content.



# Sample Preparation for Lab Analysis

• The GOAL = submit a representative sample







#### **PATIENT FOCUSED** CERTIFICATION

STANDARDS. EDUCATION. VERIFICATION.











#### Dispensary Operations



## Cannabis Dispensing Operations

- What is a distribution operation and how it must operate with regard to personnel, physical facilities and security
- What defines a cannabis product and how it can be acquired
- The product information that must be provided
- Handling Recalls
- What defines a compliant individual and requirements for purchasing cannabis products
- Patients' rights and responsibilities



## General Provisions

- Any person, group of persons, or business entity that provides cannabis or cannabisderived product to compliant individual
- Compliant individual meets all legal requirements to obtain and use cannabis or cannabisderived products
- Compliant individual, who transfers or gives cannabis or cannabis-derived product to another compliant individual, is not an operation
- All persons entities selling cannabis or cannabis-derived products must comply with the laws and regulations for the jurisdictions in which the transaction takes places



## **Types of Dispensing Operations**

#### **Types of Dispensing Operations**

- Storefront, which may or may not have delivery system
- Delivery service operation which may or may not have a storefront
- Direct-from-garden operations, which
  - May have a storefront or not
  - Be located where the cultivation takes place or another location
- Grow co-op operations





# Dispensing Organizations May Provide

- Cannabis that is cultivated by
  - The distribution operation itself
  - A co-owned cultivation operation
  - An independent cultivation operation
  - A cannabis vendor
- Cannabis-derived product manufactured by
  - The distribution operation itself
  - A co-owned cultivation operation
  - An independent cultivation operation
  - A cannabis vendor





## **Ancillary Operations**

- Cultivation of cannabis
- Processing, packing and labeling cannabis
- Manufacturing, packing and labeling cannabis-derived product
- Laboratory operations
- Sale and marketing of products other than cannabis or cannabis-derived product



## **Ancillary Operations, continued**

- At the same location where cannabis or cannabis-derived products are sold so long as it is legally permitted
- At another location where cannabis or cannabis-derived products are sold so long as it is legally permitted
- Ancillary operations must be conducted in compliance with all relevant regulations



### Personnel

- Employees must have the education, training, or experience
- Employers must ensure employees are educated in:
  - Specific uses of cannabis and cannabis-derived products
  - Clinical application of the constituents of cannabis
  - The laws, regulations, and policies relevant to providing cannabis or cannabis-derived product to compliant individuals
  - U.S. federal laws, regulations, and policies relating to individuals employed in distribution operations, and the implications of these for employees and for compliant individuals





### Personnel



- Storefront operations must have:
  - One or more employees have received adequate training to perform CPR
  - One CPR trained employee is on the premises at all times during open hours

## **Facilities**

- Adhere to any relevant regulation in the jurisdiction
  - Locations and zoning laws or guidelines
  - Business hours
  - Parking
  - Drive-through services
  - Signage
- Clean and orderly condition
- Utensils and equipment necessary to conduct all operations
- Policies that ensure the privacy of financial transactions
- Information available regarding local and federal laws



## Facilities, continued

- Adequate refrigeration if storing cannabis-derived product to ensure the safety and reduce spoilage
- Secure area for storage of cannabis or cannabis-derived product in inventory
- A secure area to keep money
- Remove money from the facility on a regular basis



## Facilities, continued

#### **Delivery Service Operations**

- Sufficient security personnel at the facility where product is acquired, stored or processed to ensure safety of staff and products
- Training for delivery staff to ensure personal and product safety and provide information to police if necessary
- Deliveries restricted to private address and never to public location.
- Comply with local regulations



## Security

- Provide security required by regulation
- Provide additional security as appropriate for the community where it operates
- Security personnel in sufficient number to ensure the safety of staff and others
- Security cameras
- Monitoring of dedicated parking with security personnel or security cameras



## Security, continued

#### **Delivery Service Operations**

Sufficient security personnel at the facility where product is acquired, stored or processed to ensure safety of staff and products

Training for delivery staff to ensure personal and product safety and provide information to police if necessary

Deliveries restricted to private address and never to public location.

Comply with local regulations



# Security, cont

#### **Direct-from-garden and Growing Co-op**

- Sufficient security personnel to ensure the safety of staff and security of cannabis
- Refrain from arming security personnel
- Provide training to make all staff aware of security procedures and employee security roles
- Must comply with all security measures required for such operations
- Should also establish and implement any relevant security measures recommended



#### Cannabis Product

#### **Products provided**

- Smoked cannabis
- Vaporized cannabis
- Oral cannabis (edibles)
- Topical cannabis (topicals)
- Up-to-date records identifying products
- Products source identified
- Identify restrictions to providing specific cannabis to consumers
- Employee limitations
- Compliant individual limitations



## **Cannabis Products Acquisition**

#### Establish and implement acquisition policies

- Identify acceptable locations for receipt of products
- Delivery schedule details
  - Scheduling appointments with vendors
  - Establish open vending times for delivery without an appointment



## Cannabis Products Acquisition, continued

- Post supplier policies
  - Cultivation practices
  - Processing or manufacturing
  - Packaging or labeling
  - Chemical analysis
  - Transport conditions such as refrigeration
- Ensure all policies conform to relevant legal requirements.



## Cannabis Products Acquisition, continued

- Must record each receipt of product
  - Name of the cultivator, processor, manufacturer or vendor
  - Description of product
  - Quantity of each product
  - Storefront operations minimize delivery times and locations where consumers are present
  - Inform all cultivation, processing, manufacturing operations of policies and requirements



## **Cannabis Products Information**

- Written or verbal information provided must be accurate.
- Must disclose extent and type of testing
- Type of test or examination used to determine strain
- If tested to determine quantitative levels of constituents contained, type of test
- If tested for absence or presence of potential contaminants (pesticides, yeasts, mold, or other microbiological)



## Cannabis Products Information, continued

- Information must be available prior to purchase
  - Posted with visible signage
  - Printed handouts
  - On website
- Identifying information must be provided as required by local and state laws
  - Accurately conveyed
  - Labeling or other accurate markings
  - Manufacturer information included



#### **Product Recalls**

- Policy must include:
  - Mechanism to contact customers who have or may have obtained product
  - Mechanism to contact supplier of product
  - Communication and outreach via media as appropriate returned
- Recalled product returned must either
  - Be disposed of to ensure it cannot be salvaged
  - Be returned to supplier



## Requirements for Purchase

- Only compliant individuals may purchase
- If restrictions exist requiring certain conditions, may not recommend for any other condition
- Must be aware of requirements for being a compliant individual
- Must have information available on regulations regarding compliant individuals



### **Purchase Limits**

- Quantitative limitations must b enforced by dispensing operation
- Quantitative limitations may be set by dispensing operation
- Limitations should be clearly communicated



#### **Personal Information**

- Obtain the following information for each customer:
  - Individual's name
  - Contact information (phone #, email, mailing address)
  - Physician of record
  - Health or medical conditions
- All information must be stored in compliance with HIPAA



### Adverse event records

- Adverse event = health-related event associated with use of cannabis product that is adverse
- Establish policy for receiving and record information on adverse reactions, including
  - Identity of person who had adverse event
  - Identity of person reporting adverse event
  - Identity of product used
  - Description of adverse event



### Adverse Event Records, continued

#### Adverse event reported to

- Public health authority
- Physician of record
- Determine if recall should be issued
- Communicate policy to employees and compliant individuals
- Note: An adverse event report may not be construed as an admission that the product involved caused or contributed to the adverse event.



### Rights and Responsibilities of Compliant Individual

#### Establish policy including:

- How compliant individual can expect to be treated
- Information compliant individual must provide
- Procedure for providing feedback and suggestions
- Contact information for operation or specific employee
- Hours of operation
- Policies related to:
- Payment
- Use of cannabis on premises
- Any other applicable policies



#### **PATIENT FOCUSED** CERTIFICATION

STANDARDS. EDUCATION. VERIFICATION.











Standards for the Cannabis Industry



# American Herbal Products Association (AHPA)



Largest trade association representing the botanical and nutraceutical industry. Played an integral role in the most successful grassroots movement in US History.

#### AHPA's ongoing role:

- Galvanizing the botanical and nutraceutical industry
- Developing sensible national regulatory policy
- Fighting onerous FDA regulations



# American Herbal Pharmacopoeia (AHP)

# American Herbal Pharmacopoeia®

#### Editors and Technical Advisors

Roy Upton RH DAyu American Herbal Pharmacopoeia\* Scotts Valley, CA

Lyle Craker PhD University of Massachusetts Amherst, MA

Mahmoud ElSohly PhD University of Mississippi University, MS

Aviva Romm MD CPM American Herbal Pharmacopoeia\* Lennox, MA

Ethan Russo MD GW Pharmaceuticals Salisbury, UK

Michelle Sexton ND BS Americans for Safe Access Washington, DC The Center for the Study of Cannabis and Social Policy Seattle, WA

#### Research Associates

Jahan Marcu PhD Green Standard Diagnostics Henderson, NV

Diana Swisher MA American Herbal Pharmacopoeia\* Scotts Valley, CA Cannabis Inflorescence Cannabis spp.

STANDARDS OF IDENTITY, ANALYSIS, AND QUALITY CONTROL



#### Cannabis Monograph:

- Standards of Identity, Analysis, and Quality Control
- Therapeutic Compendium

#### Standards That Ensure:

- Identity
- Purity
- Accuracy



### **AHPA Standards For Cultivation**

SUBPART A – GENERAL PROVISIONS

Section 1.1 Subject operations

Section 1.2 Other statutory provisions and

regulations

Section 1.3 Definitions

SUBPART B – CULTIVATION AND PROCESSING

**OPERATIONS** 

Section 2.1 Types of cultivation operations

Section 2.2 Ancillary operations

Section 2.3 Cultivation practices

Section 2.4 Processing practices

Section 2.5 Distribution practices

SUBPART C - PERSONNEL

Section 3.1 Personnel training

Section 3.2 Employee safety

PATIENT FOCUSED CERTIFICATION

a project of Americans for Safe Access Foundation

SUBPART D - FACILITIES

Section 4.1 General compliance

Section 4.2 Fire prevention

Section 4.3 Sanitation practices

Section 4.4 Electrical system

Section 4.5 Ventilation system

Section 4.6 Disposal and waste practices

Section 4.7 Security provisions

SUBPART E – WATER RESOURCE MANAGEMENT

Section 5.1 Cultivation water management

Section 5.2 Potable water for employee use

SUBPART F – RECORDKEEPING

Section 6 Recordkeeping practices

SUBPART G – INFORMATION DISCLOSURE

Section 7 Information disclosure

SUBPART H - RECALLS

Section 8 Recall plan

1-888-929-4367 patientfocusedcertification.org

### **AHPA Standards For Manufacturing**

SUBPART A – GENERAL PROVISIONS

Section 1.1 Subject operations

Section 1.2 Other statutory provisions and regulations

Section 1.3 Definitions

SUBPART B – GENERAL REQUIREMENTS

Section 2.1 Acquisition of cannabis and cannabis-derived products

Section 2.2 Distribution of cannabis and cannabis-

derived products

Section 2.3 Ancillary operations

SUBPART C - PERSONNEL

Section 3.1 Personnel training

Section 3.2 Personnel responsibilities

Section 3.3 Personnel safety

Section 3.4 Supervisor requirements



Section 4.1 Design and construction

Section 4.2 Sanitation requirements

Section 4.3 Equipment and utensils

Section 4.4 Security requirements

SUBPART E - MANUFACTURING PROCESS CONTROLS

Section 5.1 Manufacturing protocol

Section 5.2 Manufacturing component control

requirements

Section 5.3 Manufacturing batch record

Section 5.4 Allocation and charge-in of components

Section 5.5 Process monitoring and controls during

manufacturing

Section 5.6 Manufacturing sampling requirements

Section 5.7 Cannabis-derived product specifications

Section 5.8 In-process material specifications, sampling,

and testing

Section 5.9 Calculation of yield



# AHPA Standards For Manufacturing continued...

SUBPART F – PACKAGING AND LABELING PROCESS CONTROLS

Section 6.1 General considerations for packaging components, including labels

Section 6.2 Packaging and/or labeling protocol

Section 6.3 Packaging and/or labeling batch record

Section 6.4 Label content for cannabis and cannabis-derived products

SUBPART G – HOLDING CONTROLS

Section 7.1 Identification

Section 7.2 Storage and handling

Section 7.3 Withholding materials from use or distribution

SUBPART H – INVENTORY AND RECORDKEEPING

Section 8.1 Materials inventory

Section 8.2 Distributed materials

Section 8.4 Reconciliation

Section 8.5 Record retention

SUBPART I - COMPLAINTS, RETURNS, AND RECALLS

Section 9.1 Complaint files

Section 9.2 Returned products

Section 9.3 Recall procedures



### AHPA Standards For Dispensaries

SUBPART A – GENERAL PROVISIONS

Section 1.1 Subject operations

Section 1.2 Other statutory provisions and regulations

Section 1.3 Definitions

SUBPART B – DISPENSING OPERATIONS

Section 2.1 Types of dispensing operations

Section 2.2 Ancillary operations

Section 2.3 Personnel

Section 2.4 Physical facilities

Section 2.5 Security

SUBPART C - CANNABIS PRODUCT

Section 3.1 Subject cannabis products

Section 3.2 Cannabis product acquisition

Section 3.3 Cannabis product information

Section 3.4 Cannabis product recalls

SUBPART D - COMPLIANT INDIVIDUALS

Section 4.1 Requirements for purchase

Section 4.2 Purchase limits

Section 4.3 Personal information

Section 4.4 Adverse event records

Section 4.5 Rights and responsibilities of compliant individuals



#### **PATIENT FOCUSED** CERTIFICATION

STANDARDS. EDUCATION. VERIFICATION.











#### Product Safety and Consumers



### Patient Rights

- 1. Respect and non-discrimination.
- 2. Confidentiality of health information. Patients have the right to talk in confidence with with provider, and to have their healthcare information protected under all applicable laws.
- 3. Right to information disclosure. Patients have the right to accurate and easy to understand information about laws and regulations (especially in gray markets).
- 4. Right to adequate quality control. Patients have the right to cannabis products that are free of mold, mildew, pesticides, adulterants, and pests. They have the right to know how the cannabis was produced.



## Patient Rights

- 5. Right to obtain medicine in a safe environment, which includes but isn't limited to security, health and safety protocols and legal business practices.
- 6. Right to have input and to make a complaint, without the fear of losing access. This includes complaints about waiting times, operation hours, conduct of personnel, and adequacy of the facility.
- 7. Right to medicine that is labeled and weighed accurately. No dispensary should deliberately mislead a patient about the quantity of or variety of medication that is being provided.
- 8. Right to pay a fair and reasonable price for your cannabis and cannabis products.



### Disease Claims vs Standard and Function Claims

Disease Claims are product claims that describe the medical condition the product is used as a treatment or cure for:

- Disease claims are only legally applied to pharmaceutical products approved by the FDA
- Examples of Disease Claims include:
  - Chemotherapy kill cancer cells
  - Ambien treats insomnia

Standard and Function claims are claims that describe the botanical action of a product without making reference of a "disease" or medical condition

- These are the only health claims legally allowed in association with cannabis medicine
- Examples include:
  - Cannabis has anticonvulsant properties
  - Cannabis has anti-inflammatory properties
  - Cannabis is an analgesic



# **Labeling Products**

Label content for cannabis and cannabis-derived products

Each packaged and labeled product must bear on the label of its primary packaging:

- (1) Name and place of business of the manufacturer or distributor;
- (2) Identity of the product;
- (3) Net quantity of contents in terms of weight, numerical count, or other appropriate measure;
- (4) A batch, lot, or control number;



# **Labeling Products**

- (5) Either a production date or an expiration date. Products capable of supporting the rapid and progressive growth of infectious, toxigenic, or spoilage microorganisms must bear a "use by" date and/or a "freeze by" date. Any shelf life or expiration period indicated on the label of an edible product must be supported by appropriate data;
- (6) Instructions for use, including any types of compliant individuals for whom the product is recommended, as appropriate;
- (7) Appropriate warnings for use, including any types of compliant individuals for whom the product is contraindicated, as appropriate;
- (8) Instructions for appropriate storage



# Labeling Edible Products

For edible products, each product label must contain "Product Facts" box listing quantitative content and nutrient information relevant to the product including, as applicable to the product's content:

- (1) Cannabis ingredient;
- (2) Cannabinoid and/or terpenoid content;
- (3) Total calories and fat calories (when greater than 5 calories per serving);
- (4) Total fat, saturated fat, and trans fat (when greater than 0.5 g per serving);
- (5) Cholesterol (when greater than 2 mg perserving);
- (6) Sodium (when greater than 5 mg per serving);

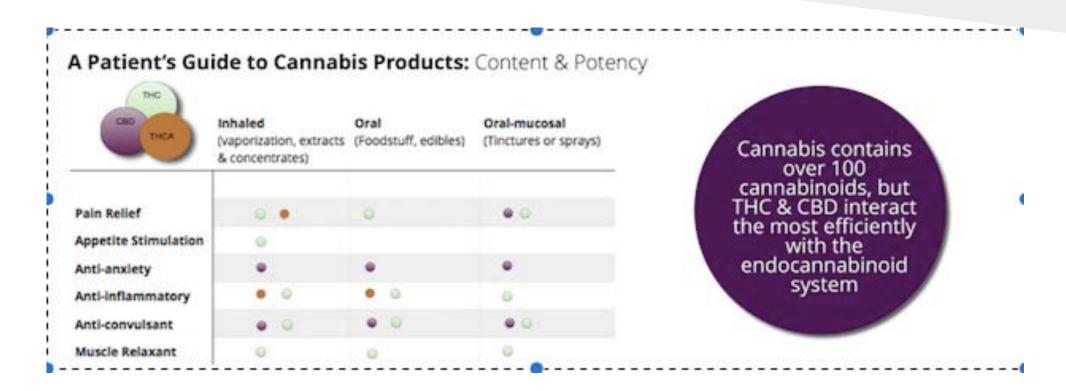


# Labeling Edible Products

- (7) Total carbohydrates (when greater than 1 g per serving);
- (8) Dietary fiber (when greater than 1 g per serving);
- (9) Sugars (when greater than 1 g per serving);
- (10) Protein (when greater than 1 g per serving);
- (11) Vitamin A, vitamin C, calcium, and iron (when present at greater than
- 2% of the recommended
- daily intake).



# Helping Patients Choose Medicine







# Selecting Delivery Method

#### **Selecting Delivery Methods:**

There are some basic things to consider before a patient chooses a delivery method for medical cannabis:

**Comfort:** One great thing about the variety of delivery methods is that patients can choose what works best for them. For example, some patients will appreciate how easy it is to self-titrate with smoked cannabis, while others may prefer an edible preparation or a vaporizer to avoid inhaling smoke (see below).

**Cost:** Cannabis is not covered under insurance, and the price is still influenced by the unregulated illicit market to some degree. The various delivery methods vary greatly in cost as well as duration of efficacy. It takes more cannabis to prepare an edible preparation or concentrate than it does to smoke cannabis from a pipe.



# Selecting Delivery Method

**Lifestyle:** Delivery methods have varying degrees of odor, side effects, and discretion associated with each. Choose a delivery method that will allow a patient to integrate the medication into all aspects of their life.

**Effectiveness:** Experimenting with various delivery methods will help patients find products that work for them. They may find that it takes a combination of products to achieve therapeutic effects.



# Delivery Method: Smoking

Types of products: whole plant, oils, waxes, and concentrates

Expected onset: 0-10 minutes

Duration: 1-4 hours

Equipment needs: grinders, pipes, rolling papers, lighter

Pros: rapid onset, easy method to titrate

Cons: odor, sore throat, throat irritation, high visibility, costs (use more cannabis

compared to other delivery methods)



# Delivery Method: Vaporizing

Types of products: whole plant, oils, waxes, concentrates

Expected onset: 0-10 minutes

Duration: 1-4 hours

Equipment needs: grinders, large table top vaporizers, portable vaporizers

Pros: rapid onset, easy method to titrate

Cons: costs (use more cannabis compared to other delivery methods and price of

vaporizer)



# Delivery Method: Topicals

Types of products: lotions, salves, oils

Expected onset: a few minutes

Duration: 1-4 hours

Equipment needs: just product

Pros: easy to use, discreet, rapid onset, localized treatment benefits

Cons: difficult to find proper medicine that works and thus requires

experimentation, odor issues



### Delivery Method: Food and Drink

Product types: edible products, beverages, teas, capsules

Expected onset: 30 to 90 minutes

Duration: Up to 8 hours

Equipment needs: just product (or foodstuffs if you are making these on your own.

Pros: longer duration, sustained therapeutic value, discreet, ease of transport, cheaper

Cons: harder to titrate, during the digestion process THC converts to a more potent

molecule creating a delayed and sometimes intense experience



# Delivery Method: Sublingual

Types of products: alcohol-based tinctures, lozenges

Expected onset: 0-60 minutes

Duration: 1-8 hours

Equipment needs: product

Pros: rapid onset, discreet

Cons: alcohol-based, cost



### Discussing Side Effects with Patients

Uneasiness
Hunger and thirst
Redness in the eyes
Drowsiness
Sleeplessness
Short-term memory loss
Feelings of euphoria
Decrease in blood pressure
Increase in heart rate



### **Factors for Side Effects**

Amount used (dosage)
Strain of cannabis used
Route of administration (delivery method)
Environment/setting
Your experience and history of cannabis use
Your individual biochemistry
Mindset or mood
Nutrition or diet
Overall health and wellbeing
Relative physical strength or weakness



# Treating THC "overdoses"

Lemon juice

Pine nuts

Water

Smelling pine essential oils

Calm breathing

See taming THC <a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3165946/">http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3165946/</a>













# PATIENT FOCUSED CERTIFICATION



a project of Americans for Safe Access Foundation

# What is PFC?



- Nonprofit Third Party
   Certification
- Peer Reviewed
- Seed to Consumption Quality Standards
- Staff Training
- Educational Materials
- Documentation & Facility 888-929-4367 Audits



### **PFC Certifications**

#### Available in US and internationally 2016





# PFC Seal of Approval



- Compliance with state and local regulatory guidelines
- Compliance with AHPA and AHP standards
- Commitment to purity and identity of products
- Implemented standardized methods:
  - Cultivation
  - Manufacturing
  - Laboratory Testing
  - Distribution



### AHPA & AHP Guidelines

#### Standards for Patient Focused Certification

#### **Enhance and Promote Product Safety**

- Ensures consistency of quality and effectiveness
- Ensures proper labeling

#### Standardized cannabis botanical medicine

- First standardized testing protocols developed for medical cannabis and medical cannabis products
- Builds foundation for human clinical trials and case studies
- Increases patient and practitioner confidence
- Medical cannabis will no longer be a last resort



### **PFC Certification Process**



**CHOOSE:** Which certification program works for your business. Depending on the focus of your business or the state in which it is located different certifications may be required.



**AUDIT:** PFC staff will then walk your business through the audit process, which includes a Documentation Audit, Staff Training, and On-site Facility Audit.





**APPLY:** Apply for a free quote. The PFC process begins with filling out an online application that will be followed by a price quote and contract.





**REVIEW:** Await the PFC staff review of audit findings.





**CERTIFY:** Receive the certification decision, which you can either accept or appeal. An affirmative decision will mean your business is now PFC certified.



### PFC Peer Review Board

### Over 300 Years of Combined Expertise

- Complementary and Alternative Medical (CAM) therapies
- USDA food and product safety protocols
- Federal regulatory development
- Medical cannabis research
- Medical cannabis industry
- Pharmacology
- Biochemistry
- Education



# Staff Training

# Minimum Mandatory Training for all staff and volunteers

#### **Core Cannabis**

- Cannabis Law & Politics
- Cannabis as Medicine, Endocannabinoid System
- General Cannabis Business Operations

#### **Operations-Specific**

- Cultivation and Processing
- Manufacturing, Packaging, and Labeling
- Laboratory Testing
- Distribution and Dispensing

#### **State-Specfic**

Laws and regulations



### Documentation

#### **All PFC Companies:**

- Documentation
  - Implementable product recall protocols
  - o Batch-number-based
  - Adverse-event reporting
- Federal, state, and local compliance with environmental laws

#### **Lab Testing Facilities:**

- American Herbal Pharmacopoeia Cannabis Plant Monograph
- Equipment calibration
- Protocol evaluation
- Methodology standardization



# **Facility Auditors**

All PFC Auditors have a minimum of 5 years applicable experience

#### **Cultivation Auditors**

- In the field of medical cannabis cultivation; or
- Inspecting food crops for the Department of Food and Agriculture
- Inspecting food crops for other appropriate certification body

#### Manufacturing, Packaging, Labeling, and Holding Auditors

- In the field of medical cannabis manufacturing; or
- Inspecting operations that produce products intended for human consumption, including topical applications

#### **Distribution**

- In the field of medical cannabis distribution management; or
- Inspecting traditional and/or Complementary Alternative Medical facilities

#### **Laboratory Analysis**

- Engaging in laboratory analysis of medical cannabis
- Degree in Bio-chemistry



# PFC Reduces Company Liability

- Employee and management training
- Patient and caregiver educational materials
- Implementation of product safety protocols
- Adverse-event reporting
- Complete product recall programs
- "Standard and Function" development
  - Case Studies
  - Non-FDA Claims
  - Botanical and Nutracuetical appropriate descriptions for cannabis
     & cannabis product actions



# PFC Program Cost & Value

#### Historically, big business with support of government:

- Onerous regulations to monopolize marketplaces
- Creating scale of economy forcing out small business

#### **Protect Your Company:**

- Show regulators and lawmakers commitment to high standards of operation
- Discourages the development of overly restrictive regulations
- Regulating cannabis akin to other botanical products



**APPLY** 

#### **PATIENT FOCUSED** CERTIFICATION

STANDARDS. EDUCATION. VERIFICATION.













#### What is PFC?

PFC offers third-party certification and support services to companies cultivating, manufacturing, analyzing or distributing medical cannabis products and is the nation's only certification program based upon the AHPA and AHP standards.

**LEARN MORE** 



#### Our Standards

Our standards were developed in two parts: 1. AHPA Recommendations to Regulators & 2. The AHP Monograph & Therapeutic Compendium for Cannabis. PFC companies are compliant with state & local regulations, AHPA & AHP standards.

**LEARN MORE** 



#### **Industry Certification**

Available to cannabis companies in states with medical cannabis and/or legal adult use laws in place. PFC is designed to show the commitment of cannabis companies to providing quality care and standards to patients and/or consumers.

**BECOME CERTIFIED** 

#### FOR MORE INFORMATION



Advancing Legal Medical Marijuana Therapeutics and Research

#### **National Office**

1806 Vernon St. NW, Suite 100, Washington DC 20009 **PHONE**: 202.857.4272 **FAX**: 202.857.4273

#### **California Office**

770 L Street, Suite 950, Sacramento, CA 95814 **PHONE**: 916.449.3975

#### **General Information**

**WEB:** www.AmericansForSafeAccess.org **TOLLFREE:** 888-929-4367

