

Cachexia, Cancer, Chronic Pain, Epilepsy, Glaucoma, HIV, AIDS, Multiple Sclerosis, Nausea, ALS, Crohn's, Hepatitis C, Anorexia, Arthritis, Migraine, Parkinson's, Damage to the Nervous Tissue of the Spinal Cord with Objective Neurological Indication of Intractable Spasticity, PTSD, Traumatic Brain Injury, Use of Azidothymidine, Tourette Syndrome, Lupus, Chemotherapy or Radiotherapy, Reflex Sympathetic Dystrophy, Neurofibromatosis, Arnold-Chiari Malformation, Hydrocephalus, Residual Limb Pain, Terminal Illness with a Life Expectancy Under One Year, Hospice Care, Huntington's, Chronic Renal Failure ...

If you or someone you know suffers or endures any one of these, you have an interest in the medical marijuana industry and recognize the importance of analytical testing.

Stakeholder Panel on Strategic Food Analytical Methods: Background and Fitness for Purpose for CANNABIS

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Cannabis Advisory Panel

- Susan Audino, Chair
- GW Pharmaceuticals – Peter Gibson
- SC Laboratories – Josh Wurzer
- SCIEX – Paul Winkler
- SPEX – Patricia Atkins
- Sigma Aldrich – Jennifer Claus
- CEM – Bob Lockerman

Medical Cannabis Background

- Medicinal Marijuana is legal in 24 states & D.C.
- Schedule I Drug = “No medicinal value” → Federal Prohibition
- States are self-regulated
- Several require analytical testing
 - Potency
 - Pesticide Residue
 - Microbial
 - Solvent Residue

Medical Cannabis Background

- The PLANT
 - Highly complex herb; heterogeneous within and between
 - More than 400 constituents – approximately 114 are “phyto cannabinoids” which are naturally occurring cannabinoids
 - About a dozen of these have demonstrated medicinal value
 - Only one is psychoactive
 - More than 29 flavonoids
- The CANNABINOIDS
 - All contain carboxylic acid groups that are kicked off with heat
 - Interest in both “acid” and “neutral” compounds
 - Cannabinoid acids are devoid of psychotropic effects

Some Medicinal Applications & Benefits

- Decreases intra-ocular pressure – **Glaucoma**
- Provides some abatement of severe anxiety – **PTSD**
- Reduces seizure activity; in some cases from 300 to 1/week
- Provides suppression of muscle spasms – **Multiple Sclerosis**
- Provides calming effect on the immune system - **Lupus**

Health Effects of Marijuana	THC	THC-A	THC-V	CBN	CBD	CBD-A	CBC	CBC-A	CBG	CBG-A	Benefits
Pain relief											Analgesis
Reduces inflammation											Anti-inflammatory
Suppresses appetite											Anorectic
Stimulates appetite											Appetite stimulant
Reduces vomiting and nausea											Antiemetic
Reduces contractions of small intestine											Intestinal antipropulsive
Relieves anxiety											Anxiolytic
Tranquilizing / psychosis management											Antipsychotic
Reduces seizures and convulsions											Antiepileptic
Suppresses muscle spasms											Antispasmodic
Aides sleep											Anti-insomnia
Reduces efficacy of immune system											Immunosuppressive
Reduces blood sugar levels											Anti-diabetic
Prevents nervous system degeneration											Neuroprotective
Treats psoriasis											Antipsoriatic
Reduces risk of artery blockage											Anti-ischemic
Kills or slows bacteria growth											Anti-bacterial
Treats fungal infection											Anti-fungal
Inhibits cell growth in tumours / cancer											Anti-proliferative


How does this work?

- Endocannabinoid Receptor System (ECS)
- Discovered in mid-1990s and found in every living being except insects.
- Two known receptors (more expected on the horizon)
 - CB1 and CB2
 - CB1: predominantly found in the brain; helps modulate and moderate pain
 - CB2: primarily found in the immune system; has anti-inflammatory properties

EXCLUSIVE INTERVIEW: STARTUP FROM EX-ITUNES PRODUCER

Cannabis in chocolate to be as normal as caffeine in drinks, says startup Défoncé Chocolatier

By Douglas Yur 01-Aug-2016
Last updated on 01-Aug-2016 at 12:19 GMT



Défoncé chocolate bars are only sold in California to people with a medical cannabis card, but that could change if the state legalizes the drug.

Related tags: Marijuana, Cannabis, Apple, California

Défoncé Chocolatier's founder and CEO, Eric Esdao, is waiting for the final vote on California's Adult Use Marijuana Act in November. If passed, his cannabis-infused chocolate can be sold in the state for recreational purposes.

"When I started this company, the market's focus was solely on creating a high-potency vehicle for people to get high," the former iTunes producer turned chocolatier told ConfectioneryNews.

Défoncé currently has eight chocolate bars. Each bar is 100 g and retails for \$20 in California.

Food Items & Label Claims



Significance

If edibles are the vehicle for dosing, then knowing what and how much of the analyte is present becomes the single most critical factor.

Reliable and Effective Testing is IMPERATIVE.

What does this mean?

- Producers are making potency and constituent claims.
- How can they be challenged?
- **Consumer Safety**



Analytical Challenges

- **COMPLEX MATRIX**

- Raw Plant material
 - Trim
 - Bud
 - Flower
 - Stem
 - Composite



- **Heterogeneity**

- Within a single plant
- Between different plants – same strain or different strains

Analytical Challenges

- **Food Matrices**

- when is cannabis introduced into the product?
 - Beginning of process
 - Mid-Process
 - Topical/surface
- What is the end product?
 - And what/if any loss in cannabis is realized?

Significance and Implications

- The LACK of consensus methods
 - Inadequate testing
 - Inappropriate testing
 - Non-Reproducibility
 - Inherently unreliable
- Constant battle between growers and test labs → SAMPLE SIZE
- Instrumentation – better testing costs more in \$\$ and time
- Balancing scientific acumen with business

General Analytical Needs

- Potency
 - THC, THCA, THCV
 - CBD, CBDA, CBDV
 - CBG
 - CBN
- Pesticide Residues
- Matrices
 - Raw
 - **Extracts**
 - **Edibles**

General Analytical Needs

- Consensus methods
 - Validated
 - Statistically Sound
 - Reproducible
 - Repeatable
 - Reliable
 - Robust
 - Correct Technology
- Affordable to consumers
- Traditional methodology

Challenges

- Federal Prohibition
- Matrix Effects
- Fiscal concerns:
 - Sample Size
 - Instrumentation
 - Analyst skill set
 - Turn-around-time
 - Qualitative vs. Quantitative
- Pesticides – which ones??

General Methods: US Herbal Pharmacopoeia Monograph

- ***No standardized methods***
- ***Methods are outlined but seem to lack validation data.***
- GC -FID: quantitation of phytocannabinoids
- ICP-MS: Metals (Ar, Cd, Cr, Pb, Hg)
- GC/HPLC: Pesticides
 - Refers to FDA Pesticide Analytical Manual
- TLC

No /Inconsistent Regulatory Guidance

- NO Federal Guidance: FDA EPA USDA
- States are self regulating and developing their own sets of standards and requirements
 - ISO/IEC 17025
 - TNI
 - Other
 - None
- State Oversight
 - DOH
 - Agriculture
 - Commissions
 - Other

Sense of Urgency

- In the interest of *consumer safety*, an advisory panel has formed and is committed to developing consensus methods for specific use in the cannabis industry.
- The field is large; our initial objective(s) is to systematically target most urgent needs which may include:
 - Determining the most cost efficient and scientifically sound sample preparation method(s)
 - Determining potency of the most significant phyto-cannabinoids
 - For example: THC, THCA, THCV, CBD, CBDA, CBDV, CBN, CBG
 - Determining pesticide residues
 - Determining solvent residues

Proposed Fitness for Purpose

~ Standard Methods Performance Requirements (SMPRs)
for quantitative methods for various measurements of
cannabinoids in raw materials and extracts ~

Next Steps

- Form Working Group(s) of interested and capable personnel with commitment to solve this problem.
- Advantages
 - Close work with highly reputable analysts
 - Be a trend setter!
 - Be among the first to establish critical methods for the benefit of consumer safety

QUESTIONS & DISCUSSION

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