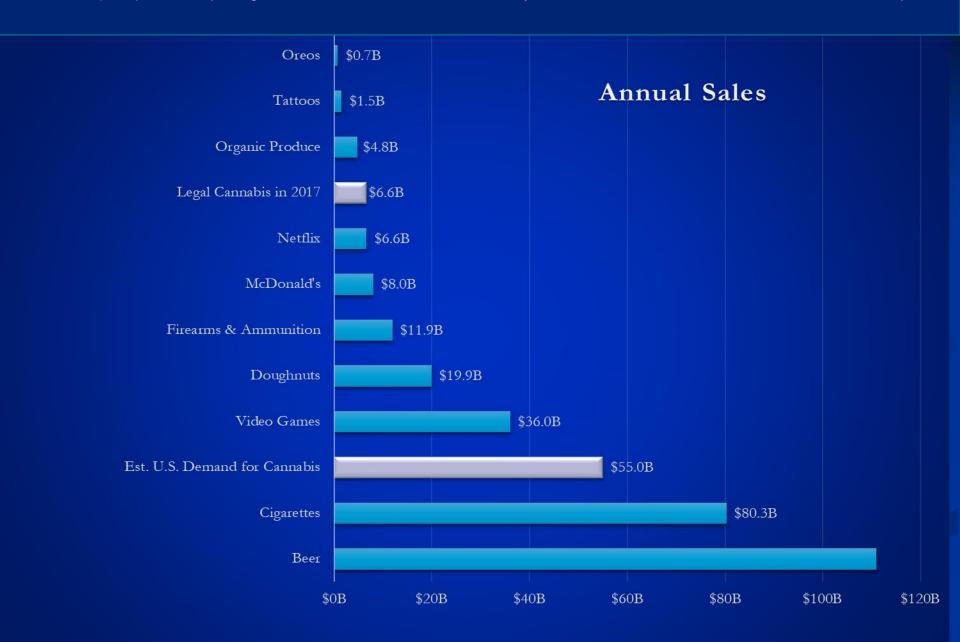
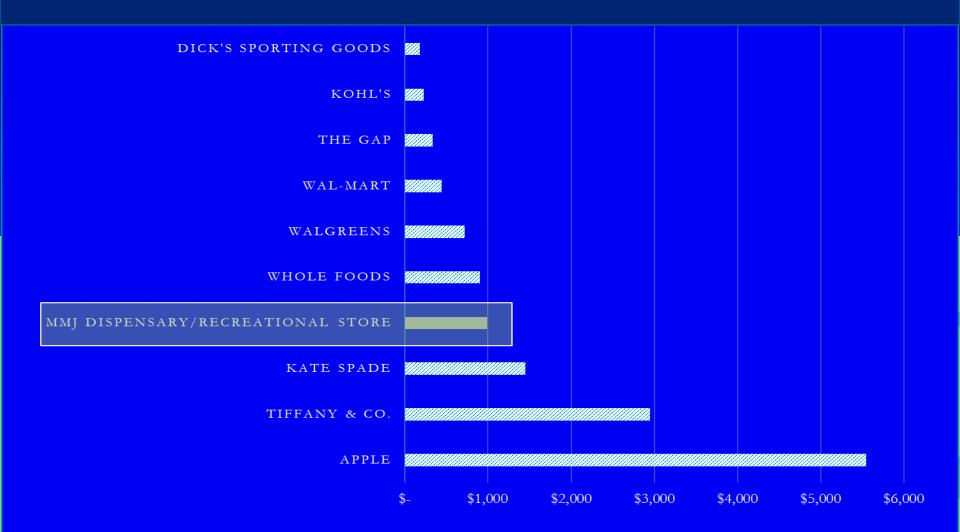
RETAIL DEVELOPMENT & LAW SYMPOSIUM

Hilton Columbus / Polaris Columbus, Ohio March 1, 2019







Avg. Annual Revenue / Sq. ft. vs. Other Retailers









THC and CBD: Where we are and need to be

Martin H. Bluth, MD, PhD

BLUTH BIO INDUSTRIES, LLC

DIAGNOSTICS, THERAPEUTICS AND CONSULTING

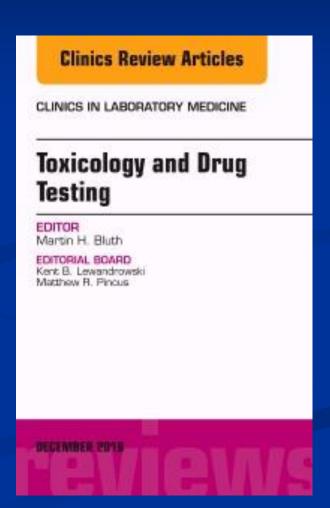




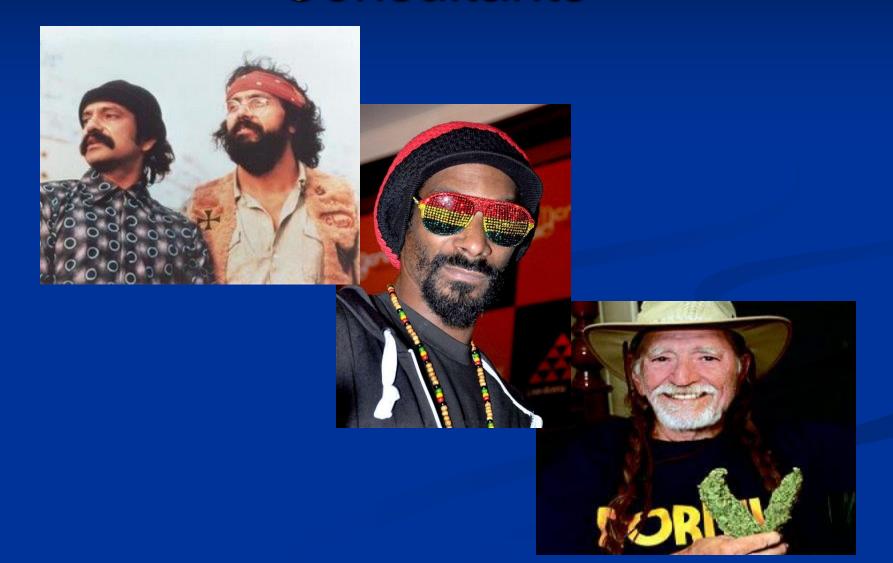


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 - Pharmacogenomics and Personalized Medicine
 - Journal of Blood Medicine
 - Journal of Applied Clinical Pathology
- Michigan State Medical Society Committees:
 - Health Care Quality Economics and Efficiency
 - Opioid Prescription Stewardship Task Force
- Published Medical guidance:
 - Toxicology and Drug Testing
 - Molecular Pathology



Consultants



Context

- Cannabis and its derivatives have been utilized for hundreds of years and applied to social, agricultural and medical uses.
- Tetrahydrocannabinol (THC) the psychoactive component differs from cannabidiol (CBD).
- Medical, legal and economic issues revolve around both substances.

Economics

- CBD products have proven themselves to be much more multifunctional compared to other legal marijuana applications as hemp-based CBD products and solutions are rapidly on the rise.
- Hemp sales reached \$688 million last year, according to the Hemp Business Journal, growing at a 22% compound annual growth rate over the past five years.
- While personal care products hold the greatest share of the market, hemp-based cannabidiol (CBD) represents the fastest growing subset of the industry with a 53% compound annual growth rate.

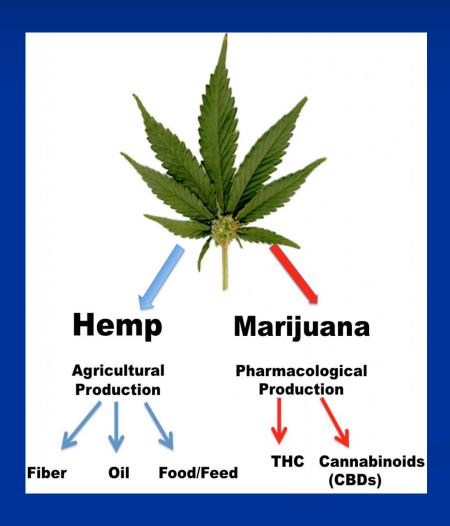
Botany

Both THC and CBD can be derived from the Cannabis species (sativa, indica, ruderalis) of plant. The distinction is in the relationship of THC vs CBD in the species and its varieties.



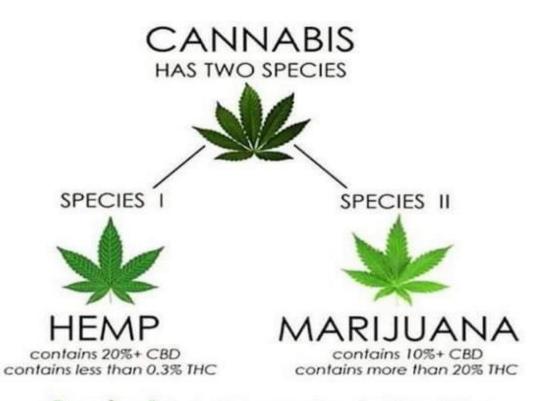
Cannabinoids (>100)

Botany



For example -Hemp has lower concentrations of THC and higher concentrations of CBD, which decreases or eliminates its psychoactive effects.

The Confusion



Species | is a Hemp extract with all the cannabinoids except for THC, which means it has all the beneficial properties of cannabis without the HIGH!

Effects

Both of these substances interact with the (endo) cannabinoid (anandamide, 2AG) receptors found in the human body and brain (CB1, CB2) – "runner's high" - but they differ dramatically in their effects.

CBD is non-psychoactive which means that it will not get the user "high". Because of this trait, CBD appears more frequently than THC in dietary and natural supplements.

THC Effects

Recreational

- Relaxation
- Altered senses of sight, smell, and hearing
- Fatigue
- Hunger
- Reduced aggression

Medicinal

- Side Effects of Chemotherapy
- Multiple sclerosis
- HIV/AIDS
- Spinal injury: Lessen tremors
- Nausea and vomiting
- Chronic pain
- Inflammation
- Digestive health

Preparations

Description
Dried plant product consisting of leaves, stems, and flowers; typically smoked or vaporized
Concentrated resin cake that can be ingested or smoked
Cannabinoid liquid extracted from plant; consumed sublingually
Oil obtained from cannabis plant by solvent extraction; usually smoked or inhaled; butane hash oil (sometimes referred to as "dabs"), for example
Plant material mixed with nonvolatile solvents such as butter or cooking oil and ingested

^a These preparations are available from state-approved medical marijuana dispensaries.

Preparations

Cannabis Preparations

Name	Part of Plant	THC
Marijuana	Leaves, stems	1-3 %
Sinsemilla Ganja	Sterile flower heads	3-8 %
Hashish	Cannabis resin	10-15 %
Cannabis/ Hash Oil	Resin concentrate (alcohol extract)	20-60 %

CBD Effects

- Pain (neuropathic, chronic, cancer-related, etc.)
- Epilepsy
- Multiple Sclerosis (MS)
- Amyotrophic Lateral Sclerosis (ALS)
- Parkinson's
- Inflammation
- Acne
- Dyskinesia
- Psoriasis
- Broken Bones

- Bacterial Infections
- Diabetes
- Rheumatoid Arthritis
- Nausea
- Anxiety
- ADHD
- Schizophrenia
- Substance Abuse/Withdrawal
- Heart Disease
- Irritable Bowel Syndrome (IBS)
- Depression
- Counteract THC effects



Different forms of CBD

Oil - oils, tinctures, creams and gels, capsules, sublingual sprays, transdermal patches or vapors.

Wax - shatter, live resin, crumble or budder

Isolate - eliminates the chance of trace amounts of THC or contaminants

Crystals/sheets - capsules, edibles and creams

E-liquids - for vaping (some with nicotine and some with THC)

How is CBD made?

Oil Extraction with Liquid Solvent

CO₂ Extraction

Extraction in a Tincture

Oil Extraction

Extraction by Molecular Separation

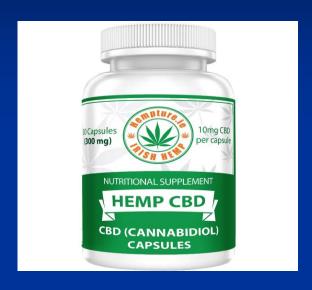
CBD Commercialism







CBD Commercialism







CBD Commercialism





Contaminants

TABLE 1. Recommended methods for cannabis analysis

Analyte	Examples	Significance	Recommended methods	
Cannabinoids	THC*, THCa, CBD, CBDa, CBN	Potency testing; important for correct dosing of medical marijuana patients	HPLC-UV GC-FID (cannot distinguish THC) THCa or CBD/CBDa without derivatization)	
Terpenes	α -pinene, limonene, β -carophylene	Confer fragrances to canna- bis and may influence medicinal properties	FET-HS-GC-FID FET-HS-GC-MS GC-FID GC-MS	
Residual solvents	butane, propane, isopropanol, acetone	Solvents left over from cannabinoid extraction; may be harmful	FET-HS-GC-FID FET-HS-GC-MS	
Pesticides	Organophosphates, pyrethroids, carbamates	Residual pesticides may be harmful, especially to young children or immunocompromised medical marijuana patients	HPLC-MS/MS GC-MS/MS GC-ECD (chlorinated)	
Heavy metals	arsenic, mercury, lead, cadmium	Contamination from soil; high levels can be toxic	ICP-OES ICP-MS	
Microbial contamination	mold, mildew, bacteria, yeast, mycotoxins, aflatoxins	May be harmful, especially to immunocompromised medical marijuana patients	Plating assays Films qPCR	

^{*}See text for abbreviations

Preparations may not contain concentrations as advertised

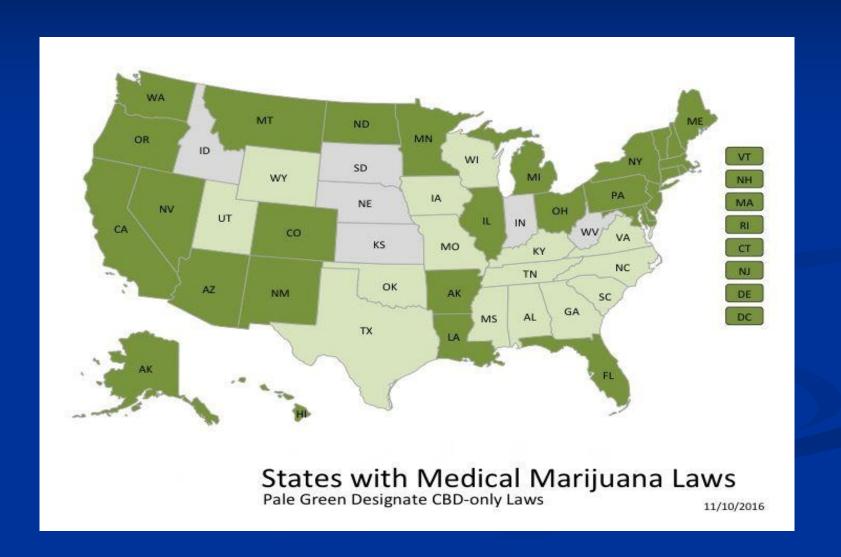
Table 1. Label Accuracy by Cannabidiol Extract Type						
	Cannabidiol Extract Product					
	Oil (n = 40)	Tincture (n = 20)	Vaporization Liquid (n = 24)	Total (N = 84)		
Label accuracy, No. of products (%) [95% CI]						
Accurate ^a	18 (45.00) [30.71-60.17]	5 (25.00) [11.19-46.87]	3 (12.50) [4.34-31.00]	26 (30.95) [22.08-41.49]		
Under ^b	10 (25.00) [14.19-40.19]	8 (40.00) [21.88-61.34]	18 (75.00) [55.10-88.00]	36 (42.85) [32.82-53.53]		
Over ^c	12 (30.00) [18.07-45.43]	7 (35.00) [18.12-56.71]	3 (12.50) [4.34-31.00]	22 (26.19) [17.98-36.48]		
Labeled concentration, mg/mL						
Mean (95% CI)	56.15 (14.23-98.07)	11.14 (5.60-16.60)	26.15 (12.50-39.74)	36.86 (16.21-57.51)		
Median (range)	22.26 (2.50-800.00)	8.33 (1.33-50.00)	18.33 (2.00-160.00)	15.00 (1.33-800.00)		
Deviation of labeled content from tested value, mg/mL						
Mean (95% CI) [% of deviation]	10.34 (4.95-15.74) [29.01]	3.94 (2.74-5.14) [220.62]	11.52 (8.10-14.94) [1098.70]	9.16 (4.96-13.36) [380.26]		
Median (range) [% of deviation]	2.76 (0.13-144.73) [12.11]	1.48 (0.01-22.30) [19.12]	4.62 (0.14-66.07) [67.34]	3.17 (0.10-144.73) [20.42]		

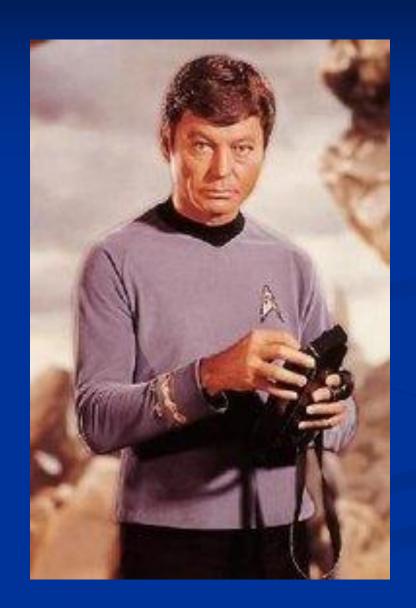
^a Cannabidiol content tested within 10% of labeled value.

^b Cannabidiol content exceeded labeled value by more than 10%.

^c Cannabidiol content tested more than 10% below labeled value.

Different states have different requirements, restrictions and regulations





How to Choose the Best Hemp CBD Oil

Buy American – somewhat more regulated

Go organic – less pesticides

Choose full spectrum - trace amounts of other cannabinoids and terpenes

Beware of health claims - FDA prohibits companies from making health claims

Avoid unnecessary ingredients - thinning agents, flavoring, harmful ingredients

Ask questions - inquire about their growing and refining practices

Summary

 Cannabis growth, processing and applications continue to evolve.

- Standardization of quality, processing and legal oversight are required to needed to provide consistency in the industry.
- Clinical research is critical to validating medical applications for cannabis preparation.

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Thank You!

BLUTH BIO INDUSTRIES, LLC

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Clinical Laboratory
Scientist.... because
without me, your
doctor is just
guessing.

somecards
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Controlled Substances Act

21 U.S.C. § 856(a). Except as authorized by this subchapter, it shall be unlawful to—

- (1) knowingly open, lease, rent, use, or maintain any place, whether permanently or temporarily, for the purpose of manufacturing, distributing, or using any controlled substance;
- (2) manage or control any place, whether permanently or temporarily, either as an owner, lessee, agent, employee, occupant, or mortgagee, and knowingly and intentionally rent, lease, profit from, or make available for use, with or without compensation, the place for the purpose of unlawfully manufacturing, storing, distributing, or using a controlled substance.



The agricultural cultivation and industrial use of hemp date back thousands of years. The regulation of hemp and its nonpsychoactive cannabinoids is much more recent. From 1937 to the late 60s, the U.S. government distinguished between industrial hemp and marijuana as distinct varieties of the Cannabis plant. After the passage of the Controlled Substances Act (CSA) of 1970, Hemp was no longer officially recognized as distinct from marijuana. The 2014 Farm Bill created a new category of "federally legal" industrial hemp in agricultural test programs. The legality and viability of this non-psychoactive cannabis was further codified in the 2018 Farm Bill, which fully de-scheduled hemp and its derivatives if produced in an approved state agricultural program.

Farm Bill Act of 2018

The term 'hemp' means the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.

Section 102(16) of the Controlled Substances Act (21 U.S.C. 802(16)) is amended

- "(B) The term 'marihuana' does not include—
- "(i) hemp, as defined in section 297A of the Agricultural Marketing Act of 1946;
 or
- "(ii) the".
- (b) Tetrahydrocannabinol.—Schedule I, as set forth in section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)), is amended in subsection (c)(17) by inserting after "Tetrahydrocannabinols" the following: ", except for tetrahydrocannabinols in hemp (as defined under section 297A of the Agricultural Marketing Act of 1946)".

Questions?

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