# POTENTIAL LEGAL PATHWAYS FOR THE SALE of non- psychotropic Cannabanoids

**PUBLIC COMMENT**

**SPECIAL ADVISORY COMMITTEE ON CANNABIS**

**SILVER SPRINGS, MD**

**MAY 31, 2019**

**Representing Farms and retail dispensaries**

**JEFFREY GITTO J.D., LL.M.**
Partner, Vanguard Legal PLLC

# A PUBLIC HEALTH APPROACH TO REGULATING Cannabis Derived Products:

## One

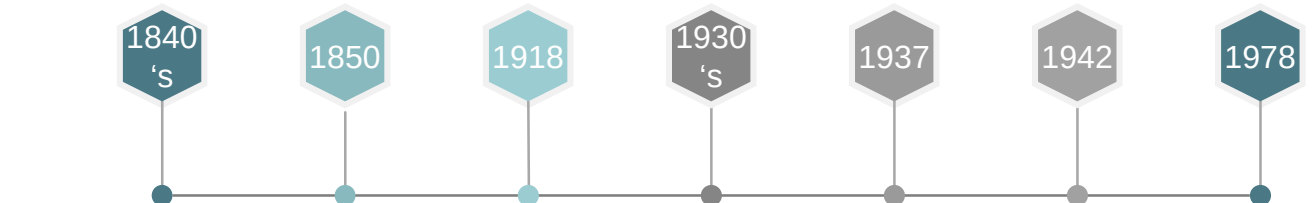
**Recognize Cannabis's unique and long history of agricultural and medicinal use from both farmers and American pharmaceutical companies, pre FDA/FD&C regulatory regimes. With such a history predating US regulatory bodies, non psychotropic variations of the plant should be considered exempt under the current dietary supplement exemption framework (Washington & Jefferson - hemp farmers).**

**The FDA holds a unique source of power in regards to public health and it is important that the committee recognizes the millennia old beneficial agricultural product, outside the confines of prohibition era politics and focus on the accountability and consistency standardized through both State, FDA, USDA oversight down to the farm level. Data analytics is crucial for trackability and safety.**

**Regulating Cannabis at a distance will allow the integrity of the currently 33 states and the District of Columbia to continue their medical programs as they have uniquely fit their State's and constituent's needs, without current Federal intervention. The medicinal regime that each State has implemented must be taken into consideration as the State's right if the operation is within the State.**

# Tracing Cannabis in U.S. History

Timeline tracing how cannabis has always been seen as medicine in the US




**Marijuana Becomes Mainstream Medicine in the West**
In the 19th Century, marijuana emerged as a mainstream medicine in the West. It was found that marijuana suppressed headaches, increased appetites, and aided people to sleep.

**Marijuana Added to US Pharmacopeia**
By 1850, marijuana had made its way into the United States Pharmacopeia [an official public standards-setting authority for all prescription and over-the counter medicines], which listed marijuana as treatment for numerous afflictions, including: neuralgia, tetanus, typhus, cholera, rabies, dysentery, alcoholism, **opiate addiction**, anthrax, leprosy, incontinence, gout, **convulsive disorders**, tonsillitis, insanity, excessive menstrual bleeding, and uterine bleeding, among others. Patented marijuana tinctures were sold

**US Pharmaceutical Farms Grow 60,000 Pounds of Cannabis Annually**
By 1918, some 60,000 pounds were being produced annually, all from pharmaceutical farms east of the Mississippi.

**American Pharmaceutical Firms Sell Extracts of Marijuana as Medicine**two American Companies, Parke-Davis and Eli Lily, were selling standardized extracts of marijuana for use as an analgesic, antispasmodic and sedative

**American Medical Association Opposes the Proposed Marihuana Tax Act and Supports Research on Medical Cannabis**
Dr. William C. Woodward, legislative counsel of the American Medical Association (AMA) announced his opposition to the bill. He believed cannabis might have important uses in medicine and psychology.

**Marijuana Removed from US Pharmacopeia**
Marijuana was removed from the US Pharmacopeia in 1942, thus losing its remaining mantle of therapeutic legitimacy.

**US government's Compassionate Investigational New Drug (IND) Program for Medical Marijuana**
In 1978, as part of a lawsuit settlement by the Department of Health and Human Services, NIDA began supplying cannabis to patients whose physicians applied for and received such an USID from the FDA.

# A DUAL REGULATORY APPROACH - SIMILAR TO ALCOHOL - IN REGULATING Cannabis Derived Products:

**TWO**

**Subject Cannabis derived products to two proven regimes:**

**<u>Impose similar minimum standards</u> (purity, dosage, age, no labeling with medical claims, health warnings, etc) on cannabis derived products as there is upon alcohol and tobacco (which are arguably less healthy) and regulate under the proven systems already in place on both a Federal and State level.**

**<u>Require Prescriptions</u> for higher doses/purity of a Cannabinoid and subject such approvals to an abbreviated review process, thereby increasing incentives for the research, which assists in the necessary data collection. With Data being collected by the States and Canada, it will not be so much as proving what is harmful about the plant, it will be for the unrealized potentiality to be seen.**

# RESPECTNG STATE POWERS IN REGULATING - IN STATE - Cannabis Derived Products:

## THREE

## ALLOW STATE LEGISLATION AND REGULATION TO CONTINUE

**Each State should be allowed to regulate their respective Cannabis market, under the FDA's minimum standards. The State's commerce must stay within the state to be exempt. Companies who wish to operate in multiple states would need to be based out of that State.**

**If any intrastate pacts are made, transfers of plant materials would need to be agriculturally exempt, allowing farmers access to larger out of state markets.**

**FDA's workload can be more focused on its current regime of regulatory expertise. Each state has agricultural departments that must comply with the USDA. State's can regulate and enforce according to the minimum federal standards with their own thresholds, as they do with other heavily regulated industries like alcohol – tobacco and gambling.**

# FINAL THOUGHTS

THANK YOU

Assisted by Sebastian Jacober