

**New York State Bar Association  
2018 Seasonal Meeting of the International Section**

**Panel 6**

**Thursday, October 25, 2018, 13:30 PM – 14:45 PM**

**Cannabis Legalization and Distribution**

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**Speakers:**

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**I. OVERVIEW.**

- a. Until recently, the word Marijuana, was related with a number of criminal activities and not particularly an industrial, medical or acceptable product for any kind of use;
- b. Many of us, were provided a very considerable amount of information, whether at home, school or through general communication that this product was, per se, a dangerous and very risky product that was directly related to criminal activities, danger to the general health and social issues;
- c. In Mexico, the word marijuana was during most of the 70s and 80 also related with subversive groups and guerilla activities in diverse western states like Guerrero, Oaxaca and Michoacán;
- d. However, during all that time, I do not recall having received any kind of information about the industrial and medical properties that this plant has, other than some comments by older people and farmers in the sense that a good remedy for arthritis and pain was by rubbing alcohol infused with marihuana leaves;

- e. Most, if not all of the information available, was focused, rather only on the negative side of the plant and the risks involved with any activity related to it. Interestingly as many of us may recall, the publicity and information regarding the use of tobacco and alcohol was extremely permissive (and at least in Mexico is still quite permissive) and would seldom make any reference to the possible health and social issues arising from the abuse of these products;
- f. To this day, I believe that there is still a long way to go in connection with the proper information for the actual health damages arising from the use and particularly the abuse, of any kind of product, whether marijuana, tobacco, alcohol, sugar, fats, etc...
- g. In the specific case of marijuana, a very different perspective and position exists today. We are discovering and rediscovering a huge number of industrial, medical, pharmaceutical and positive uses for this plant and possibly a greater tolerance to the "recreational" use of this product is present in a great number of countries, interestingly the "tolerance" to the use of other products (alcohol, tobacco, animal fur, meat) has also been considerably diminished in many other jurisdictions;
- h. From the industrial perspective, we are seeing a larger number of industries taking advantage of the plant's characteristics, including of course the pharmaceutical and medical related products industry, textiles and fibers, food and beverage, dietary supplements, paper, energy and many other industries which interest in this plant has dramatically increased in recent years;
- i. These changes in the use, attitude and industrial interest towards this plant (and many other products having possible industrial and medical uses) require very relevant a modification to the applicable legal provisions governing their use and prohibition;
- j. Reverting the provisions and regulations enacted during decades used to avoid any kind of use for this product are not easy to change. Likewise the possible effects from a decriminalization in the use of such product will have, at least in some jurisdictions, very relevant social effects;
- k. In addition to specific legal provisions governing the decriminalization of activities involving this product it will also be necessary to issue those provisions regarding the technical characteristics and activities that will be effectively permitted, restrictions to its marketing, to the import and export procedures, packaging, testing and many other related activities;

- l.** It is also worth mentioning that the actual use of the this plant will also require the analysis and follow up of the possible risks associated with its use, not only as a “recreational” product but also as an industrial and pharmaceutical product, very possibly with a greater “legal” use, the actual health risks and damages, as well as the social issues related with its use may be better understood and regulated;
  
- m.** From the international perspective, it shall also be necessary review the actual international obligations that each one of the countries permitting or regulating this product are subject to, and how will this obligations be modified due to the internal regulation or legalization of its use.

## **II. Canada.**

### **Background on Cannabis in Canada**

- **Recreational Cannabis:**
  - Until October 17, 2018 “cannabis, its preparations and derivatives” were “controlled substances” under the *Controlled Drugs and Substances Act* (“CDSA”) and “narcotics” under the *Narcotic Control Regulations*
  
- **Industrial Hemp:**
  - Since 1998, the *Industrial Hemp Regulations* have authorized the production, possession, import and sale of low-THC cannabis for industrial use via a system of licensed, permits and authorizations
  - *Industrial Hemp Regulations* were updated to reflect new cannabis regime effective October 17, 2018
  
- **Medical Cannabis:**
  - Legal access to dried cannabis for medical purposes was first permitted in 1999 using CDSA exemptions
  - *Marihuana Medical Access Regulations* (2001): prescription-based access to cannabis for medical purposes; home production or purchase government supply
  - *Marihuana for Medical Purposes Regulations* (2013): commercial sale of cannabis for medical purposes
  - *Access to Cannabis for Medical Purposes Regulations* (2016-2018): licensing regime for commercial industry; home production

## Cannabis Act – Oct. 17, 2018

- The *Cannabis Act* (the “*Act*”) removes “cannabis, its preparations and derivatives” from the CDSA to provide legal access to cannabis for recreational, industrial and medical purposes
- Controls and regulates the production, distribution, promotion and sale of cannabis
- Persons 18+, subject to additional provincial restrictions, can legally:
  - Possess a total of 30 g of dried cannabis or equivalent in public
  - Distribute up to 30 g of dried cannabis or equivalent to other adults
  - Cultivate, propagate or harvest a maximum of four cannabis plants per household for personal use, licensed seeds or seedlings from licensed suppliers
  - Purchase limited amounts of cannabis from retailers authorized by the provinces and territories
  - Consume cannabis in locations authorized by local jurisdictions
  - Make legal cannabis-containing products at home, such as food and drinks, provided that dangerous organic solvents are not used in making them

## Cannabis Regulations

- On July 11, 2018, the *Cannabis Regulations* were finalized to support the coming into force of the *Act*
- Provide additional regulation with respect to commercial activities:
  - Licensing (for cultivation, processing, research, medical cannabis, cannabis drugs, analytical testing)
  - Security
  - Quality
  - Product standards
  - Packaging and labelling
  - Retention of documents
  - Reporting and disclosure

- Regulate medical cannabis:
  - Access to cannabis for medical purposes
  - Drugs containing cannabis and cannabis drug/device combination products (additional *Food and Drugs Act* and *Food and Drug Regulations* requirements)
- Do not regulate the production of industrial hemp (new *Industrial Hemp Regulations* promulgated)

### Regulated Cannabis

- Under the *Act*, cannabis is:
  - “Any part of a cannabis plant, including the phytocannabinoids produced by, or found in, such a plant, regardless of whether that part has been processed or not [...]”;
  - “Any substance or mixture of substances that contains or has on it any part of such a plant”; and
  - “Any substance that is identical to any phytocannabinoid produced by, or found in, such a plant, regardless of how the substance was obtained”
- Expressly exempted:
  - Non-violable seed of a cannabis plant or a mature stalk without any leaf, flower, seed or branch (and fiber from such a stalk) and the root (or any part of the root) of such a plant.
- *Industrial Hemp Regulation* exemptions enable natural health products and consumer products containing low THC (10 µg/g) industrial hemp derivatives (e.g. hemp protein, hemp seed oil, cosmetics, etc.)
- **Important:**
  - Isolated and concentrated phytocannabinoids (e.g. THC, CBD etc.) are regulated as **prescription drugs**, and are expressly excluded as natural health products, cosmetics or recreational products

### Legal Sale of Cannabis

- Classes of cannabis **legal for sale** include:

- Dried cannabis
  - Cannabis oil
  - Fresh cannabis
  - Cannabis plants
  - Cannabis plant seeds
- Anticipated legal sale **after October 17, 2019** (subject to regulatory amendment):
    - Edibles containing cannabis (solid and liquid)
    - Cannabis concentrates

Categorization of Cannabis Products

<b>Non-Medical</b> <i>(Cannabis Act)</i>	<b>Medical</b> <i>(Cannabis Act)</i>	<b>Health Products with Cannabis</b> <i>(Cannabis Act &amp; Food and Drugs Act)</i>
<ul style="list-style-type: none"> <li>• Limited classes initially</li> <li>• Health care practitioner authorization <b>not</b> required</li> <li>• <b>No pre-market review</b> for safety and efficacy</li> </ul>	<ul style="list-style-type: none"> <li>• Same limited classes as non-medical</li> <li>• Health care practitioner authorization required</li> <li>• <b>No pre-market review</b> for safety and efficacy</li> </ul>	<ul style="list-style-type: none"> <li>• No restrictions on product classes that may be approved under FDA (e.g., dosage forms for prescription drugs)</li> <li>• Practitioner oversight</li> <li>• <b>Pre-market review</b> for safety, efficacy and quality</li> </ul>

<ul style="list-style-type: none"> <li>• Quality and security requirements under <i>Cannabis Act</i></li> <li>• <b>Cannot make health claims</b></li> </ul>	<ul style="list-style-type: none"> <li>• Quality and security requirements under <i>Cannabis Act</i></li> <li>• <b>Cannot make health claims</b></li> </ul>	<ul style="list-style-type: none"> <li>• under FDA</li> <li>• Manufacturing subject to quality and security requirements under the FDA and <i>Cannabis Act</i></li> <li>• <b>Can make health claims</b>, if authorized</li> </ul>
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### Major Legal Issues for Industry

- **Licensing**
  - Sale and Distribution:
    - Provincial/Territorial authorization required
      - Patchwork of 12 different regimes with varying degrees of public/private involvement
    - Medical cannabis sale requires federal licence
    - Business-to-business distribution and sale authorized among licensees
  - Cultivation and processing cannabis and cannabis products:
    - Federal licence required but facilities subject to municipal restrictions
  - Research:

- Federal licence required for R&D
  - Licensees may be permitted to research within the scope of another licence (e.g. cultivation), but Health Canada's position is unclear
  
- **Security Requirements**
  
- **Good Production Practice and Record Keeping Requirements**
  
- **Import and Export**
  - Federal authorization required to import and export cannabis for medical or scientific purposes
  - No import or export of recreational cannabis

#### Major Legal Issues for Industry

- **Promotion:**
  - Unless authorized by the *Act*, no promotion of cannabis, cannabis accessories and services related to cannabis
  - Sponsorship and giveaway restrictions
  - Promotion limited at point of sale (price and availability)
  - Permitted informational/brand-preference promotion cannot be accessible by or appealing to persons under 18
  - Brand element promotion permitted on things that are not associated with or appealing to persons under 18
  - Cannot be associated with a way of life that includes glamour, recreation, excitement, vitality, risk or daring
  
- **Packaging and Labelling:**



- Regulatory restrictions and requirements for packaging and labelling cannabis
  - Restrictions include: brand element (size, location), use of images, packing colour, texture, etc.
  - Requirements include: security features and child resistant packaging, health warning symbols, standardized cannabis symbol, bilingual labelling, etc.

#### Challenges & Potential Complications for Growth:

- Limitations on importation
- Limitations on trade:
  - Inter-provincially
  - Internationally
- Municipal restrictions on production facilities
- Patchwork of inconsistent provincial laws
- Challenges for collaborations and joint ventures where licensing is a requirement
- Cross-border issues for individuals involved in the legal cannabis industry in Canada
- Supply vs. demand for recreational cannabis

#### Current Trends:

- **Consolidation** – M&A within the industry
- **Product Innovation** – Novel strains, delivery, etc.
- **Inconsistent Regulation** – Multi-jurisdictional with respect to sale and use
- **Global Opportunity** – Canadian industry positioned to become global leader in the commercial production of recreational cannabis
- **Safer and More Responsible Consumption** – Increased focus on empirical data and sound evidence

- **New Businesses** – Emerging commercial opportunities ancillary to cannabis production and sale
- **Edibles and phytocannabinoids** – While not currently legal for sale, major focus on production of edibles and other phytocannabinoid containing products

### III. United States

#### I. Cannabis as a Forbidden Product (legal background)

##### a. “Controlling People By Controlling their Customs”

Anti-opium laws in the 1870’s were directed at Chinese immigrants because opium smoking was markedly a Chinese practice.<sup>i</sup> Anti-cocaine laws in the early 1900’s were directed at black males in the South based on a racist fiction that violent, anti-social behavior expressed by black men was linked to cocaine use.<sup>ii</sup>

Then, in the 1920’s marijuana began to be viewed as a direct cause of “Mexican lawlessness” in the southwest.<sup>iii</sup> Drug laws in the United States have demonstrated a trend throughout history of finding its basis in racial prejudice and social conditions, rather than in science and logic.

##### b. Cannabis’s Unfortunate Place in US History

Negative attention to cannabis populated as more and more immigrants from central and south American made their way to North America in the early 1900’s at a time when various other prohibitions were taking place (e.g., alcohol).<sup>iv</sup> As the various and abundant uses of industrial hemp were rapidly discovered, the cotton industry and other producers of textiles were threatened.<sup>v</sup> Between 1915 and 1931, twenty-nine states banned cannabis.<sup>vi</sup> From the 1930’s onward, laws creating barriers to the production, sale and consumption of marijuana saw an upward trend:

**Marihuana Tax Act of 1937.** The first federal anti-marijuana regulatory effort against cannabis was largely the product of Federal Bureau of Narcotics Commissioner Harry Anslinger’s efforts geared toward associating marijuana with murder, suicide, and insanity.<sup>vii</sup> Anslinger had no basis for these assertions, social scientific evidence was not considered

in the enactment of the bill, and therefore neither scientific study nor enforcement need were tied to the Marihuana Tax Act of 1937.<sup>viii</sup>

***Leary v. United States, 395 U.S. 1532-1559 (1969).*** The Court held unconstitutional a provision in the Marihuana Tax Act of 1937 that required a person to report himself to the Internal Revenue Service as a transferee of marihuana who had not registered and paid the occupational tax required under the Act on the grounds that compliance would violate a person's right against self-incrimination.

**Comprehensive Drug Abuse Prevention and Control Act of 1970.** In response to the *Leary* decision, Congress repealed the Marihuana Tax Act of 1937 and replaced it with the Comprehensive Drug Abuse Prevention and Control Act of 1970. Title II of this Act-the Controlled Substances Act (CSA)- created schedules for drugs and placed marijuana on Schedule I, where it still sits today. Schedule I drugs are characterized by a lack of medical purpose and a high potential for addiction and abuse. The cultivation, sale, possession, and use of cannabis are prohibited under the CSA.

**Nixon's War on Drugs – 1970's.** In 1971, President Richard Nixon declared a "war on drugs" when he announced at a press conference he identified drug abuse as "public enemy number one in the United States".<sup>ix</sup>

In 1973, Nixon created the Drug Enforcement Agency, whose mission to this day is to "enforce the controlled substances law and regulations of the United States, and bring to the criminal civil justice systems of the United States, or any competent jurisdiction, organizations and their principle members involved in the growing, manufacture, or distribution of controlled substances appearing, in or destined for, illicit traffic in the United States".<sup>x</sup>

#### **Anti-Drug Abuse Act of 1986.**

Purpose: "To strengthen Federal efforts to encourage foreign cooperation in eradicating illicit drug crops and in halting international drug traffic, to improve enforcement of Federal drug laws and enhance interdiction of illicit drug shipments, to provide strong Federal leadership in establishing effective drug abuse prevention and education programs, to expend Federal support for drug abuse treatment and rehabilitation efforts, and for other purposes".<sup>xi</sup>

Effect: Established mandatory minimum sentences for drug offenses; allocated billions of dollars to the war on drugs.

The reason marijuana has been treated differently than any other drug in the United States finds no place in logic, and only in unfortunate historical timing and poor government tactics. In a 1994 interview with President Nixon's domestic policy chief John Ehrlichman, Ehrlichman revealed Nixon's true motives to reporter Dan Baum:

The Nixon campaign in 1968, and the Nixon White House after that, had two enemies: the antiwar left and black people. You understand what I'm saying? We knew we couldn't make it illegal to be either against the war or blacks, but by getting the public to associate the hippies with marijuana and blacks with heroin, and then criminalizing them both heavily, we could disrupt those communities. We could arrest their leaders, raid their homes, break up their meeting, and vilify them night after night on the evening news. Did we know we were lying about the drugs? Of course we did.<sup>xii</sup>

## II. Federal and state (local) regulations. What can and cannot be regulated.

### a. State

**Medical patient registries.** The states have instituted programs to regulate the use of medical cannabis by approved patients using patient registry databases and ID card systems.

California's Compassionate Use Act – 1996. California became the first state to legalize medical use. The text of the act was short and did not address how state or local governments should regulate the marijuana industry. In 2003, California enacted the Medical Marijuana Program Act, which provided for regulations restricting the number of plants medical marijuana patients or designated caregivers could cultivate. Today, **plant restrictions** are a common regulation for both medical and recreational marijuana.

**Licensing Regulatory Authorities.** Industry operators will typically require a license to engage in their marijuana-related activities, including businesses, cultivators, manufacturers and distributors. Some states consolidate the regulatory authority for marijuana into one state agency (e.g., Colorado's Marijuana Enforcement Division) and that agency is responsible for all licensing matters regarding cannabis. Other states have assigned different roles and responsibilities to several agencies and regulate cooperatively.

*Other typical general regulations:* age limits, product labeling requirements, product quality testing, potency limits, advertising restrictions, land use laws.

### b. Locality

Some states that have authorized the personal use of marijuana, medically or recreationally, provide in their constitutions authorization for localities to enact ordinances or regulations. For example, the section of the Colorado Constitution addressing medical marijuana establishments provides:

(f) A locality may enact ordinances or regulations, not in conflict with this section or with regulations or legislation enacted pursuant to this section, governing the time, place, manner and number of marijuana establishment operations; establishing procedures for the issuance, suspension, and revocation of a license issued by the locality in accordance with paragraph (h) or (i), such procedures to be subject to all requirements of article 4 of title 24 of the Colorado Administrative Procedure Act or any successor provision; establishing a schedule of annual operating, licensing, and application fees for marijuana establishments, provided, the application fee shall only be due if an application is submitted to a locality in accordance with paragraph (i) and a licensing fee shall only be due if a license is issued by a locality in accordance with paragraph (h) or (i); and establishing civil penalties for violation of an ordinance or regulation governing the time, place, and manner of a marijuana establishment that may operate in such locality. A locality may prohibit the operation of marijuana cultivation facilities, marijuana product manufacturing facilities, marijuana testing facilities, or retail marijuana stores through the enactment of an ordinance or through an initiated or referred measure; provided, any initiated or referred measure to prohibit the operation of marijuana cultivation facilities, marijuana product manufacturing facilities, marijuana testing facilities, or retail marijuana stores must appear on a general election ballot during an even numbered year.<sup>xiii</sup>

Other marijuana statutes do not clearly establishment the local government's powers to prohibit and control marijuana establishments. Unless preemptive intent is clearly indicated, local land use authority is not generally found to be preempted by state law unless it is in direct conflict with the state law.<sup>xiv</sup>

### c. Federal

**Controlled Substances Act.** Directly establishes federal control over the possession, use, manufacturing and distribution of marijuana. The Supreme Court has twice ruled that the federal government can regulate and criminalize marijuana sales and use even when state law permits such for medical purposes.

***Gonzalez v. Raich*, 545 U.S. 1 (2005):** Congress's power to prohibit even purely intrastate cultivation and possession of marijuana is upheld.

***United States v. Oakland Cannabis Buyers' Coop*, 532 U.S. 483 (2001):** Medical necessity is not a defense to the manufacture and distribution of marijuana as prohibited by federal law.

\*CANNOT commandeer state legislatures or state executive officials by mandating states enact legislation or implement or enforce federal law. *New York v. United States*, 505 U.S. 144 (1992) (holding Congress may not compel states to enact or administer a federal regulatory program).

\*However, may condition receipt of federal funds upon state enactment of certain legislation. See *South Dakota v. Dole*, 483 U.S. 203 (1987).

\***Drug Enforcement Agency.** Main task is to carry out the CSA.

However, **Consolidated Appropriations Acts** from 2014-2016 have all contained some sort of language like: “*None of the funds made available in this Act to the Department of Justice may be used with respect to the States of. . . to prevent such States implementing their own State laws that authorize the use, distribution, possession, or cultivation of medical marijuana*”

***United States v. McIntosh* (2016):** Consolidated Appropriations Acts from 2014-2016 do not allow federal prosecutions to be made against those who are in compliance with state medical marijuana laws.<sup>xv</sup>

**Consolidated Appropriations Act of 2018:** specifically forbids the use of federal funds from being used “in contravention of section 7606 of the Agricultural Act of 2014 (7 U.S.C. 5940) or “to prohibit the transportation, processing, sale, or use of industrial hemp, or seeds of such plant, that is grown or cultivated in accordance with subsection section 7606 of the Agricultural Act of 2014, within or outside the State in which the industrial hemp is grown or cultivated”<sup>xvi</sup>.

**Jeff Sessions Memorandum and State-level Responses.**

[Sessions Memo](#)

[Troyer Memo](#)

[Massachusetts Memo](#)

[Oregon Memo](#)

**DEA = ultimate decision to re-schedule drugs.** Factors looked at in determining “currently accepted medical use” for purposes of rescheduling:

- (1) Drug's chemistry must be known and reproducible;
- (2) There must be adequate safety studies;
- (3) There must be adequate and well-controlled studies proving efficacy;
- (4) The drug must be accepted by qualified experts; and
- (5) The scientific evidence must be widely available.<sup>xvii</sup>

**Civil Asset Forfeiture.** Federal adoption is a program within the DOJ that was created by statute in response to the War on Drugs in the 1980's. Essentially, civil asset forfeiture allows state and local law enforcement officials to by-pass state laws to search and seize property without ever making any arrests. The state and local officials then request the DOJ "adopt" their seizures. The DOJ adopts the seized property if the "conduct giving rise to the seizure violates federal law." If the property is ultimately adopted, then the case is tried in federal, rather than state court. This allows the case to proceed under federal forfeiture laws and federal standards.

The procedure in a civil asset forfeiture case begins with the government filing a civil action *in rem* — a legal action directed toward property, in contrast to a particular person. Because it is *civil* forfeiture, the government must only prove by a preponderance of the evidence (as opposed to beyond a reasonable doubt in a criminal case) that the property was used to commit a crime or was associated with the act of committing a crime. For the same reason, there is no requirement of a criminal indictment for the forfeiture action to be filed. This questionable concept flies because it is based on the legal fiction that the action is against the property itself. Further, the seized property is suspected of involvement with a crime, not the owner.

**Securities Exchange Commission (SEC).** Investment funds often have to file paperwork with the SEC to ensure compliance with the federal securities laws. The SEC has not issued specific guidance regarding marijuana businesses.

**\*Internal Revenue Service (IRS).** Investment funds and the companies in which they invest are required to declare or otherwise account for all income made in the yearly tax collection. Unlike SEC, has issued guidance with regards to taxing medical cannabis companies and the tax benefits those companies are permitted to take: "IRS has stated it disallows deductions incurred in the trade or business of

trafficking in controlled substances that federal law or the law of any state in which the taxpayer conducts the business prohibits...”<sup>xviii</sup>

**Internal Revenue Code Section 280E:** “No deduction or credit shall be allowed for any amount paid or incurred during the taxable year in carrying on any trade or business if such trade or business (or the activities which comprise such trade or business) consists of trafficking in **controlled substances (within the meaning of schedule I and II of the Controlled Substances Act)** which is prohibited by Federal law or the law of any State in which such trade or business is conducted”<sup>xix</sup>.

Effects:

- (1) Businesses in cannabis industry cannot deduct their business expenses like other businesses do;  
(*e.g., Rent, employee payroll, lights and heating*)
- (2) Businesses touching the plant are taxed on their gross revenues as opposed to their gross profits.

As a general rule, illegal businesses are subject to taxes on its income in the same manner as legal businesses would be, and those illegal businesses are usually still entitled to the same business deductions as are available to legal businesses. See *Commissioner v. Tellier*, 383 U.S. 687, 691 (1966).

**Imposition of Liability onto third parties.** 21 U.S.C. § 846 makes it illegal to conspire to violate the Controlled Substances Act. Banks, investors, attorneys, and other third parties involved indirectly with a marijuana industry operator is acting in conflict with Federal law.

**Trademarks.** Because trademark and patent law is a field preempted by the Federal government, marijuana businesses are impeded from building brand names for themselves and their products.

**Trademark:** must demonstrate actual use in commerce or bona fide intent to use.

**Patent and copyright:** need not currently use.

### III. Cannabis from the US legal perspective

#### a. Medical Cannabis



\*31 States and the District of Columbia have enacted legislation authorizing the use of medical cannabis.<sup>xx</sup>

\*2011 CBS News study: Of 1,033 adults randomly surveyed by phone nationwide, 77% favored legalizing medical use of marijuana.<sup>xxi</sup>

## **b. Pharmaceutical Products**

**Epidiolex.** June 25, 2018 the Federal Drug Administration approved a CBD-based drug aimed at treating two types of epilepsy: Lennox-Gastaut syndrome and Dravet syndrome.<sup>xxii</sup> This is the first FDA-approved drug that contains a purified derivative of marijuana. The DEA has not yet spoken on rescheduling marijuana, at least CBD, in response to the FDA approval. GW Pharmaceuticals, the British-based company who makes the drug, recently revealed the Epidiolex would cost roughly \$32,500 per year.<sup>xxiii</sup>

## **c. Beverage**

Cannabis-infused beer-like beverages

- Lagunitas Hi-Fo Hops. Cannabis infused hoppy sparkling water
- Two-roots brewing company – California

Cannabis-infused tea

- Just Society Cold Brew Beverages – combines marijuana with caffeine

## **d. Agricultural Product**

Marijuana prohibition laws were passed long before cultivation regulations could have been fathomed. States now face the challenge of regulating one of the United States' largest agricultural industries for the first time. Whether medical or recreational, the immediate regulatory priority in many states is the distribution, sale, and consumption of marijuana, as opposed to the cultivation.<sup>xxiv</sup>

Although California was the first to legalize medical use, it was not until 2016 the state enacted the Medical Marijuana Regulation and Safety Act, which was instituted to recognize marijuana cultivation as an agricultural activity. The author of the bill said, “cultivators are going to have to comply with the same kinds of regulations that typical farmers do . . . . [I]t’s going to be treated like an agriculture product”.<sup>xxv</sup>

Farms on private property remain vulnerable to police raids and asset forfeiture laws. Farmers are unable to take advantage of typical agricultural government services like crop insurance programs or pesticide-free certifications.<sup>xxvi</sup> As a result, many farmers would welcome the idea of laws like California's with open arms.

So far, states and private insurers have only entertained the idea of possibly providing crop insurance to marijuana cultivators. Insurance companies are growing more and more receptive working with dispensaries, but crop insurance is still largely undeveloped.<sup>xxvii</sup>

Courts have gone different ways in different jurisdictions regarding insurance policies for marijuana farmers. In *Tracey v. USAA Casualty Insurance* (2012) a federal court in Hawaii held the loss of state-legal marijuana plants was not a compensable claim under the farmer's insurance policy because even though state-legal marijuana plants are an insurable interest, federal marijuana prohibition preempts state marijuana law and makes the insurance policy an unenforceable contract contrary to public policy. On the other hand, in 2016 a federal court in Colorado upheld the validity of an insurance policy's coverage of loss from wildfire smoke damage to marijuana plants and products. See *Green Earth Wellness Center v. Atain Specialty Insurance*, (2016).

**e. Industrial Use (paper, fuel, textile, other)**

[subject to change prior to conference- 2014 Farm Bill expires on September 30, 2018 and unknown at this time whether the Bill is going to truly expire, or be extended]

**Agricultural Act of 2014.** Authorizes an institution of higher education or a state department of agriculture to grow or cultivate industrial hemp:

If the industrial hemp is grown or cultivated for purposes of research conducted under an agricultural pilot program or other agricultural or academic research; and the growing or cultivating of industrial hemp is allowed under the laws of the State in which such institution of higher education or state department of agriculture is located and such research occurs.<sup>xxviii</sup>

**Industrial Hemp:** "any part of the cannabis sativa L., with a maximum THC concentration of 3 percent on a dry-weight basis"<sup>xxix</sup> Must be used for industrial purposes--e.g., the hemp must be grown for the fiber from the stalks and seeds.<sup>xxx</sup>

**Agricultural Act of 2018.** Would remove industrial hemp entirely from the CSA and legalize growing industrial hemp as an agricultural crop. The Bill specifically authorizes CBD extraction from hemp flowers, allows hemp farmers to get crop insurance and access to federal water rights, and would even protect hemp farmers who grow plants with elevated THC content from criminal prosecution so long as the farmer does not have a culpable mental state (mere negligence would not be enough).<sup>xxxii</sup>

The Bill passed the Senate Agricultural Committee on June 13, 2018 but the House measure failed because of a battle over immigration and also because the measure promised greater job training opportunities for recipients of food stamps.<sup>xxxiii</sup> The 2014 Farm Bill is set to expire on September 30, 2018. A short-term extension of the current Farm Bill is a foreseeable option.

#### **f. Recreational Use**

\*9 states and the District of Columbia have enacted legislation authorizing recreational use of marijuana.<sup>xxxiii</sup>

### **V. Main legal issues surrounding the industry**

#### **a. Import and export matters**

Threshold Question: what part of the cannabis plant did the marijuana product come from?<sup>xxxiv</sup>

**Illegal parts:** the flowering tops, leaves, seeds capable of germination, resin extracted from any part of the plant, and any processed version of the foregoing plant materials.<sup>xxxv</sup>

**Legal parts:** mature stalks and fibers, oil made from seeds, cake made from seeds, and sterilized seeds incapable of germination.

If the product consists of the legal parts, it may be imported and exported so long as the laws of the other country involved are in favor of such.<sup>xxxvi</sup>

#### **b. Manufacturing of finished products**

Unlike drugs approved by the FDA, the manufacture of marijuana products have not been subject to FDA review and there has been no evaluations regarding

effectiveness, proper dosage, interaction with other drugs, and other safety concerns.<sup>xxxvii</sup> As a result, edibles and other products sold at dispensaries do not face the quality control measures used to ensure quality and consistency of other legalized medicines and drugs like alcohol and tobacco.<sup>xxxviii</sup> The rules that will govern manufacturing will drastically vary from state-to-state.<sup>xxxix</sup>

However, the FDA is stepping in to prevent health fraud. For example, the FDA has issued warning letters to companies who market their products as means to prevent, diagnose, treat, or cure cancer without any evidence in support of these claims.<sup>xl</sup> Failure to correct their violations could result in product seizures and injunctive action.<sup>xli</sup>

### c. Packaging

**Childproof.** The Consumer Product Safety Commission lays out a complex set of required protocols to be established before labeling a product as childproof.<sup>xlii</sup>

**National Association of Cannabis Businesses (NACB).** First and only self-regulatory organization in the United States cannabis industry. In January 2018, NACB proposed industry standards for packaging, including requirements of tamper-evident packaging, childproof packaging, warning labels, and allergen disclaimers.<sup>xliii</sup> This becomes important because if a state does not have a statute for strict liability standards, the standards set by the NACB could control.<sup>xliiv</sup> An eleventh circuit ruling held that “advisory guidelines and recommendations, while not conclusive, are admissible as bearing on the standard of care in determining negligence”.<sup>xlv</sup>

### d. Distribution and sale to final users

Sweatleaf, a Colorado dispensary, went from bringing in an upward of \$5 million a month in sales, to experiencing asset seizure, location shut-downs, and criminal charges.<sup>xlvi</sup> The company was accused of a practice known as “looping”- the Dispensary was selling more than one ounce of retail marijuana flower to a single customer in violation of state law. There was an instance documented where a customer made 24 trips to a Sweat Leaf location in just over four hours.

A not-yet-agreed-upon issue that arises is whether criminal prosecution should be able to ensue for a violation of a civil regulation.

## VI. Challenges and potential complications for the growth of the industry

**Financial.** Until there are changes to federal law, financial institutions are going to remain reluctant to work with marijuana industry operators. Currently, these businesses are forced to operate largely on a cash-only basis, endangering the businesses and imposing severe hardship.

**International.** The federally illegal status of marijuana, while marijuana is one of the top cash crops in the United states, puts us at a severe disadvantage in the industry. Unless and until there is federal reform, the market in the United States cannot be utilized at its maximum potential.

**Free Trade Agreements.** In 2015, 47% of U.S. goods exports went to Free Trade Agreement partner countries and U.S. merchandise exports totaled \$710 billion.<sup>xlvi</sup> Canada and Mexico are our first and third largest merchandise trading partners. Our trade with Canada and Mexico accounted for 32.3 percent of the U.S. exports in 2010.<sup>xlvi</sup>

## VII. Current trends and possible scenarios

**Regulatory Framework.** Regulators, state and local governments, must make a choice between an approach that incorporates the marijuana industry into existing agricultural frameworks, or to create a separate regulatory framework for marijuana. With the transition from the black market, a targeted regulatory scheme may be necessary. If marijuana is not regulated as an agricultural commodity, the industry could quickly become dominated by large-scale farms that mass-produce the product and flood the market, there-by driving down prices.

### Regulatory model options:

- (1) Preserve markets for regional marijuana products; maintain quality standards;
- (2) Limit cultivation to a small handful of businesses;
- (3) Vertical Integration: farmers must sell what they grow; dispensaries must grow what they sell.

*\*State of Washington prohibits vertical integration: cultivators cannot hold dispensary licenses while dispensaries cannot hold cultivation licenses.*

### **Proposed Legislation.**

**S.T.A.T.E.S. Act** (Gardner-Warren Bill). Would ensure each state has the right to determine how to approach marijuana in its borders by amending the CSA to

include a provision that the CSA shall not apply to “any person acting in compliance with State law relating to the manufacture, production, possession, distribution, dispensation, administration, or delivery of marihuana”<sup>xlix</sup>.

**Marijuana Freedom and Opportunity Act.** Would decriminalize marijuana on the federal level by removing marihuana entirely from the schedule of controlled substances.<sup>1</sup>

### CURRENT STATUS OF STATE PROGRAMS

<b>Alaska.</b> Med. No out-of-state patients	<b>*Mass.</b> Med./Rec. No out-of-state pat.
<b>*Arizona.</b> Med/Rec. Out-of-state (AZ-app)	<b>Michigan.</b> Med. Out-of-state, No disp.
<b>Arkansas.</b> Med.- all details pending	<b>Minnesota.</b> Med. No out-of-state pat.
<b>*California.</b> Med/Rec. No out-of-state pat.	<b>Montana.</b> Med. No out-of-state pat.
<b>*Colorado.</b> Med/ Rec. No out-of-state pat.	<b>*Nevada.</b> Med./Rec. Out-of-state pat. if “Sub. Similar” Program
<b>Connecticut.</b> Med. Out-of-state not spec.	<b>New Hampshire.</b> Med. Out-of-state pat., No disp. purc.
<b>Delaware.</b> Med. Out-of-state if DE-app.	<b>New Jersey.</b> Med. No out-of-state pat.
<b>*D.C.</b> Med/Rec. Out-of-state not spec.	<b>New Mexico.</b> Med. No out-of-state pat.
<b>Florida.</b> Med.-all details pending	<b>New York.</b> Med. No out-of-state pat.
<b>Guam.</b> Med. App.- not yet operational	<b>North Dakota.</b> Med.- final details pending
<b>Hawaii.</b> Med. No out-of-state pat.	<b>Ohio.</b> Med.- not yet operational
<b>Illinois.</b> Med. No out-of-state pat.	<b>Oklahoma.</b> Med.- not yet operational
<b>Louisiana.</b> Med.- not yet in effect.	<b>*Oregon.</b> Med./Rec. No out-of-state pat.
<b>*Maine.</b> Med./Rec. Out-of-state, No disp.	
<b>Maryland.</b> Med. No out-of-state pat.	

**Pennsylvania.** Med.- not yet operational

**Puerto Rico.** Med.- not yet operational

**Rhode Island.** Med.- Out-of-state pat.

**\*Vermont.** Med./Rec. No out-of-state pat.

**\*Washin.** Med./Rec. No out-of-state pat.

**West Virginia.** Med. No out-of-state pat.

*\*Recreational*

<http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx>

## PENDING CANNABIS LAW CHANGES – November Ballot

**Colorado.** “The Definition of Industrial Hemp Amendment”

**Michigan.** “Marijuana Legalization Initiative”

**Missouri.** “Medical Marijuana and Veterans Healthcare Services, Education, Drug Treatment, and Public Safety Initiative”; “Medical Marijuana and Biomedical Research and Drug Development Institute Initiative”; “Medical Marijuana and Veteran Healthcare Services Initiative”

**North Dakota.** “Marijuana Legalization and Automatic Expungement Initiative”

**Utah.** “Utah Medical Cannabis Act”

[https://ballotpedia.org/Marijuana\\_on\\_the\\_ballot#By\\_year](https://ballotpedia.org/Marijuana_on_the_ballot#By_year)

<sup>1</sup> Gerald J. McKenna, *The Current Status of Medical Marijuana in the United States*, 73(4) HAWAII J. MED. PUB. HEALTH 105 FIND PAGE (2014).

<sup>1</sup> Carl L. Hart, *How the Myth of the ‘Negro Cocaine Fiend’ Helped Shape American Drug Policy*, THE NATION (Jan. 29, 2014).

<sup>1</sup> Erwin Chemerinsky, Jolene Forman, Allen Hopper, and Sam Kamin, *Cooperative Federalism and Marijuana Regulation*, 62 UCLA L. Rev. 74, 81 (2015).

<sup>1</sup> Matthew A. Christiansen, *A Great Schism: Social Norms and Marijuana Prohibition*, 4 HAR. L. POL. & REV. 229, 233 (2010).

<sup>1</sup> Ryan B. Stoa, *Marijuana Agriculture Law: Regulation at the Root of an Industry*, 69 FL L. R. 297, 307 (Mar. 2017).

<sup>1</sup> Ryan B. Stoa, *Marijuana Agriculture Law: Regulation at the Root of an Industry*, 69 FL L. R. 297, 307 (Mar. 2017).

<sup>1</sup> Matthew A. Christiansen, *A Great Schism: Social Norms and Marijuana Prohibition*, 4 HAR. L. POL. & REV. 229, 232 (2010).

<sup>1</sup> Matthew A. Christiansen, *A Great Schism: Social Norms and Marijuana Prohibition*, 4 HAR. L. POL. & REV. 229, 235 (2010).

<sup>1</sup> <http://www.aei.org/publication/the-shocking-and-sickening-story-behind-nixons-war-on-drugs-that-targeted-blacks-and-anti-war-activists/>



<sup>1</sup> <https://www.dea.gov/history>

<sup>1</sup> <https://www.govtrack.us/congress/bills/99/hr5484/text>

<sup>1</sup> <http://www.aei.org/publication/the-shocking-and-sickening-story-behind-nixons-war-on-drugs-that-targeted-blacks-and-anti-war-activists/>

<sup>1</sup> Colorado Constitution Article XVIII, Section 16(5)(f).

<sup>1</sup> Martha Harrell Chumbler, *Land Use Regulation of Marijuana Cultivation: What Authority is left to Local Government*, 49 URB. LAW. 505, 509 (2017).

<sup>1</sup> *United States v. McIntosh*, 833 F.3d 1163 (9th Cir. 2016).

<sup>1</sup> Consolidated Appropriations Act of 2018, H.R. 1625, 115th Cong. § 729(1)-(2)(2018).

<sup>1</sup> 76 Fed. Reg. at 40,579.

<sup>1</sup> Letter from Andrew J. Keyso, Deputy Associate Chief Counsel of the U.S. Department of the Treasury, to Sam Farr, Congressman, U.S. House of REpresenatives (Dec. 16, 2010).

<sup>1</sup> 26 U.S.C.A. § 280E (1982).

<sup>1</sup> <https://medicalmarijuana.procon.org/view.resource.php?resourceID=000881>

<sup>1</sup> Muni Rubens, *Political and Medical Views on medical Marijuana and its Future*, 29 SOCIAL WORK IN PUB. HEALTH 121, 126 (2014).

<sup>1</sup> <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm611046.htm>

<sup>1</sup> <https://www.businessinsider.de/cost-first-fda-approved-marijuana-medication-epidiolex-2018-8?r=US&IR=T>

<sup>1</sup> <http://www.floridalawreview.com/wp-content/uploads/2-Stoa-1.pdf> at 301-302

<sup>1</sup> <http://www.floridalawreview.com/wp-content/uploads/2-Stoa-1.pdf> at 301

<sup>1</sup> <http://www.floridalawreview.com/wp-content/uploads/2-Stoa-1.pdf> at 301-302

<sup>1</sup> <http://www.floridalawreview.com/wp-content/uploads/2-Stoa-1.pdf> at 348

<sup>1</sup> 7 U.S.C. § 5940(a)(1)-(2).

<sup>1</sup> 7 U.S.C. § 5940(b)(2).

<sup>1</sup> Statement of Principles on Industrial Hemp, 81 Fed. Reg. 53395, 53395 (Aug. 12, 2016).

<sup>1</sup> Hemp Industry Daily Staff, *Senate Votes to Remove Hemp From Controlled Substances Act, Expand Opportunities*, (June 28, 2018), <https://hempindustrydaily.com/senate-votes-remove-hemp-controlled-substances-act/>.

<sup>1</sup> Associated Press, *Senate Panel OKs Farm Bill, but House Wants Work Provisions*, WTOP (June 13, 2018 at 2:21 PM), <https://wtop.com/national/2018/06/senate-panel-oks-farm-bill-but-house-wants-work-provisions/> .

<sup>1</sup> <https://medicalmarijuana.procon.org/view.resource.php?resourceID=000881>

<sup>1</sup> DEA, “Internal Directive Regarding the Presence of Cannabinoids in Products and Materials Made from the Cannabis Plant” (May 22, 2018)(DEA Directive),

[https://www.deadiversion.usdoj.gov/schedules/marijuana/dea\\_internal\\_directive\\_cannabinoids\\_05222018.html](https://www.deadiversion.usdoj.gov/schedules/marijuana/dea_internal_directive_cannabinoids_05222018.html)

<sup>1</sup> 21 U.S.C.A. § 802(16); 21 C.F.R. § 1308.11(d)(23).

<sup>1</sup> DEA, “Internal Directive Regarding the Presence of Cannabinoids in Products and Materials Made from the Cannabis Plant” (May 22, 2018)(“DEA Directive”).

<sup>1</sup> <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm583295.htm>

<sup>1</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5260817/>

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<sup>1</sup> <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm583295.htm>

<sup>1</sup> <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm583295.htm>

<sup>1</sup> See Consumer Product Safety Commission, 16 C.F.R. ch. II, pt. 1610.

<sup>1</sup> Michelle L. Burton and Robert S. May, *A New Era of Liability, a Comparative Analysis of Regulation on Marijuana and Other Controlled Substances*, 60 DRI for Def. 26 (2018).

<sup>1</sup> Michelle L. Burton and Robert S. May, *A New Era of Liability, a Comparative Analysis of Regulation on Marijuana and Other Controlled Substances*, 60 DRI for Def. 26 (2018).

<sup>1</sup> *Holderbaum v. Carnival Corp.*, 87 F. Supp. 3d 1345 (S.D. Fla. 2015).

<sup>1</sup> <https://www.denverpost.com/2018/07/29/colorado-marijuana-business-enforcement/>

<sup>1</sup> <https://2016.export.gov/fta/nafta/index.asp>

<sup>1</sup> <https://2016.export.gov/fta/nafta/index.asp>

<sup>1</sup> <sup>1</sup> Strengthening the Tenth Amendment Through Entrusting States Act, SEL18725, 115th Cong., 2d Session (2018).

<sup>1</sup> Marijuana Freedom and Opportunity Act, SIL 18820, 115th Cong., 2d Session (2018).

#### **IV. Mexico**

a. General outline regarding cannabis as a forbidden product (legal background).

The history of the prohibition regarding cannabis in Mexico is quite old, possibly older than Mexico itself.

Since the Spanish conquest of Aztec Empire in the 16<sup>th</sup> century, diverse activities and products related with this plant have been permitted and prohibited in an itinerant manner.

Starting with the discovery of America on October 12, 1492, an amazing interchange of all kinds of plants and animals took place. During the early 16<sup>th</sup> Century (1520), Hernan Cortes imported, among other plants, cannabis bound for its industrial use by the Mexican Indians.

In 1545 Charles V, authorized the production of hemp (cañamo) in all the Western Indies and ordered that the necessary agricultural techniques and textile production knowledge was provided to the Indians. Very possibly, following this attempted industrial use of cannabis, the Indians discovered the potential use of this

plant from a medicinal and “magic” perspective, situation that gave rise to the first restrictions of its production and use.

This first restrictions were ordered in 1550 by Antonio de Mendoza (vice king ) took place, most of which were really bound to avoid the Indians not “properly” following the catholic religion imposed and avoiding traditional medicine, culture and activities to be practiced.

After the Mexican independence war (1810-1821) the governor of the State of Colima (Western Pacific coast) attempted to forbid the growth and use of Marijuana based on the general position that this product created dangerous conducts and activities by the most impoverished sectors of society, which were mainly composed of Indian cultures.

However, this was only an isolated attempt, and from a national level, not much interest was paid to the regulation of marijuana. During most of the 19<sup>th</sup> century, Marijuana’s medical properties were recognized and the product was openly sold in drugstores, pharmacies and markets.

Due to the availability of the product, greater recreational usage by the least privileged sectors of society became a common practice. This was highly criticized by the Catholic Church, which had a very relevant power in the Mexican political arena.

Following the Mexican revolution of 1910, the first laws regarding the prohibition were enacted. In 1915 the government forbids the use of Marijuana and this prohibition is further included in the 1917 Constitution.

Venustiano Carranza as president of Mexico confirms this prohibition in 1920 and the plant ceases to have any legally recognized medical benefit and is deemed as a product which use is considered as a criminal offense.

The first attempts to reverse this criminalization start only a couple years following the implementation. These efforts to avoid the criminalization of this plant were mainly by the artistic community.

Although the marijuana prohibition was further enforced following the US prohibition in 1937, in 1939, during a six-month period, Lazaro Cardenas government decriminalized the use of marijuana and its use was considered as a matter of public health concern rather than as a criminal activity. However, this position was cancelled due to the international pressure and the criminalization position re started.

Some isolated attempts to decriminalize the use of marijuana were initiated during the early 90s however; none of these actually prospered and greater restrictions and efforts to combat the production and use of this, and many other narcotic and psychoactive substances were strongly implemented by the Mexican government.

After the “war on drugs” initiated by President Felipe Calderon (2006-2012), which gave rise to unprecedented levels of violence and criminal activity in Mexico, a considerable interest in the decriminalization on the use of marijuana was analyzed as a possible solution to this problem.

The first results of these new positions were reflected through diverse amendments to the General Health Law in 2017 and are more related with the possibility to import and use pharmaceutical products that contain cannabinoids rather than the actual use of cannabis as a medical product.

b. Federal and local regulations. What can and cannot be regulated under local (state) laws and what can and cannot be regulated under federal provisions;

a. Cannabis from the Mexican legal perspective:

Cannabis, and in general all matters related with Health correspond to the Federal Government.

The only “exemption” to this federal regulation is included in the Mexico City Constitution. This provision is more of a political statement rather than an actual legal provision that permits the use for any activity of marihuana.

The Mexico City Constitution issued on February 5, 2017, establishes that any individual may be permitted to use cannabis sativa, indica or of any other kind and it’s by products for medical and therapeutic purposes based on the applicable legal provisions.

This article is in practice useless due that the applicable legal provisions included in the General Health Law do not permit its use for such purposes.

The General Health Law.

On June 2017, diverse amendments to the General Health Law were enacted due to internal pressure and legal precedents regarding the possibility to import and use pharmaceutical products having marijuana derivatives.

These amendments to the Mexican General Health Law (specifically article 235 Bis) in essence permit the Mexican Health Authorities to:

*“design and execute public policies that regulate the medical use of pharmacological derivatives of cannabis sativa, indica or American or marijuana, including THC, its isomers and ester chemical variants, as well as to regulate domestic research and production of these”.*

This provision does not permit the use of marijuana for medical or any other purpose, but rather only establishes that:

- a. The Health Authorities are authorized to design and execute public policies regarding the use of marijuana. This does not imply that individuals or legal entities may carry out specific acts or activities involving cannabis;
- b. The public policies are restricted to the medical use of pharmacological derivatives, not pharmaceutical or medical use of marijuana itself.

This article does not permit, in any manner the actual use of medical marijuana nor its growth, marketing, extraction of pharmaceutical derivatives or other activities by third parties.

The specific prohibitions included in articles 235 and 247 of the General Health Law continue in place without any amendment.

These provisions expressly prohibit growing, elaborating, preparing, packaging, buying, selling, transporting prescription, supply, use, consumption and any other activity related with products among which is cannabis, except for some specific cases regarding medical and scientific purposes and which will require specific permit from the Health Authorities.

In this same regard, article 245 of the General Health Law, includes THC in concentrations greater to 1%, in its section II. This Section corresponds to those substances having some therapeutic value but which constitute a major public health issue.

Likewise, in Section IV, that corresponds to those having ample therapeutic value but which constitute a minor public health problem is included THC in concentrations lesser than 1%.

A final paragraph to this article is added, same that establishes that in case of industrial products containing cannabis derivatives with THC concentrations lesser than 1% may be marketed, exported or imported as applicable under the corresponding provisions.

In this same regard, the General Health Law article 290 establishes that the Health Authorities may grant import permits for pharmacological derivatives of cannabis (including THC) to specific entities authorized to manufacture medicines or finished pharmaceutical products.

Based on such provisions in our view:

- A. The medical use of cannabis is forbidden in Mexico;
- B. Specific individuals or legal entities to which certain licenses or authorization are granted may import pharmacological derivatives of cannabis;
- C. Activities regarding the potential use of cannabis are restricted to medical and scientific research.

Finally, it is worth noting, that the health authorities were obligated to issue the corresponding regulations within 180 days following the publication of these amendments (June 2017), period that has clearly been surpassed to this date.

Cannabis is also considered as a narcotic drug. Its nature as such is not restricted nor limited by the kind of cannabis nor its particular characteristics.

Based on such lack of differentiation, we believe that irrespective of its THC or other chemical characteristics, all kinds of marihuana, seeds, resins and preparations (understood in a broad sense) are a narcotic drug included in such provision.

Likewise, article 235 of the General Health Law establishes that all activities involving narcotic drugs or any other product that contains narcotics is subject to the provisions of the General Health Law, international treaties and conventions executed by Mexico, provisions of the General Health Board and other laws and general provisions issued by the competent authorities.

In this regard, we should mention that these activities include planting, growing, cropping, elaboration, preparation, packaging, acquisition, possession, marketing, transportation, supply, use, consumption, prescription, etc.

This article also establishes as an exception to this general prohibition of narcotic drugs, specific activities regarding medical and scientific research when the authorities issue the corresponding authorization.

Based on the above, we believe that under the current provisions, the use of marihuana for other purpose or products different to medical or pharmaceutical derivatives is forbidden.

The recent amendments to the General Health Law only permit the use of some pharmaceutical derivatives of marihuana and not marihuana itself as could be hemp (cannabis sativa).

Based on the foregoing, in our view any kind of activity with, among other, marihuana is forbidden in Mexico, whether this marihuana is cannabis sativa, indica or americana, and whether it has or not specific characteristics or chemical compositions that may give it certain psychoactive or chemical attributes.

Based on the foregoing, we believe that to this date, “Hemp”, as a strain or kind of cannabis sativa, specifically falls within the concept of the narcotic drug of the General Health Law article 234. This, even if it does not contain more than 1% THC, since under the current provision this is not a factor for purposes of determining its nature as a narcotic drug.

The above is irrespective of the fact that under the recent amendments to the General Health Law article 245, in connection with the possibility for the health authorities to issue particular policies in connection with pharmaceutical derivatives from cannabis.

A last paragraph was added to Article 245 establishing that industrial products containing cannabis derivatives with THC concentrations lesser than 1% may be imported, exported or marketed under the corresponding provisions.

However, we believe that this does not implies that a cannabis sativa strain having a minimum THC content (hemp) is excluded from the scope of a narcotic substance and applicable restrictions in other provisions of the same law.

Likewise, in case of products bound for human consumption as could be food products, dietary supplements, cosmetics and the like, a specific prohibition for its importation and marketing exists in other applicable provisions.

Under the Regulations for Sanitary Control of Goods and Services (Reglamento de Control Sanitario de Productos y Servicios) (GS Regulations) plants used for the manufacturing of, among other, teas, dietary supplements and cosmetics must be duly authorized based on their classification as permitted, restricted or forbidden as well as in the potential pharmacological or therapeutic activity that these may have.

In this connection, the specific list of plants that may not be used for the manufacturing of dietary supplements or teas specifically includes in its article second as a forbidden ingredient, the products listed in the General Health Law articles 234 and 245, which include cannabis in any of its presentations.

Likewise, in case of dietary supplements, these are regulated by among other, the GS Regulations article 169 that establishes that these may not include among its ingredients plants forbidden for its use in teas or containing any other recognized pharmacological substance that may represent a health risk.

In this connection, if cannabinoids are now considered as substances having recognized therapeutic properties, a plant (hemp) containing a considerable amount of these cannabinoids with proven therapeutic properties could be not considered as suitable as ingredient in a dietary supplement.

Further elements in this regard are found in article 171 of the GS Regulations that establishes that those products, to which recognized pharmacological substances are added, may not be marketed within the country unless such are meet the requirements of “health goods” which refer to pharmaceutical products.

In case of cosmetics, a specific prohibition regarding the use of the products listed in the General Health Law article 234 and 245 is established. Among the products listed in these articles are of course cannabis (any kind of it) its seeds, by products, derivatives, etc...

Based on such provision, in our view, the marketing of any kind of toiletry or cosmetic product which includes in its formulation hemp, is not valid, irrespectively that an isolated provision, consisting of the last paragraph of article 245 of the General Health Law makes reference to the potential “industrial use” of cannabis derivatives that have less than 1% THC. This, due that other more specific provision restricting its use are in full force and effect.

Not because the last paragraph of a single article of the General Health Law, which is specifically applicable to psychotropic substances, refers to the possibility to import and market products having less than 1% THC and broad industrial uses, does this means that it may be used for products bound for human consumption.

Industrial uses may refer to other uses of hemp as could be for textiles products, vegetable based fuels (alcohol), fibers, etc... and not necessarily cosmetics, food supplements, etc.



b. Current trends, possible scenarios and expected changes.

As mentioned, we are currently expecting the issuance of the applicable regulations that will provide a clearer perspective as to the activities that will be allowed in connection with pharmacological derivatives of marihuana as well as in connection with the “industrial products” containing less than 1% THC.

In this regard, Mexico’s elected president (Mr. Lopez Obrador) and his proposed Minister of the Interior (Olga Sanchez Cordero) have mentioned that among their priorities is the decriminalization of marihuana as a restricted substance for recreational purposes. The main arguments that have been enacted in this regard are those pertaining the current violence issues by drug cartels and the possibility to reduce the profits from the sale and distribution of marihuana as an illegal drug.

It is also very relevant from a Mexican perspective the fact that our main trade partners are regulating this product for its use in the pharmaceutical, medical, food and beverage and other industries. Possibly the North American market is one of the most integrated markets worldwide and a product having the industrial potential of cannabis may very well become one of the most profitable cash crops. This situation must be addressed for the most elemental trade purposes between the three countries.

VI. Q&A.

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<sup>i</sup> Gerald J. McKenna, *The Current Status of Medical Marijuana in the United States*, 73(4) HAWAII J. MED. PUB. HEALTH 105 FIND PAGE (2014).

<sup>ii</sup> Carl L. Hart, *How the Myth of the ‘Negro Cocaine Fiend’ Helped Shape American Drug Policy*, THE NATION (Jan. 29, 2014).

<sup>iii</sup> Erwin Chemerinsky, Jolene Forman, Allen Hopper, and Sam Kamin, *Cooperative Federalism and Marijuana Regulation*, 62 UCLA L. Rev. 74, 81 (2015).

<sup>iv</sup> Matthew A. Christiansen, *A Great Schism: Social Norms and Marijuana Prohibition*, 4 HAR. L. POL. & REV. 229, 233 (2010).

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- <sup>v</sup> Ryan B. Stoa, *Marijuana Agriculture Law: Regulation at the Root of an Industry*, 69 FL L. R. 297, 307 (Mar. 2017).
- <sup>vi</sup> Ryan B. Stoa, *Marijuana Agriculture Law: Regulation at the Root of an Industry*, 69 FL L. R. 297, 307 (Mar. 2017).
- <sup>vii</sup> Matthew A. Christiansen, *A Great Schism: Social Norms and Marijuana Prohibition*, 4 HAR. L. POL. & REV. 229, 232 (2010).
- <sup>viii</sup> Matthew A. Christiansen, *A Great Schism: Social Norms and Marijuana Prohibition*, 4 HAR. L. POL. & REV. 229, 235 (2010).
- <sup>ix</sup> <http://www.aei.org/publication/the-shocking-and-sickening-story-behind-nixons-war-on-drugs-that-targeted-blacks-and-anti-war-activists/>
- <sup>x</sup> <https://www.dea.gov/history>
- <sup>xi</sup> <https://www.govtrack.us/congress/bills/99/hr5484/text>
- <sup>xii</sup> <http://www.aei.org/publication/the-shocking-and-sickening-story-behind-nixons-war-on-drugs-that-targeted-blacks-and-anti-war-activists/>
- <sup>xiii</sup> Colorado Constitution Article XVIII, Section 16(5)(f).
- <sup>xiv</sup> Martha Harrell Chumbler, *Land Use Regulation of Marijuana Cultivation: What Authority is left to Local Government*, 49 URB. LAW. 505, 509 (2017).
- <sup>xv</sup> *United States v. McIntosh*, 833 F.3d 1163 (9th Cir. 2016).
- <sup>xvi</sup> Consolidated Appropriations Act of 2018, H.R. 1625, 115th Cong. § 729(1)-(2)(2018).
- <sup>xvii</sup> 76 Fed. Reg. at 40,579.
- <sup>xviii</sup> Letter from Andrew J. Keyso, Deputy Associate Chief Counsel of the U.S. Department of the Treasury, to Sam Farr, Congressman, U.S. House of Representatives (Dec. 16, 2010).
- <sup>xix</sup> 26 U.S.C.A. § 280E (1982).
- <sup>xx</sup> <https://medicalmarijuana.procon.org/view.resource.php?resourceID=000881>
- <sup>xxi</sup> Muni Rubens, *Political and Medical Views on medical Marijuana and its Future*, 29 SOCIAL WORK IN PUB. HEALTH 121, 126 (2014).
- <sup>xxii</sup> <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm611046.htm>
- <sup>xxiii</sup> <https://www.businessinsider.de/cost-first-fda-approved-marijuana-medication-epidiolex-2018-8?r=US&IR=T>
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- <sup>xxv</sup> <http://www.floridalawreview.com/wp-content/uploads/2-Stoa-1.pdf> at 301
- <sup>xxvi</sup> <http://www.floridalawreview.com/wp-content/uploads/2-Stoa-1.pdf> at 301-302
- <sup>xxvii</sup> <http://www.floridalawreview.com/wp-content/uploads/2-Stoa-1.pdf> at 348
- <sup>xxviii</sup> 7 U.S.C. § 5940(a)(1)-(2).
- <sup>xxix</sup> 7 U.S.C. § 5940(b)(2).

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- <sup>xxx</sup> Statement of Principles on Industrial Hemp, 81 Fed. Reg. 53395, 53395 (Aug. 12, 2016).
- <sup>xxx</sup><sub>i</sub> Hemp Industry Daily Staff, *Senate Votes to Remove Hemp From Controlled Substances Act, Expand Opportunities*, (June 28, 2018), <https://hempindustrydaily.com/senate-votes-remove-hemp-controlled-substances-act/>.
- <sup>xxx</sup><sub>ii</sub> Associated Press, *Senate Panel OKs Farm Bill, but House Wants Work Provisions*, WTOP (June 13, 2018 at 2:21 PM), <https://wtop.com/national/2018/06/senate-panel-oks-farm-bill-but-house-wants-work-provisions/> .
- <sup>xxx</sup><sub>iii</sub> <https://medicalmarijuana.procon.org/view.resource.php?resourceID=000881>
- <sup>xxx</sup><sub>iv</sub> DEA, “Internal Directive Regarding the Presence of Cannabinoids in Products and Materials Made from the Cannabis Plant” (May 22, 2018)(DEA Directive), [https://www.deadiversion.usdoj.gov/schedules/marijuana/dea\\_internal\\_directive\\_cannabinoids\\_05222018.html](https://www.deadiversion.usdoj.gov/schedules/marijuana/dea_internal_directive_cannabinoids_05222018.html)
- <sup>xxx</sup><sub>v</sub> 21 U.S.C.A. § 802(16); 21 C.F.R. § 1308.11(d)(23).
- <sup>xxx</sup><sub>vi</sub> DEA, “Internal Directive Regarding the Presence of Cannabinoids in Products and Materials Made from the Cannabis Plant” (May 22, 2018)(“DEA Directive”).
- <sup>xxx</sup><sub>vii</sub> <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm583295.htm>
- <sup>xxx</sup><sub>viii</sub> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5260817/>
- <sup>xxx</sup><sub>ix</sub> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5260817/>
- <sup>xl</sup> <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm583295.htm>
- <sup>xli</sup> <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm583295.htm>
- <sup>xlii</sup> *See* Consumer Product Safety Commission, 16 C.F.R. ch. II, pt. 1610.
- <sup>xlii</sup><sub>iii</sub> Michelle L. Burton and Robert S. May, *A New Era of Liability, a Comparative Analysis of Regulation on Marijuana and Other Controlled Substances*, 60 DRI for Def. 26 (2018).
- <sup>xli</sup><sub>iv</sub> Michelle L. Burton and Robert S. May, *A New Era of Liability, a Comparative Analysis of Regulation on Marijuana and Other Controlled Substances*, 60 DRI for Def. 26 (2018).
- <sup>xli</sup><sub>v</sub> *Holderbaum v. Carnival Corp.*, 87 F. Supp. 3d 1345 (S.D. Fla. 2015).
- <sup>xli</sup><sub>vi</sub> <https://www.denverpost.com/2018/07/29/colorado-marijuana-business-enforcement/>
- <sup>xli</sup><sub>vii</sub> <https://2016.export.gov/fta/nafta/index.asp>
- <sup>xli</sup><sub>viii</sub> <https://2016.export.gov/fta/nafta/index.asp>
- <sup>xlix</sup> <sup>xlix</sup> Strengthening the Tenth Amendment Through Entrusting States Act, SEL18725, 115th Cong., 2d Session (2018).
- <sup>1</sup> Marijuana Freedom and Opportunity Act, SIL 18820, 115th Cong., 2d Session (2018).