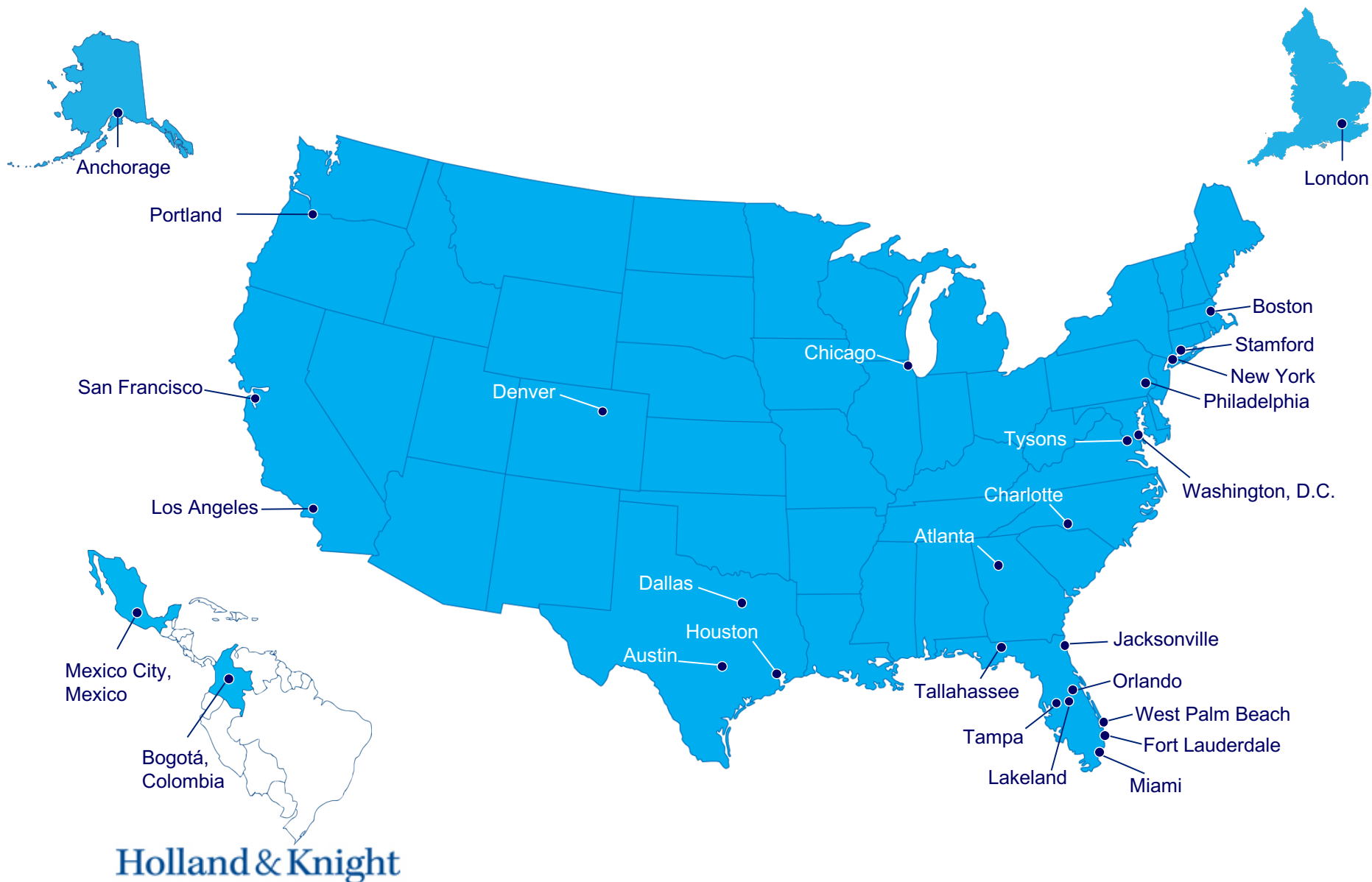




# ***Cannabis Industry: Political Overview and Insights***

*October 25, 2019*

# Holland & Knight Offices



# Adrian F. Snead, Esq.

**Adrian F. Snead**



## **Counsel to U.S. Senate Jeff Merkley (D-OR) 2014-2017**

- ❖ **Drafted 2/3 of marijuana reform legislation passed by Senate as of 2017**
- ❖ **Drafted Marijuana Business Access to Banking Act (114th) and SAFE Banking Act (115<sup>th</sup>)**
- ❖ **Founded Senate Cannabis Staff Working Group**

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» **Associate**  
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» **Washington, DC**

### **Practice**

- **Litigation**
- **International Arbitration**
- **Public Policy**

### **Education**

- **JD, The George Washington University Law School**
- **BA, The University of Texas at Austin**

### **Bar Admission**

- **New York**
- **District of Columbia**

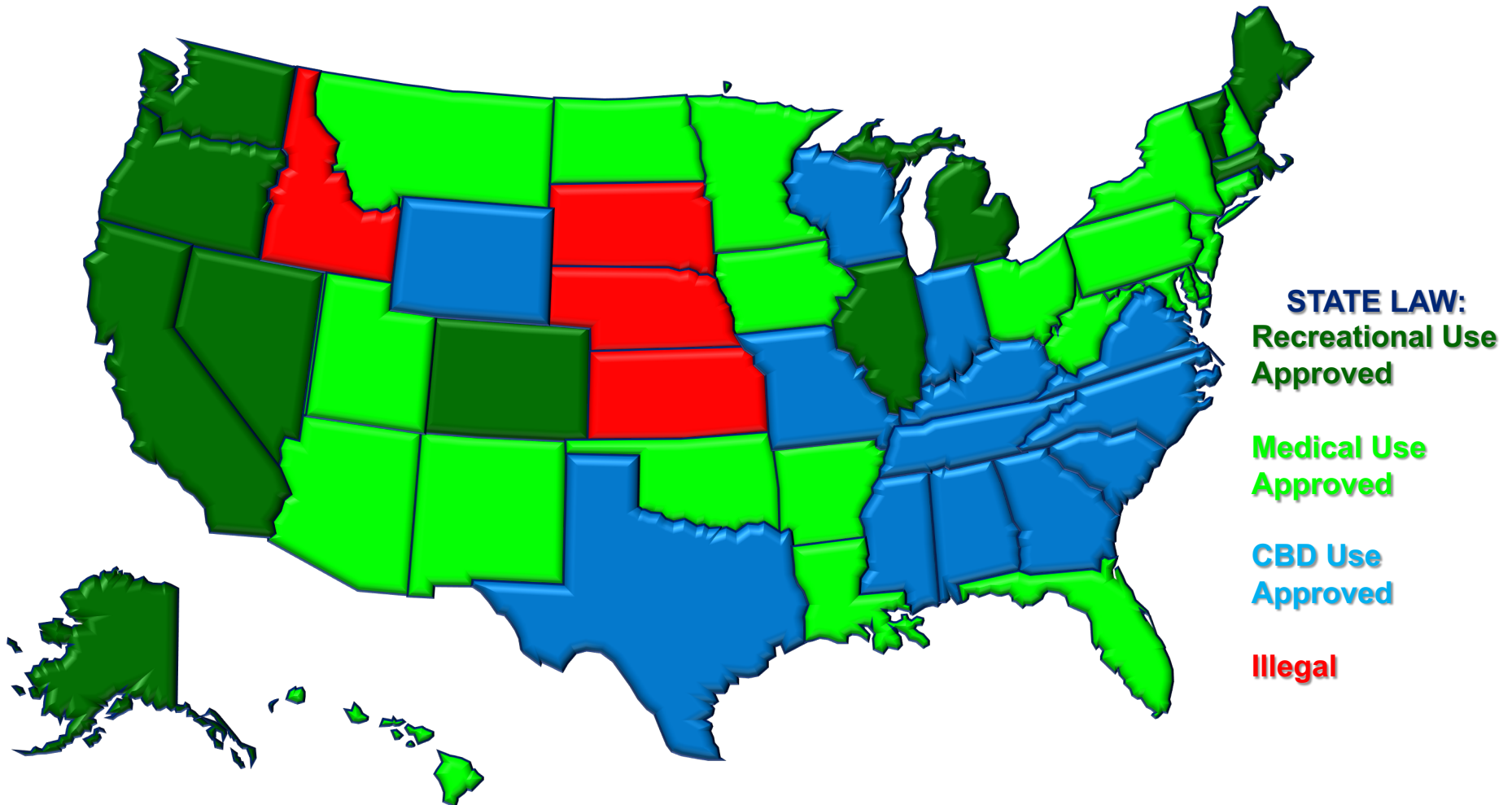
# Major Issues Facing Cannabis Industry

**\*\*\*Marijuana remains a Schedule I Drug and illegal nationwide pursuant to federal Law\*\*\***

- ❖ **Hemp/CBD recently legalized**
- ❖ **Unclear and ever-evolving regulatory landscape**
- ❖ **Numerous Federal, State, and Local Laws**
- ❖ **Lack of Access to Traditional Banking and Financing**
- ❖ **Cannot Deduct Business Expenses From Federal Taxes**
- ❖ **Expensive to Operate; Low Margins**



## Cannabis Legalization: Medicinal and Recreational States



# WHAT IS THE “CANNABIS INDUSTRY”?



## CANNABIS

*Genus of flowering plants*

### MARIJUANA PLANT

#### TETRAHYDRO-CANNABINOL (THC)

Psychoactive compound found in marijuana that when activated and consumed, may associate with feelings of a "high", "euphoria", or "intoxication"

#### CANNABIDIOL (CBD)

Non-psychoactive compound associated with medicinal benefits for holistic health when activated and consumed.

#### COMPOUNDS DERIVED FROM PLANT

#### BIOLOGICAL & NEUROLOGICAL IMPACT

### HEMP PLANT

#### HEMP OIL & HEMP SEEDS

Do not contain THC and have no noteworthy amount of CBD. Products are non-psychoactive, so will not cause a high nor impact immune function, appetite, pain, sleep, or mood.

#### CANNABIDIOL (CBD)

Non-psychoactive compound associated with medicinal benefits for holistic health when activated and consumed. Plant must have <.3% THC.

# WHAT IS THE “CANNABIS INDUSTRY”?

## “Touch the Plant”

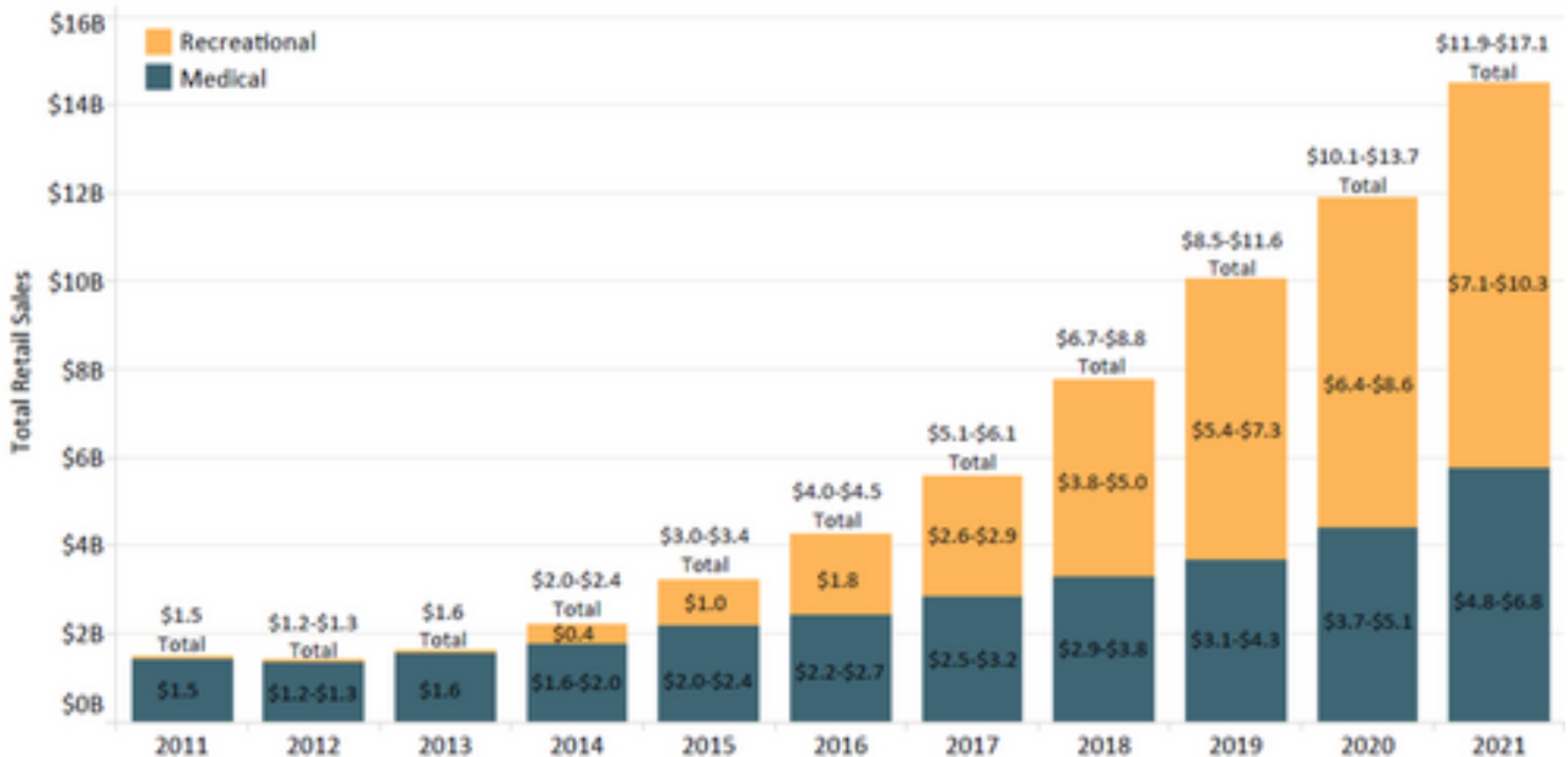
- **Growers**
- **Distributors**
- **Dispensaries**

## “Ancillary Businesses”

- **Insurance**
- **Security Solutions**  
(Safe Companies, Private Security)
- **Professional Services**  
(CPAs, Attorneys, Compliance)
- **Banking & Finance**
- **Real Estate and Utilities**

# How Big Is The Cannabis Industry?

U.S. Cannabis Retail Sales Estimates: 2011 - 2021  
(In Billions Of U.S. Dollars)



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# How Big Is The Cannabis Industry?

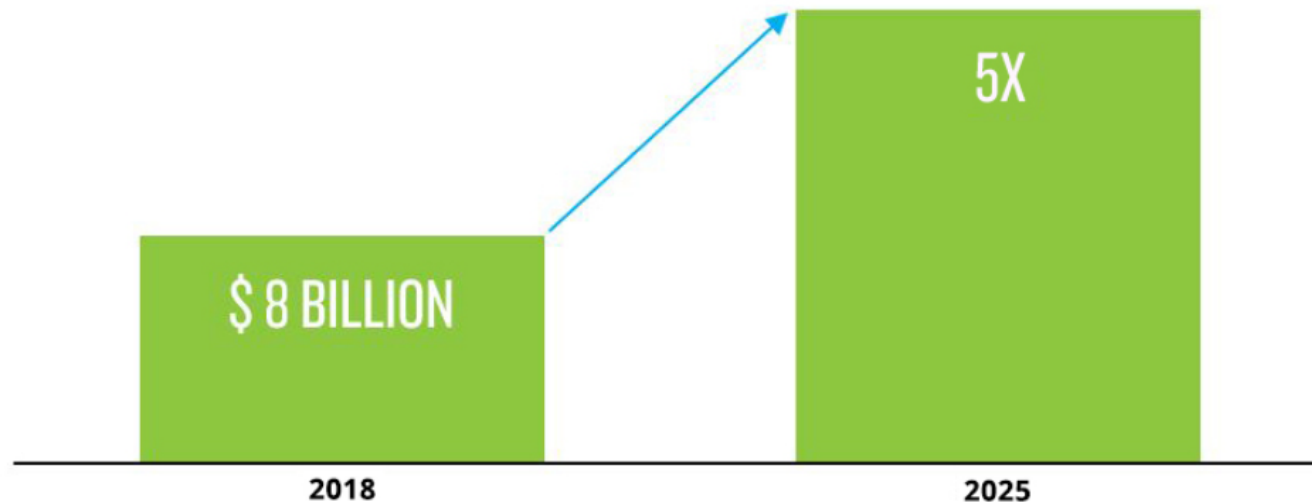
## *Size of Selected U.S. Wholesale Agricultural Commodity Markets in 2017*



Commodity	Tobacco	Cannabis Flower	Wheat	Soybeans	Corn
Market Size (\$)	\$1.5 billion	\$5.7 billion	\$7.4 billion	\$42 billion	\$51 billion
Market Size (lbs)	0.72 billion	3.7 million	104 billion	266 billion	2,863 billion

# How Big is the Cannabis Industry?

## PROJECTED U.S. CANNABIS SALES

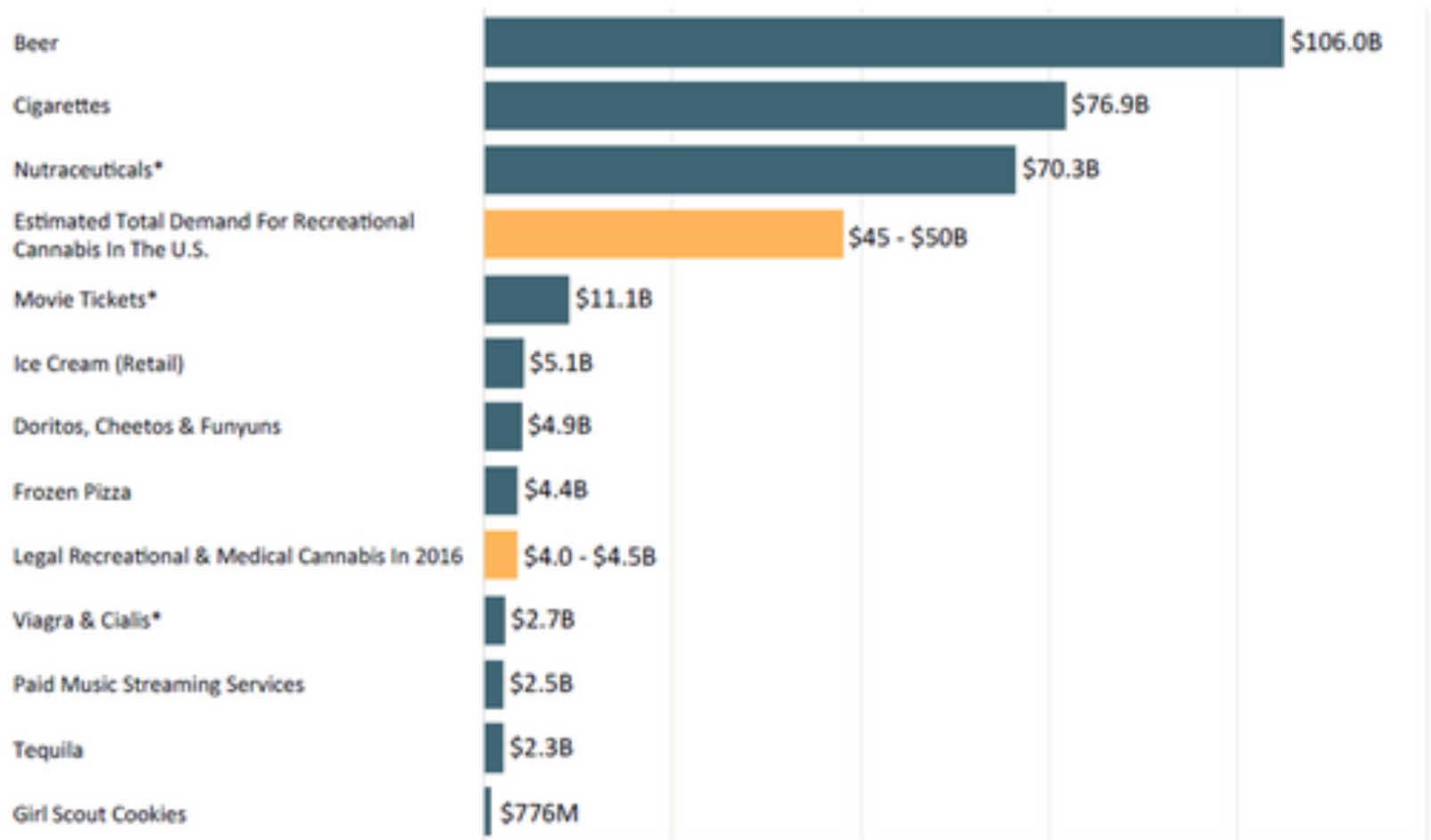


IN 2018, THE U.S. MARKET SAW AN ESTIMATED **\$8 BILLION** IN  
LEGALIZED **CANNABIS** SALES.

**THIS COULD RISE TO OVER \$40 BILLION BY 2025**

# How Big is the Cannabis Industry?

Annual U.S. Cannabis Sales Vs. Other Industries & Goods



\*Includes U.S. and Canada

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# How Big is the Cannabis Industry?

Comparison between Cannabis and Common Stimulants and Substances

	Alcohol	Coffee	Tobacco	Painkillers	Anti-depressants	Cannabis (Future)
Primary Usage	Recreational	Recreational	Recreational	Medicinal	Medicinal	Recreational / Medicinal
Adult Penetration %	50%	50%	17%	40%	25%	20%
Monthly Consumer Spending	\$45 to \$200	\$80 to \$100	\$40 to \$80	\$50 to \$200	\$50 to \$100	\$50 to \$500
U.S. Retail Market Size	\$200B	\$35B	\$100B	\$300B	\$60B	\$100B





# **POLITICAL AND REGULATORY LANDSCAPE**

# Overview: Obama Administration

## DEALING WITH A NEW REALITY

### The “Cole Memo”

- ❖ Set prosecutorial priorities

### The 2014 FinCEN Guidance

- ❖ Gave guidance to financial institutions wishing to service the industry

\*\*\*Neither had force or protection of law\*\*\*

\*\*\*Trump Admin Revoked Cole Memo\*\*\*

# Overview: The Cole Memo

- » **Issued August 29, 2013 by then-Deputy Attorney General James Cole to all USAs**
- » **Set out 8 DOJ Enforcement Priorities re: Cannabis**
  - 1. Prevent distribution to minors
  - 2. Prevent revenue from reaching organized crime/gangs
  - 3. Prevent interstate diversion of “legal” cannabis
  - 4. Prevent “legal” cannabis serving as a covering for other illegal activity
  - 5. Prevent violence in cultivation/distribution of cannabis
  - 6. Prevent “drugged-driving” and protect public health
  - 7. Prevent cultivation on public lands
  - 8. Prevent possession/use on Federal property.
- » **While revoked, Cole Memo still has persuasive effect on USAs and DOJ.**

# Overview: 2014 FinCEN Guidance

## FIN-2014-G001:

**\*\*If you are not familiar with FIN-2014-G001, you should read the 7-page document in its entirety. \*\*\***

- » Reiterates that marijuana is still illegal.
- » Details DOJ focus on individuals or organizations who violate Cole Memo priorities.
- » States that the decision to open/close MRBs should be made by the financial institution (FI).
- » Covers due-diligence recommendations for FIs.
- » **Requires marijuana SAR filings**
- » Identifies MRB red flags.

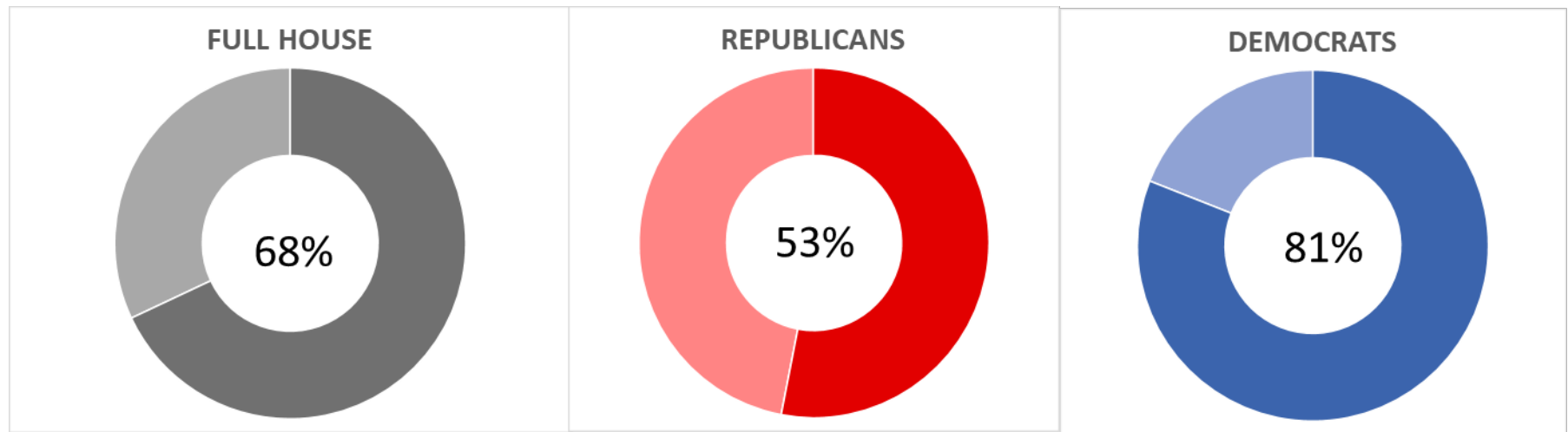
# Overview: Trump Administration

## Tough Talk/Benign Neglect

- ❖ **Tough talk from former A.G. Sessions and Revocation of Cole Memo in Jan. 2018.**
- ❖ **A.G. Barr favors “lenient” approach and a single Federal rather than state-centric policy. April 10, 2019, Sen. Approp. Comm. Hr’g.**
  - **“Accepts” Cole Memo “for now”**
  - **Leaving enforcement to U.S. Attorneys in Each State**
- ❖ **DEA still strongly opposed to legalization of cannabis.**
  - **Recently forced by lawsuit to move forward with applications to grow cannabis for research.**
- ❖ **No Significant Federal Enforcement Or Crackdown**

# Overview: Congress (116<sup>th</sup>)

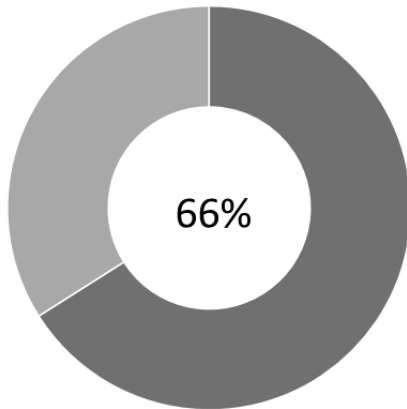
## Percent of House Members from Cannabis-Legal States



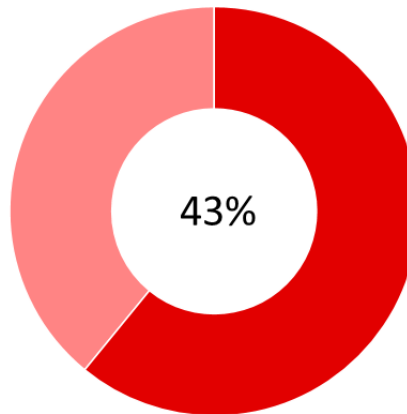
# Overview: Senate (116<sup>th</sup>)

## Percent of Senate Members from Cannabis-Legal States

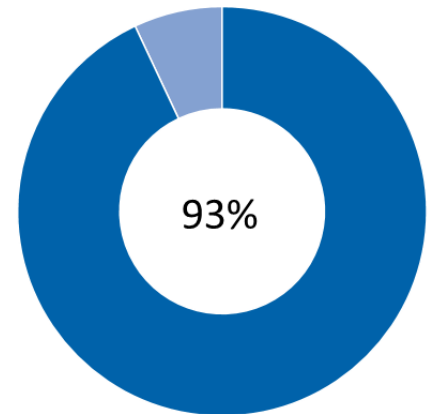
FULL SENATE



REPUBLICANS



DEMOCRATS



# Overview: Congress

## Consolidated Appropriations Act of 2017, Sec. 537:

*None of the funds made available to the Department of Justice may be used...to prevent any of [the States with cannabis legalization laws] from implementing their own laws that authorize the use, distribution, possession, or cultivation of **medical marijuana**.*

*--Rohrabacher-Farr Amendment in House/Mikulski Amendment in Senate*

## Limitations

- Only protects medical marijuana.
- Must be passed every year to be effective against DOJ enforcement.
- President has threatened to ignore the provision based on his constitutional authority “to take care that the laws be faithfully executed.”



# Overview: Congress

## Congressional Cannabis Caucus

- ❖ The Caucus is a bipartisan, pro-cannabis-reform group of members of Congress.
- ❖ Members include: Reps. Blumenauer (D-OR), Perlmutter (D-CO), Polis (D-CO), Rohrabacher (R-CA), and Young (R-AK).
- ❖ **The Senate has an unofficial bipartisan staff-level working group.**

## MAJOR PROPOSED CANNABIS LEGISLATION

- ❖ SAFE Banking Act (Passed House 321 – 103 on 9/25/19; 34 Senate Cosponsors)
  - Would allow for banking activities without fear of penalty
- ❖ STATES ACT (63 House Cosponsors; 10 Senate Cosponsors)
  - Would defers federal law to state law on cannabis
- ❖ Sensible Enforcement of Cannabis Act (11 House Cosponsors; no Senate bill)
  - Would prohibit DOJ from prosecuting marijuana-related conduct authorized by State Law
- ❖ Expanding Cannabis Research and Information Act (4 House Cosponsors; 1 Senate Cosponsor)
  - Reschedules Marijuana to Schedule III and Provides for Further Research

# Overview: SAFE Banking Act

## **SAFE BANKING ACT (2018)**

**H.R. 1595/S. 1200**

- » Would provide a safe harbor for financial institutions serving Cannabis businesses.
- » Protects Ancillary Businesses
- » Protects Federal Reserve Banks
- » Prohibits Forfeitures
- » Does *Not* End Cannabis SARs
- » Requires The Financial Institutions Examination Council Develop Uniform Guidance and Examination Procedures for Depository Institutions Banking Cannabis
- » Protections are tied to state and local cannabis laws

# Hemp/CBD: Overview

 **USDA Regulatory Update**

 **FDA Regulatory Update**

# Disclaimer

This is a highly complex and fluid regulatory environment:

- ❖ Marijuana business remains federally illegal while hemp/CBD business is legal but evolving rapidly
- ❖ Federal regulations undergoing interagency review as we speak
- ❖ How federal rules interact with existing state laws remains an open question
- ❖ Competing mandates among federal agencies could mean lingering uncertainty in some areas
- ❖ Legislative “fixes” forthcoming
- ❖ Congressional developments occurring on a daily, if not hourly basis!



# Hemp/CBD Overview

## I. USDA Regulatory Update

# Hemp in the 2018 Farm Bill

## Provisions in 2018 Farm Bill designed to greatly expand industrial hemp production

- ❖ “Industrial Hemp” defined broadly
  - ❖ Includes seeds, derivatives, cannabinoids, extracts, and other parts of the *Cannabis sativa* L. plant.
  - ❖ Any hemp-derived product will be legal as long as it contains no more than 0.3% THC on a dry weight basis.
- ❖ State and Tribal plans
  - ❖ Farm Bill allows states and tribes to submit plans for hemp production to USDA.
  - ❖ Plans must include procedures for testing, disposal, enforcement, etc.
  - ❖ USDA must approve plan within 60 days, or impose its own.

## USDA is Primary Federal Regulatory Agency for Industrial Hemp Program

- ❖ This aspect of the hemp and cannabis regulatory framework is severely misunderstood
- ❖ 2018 Farm Bill directs USDA to develop federal hemp regulations “as expeditiously as practicable”
  - ❖ Until USDA issues its regulations, hemp cultivators and processors will continue to be subject to state pilot programs under the 2014 Farm Bill
- ❖ OMB currently reviewing proposed USDA regulations, in consultation with DEA, FDA, DOJ, EPA, and other agencies



## Other Relevant USDA Issues

Beyond the rules governing the growth and processing of hemp, USDA making progress on issues important to the industry:

- ❖ Hemp will be covered under whole-farm insurance for 2020, and until crop insurance specific to hemp is developed
- ❖ Legal opinion clarifying that states and tribes cannot prohibit interstate transportation of hemp produced under a state or tribal plan, or under a USDA license
- ❖ Pathway for importation of hemp seeds from Canada and elsewhere
- ❖ USDA regulation also applies to hemp-based products

# Implications of Interim Final Rule

OMB and USDA have announced that an Interim Final Rule (IFR) will be published this fall

- ❖ IFRs are not uncommon, but this means USDA is not following the typical “notice and comment” rulemaking process
  - ❖ Limited opportunity for stakeholder engagement before start of 2020 growing season
  - ❖ Uncertain timeline for when/if USDA amends IFR and publishes a Final Rule
  - ❖ States likely to have greater ability to help shape industrial hemp marketplace
- ❖ Earliest updated IFR will be mid-2020



# Hemp/CBD Overview

## II. FDA Regulatory Update

# FDA Regulatory Update

## US Food and Drug Administration (FDA) regulates cosmetics, foods, dietary supplements, and drugs

- » FDA regulating CBD the same as other products
- » FDA regulates products based on their intended use as evidenced by claims and labeling.
- » FDA takes enforcement against companies who are in violation of the Food, Drug, and Cosmetic Act (FDCA).

- ❖ Farm Bill preserved FDA jurisdiction over CBD products
- ❖ CBD cannot legally be sold in a food or dietary supplement per the Food, Drug, and Cosmetic Act because CBD is already in an approved drug – Epidiolex.
- ❖ The same statutory prohibition does not exist for cosmetics.
- ❖ FDA has taken enforcement discretion against companies making egregious claims regarding CBD. Can include product seizure.
  - ❖ E.g.: “Fights against cancer,” “decreased chronic inflammatory and neuropathic pain”

# FDA Regulatory Update

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FDA has convened an internal working group to address cannabis issues.

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FDA held a public hearing about cannabis on May 31<sup>st</sup>.

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4,492 comments were submitted to FDA's docket request for Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds, which closed on July 16.

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FDA can issue rulemaking finding an article to be lawful.

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FDA can ask Congress to amend the FDCA.

**We expect FDA to issue guidance/rulemaking in coming weeks**



**Questions?**

**Thank you!**

- » **Adrian F. Snead, Esq.**
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An aerial photograph of the New York City skyline at dusk. The Empire State Building is prominent on the left, and the Hudson River is visible in the background. The sky is filled with soft, colorful clouds in shades of orange, yellow, and blue. The city lights are beginning to glow, reflecting off the water and illuminating the buildings.

# Discussion Materials

Jacqueline Bennett  
Director  
Sands Lane Capital



# Executive summary – the global paradigm shift

## A category realizing explosive growth shifting from an illicit to a regulated market

- Legal cannabis market is estimated to reach **\$500bn globally per year**
- **US market is estimated to exceed \$100bn annually** after US federal legalization

## Drawing mass consumer appeal around the world

- Estimated **+190 million users globally**
- Consumer acceptance expected to increase as conversation around cannabis is destigmatized

## Rapidly evolving regulatory framework in U.S. and internationally

- **Thirty-three states currently have passed laws** broadly legalizing marijuana in some form with Illinois became the 11<sup>th</sup> state to legalize recreational use of cannabis
- **Forty-one countries have legalized medical cannabis** paving the road for the eventual recreational framework
- **SAFE Banking Act** received overwhelming support from the House of Representatives and bill passed September 25, 2019 and expected to Senate vote in Q1 2020

## Significant use potential across consumer markets and adjacent categories

- Leading consumer and pharmaceutical companies have been **actively pursuing opportunities in cannabinoid-based products**
- Cannabis has **flexible and extensible applications** that can be infused to products in various formats (food, beverages, HPC, etc.)

## Proven mandate for medical use and treatment

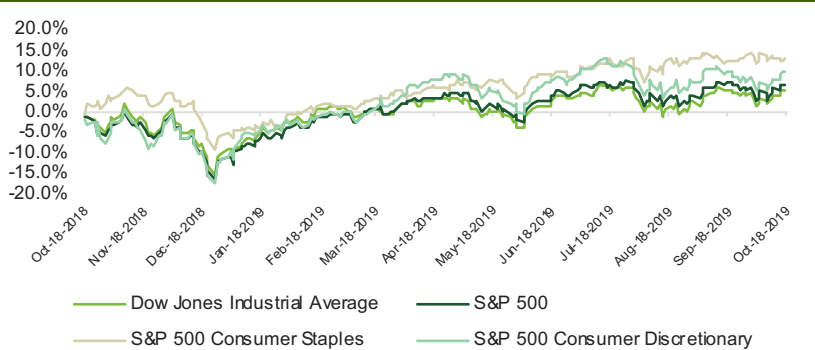
- Cannabis is currently being used to manage numerous medical conditions having been **recognized as a form of therapy or medicine for 50+ medical conditions**

▪ GW Pharmaceuticals developed Epidiolex, the first **FDA-approved plant-derived cannabinoid medicine**

# State of the Markets

With the continued trade negotiation, Brexit and global slowdown, the broad markets have been volatile with the cannabis markets experiencing a broad reset in valuations

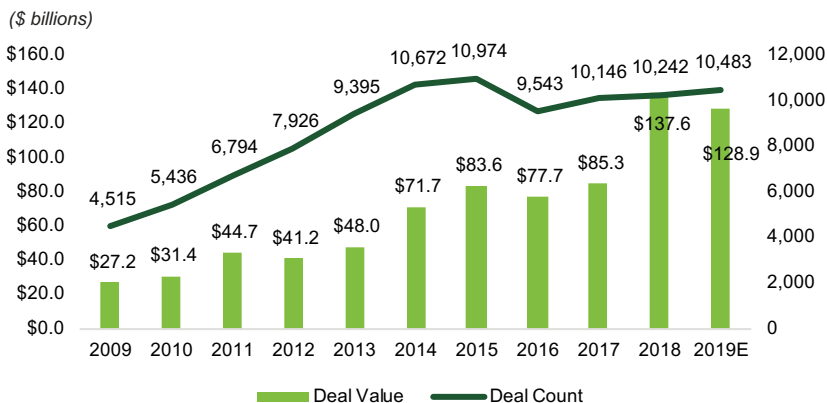
## Public Equity Markets<sup>(1)</sup>



## Cannabis Forwards EV/Revenue Multiples<sup>(1)</sup>



## VC Investment Activity<sup>(2)</sup>



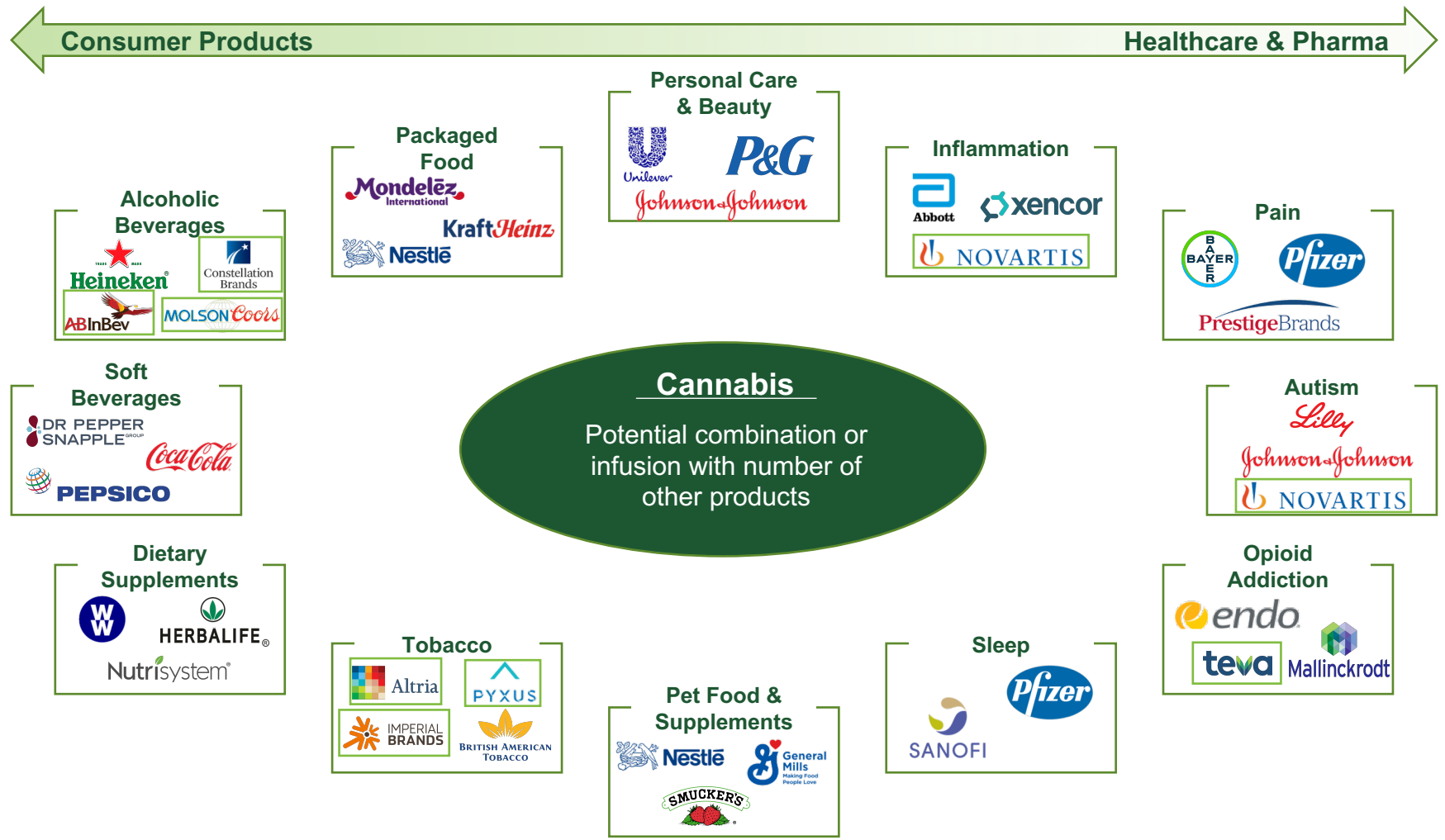
## Observations

- Sustained improvement in consumer spending supported by labor market health and wage increases has led to **significant growth in the Consumer Discretionary sector**
- After setting an all-time high in 2018, **private capital investment** had a vigorous start in Q1 2019
- Publicly traded cannabis **valuations are being reset** to more reasonable levels that more closely align with private market expectations
- Capital raised in the Cannabis sector August YTD is \$5.4 billion, compared to the \$3.5 billion raised in the same prior year period, **and on pace for a record breaking run-rate \$8.1 billion for 2019**

(1) CapIQ

(2) Pitchbook – Total VC Investment in the U.S.

# Cannabis Impacts a Broad Spectrum of Industries



Source: 2018 Ackrell Capital Cannabis Investment Report, Public filings  
Denotes publicly announced current involvement or partnerships in the cannabis industry

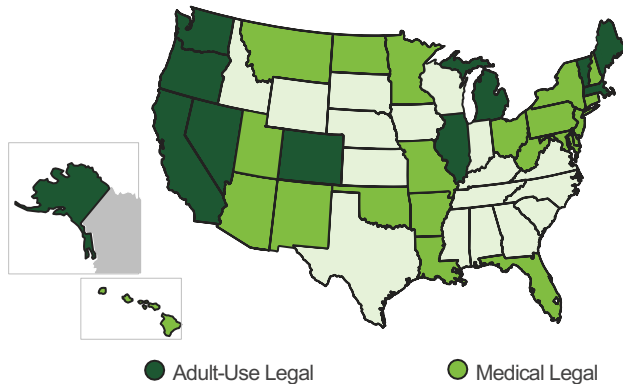
# Current Regulatory Environment

Cannabis regulations is bifurcated by THC and Hemp/CBD governing bills and near term prospects

## Regulatory Environment

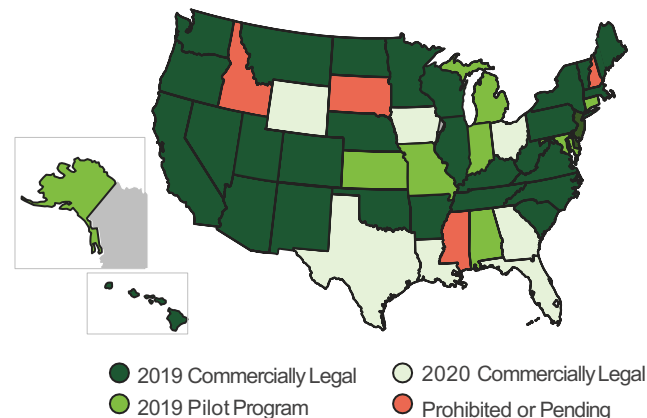
### THC

**33 US STATES & D.C.** allow medical or adult use cannabis



### Hemp / CBD

**4 US STATES** do not have legal hemp/CBD programs



## Respective Government Bills

### SAFE Banking Act

- Protects financial institutions that choose to do business with cannabis companies
  - If passed, bars federal regulators from interfering, or punishing, financial institutions that provide related services
  - As of today, banks and credit unions avoid serving cannabis firms because of the limbo between federal and state laws
- The bill was passed by the House of Representatives with bipartisan support in September (321-103 final vote)
  - According to the popular opinion, bill is unlikely to pass the Senate if it also covers THC products
  - Final bill expected to only provide additional guidance to the 2018 Farm Bill

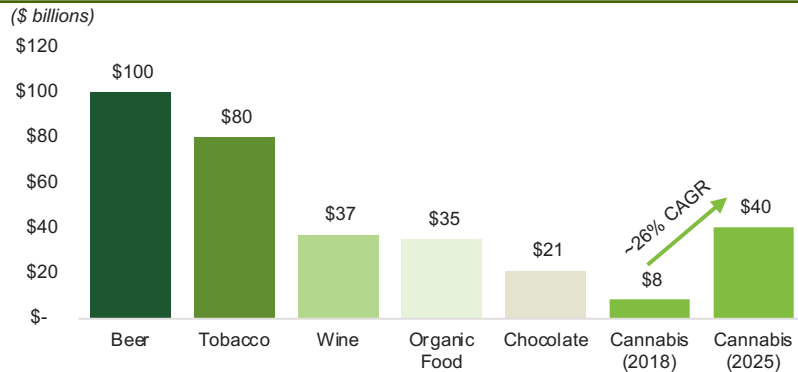
### 2018 Farm Bill

- Legalized hemp in the U.S. by removing it from the controlled substance list including hemp-derived CBD
  - Enabled intrastate commerce of hemp products, removing impact of IRS Code Section 280E
  - Granted access to banking services and structured borrowing agreements
- FDA and USDA remain the main regulatory authorities on consumable hemp and CBD products
  - Cannot contain more than 0.3% THC and shared state-federal regulatory power over cultivation and production
- Senate Majority Leader Mitch McConnell's has taken leadership position on hemp as substitute crop to tobacco
  - Seeking to compel the FDA to finalize rules surrounding CBD with language in the appropriations bill

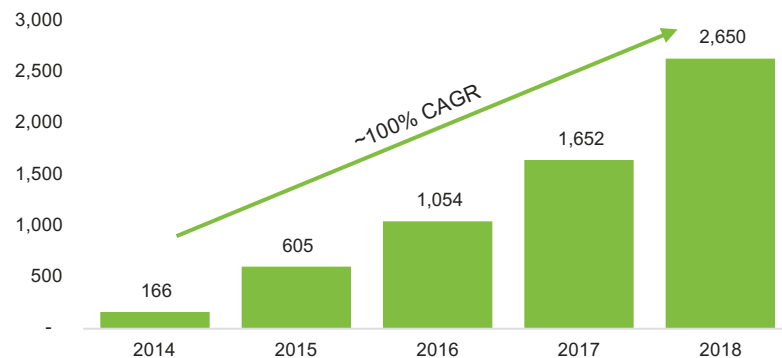
# U.S. Cannabis & Hemp Markets

## Cannabis

While the cannabis market is substantial, it still lags behind other relevant product markets<sup>(1)</sup>



The U.S. market has experienced an explosion in growth of branded cannabis products<sup>(1)</sup>

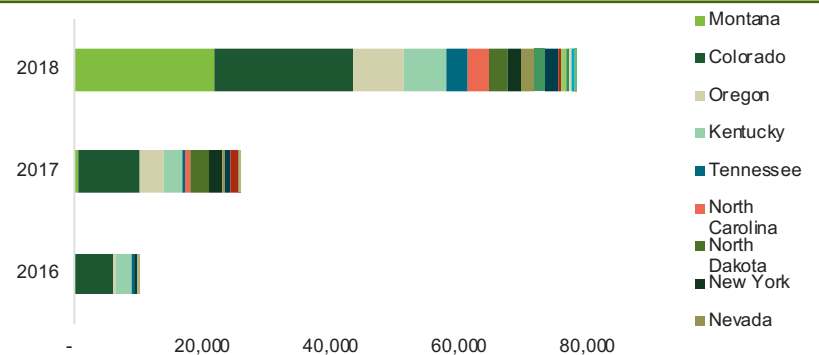


(1) Nielsen  
(2) Hemp Business Daily

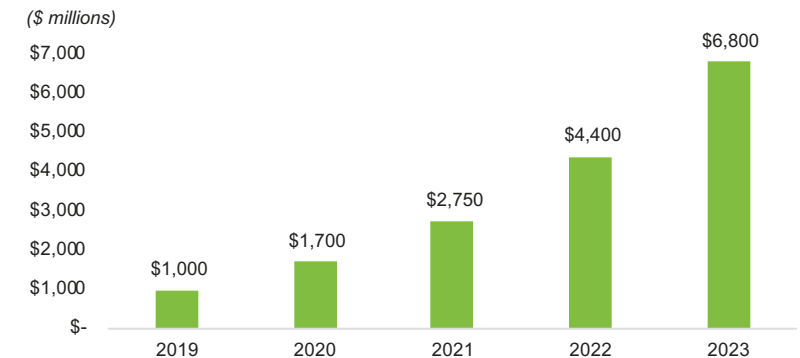
(3) Markets and Markets

## Hemp

US hemp acreage has increased significantly leading up to the passing of the 2018 Farm Bill<sup>(2)</sup>



Hemp derived CBD retail sales estimated to increase exponentially over the next few years<sup>(3)</sup>



# Regulatory Landscape and History

According to the 2018 Farm Bill, FDA and USDA remain the primary authorities for regulating hemp and CBD in consumable products

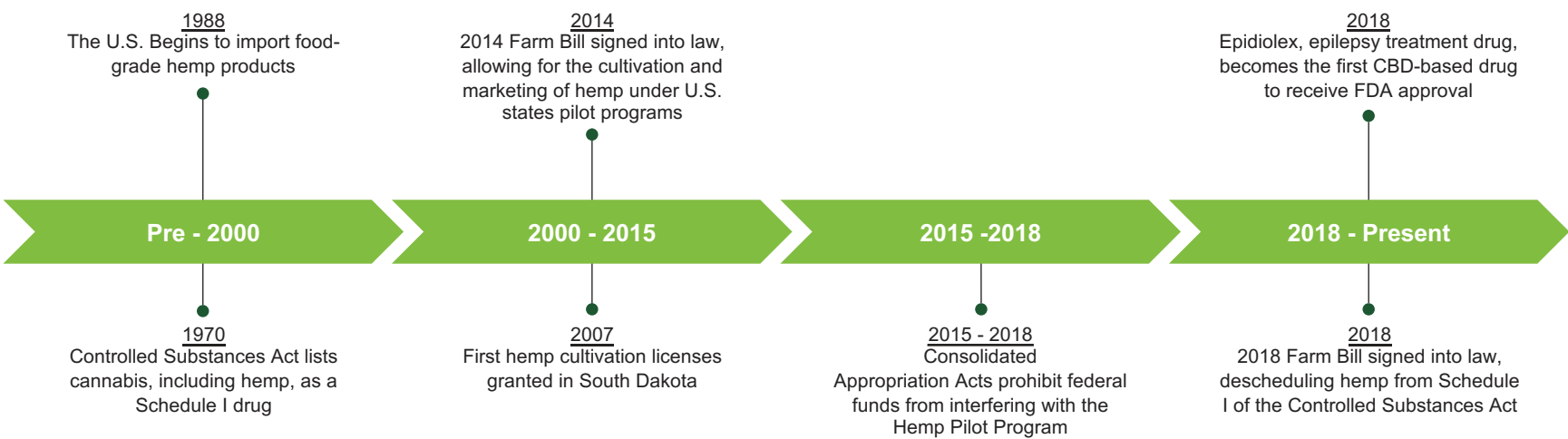
## FDA Regulations

- Following the passage of the 2018 Farm Bill, FDA still remains the main authority for regulating consumable products containing CBD
- It remains federally illegal to market products that add CBD to foods, or label CBD as a dietary supplement
- Regulators have issued warnings to companies that have advertised that their CBD products can treat or cure serious diseases and various health conditions
- As of today, topical products have the strongest position from a regulatory perspective

## USDA Regulations

- USDA is the primary regulatory authority on establishing standards for producing hemp safely and lawfully and setting testing standards
- Currently USDA is drafting hemp regulations for publication in the Federal Register and public comment
- USDA aims to have regulations in effect in the fall of 2019 to accommodate the 2020 planting season

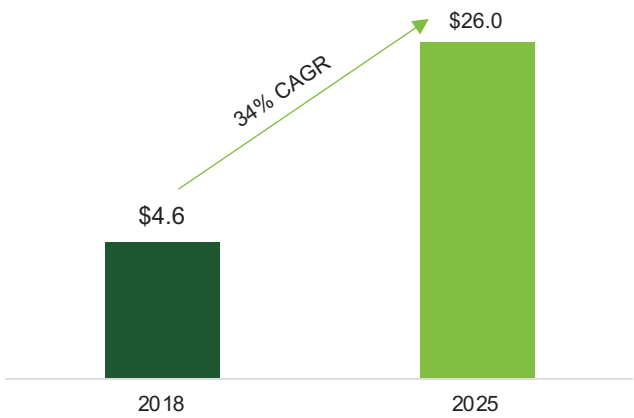
## Hemp and CBD Regulatory Timeline



# Global Hemp Market Overview

## Hemp Industry Forecast<sup>(1)</sup>

(\$ billions)



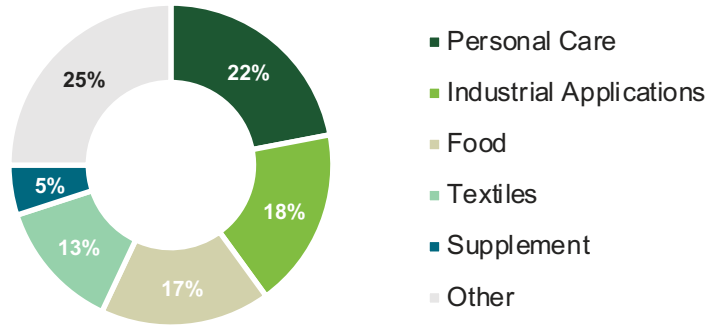
## Top 4 Producers

Country	Primary Use
1. China	Hemp textiles & fiber
2. Canada	Hemp food ingredients
3. U.S.	<b>Hemp-derived CBD oil</b>
4. France	Fiber for manufacturing

CBD Oil is the most lucrative industrial use of Hemp



## Top 5 Applications



## Growth Factors

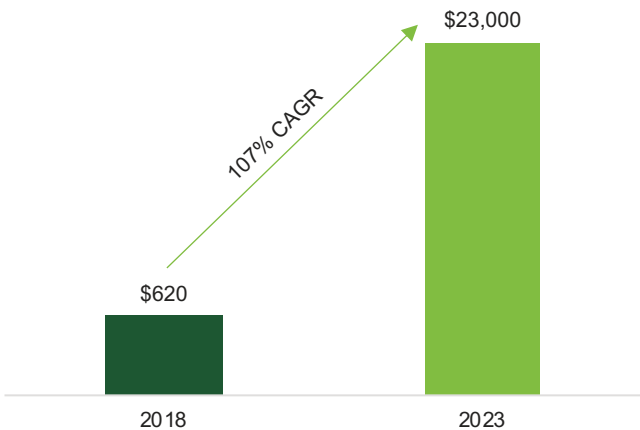
- ✓ Changes in global crop market dynamics
- ✓ Increase in legalization of cultivating industrial hemp
- ✓ Advances in hemp cultivation, extraction and utilization technologies
- ✓ Popularization of hemp-derived CBD in wellness industry

(1) Markets & Markets Research Analytics

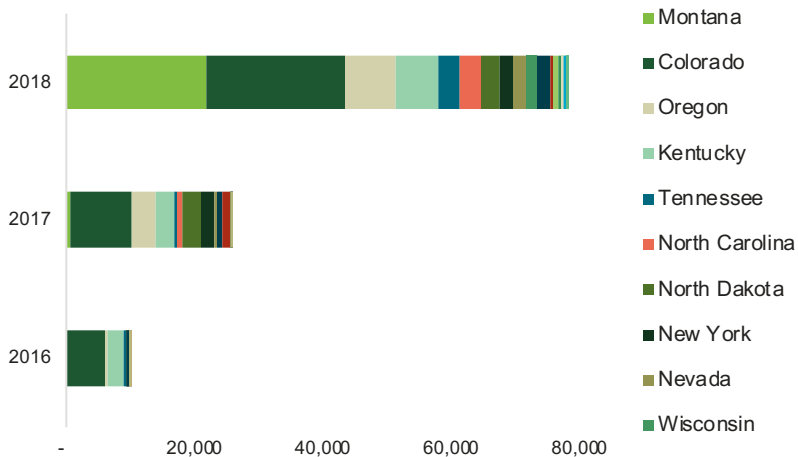
# U.S. Hemp and CBD Market

## CBD Sales Growth<sup>(1)</sup>

(\$ millions)



## US Hemp Acreage<sup>(3)</sup>



## 2019 Hemp Harvest<sup>(2)</sup>

**46**  
States Growing

**430k**  
Acres Licensed

**\$3.6b**

**128k**  
Acres Planted  
300x year prior

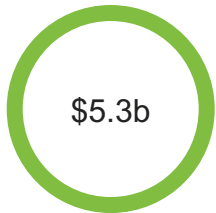
**130m**  
Lbs. suitable for  
CBD Extraction

Estimated Market  
Value of CBD-  
Suitable Biomass  
From 2019 Harvest

## CBD Sales Channel Forecasts<sup>(4)</sup>



Pharmacy



Dispensary



General Retail

(1) Brightfield  
(2) Hemp Benchmarks

(3) Hemp Business Daily  
(4) Arcview, BDS Analytics

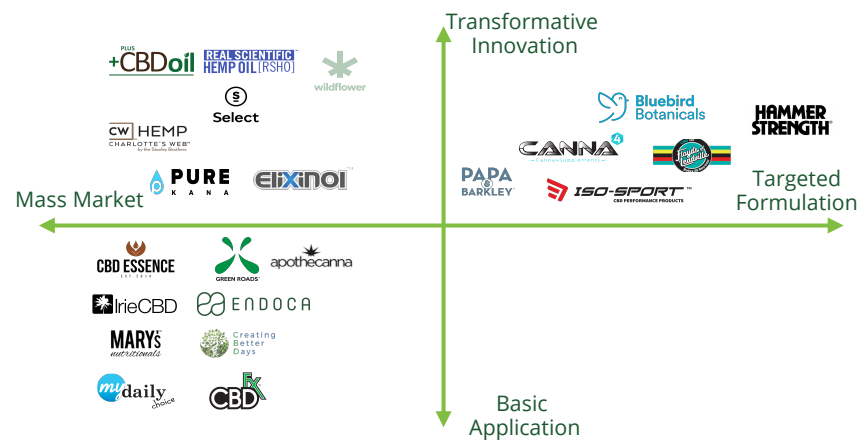


# Consumer Applications and Related Brands

## Application Overview

Consumer	Application	Products
Women	WOMEN'S WELLNESS	Daily oils, capsules and sublinguals
	EVERYDAY COSMETICS	Affordable soaps, cleansers, lotions and creams
	LUXURY COSMETICS	Specialized serums, masks and creams
Men	MEN'S WELLNESS	Daily oils, capsules, sublinguals and topicals
Kids	KID'S TREATMENT	Drops, sprays, gels, suppositories for illness and acute issues
Pets	PET TREATMENT	Tinctures, sprays and capsules for illness and acute issues
	PET WELLNESS	Daily Treats and tinctures
Other	TOBACCO	Hemp flower, pre-rolls and vapes
	SPORTS RECOVERY	Beverages, sprays, creams, gels and lotions
	BEVERAGES	Water, coffee, tea and sports drinks
	ADULT TREATMENT	Drops, sprays, gels, suppositories for illness and acute issues
	HEALTH EDIBLES	Granola, nut butters, olive oil, condiments, chocolate
	NIGHTLY SLEEP	Sublinguals, capsules, oils and vapes
	LUXURY HEMP	Hemp flower, pre-rolls and vapes

## Athletic Brands



## Cosmetic Brands

