Presentation to Office of Management and Budget (OMB)

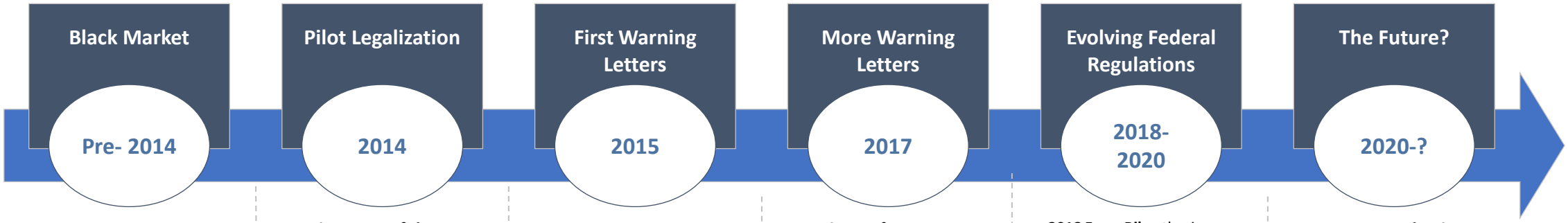
RE: RIN 0910-ZA76 – U.S. Food and Drug Administration "Cannabidiol Enforcement Policy“

Jessica Wasserman, Brett Goldman, Steve Bevan

FDA and CBD -- Background and Brief History

Background

- FDA has been monitoring and studying CBD products since at least 2015, as demonstrated from warning letters and approval of CBD-based Pharmaceuticals;
- Those early warning letters were focused on two areas: improper health and label claims, and **not** on product safety or quality;
- FDA indicated in 2018 that CBD does not meet criteria for drug scheduling but moved to schedule based on DEA recommendations.



- Hemp and Cannabinoids are considered illegal controlled substances with very few exceptions.
- **Section 7606 of the 2014 Farm Bill** legalized the production of hemp for research purposes, regulated by state agriculture departments
- **FDA** issues two warning letters for unapproved new drugs and labeling claims
- **FDA issues** four warning letters for unapproved new drugs and label claims
- **2018 Farm Bil** authorizes commercial production and regulation of hemp and cannabininoids;
- **FDA** Approves epidiolex as schedule V;
- **FDA issues 17 warning letters during this period,** enforcing against medical claims and not low-quality products
- **FDA** is slow to act post 2018 farm bill, and freezes downstream markets for CBD
- **COVID-19 Pandemic** further slows down market development
- **Large food manufacturers** are unable to work with CBD products due to FDA inaction
- **Legislation is proposed** to regulate CBD as a Dietary Supplement

FDA Has Previously determined CBD as safe

Scheduling Epidiolex

- The Department of Health and Human Services clearly told the DEA that Epidiolex — containing only CBD as an "active" ingredient— should not be scheduled because it had no human abuse liability and did not meet the requirements for scheduling.
- **In response, DEA insisted that CBD was a scheduled substance** and therefore Epidiolex had to be scheduled. Based on the safety profile of CBD, the default scheduling was at the very lowest level possible, Schedule V.
- In the view of HHS, if CBD was not a controlled substance, then the scheduling would need revisiting.

Criteria to Evaluate CBD	HHS/FDA Findings on CBD	CBD Safe?
Its actual or relative potential for abuse	**HHS/FDA** found that CBD does not appear to have abuse potential under CSA.	
Scientific evidence of its pharmacological effect, if known	**HHS/FDA** found CBD did not produce significant abuse liability.	
The state of current scientific knowledge	**HHS/FDA** found no adverse events including euphoria or abuse.	
Its history and current pattern of abuse	**HHS/FDA** found no signals for abuse.	
The scope, duration, and significance of abuse	**HHS/FDA** found that this was too low to quantify.	
What, if any, risk there is to the public health	**HHS/FDA** found that there is little indication that CBD has abuse potential or presents a significant risk to the public health.	
Its psychic or physiological dependence liability	**HHS/FDA** found no evidence for a classic drug withdraw syndrome for CBD, and no evidence that CBD causes physical or psychic dependence.	
Whether the substance is an immediate precursor of a substance already	**HHS/FDA** found that given the available data, it is unlikely that CBD would act as an immediate precursor to THC for abuse purposes.	

Need for Regulation Based on Consumer Safety and Sound Science

Producers and processors of federal and state-legal Cannabinoids (Hemp/MJ) have faced significant uncertainty due to lack of clearly defined enforcement discretion or regulations.

Studies and data show that CBD is safe for human consumption. So why the delay?

- FDA has indicated that it needs legal clarity on cannabinoids.
- Enforcement discretion is a great topic, but how does this concept move forward without industry or public participation?

What needs is the agency addressing? Legal or Political? Or Something else?

- How is the evaluation process defined? What is a realistic timeline?
- Will the agency put Farmers before Pharma or block demand derived from a new cash crop?

For now, the only beneficiary is a foreign marijuana manufacturer – not American Farmers and CBD producers—this seems antithetical to congressional intent.

Enforcement Discretion and/or Regulation for CBD is a Necessity

Preclusion has led a to gray area that needs clarification. It is our hope that the regulations under review will alleviate this need.

- Informal enforcement discretion has led to confusion for producers and customers alike. It threatens consumer health and safety.
- Informal enforcement discretion blocks demand through the supply chain, resulting in the proliferation of low-quality and potentially dangerous products
- FDA should make formal its exercise of enforcement discretion based off medical claims and product safety requirements.

FDA Has Not Provided Appropriate Pathway for Showing Safety of CBD

- FDA has denied the hemp/CBD industry the opportunity to show the safety of its product through the traditional GRAS or NDI process that is set up for industry to work with FDA to show the safety of food and dietary supplement products.
- FDA has signaled that the basis of keeping CBD out of the process is to provide an incentive for the pharmaceutical industry to invest in new drugs and relies on its "preclusion policy" as the "legal" basis (although FDA agrees it has discretion to override this policy). This removes CBD from the public for the benefit of a small group.
- FDA demands the industry to provide more safety data before regulating the industry and denies the industry the traditional pathway for showing product safety.
- FDA must provide a pathway for the CBD industry to show the safety of its product.
- Epidiolex was approved as a drug with CBD as an active ingredient at approximately 1200 mg/kg whereas CBD is in products at approximately 50-100 mg/serving.

Previous FDA Statements on Safety

As stated by former FDA Commissioner Dr. Scott Gottlieb:

"These changes [in the 2018 Farm Bill] include removing hemp from the Controlled Substances Act, which means that it will no longer be an illegal substance under federal law. In addition, pathways remain available for the FDA to consider whether there are circumstances in which certain cannabis-derived compounds might be permitted in a food or dietary supplement. Although such products are generally prohibited to be introduced in interstate commerce, the **FDA has authority to issue a regulation allowing the use of a pharmaceutical ingredient in a food or dietary supplement**. We are taking new steps to evaluate whether we should pursue such a process." – *FDA Press Release 12/20/18*

"Congress can help by passing language saying that the FDA doesn't need to issue a broad regulation on CBD and can instead rely on petitions filed by individual, prospective producers. In the meantime, the **FDA could exercise enforcement discretion to allow CBD to be marketed in food so long as the products meet certain conditions. These criteria can include meeting good manufacturing requirements, demonstrating traceability, adhering to safe levels for the purity** and potency of the CBD being added, and demonstrating that CBD is being added to food products only in very low concentrations that are unlikely to pose health risks." – *Washington Post 7/30/19*

The industry noticed these and other statements. Subsequently, solutions were developed to self regulate, create and apply standards, and produce reliable, consistent, and safe products to the ultimate benefit of the end user.

US HEMP AUTHORITY CERTIFIED

FOCUS Foundation Of Cannabis Unified Standards

ANSI American National Standards Institute

ASTM INTERNATIONAL

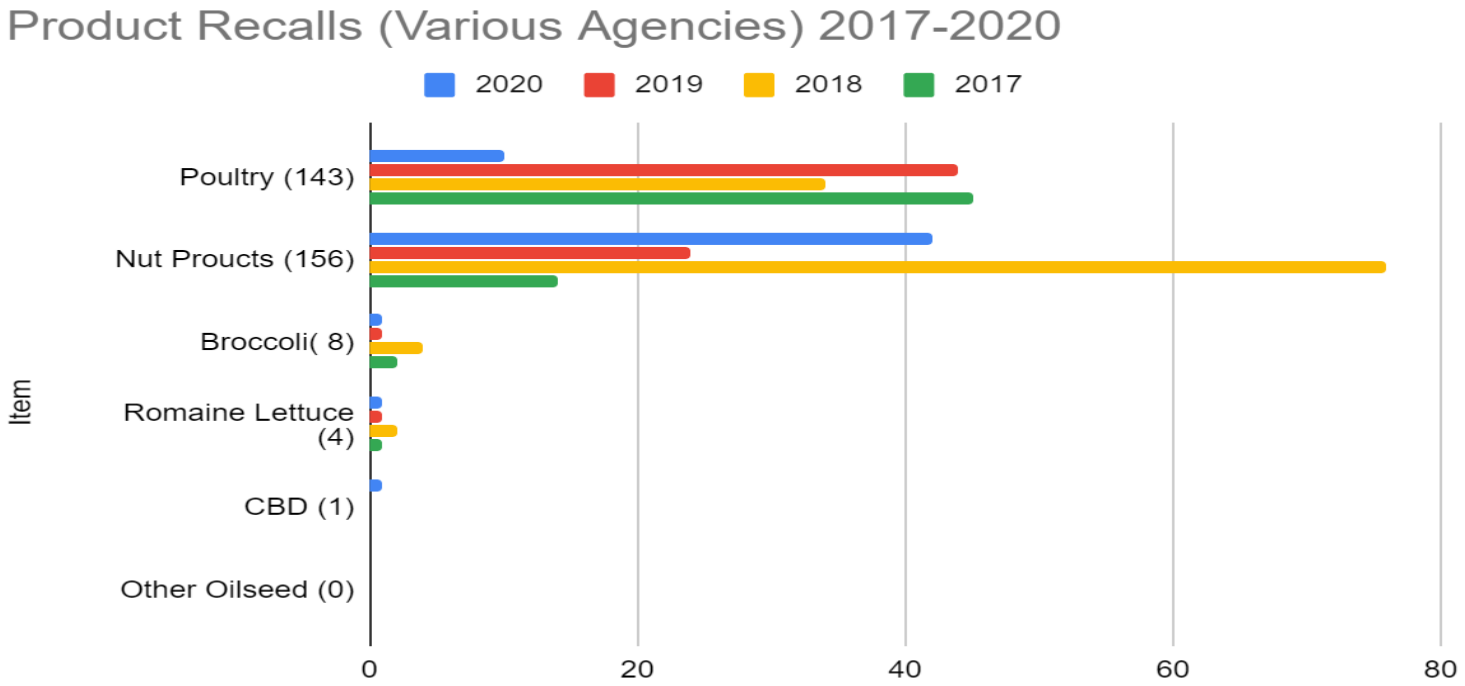
NIST

BRCGS

GOOD MANUFACTURING PRACTICE GMP QUALITY PRODUCT

Kosher KY

Cannabinoid Products are SAFE!



Item	2020	2019	2018	2017
Poultry (143)	10	44	34	45
Nut Proucts (156)	42	24	76	14
Broccoli(8)	1	1	4	2
Romaine Lettuce (4)	1	1	2	1
CBD (1)	1	0	0	0
Other Oilseed (0)	0	0	0	0

- **Congressional intent:** safe and reliable products produced by farmers
- **More recalls** for broccoli than CBD products
- If CBD products derived from hemp weren't inherently safe, **wouldn't the FDA issue recalls?**
- In five years, **one CBD product has been voluntarily recalled due to high lead content from poor quality packaging**

Sources: USDA Food Safety Inspection Service Summaries of Recall Cases in Calendar Year 2014-2019
U.S. Food and Drug Administration Recalls, Market Withdrawals, & Safety Alerts (2014-2020)

Congressional Intent of the Farm Bill and International Context

"The proper role of government, however, is that of partner with the farmer — never his master. By every possible means we must develop and promote that partnership — to the end that agriculture may continue to be a sound, enduring foundation for our economy and that farm living may be a profitable and satisfying experience."
-President Dwight D. Eisenhower, Special Message to Congress on Agriculture, January 9, 1956

The Congressional intent in including hemp in the 2018 Farm Bill (PL 115-334) was simply put to help American farmers derive economic value through a legacy crop.

To achieve this, the 2018 Farm Bill purposefully:

1. **Removed** hemp from the Controlled Substances Act (CSA) and declassified it from a schedule 1 drug; and
2. **Redefined** hemp as a legal crop (i.e., food and industrial product); and
3. **Gave USDA** regulatory authority over hemp cultivation; and
4. **Mandated** crop insurance for hemp farmers; and
5. **Recognized FDA** regulatory authority.

US based producers of hemp and cannabinoids have been at an advantage, thanks to congressional intent.

This advantage is waning as other countries overtake this advantageous position.

- Many countries in Latin America, some with similar farmland to that in the US, have more relaxed cultivation and processing rules. They will naturally favor their farmers over the US.
- The considerable edge that the US now enjoys in the production of floral hemp is just a fleeting glimpse of what might have been.
- The competition is coming, and the slower the demand, the lesser of a competitive edge the US farmer will get.

Bottom Line: Our contacts in foreign countries applaud the US legalization, the USDA involvement, the DEA signals for non-involvement, and are very pleased that the FDA is delaying action while farmers and processors suffer.

Enforcement Discretion Around the Globe

Jurisdiction	Definition/THC Limits	Enforcement Discretion Defined?	Other
United States (US)	Cannabis Sativa L. With Less than 0.3% THC. Includes all cannabinoids	No	The production of hemp was authorized in the 2018 Farm Bill
United Kingdom (UK)	CBD extracts can be derived from most parts of hemp / cannabis plants. They are selectively extracted, concentrating CBD and removing or reducing other chemical components. This process means the final product is different from hemp.	CBD is considered a Novel Food regulated by the FSA. FSA will move forward without EU post-Brexit.	Pending Brexit
European Union (EU)	Cannabis Sativa L. With less than 0.2% THC	Safety assessment under EU Novel Foods is needed	Status pending
South Africa (RSA)	Cannabis Sativa L. with less than 0.2% THC	**Medical Path**- cannabinoids are considered drug **Supplement Path**- 600mg packages 20mg/day	
World Anti Doping Agency (WADA)	All natural and synthetic cannabinoids are prohibited except for cannabidiol (CBD). Cannabis, hashish and marijuana are prohibited. Products, including foods and drinks, containing cannabinoids, are also prohibited. All synthetic cannabinoids that mimic the effects of THC are prohibited	CBD is not prohibited; however, athletes should be aware that some CBD oils and tinctures extracted from cannabis plants, may also contain THC and other cannabinoids that could result in a positive test for a prohibited cannabinoid.	
World Health Organization (WHO)	Cannabidiol (CBD) is one of the naturally occurring cannabinoids found in cannabis plants. It is a 21-carbon terpenophenolic compound which is formed following decarboxylation from a cannabidiolic acid precursor, although it can also be produced synthetically.	Naturally occurring non synthetic CBD is safe and well tolerated in humans (and animals), and is not associated with any negative public health effects	
United Nations (UN)	TBD	TBD	TBD

Economic Possibilities and Consumer Demand

Hemp for floral material is the highest yielding cash crop in the US, with farmer incomes potentially greater than tobacco. **The 3 key hemp states KY, CO, OR,** produced over 100,000 acres of hemp in 2019. **Hemp grown for floral material represented over 90,000 of those acres.**

By the Numbers, What is One Acre of Floral Hemp?

- 3,500 plants, yielding 0.5 lb per plant [dry] at harvest.
- Roughly 1,750lbs, or 800kg, of harvested [dry] biomass.
- At 5% CBD content, the biomass yields ~40kg CBD at maximum. Considering 50% downstream production loss, each acre produces ~20kg of saleable CBD.

How Much CBD Do We Need?

- The most popular products in the U.S. market contain 750mg of CBD, packaged in various forms like Oil Drops, Softgels, Dry Capsules, and Topical Creams. This means each acre of hemp farmed supports the production of roughly 25,000 units of 750mg products.
- If consumers use 750mg month, or 25mg per day, then each acre supports 2,000+ individuals CBD demands each year.

Rounding up and assuming incremental growth, this means:

- **If 1 in 4 Americans use CBD products daily, then we estimate demand at 100m people;**
- **100m consumers ÷ 2,000 Users Per Acre = 50,000 Acres Max Production;**
- **Only one state, like OR or CO or KY needs to grow hemp to supply cannabinoids to the nation if only used as a supplement.**

In 2019, several years worth of dietary supplement consumer demand was harvested. Without a pathway for food and beverage:

- There is no need to produce more hemp for at least two years.
- Farmers will continue to have an oversupply of the crop input, resulting in lost incomes and more bankruptcies throughout the value chain.
- As growing techniques and better genetics dominate, less and less acres are needed for production, as with any other crop. American producers remain at an advantage, but that advantage is waning.

What should regulation look like?

1. Defined enforcement discretion
2. Mechanism to address concerns of law enforcement throughout value chain
3. Evolving, iterative framework based on suggestions of fmr. Commissioner Gottlieb
4. “Swim Lanes” to address different downstream uses of hemp/cannabis

Each type of downstream product needs its own appropriate regulation, e.g. Corn, soy, wheat:

- **Pharma** – Nano-glycogens
- **Food** – Cereals, oils
- **Supplements** – Corn silk
- **Alcohol** – Bourbon, Whiskey
- **Feed** – Silage
- **Fuel** - Ethanol

Cannabinoids, derived from a crop (hemp) are no different:

- **Pharma** – Drug Development
- **Food/Beverage** –additives to existing products, beverages
- **Supplements** – oil drops, soft gels, chewables, lozenges
- **Cosmetics** – topical creams, sprays

The Definition of CBD Matters

- **2018 Farm Bill defined federally legal cannabinoids from hemp** except for concentrations above 0.3% Delta-9 Tetrahydrocannabinol. The legislative definition was left exceptionally broad.

  (*The term 'hemp' means the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. as a part of Hemp (Cannabis Sativa L.*)- Section 10113 of the 2018 Farm Bill.
- **Enforcement discretion of CBD** must necessarily define what CBD is in a scientific manner. This is the intersection of the intention of the legislation with the reality of science and regulation.
- **CBD exists in many forms** the definition and enforcement discretion must take this into account. CBD can be:
  - An isolate (99.5% pure)
  - In an extracted oil formulation with less than 0.2% THC
  - In an extracted oil formulation with zero THC
  - In a nano-encapsulated form
  - in a water-soluble form
  - in its non-decarboxylated acid form
  - and many other quickly evolving forms that serve as ingredients to ingestible products and cosmetics.

Conclusion

1. It is time for FDA to step up to the plate and provide regulation to protect consumers who want to purchase a safe and reliable product, product regulated by FDA.
2. FDA has been studying CBD for over 5 years. There is adequate safety data that could be developed by working together and without this, FDA is adding to the risk to consumers by inaction.
3. FDA regulation is needed to provide leadership, certainty, and guiderails for an industry that is not fully mature in the United States and in other countries.
4. Without regulatory certainty for US production and marketing, other countries will be the first movers and get the competitive advantage in this industry-one important to US farmers and job creators.
5. The first step is for FDA to establish a formal, appropriate and realistic enforcement policy to drive a national standard.
6. The next step is for FDA to remove preclusion and allow cannabinoids into food and supplements, so long as it is safe, and there is NO DATA that indicates any statistically significant safety issues.

These steps will allow hemp farming in the US to meet the congressional intent as embodied in the Farm Bill, and let American growers, processors and brands can lead the world.

Appendix and Supplemental Information

Appendix 1: State of the Hemp Industry in 2020

- 2020 an 'extinction event' for thousands of CBD companies, but industry remains crowded *Hemp Industry Daily 8/3/20*
- European Commission weighs narcotic label for CBD, halts 'novel food' applications *Hemp Industry Daily 7/21/20*
- FDA Announces Recall Of Dozens Of Hemp Products For Humans And Pets *Marijuana Moment 7/21/20*
- FDA Updates Congress On CBD Product Labelling Accuracy *Marijuana Moment 7/9/20*
- USDA Denies Coronavirus Benefits For Hemp Farmers But Later Seems To Reverse Reevaluation Block *Marijuana Moment 5/20/20*
- Leading Kentucky hemp processor GenCanna files for bankruptcy *Market Watch 2/6/2020*
- Oregon CBD company lays off dozens of workers, blames FDA uncertainty *Hemp Industry Daily 2/28/2020*
- Colorado CBD producer Mile High Labs lays off 20 employees just months after major expansion *Denver Post 1/10/2020*
- Hemp farmers gathering to weigh options in the wake of Bluegrass BioExtracts controversy *Messenger Inquirer 1/28/2020*
- NY's hemp boom turned into an early bust *USA Today 2/28/2020*
- Pennsylvania hemp processor closes, citing falling hemp and CBD prices *Hemp Industry Daily 2/18/2020*
- Some who gambled on hemp lost all *Mail Tribune 11/24/2019*
- Statement from FDA Commissioner Scott Gottlieb, M.D., on signing of the Agriculture Improvement Act and the agency's regulation of products containing cannabis and cannabis-derived compounds *FDA Press Release 12/20/2018*
- FDA warns 15 companies for illegally selling various products containing cannabidiol as agency details safety concerns *FDA Press Release 11/25/2019*

Appendix 1: State of the Hemp Industry in 2020

1. Tens of thousands of acres of floral hemp harvest --- arguably **the nation's highest yielding cash crop** --- have been lost in 2019 and are likely to be lost in 2020 due to lack of demand.

2. Congressional leaders promised to normalize hemp as a food crop. **This process was not finished.**

3. **Why?** FDA's default position on the high economic value floral hemp is that it is a "cannabis derived compound" connoting some sort of drug-like substance when the 2018 Farm Bill removed it from the CSA

4. The economics of hemp-derived products are dominated by Cannabidiol (CBD). **Many CBD products are produced in food grade environments with focus on quality and compliance**, as described by former FDA Commissioner Gottlieb immediately following the signing of the 2018 Farm Bill, and again during a House Appropriations Committee hearing on April 3rd, 2019.

5. **But many hemp-derived products are produced in basements, garages, and barns, in a fashion that is not compliant with food or supplement standards.** The FDA has never taken action against these substandard offerings. The implication is that even poor quality products are safe.

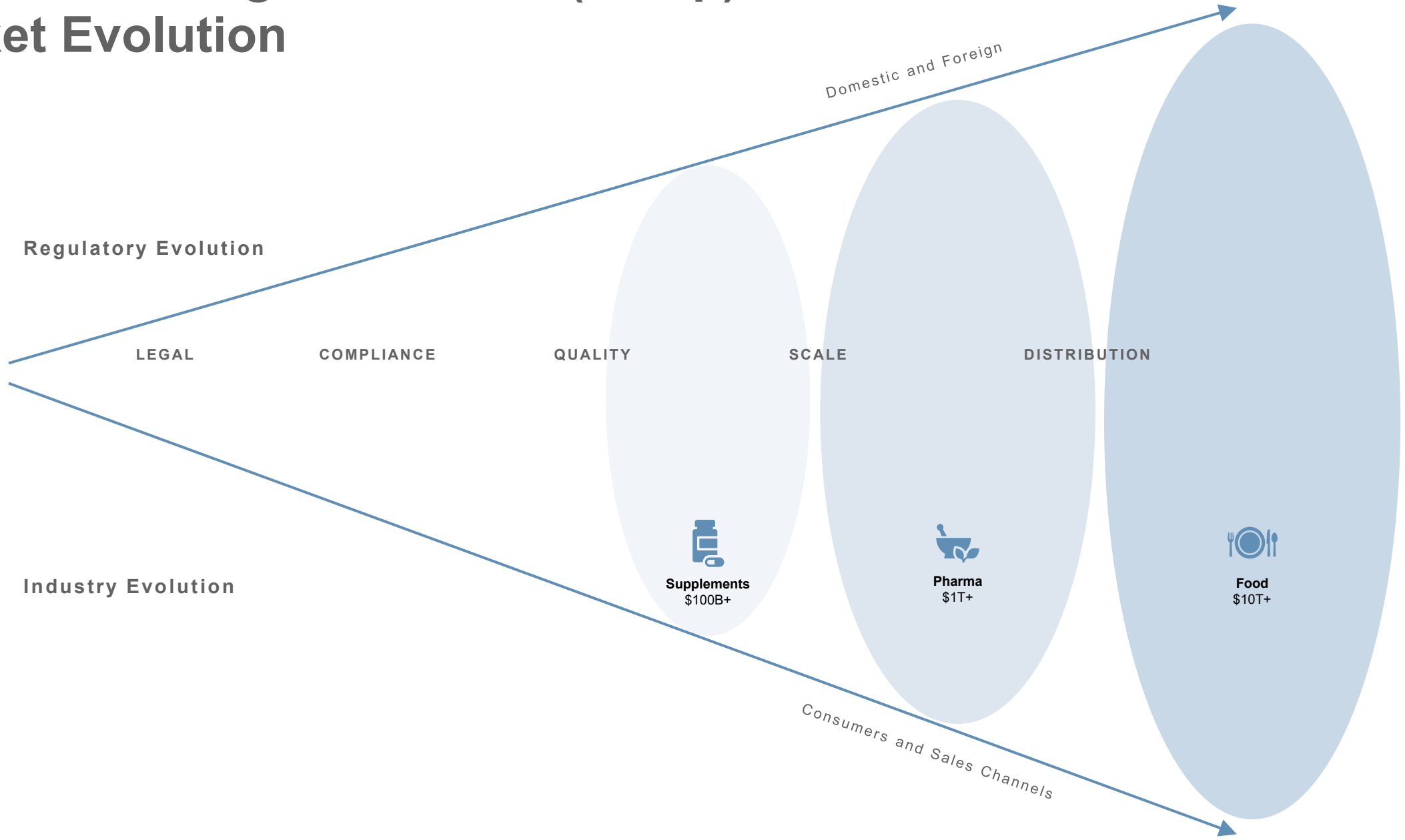
6. **The FDA has sent many warning letters about health/drug claims –and only recently for poor quality products with substandard packaging.**

7. At the same time, the **FDA admonishes the responsible producers** like those in the mainstream food and supplement industries and overlooks poor quality products that are still available. Compliant producers are not participating as they would, and thereby significant pull-thru demand is limited, which hurts the best part of the hemp economic value chain. Thus, there is lack of demand for hemp products, including CBD, by American "Food Inc." specifically because of FDA.

8. There are high expectations across the hemp industry for a regulatory framework like dietary supplements, which is an incremental achievement at best. **Dietary supplements have limitations: defining CBD as a dietary supplement is not anywhere close to enough to support a viable, valuable hemp crop.** Curcumin farmers, Echinacea growers, etc. are nothing more than small, novelty crops.

9. **In the meantime, farmers continue to suffer** as high-quality manufacturers and brands cannot create pull through demand for farm products **and in turn, face their own issues—the exact opposite effect of the original congressional intent for legalizing hemp.**

Appendix 2: Legal Cannabis (Hemp) Market Evolution

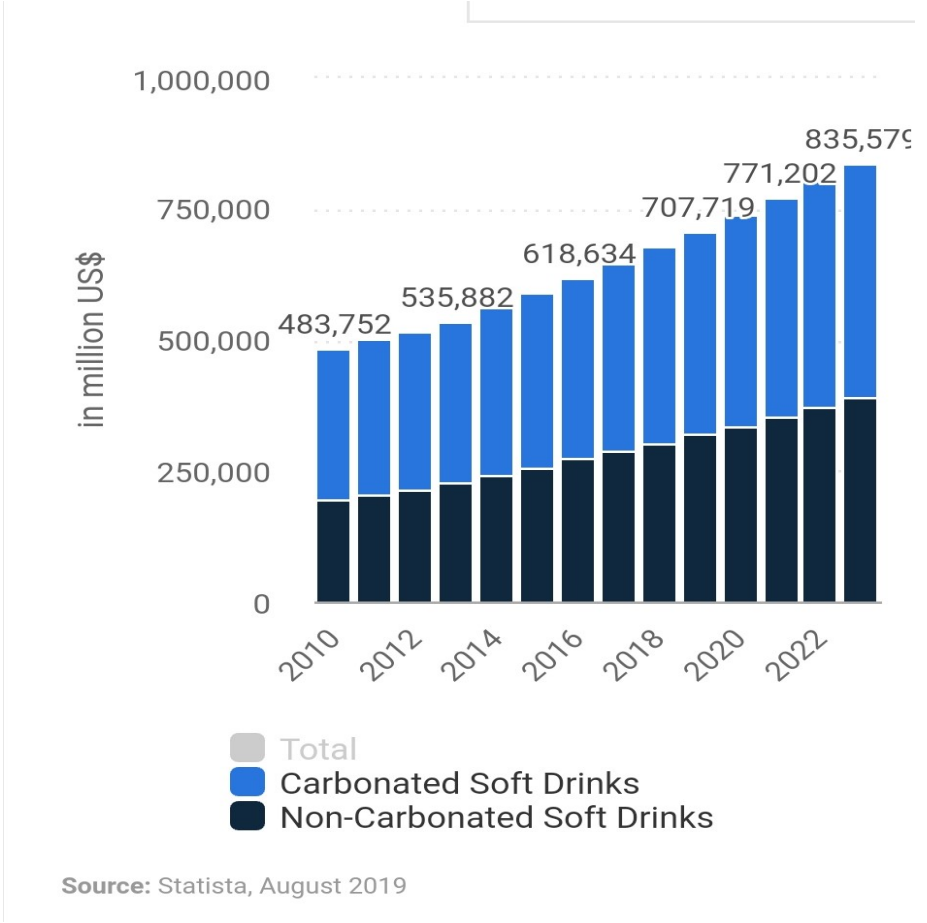


Appendix 3: CBD Beverage Potential

- Energy drinks = **$60 billion in revenue in 2020**; average price $2/drink (**10 billion drinks sold)**
- Soft Drinks = **$720 Billion in 2020**
- New Categories = CBD + Cannabinoids

Global market demand will be met by either domestic or international supply.

CBD represents a generational opportunity to grow (hemp) and make value added products right here in the US.



Appendix 4: Estimated CBD Consumption

In May 2019 we submitted comments to the FDA following the May 31st, 2019 Hearing on *Cannabis and Cannabis Derived Compounds* (Docket No. FDA-2019-N-1482-0001: Request for Comments on Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds). In these comments, we stated:

"Our estimation for 2018 is that the US population used 40,000-50,000 kg of CBD in various forms. From this conservative estimate, we can glean several important takeaways:

- ***A. if the average daily serving size was 25 mg, then 1.8 billion servings were consumed in 2018. On a daily basis, 4.9 million people used 25mg CBD daily.***
- ***B. if the average daily serving size was 50 mg, then 900 million servings were consumed in 2018. On a daily basis, 2.5 million people used 50mg CBD daily.***
- ***C. if the average daily serving size was 100 mg, then 450 million servings were consumed in 2018. On a daily basis, 1.2 million people used 100mg CBD daily.***

Several implications are possible from the above:

1. *if the lower average serving size is correct then almost 5 million Americans are daily consumers of CBD. Any negative health effects should be observable in that large cohort.*
2. *if the higher average serving size is correct then well over a million Americans use 100mg CBD daily. Any negative health effects should be observable in that cohort.*
3. *If the market size estimates are too low, then the number of Americans using CBD products is higher, and the population should show any negative effects of significant CBD usage.*

Our conclusion is that millions of Americans already consume CBD in a meaningful way. While more specific data is not yet readily available, it is clear that the population tolerates CBD very well."

We believe that we underestimated American CBD production and usage by at least half in 2018. Since then, we increased production and usage in 2019. And still no serious adverse health effects have been reported.

Our conclusion that the population tolerates CBD very well is still true.

By comparison, the FDA has initiated full and partial recalls of romaine lettuce in that same timeframe. **If the FDA had any belief that CBD was unsafe**, then why have they never once pulled any CBD product off any American shelf or internet sales platform because of adverse health effects)