A Year in Review For Cannabidiol (CBD):

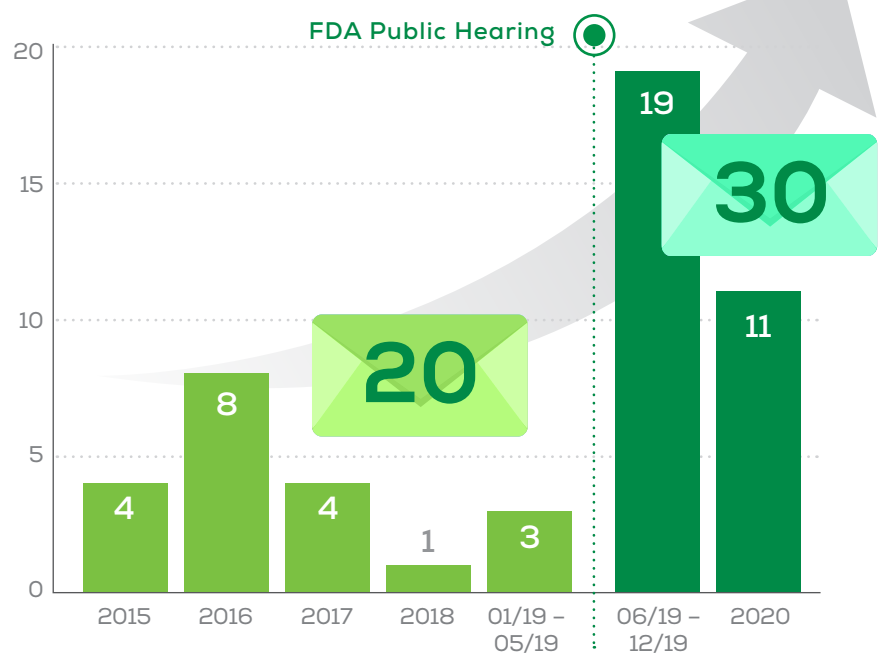
Measured Progress and Path Forward

Since the U.S. Food and Drug Administration held a public hearing on "Products Containing Cannabis or Cannabis-derived Compounds" on May 31, 2019, consumer utilization of CBD-containing products has continued unabated with some estimates projecting CBD sales surpassing $20 billion by 2024[1]. FDA has been actively engaged, yet more must be done to develop a regulatory framework that will incentivize research and drive innovation while protecting consumer safety.

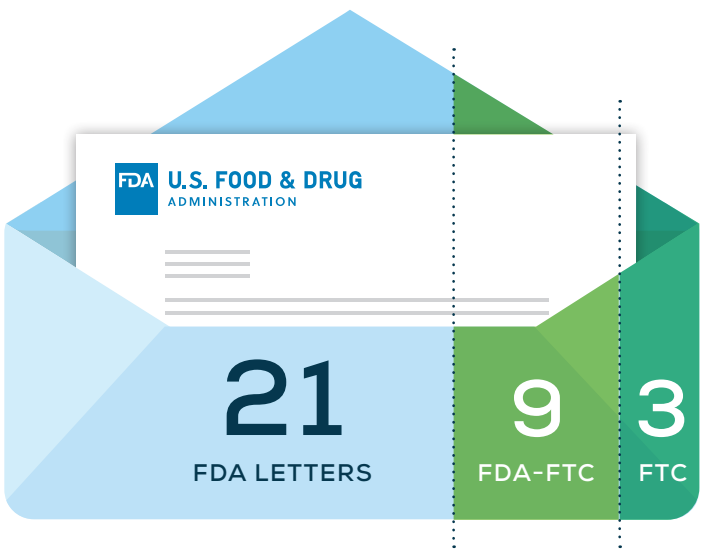
Federal agencies step up warnings of fraudulent, misbranded, misleading, or otherwise unapproved new CBD dietary supplements and medicines

↑ 50%

in FDA warning letters issued when comparing pre- and post-hearing actions.



Since May 2019: 33 total warning letters have been issued



FDA LETTERS related to infractions for new, misbranded, or unapproved CBD drugs.

JOINTLY ISSUED FDA-FTC LETTERS related to the confluence of COVID-19 and CBD fraud.

FTC-ONLY LETTERS to companies making illegal claims.

FDA Must Act to Avoid Patchwork Regulatory Frameworks Promulgated by States

States have enacted a varied set of laws and regulations related to the legality of hemp-derived CBD sales.

Can CBD be sold in a state?[2]

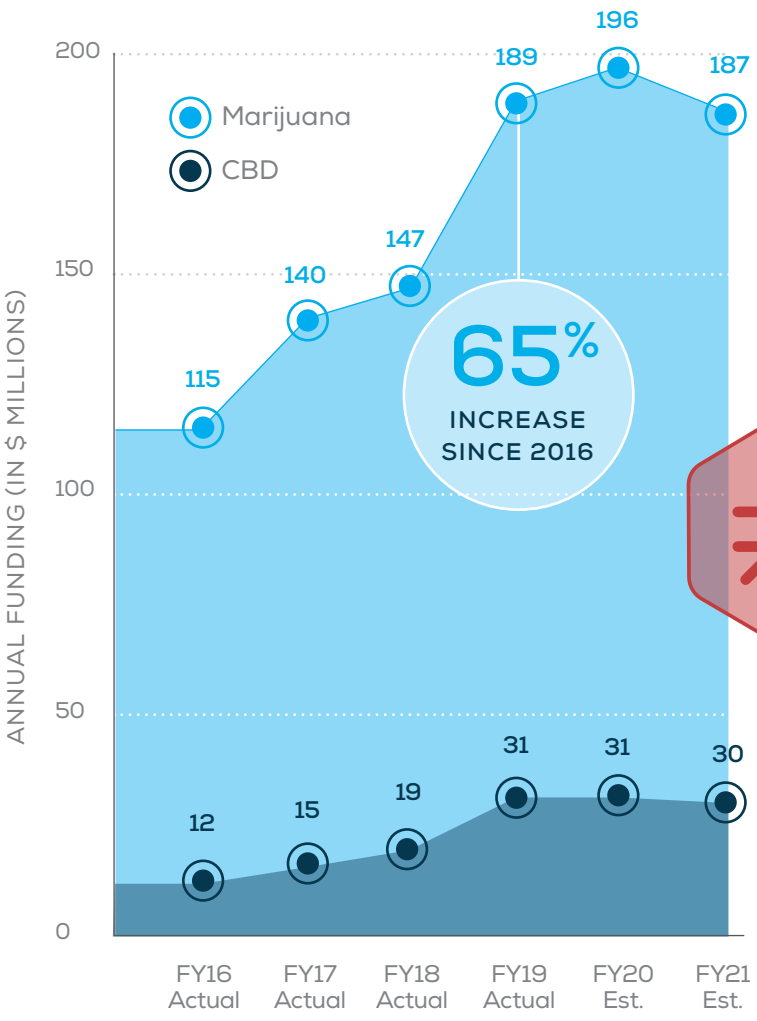
18	21	12
Permitted	Not Permitted	Unclear

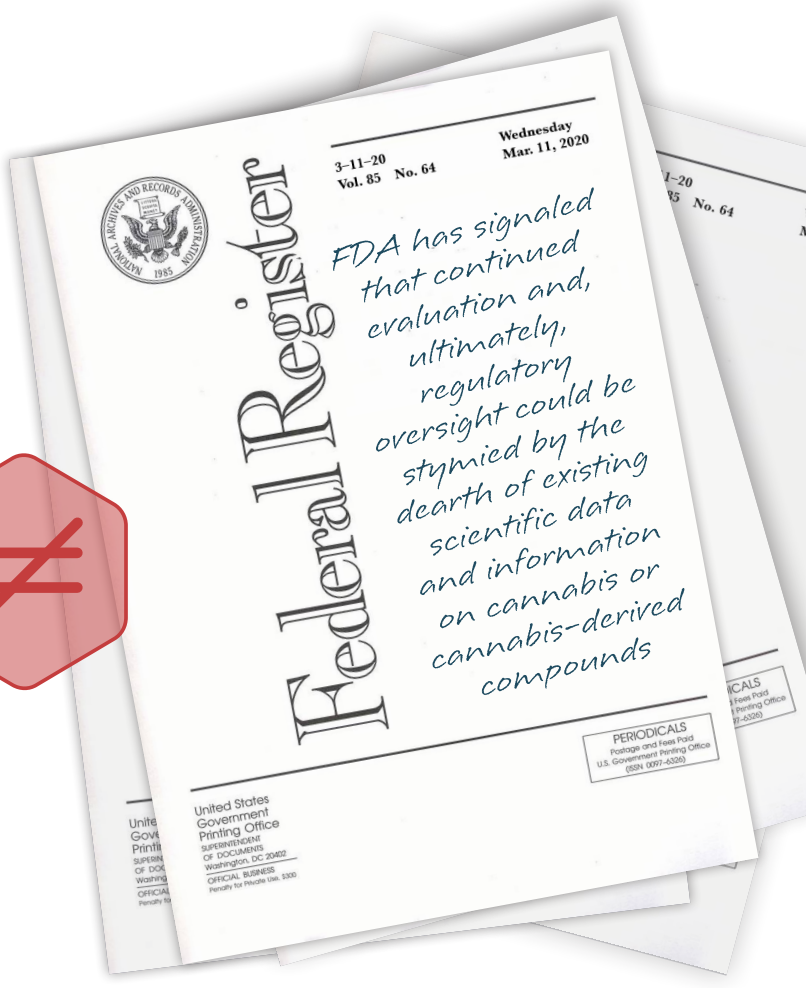
Regulators in other countries are moving forward on CBD, alongside FDA.

Areas where they're acting:

Regulatory · Legislative · Legal · Dosing

Despite greater federal cannabis research funding, significant data gaps and uncertainties remain





Despite FDA's increased actions, unscrupulous CBD manufacturers continue to engage in misleading marketing practices and leverage ongoing circumstances, such as the COVID-19 pandemic, for profit. By touting CBD as a potential treatment and other misleading claims related to the prevention, mitigation, or cure of disease, they act on consumer fear and confusion for their benefit and place consumers at significant risk.

We must support incentives to drive research, development, and product testing to ensure the quality and safety of CBD-containing products for consumer use.

FOR MORE INFORMATION

Visit www.cbd-collaborative.org or email caroline.waldo@faegredrinker.com

CCSS
The Collaborative for CBD Science & Safety

SOURCES:

1 Forbes. CBD Market Could Reach $20 Billion by 2024, Says New Study. May 20, 2019. https://www.forbes.com/sites/irisdorbian/2019/05/20/cbd-market-could-reach-20-billion-by-2024-says-new-study/#17dcbe349d05

2 Council for Responsible Nutrition

CCSS
The Collaborative for CBD Science & Safety

STEERING COMMITTEE

Aimed Alliance

Arthritis Foundation

Consumer Brands Association

Council for Responsible Nutrition

Greenwich Biosciences

LegitScript

NACBHDD

National Alliance on Mental Illness

National Council for Behavioral Health

National Consumers League

One Year Later, More Remains on the Agenda for Cannabidiol (CBD)

One Year After FDA's CBD Public Hearing,
Limited Clinical Data Available to Inform Further Federal Guidance for Consumer Safety

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WASHINGTON, DC – One year after the landmark May 2019 Food and Drug Administration (FDA) public hearing on "Products Containing Cannabis or Cannabis-derived Compounds," the Collaborative for CBD Science and Safety (CCSS) is calling on stakeholders—industry, researchers, academia, healthcare practitioners and regulators—to accelerate both research and the development of an appropriate federal regulatory framework for cannabidiol (CBD) and CBD-containing products.

The need is obvious. Since 2016, a nearly 65-percent increase has occurred in cannabis research funding, from $115 million to $189 million. However, the dollars flowing in remain insufficient to keep up with public demand for CBD-containing products, with some estimates projecting CBD sales surpassing $20 billion by 2024. By reopening the public docket and "extending it indefinitely," FDA signaled that regulatory oversight and continued evaluation remain stymied by the dearth of existing scientific data and information on cannabis or cannabis-derived compounds.

The 2019 public hearing aimed to assist the agency in gathering scientific data and related quality, marketing and labeling information for CBD and related products for the purposes of developing a robust regulatory framework. Many individuals and organizations, including CCSS participants, engaged in the 2019 hearing, encouraging FDA to establish a clear path forward for safe, high-quality products containing CBD.

"We must ensure consumers can trust the safety and quality of CBD-containing products and can rely on the product's claims where appropriate," said Sally Greenberg, Executive Director of the National Consumers League and CCSS Steering Committee Member. "The importance of a separate regulatory pathway for CBD-containing products is underscored by the current spread of the coronavirus and the false, dangerous claims and misinformation about CBD that have accompanied the pandemic. In all cases, consumers remain at risk. FDA must continue to take action towards developing a regulatory pathway for CBD and begin mitigating threats posed by poor-quality products."

Even as COVID-19 has consumed much of the agency's bandwidth over the past four months, FDA's actions against illegal actors have spiked over the last twelve months. The agency has issued 30 CBD-specific warning letters since the public hearing, a 50% increase compared to pre-hearing statistics going back to 2015. Though these steps are necessary and important, still more needs to be accomplished to protect public health and safety and remain on par with other national regulatory bodies – such as the United Kingdom, Sweden and Australia – addressing CBD for their consumers.

"FDA has adopted a cautious approach to addressing the use of CBD in dietary supplements – it still does not consider CBD a legal dietary ingredient, nor recognize it to be 'generally recognized as safe,' or GRAS in food," noted Steve Mister, President & CEO of the Council for Responsible Nutrition and CCSS Steering Committee member. "FDA should continue to advance efforts that address the research gaps it has identified around CBD and establish a clear evidence-based path forward for their regulation of CBD-containing products as they are already widespread on pharmacy, grocery and convenience store shelves nationwide absent of a federal regulatory framework."

Looking ahead, the Collaborative encourages the FDA to continue its effort to drive evidence-based decision making such that the regulatory environment shifts away from warning letters and towards promotion of safe, high-quality products on the market.

To learn more about the CBD Collaborative, please visit: www.CBD-Collaborative.org.

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About CCSS
The Collaborative for CBD Science and Safety (CCSS) provides a forum for stakeholders to exchange information, build alliances around shared interests and priorities, and respond to policies and practices affecting cannabidiol (CBD) research, safety and quality. Please visit www.CBD-Collaborative.org for more information.

A YEAR IN CANNABIDIOL (CBD):

Measured progress and path forward

Since the U.S. Food and Drug Administration (FDA) held its Public Hearing on "Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds" on May 31, 2019, substantial efforts have been made to address poor quality, fraudulent or otherwise dangerous CBD-containing products on the market. In response to the COVID-19 pandemic, state, federal and international regulators and enforcement bodies continue to address consumer health and safety threats – including targeting fraudulent CBD-containing products marketed to mitigate, prevent, treat, diagnose or cure COVID-19.

Coupled with increased efforts to educate consumers and to incentivize further CBD research and data development aligned with FDA's needs, opportunities exist to create a regulatory structure that promotes the availability of safe and quality CBD-containing products and gives industry and consumers alike a stable, predictable and safe CBD marketplace.

FEDERAL ACTIONS

FDA Indefinitely Reopens the CBD Public Docket to Collect Data Needed to Address Research Gaps and Uncertainties

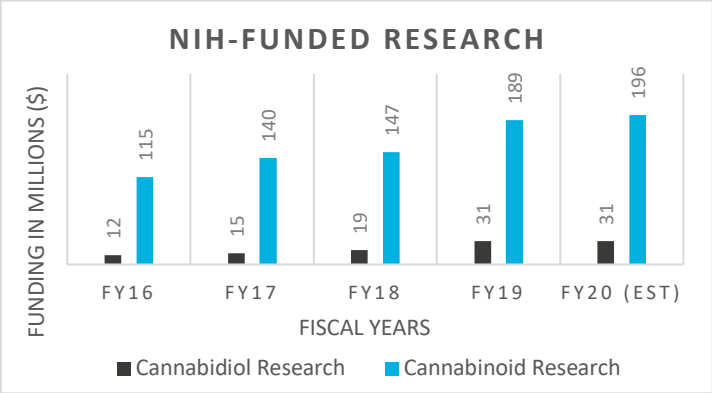
- On March 11, 2020, FDA reopened the public docket that accompanied the May 2019 hearing to provide a public and transparent way for stakeholders to provide new and emerging information regarding CBD in real time as it becomes available while protecting confidential data that should be accessible by FDA.
- The areas noted that would be most useful to inform FDA on the safety of CBD to further address data gaps and include opportunities to advance clinical data and systematic surveillance:[i]
  - Clinical Studies: These include studies regarding safety and tolerability, driving impairment, alcohol interaction, and dermal penetration.
  - Systematic Surveillance: The broad availability of CBD provides an opportunity to establish safety surveillance systems that could capture data about exposure and outcomes related to CBD uses that are not feasible or practical to generate using traditional clinical trials or studies.

FDA Warning Letters

Warning Letters Issued Since May 2019 **January 2015 – May 2019:** 20 total warning letters | **May 2019 – Present:** 30 total warning letters[ii]		
Joint FDA/FTC Warning Letters (21)	***COVID-19/CBD Specific Warning Letters (8)***	***FTC Specific Warning Letters (3)***
July 22, 2019: • Curaleaf, Inc.	March 31, 2020: • NeuroXPF	September 10, 2019: [iii] • 4Bush Holdings, LLC • NuLife CBD Oils, LLC • Ocanna Co.
September 12, 2019: • Herbal Healer Academy, Inc.	April 6, 2020: • Native Roots Hemp • Indigo Naturals	
September 18, 2019: • Alternative Laboratories	April 7, 2020: • CBD Online Store	
October 10, 2019: • Rooted Apothecary, LLC	April 16, 2020: • Nova Botanix LTD DBA CanaBD	***FDA Warning Letters (1)***
November 22, 2019: • Natural Native LLC • Private I Salon, LLC • CDRL Nutritional, Inc • Red Pill Medical Inc • Apex Hemp Oil LLC • Daddy Burt Hemp Co • Organix Industries, Inc dba Plant Organix • Sabai Ventures Ltd • Noli Oil, LLC • Bella Rose Labs • Sunflora, Inc./The CBD Store, LLC dba Your CBD Store • Infinite Product Company LLLP DBA Infinite CBD • Mr. Pink Collections, LLC • Whole Leaf Organics, LLC • KOI CBD LLC	April 20, 2020: • Homero Corp DBA Natures CBD Oil Distribution	April 28, 2020: • The Dragontree Apothecary LLC
	May 7, 2020: • AgroTerra, Ltd. dba Patriot Hemp Company	
	May 15, 2020: • Noetic Nutraceuticals	
	May 21, 2020: • Apollo Holdings, LLC	
	May 26, 2020: • CBD Gaze	

Overview of NIH-funded research for CBD-containing products.

NIH funding for research for both cannabidiol and cannabinoids has generally increased annually since 2016: [iv]



Year	CBD Research	Marijuana Research
FY16	$12 million	$115 million
FY17	$15 million	$140 million
FY18	$19 million	$147 million
FY19	$31 million	$189 million
FY20 (est)	$31 million	$196 million

Federal Enforcement Action

- In response to a Federal Trade Commission complaint, a California-based marketer of a dietary supplement has agreed to a preliminary order barring it from claiming that it is effective at treating, preventing, or reducing the risk of COVID-19. Pending the resolution of a parallel administrative case, the proposed preliminary order also bars the company, doing business as Whole Leaf Organics, from claiming that three CBD-based products he sells are effective cancer treatments.[v]

FDA ACTION NEEDED TO PREVENT FURTHER PATCHWORK OF STATE CBD REGULATIONS ON USE AND SALES

Examples of CBD-Specific State Legislation

While some states have passed a patchwork of inconsistent laws governing the use of CBD, others have engaged in enforcement actions against CBD manufacturers. Such activity has created widespread confusion as to the legality of the products and highlighted the need for one clear regulatory pathway.

State	Bill Number	Date Enacted	Purpose/Scope
Florida	SB 1020[vi]	Signed June 25, 2019. Enacted on July 1, 2019.	• Authorizes the distribution and retail sale of hemp extract. • Before hemp extract may be distributed or sold, it must be analyzed and certified by an independent testing laboratory to confirm the THC concentration does not exceed 0.3 percent on a dry-weight basis. • The bill also provides package labeling requirements for hemp extract products.
Oklahoma	SB 238[vii]	Signed May 13, 2019. Enacted November 1, 2019.	• SB 238 requires any product containing cannabidiol to contain a label showing the country of origin and whether the cannabidiol is synthetic or natural. • Doesn't apply to any FDA-approved pharmaceutical product. • Allows those selling hemp and hemp products to sell such products and add such products to other goods without a license.
Virginia	SB918[viii]	Signed April 6, 2020.	• Defines hemp extracts as food products for human consumption, failing under the Dept. of Agriculture and Consumer Services.

State enforcement actions regarding unauthorized sale of CBD-containing products.

- **On July 17, 2019, a coalition of 37 bipartisan Attorneys General** urged federal cooperation with the states to protect consumers from false advertising and potential harms to their health from products containing cannabis or cannabis-derived compounds, including cannabidiol (CBD).[ix]
- **New York (April 6, 2020):** The office of the New York Attorney General sent a cease and desist letter[x] to CBD company Finest Herbalist for marketing through emails, text messages, and websites that consumers could use its products to "[f]ight back against the coronavirus outbreak," among other claims.
- **Oregon (April 28, 2020):** The Oregon Attorney General's Office warned a store in Portland that advertising that CBD products could boost immunity against the coronavirus was likely a violation of consumer protection laws.[xi]

U.S. ON PACE WITH OTHER INTERNATIONAL REGULATORY AGENCIES

While the US struggles with how to best address CBD, governments and regulators across the globe have been facing similar challenges. While governments have been moving forward at different paces, the US has kept on pace with most of our international counterparts.

	Australia	UK	Sweden	US
Court Action		CBD products with >1mg THC per container illegal.	• Supreme Court has ruled that CBD products are illegal if they contain any amount of THC • Without a prescription, it is illegal to possess CBD (or any form of cannabis)	Spike in CBD class actions suit, with 18 new suits filed since the May 2019 public meeting. Suits based on potential harms to class members caused by, among other things, manufacturers marketing their products with unsubstantiated health claims and mislabeling the CBD and THC content in their products.
Legislative Action				CBD and other cannabinoid products containing ≤0.3% THC are not controlled substances
Regulatory Action	• CBD currently listed in National Poisons Standard as Schedule 4 – Prescription Only Medicine • May 2020 publication of "Safety Review on the Safety of Low Dose Cannabidiol" • Proposal to shift CBD to Schedule 3 - Pharmacist Only Medicine - but subject to safety, quality and efficacy assessment and regulator approval. • Pharmacist consultation required, with Product Information supplied, before allowing purchase.	• Food Standards Agency (FSA) published consumer guidance and risk assessment for cannabidiol in February 2020 • No new products allowed on the market • FSA issued a March 2021 deadline for companies to submit and have validated a European Union novel food application; post deadline, unauthorized products removed from shelves • Medium-term – only authorized novel foods to be sold with requisite safety and quality data	The Swedish Medical Products Agency (MPA) position is that all CBD oils for oral consumption are medical products and therefore require approval from the MPA before being allowed to be sold.	FDA announces: • CBD cannot lawfully be added to foods and dietary supplements • CBD is not currently Generally Recognized as Safe • to reopen /"extend indefinitely" comment period given persistent dearth of existing scientific data and information on cannabis or cannabis-derived compounds If FDA eventually permits, CBD wouldbe a New Dietary Ingredient subject to pre-market notification of a reasonable expectation of safety
Dosing	• Proposed maximum < 60mg/ for adults aged 18 and over. • Pharmacist consultation would be required, with Product Information supplied, before allowing purchase.	Proposed maximum < 70 mg/day for healthy adults and advice to consult doctor before using CBD products		

[i] https://www.fda.gov/news-events/public-health-focus/information-cbd-data-collection-and-submission
[ii] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters
[iii] https://www.ftc.gov/system/files/documents/foia_requests/foia-2019-01289_warning_letters_sent_to_cbd_companies_9-30-19.pdf
[iv] https://report.nih.gov/categorical_spending.aspx
[v] https://www.ftc.gov/news-events/press-releases/2020/04/thrive-supplement-marketer-agrees-preliminary-order-barring-him?utm_source=slider
[vi] https://www.flsenate.gov/Committees/billsummaries/2019/html/2027
[vii] http://webserver1.lsb.state.ok.us/cf_pdf/2019-20%20ENR/SB/SB238%20ENR.PDF
[viii] https://www.usnews.com/news/best-states/virginia/articles/2020-04-16/northam-signs-bill-to-regulate-cbd-products-as-food
[ix] https://oag.dc.gov/release/ag-racine-leads-37-attorneys-general-urging-fda
[x] https://ag.ny.gov/sites/default/files/letter_from_ny_attorney_general_to_finest_herbalist.pdf
[xi] https://www.doj.state.or.us/media-home/news-media-releases/oregon-department-of-justice-warns-against-making-coronavirus-cure-claims/