

Cannabidiol (CBD): Implicit, Unsubstantiated Therapeutic Claims through Academic Joint Ventures in an Unregulated Marketplace Could Risk Public Health

Executive Summary

Cannabidiol (CBD) use has increased recently, owing in part to the declassification of hemp from the Controlled Substances Act (CSA) in 2018. Despite a Food and Drug Administration (FDA)-approved CBD prescription drug product for the treatment of some epileptic seizures, a direct-to-consumer market has also emerged, which lacks sufficient regulatory oversight. The National Consumers League (NCL) studied the CBD direct-to-consumer market landscape, including the “research as marketing” phenomenon, and compiled its findings into this white paper. With the FDA taking enforcement action against companies making explicit health treatment claims, other entities are turning to partnerships with academia to further investigate CBD’s therapeutic potential. Some companies appear to be leveraging these partnerships as “research as marketing,”¹ which could potentially mislead the consumer and risk public health.

Introduction

In recent years, there has been a surge in cannabidiol (CBD) use and sales in the United States. Subsequent to the passage of the Farm Bill in 2018, sales of CBD jumped from \$512 million in 2018 to \$813 million in 2019,² and a poll from July 2019 showed 14% of adults use CBD products.³ According to the Food and Drug Administration (FDA), “in many cases, product developers make unproven claims to treat serious or life-threatening diseases, and patients may be misled to forgo otherwise effective, available therapy and opt instead for a product that has no proven value or may cause them serious harm.”⁴

FDA has stated very clearly that:

Congress explicitly preserved the agency's current authority to regulate products containing cannabis or cannabis-derived compounds under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and section 351 of the Public Health Service Act (PHS Act). In doing so, Congress recognized the agency's important public health role with respect to all the products it regulates. This allows the FDA to continue enforcing the law to protect patients and the public while also providing potential regulatory pathways for products containing cannabis and cannabis-derived compounds.⁵

Despite this pronouncement, businesses are selling unregulated products containing CBD to the public. The FDA has been active in exercising its regulatory authority over entities making overt and explicit – but unsubstantiated – health claims. But there is much left for the FDA to do: some companies strategically sponsor and publicize the results of less-robust studies, in lieu of undertaking the necessary and expensive, large-scale clinical trials required for FDA approval of drug treatments.⁶ Furthermore, some companies are providing their products to academic institutions, with the intention that the studies will be funded by NIH or published in peer-reviewed journals.⁷ Those companies then use the limited data from such studies – or even the simple announcement of such studies – to promote their products for medical uses to patients, health care professionals, policymakers, and other stakeholders.

Such tactics could mislead consumers into conflating, for example, the value of evidence from a series of highly rigorous randomized controlled trials – two of which are generally necessary for meeting the “substantial evidence” standard⁸ required by law for FDA approval of prescription drugs – with evidence from a correlational study or, indeed, the mere announcement of such a study. Consequently, consumers may forego necessary and proven medical treatments. CBD, while proven safe and effective for treatment of some illnesses as an FDA-approved and regulated drug, is nevertheless being sold directly to consumers. As long as some companies continue to drive unsubstantiated claims, CBD may suffer a “chilling” effect, where consumers do not distinguish its legitimate use from unsubstantiated therapies. This presents a clear and present public health issue.

NCL assessed the research into CBD in the United States, as related to companies' promotion of their products through making health claims based on this mixed research to drive sales, despite a potential risk to the consumers. In its new campaign, “Consumers for Safe CBD,” NCL is calling for all CBD products that claim specific “drug-like” benefits to demonstrate substantial evidence of safety and effectiveness, as required under current law for all drugs and as implemented by FDA, to protect consumers. While CBD clearly has the potential to provide therapeutic benefits, the fact that the market is exploding with unregulated and untested products, puts consumers at risk.

Cannabis and Hemp in the 2018 Farm Bill

CBD is derived from marijuana (also known as cannabis, *Cannabis sativa L.*), which has been used for centuries in industrial products, food, and recreation.⁹ CBD is one of more than 100 cannabinoids found in cannabis.¹⁰ Tetrahydrocannabinol (THC), probably the most well-known cannabinoid, causes the “high” when people consume cannabis. CBD, however, does not produce the “high” of THC, and has been shown to have therapeutic use as well as being used in direct-to-consumer products, some of which are advertised to consumers to provide health and wellness benefits.¹¹

At the federal level, most cannabis and cannabis derivatives are classified as “marihuana [sic]” under the Controlled Substances Act (CSA)¹² and are deemed as Schedule I substances.¹³ It remains a federal offense to distribute, purchase, possess or use these substances. Schedule I status means a substance is considered to have no currently accepted medical use, has a high potential for abuse, and lacks accepted safety for use even under medical supervision.¹⁴

However, the 2018 Farm Bill changed how cannabis is treated under the CSA, removing “hemp” from the CSA’s schedule of controlled substances.¹⁵ Hemp is a variant of the cannabis plant that has lower concentrations of THC.¹⁶ As important, the Farm Bill also preserved the authority of the FDA to regulate products containing cannabis or cannabis derivatives, regardless of whether they are classified as “marihuana” or “hemp.” This is important because it is unlawful under the Federal Food, Drug & Cosmetic Act, enforced by the FDA, to include either THC or CBD in any food or dietary supplement.

Importance of FDA Regulatory Approval and Oversight

The FDA is “responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation’s food supply.”¹⁷ Drugs are defined as “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease,” where such articles are ingested, used topically, or injected into the body.¹⁸ The key to the definition of a drug is the *intended use* and the associated claims: a drug is approved based on its benefits outweighing its risks for a specific use (also called the indication). The approval process is a careful, often lengthy, series of steps performed by a sponsor – usually the manufacturer who makes the drug – which is ultimately reviewed and approved by FDA.

Once approved, a drug is regarded as safe and effective for the indication(s) that the FDA has evaluated and approved it for. Absent this approval, it is illegal to sell a product with a therapeutic or medicinal claim in the US.

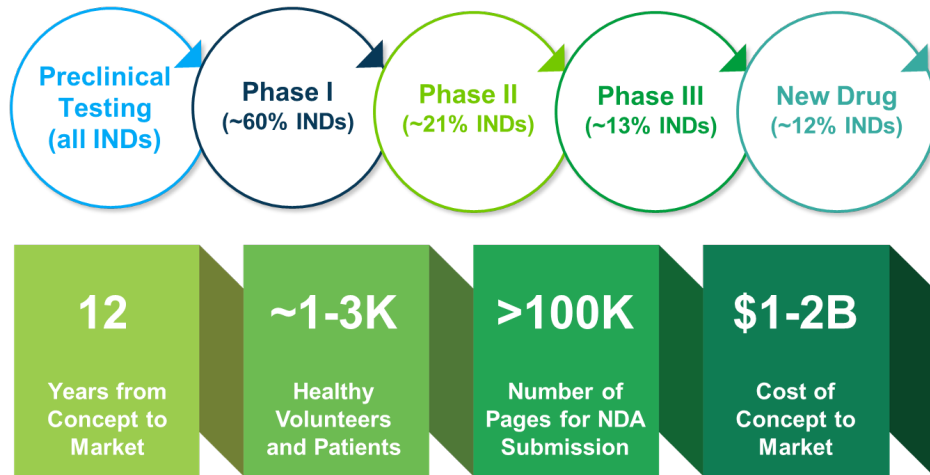
Obtaining FDA approval for a drug is a significant financial undertaking. Sponsors submit documentary evidence to FDA for review, along with a user fee of about \$3 million to pay for that review which will take almost 1 year to complete.¹⁹ These documents include scientific data supporting the safety and efficacy (effectiveness within a specific population) of the drug. In total, it takes over a decade and as much as \$2.3 - \$2.8 billion to research and develop a new medicine.²⁰ This is because the sponsor must conduct successful preclinical studies in cell culture and animal models before undertaking any first-in-human studies as an investigational new drug (IND), as well as a series of subsequent clinical trials. Phase I trials are typically performed in healthy human volunteers to demonstrate preliminary safety of the product, while Phase II trials are used to assess dose and efficacy in addition to safety in patients, before pivotal Phase III trials affirming safety and efficacy in large patient cohorts are conducted. The investment for bringing a new drug to market is estimated and summarized in **Figure 1**. Even after FDA approval, the sponsor continues submitting documents establishing the safety of the product in use in the general population as part of required post-market monitoring.

FDA oversight for drug safety addresses two major areas of interest for public health: inherent adverse effects of a molecule that result in negative side effects and knowing what is (or is not) in the drug product. FDA uses a risk-benefit analysis to determine safety of a product *for a specific indication*. Once approved, FDA also requires that the active ingredient is present in the correct concentration, does not contain contaminants, and that the supply of the product, including manufacturing and distribution, ensures that patients are getting in the bottle what is on the label. FDA can withdraw an approval at any time if a product does not live up to what was expected during its development. The Agency also monitors sponsors for what they say about their products and limits them to what the FDA has approved on the label. Not a word can change on that label without further approval.

FDA and CBD: “Collect Better Data”²¹

Unfortunately, over 90 percent of American consumers incorrectly assume or have no idea if CBD is federally regulated, according to a recent survey.²² FDA has recently expressed a growing concern that:

Figure 1. Estimated costs of investigational new drug (IND) development, representing what it takes to demonstrate to FDA of a drug’s safety and efficacy for a given indication. Top: required trials and approval as a new drug (and estimated success rates). Bottom: estimated costs for drug development. NDA: New Drug Application



Adapted from Van Norman GA, “Drugs, Devices, and the FDA: Part 1, An Overview of Approval Process for Drugs.” 1 J. Am. Coll. Cardiology, 170-79 (2016).

[S]ome people wrongly think that the myriad of CBD products on the market, many of which are illegal, have been evaluated by the FDA and determined to be safe, or that trying CBD ‘can’t hurt.’ We want to be clear that a number of questions remain regarding CBD’s safety – including reports of products containing contaminants, such as pesticides and heavy metals – and there are real risks that need to be considered.²³

That is not to say that FDA is antagonistic to CBD; indeed, the FDA has approved several pharmaceutical cannabinoid medicines for the treatment of specific medical indications. Three are synthetic THC products, and one is a highly purified CBD. The latter is plant-derived and approved for use in treatment of two rare and severe forms of childhood-onset epilepsy: Dravet Syndrome and Lennox-Gastaut Syndrome.²⁴

The Agency has continued to reinforce its position through testimony, enforcement actions against companies in violation of the FD&C Act, and consumer statements. On November 25, 2019, the FDA issued such a statement on its website after warning 15 companies of illegally marketing CBD products.²⁵ The statement reminded consumers that the Agency has seen only limited data about CBD safety and these data point to real risks which need to

be considered before taking CBD for any reason. While FDA agrees that there are legitimate therapeutic and medicinal uses for CBD as drugs, there is no “basis to conclude that CBD is GRAS [Generally Recognized as Safe],”²⁶ and further stated that “CBD was not an ingredient considered under the OTC [Over-The-Counter] review.”²⁷ Furthermore, the Agency has said:

*We don't approach CBD or other cannabis-derived substances with any sort of animus or impose unique burdens. At the same time, we don't absolve them of having to meet the relevant safety standards and other requirements for whatever type of FDA-regulated product they're found in. Consumers have a right to expect as much.*²⁸

Finally, the Agency cautions that “unsubstantiated therapeutic claims — such as claims that CBD products can treat serious diseases — can lead consumers to put off getting important medical care.”²⁹ And while there are studies that support CBD’s efficacy as a medicine, to date most of those studies are preclinical or observational. FDA requires that sponsors demonstrate “substantial evidence”³⁰ of their drug’s safety and efficacy, which means:

*[E]vidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.*³¹

This is a high bar to meet, but it is reasonable considering that patients are relying on their drugs to be safe and effective. Some companies selling direct-to-consumer products containing CBD circumvent these processes, however. FDA has again raised concern about this, noting that “If the widespread availability of consumer CBD products were to significantly discourage clinical research, our knowledge of CBD’s potential medical uses could be stunted.”³² The risk is that the consumer may be misled by a perception created that because CBD is contained in an FDA-approved product, CBD writ large must also be safe, regardless of the source. And the consumer may further be misled by a company selling CBD announcing research initiatives into disease states with universities and research institutions, *necessarily* means that CBD is effective for that condition, regardless of the data (or lack thereof) generated by such a study. It is ultimately a false perception.

Snapshot of the Market: Research Approaches Employed by Some CBD Companies Could Mislead the Public

A comprehensive analysis of ClinicalTrials.gov yielded almost 500 clinical trials studying CBD as of December 5, 2019. Of those, 200 are currently active and 22 are Phase III clinical trials. While Phase III clinical trials are required for an FDA approval, without FDA review the results should not be interpreted to mean CBD is safe or effective for the trial indication. A summary of findings is in **Figure 2**.

A PubMed search for peer reviewed literature revealed numerous studies centered on pain, neurologic function, and epilepsy. Again, without FDA approval, these studies are simply describing potential benefits of CBD, and are not fully vetted for safety and efficacy for the population writ large.

A research-intensive Google search for “CBD Benefits” or “CBD Effects” returned websites claiming CBD treats over 30 diseases including cancer, Alzheimer’s, and diabetes, as well as aiding in weight loss and reducing insomnia. These claims are largely found on blog postings or in news articles where there is little or no accountability. Websites of companies that sell CBD are often more restrained, suggesting these companies may be attempting to comply with FDA or are aware it has significant oversight authority. Furthermore, FDA has taken enforcement action against companies making dubious claims of their CBD products in the last 5 years, issuing 41 separate companies Warning Letters since 2015 as of December 15, 2019. ³³

Despite FDA Warning Letters, misleading information about CBD and its value continue to proliferate. More ingenious entities cite research articles from peer-reviewed literature (the gold standard in scientific research, but not for FDA approval) as if to imply that it is sufficient for their claims to be true.³⁴ **It is not.** Furthermore, in doing so, such companies might give consumers a false impression that just because a company is citing to a study, that CBD is effective for that condition or function as a general matter, and that the company’s CBD product is effective specifically. This is arguably both misleading and irresponsible. Often the studies were completed using cell culture models, in animals such as mice or rats, or in small studies of humans, all of which are insufficient for demonstrating safety and efficacy in the population at-large. This may be a proof-of-concept, at best. It is only by conducting the complete set of studies shown in **Figure 1**, and by assembling compelling results, that a manufacturer obtains FDA approval. They must also provide all the relevant manufacturing quality assurances and pass facility inspections that ensure that the drug made is safe and effective for sale to US consumers.

Figure 2. Summary results of a December 5, 2019 search of the National Institutes of Health (NIH) Clinical Trials database. While 493 clinical trials focusing on CBD have been initiated, only 1 product is FDA-approved.



US National Library of Medicine, NIH, available at www.clinicaltrials.gov (relevant search terms included “cannabis” and “CBD”); last accessed December 5, 2019.

FDA, Warning Letters, available at www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters; last accessed December 5, 2019; see also, e.g., FDA Drug Approval Package: Epidiolex® (Cannabidiol), available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210365Orig1s000TOC.cfm.

In several instances, companies point to clinical trials on CBD to demonstrate that their CBD products may be effective for a specific disease.³⁵ These companies engage in and promote collaborative ventures with prestigious academic institutes as an apparent demonstration of legitimacy. Some companies are forming partnerships with prestigious US institutions, and others feature testimonials on their website to further press their claims to good medical outcomes without explicitly saying it themselves.

More ingenious entities cite research articles from peer-reviewed literature as if to imply that it is sufficient for their claims to be true. **It is not.** Furthermore, in doing so, such companies might give consumers a false impression that just because a company is citing to a study, that CBD is effective for that condition or function as a general matter, and that the company’s CBD product is effective specifically. This is arguably both misleading and irresponsible.

Companies announce the studies and may even publish the results in peer reviewed publications, but still this is insufficient to meet the stringent FDA approval requirements to market a product as treating whatever condition a company may, in fact, have legitimate (but limited) data for. Then the reasonable consumer, possibly searching for hope in dealing with some condition - and having heard about the wonders of CBD - stumbles across a research study for their indication conducted at a university they have heard of, and sponsored or supported by a company selling the very thing which they have heard about. It presents a very real risk to the consumer that they may be - even unintentionally - misled into thinking that because there are such studies going on, that CBD is necessarily the cure they have been looking for. This is the quintessence of “putting the cart before the horse.” Companies are leaning on the - often widely recognized - names of their academic and scientific partners to market products and attempt to substantiate their claims. However, the claims are not being made by the researchers or those institutions themselves, and most significantly, the claims fail to meet the burden of proof required by law and by FDA. Therein lies the danger for patients.

Discussion and Stakeholder Perspectives

This paper does not claim that the research being done is, in and of itself, illegitimate. Indeed, preclinical and clinical trials are necessary for responsible - and legal - drug development. But a single clinical study - even in partnership with a prominent academic research institution - is not sufficient to claim, implicitly or explicitly, that a product is effective to treat certain disorders or diseases. Research is important, and it is entirely fair and reasonable to be optimistic about the potential of CBD. However, it is arguably unethical and misleading for commercial entities to use the legitimacy of early scientific clinical research - and the announcement of such endeavors - as a marketing tool. It is tantamount to making, or at minimum implying, a claim without substantial evidence: **simply put, that is not how it should be done.**

Until FDA, through a careful and unbiased evaluation of the data, determines that CBD is safe and effective for a specific indication in a specific population at a specific dose, let the buyer beware. Some academics have proposed that FDA directly regulate marketing in this space,³⁶ calling out these tactics by name as “research as marketing.”³⁷ While it would be within FDA’s authority to do so, the explosion in companies interested in manufacturing and selling CBD make it very difficult for the Agency to keep up with all the CBD products

flooding the US market. For now, consumers must take it upon themselves to be more aware of the risks in the choices that they are making.

A recent poll found that 83 percent of voters support the need for FDA to evaluate and regulate CBD products, and that evaluating the safety and effectiveness of CBD is even greater among those who have used CBD products or describe themselves as very familiar with them.³⁸ Moreover, a growing number of stakeholders in the scientific, medical, and agricultural communities are calling for additional regulatory oversight and standards in the CBD space.

In a January 2017 Report, the National Academies of Sciences, Engineering, and Medicine, while optimistic about cannabinoids' utility as a potential medicine, nevertheless cited “[a] lack of definitive evidence,” and “a significant public health concern for vulnerable populations such as adolescents, pregnant women, and others.”³⁹

In a September 2019 letter to Senators urging against CBD legalization in dietary supplements or food products, the Center for Science in the Public Interest (CSPI) and the Consumer Federation of America (CFA) underscored some of the remaining unknowns about CBD, including “risks and safety[,]” “potency[,]” contaminants including psychoactive THC, and “[m]islabeling and adulteration[,]” among others, urging increased FDA oversight.⁴⁰

In May 2019, FDA convened a Public Hearing, “Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds,”⁴¹ where numerous stakeholders offered differing perspectives on CBD and other issues. One noted: “Nature abhors a vacuum. What’s the relevant messages for the nascent, but swiftly growing CBD industry? First, that aggressive and misleading marketing campaigns need to be put on hold now that the FDA has stepped up to the plate[...] the plural of anecdote isn’t data.”⁴² Another said: “there is a need for specific federal oversight to guarantee consumer safety and to make sure that frankly people know what they’re taking.”⁴³ And yet another explained:

*[W]e desperately need to conduct cannabis regulatory science to inform appropriate product standards for the various forms of cannabis that are available today or that might become available tomorrow. Researchers need a streamlined, regulatory pathway that can facilitate research on the spectrum of commercially available products. Clinical research studies have barely scratched the surface when considering the vast array of cannabis products available to consumers. The risk of retail cannabis products harming public health must be mitigated by swift and evidence-based regulatory action.*⁴⁴

State officials are weighing in, too. In 2019, 37 state Attorneys General cosigned a letter to FDA Acting Commissioner Ned Sharpless, stressing the need for FDA “to explore manufacturing, testing, and marketing best practices so that consumers are not at risk of misleading advertising or harm to their health” and that “[CBD] products should be subject to testing and manufacturing guidelines in order to keep consumers appropriately informed and safe.”⁴⁵ The key takeaway from these comments is that there is a growing concern that, in the absence of clear and enforced regulation, a risk to consumers exists and will persist.⁴⁶

For its part, the National Consumers League has teamed with the CFA and the Community Anti-Drug Coalitions of America to form the initiative, Consumers for Safe CBD, and continues to advocate for responsible change in this as yet inappropriately regulated space.⁴⁷

Conclusion

For now, the CBD market remains largely unregulated. FDA has begun to more actively enforce its authority in this space by issuing Warning Letters to companies making unsubstantiated claims. But companies continue to market their products by promoting research collaborations with academic research institutions. Data and science are good, and sufficient quantities of both can lead to FDA approval that a substance is safe and effective for an indicated use. But a study – much less the announcement of one – cannot be an end unto itself. Such practices risk consumers choosing unproven products while forgoing legitimate medical treatments. More generally, consumers risk consuming products which have not proven to be safe as a matter of medical fact, nor as a matter of quality control and manufacturing. And efficacy remains even more questionable. CBD is a drug – as both a regulatory and scientific matter - and should be treated as such.

FDA is focusing its efforts on the most open and notorious entities which make the most explicit and inappropriate claims unsupported by substantial evidence. FDA should also look at those companies which are promoting joint research endeavors with academia, and what they are doing promotionally with those endeavors, to ensure that those companies are not misleading consumers. Simultaneously, FDA should vigorously develop guidance and conduct notice-and-comment rulemaking to better advise and regulate an industry which has been growing exponentially and will continue to grow in the coming years. Where possible, the Federal Trade Commission (FTC) could exercise

its authority under Section 6 of the FTC Act,⁴⁸ to either investigate companies or to require them to answer questions on what they are making and how they are promoting them to the public – particularly with respect to what evidence they are relying on. That said, Congress has the option to consider legislation, potentially to rethink what false advertising is. Meanwhile, the public must have access to more information and education and understand that FDA approval is the only legitimate guarantee of a drug’s safety and efficacy, and that anything else is insufficient. It is up to the FDA to regulate, and Congress to legislate, to safeguard consumers against as yet unknown and potentially dangerous risks to public health. Meanwhile, consumers need to proceed with caution about CBD products that have not been approved by the FDA.

Appendix - Methodology

Avalere Health provided the supporting research referenced in this publication, however, the opinions expressed herein do not expressly or implicitly endorse NCL’s product. The research referenced herein was factually based, neutral in nature, and such citations are referenced below. A survey was conducted of the US National Library of Medicine’s Clinical Trials database⁴⁹ within the last 5 years (through December 5, 2019) to develop an in-depth understanding of clinical trials which included Cannabis or CBD. Next, a search of the US National Library of Medicine’ scientific literature database, PubMed,⁵⁰ was completed and a list of articles compiled from a search of (“Cannabis”) and (“Cannabidiol” or “CBD”), with a specific focus on treatment or for a specific medical indication. Then a Google search using search terms (“CBD Benefits” or “Cannabis Benefits”), (“CBD Effects” or “Cannabis Effects”), (“CBD Health” or “Cannabis Health”), and (“CBD Claims” or “Cannabis Claims”), completed and the findings compiled from the first 2 pages of results from each search string, specifically with regards to health claims made. Finally, FDA publications were examined to elucidate Agency policy on CBD, with a focus on Warning Letters issued to companies in the business of selling CBD. NCL included a more thorough investigation of several players operating large cannabis businesses both within and ex-US, especially those making treatment claims or otherwise engaging in research joint ventures with academia. Websites and promotional materials made by said entities were examined and note made of FDA action taken against them, if any.

Endnotes

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- 39** E.g., National Academies of Sciences, Engineering, and Medicine, Report Highlights, The Health Effects of Cannabis and Cannabinoids (January 2017); available at <http://nationalacademies.org/hmd/~media/Files/Report%20Files/2017/Cannabis-Health-Effects/Cannabis-report-highlights.pdf>.
- 40** CSPI & CFA, Letter to US Senators (September 19, 2019); available at https://cspinet.org/sites/default/files/attachment/CBD_Letter_to_Hill_final.pdf
- 41** FDA, Center for Food Safety and Applied Nutrition, Part 15 Public Hearing, Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds (May 31, 2019); available at <https://www.fda.gov/media/128593/download>.
- 42** FDA, Center for Food Safety and Applied Nutrition, Part 15 Public Hearing, Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds (May 31, 2019), at 37-39; available at <https://www.fda.gov/media/128593/download>.
- 43** *Ibid.*, at 312.
- 44** *Ibid.*, at 41-42.
- 45** National Association of Attorneys General, Letter to Norman E. Sharpless, M.D., Commissioner, FDA in re: Docket No. FDA-2019-N-1482, Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds, at 1-2.
- 46** The United States Pharmacopeia (USP) should vigorously pursue monographing to set the standard of identity for CBD. USP is a nonprofit organization that, in cooperation with drug manufacturers, sets standards of identity, strength, quality, and purity for medicines. Were USP to establish a standard, the direct-to-consumer industry would not be able to claim their product was CBD without meeting that standard – a palpable and easily attainable win for quality. USP, Recognition of USP Compounding Standards; available at <https://www.usp.org/compounding/legal-considerations> (last accessed March 4, 2020).
- 47** NCL, Press Releases, “Consumer groups call for FDA oversight of rapidly growing CBD market,” (November 19, 2019); available at https://www.nclnet.org/safe_cbd.
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- 49** NIH, U.S. National Library of Medicine, ClinicalTrials.gov (last accessed March 4, 2020); available at <https://clinicaltrials.gov/>.
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