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GOING HEMP WILD: UNDERSTANDING THE
CHALLENGES AND OPPORTUNITIES FOR FDA
REGULATION OF CBD IN FOOD PRODUCTS

Hannah Catt

Going Hemp Wild: Understanding the Challenges and Opportunities for FDA Regulation of CBD in Food Products¹

Hannah Catt*

Abstract

After the passage of the 2018 Farm Bill, champions of hemp began to tout opportunities for farmers and businesses involved with the crop. The industry has rallied around one of hemp's major byproducts, cannabidiol, or CBD. However, the demand for CBD has left the Food and Drug Administration ("FDA") playing catch-up. This article explains what CBD is, how it is derived, current FDA-approved uses, and a current path forward for the FDA in creating guidance for industry and consumers.

I. Introduction

It is difficult today to read the news, browse social media, or even shop in some stores without encountering people extolling the virtues of cannabidiol ("CBD") or questioning its therapeutic value.² The Food and Drug Administration has been challenged by the proliferation of CBD in many markets. The hype has not escaped the FDA's notice, but a federal agency is not poised to quickly respond to trends like these, therefore, the agency has yet to promulgate a full set of regulations.

The production and use of CBD involve competing interests, from the pharmaceutical sector, food producers, farmers, and consumers. Each of these parties has an interest in regulations being developed sooner rather than later, in part because there is currently significant market opportunity for CBD products. This article explores the following issues relating to CBD: what CBD is; how it is different from other cannabis products; what CBD is being used for; and how the federal government can appropriately regulate the production and use of the product. Due to the limited existing research on the effects of CBD, the best option may be for the FDA

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¹ Some companies that market CBD products are mentioned by name in this article. No mention of a specific company serves as an endorsement; it is purely for illustrative purposes.

² See, e.g., Alex Williams, *Why is CBD Everywhere?*, N.Y. TIMES (Oct. 7, 2018), <https://www.nytimes.com/2018/10/27/style/cbd-benefits.html>.

to allow CBD to be sold as a supplement in limited concentrations while also working towards new drug approvals.

II. Hemp and Cannabinoids

In recent years, many states have legalized medicinal and/or recreational marijuana use.³ Recent legislation expanding programs for legal hemp production has increased interest in by-products of the plant beyond traditional, industrial uses.⁴ Despite the differences in the use and availability of marijuana and hemp, the two are inextricably linked, usually under the banner of “cannabis.” While confusing, this is not a mistake. Marijuana and hemp are both products of *Cannabis sativa*, however, they are distinguishable based on their relative concentration of tetrahydrocannabinol (“THC”).⁵ The plants can also be distinguished by their physical features when growing, as explained in Section II.

Marijuana is often consumed for the psychoactive effects of THC, which is present in varying amounts based on the plant variety or cultivar.⁶ CBD is commonly considered non-psychoactive because it does not produce the “high” associated with consuming marijuana.⁷ In his work, prominent cannabis researcher Dr. Ernest Small has clarified that this common usage of the term non-psychoactive for describing CBD is not proper because any significant change in mental state, including anxiety changes, should be considered a psychoactive effect.⁸

CBD and THC are also both cannabinoids, a chemical component of the cannabis sativa plant.⁹ While cannabinoids have been found in other plants, CBD is noted as the “principal cannabinoid of hemp.”¹⁰ There have been over 100 cannabinoids identified in cannabis.¹¹ The cannabinoids act by binding to

³ NAT’L CONF. OF STATE LEGISLATURES, MARIJUANA OVERVIEW (2019), <http://www.ncsl.org/research/civil-and-criminal-justice/marijuana-overview.aspx>.

⁴ 7 U.S.C. § 5940 (2018).

⁵ CONG. RES. SERV., *Defining Hemp: A Fact Sheet 1* (March 22, 2019), <https://fas.org/sgp/crs/misc/R44742.pdf>.

⁶ Variety is technically used to note the plant types that are found in nature, while cultivars are bred for specific characteristics. *Id.* (citing Cindy Haynes, *Cultivar Versus Variety*, IOWA ST. UNIV. HORTICULTURE & HOME PEST NEWS (Feb. 6, 2008), <https://hortnews.extension.iastate.edu/2008/2-6/CultivarOrVariety.html>).

⁷ ERNEST SMALL, CANNABIS: A COMPLETE GUIDE 204 (2016).

⁸ *Id.*

⁹ *Id.* at 205.

¹⁰ *Id.*

¹¹ Genevieve Lafaye, et al., *Cannabis, Cannabinoids, and Health*, 19 DIALOGUES IN CLINICAL NEUROSCIENCE 3, 309 (2017).

receptors in the body's endocannabinoid system.¹² This system and the resulting effects of cannabinoids in the body were not discovered until the late twentieth century.¹³

CB₁ and CB₂ are both found in the central nervous system and various organs throughout the body.¹⁴ Because of the relatively recent discovery of the endocannabinoid system and the many restrictions around research related to cannabis, a full understanding of the effects of cannabinoids is still developing. The different receptor locations where the binding takes place can impact the ultimate effects of cannabis consumption, the potency of the product, and how CBD and THC will impact the body.¹⁵

An additional area of study is how different cannabinoids work together. Those involved in the illicit trade or consumption of marijuana are seeking out a higher THC content, which will increase the psychoactive effects. New strains of cannabis have been bred to have a higher THC content at the expense of the CBD content. In the reverse, cannabis bred for fiber or oilseed has high CBD content and minimal THC.¹⁶ Further, manufacturers of marijuana edibles do not currently have an incentive to add CBD to the final product.¹⁷ This may change as more is discovered about the combined effects of THC and CBD, referred to as “entourage” or “ensemble” effects.¹⁸ Consumption of THC and CBD has been shown to lessen some of the psychoactive symptoms of THC.¹⁹ The reason for this is not immediately clear, but researchers have noticed this in patients who take approved drugs with THC, such as Marinol, an appetite stimulant primarily prescribed for patients with AIDS.²⁰

CBD is produced through an extraction process which should be highly monitored to ensure there is no THC present. To

¹² Pál Pacher, et al., *The Endocannabinoid System as an Emerging Target of Pharmacotherapy*, 58 PHARMACOL REV. 3, 389 (2006).

¹³ Matt Simon, *THC! CBD! Terpenoids! Cannabis Science is Getting Hairy*, WIRED (Nov. 6, 2018), <https://www.wired.com/story/cannabis-science-entourage-effect/>.

¹⁴ *Id.*

¹⁵ SMALL, *supra* note 7, at 304–06.

¹⁶ *Id.* at 208.

¹⁷ Simon, *supra* note 13.

¹⁸ Some researchers prefer the term “ensemble effect” because it does not suggest that THC is the most important cannabinoid for the endocannabinoid system response. Simon, *supra* note 13.

¹⁹ Ethan B. Russo, *Taming THC: Potential Cannabis Synergy and Phytocannabinoid Terpenoid Entourage Effects*, 163 BRIT. J. PHARMACOLOGY 1344, 1354 (2011).

²⁰ Simon, *supra* note 13; Pácher, et al., *supra* note 12, at Table 1 (reporting that patients taking Marinol experienced improvement in the areas of “spasticity, pain, and sleep quality” and “was found to suppress otherwise intractable cholestatic pruritus in a case report”).

extract the CBD, hemp plants are harvested and then left to cure for a few weeks.²¹ The flower of the plant is then removed and sent to a processor.²² The processor grinds the flowers, then steeps them to remove some terpenoids.²³ After a cold treatment, it is distilled, sometimes twice, to achieve the right color and purity.²⁴ Many brands have their products tested to guarantee purity and low or no THC content.²⁵

III. Examining Hemp Production

The revenue that states and businesses have generated from selling recreational marijuana is frequently labeled as a “Green Rush.”²⁶ The value of the CBD market could be a second wave in this rush because it is worth around half a billion dollars today and has the potential to reach twenty billion dollars by 2020.²⁷ However, hemp has a long history of use for other industrial purposes and has proven to be a versatile crop.²⁸ Hemp uses less inputs than a more traditional crop like corn.²⁹ Once out of the initial development time, producers use less water, pesticides, and fertilizers.³⁰ The terpenoids

²¹ Eric Hurlock, *Harvesting, Drying, Trimming, & Curing Industrial Hemp Flower*, LANCASTER FARMING (Sep. 3, 2019), <https://www.lancasterfarming.com> (search article name) (discussing measures a farm takes to monitor CBD and THC levels in hemp flowers prior to harvest); Rajul Punjabi, *There’s CBD in Everything so We Found Out How It’s Made*, VICE (Oct. 23, 2018), http://www.vice.com/en_us/article/wj9knb/i-visited-a-cannabis-farm-to-find-out-how-cbd-oil-is-made.

²² Punjabi, *supra* note 21.

²³ *Id.*

²⁴ *Id.*

²⁵ Medterra is an example of this. This company sources all of its hemp from products grown as a part of the Kentucky Department of Agriculture Pilot Program. *Frequently Asked Questions*, MEDTERRA, <https://medterracbd.com/faq> (last visited Nov. 9, 2019) (linking interested consumers to the third-party lab test results of the company’s CBD products).

²⁶ See, e.g., Nick Kovacevich, *Green Rush: How Legal Hemp Opens the Door for Cannabis Investment*, FORBES (Aug. 8, 2019), <https://www.forbes.com> (search article title).

²⁷ Brian Barth, *The Rise and Rise of the Artisanal Hemp Farm. From Seed-to-CBD, Our Writer Doses Up Then Files This Report*, MODERN FARMER (Feb. 25, 2019), <https://modernfarmer.com/2019/02/the-rise-and-rise-of-the-artisanal-hemp-farm-fr-om-seed-to-cbd-our-writer-doses-up-then-files-this-report/>.

²⁸ Ernest Small & David Marcus, *Hemp: A New Crop with New Uses for North America*, in TRENDS IN NEW CROPS AND NEW USES 284-326 (J. Janick & A. Whipkey eds., 2002), <https://www.hort.purdue.edu/newcrop/ncnu02/v5-284.html> (describing some of the historical uses of hemp in industry).

²⁹ Logan Yonavjak, *Industrial Hemp: A Win-Win For the Economy and the Environment*, FORBES (May 29, 2013), <https://www.forbes.com/> (search “Industrial Hemp Win Win” and select the first result); Brian Barth, *So, You Want to Be a Hemp Farmer?*, MODERN FARMER (July 9, 2018), <https://www.modernfarmer.com/2018/07/so-you-want-to-be-a-hemp-farmer/>.

³⁰ *Id.*

that give cannabis its unique smell have also been found in other plants as a method of insect deterrent.³¹ Hemp plants grow tall, occasionally up to sixteen feet.³² Plant height is one way to easily distinguish hemp from marijuana, with the latter usually being short and stubby.³³

Once harvested, hemp can be made into almost 25,000 different products in categories including: textiles, automotive parts, food and beverages, and personal care products.³⁴ Most of the hemp going into these products had to be imported though, due to restrictions on growing hemp.³⁵ China accounts for the largest share of production, growing roughly one-fifth of the world supply and importing the most to the United States (“U.S.”).³⁶ Hemp fiber and seeds can have returns of up to \$700 per acre or \$1,200 per acre, respectively.³⁷ The total market value is approaching one billion dollars.³⁸ The opportunity to grow hemp for use in American industry and processing is an attractive one, and it presents a valuable market opportunity for potential hemp farmers.³⁹ The history of hemp production shows that there are many uses for the crop beyond focusing exclusively on CBD. The CBD market could collapse at any time or be severely restricted if the FDA takes a more aggressive stance on non-prescribed uses of the compound.

China has historically produced large volumes of hemp, and evidence suggests that they have been growing it for anywhere from six to ten thousand years.⁴⁰ Hemp was spread from China to Western Asia and Egypt, and then to Europe.⁴¹ The crop did not arrive in North America until the seventeenth century.⁴² From approximately that time until the nineteenth century, hemp was at its peak, being used for textiles, paper, and even sails for ships.⁴³ Many reasons are suggested for its decline in popularity, including the labor involved

³¹ Russo, *supra* note 19, at 349.

³² Cheryl Thayer et al., *Industrial Hemp: From Seed to Market*, HARVEST N.Y., (2017), <http://putknowledgetowork.org/resources/industrial-hemp-from-seed-to-market>.

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

³⁷ CONG. RES. SERV., *supra* note 5, at 8.

³⁸ *The U.S. Hemp Industry Grows to \$820mm in Sales in 2017*, HEMP BUS. J., (2017), hempbizjournal.com/size-of-us-hemp-industry-2017/.

³⁹ Comparing it to grain, Brian Barth asserts that fifty acres should be a minimum for growing hemp to retain profitability. Barth, *supra* note 29.

⁴⁰ SMALL, *supra* note 7, at 91.

⁴¹ *Id.* at 92.

⁴² *Id.*

⁴³ *Id.* at 93–94.

with cultivation, cheaper fibers becoming available during the Industrial Revolution, and the decreased use of sailing ships in favor of fuel-powered ships.⁴⁴

Until the 2014 Farm Bill hemp provisions, hemp was regulated along with marijuana.⁴⁵ Hemp was listed as a Schedule I substance under the Controlled Substances Act (“CSA”), and the Drug Enforcement Administration (“DEA”) provided oversight.⁴⁶ This classification required anyone who wanted to grow hemp to get approval from the DEA, but applications were usually not approved.⁴⁷ One early university research plot was approved in North Dakota, but it involved significant costs.⁴⁸ Similar to states choosing to allow recreational marijuana consumption while it is restricted federally, states could create their own policies to allow hemp cultivation if a DEA license was granted.

Hemp provisions found in the 2014 Farm Bill created an agricultural pilot program “to study the growth, cultivation, or marketing of industrial hemp.”⁴⁹ While states are allowed to create their own regulations for programs, growing sites have to be registered with and certified by the state’s department of agriculture, and the growing is limited to research purposes of agriculture departments or colleges and universities.⁵⁰ “Industrial hemp” is defined as *cannabis sativa* with less than 0.3% THC on a dry weight basis.⁵¹ This figure is widely used to distinguish hemp from marijuana. The THC amount was proposed by Ernest Small, who indicated that, at 1% THC presence, marijuana begins to have “intoxicating potential.”⁵² In addition to the U.S., Canada and portions of Europe and Australia use the same threshold.⁵³ Small is quick to note this is a low threshold but contends that this makes it

⁴⁴ *Id.* at 94.

⁴⁵ CONG. RES. SERV., *supra* note 5, at 3–4.

⁴⁶ 21 U.S.C. § 812 (b)(1) (2018) (providing that Schedule I substances have “a high potential for abuse,” “no currently accepted medical use in treatment in the United States,” and a “lack of accepted safety for use of the drug or other substance under medical supervision.”)

⁴⁷ Christine A. Kolosov, *Evaluating the Public Interest: Regulation of Industrial Hemp Under the Controlled Substances Act*, 57 UCLA L. REV. 237, 247 (2009) (providing an overview of the legal status of hemp cultivation over time in the U.S. and explaining how state programs to allow cultivation are limited by DEA approval).

⁴⁸ *Id.*

⁴⁹ 7 U.S.C. § 5940.

⁵⁰ *Id.* § 5940(A)–(B).

⁵¹ *Id.*

⁵² SMALL, *supra* note 7, at 208.

⁵³ *Id.*

highly unlikely that hemp would be repurposed for illegal consumption.⁵⁴

The 2018 Farm Bill loosened the restrictions on hemp further, officially removing it from the federal schedule of controlled substances.⁵⁵ Because it was removed from the schedule, the DEA also cannot interfere with the passage of hemp across state lines.⁵⁶ Growers still have to operate under a state pilot program, of which there are currently forty-one.⁵⁷

Kentucky was an early leader in the U.S. hemp market after pilot program rules were released in the 2014 Farm Bill. State law requires producers, handlers, processors, and marketers to obtain a license from the Kentucky Department of Agriculture.⁵⁸ Violation of the licensing requirements is penalized by the same provisions for violations of state rules relating to marijuana.⁵⁹ These penalties are found in state statutes for controlled substances.⁶⁰ The state publishes a list of licensees, which can help facilitate the market for hemp.⁶¹ There are over one hundred processors and handlers licensed, and, in 2018, farmers were paid over \$17 million for hemp, and over \$50 million of gross products were sold.⁶² The acreage in use is also rapidly increasing, approaching 10,000 acres.⁶³ Kentucky Commissioner of Agriculture Ryan Quarles has noted that these

⁵⁴ *Id.*

⁵⁵ KY. DEP'T OF AGRIC., 2018 FARM BILL AND WHAT IT MEANS FOR HEMP IN KENTUCKY (2018), http://www.kyagr.com/marketing/program_id/70/documents/HEMP_OV_2018FarmBillandKentuckyHemp.pdf.

⁵⁶ *Id.*

⁵⁷ INDIGENOUS FOOD & AGRIC. INITIATIVE, THE 2018 FARM BILL AND THE LEGAL LANDSCAPE FOR INDUSTRIAL HEMP PRODUCTION IN INDIAN COUNTRY 3, UNIV. OF ARK. (2019), <https://static1.squarespace.com/static/5aaaa2bd4611a0a9a6f8353d/t/5c996196104c7b647468f5da/1553555912189/Final+IFAI+Hemp+Analysis.pdf> (showing that the nine states that still outlaw hemp are Idaho, Georgia, South Dakota, Texas, Iowa, Louisiana, Mississippi, Ohio, and Connecticut); Fran Howard, *Hemp Producers Stuck Somewhere Between Two Farm Bills*, AGRI PULSE (April 17, 2019), <https://www.agri-pulse.com/articles/12104-regulatory-confusion-leaves-hemp-producers-stuck-somewhere-between-two-farm-bills>.

⁵⁸ INDUSTRIAL HEMP RESEARCH PILOT OVERVIEW, KY. DEP'T OF AGRIC., <https://www.kyagr.com/marketing/hemp-overview.html> (last visited Nov. 27, 2019).

⁵⁹ HEMP AND THE LAW, KY. DEP'T OF AGRIC., <https://www.kyagr.com/marketing/hemp-law.html> (last visited Nov. 27, 2019).

⁶⁰ KY. REV. STAT. ANN. § 218A.140 (West 2011).

⁶¹ 2018 LICENSE HOLDER LIST (2018), KY. DEP'T OF AGRIC., https://www.kyagr.com/marketing/documents/HEMP_OV_License-Holder-List_2018.pdf.

⁶² Bruce Schreiner, *Hemp is Growing Like Crazy in Kentucky. Just Look at Last Year's Sales*, COURIER J. (March 18, 2019), <https://www.courier-journal.com/story/news/2019/03/18/kentucky-hemp-sales-surged-2018-ryan-quarles-says/3201995002/>.

⁶³ *Id.*

figures represent a small portion of the state's total agricultural production, but the program's goal was to ensure that Kentucky could gain a lead on the market when it became legal to start production and interstate transport.⁶⁴

The hemp provisions found in the 2018 Farm Bill have not yet been enacted by the United States Department of Agriculture ("USDA"). Until enacted, the market needs to operate under the rules from the 2014 bill. Growers have major questions about crop insurance, organic certification, interstate transportation, and banking access.⁶⁵ Secretary of Agriculture Sonny Perdue estimated that there will not be rules in time for this season, but they will be ready for 2020 planting.⁶⁶ Growers are also having trouble getting access to seeds to purchase, because they may have to be imported, and growers need to ensure they have varieties with THC levels below the legal threshold.⁶⁷

Due to the natural resilience of hemp, it is well-suited to organic growing methods.⁶⁸ The USDA, which oversees the National Organic Program, has allowed organic certification for hemp, but not marijuana.⁶⁹ Allowing organic certification for hemp byproducts like CBD could be beneficial, particularly if it is being utilized as an ingredient in pharmaceuticals. Organic textiles are also specially marketed, often for clothing.⁷⁰ Kentucky is home to the Kentucky Organic Hemp Cooperative, one of the country's first, which has brought together farmers with smaller-than-usual acreage who want to get market access.⁷¹ Many of these farmers are growing on land that has not recently been used for conventional crops, so they do not have to wait through the three-year transitional period that conventional farms need for organic certification.⁷² Most of

⁶⁴ *Id.*

⁶⁵ Ryan McCrimmon, *Washington Has Work to Do on CBD, Hemp*, POLITICO (Feb. 26, 2019), <https://www.politico.com/newsletters/morning-agriculture/2019/02/27/washington-has-work-to-do-on-cbd-hemp-526036>.

⁶⁶ Ryan McCrimmon, *Perdue, Senate Ag Talk Farm Bill Today*, POLITICO (Feb. 28, 2019), <https://www.politico.com/newsletters/morning-agriculture/2019/02/28/perdue-senate-ag-talk-farm-bill-today-528350>.

⁶⁷ Howard, *supra* note 57.

⁶⁸ Seth Waggener, *Organically Grown Hemp: Why Is It So Important?*, PURE SPECTRUM (Feb. 8, 2018), <https://www.purespectrumcbd.com/organically-grown-hemp-why-is-it-so-important/>.

⁶⁹ Barth, *supra* at note 29.

⁷⁰ *Does Organic Fabric Really Make a Difference?*, HYDE YOGA BLOG (Aug. 1, 2019), <https://yogahyde.com/yoga-wear-organic-vs-non-organic/>.

⁷¹ Austyn Gaffney, *Kentucky Farmers Gamble on the South's First Organic Hemp Cooperative*, SOUTHERLY (Mar. 13, 2019), <https://southerlymag.org/2019/03/13/kentucky-farmers-gamble-on-the-souths-first-organic-hemp-cooperative/>.

⁷² *Id.*

them are also growing hemp that will have CBD extracted because as much as seventy percent of the state's hemp is sold to the CBD market.⁷³

IV. Current FDA Stance

A. Food, Drug, and Cosmetic Act Rules

At its core, the primary concern with the regulation of CBD products is about consumer safety. The FDA does not want the public taking products that have not been tested for purity or because a company has made a wild claim about CBD's ability to cure an ailment.⁷⁴ Concerns about the safety of food and drugs have existed since time immemorial, but the first major U.S. legislation on the subject was the 1906 Food and Drugs Act, passed by President Theodore Roosevelt.⁷⁵ This Act cracked down on adulterated and misbranded food and drugs.⁷⁶ The enactment was motivated by problems in the industry, including a 1902 tragedy in St. Louis, when thirteen children died after taking a contaminated drug.⁷⁷ The children were administered a diphtheria antitoxin, but it was contaminated with tetanus spores.⁷⁸

The Act was updated under the administration of President Franklin Roosevelt, with the 1938 Federal Food, Drug, and Cosmetic Act ("FDCA").⁷⁹ Although the FDCA has been amended since its inception, it remains the key starting point for understanding food and drug regulation.

⁷³ *Id.*

⁷⁴ WHAT YOU NEED TO KNOW (AND WHAT WE'RE WORKING TO FIND OUT) ABOUT PRODUCTS CONTAINING CANNABIS OR CANNABIS-DERIVED COMPOUNDS, INCLUDING CBD, U.S. FOOD & DRUG ADMIN. (July 17, 2019), <https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis>.

⁷⁵ MILESTONES IN U.S. FOOD LAW, N.D. STATE UNIV., <https://www.ag.ndsu.edu/food-law/overview/history/milestones> (last visited Dec.2, 2019).

⁷⁶ HOW DID THE FEDERAL FOOD, DRUG, AND COSMETIC ACT COME ABOUT, U.S. FOOD & DRUG ADMIN. (Mar. 28, 2018), <https://www.fda.gov/about-fda/fda-basics/how-did-federal-food-drug-and-cosmetic-act-come-about>.

⁷⁷ Linda Bren, *The Road to the Biotech Revolution – Highlights of 100 Years of Biologics Regulation*, FDA CONSUMER MAG. 1 (Jan.-Feb. 2016), <https://www.fda.gov/files/about%20fda/published/The-Road-to-the-Biotech-Revolution--Highlights-of-100-Years-of-Biologics-Regulation.pdf>.

⁷⁸ PETER BARTON HUTT ET AL., FOOD & DRUG LAW 6–7 (Robert C. Clark et al. eds., 4th ed. 2014).

⁷⁹ HISTORIES OF PRODUCT REGULATION: THE 1938 FOOD, DRUG, AND COSMETIC ACT, U.S. FOOD & DRUG ADMIN. (Jan. 31, 2019), <https://www.fda.gov/about-fda/historic-product-regulation/1938-food-drug-and-cosmetic-act>.

The FDCA defines drugs as “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals and articles (other than food) intended to affect the structure or any function of the body of man or other animals.”⁸⁰ Before any drug can be sold, manufacturers submit an application to the FDA Center for Drug Evaluation and Research (CDER).⁸¹ New products are submitted under a new drug application; however, there are many other types of approval processes, including for investigational new drugs, therapeutic biologics, and over-the-counter drugs.⁸² All of this application information will help the FDA make a decision about approved doses, potential interactions with other drugs, side effects that require warnings, and whether a drug can be used continuously.⁸³

Although the 2018 Farm Bill removed hemp from DEA oversight, it did not modify the FDA’s authority on cannabis products or compounds.⁸⁴ Cannabis remains a Schedule I drug according to the DEA, indicating no accepted medical use.⁸⁵ However, the FDA has approved one cannabis-derived drug and three “cannabis-related” drugs.⁸⁶ The only approved drug with CBD as an active ingredient is Epidiolex, and it was approved to treat seizures in children suffering from Lennox-Gastaut or Dravet syndrome.⁸⁷ The cannabis-derived drugs rely on synthetic THC, either dronabinol or nabilone. The drugs are Marinol, Syndros, and Cesamet.⁸⁸ The first two have been useful in combatting appetite loss in AIDS patients.⁸⁹ Cesamet was approved for chemotherapy patients to reduce nausea and vomiting from the treatment.⁹⁰

⁸⁰ Federal Food, Drug, And Cosmetic Act, 21 U.S.C. § 321 (2016).

⁸¹ HOW DRUGS ARE DEVELOPED AND APPROVED, U.S. FOOD & DRUG ADMIN. (Jan. 7, 2019), <https://www.fda.gov/drugs/development-approval-process-drugs/how-drugs-are-developed-and-approved>.

⁸² *Id.*

⁸³ *Id.*

⁸⁴ FDA REGULATION OF CANNABIS AND CANNABIS-DERIVED PRODUCTS: QUESTIONS AND ANSWERS, FOOD & DRUG ADMIN. (Apr. 2, 2019), <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers> [hereinafter U.S. FOOD & DRUG ADMIN., REGULATION OF CANNABIS].

⁸⁵ *Id.*

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ Valeant Pharmaceuticals, *Cesamet FDA Application*, U.S. FOOD & DRUG ADMIN. (May 2006), https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/018677s011bl.pdf.

The trial conducted for epilepsy, which led to the approval of Epidiolex, was supported by the drug manufacturer GW Pharmaceuticals.⁹¹ This presents a challenge for drug development—large pharmaceutical companies have significant resources to pour into research and development, go through the lengthy administrative process to get a drug approved by the FDA, and conduct testing to ensure they have a pure and safe product. Once hemp research is less restricted, it is possible that these large companies may try to get in on the market for legal drugs first, capturing most of the revenue. However, an increase in the number of approved hemp-derived drugs could create a stable market for farmers.⁹²

The FDA approval of CBD as an active ingredient in Epidiolex was a victory for the patients it will help. The market for CBD supplements and food products was hindered, however, because of FDCA rules which restrict the use of active ingredients in FDA-approved drugs for food and dietary supplements. A dietary supplement can contain an herb or botanical, but because it is an active ingredient in a drug, CBD cannot be marketed as a dietary supplement.⁹³ The FDA does have the discretion to go through the notice and comment process to create a regulation allowing the sale of dietary supplements with an approved-drug active ingredient.⁹⁴ However, the FDA has not chosen to exercise that discretion at this time.⁹⁵

The same restriction outlaws the introduction of CBD-containing products into interstate commerce. Section 331 of the FDCA prohibits “[t]he introduction or delivery for introduction into interstate commerce of any food to which has been added a drug approved under section 355 of this title.”⁹⁶ Similar to the rules on supplements, the FDA Secretary can use his discretion to issue a regulation that allows the use of the drug in food.⁹⁷ There are already

⁹¹ Orrin Devinsky et. al., *Trial of Cannabidiol for Drug-Resistant Seizures in Dravet Syndrome*, 376 NEW ENG. J. MED. 2011, 2012 (2017).

⁹² April Simpson, *Farmers Hope for Hemp Riches Despite Risks*, PEW CHARITABLE TRUSTS (Feb. 27, 2019), <https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2019/02/27/farmers-hope-for-hemp-riches-despite-risks>.

⁹³ 21 U.S.C.A. § 321(ff).

⁹⁴ U.S. FOOD & DRUG ADMIN., REGULATION OF CANNABIS, *supra* note 84.

⁹⁵ *Id.*

⁹⁶ 21 U.S.C. § 331(II) (2018).

⁹⁷ *Id.*

foods derived from hemp, and some, like hempseed, are easy to find.⁹⁸

The interest in CBD for food products is not limited to humans, either. Martha Stewart has formed a partnership with the Canadian company “Canopy Growth” to launch a line of pet products with CBD.⁹⁹ Another celebrity getting in on the market is rock star Gene Simmons, who recently announced a CBD soda.¹⁰⁰ There are many other edible products, topical products, and cosmetics that are available, creating a lot of work for anyone attempting to enforce the FDCA provisions, whether by preventing products from being shipped in interstate commerce or completely stopping their sale.¹⁰¹

An additional and interesting component of the market for CBD products is how they move in commerce, either inter- or intrastate. Earlier this year, the U.S. Postal Service (USPS) issued an advisory about the mailing of CBD products.¹⁰² Specifying that these rules are temporary until the 2018 Farm Bill can be fully implemented, the USPS is allowing shipment of CBD products under certain circumstances.¹⁰³ In connection with the permitted research production of hemp, mailers have to sign a statement certifying that they have a valid license from the state department of agriculture in the mail piece’s originating state.¹⁰⁴

⁹⁸ Cathy Siegner, *Now That Hemp and CBD are Legal, What Comes Next for Food and Beverage?*, FOOD DIVE (Dec. 20, 2018), <https://www.fooddive.com/news/now-that-hemp-and-cbd-are-legal-what-comes-next-for-food-and-beverage/544354>.

⁹⁹ Thomas Franck & Angela LaVito, *Martha Stewart Partnering with Marijuana Grower Canopy Growth to Develop Hemp-Derived Products*, CNBC (Feb. 28, 2019, 6:36 PM), <https://www.cnbc.com/2019/02/28/martha-stewart-to-join-marijuana-grower-canopy-growth.html>. The regulation of pet food and the potential implications for CBD is a topic deserving of its own article, particularly because of the potential, diverse side effects various animal species could have to CBD. See generally Consumer Reports, *CBD for Pets’ Ailments? Many People Swear By it, But There’s Very Little Animal Research.*, THE WASHINGTON POST (Feb. 18, 2019, 1:00 PM), <https://www.washingtonpost.com> (search “CBD for pets ailments” and select the first result).

¹⁰⁰ Joanne Cachapero, *KISS Co-founder Gene Simmons Debuts CBD-Infused Soda Line*, MG (Apr. 30, 2019), <https://mgretailer.com/cannabis-news/kiss-co-founder-gene-simmons-debuts-cbd-infused-soda-line/>.

¹⁰¹ Mary Schmich, *CBD Oil is Suddenly Everywhere. It is Really Going to Cure Your Anxiety, Your Migraines and Your Acne?*, CHICAGO TRIBUNE (May 1, 2019, 5:00 AM), <https://www.chicagotribune.com/news/columnists/schmich/ct-met-mary-schmich-cbd-20190430-story.html>.

¹⁰² Kyle Jaeger, *U.S. Postal Service Issues Advisory On Mailing Hemp-Derived CBD*, MARIJUANA MOMENT (Mar. 19, 2019), <https://www.marijuanamoment.net/u-s-postal-service-issues-advisory-on-mailing-hemp-derived-cbd/>.

¹⁰³ *Id.*

¹⁰⁴ *Id.*

The FDA has been proactive in releasing information about CBD and ensuring that the public can find and understand the agency's position. However, the momentum was stalled when FDA Commissioner Scott Gottlieb announced in March that he would be stepping down from his post in April. Gottlieb surprised many people with his progressive work during his two years at the agency, and he commented frequently on CBD in particular.¹⁰⁵ Because of the limits of agency rulemaking, he suggested that Congress make rules for the use of CBD in food products, because Congress could act more quickly.¹⁰⁶ Gottlieb has since left the FDA, but the agency moved ahead with a public hearing on May 31, 2019, with the purpose to "obtain scientific data and information about the safety, manufacturing, product quality, marketing, labeling, and sale of products containing cannabis or cannabis-derived compounds."¹⁰⁷

At the hearing, presentations were made on topics ranging from prescription interactions with cannabidiol to the use of hemp-derived ingredients in animal feed.¹⁰⁸ There were representatives from consumer groups, state departments of agriculture, and academia, among others.¹⁰⁹ The breadth of representation is a good indication of the interest in creating regulations for cannabinoids and creating a path for researchers to understand them. In a letter addressed to Ned Sharpless, the acting commissioner of the FDA after Gottlieb's departure, a bipartisan group of Congressional

¹⁰⁵ See Kyle Jaeger, *FDA Is Exploring 'Alternative Approaches' to CBD Regulation, Commissioner Says*, MARIJUANA MOMENT (Feb. 26, 2019), <https://www.marijuanamoment.net/fda-is-exploring-alternative-approaches-to-cbd-regulation-commissioner-says/>; see also Helena Bottemiller Evich (@hbottemiller), Twitter (Feb. 26, 2019, 11:21 AM), <https://twitter.com/hbottemiller/status/1100476071252758528>.

¹⁰⁶ Scott Gottlieb, Comm'r, Food and Drug Admin., Speech: New Steps to Promote Food Safety (Feb. 26, 2019), <https://www.fda.gov/news-events/speeches-fda-officials/new-steps-promote-food-safety-02262019>.

¹⁰⁷ Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing; Request for Comments, 84 Fed. Reg. 12,969, 12,969 (Apr. 3, 2019) (to be codified at 21 C.F.R. pt. 15).

¹⁰⁸ See *Presentations: FDA's Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds Public Hearing*, U.S. FOOD & DRUG ADMIN. (last updated July 3, 2019), <https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/presentations-fdas-scientific-data-and-information-about-products-containing-cannabis-or-cannabis> (listing the presentations given at the FDA public hearing on cannabis or cannabis-derived products, including presentations by Erin Bubb on hemp-derived ingredients in animal feed and Barry Gidal on drug interactions with cannabis-derived products).

¹⁰⁹ See *id.* (listing the various representatives present at the FDA public hearing on cannabis or cannabis-derived products, including those from consumer groups, state departments of agriculture, academia, health professions, manufacturers, and other interested parties).

representatives addressed the issue of CBD in food products.¹¹⁰ They specifically proposed that the agency create an interim final rule for the use of CBD in food products and dietary supplements in addition to creating enforcement guidance and standards evaluating the safety and accuracy of labeling.¹¹¹

The agency rulemaking process has many layers and can seem quite complex, but every step is designed to ensure interested parties can make their voice heard and that the agency can gather appropriate technical information before promulgating a new rule. Agencies publish a proposed rule or Notice of Proposed Rulemaking (“NPRM”) in the Federal Register.¹¹² Comment periods are typically thirty to sixty days, but can be longer if the rule is particularly complicated.¹¹³ The upcoming public meeting on CBD will allow people to share comments and information with the FDA, and the agency is also taking written comments. A final rule should be based on the entire rulemaking record, including these public comments.

Former Commissioner Gottlieb expanded on the potential of rulemaking for CBD in an interview with the Brookings Institution in March.¹¹⁴ He stated that a standard rule takes “two to three years,” and that he didn’t believe he could have accomplished rule formation during his tenure, nor will the person who succeeds him.¹¹⁵ Gottlieb considers a rule for CBD in food to be novel and complex, because it has already been used in a drug and was not previously approved for use in food.¹¹⁶ He also described the imminent creation of a workgroup that would consider methods for Congress to create a legal route, noting that this was done for human growth hormone and fish oil.¹¹⁷

The FDA has less control over dietary supplements than it does over prescription drugs. Premarket approval or notification to the FDA is limited, and the labeling rules are more expansive than

¹¹⁰ See Letter from Cong. of the United States to Ned Sharpless, Acting Comm’r, U.S. Food & Drug Admin. 1 (Sept. 19, 2019), https://pingree.house.gov/uploadedfiles/pingree_comer_cbd_letter_to_fda_9.19.19.pdf.

¹¹¹ *Id.* at 2.

¹¹² *A Guide to the Rulemaking Process*, OFF. OF THE FED. REG., https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf.

¹¹³ *Id.*

¹¹⁴ Interview by Anna Edney with Scott Gottlieb, Former Comm’r, Food and Drug Admin., at Brookings Institution, (Mar. 19, 2019), (transcript available at <https://www.brookings.edu/events/a-conversation-with-departing-fda-commissioner-scott-gottlieb-on-his-tenure-and-policy-reforms/>).

¹¹⁵ *Id.*

¹¹⁶ *Id.*

¹¹⁷ *Id.*

those for prescription drugs.¹¹⁸ Presently, there are companies that market CBD and label it as supplements.¹¹⁹ Medterra, the company that sources hemp from Kentucky, labels its products as supplements.¹²⁰ The company does list a disclaimer at the bottom of every web page that reads: “[r]epresentations regarding the efficacy and safety of Medterra have not been evaluated by the Food and Drug Administration. These products are not intended to diagnose, prevent, treat, or cure any disease.”¹²¹ This has not stopped many reviews from extolling the uses of the product for joint pain, anxiety, hearing loss, and other issues.¹²² The company ships to every state in the U.S. and internationally.

Other companies advertising CBD supplements are easy to find. The FDA has issued warning letters to numerous companies, most of them for making unsubstantiated therapeutic claims about the products for sale.¹²³ Warning letters give businesses time to take corrective action before more serious consequences are imposed, including product seizures or injunctions to halt the sale of items.¹²⁴

At the local and state level, health departments are cutting into the sales of CBD in food. The Los Angeles County Health Department issued its own guidance for restaurants, noting that beginning in July 2019, points would be deducted on inspections for selling food products adulterated with CBD.¹²⁵ One reason that health officials are concerned is their belief that it can be difficult for customers to differentiate products with and without CBD and the

¹¹⁸ Rahi Azizi, “Supplementing” the DSHEA: Congress Must Invest the FDA with Greater Regulatory Authority over Nutraceutical Manufacturers by Amending the Dietary Supplement Health and Education Act, 98 CALIF. L. REV. 439, 440 (2010).

¹¹⁹ CBD Oil – How Do You Successfully Market Products With No Standards?, CLOCK TOWER INSIGHT, (Apr. 20, 2019), <http://clocktowerinsight.com/cbd-oil-how-do-you-successfully-market-a-product-with-no-standards/>.

¹²⁰ MEDTERRA CBD, <https://medterracbd.com/category-wellness> (last visited Nov. 8, 2019).

¹²¹ MEDTERRA CBD, <https://medterracbd.com/> (last visited Nov. 8, 2019).

¹²² See MEDTERRA CBD, <https://medterracbd.com/reviews> (last visited Nov. 7, 2019).

¹²³ WARNING LETTERS AND TEST RESULTS FOR CANNABIDIOL-RELATED PRODUCTS, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products> (last visited Nov. 7, 2019).

¹²⁴ U.S. FOOD & DRUG ADMIN., WARNING LETTER TO POTNETWORK HOLDINGS, INC., (Mar. 28, 2019), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/potnetwork-holdings-inc-564030-03282019>.

¹²⁵ INDUSTRIAL HEMP DERIVED PRODUCTS, L.A. CTY DEP’T OF PUB. HEALTH, <http://publichealth.lacounty.gov/eh/docs/IndustrialHempDerivedProducts.pdf> (last visited Nov. 7, 2019).

relative dosage in each product.¹²⁶ Acting under rules created for the state's medical marijuana program, officials from the Ohio Department of Agriculture, Health Departments, and Policy have visited stores and instructed them to stop selling CBD products or risk having them seized.¹²⁷ The state's law prohibits the sale of CBD except in a licensed dispensary.¹²⁸

Despite the de-scheduling of hemp, there can still be a stigma associated with the consumption of hemp products. Consumers of untested products also run the risk of testing positively for THC if they are drug-tested, which can lead to serious consequences, especially for work-related drug testing.¹²⁹ Some evidence shows that consuming large amounts of CBD can yield a false positive.¹³⁰ One expert in cannabis testing has clarified that most drug tests are designed for finding THC, not other cannabinoids.¹³¹ This is an extremely discrete issue related to CBD consumption, so most people would be better off locating information related to their specific situation rather than relying on anecdotal information online.

V. Why should the FDA make rules for CBD?

The CBD market is not slowing down, and full implementation of the 2018 Farm Bill is likely to expand it. The FDA needs to make rules for consumer safety and to allow the regulated creation of new drugs. The FDA can create rules for testing products, creating a guarantee that a product is CBD, verifying the levels of THC, and confirming product purity.¹³² Access to quality CBD products will also assist researchers, who can conduct approved trials for new drugs and therapies that use CBD. Researchers at

¹²⁶ Amanda Mull, *The CBD Crackdown Has Begun*, THE ATLANTIC (Feb. 6, 2019), <https://www.theatlantic.com/health/archive/2019/02/new-york-city-cbd-crack-down/582193/>.

¹²⁷ Randy Tucker, *Officials in Ohio Raid CBD Sellers, Order Products Removed*, CINCINNATI ENQUIRER (Feb. 4, 2019, 6:26 PM), <https://www.cincinnati.com/story/money/2019/02/04/local-cbd-products-under-scrutiny-for-food-safety/2766115002/>.

¹²⁸ *Id.*

¹²⁹ Mike Adams, *Marijuana Madness: This is How CBD Oil Can Cause a Failed Drug Test*, FORBES (Oct. 18, 2018, 3:38 PM), <https://www.forbes.com> (search "Mike Adams Marijuana Madness").

¹³⁰ *Id.*

¹³¹ Elizabeth Brico, *We Looked Into Whether CBD Would Show Up in a Drug Test*, VICE (Dec. 14, 2018, 12:40 PM), https://tonic.vice.com/en_us/article/xwjmpj/cbd-drug-test.

¹³² Helena Bottemiller Evich, *Gottlieb Suggests 'Alternative Approaches' for CBD to Discuss in Congress*, POLITICO, (Feb. 26, 2019, 1:34 PM), <https://politico.com> (search "Gottlieb suggests alternative").

Johns Hopkins University are planning a clinical trial that will test the potential benefits of CBD for smoking cessation.¹³³

Many potential benefits have been advertised, but not as much focus has been put on the side effects. The listed side effects of Epidiolex can include: decreased appetite, diarrhea, rashes, and lower sleep quality.¹³⁴ Consumers also need guidance on dosing and the variety of ingestion methods that could change the effectiveness of a CBD drug. Research into CBD could also yield information about other cannabinoids and a new understanding of the ensemble effect in cannabinoids.

It is possible for research to be conducted with synthetic cannabinoids.¹³⁵ The FDA-approved, cannabis-related drugs rely on synthetic cannabinoids.¹³⁶ More recently, yeast has been used to produce synthetic THC and CBD.¹³⁷ The obvious benefits are for companies that want to begin research without cultivating hemp and also ensure that the CBD is uncontaminated by THC. There is also an opportunity to produce other synthetic cannabinoids and begin to understand how many there actually are, potentially with more benefits than what we are already aware of.¹³⁸ If synthetic CBD were marketed, though, regulators would do right by consumers by requiring a new name for the synthetic chemical, or a clear label that indicates it is not a naturally-derived product.

VI. How should CBD be treated?

Regulators have many options for designing CBD rules. The most formal process, and what would allow the most public input, would be agency rulemaking. However, the agency could, through rulemaking, use its discretion to allow the use of CBD in food products and supplements, despite it not being used in either of these products prior to the approval of Epidiolex. It also seems likely that

¹³³ Roni Caryn Rabin, *CBD is Everywhere, but Scientists Still Don't Know Much About It*, N.Y. TIMES (Feb. 25, 2019), <https://www.nytimes.com/2019/02/25/well/live/cbd-cannabidiol-marijuana-medical-treatment-therapy.html>.

¹³⁴ See Greenwich Biosciences, Inc., *Highlights of Prescribing Information*, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/2103651bl.pdf (listing common "Adverse Reactions" from the drug Epidiolex) (last visited Nov. 10, 2019).

¹³⁵ See e.g., Devinsky et al., *supra* note 91, at 2011 (noting the research trials conducted before Epidiolex was FDA-approved).

¹³⁶ See U.S. FOOD & DRUG ADMIN., REGULATION OF CANNABIS, *supra* note 84 (discussing approved medical products).

¹³⁷ Matt Simon, *Forget Growing Weed – Make Yeast Spit Out CBD and THC Instead*, WIRED (Feb. 27, 2019, 1:00 PM), <https://www.wired.com/story/yeast-cbd-and-thc/>.

¹³⁸ *Id.*

there will be more research on the therapeutic value of CBD, so Epidiolex will not be the only drug on the market for very long.

In addition to his comments supporting Congressional action on the regulation, Gottlieb envisioned it as a tier or schedule of concentrations for different products containing CBD, in part because the side effects at different concentrations are not yet studied and understood.¹³⁹ Congress could authorize the use in food and supplements and then direct the FDA to establish the acceptable thresholds for each product.¹⁴⁰ The collaboration between Congress and the agency is not uncommon and would be the fastest way to reach at least a temporary resolution until the FDA can solidify rules. Gottlieb also believes that the committee will have recommendations by the summer,¹⁴¹ which would be prior to the full 2018 Farm Bill implementation. If producers of CBD products have a better idea of their legality, it will also give farmers some clarity on the market for hemp.

VII. Conclusion

CBD has captured the interest of many different groups and created a headache for federal and state agencies. This is an exciting product, simply because of its untapped potential. It is, of course, added to the long list of useful hemp products, providing farmers with a new way to use their crops. The FDA and Congress should work together to create rules that allow food and drug producers to each have a piece of the market and provide consumers with tools for health and overall wellness.

¹³⁹ Interview with Scott Gottlieb, *supra* note 114.

¹⁴⁰ *Id.*; see also Evich, *supra* note 132.

¹⁴¹ Interview with Scott Gottlieb, *supra* note 114.