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NORTH CAROLINA LAW REVIEW

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Volume 98  
Number 7 *Forum*

Article 4

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2019

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### Recommended Citation

Shannon Smith, *Hemp on the Horizon: The 2018 Farm Bill and the Future of CBD\**, 98 N.C. L. REV. 1503 (2019).

Available at: <https://scholarship.law.unc.edu/nclr/vol98/iss7/4>

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## Hemp on the Horizon: The 2018 Farm Bill and the Future of CBD\*

*The 2018 Farm Bill has signaled a sea change in hemp cultivation and sale in the United States. In addition to legalizing the crop and sketching out a framework for its regulation, the bill has brought some clarity to the legal status of cannabidiol, or “CBD,” a hemp-derived non-psychoactive compound that has become immensely popular in recent years. In the wake of the bill’s passage, however, the CBD market remains severely under-regulated, a state of affairs that threatens consumer safety and leaves businesses without assurance that their operations are legal. To ameliorate the present confusion, at least two significant regulatory issues must be resolved. The first concerns the U.S. Food and Drug Administration’s current, yet largely unenforced, position that the addition of CBD to ingestible products is illegal. The second involves the lack of guidance in the Farm Bill regarding the labeling of CBD products.*

*After providing background on the history of hemp in the United States and detailing the 2018 Farm Bill’s regulatory framework, this Recent Development argues that the federal government must act quickly to fill the holes in the legislation. In the absence of swift federal action, it contends that states will need to address these questions themselves. Such action is necessary to ensure consumer safety and make certain that products and businesses can enter the CBD industry on solid legal footing.*

The United States’ eighty-year-long prohibition on hemp cultivation<sup>1</sup> has come to an end. On December 20, 2018, President Trump signed into law the Agriculture Improvement Act, most commonly known as the 2018 Farm Bill.<sup>2</sup> Among the many provisions altering agriculture and nutrition policy within the \$867 billion package deal<sup>3</sup> are several that work together to legalize hemp and sketch out a regulatory scheme for the crop’s commercial production.<sup>4</sup> With the

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1. Congress effectively outlawed the production and sale of both hemp and marijuana in 1937 with the Marihuana Tax Act. ROBERT DEITCH, HEMP—AMERICAN HISTORY REVISITED 150–51 (2003); David R. Katner, *Up in Smoke: Removing Marijuana from Schedule I*, 27 B.U. PUB. INT. L.J. 167, 177 (2018); see Marihuana Tax Act of 1937, Pub. L. No. 75-238, ch. 553, 50 Stat. 551 (repealed 1970).

2. *Actions Overview H.R.2—Agriculture Improvement Act of 2018*, CONGRESS.GOV, <https://www.congress.gov/bill/115th-congress/house-bill/2/actions> [https://perma.cc/W4E5-4PAV]; see Agriculture Improvement Act of 2018, Pub. L. No. 115-334, 132 Stat. 4490 (2018).

3. MARK A. MCMINIMY, CONG. RESEARCH SERV., R45275, THE HOUSE AND SENATE 2018 FARM BILLS (H.R. 2): A SIDE-BY-SIDE COMPARISON WITH CURRENT LAW 1 (2018) <https://fas.org/sgp/crs/misc/R45275.pdf> [https://perma.cc/UX7X-YVGS].

4. See Agriculture Improvement Act of 2018, Pub. L. No. 115-334, §§ 10113–10114, 12619, 132 Stat. 4490, 4908–14, 5018. Other sections of the 2018 Farm Bill, which are not discussed in this piece,

reins on hemp considerably loosened, the industry promises to be a boon to the economies of many states—particularly those with hospitable growing climates that have developed infrastructures under hemp pilot programs over the last five years.<sup>5</sup> Some analysts, in fact, believe hemp will become a \$20 billion industry in the country by 2024.<sup>6</sup>

Due to its association with marijuana, hemp has had a fraught and complicated history in the United States.<sup>7</sup> Sometimes referred to as cousins,<sup>8</sup> both hemp and marijuana are varieties of the *Cannabis sativa* plant species,<sup>9</sup> and both contain a high number of cannabinoids—chemicals unique to the cannabis plant.<sup>10</sup> The main distinction between the two crops is that hemp has a significantly lower concentration of delta-9 tetrahydrocannabinol (“THC”), a

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facilitate research into the commercial viability of hemp and also add hemp to the list of commodities covered under crop insurance. *See id.* §§ 7129, 7501, 7605, 11101, 132 Stat. at 4795, 4819, 4828–29, 4919.

5. *See generally* HEMP REPORT: TOP 10 U.S. STATES, HEMP INDUSTRY DAILY (2018), [https://mjbizdaily.com/wp-content/uploads/2018/04/Hemp-Report\\_Top-10-US-States.pdf](https://mjbizdaily.com/wp-content/uploads/2018/04/Hemp-Report_Top-10-US-States.pdf) [<https://perma.cc/HYR5-GVQD>] (discussing the top ten most developed hemp growing states—Colorado, Kentucky, Oregon, North Dakota, Minnesota, New York, North Carolina, Tennessee, Vermont, and Nevada—as well as key states with emerging markets—Arkansas, California, Pennsylvania, South Carolina, Virginia, Washington, and Wisconsin); *see also infra* text accompanying notes 49–56.

6. Hank Schultz, *Hemp Market Forecast To Hit \$20 Billion by 2024*, NUTRAINGREDIENTS-USA (May 6, 2019), <https://www.nutraingredients-usa.com/Article/2019/05/06/Hemp-market-forecast-to-hit-20-billion-by-2024#> [<https://perma.cc/DT77GDY3>] (reporting the prediction of Roy Bingham, the CEO of the data firm BDS Analytics).

7. For a historical overview of hemp cultivation and prohibition in the United States, see Seaton Thedinger, Note, *Prohibition in the United States: International and U.S. Regulation and Control of Industrial Hemp*, 17 COLO. J. INT’L ENVTL. L. & POL’Y 419, 425–27, 433–37 (2006).

8. *See, e.g.*, Courtney N. Moran, *Industrial Hemp: Canada Exports, United States Imports*, 26 FORDHAM ENVTL. L. REV. 383, 385 (2015).

9. CONG. RESEARCH SERV., R44742, *DEFINING HEMP: A FACT SHEET 1–2* (2019), <https://fas.org/sgp.crs/misc/R44742.pdf> [<https://perma.cc/HXN2-Z5R3>].

10. Univ. of Wash. Alcohol & Drug Abuse Inst., *Cannabinoids*, LEARN ABOUT MARIJUANA, <http://learnaboutmarijuanawa.org/factsheets/cannabinoids.htm> [<https://perma.cc/XTN6-A3JR>].

cannabinoid with psychoactive effects.<sup>11</sup> In brief, this difference means that marijuana can get you “high” and hemp cannot.<sup>12</sup>

While marijuana is primarily grown for its psychoactive properties,<sup>13</sup> hemp is cultivated for a wide variety of industrial uses.<sup>14</sup> These uses predominantly fall into three categories: fibers (such as paper and cloth), seeds (for food and the production of hemp oil), and cannabinoid oils.<sup>15</sup> This final category is particularly important because it encompasses the oil of the immensely popular cannabinoid called cannabidiol, or “CBD,” the regulation of which is the primary focus of this piece.

CBD is a non-psychoactive compound that has several promising therapeutic uses; it is the main ingredient of a drug recently approved to treat severe childhood-onset epilepsy<sup>16</sup> and has many other touted, albeit oftentimes anecdotal, benefits for the management of disorders such as anxiety, chronic pain, and insomnia.<sup>17</sup> In the past several years there has been an upsurge in sales

11. *Id.* As now defined by federal law, hemp has a maximum THC concentration of 0.3%. 7 U.S.C. §§ 1639o(1), 5940(a)(2) (2018). By comparison, marijuana had an average THC concentration of 12% as of 2014. Mahmoud A. ElSohly et al., *Changes in Cannabis Potency over the Last Two Decades (1995–2014): Analysis of Current Data in the United States*, 79 BIOLOGICAL PSYCHIATRY 613, 613 (2016). In addition to their divergent THC concentrations, hemp and marijuana are generally cultivated differently. CONG. RESEARCH SERV., *supra* note 9, at 7. Marijuana is grown like a bush, with the goal to produce numerous branches holding resinous flowers or “buds” with high THC content. DEITCH, *supra* note 1, at 4. In contrast, growing methods for hemp vary based on the desired end product. CONG. RESEARCH SERV., *supra* note 9, at 7. For instance, growers who cultivate hemp for fiber focus on growing tall plants with long stalks. *Id.* at 8. On the other hand, those who cultivate hemp for CBD extraction often grow the plant much like they would grow marijuana because that method promotes the growth of flowers containing high concentrations of CBD. *See id.* at 8. Similar to marijuana, CBD comes almost exclusively from unpollinated female plants, while fiber- and seed-producing hemp plants are both male and female (or even some combination of the two). *How To Grow Hemp for CBD*, CHI. CANNABIS CO. (Apr. 28, 2019), <https://www.chicannaco.com/blogs/chicago-cannabis-blog/how-to-grow-hemp-for-cbd> [<https://perma.cc/YA4F-8FK4>].

12. Harmeet Kaur, *Hemp Won't Get You High (and Other Things To Know Now That It's Legal)*, CNN (Dec. 20, 2018), <https://www.cnn.com/2018/12/15/us/congress-hemp-legalization/index.html> [<https://perma.cc/6PQM-7DPH>]. Note, however, that some users of hemp-derived products report feeling a “body high.” Alex Williams, *Why Is CBD Everywhere?*, N.Y. TIMES (Oct. 27, 2018), <https://www.nytimes.com/2018/10/27/style/cbd-benefits.html> [<https://perma.cc/87Z4-79RY> (dark archive)].

13. Aaron Cadena, *Hemp vs. Marijuana: The Difference Explained*, CBD+ ORIGIN (Sept. 10, 2018), <https://cbdorigin.com/hemp-vs-marijuana/> [<https://perma.cc/8N8R-WSZT>].

14. Chris Chafin, *CBD Poised for Boom After Farm Bill*, ROLLING STONE (Dec. 19, 2018), <https://www.rollingstone.com/culture/culture-features/cbd-farm-bill-legalization-marijuana-hemp-769944/> [<https://perma.cc/Y7QJ-3E6P>].

15. *Id.*

16. John Hudak, *The Farm Bill, Hemp Legalization and the Status of CBD: An Explainer*, BROOKINGS (Dec. 14, 2018), <https://www.brookings.edu/blog/fixgov/2018/12/14/the-farm-bill-hemp-and-cbd-explainer/> [<https://perma.cc/L6SU-5376>]; *see About Epidiolex*, EPIDIOLEX, <https://www.epidiolex.com/about-epidiolex/story> [<https://perma.cc/63WW-MREQ>].

17. Peter Grinspoon, *Cannabidiol (CBD)—What We Know and What We Don't*, HARVARD HEALTH PUB. (Aug. 24, 2018, 6:30 AM), <https://www.health.harvard.edu/blog/cannabidiol-cbd-what-we-know-and-what-we-dont-2018082414476> [<https://perma.cc/M577-8GZ6>]; *see, e.g.,*

of foods, tinctures, and lotions with added CBD.<sup>18</sup> Consumers can now purchase these products at a variety of mainstream establishments, including restaurants,<sup>19</sup> grocery stores,<sup>20</sup> and pharmacies,<sup>21</sup> in addition to specialty shops<sup>22</sup> and online stores.<sup>23</sup> A Gallup poll conducted in the summer of 2019 indicates that one in seven U.S. adults personally uses CBD products—and that statistic increases to one in five for Americans between the ages of eighteen and twenty-

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Brightfield Group, *The CBD Phenomenon*, PREVENTION, Oct. 2019, at 6, 8–10 (describing the experience of one woman who stated that using CBD “was like someone had doused my brain with a gentle warmth and slight tingling sensation. . . . My headache softened, my nerves relaxed. . . . CBD has opened a whole world for me and my family”); Williams, *supra* note 12 (reciting one man’s testimonial about how CBD has improved his anxiety—“I’m a 30 y.o. male who has not experienced a single anxiety free day in my adult life. . . . About 3 weeks ago I started taking CBD-oil 10 percent and I can’t even describe how amazing I feel. For the first time in 15+ years I feel happy and look forward to living a long life”); Jim Berry, *Former NFL Player Larry Chester, ‘CBD Saved My Life’*, CBS MIAMI (Sept. 24, 2018), <https://miami.cbslocal.com/2018/09/24/former-nfl-player-cbd-saved-my-life/> [<https://perma.cc/4MF8-28TU>] (explaining the benefits of CBD for a former NFL lineman suffering from chronic pain and depression who says he now “feels more like himself than he has felt in a long time”). Consumers are even using CBD for nonhuman ailments—many are using the compound to treat their companion animals for epilepsy, soreness, pain, stress, and anxiety. Lindsey Corbett, *CBD and Your Pet*, PREVENTION, Oct. 2019, at 82, 84. Studies are beginning to substantiate some of these anecdotal claims. For instance, one study using animal models demonstrated that CBD applied topically may reduce arthritis-induced pain and inflammation. Grinspoon, *supra*. Another study identified a mechanism by which CBD inhibits certain types of chronic pain, and multiple studies suggest that CBD alleviates insomnia. *Id.*

18. Carla K. Johnson, *FDA Casts Shadow on Hemp Win, Calling CBD Products Illegal*, CHI. TRIB. (Dec. 24, 2018), <https://www.chicagotribune.com/business/ct-biz-cbd-oil-fda-warning-20181224-story.html> [<https://perma.cc/JNZ5-9DSD> (dark archive)].

19. See, e.g., Joey Peña, *Restaurant CBD Sales Are Booming, but New Liability Concerns Keep Cannabis Producers from Cashing in*, HEMP INDUSTRY DAILY (June 10, 2019), <https://hempindustrydaily.com/restaurant-cbd-sales-are-booming-but-new-liability-concerns-keep-cannabis-producers-from-cashing-in/> [<https://perma.cc/VF38-9C98>] (discussing the “huge demand” for CBD in the marketplace, including in restaurants in the form of infused food items like coffee, tea, donuts, pizza, and hamburgers).

20. See, e.g., Russell Redman, *More Kroger Co. Stores To Carry CBD Products*, SUPERMARKET NEWS (July 29, 2019), <https://www.supermarketnews.com/organic-natural/more-kroger-co-stores-carry-cbd-products> [<https://perma.cc/G6NQ-VK95>] (reporting that over 1000 Kroger grocery stores will carry CBD products).

21. See, e.g., Angelica LaVito, *Walgreens To Sell CBD Products in 1,500 Stores*, CNBC (Mar. 28, 2019), <https://www.cnbc.com/2019/03/27/walgreens-to-sell-cbd-products-in-some-stores.html> [<https://perma.cc/TRG4-KM4P>]; Kelly Tyko, *Some CVS Stores Selling Topical Products Infused with Cannabis Extract CBD But Not Edibles*, USA TODAY (Mar. 21, 2019), <https://www.usatoday.com/story/money/2019/03/21/cbd-products-go-sale-select-cvs-stores-eight-states/3241379002/> [<https://perma.cc/N3DB-JHBW>] (reporting that CVS stores in seven states are selling CBD products).

22. See, e.g., *Products*, HEMP STORE N.C., <https://www.thehempstorenc.com/products> [<https://perma.cc/3VYY-3UBE>].

23. See, e.g., PUREKANA, <https://purekana.com> [<https://perma.cc/F6EJ-RH83>].

nine.<sup>24</sup> Increasing media attention about CBD<sup>25</sup> has accompanied and likely amplified the compound's popularity. Despite its growing sales and use among Americans, however, CBD has continued to occupy a legal gray area.<sup>26</sup>

With the enactment of the 2018 Farm Bill, Congress has clarified CBD's ambiguous legal status in several respects and paved the way for massive growth in the CBD product industry. Nonetheless, the Farm Bill merely provides a basic framework for the regulation of hemp and hemp-derived products and leaves open several important regulatory questions concerning the future of CBD.

Two of the most pressing questions that the 2018 Farm Bill has left unanswered involve matters within the purview of the U.S. Food and Drug Administration ("FDA"), which is charged with ensuring the safety of drugs and the nation's food supply.<sup>27</sup> The first question concerns the FDA's current, yet largely unenforced, position that the addition of CBD to food and health supplements is illegal.<sup>28</sup> As the supply and demand for CBD-infused food products continue to grow, manufacturers, retailers, and consumers of such goods need clear guidance about the legality of their activities. What regulatory decision will the FDA ultimately make, and should states use their limited resources in the meantime to crack down on retailers?

The second open question involves the lack of guidance in the Farm Bill regarding the labeling of CBD products. The CBD industry is severely under-regulated, which has allowed some manufacturers to add potentially dangerous ingredients to CBD products without disclosing that fact to consumers.<sup>29</sup> Consumers may also be concerned about possible legal ramifications for possessing goods that resemble marijuana products.<sup>30</sup> Given the importance of robust and consistent labeling standards for CBD products, what should states do if the FDA fails to take the lead?

With respect to both of these issues, this Recent Development contends that the federal government should take the lead. After appropriate deliberation

24. Megan Brennan, *14% of Americans Say They Use CBD Products*, GALLUP (Aug. 7, 2019), <https://news.gallup.com/poll/263147/americans-say-cbd-products.aspx> [<https://perma.cc/E598-WXBG>].

25. See e.g., Williams, *supra* note 12 (detailing the wide variety of popular CBD products such as detox drinks, lotions, bath bombs, ice cream, tinctures, gel caps, and dog treats).

26. See *infra* Section II.C.

27. *What We Do*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/about-fda/what-we-do#responsibilities> [<https://perma.cc/Z3VF-93HF>].

28. See Press Release, Scott Gottlieb, M.D., Comm'r, Statement from FDA Commissioner Scott Gottlieb, M.D., on Signing of the Agriculture Improvement Act and the Agency's Regulation of Products Containing Cannabis and Cannabis-Derived Compounds (Dec. 20, 2018), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-signing-agriculture-improvement-act-and-agencys> [<https://perma.cc/JBW5-P2AU>].

29. See *infra* Section III.B.

30. See *infra* Section III.B.

to determine the safety profile of CBD, the FDA should promptly adopt regulations approving the addition of CBD to food and dietary supplements and establishing comprehensive labeling requirements. If, however, the agency fails to act in a timely manner, states should step in and (1) conform their laws and policies regarding CBD-infused ingestibles to those of the FDA, and (2) establish labeling standards to ensure product safety and the accuracy of product packaging. Such action is necessary in order to ensure consumer safety and to make certain that products and businesses can enter the industry on solid legal footing.

The following discussion will proceed in three parts. Part I provides a brief history of hemp and CBD regulation in the United States. Part II lays out the hemp-related provisions of the 2018 Farm Bill and discusses the clarity that the Farm Bill brings to the legal status of CBD. Finally, Part III addresses the two big regulatory questions about CBD that the Farm Bill fails to answer and suggests solutions for each.

## I. A BRIEF HISTORY OF HEMP AND CBD REGULATION IN THE UNITED STATES

### A. *Legality of Hemp Prior to the Twenty-First Century*

Until very recently, the legal status of hemp and its derived products was bound up with that of marijuana. Stated somewhat simplistically, hemp production became effectively illegal in 1937, alongside marijuana, due to the taxes and punishments imposed under the Marihuana Tax Act.<sup>31</sup> In 1970, hemp

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31. See Marihuana Tax Act of 1937, Pub. L. No 75-238, § 2, 50 Stat. 551, 551–52 (repealed 1970); DEITCH, *supra* note 1, at 146, 150–51. Harry Anslinger, the Director of the Federal Bureau of Narcotics at the time, had made it his mission in the 1930s to criminalize marijuana. DEITCH, *supra* note 1, at 117, 142–46. However, there were concerns in President Franklin D. Roosevelt’s administration that criminalizing marijuana did not comport with the Constitution. *Id.* at 146. The Marihuana Tax Act sidestepped this problem by taxing commerce in marijuana out of existence. *Id.* at 146, 150. The Act required marijuana manufacturers, importers, dealers, and users to register with the U.S. government and pay annual occupational taxes. *Id.* at 146; Marihuana Tax Act § 2, 50 Stat. at 551–52. In addition, it placed a \$1-per-ounce tax on transfers of marijuana to registered persons, a \$100-per-ounce tax on transfers to unregistered persons, and subjected violators to fines up to \$2000 and up to five years in prison. Marihuana Tax Act §§ 7(2), 12, 50 Stat. at 554, 556. Although those taxes may not seem unreasonable today, they were “exorbitant” in comparison to the low selling price of marijuana in the 1930s. DEITCH, *supra* note 1, at 146. The high cost of the tax and the punishments for violating it thus effectively outlawed marijuana production. Katner, *supra* note 1, at 177. Moreover, despite the fact that the language of the Act seemed to distinguish hemp from marijuana by stating that “[t]he term ‘marijuana’ . . . shall not include the mature stalks of such plant[s],” Marihuana Tax Act § 1(b), 50 Stat. at 552, the cultivation of hemp in the United States drastically declined because of confusion about the Act’s applicability to hemp, Nicole M. Keller, *The Legalization of Industrial Hemp and What It Could Mean for Indiana’s Biofuel Industry*, 23 IND. INT’L & COMP. L. REV. 555, 562–63 (2013), and ultimately ended, DEITCH, *supra* note 1, at 151. The United States Supreme Court later ruled the Act unconstitutional in 1969 in *Leary v. United States*, 395 U.S. 6, 12, 16 (1969) (holding that the Marihuana

cultivation was formally outlawed via the Controlled Substances Act (“CSA”)<sup>32</sup> and the Drug Enforcement Agency’s (“DEA”) subsequent interpretation of the law.<sup>33</sup> The CSA repealed the Marihuana Tax Act<sup>34</sup> and classified “marihuana”<sup>35</sup> as a Schedule I controlled substance.<sup>36</sup> Interestingly, the CSA arguably distinguished hemp from marijuana by stating that the Act’s definition of marijuana “does not include the mature stalks of [*Cannabis sativa* L.] plant[s],”<sup>37</sup> thus leaving open the possibility that hemp was excluded from the Schedule I list.<sup>38</sup> However, the CSA also classified “any material, compound, mixture, or preparation, which contains any quantity of . . . [THC]” as a Schedule I controlled substance.<sup>39</sup> The DEA later relied on that language to insist that hemp and hemp-derived products are controlled under the CSA because all hemp contains some amount of THC.<sup>40</sup> As a consequence, hemp hitched a ride with marijuana to become one of the most highly regulated drugs in the country.

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Tax Act violates the Fifth Amendment privilege against self-incrimination: obtaining a tax “order form” as required by the act necessitated one to admit he was an unregistered transferee of marijuana, which “would surely prove a ‘significant link in a chain’ of evidence tending to establish his guilt” under state marijuana prohibition laws); DEITCH, *supra* note 1, at 151. The Controlled Substances Act officially repealed the Act the following year. Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, § 1101(b)(3), 84 Stat. 1236, 1292.

32. See Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (codified as amended in scattered sections of 21 U.S.C.) (“Controlled Substances Act”). Note that the CSA did not technically outlaw hemp and marijuana cultivation without exception, but rather restricted production of the crops to growers with federal permits. Dwight L. Pringle, *Advising Clients Who Want To Grow Hemp*, 43 COLO. L., 71, 74 (2014). However, as of 2014, the Drug Enforcement Agency had only ever issued two permits for hemp production. *Id.*

33. See Interpretation of Listing of “Tetrahydrocannabinols” in Schedule I, 66 Fed. Reg. 51,530, 51,530–32 (Oct. 9, 2001) (to be codified at 21 C.F.R. pt. 1308). Notably, certain noningestible hemp products, such as paper products, fibers, and animal feeds, are exempted from this rule. *Id.*

34. Controlled Substances Act § 1101(b)(3), 84 Stat. at 1292.

35. Older statutes referred to the drug as “marihuana.” JEAN M. RAWSON, CONG. RESEARCH SERV., RL32725, HEMP AS AN AGRICULTURAL COMMODITY 1 n.1 (2005). This Recent Development will use the modern spelling “marijuana.”

36. Controlled Substances Act § 202, 21 U.S.C. § 812(c)(10) (2012 & Supp. VI 2018). Schedule I substances are those for which there is “no currently accepted medical use” and “a high potential for abuse.” *Id.* § 812(b)(1).

37. *Id.* § 802(16). This definition was imported directly from the Marihuana Tax Act of 1937. Interpretation of Listing of “Tetrahydrocannabinols” in Schedule I, 66 Fed. Reg. at 51,530.

38. See Interpretation of Listing of “Tetrahydrocannabinols” in Schedule I, 66 Fed. Reg. at 51,530–31; Thedinger, *supra* note 7, at 435.

39. § 812(c)(10).

40. The DEA interpreted the THC listing in the CSA’s Schedule I list to encompass “any product that contains any amount of [THC] . . . even if such product is made from portions of the cannabis plant that are excluded from the CSA definition of ‘marihuana.’” Interpretation of Listing of “Tetrahydrocannabinols” in Schedule I, 66 Fed. Reg. at 51,530.

B. *The 2014 Farm Bill*

Following the CSA, the first major change in federal law regarding hemp production came in the 2014 Farm Bill.<sup>41</sup> Section 7606 of the bill permitted states, “[n]otwithstanding the Controlled Substances Act,” to develop pilot programs for hemp whereby state agricultural departments and universities could grow the crop for the purpose of “study[ing] the growth, cultivation, or marketing of industrial hemp.”<sup>42</sup> The bill defined “industrial hemp” as “the plant *Cannabis sativa* L. and any part of such plant, whether growing or not, with a [THC] concentration of not more than 0.3 percent on a dry weight basis.”<sup>43</sup> Accordingly, the bill allowed a small category of state institutions to oversee the cultivation of cannabis containing a THC concentration of 0.3% or less for limited research purposes so long as the institution’s state permitted the practice by law. Individual growers can produce hemp under the bill if they do so for “purposes of research” in accordance with a state pilot program and are registered and certified by the state’s department of agriculture.<sup>44</sup>

Notably, the 2014 Farm Bill did not amend the CSA, but rather carved out a narrow exception for hemp cultivated in compliance with the bill.<sup>45</sup> Thus, hemp remained a Schedule I substance after the bill’s enactment and hemp produced in contravention of the bill’s provisions continued to be illegal under federal law.<sup>46</sup> That state of affairs, combined with the bill’s rather vague language, led to controversy about whether the bill permitted the commercial sale of hemp and hemp-derived products like CBD.<sup>47</sup> Notwithstanding the existing confusion, growers participating in state pilot programs engaged in

41. Agricultural Act of 2014, Pub. L. No. 113-79, § 7606, 128 Stat. 649, 912–13 (codified as amended at 7 U.S.C. § 5940 (2018)); see Press Release, Vote Hemp, President Obama Signs Farm Bill with Amendment To Allow Industrial Hemp Research (Feb. 7, 2014), [https://www.votehemp.com/press\\_releases/president-obama-signs-farm-bill-with-amendment-to-allow-industrial-hemp-research/](https://www.votehemp.com/press_releases/president-obama-signs-farm-bill-with-amendment-to-allow-industrial-hemp-research/) [<https://perma.cc/BE9C-MJUH>] (quoting Vote Hemp President Eric Steenstra as saying that “[t]his is the first time in American history that industrial hemp has been legally defined by our federal government as distinct from drug varieties of *Cannabis*”).

42. Agricultural Act § 7606(a), (b)(1), 128 Stat. at 912.

43. *Id.* § 7606(b)(2), 128 Stat. at 912–13.

44. *Id.* § 7606(a)(1), (b)(i)(B)(ii), 128 Stat. at 912.

45. See Statement of Principles on Industrial Hemp, 81 Fed. Reg. 53,395–96 (Aug. 12, 2016).

46. *Id.*

47. See Hemp Industry, *Letter to Secretary Vilsack*, HEMP BIZ J. (Aug. 17, 2016), <https://www.hempbizjournal.com/wp-content/uploads/2016/08/Hemp-Coalition-Multi-Agency-Reply.pdf> [<https://perma.cc/S875-68SD>]. While the bill allowed cultivation for “purposes of research,” it did not directly address commercial sales. See Agricultural Act § 7606, 128 Stat. at 912–13. In an attempt at clarification, the U.S. Department of Agriculture, DEA, and FDA issued a joint statement in 2016 in which the agencies stated that the law does not permit “general commercial activity” but *does* allow hemp products to be sold “for purposes of marketing research” within a state with a pilot program or among states with pilot programs. Statement of Principles on Industrial Hemp, 81 Fed. Reg. at 53,395. Several members of the hemp industry pressed the agencies for further explanation of the distinction between “general” commercial activity and commercial activity for research purposes. See Hemp Industry, *supra*. However, the agencies did not issue any further guidance.

widespread commercial sale of hemp-derived goods, with CBD as their highest-selling product.<sup>48</sup>

In the years since the bill's enactment, forty-seven states have passed laws to establish hemp pilot programs.<sup>49</sup> Programs in several states have been very successful. For instance, North Carolina passed its own law in 2015<sup>50</sup> and, as of August 2019, the state had 1124 licensed growers representing over fourteen thousand licensed acres, and nearly seven hundred registered processors.<sup>51</sup> Kentucky has also seen a surge in hemp production. In 2019, its government approved over fifty thousand acres for outdoor hemp cultivation and over six million square feet of greenhouse space for indoor growing.<sup>52</sup> Only three states—Idaho, Mississippi, and South Dakota—and Washington, D.C., prohibit hemp cultivation.<sup>53</sup>

## II. THE 2018 FARM BILL

Building upon the 2014 Farm Bill's pilot programs, the 2018 Farm Bill ("Farm Bill" or "Bill") significantly broadens the horizon for hemp cultivation

48. See, e.g., Debra Borhardt, *Hemp Cannabis Product Sales Projected To Hit \$1 Billion in 3 Years*, FORBES (Aug. 23, 2017), <https://www.forbes.com/sites/debraborhardt/2017/08/23/hemp-cannabis-product-sales-projected-to-hit-a-billion-dollars-in-3-years/#ccc8d3474c0> [https://perma.cc/2SL3-4JY6] (discussing the remarkable size of the CBD market and its anticipated growth). Parija Kavilanz, *These Hemp Farmers Are Making a Killing on the CBD Industry*, CNN: BUS. (Apr. 10, 2019), <https://www.cnn.com/2019/04/09/success/hemp-farmer/index.html> [https://perma.cc/QT6C-JLU3].

49. See *State Industrial Hemp Statutes*, NAT'L CONF. ST. LEGISLATURES (Aug. 2, 2019), <http://www.ncsl.org/research/agriculture-and-rural-development/state-industrial-hemp-statutes.aspx> [https://perma.cc/DX2E-7L55].

50. See N.C. GEN. STAT. §§ 106.568.50 to .57 (2017). As amended in 2016, the North Carolina statute clarifies that the state's industrial hemp research program is to be managed by two land-grant universities—North Carolina State University and North Carolina A&T State University, *id.* § 106.568.53(1)—and the state's Industrial Hemp Commission is responsible for issuing licenses to growers, *id.* § 106.568.53(2).

51. N.C. Indus. Hemp Comm'n, *Minutes of July 12, 2019 Meeting*, N.C. DEP'T AGRIC. & CONSUMER SERVS. (July 12, 2019), <https://www.ncagr.gov/hemp/documents/2019-July12-NCIHCMminutes.pdf> [https://perma.cc/V8LB-VLWZ].

52. *Sales of Hemp Products in Kentucky Surged in 2018*, HEMP INDUSTRY DAILY (Mar. 19, 2019), <https://hempindustrydaily.com/sales-hemp-products-kentucky-surged-2018/> [https://perma.cc/ZMW6-94C6 (staff-uploaded archive)].

53. See *State Industrial Hemp Statutes*, *supra* note 49. Officials in Idaho, Mississippi, and South Dakota have cited concerns that legalizing hemp would interfere with law enforcement efforts to enforce marijuana prohibition. See, e.g., Lisa Kaczke, *What's South Dakota Missing Without Legal Industrial Hemp?*, ARGUS LEADER (Mar. 22, 2019), <https://www.argusleader.com/story/news/politics/2019/03/22/south-dakota-marijuana-industrial-hemp-agriculture-laws-kristi-noem/3215905002/> [https://perma.cc/FCP4-59S6 (dark archive)]; Lucas Ramseth, *Could You Start Growing Hemp in Mississippi Next Year? State Task Force Begins Study*, CLARION LEDGER (July 9, 2019), <https://www.clarionledger.com/story/news/politics/2019/07/09/mississippi-farmers-want-know-when-can-we-grow-hemp/1641385001/> [https://perma.cc/3R3W-D83W (dark archive)]; Keith Ridler, *House Kills Hemp Legislation, So Even Transporting It Across Idaho Is Still Illegal*, IDAHO STATESMAN (Apr. 11, 2019), <https://www.idahostatesman.com/latest-news/article229130249.html> [https://perma.cc/N9G7-ZDY9 (staff-uploaded archive)].

by legalizing commercial production; establishing a dual state-federal regulatory scheme; and facilitating the cultivation, transport, and sale of the crop and its products. The following discussion lays out the Bill's most important provisions for the future of CBD and considers their implications.

#### A. *Hemp Legalization*

The very last section of the Farm Bill brings about its most important change for the hemp industry: it removes hemp and hemp-derived products from the purview of the CSA, thereby legalizing the general commercial cultivation of hemp.<sup>54</sup> The Bill accomplishes this task by amending the CSA to exclude “hemp” from the definition of “marihuana”<sup>55</sup> and the phrase “[THC] in hemp” from the THC listing in Schedule I.<sup>56</sup> In addition, the Bill adds hemp to the list of crops covered under the Agricultural Marketing Act of 1946<sup>57</sup> and consequently moves regulatory authority over hemp from the DEA to the U.S. Department of Agriculture (“USDA”).<sup>58</sup> Importantly, the Bill also adopts the 2014 Farm Bill’s definition of hemp, which defines “hemp” as cannabis plants and derivatives containing no more than 0.3% THC.<sup>59</sup> Accordingly, any cannabis plant or derived product with greater than 0.3% THC constitutes “marijuana” under the legislation and therefore remains federally illegal.<sup>60</sup>

#### B. *Regulatory Framework*

Despite the Farm Bill’s broad legalization of hemp, the Bill dictates that the government will maintain a tight regulatory grip over hemp cultivation. The Bill’s hemp provisions sketch out a regulatory framework over which states and the federal government will share power.<sup>61</sup> Nevertheless, this framework is very basic.

The Bill authorizes states<sup>62</sup> to implement their own hemp regulatory programs.<sup>63</sup> To do this, a state’s department of agriculture, in consultation with its governor and chief law enforcement officer, must submit a monitoring and

54. See Agriculture Improvement Act of 2018, Pub. L. No. 115-334, § 12619, 132 Stat. 4490, 5018 (2018).

55. *Id.* § 12619(a), 132 Stat. at 5018.

56. *Id.* § 12619(b), 132 Stat. at 5018.

57. *Id.* § 10113, 132 Stat. at 4908.

58. See Steve Levine & Benjamin Jones, *2018 Farm Bill: Opportunities in Hemp*, CANNABIS BUS. TIMES (Jan. 16, 2019), <https://www.cannabisbusinesstimes.com/article/2018-farm-bill-opportunities-in-hemp/> [<https://perma.cc/P9K4-TJTA> (staff-uploaded archive)].

59. Agriculture Improvement Act § 10113, 132 Stat. at 4908, 4912.

60. See *id.*

61. See *id.* § 10113, 132 Stat. at 4909–10.

62. The Farm Bill allocates the same authority to Indian tribes, see *id.*, although this Recent Development focuses primarily on states.

63. See *id.*

regulation plan to the Secretary of Agriculture.<sup>64</sup> The plan must contain, most importantly, (1) a method of recording and describing land on which hemp is grown, (2) a procedure for testing THC concentration in hemp, (3) a procedure for disposing of hemp and hemp products that violate the 0.3% THC limit, and (4) a procedure for enforcing the regulations.<sup>65</sup> The state may also include any other provisions it chooses in its plan so long as those practices or procedures are consistent with the Farm Bill.<sup>66</sup> If a state does not wish to regulate hemp itself, or if the Secretary of Agriculture rejects its proposed plan, the Secretary will then create a plan for the state and the federal government will oversee hemp cultivation in that state.<sup>67</sup>

Under the federal program, individual growers need to obtain a license from the Secretary of Agriculture, the head of the USDA.<sup>68</sup> The Bill provides states more leeway regarding how they regulate cultivation, although many commentators assume that states will issue licenses or permits to growers as well.<sup>69</sup>

Notably, the Secretary of Agriculture must approve a state's plan before the state can begin issuing licenses or otherwise allow cultivation under the 2018 Farm Bill.<sup>70</sup> For those states that choose to cede regulation to the federal government, the Secretary must establish a plan for a state before licenses can be issued to growers.<sup>71</sup> The Secretary published a federal plan in late October 2019 in the form of an interim final rule that took immediate effect.<sup>72</sup> At least seven states had submitted plans to the Secretary as of October 2019<sup>73</sup> and the USDA subsequently began reviewing state plans.<sup>74</sup> In the meantime, however, any ongoing hemp cultivation remains governed by the state programs that

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64. *Id.* § 10113(a)(1), 132 Stat. at 4909.

65. *Id.* § 10113(a)(2)(A), 132 Stat. at 4909.

66. *Id.* § 10113, 132 Stat. at 4910.

67. *See id.* § 10113, 132 Stat. at 4912.

68. *See id.* § 10113, 132 Stat. at 4913.

69. *See, e.g.*, Hudak, *supra* note 16.

70. *Id.*

71. *Id.*

72. Establishment of a Domestic Hemp Production Program, 84 Fed. Reg. 58,522–23 (Oct. 31, 2019) (to be codified at 7 C.F.R. pt. 990). Under the Administrative Procedure Act, an agency may expedite the rulemaking process by issuing an interim final rule if it decides that it would be “impractical, unnecessary, or contrary to the public interest” to follow the usual but slow-going requirement that it first issue a proposed rule. Administrative Procedure Act, 5 U.S.C. § 553(b)(B) (2018). For an overview of the rule's provisions, see *USDA Releases Long-Awaited Industrial Hemp Regulations*, FARM BUREAU (Oct. 31, 2019), <https://www.fb.org/market-intel/usda-releases-long-awaited-industrial-hemp-regulations> [<https://perma.cc/65GD-SMLR>].

73. Gene Markin, *USDA Clarifies Hemp Production, Use, and Transportation*, N.J. L. BLOG (June 21, 2019), <https://www.njlawblog.com/2019/06/articles/cannabis-lawyer/usda-clarifies-hemp-production-use-and-transportation/> [<https://perma.cc/YW3Q-8GHX>]. At least eight tribes had also submitted plans to the USDA as of October 2019. *Id.*

74. Establishment of a Domestic Hemp Production Program, 84 Fed. Reg. at 58,523.

were adopted under the purview of the 2014 Farm Bill.<sup>75</sup> This leaves some activities that were legally questionable under the 2014 Farm Bill—including the commercial sale of CBD products—in murky legal territory for the time being.<sup>76</sup>

### C. The 2018 Farm Bill Clarifies the Legal Status of CBD

As indicated earlier, there was substantial confusion about the legal status of CBD after the enactment of the 2014 Farm Bill.<sup>77</sup> Indeed, two months before Congress passed the 2018 Farm Bill, one legal expert in the field called the legal status of CBD “one of the most misunderstood issues in the cannabis industry.”<sup>78</sup> Many companies began shipping CBD products across state lines and claiming that those products were legal.<sup>79</sup> Adding to the uncertainty, some media outlets reported that CBD was “legal”<sup>80</sup> while others claimed the opposite.<sup>81</sup>

75. See, e.g., Ellen Essman, *Hemp for One, Hemp for All? The Farm Bill, Industrial Hemp and What It Means for Ohio*, FARM OFF.—OHIO STATE U. EXTENSION (Dec. 27, 2018), <https://farmoffice.osu.edu/blog/thu-12272018-541pm/hemp-one-hemp-all%C2%A0-farm-bill-industrial-hemp-and-what-it-means-ohio> [<https://perma.cc/BLX7-398E>] (noting that Ohio’s bans on hemp cultivation and CBD oil sales are still in force regardless of the 2018 Farm Bill); Bart Taylor, *The Farm Bill Passed and Hemp Is Legal, Right? Not Quite. Here’s What’s Next*, COMPANY WK. (Jan. 27, 2019), <https://companyweek.com/articles/the-farm-bill-passed-and-hemp-is-legal.-well-not-yet.-heres-what-business-needs-to-know> [<https://perma.cc/JG6G-EHC4>] (explaining that the Colorado Department of Agriculture continues to operate under its pre-2018 hemp regulatory framework).

76. See, e.g., Hudak, *supra* note 16; Ian Stewart, *Will Hemp-Derived CBD Be Fully Legal with the Passage of the 2018 Farm Bill? Not Quite . . .*, CANNABIS BUS. EXECUTIVE (Dec. 5, 2018), <https://www.cannabisbusinessexecutive.com/2018/12/will-hemp-derived-cbd-be-fully-legal-with-passage-of-the-2018-farm-bill-not-quite/> [<https://perma.cc/67BS-PG53>] (noting that the FDA “still considers CBD unlawful in foods and supplements”).

77. See, e.g., Rod Kight, *Did Congress Just Quietly Legalize Hemp and CBD Nationwide?*, KIGHT ON CANNABIS (Mar. 3, 2016), <https://cannabusiness.law/did-congress-just-quietly-legalize-hemp-and-cbd-nationwide/> [<https://perma.cc/66R8-PV8C>] [hereinafter Kight, *Legalize Hemp*] (arguing that the Omnibus Appropriations Act of 2016 legalized the production, interstate transport, and sale of CBD in all fifty states regardless of states’ existing laws); Rod Kight, *The Rapidly Evolving Legal Status of CBD*, KIGHT ON CANNABIS (Oct. 12, 2018), <https://cannabusiness.law/the-rapidly-evolving-legal-status-of-cbd/> [<https://perma.cc/67BS-QLHJ>] [hereinafter Kight, *Legal Status of CBD*].

78. Kight, *Legal Status of CBD*, *supra* note 77.

79. See, e.g., *Is It Legal To Mail CBD Oil? [Here’s What the Laws Say]*, MARIJUANABREAK: BLOG (Aug. 6, 2019), <https://www.marijuanabreak.com/is-it-legal-to-mail-cbd-oil-the-right-answer/> [<https://perma.cc/G2W5-J3LV>].

80. See, e.g., Aaron Cadena, *Is CBD Legal? The Legal Status of CBD in 2018*, CBD+ ORIGIN, <https://cbdorigin.com/is-cbd-legal/> [<https://perma.cc/N3PR-WKYD>] (citing “[a] common misconception [that] the 2018 Farm Bill . . . legalized CBD regardless of if it was derived from hemp or marijuana”).

81. See, e.g., Mona Zhang, *No CBD Is Not ‘Legal In All 50 States,’* FORBES (Apr. 5, 2018), <https://www.forbes.com/sites/monazhang/2018/04/05/no-cbd-is-not-legal-in-all-50-states/#bf49887762c1> [<https://perma.cc/WR75-R5SL>] (“At best, the law is murky and open to differing interpretations.”).

In the midst of this confusion, the DEA maintained the position that the production of CBD remained illegal, whether derived from hemp or marijuana.<sup>82</sup> As the DEA emphasized, the CSA still listed THC as a Schedule I substance, and all CBD products contain some amount of THC.<sup>83</sup> Furthermore, the Federal Food, Drug, and Cosmetic Act (“FD&C Act”) prohibits the production of non-FDA-approved drug products for human consumption.<sup>84</sup> Regardless of its official position, there is no evidence that the DEA ever charged anyone for illegally producing CBD.<sup>85</sup>

The 2018 Farm Bill brings some clarity to the legal status of CBD. Contrary to some assertions by industry and media enthusiasts, however, the Bill does not legalize the compound generally.<sup>86</sup> Rather, it legalizes any cannabinoid derived from hemp plants (as opposed to marijuana plants), “if and only if that hemp is produced in a manner consistent with the Farm Bill, associated federal regulations, associate[d] state regulations, and by a licensed grower.”<sup>87</sup> This means that hemp-derived CBD is now legal, while CBD derived from plants containing greater than 0.3% THC (i.e., marijuana plants) continues to be an illegal Schedule I substance. Furthermore, until growers obtain a USDA- or state-issued permit, they may not legally produce hemp unless they are in compliance with the 2014 Farm Bill’s requirements.<sup>88</sup> Thus, to operate legally, hemp growers must obtain a license with a state that has an established hemp pilot program and must continue to qualify as growing hemp for “purposes of research,” as the 2014 Farm Bill prescribes.<sup>89</sup>

82. Alicia Wallace, *In the DEA’s Words: Agency Stance on CBD, Hemp Products and the Farm Bill*, CANNABIST (July 7, 2017, 7:16 PM), <https://www.thecannabist.co/2017/07/05/dea-statement-cbd-hemp-farm-bill-controlled-substances-act/83100/> [<https://perma.cc/S52S-MYWK>] (relaying a statement that the DEA provided to the media outlet).

83. *Id.*

84. *Id.* As part of its explanation of the illegality of CBD, the DEA also emphasized that shipping CBD across state lines violated the Justice Department’s guidance that has allowed states to operate their recreational marijuana industries. See John Hudak & Christine Stenglein, *DEA Guidance Is Clear: Cannabidiol Is Illegal and Always Has Been*, BROOKINGS (Feb. 6, 2017), <https://www.brookings.edu/blog/fixgov/2017/02/06/cannabidiol-illegal-and-always-has-been/> [<https://perma.cc/H59U-AWYL>].

85. Research into the DEA’s actions related to CBD revealed no indication that the agency has ever arrested anyone for the production, sale, or use of CBD. In 2017, a DEA spokesperson suggested that the agency had no intention to crack down on CBD in the future. Bob Segall, *DEA: Feds Won’t Arrest CBD Oil Users, Neither Should Indiana*, 13 WTHR (Nov. 6, 2017), <https://www.wthr.com/article/dea-feds-wont-arrest-cbd-oil-users-neither-should-indiana> [<https://perma.cc/QMR4-VHEA>] (quoting a DEA spokesperson who stated, “People are not dying from CBD. Some would argue lives are being saved by CBD. Are we going to get in the middle of that? Probably not”).

86. Hudak, *supra* note 16.

87. *Id.*

88. *Industrial Hemp*, U.S. DEP’T AGRIC. NAT’L INST. FOOD & AGRIC., <https://nifa.usda.gov/industrial-hemp> [<https://perma.cc/2GDN-6G7V>].

89. Agricultural Act of 2014, Pub. L. No. 113-79, § 7606(a)(1), (b)(B)(ii), 128 Stat. 649, 912 (codified as amended at 7 U.S.C. § 5940(a)(1), (b)(B)(ii) (2018)).

## III. REMAINING QUESTIONS UNDER THE 2018 FARM BILL

Although the 2018 Farm Bill in part clarifies the legal status of CBD on the federal level, two significant regulatory questions related to CBD remain. These questions concern (1) the FDA's stance on CBD added to ingestible products and (2) the labeling of CBD products. Resolving these issues in a timely way that both facilitates commerce in CBD products and safeguards consumers is essential for effective implementation of the 2018 Farm Bill and the future growth and legitimacy of the hemp products industry.

A. *Hemp-Derived CBD Added to Ingestible Products*

Food, drinks, and dietary supplements containing CBD have become increasingly available in recent years. Consumers in many cities can buy CBD-infused drinks and baked goods at local shops;<sup>90</sup> restaurants and bars across the country offer CBD entrees, desserts, and cocktails;<sup>91</sup> and CBD drinks and treats are widely available for purchase online.<sup>92</sup> Dietary supplements like CBD oil and capsules are even more widespread.<sup>93</sup>

90. See, e.g., Daniel Gerzina, *A Chicago Cafe Chain Will Start Serving CBD Coffee and Shakes*, EATER CHI. (Mar. 20, 2019), <https://chicago.eater.com/2019/3/20/18274130/protein-bar-cbd-coffee-shakes-chicago-purple-pig-restaurant-move-intel> [<https://perma.cc/ZZ3V-JACA>] (stating that a Chicago-based coffee chain is adding CBD oil to its menu as an optional add-on to any shake or coffee); Trevor Hughes, *Cannabis Food, Drinks To Be 2019's Hottest Dining Trend, Top Chefs Say*, USA TODAY (Jan. 10, 2019), <https://www.usatoday.com/story/news/2019/01/10/chefs-cannabis-food-drinks-2019-s-hottest-dining-trend/2520890002/> [<https://perma.cc/BDC2-SHW4>] (discussing a doughnut shop in Denver that tops their doughnuts with CBD-infused frosting and another restaurant in Colorado where customers can add CBD powder to cereal, coffee, and milkshakes); Amy McCarthy, *Houston's First CBD-Obsessed Coffee Shop Will of Course Open on 4/20*, EATER HOUS. (Apr. 15, 2019), <https://houston.eater.com/2019/4/15/18310990/houston-cbd-infused-coffee-the-smoking-pot-opening-spring-branch-420> [<https://perma.cc/L6HX-H75F> (staff-uploaded archive)] (announcing the opening of two CBD-focused coffee shops in Houston).

91. See, e.g., Melena Gurganus, *8 Bars Serving CBD-Infused Cocktails You Won't Want To Miss*, REMEDY REV. (June 18, 2019), <https://www.remedyreview.com/best-of-2018/8-bars-serving-cbd-infused-cocktails-you-wont-want-to-miss/> [<https://perma.cc/VGV5-CNWB> (staff-uploaded archive)] (reviewing bars that serve CBD-infused cocktails, including one Manhattan cocktail lounge that serves a cocktail called "Rocky Mountain High" containing bourbon and CBD-infused syrup); Erin Kuschner, *James Beard Award Winner Jody Adams Is Hosting a CBD-Infused Dinner*, BOSTON.COM (Feb. 21, 2019), <https://www.boston.com/food/restaurants/2019/02/21/jody-adams-trade-cbd-infused-dinner> [<https://perma.cc/NY9J-XJBE>] (detailing a four-course CBD-infused dinner featured at an upscale restaurant in Boston).

92. See, e.g., *Beverages*, VYBES, <https://idrinkvybes.com> [<https://perma.cc/MQP9-MJMF>] (selling CBD-infused drinks that come in flavors like blueberry mint and strawberry lavender); *Edibles*, HEMP STORE N.C., <https://www.thehempstorenc.com/edibles> [<https://perma.cc/PKX8-LGQW>] (selling CBD-infused honey, gummies, and fruit strips); *Shop*, CANNABINOID CREATIONS, <https://cannabinoidcreations.com/shop-cbd/> [<https://perma.cc/PW9K-2R64>] (selling CBD chocolate, soda, and hard candy).

93. See, e.g., *CBD Oil*, CBDISTILLERY, [https://www.thecbdillery.com/cbd-shop/tinctures/?irclid=W0mzNaQxwxyJRvD0MKVsfWfHUklVbJWcN2lp3g0&irgwc=1&utm\\_source=impact&Partner=Tuck&impactmediapartner=1233726](https://www.thecbdillery.com/cbd-shop/tinctures/?irclid=W0mzNaQxwxyJRvD0MKVsfWfHUklVbJWcN2lp3g0&irgwc=1&utm_source=impact&Partner=Tuck&impactmediapartner=1233726) [<https://perma.cc/RQ78-9BUY> (staff-uploaded archive)] (claiming that their products "work wonders for your overall well-being"); *CBD Products*,

The FDA, which retains authority under the 2018 Farm Bill to regulate cannabis-derived products,<sup>94</sup> did not take direct enforcement action to halt the infusion of CBD into food and beverages prior to the enactment of the Bill.<sup>95</sup> Shortly after the Bill was signed, however, then-FDA Commissioner Scott Gottlieb issued a statement in which he expressed the FDA's official view that introducing food or dietary supplements containing CBD or THC into interstate commerce is illegal per the FD&C Act.<sup>96</sup> Under the Act, a substance cannot be marketed as a dietary supplement or introduced into interstate commerce as a food ingredient if it is an active ingredient in an FDA-approved drug product or has been authorized for investigation as a new drug.<sup>97</sup> Given that both CBD and THC fall into the former category, it remains unlawful to sell CBD-infused food products across state lines or market CBD products as dietary supplements.<sup>98</sup> In his statement, Commissioner Gottlieb further asserted (rather opaquely) that the FDA planned to take "enforcement action needed to protect public health."<sup>99</sup>

Despite this ostensibly strict position, Commissioner Gottlieb suggested that the FDA may be willing to undertake additional evaluation of its position on hemp-derived CBD. He acknowledged that the FDA "has authority to issue a regulation allowing the use of a pharmaceutical ingredient in a food or dietary supplement" and indicated that the agency was taking "new steps to evaluate whether we should pursue such a process."<sup>100</sup> In keeping with that promise, the FDA held a public hearing in May 2019 to gather scientific data and information about products containing cannabis and cannabis-derived compounds,<sup>101</sup> and opened a comment period that closed in mid-July to solicit

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+CBDOIL, <https://pluscbdoil.com/cbd-products/> [<https://perma.cc/22EX-24FH>] (offering CBD sprays, gels, and capsules); *NuLeaf Naturals CBD Oil: Discover the Power Nature*, NULEAF NATS., <https://nuleafnaturals.com/shop/?rfsn=1725786.47e2e> [<https://perma.cc/ERQ5-Q3YZ> (staff-uploaded archive)] (advertising several human and pet products with a "full spectrum of synergistic cannabinoids and terpenes to optimize your wellness").

94. The FDA's regulation authority in this area comes from the FD&C Act and section 351 of the Public Health Service Act. *See* Agriculture Improvement Act of 2018, Pub. L. No. 115-334, § 10113, 132 Stat. 4490, 4914 (2018) (stating that nothing in the bill affects or modifies the FD&C Act or Section 351 of the Public Health Service Act); *see also* 21 U.S.C. §§ 321(ff)(3)(B), 331(ll) (2012); 42 U.S.C. § 262(a) (2012).

95. Based upon Commissioner Gottlieb's December 20, 2018, statement, the only steps taken by the FDA before passage of the 2018 Farm Bill involved sending warning letters to CBD companies that "claim to prevent, diagnose, treat, or cure serious diseases, such as cancer." Press Release, Scott Gottlieb, *supra* note 28.

96. *Id.*

97. *Id.*; *see also* 21 U.S.C. § 321(ff)(3)(B) (2012) (prohibiting use as a dietary supplement); *id.* § 331(ll) (prohibiting introduction into interstate commerce).

98. Press Release, Scott Gottlieb, *supra* note 28.

99. *Id.*

100. *Id.*

101. *See* Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing; Request for Comments, 84 Fed. Reg. 12,969–75 (Apr. 3, 2019)

input on the agency's future regulatory strategy.<sup>102</sup> The head of the FDA's work group on cannabinoids has said that the agency plans to provide an update on the agency's progress at the end of summer or during early fall 2019.<sup>103</sup> However, as of November 2019, the agency had not done so.

Since issuing the December 2018 statement, the FDA has sent seven warning letters to manufacturers selling CBD products as dietary supplements or food products.<sup>104</sup> Each of the companies that received letters had also made claims that CBD treats or prevents various diseases.<sup>105</sup> Beyond this, the agency has taken virtually no action to enforce its position that CBD may not legally be added to food or supplements.<sup>106</sup> The only exception appears to be an incident in January 2019 in which FDA officials reportedly confiscated several edible CBD products from the shelves of a smoke shop located in Yuma,

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(to be codified at 21 C.F.R. pt. 15); see also *Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing*, U.S. FOOD & DRUG ADMIN. (May 31, 2019), <https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/scientific-data-and-information-about-products-containing-cannabis-or-cannabis-derived-compounds> [<https://perma.cc/GJ7K-XB57>].

102. See *Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing; Request for Comments*, 84 Fed. Reg. at 12,969–75; see also *Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds; Request for Comments*, REGULATIONS.GOV, <https://www.regulations.gov/docket?D=FDA-2019-N-1482> [<https://perma.cc/N7ZK-GW77>].

103. Amy Abernethy (@DrAbernethyFDA), TWITTER (July 12, 2019, 12:44 PM), <https://twitter.com/drabernethyFDA?lang=en> [<https://perma.cc/5F6A-NJM8> (staff-uploaded archive)].

104. See *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> [<https://perma.cc/RS4E-9PFW> (staff-uploaded archive)] (listing warning letters to firms in Massachusetts, New Jersey, Arkansas, Washington, and Florida). One of these warning letters made headlines in July 2019 when the FDA issued a letter to Curaleaf, Inc., an online retailer in CBD products, for making “unsubstantiated claims that [their] products treat cancer, Alzheimer’s disease, opioid withdrawal, pain and pet anxiety, among other conditions or diseases.” *FDA Warns Company Marketing Unapproved Cannabidiol Products with Unsubstantiated Claims to Treat Cancer, Alzheimer’s Disease, Opioid Withdrawal, Pain and Pet Anxiety*, U.S. FOOD & DRUG ADMIN. (July 23, 2019), <https://www.fda.gov/news-events/press-announcements/fda-warns-company-marketing-unapproved-cannabidiol-products-unsubstantiated-claims-treat-cancer> [<https://perma.cc/7U94-K4WQ>]. Although the warning letter also admonished Curaleaf for suggesting that some of its products were dietary supplements, *Warning Letter: Curaleaf, Inc.*, U.S. FOOD & DRUG ADMIN. (July 22, 2019), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/curaleaf-inc-579289-07222019> [<https://perma.cc/63DZ-7R5U>], the FDA’s press release on the subject strongly suggests the FDA was primarily concerned about the company’s therapeutic and disease claims, see *FDA Warns Company Marketing Unapproved Cannabidiol Products with Unsubstantiated Claims to Treat Cancer, Alzheimer’s Disease, Opioid Withdrawal, Pain and Pet Anxiety*, *supra*.

105. See *Warning Letters and Test Results for Cannabidiol-Related Products*, *supra* note 104.

106. See Tiffany Hsu, *Ads Pitching CBD as a Cure-All Are Everywhere. Oversight Hasn’t Kept Up*, N.Y. TIMES (Aug. 13, 2019), <https://www.nytimes.com/2019/08/13/business/media/cbd-marijuana-fda.html> [<https://perma.cc/Y6SZ-DPD4> (dark archive)].

Arizona, without showing a warrant, and told the owner that CBD cannot be sold for human consumption.<sup>107</sup>

Perhaps due to the FDA's lack of enforcement activity, or to the prodding of the agency, some state and local officials have started taking action to prohibit CBD-infused food products.<sup>108</sup> For example, the California Department of Public Health has taken a hard line against the addition of CBD to food products, even though the state permits the addition of marijuana-derived compounds to "edible" products.<sup>109</sup> In February 2019, the North Carolina Department of Agriculture announced that it would begin issuing warning letters informing businesses that they must discontinue selling any food products or dietary supplements that contain CBD.<sup>110</sup> Moreover, New York City began notifying restaurants in early 2019 that they may not offer products containing CBD until the product is deemed safe as a food additive and the city implemented an official ban in July 2019.<sup>111</sup> The state of Washington joined the trend in August 2019 and banned CBD as a food and drink ingredient.<sup>112</sup>

107. Alison Malsbury, *FDA Enforcement Against Hemp-CBD Products Has Begun*, CANNA L. BLOG (Jan. 15, 2019), <https://www.cannalawblog.com/fda-enforcement-against-hemp-cbd-products-has-begun/> [<https://perma.cc/HJY7-MP6S>].

108. See Gaby Del Valle, *CBD Edibles Are Everywhere Now. They Also Might Be Illegal.*, VOX (Feb. 20, 2019), <https://www.vox.com/the-goods/2019/2/7/18215829/cbd-edibles-illegal-new-york-maine-ohio> [<https://perma.cc/YGL8-X6HA>]; Mona Zhang, *The FDA Won't Say Whether It's Behind the CBD Crackdown*, WORD ON THE TREE (Feb. 11, 2019), <https://wordonthetree.com/2019/02/11/the-fda-wont-say-whether-its-behind-the-cbd-crackdown/> [<https://perma.cc/C5VR-4FT8>].

109. See *FAQ—Industrial Hemp and Cannabidiol (CBD) in Food Products*, CAL. DEP'T PUB. HEALTH, <https://www.cdph.ca.gov/Programs/CEH/DFDCS/CDPH%20Document%20Library/FDB/FoodSafetyProgram/HEMP/Web%20template%20for%20FSS%20Rounded%20-%20Final.pdf> [<https://perma.cc/3XDH-S9E4>] ("[A]lthough California currently allows the manufacturing and sales of cannabis products (including edibles), the use of industrial hemp as the source of CBD to be added to food products is prohibited.")

110. Kamran Aryah, *North Carolina Is Most Recent State To Follow FDA Position on CBD*, KIGHT ON CANNABIS (Feb. 22, 2019), <https://cannabusiness.law/north-carolina-is-most-recent-state-to-follow-fda-position-on-cbd/> [<https://perma.cc/U9DX-2BGT>]. The North Carolina House of Representatives also voted in August 2019 to ban "smokable" hemp products. Dawn Baumgartner Vaughan, *NC House Votes for Ban on Smokable Hemp, Reacting to Police Concern over Pot Arrests*, NEWS & OBSERVER (Aug. 21, 2019), <https://www.newsobserver.com/news/politics-government/article234178387.html> [<https://perma.cc/JAL7-TLXE> (staff-uploaded archive)].

111. Eva Kis, *New York Suddenly Bans Trendy CBD from Bars and Restaurants*, METRO (Feb. 5, 2019), <https://www.metro.us/things-to-do/new-york/nyc-cbd-ban-bars-restaurants> [<https://perma.cc/K4ER-M7RK>]. The New York City Department of Health announced that it would not embargo products containing CBD until July 1, 2019, and would not start issuing violations and fines to non-compliant businesses until October 1, 2019. Serena Dai, *Health Department Slows Down Controversial CBD Edible Crackdown*, EATER NEW YORK (Feb. 15, 2019), <https://ny.eater.com/2019/2/15/18226472/cbd-edibles-ban-october-fine-doh-nyc> [<https://perma.cc/G6PD-DKKZ>]; Anna Sanders, *NYC Ban on CBD Food and Drink Products Goes into Effect*, N.Y. DAILY NEWS (July 1, 2019), <https://www.nydailynews.com/news/politics/ny-nyc-cbd-ban-food-drink-cannabis-cannabidiol-20190701-zeujlfujjdfjp4i5vt46rhnmm-story.html> [<https://perma.cc/A6ER-5JRY>].

112. Press Release, State of Wash. Dep't of Agric., *Restrictions on the Use of CBD as a Food Ingredient* (Aug. 1, 2019), [https://cms.agr.wa.gov/getmedia/595b6e0a-8490-40cf-8fd6-7669f1610c60/CBD\\_Statement\\_08-01-19-\(002\)](https://cms.agr.wa.gov/getmedia/595b6e0a-8490-40cf-8fd6-7669f1610c60/CBD_Statement_08-01-19-(002)) [<https://perma.cc/NDW9-MUB7>].

Several hemp-related businesses and associations have been critical of the FDA statement and subsequent inaction. In January 2019, a group of health and natural products-related associations jointly urged the FDA to use its rulemaking authority to expressly confirm that the FD&C Act permits the sale of foods and dietary supplements containing CBD.<sup>113</sup> They warned that, “if [the] FDA fails to act, consumer interest in CBD will continue to grow along with a thriving—albeit potentially unlawful—array of CBD and hemp products.”<sup>114</sup> Members of Congress have also urged the FDA to update its regulations and alleviate the confusion that has resulted from the FDA statement and state and local enforcement efforts.<sup>115</sup>

As at least one legal expert has stated, at this point it appears that the FDA will either (1) authorize CBD as an ingredient for food and dietary supplements, (2) continue holding its present position without enforcing it, or (3) attempt to enforce its current position.<sup>116</sup> Unfortunately, it continues to be unclear which avenue the FDA will follow.

The most prudent course of action would be for the FDA to select the first avenue and take swift action to adopt formal rules that authorize hemp-derived CBD as an ingredient in foods and dietary supplements.<sup>117</sup> Having a consistent and binding federal approach would facilitate interstate transportation of CBD products as intended by the 2018 Farm Bill, allow economic certainty for hemp farmers and retailers across the country, and preserve state and local health and law enforcement resources for more pressing concerns.<sup>118</sup>

113. See Letter from Michael McGuffin et al., to Scott Gottlieb, Comm’r of Food & Drug Admin. 1–3 (Jan. 8, 2019), <https://www.crnusa.org/sites/default/files/thereport/190121/Gottlieb-CBD%20letter-trade%20associations%201-8-2019.pdf> [<https://perma.cc/EC4W-Z7D5>].

114. *Id.* at 2.

115. Emilie Munson, *Schumer Presses FDA To Regulate Budding CBD Industry*, TIMESUNION (Oct. 23, 2019), <https://www.timesunion.com/news/article/Schumer-presses-FDA-to-regulate-budding-CBD-14556538.php> [<https://perma.cc/UWV5-XTXG>]; Bill Weinberg, *Congress Members Demand Clarification on CBD*, CANNABISNOW (Feb. 20, 2019), <https://cannabisnow.com/congress-members-demand-fda-clarification-on-cbd/> [<https://perma.cc/N5SS-NS75>]. In addition to California, North Carolina, and New York City, other states and local governments have taken action. Meghana Shah & Melissa L. Fox, *The Uncertain Status of Food Products Containing CBD*, N.Y. L.J. (July 30, 2019), <https://www.law.com/newyorklawjournal/2019/07/30/the-uncertain-status-of-food-products-containing-cbd/> [<https://perma.cc/X6HK-RME2>]. For instance, Massachusetts banned the sale of CBD-infused foods and dietary supplements, Ohio embargoed all CBD products being sold outside of licensed dispensaries, and Maine took similar steps but reversed its ban a mere three months later due to a negative public response. *Id.*

116. Rod Kight, *Two Pivotal Issues Will Define Hemp and CBD in 2019*, KIGHT ON CANNABIS (Dec. 26, 2018), <https://cannabusiness.law/two-pivotal-issues-will-define-hemp-and-cbd-in-2019/> [<https://perma.cc/UGW7-X2KS>].

117. This was one of the possible approaches mentioned in Commissioner Gottlieb’s December 2018 statement. See Press Release, Scott Gottlieb, *supra* note 28.

118. See, e.g., Liam Niemeyer, *‘Gold Rush’: Cannabidiol Industry Booms Amid Uncertain Regulation*, NPR (May 30, 2019), <https://www.npr.org/2019/05/30/727523290/gold-rush-cannabidiol-industry-booms-amid-uncertain-regulation> [<https://perma.cc/MYN4-KM26>] (discussing the economic

Before adopting such an approach, the FDA would, of course, need to be convinced that CBD is safe for inclusion in such products. Research into the safety of CBD is in its early stages.<sup>119</sup> However, early reports have shown little abuse or dependence potential and have not identified major public health concerns.<sup>120</sup> Nonetheless, CBD has been shown to cause some undesirable side effects, including nausea, fatigue, and negative interactions with a certain type of blood thinner.<sup>121</sup> More research into CBD is certainly needed, and future studies will undoubtedly illuminate the compound's effects, both positive and negative.

Should the FDA simply continue to hold the position that hemp-derived CBD may not be added to food or dietary supplements, with or without pursuing active enforcement, the most prudent position for states to take is to follow the FDA's guidance on the issue and enlist the help of local authorities to enforce the prohibition of CBD-infused products. It seems wise to follow New York City's approach, under which authorities first take time to educate restaurants and producers about the prohibition and only impose "embargos" or fines if noncompliance persists.<sup>122</sup> States should also adopt formal rules to ensure regulated members of the public have adequate notice of the prohibited conduct. As noted by North Carolina Department of Agriculture and Consumer Services Commissioner Joe Reardon, it would also be advisable for states to use their rulemaking authority to adopt standards for the extraction, production, packaging, and labeling of CBD products.<sup>123</sup>

#### B. *Labeling of CBD Products*

The 2018 Farm Bill legalizes the cultivation of hemp by licensed growers and the interstate commerce of hemp-derived products but is silent on how to label those products.<sup>124</sup> This lack of guidance is a problem for consumers—particularly those who buy products online or live in states without regulated dispensaries—because it leaves online retailers and unlicensed shops to their

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uncertainty that exists for companies selling CBD products while they await the FDA's next move—one company's high ranking officer expressed the view that "the over \$1 billion in sales predicted by his firm is largely dependent on if the FDA is lenient on regulation").

119. See Grinspoon, *supra* note 17.

120. *Id.*

121. *Id.*

122. Angelica LaViot & Thomas Franck, *New York City Plans To Start Fining Restaurants that Use CBD in Food and Drink*, CNBC (Feb. 15, 2019), <https://www.cnbc.com/2019/02/15/new-york-may-start-fining-restaurants-for-using-weed-related-cbd-.html> [<https://perma.cc/FA5X-LQXM>].

123. See *Q&A with Joe Reardon of NCDACS About Medicine Mamas, CBD Prohibition, Inspections and Pigs*, CBD OIL FOR PETS (Feb. 13, 2019), <https://cbdOilforpets.org/qa-with-joe-reardon-of-ncdacs-about-medicine-mamas-cbd-prohibition-inspections-and-pigs-carolina-cannabis-news/> [<https://perma.cc/HZ9X-NYUD>].

124. See Agriculture Improvement Act of 2018, Pub. L. No. 115-334, § 10113, 132 Stat. 4490, 4908 (2018) (omitting any guidance regarding the labeling of hemp-derived products).

own devices regarding what ingredients to put in the product, how much of each ingredient to include, and what to communicate to the public on the product's packaging.<sup>125</sup> For this very reason, the deputy director of one prominent legal reform organization has referred to the CBD market as “the Wild West.”<sup>126</sup>

In all likelihood, the FDA has jurisdiction over the labeling of all hemp-derived products. Given the agency's authority to regulate the labeling of food,<sup>127</sup> dietary supplements,<sup>128</sup> and cosmetics,<sup>129</sup> CBD products within those categories certainly fall under the FDA's purview. Somewhat less clear, however, is whether the FDA has jurisdiction over “smokable” hemp products, including vaporizer pens and hemp flowers (or “buds”).<sup>130</sup> The agency's most likely hook for establishing jurisdiction over smokable hemp products is to consider them as “drugs” under the FD&C Act.<sup>131</sup> The FD&C Act defines drugs as products “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” or “intended to affect the structure or any function of the body.”<sup>132</sup> To determine a product's “intended use,” the FDA considers how the product is labeled, advertised, and perceived by consumers, or if it contains an ingredient with a well-known therapeutic use.<sup>133</sup> Due to the health claims that frequently accompany CBD products, and perhaps due to public perception of CBD as a treatment for various maladies, CBD products, including those in smokable form, would very likely constitute drugs under the FDA's definition. Accordingly, it appears the FDA will have authority to regulate any product containing CBD.

Standardized labeling of hemp products and oversight of that labeling are key issues for several reasons. Most importantly, labeling regulations would ensure a degree of safety for consumers that is shockingly missing in the

125. See Paul Armentano, *The Dangers of CBD*, PREVENTION, Oct. 2019, at 48, 51–53.

126. *Id.* at 53 (quoting Paul Armentano, deputy director of the National Organization for the Reform of Marijuana Laws (“NORML”).

127. U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: FOOD LABELING GUIDE (2013), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-labeling-guide> [<https://perma.cc/BRV9-7H56>].

128. See, U.S. FOOD & DRUG ADMIN., DIETARY SUPPLEMENT LABELING GUIDE (2005), <https://www.fda.gov/food/dietary-supplements-guidance-documents-regulatory-information/dietary-supplement-labeling-guide> [<https://perma.cc/4HR3-FCTK>].

129. See *Cosmetics Labeling*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/cosmetics/cosmetics-labeling> [<https://perma.cc/F37Q-XGC7>].

130. See Nathalie Bougenies, *The Federal Legality of CBD Smokable Products*, CANNA L. BLOG (Mar. 7, 2019), <https://www.cannalawblog.com/the-federal-legality-of-cbd-smokable-products/> [<https://perma.cc/4JPK-KNLW>].

131. See *id.*

132. 21 U.S.C. § 321(g)(1) (2012).

133. See *Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)*, U.S. FOOD & DRUG ADMIN., [https://www.fda.gov/cosmetics/cosmetics-laws-regulations/it-cosmetic-drug-or-both-or-it-soap#Intended\\_use](https://www.fda.gov/cosmetics/cosmetics-laws-regulations/it-cosmetic-drug-or-both-or-it-soap#Intended_use) [<https://perma.cc/TA5Z-JWTD>].

industry at the present moment. For instance, a November 2018 study found that samples of CBD oil obtained from one manufacturer contained chemicals not disclosed in company materials that “may lead to unexpected psychoactive effects,” such as a synthetic cannabinoid and dextromethorphan, a chemical found in cough medicine with a history of recreational abuse.<sup>134</sup> Another study, which examined eighty-four CBD products purchased online from thirty-one different companies, determined that only about a third of the products contained the amount of CBD promised on the label, and eighteen products had unexpected amounts of THC.<sup>135</sup> While the researchers stated that the underlabeling of CBD content was “less concerning” than overlabeling,<sup>136</sup> consuming more CBD than anticipated could intensify unwanted side effects or even increase the possibility that CBD will interfere with other medications in a person’s system.<sup>137</sup> The authors concluded that “[d]iscrepancies between federal and state cannabis laws have resulted in inadequate regulation and oversight, leading to inaccurate labeling of some products.”<sup>138</sup>

The rampant mislabeling of hemp products is further concerning because consumers and industry members may face legal ramifications for possessing legal products that appear to be derived from marijuana. For instance, the fact that the hemp plant and its flowers are nearly identical to their marijuana counterparts may lead to false arrests.<sup>139</sup> In one alarming example, local police in Oklahoma seized a truckload of industrial hemp that was in transit from Kentucky to Colorado and arrested the driver and three others based on a mistaken belief that they were trafficking in illegal marijuana.<sup>140</sup> Consumers in possession of CBD products may also be at risk because CBD derived from marijuana is illegal. Thus, it is important to accurately label the product with

134. Janet Burns, *Tests of CBD Oils Reveal Three Surprise Chemicals, One Big Problem*, LEAFLY (Dec. 20, 2018), <https://www.leafly.com/news/industry/tests-of-cbd-oils-reveal-three-surprise-chemicals-one-big-problem> [https://perma.cc/88U4-72JH].

135. Marcel O. Bonn-Miller et al., *Labeling Accuracy of Cannabidiol Extracts Sold Online*, JAMA 1708, 1708–09 (2017), <https://jamanetwork.com/journals/jama/fullarticle/2661569> [https://perma.cc/RM6J-GKXH] (finding that more than 42% of the products contained a higher concentration than indicated on the package label and 26% contained a lower concentration of CBD than shown on the label).

136. *Id.* at 1709 (“Underlabeling is less concerning [than overlabeling] as CBD appears to neither have abuse liability nor serious adverse consequences at high doses.”).

137. Armentano, *supra* note 125, at 53.

138. Bonn-Miller et al., *supra* note 135, at 1709.

139. See Will Doran, *NC Rep Says Concerns Over Link Between Hemp, Marijuana Aren’t Based in Science*, POLITIFACT N.C. (June 14, 2016), <https://www.politifact.com/north-carolina/statements/2016/jun/14/larry-yarborough/fears-marijuana-inspire-more-hemp-regulations-stat/> [https://perma.cc/UWB6-FCD2]; Damian Mann, *It Could Be Hemp*, MAIL TRIB. (Oct. 10, 2016), <http://mailtribune.com/news/happening-now/it-could-be-hemp> [https://perma.cc/AW28-MP2Y (dark archive)].

140. Michael Konopasek, *Local Hemp Manufacturer Claims \$500k-Worth of Legal Hemp Confiscated in Oklahoma*, FOX 31 DENVER, <https://kdvr.com/2019/01/14/local-hemp-manufacturer-claims-500k-worth-of-legal-hemp-confiscated-in-oklahoma/> [https://perma.cc/HX6R-6VCJ].

the identity of the plant from which it was extracted and accurately report the THC level as falling within the parameters allowed by the Farm Bill so that consumers avoid unwanted interactions with law enforcement or even mistaken arrests.

Thus far, the FDA has not stepped forward with a proposal to fill the regulatory void. Some states, such as Indiana,<sup>141</sup> Utah,<sup>142</sup> and California,<sup>143</sup> have put laws and rules in place governing the manufacturing and labeling of CBD and other hemp products. In addition, some hemp industry associations have devised their own manufacturing and labeling protocols. Most notably, the Hemp Roundtable and Hemp Industries Association have developed the U.S. Hemp Authority Certification Program under which hemp producers would be required to pay to participate in a program to obtain licensing and certification.<sup>144</sup> Others in the hemp industry have expressed concern that large operators would control this labeling program and that the cost of participation in the program would pose a barrier to many small farmers.<sup>145</sup> Among other things, they have objected to the program's failure to ensure that consumers are notified of the territorial source of hemp products, the use of genetically-modified organisms, or whether organic methods or materials were used in cultivation.<sup>146</sup> Particularly given the concern that large operators would limit

141. See IND. CODE ANN. §§ 24-4-21 to -22 (Westlaw through 2019 legislation); see also Daniel Shortt, *Labeling CBD Products: The Unique Case of Indiana*, CANNA L. BLOG (July 14, 2018), <https://www.cannalawblog.com/labeling-cbd-products-the-unique-case-of-indiana/> [<https://perma.cc/R9UV-BYF9>].

142. See UTAH CODE ANN. § 4-41-101 to -104 (Westlaw through 2019 First Special Sess.); UTAH ADMIN. CODE r. 68-26 (Westlaw through rules published in the Utah State Bulletin Number 2019-20, Oct. 15, 2019); see also Cristina Flores, *CBD Companies Must Register and Label Their Products, per New Utah Rule*, 2 KUTV (Nov. 19, 2018), <https://kutv.com/news/local/cbd-companies-register-and-label-their-products-per-new-utah-rule> [<https://perma.cc/6DSS-5GMJ>]; Taylor Hartman, *Utah Department of Agriculture and Food Announces New Rule for Sale of CBD Oils*, FOX 13 SALT LAKE CITY (Nov. 16, 2018), <https://fox13now.com/2018/11/16/utah-department-of-agriculture-and-food-to-register-hemp-based-products-like-cbd-oil-for-legal-purchase/> [<https://perma.cc/F5FW-Y5FP>].

143. See CAL. FOOD & AGRIC. CODE §§ 81000-81011 (West Supp. 2019).

144. See U.S. HEMP AUTH. CERTIFICATION PROGRAM, GUIDANCE PROCEDURES (2019), [https://www.ushempauthority.org/docs/US-Hemp-Authority\\_Certification-Program-Guidance\\_05-28-19.pdf](https://www.ushempauthority.org/docs/US-Hemp-Authority_Certification-Program-Guidance_05-28-19.pdf) [<https://perma.cc/6RKY-Z8T2>]. To become certified under the U.S. Hemp Authority Certification Program, producers must pass a third-party audit, sign a licensing agreement, and pay an annual licensing fee. U.S. HEMP AUTH. CERTIFICATION PROGRAM, FREQUENTLY ASKED QUESTIONS 1-3 (2019) [hereinafter U.S. HEMP AUTH., FAQ], [https://www.ushempauthority.org/docs/US-Hemp-Authority\\_FAQ\\_04-16-19.pdf](https://www.ushempauthority.org/docs/US-Hemp-Authority_FAQ_04-16-19.pdf) [<https://perma.cc/2FM6-Y8CV>].

145. Rod Kight, *Open Letter Regarding the US Hemp Authority Certification Program*, KIGHT ON CANNABIS (Feb. 17, 2019), <https://cannabusiness.law/open-letter-regarding-the-us-hemp-authority-certification-program/> [<https://perma.cc/4DXD-B9L9>] [hereinafter Kight, *Open Letter*]. The grower licensing fee for farms under ten acres is \$1000 per year. U.S. HEMP AUTH., FAQ, at 1. For farms over ten acres, the annual fee is \$2000. *Id.* at 1.

146. Kight, *Open Letter*, *supra* note 145.

industry participation, self-regulation of manufacturing and labeling may not be good public policy.

In order to ensure the quality and safety of hemp and its derived products, there is a need to develop and enforce uniform standards governing the manufacturing and labeling of such products. Thus, the best approach to facilitate nationwide consistency and interstate marketing of these products would be federally imposed standards and oversight. However, if Congress and federal regulatory agencies continue to be slow to develop a regulatory scheme for this rapidly expanding industry, states should take proactive steps to implement their own regulations.

The approach taken in Indiana provides a helpful framework for other states to follow. In March 2018, Indiana legalized the distribution and retail sale of “low THC hemp,”<sup>147</sup> which is defined as a product that meets the definition of industrial hemp, contains no more than 0.3% THC, and contains “no other controlled substances.”<sup>148</sup> This statute also imposes mandatory testing and labeling requirements.<sup>149</sup> As a threshold matter, low-THC hemp extracts may only be sold in Indiana if (1) a random sample of the batch of hemp from which the product was extracted has been tested by an accredited, independent laboratory, and (2) the results of that testing show that the sample contains no more than 0.3% THC.<sup>150</sup>

If that initial testing requirement is satisfied, Indiana allows low THC hemp products to be distributed in packaging that meets two requirements. First, the packaging must have a scannable bar code or QR code that is linked to a document that contains required information about the manufacturing process, such as the ingredients used, the batch identification number, expiration date, and a link that can be used to download the certificate of analysis for the low THC extract.<sup>151</sup> Second, the packaging itself must also identify the batch number, provide an internet address where batch information can be obtained, specify the expiration date, state the number of milligrams of low-THC hemp extract in the package, identify the manufacturer, and confirm that the product does not contain more than 0.3% THC.<sup>152</sup> This list of required disclosures is quite similar to those required for cannabis products in Washington, Oregon, and California.<sup>153</sup>

While the Indiana law provides a good starting point for other states to follow, states should consider how significant the costs associated with the

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147. IND. CODE ANN. § 24-4-21 (Westlaw through First Reg. Sess. of 121st Gen. Assemb.).

148. *Id.* §§ 24-4-21-1(3), 35-48-1-17.5.

149. *Id.* §§ 24-4-21-3 to -4.

150. *Id.* § 24-4-21-3.

151. *Id.* § 24-4-21-4(a)(1).

152. *Id.* § 24-4-21-4(a)(2)-(7).

153. Shortt, *supra* note 141.

testing and labeling provisions will be and whether public grants or other measures could be used to alleviate the impact on small farmers and those from disadvantaged or economically depressed areas.<sup>154</sup> In keeping with the recommendations made for improvement in the U.S. Hemp Authority Certification Program that were discussed above, states should also consider requiring that the packaging include information about country of origin and organic materials. Finally, to avoid drawing the FDA's ire, statutes or rules governing labeling should contain strong language prohibiting industrial hemp producers from making any claim that their product prevents or treats serious diseases.

### CONCLUSION

By legalizing large-scale hemp cultivation and establishing a framework for its regulation, the 2018 Farm Bill removes much of the marijuana-associated stigma from the crop, largely alleviates the confusion that existed under the 2014 Farm Bill, and introduces a significant business opportunity for farmers and retailers across the United States. Nonetheless, the unique position of hemp and CBD as close relatives of a controlled substance creates complications for their regulation that do not exist for other crops and consumer goods. To ensure consumer safety and provide clear and consistent guidelines for producers and sellers, federal agencies should act swiftly to study and approve the addition of CBD to food products and establish CBD labeling requirements. In the absence of federal action, states must step in and regulate those aspects of the industry themselves. The 2018 Farm Bill certainly sets the stage for the hemp and CBD markets to flourish, but the manner in which the Bill's regulatory gaps are resolved will play a significant role in determining the success of these fledgling industries.

SHANNON SMITH\*\*

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154. North Carolina's industrial hemp law directs the Industrial Hemp Commission to include "incentive provisions" in its license fees "to encourage the participation of small acreage farmers." N.C. GEN. STAT. § 106-568.53(3)(a) (2017). It also permits the Commission to create "fair and reasonable licensing preferences" for license applicants from North Carolina counties that have been recognized as economically depressed or disadvantaged. *Id.* § 106-568.53(3)(b). The Commission is further empowered to "receive gifts, grants, federal funds, and any other funds both public and private needed to support the Commission's duties and programs." *Id.* § 106-568.53(4).

\*\* I would like to thank my Primary Editor, Erin Bennett, as well as the entire *North Carolina Law Review* Volume 98 Board of Editors and Staff for their diligent editing of this piece. I am also forever grateful to my mom and dad, who ingrained in me an interest in law and politics and continuously support me in everything I do. Finally, I would like to thank my partner, Justin, who frequently reminds me that there are more important things in life than law school.