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# THE LEGAL STATUS OF CANNABIDIOL OIL AND THE NEED FOR CONGRESSIONAL ACTION

SHELLY B. DEADDER, J.D.<sup>1</sup>

## INTRODUCTION

Over 65 million people worldwide suffer from epileptic conditions and approximately one-third of these individuals have medically refractory epilepsy, meaning they are unresponsive to medical therapy.<sup>2</sup> Dravet syndrome (DS), also known as severe myoclonic epilepsy in infancy, is one type of medically refractory epilepsy that “leads to intellectual disability, motor impairment, and dependence in adulthood.”<sup>3</sup> Approximately one child in every 40,900 is born with this catastrophic disease, most commonly the result of a mutation in the SCN1A sodium channel gene.<sup>4</sup> Typically, the first seizure occurs during the child’s first year of life and is mistakenly diagnosed as “accidental” or fever related; however, within weeks or months, additional seizures occur.<sup>5</sup> Between one and five years of age, up to

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2. Craig A. Press et al., *Parental Reporting of Response to Oral Cannabis Extracts for Treatment of Refractory Epilepsy*, 45 *EPILEPSY & BEHAVIOR* 49, 49 (2015).

3. Elaine C. Wirrell et al., *Stripentol in Dravet Syndrome: Results of a Retrospective U.S. Study*, 54(9) *EPILEPSIA* 1595, 1595 (2013).

4. *Id.*

5. Charlotte Dravet, *The Core Dravet Syndrome Phenotype*, 52 *EPILEPSIA* (Suppl. 2) 3, 4 (2011).

five different types of seizures emerge of varying duration and intensity, coinciding with developmental delays and behavioral regression.<sup>6</sup> After age five, the disease tends to stabilize and seizures become less frequent, but many children have already suffered irreparable mental and physical impairments, including the inability to construct simple sentences, undeveloped fine motor skills, and poor hand-eye coordination.<sup>7</sup>

Studies indicate that the prognosis is improved if seizure control is established at a young age.<sup>8</sup> However, DS is one of the most pharmacoresistant forms of epilepsy; various pharmaceuticals have been prescribed alone and in combination, but none have been able to eliminate the seizures these children endure.<sup>9</sup> A promising treatment using cannabidiol (CBD) oil, derived from industrial hemp, offers hope to many of these children and their families. The problem is that the federal Controlled Substances Act (CSA), enforced by the Department of Justice (DOJ) and the Drug Enforcement Administration (DEA), classifies domestically grown industrial hemp as a Schedule 1 controlled substance.<sup>10</sup> Consequently, with limited exceptions, American companies that produce CBD oil with domestically grown industrial hemp, and parents who administer it to their children, are in violation of federal law.

This article examines the need to enact federal legislation to legalize the domestic production of industrial hemp and CBD oil. Part One explores the recent surge in the use of CBD oil to reduce seizures. Part Two examines the inconsistencies between federal statutes, case law, and federal enforcement policy, as well as the various legislative responses from the states. Part Three discusses

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6.*Id.* at 4, 6.

7.*Id.* at 6.

8. See Mari Akiyama et al., *A Long-term Follow-up Study of Dravet Syndrome Up to Adulthood*, 51(6) *EPILEPSIA* 1043, 1051 (2001).

9. Catherine Chiron et al., *The Pharmacologic Treatment of Dravet Syndrome*, 52 *EPILEPSIA* (Suppl. 2) 72, 72-73 (2011).

10. 21 U.S.C. § 802(16) (2012) (defining marijuana); 21 U.S.C. § 812(c)(10) (2012) (designating any part of the plant *Cannabis sativa* as a Schedule 1 controlled substance); 21 C.F.R. § 1308.11(d)(23), (31). The CSA classifies all drugs within five schedules. 21 U.S.C. § 801(a) (2012). Drugs placed in Schedule 1 have “no currently accepted medical use in treatment in the United States” and a high potential for abuse. 21 U.S.C. § 812(b).

the resulting limitations on research efforts. Finally, Part Four recommends a federal legislative solution.

#### PART 1: THE RISE OF CBD OIL

In 2006, Paige Figi gave birth to two healthy twin girls, Charlotte and Chase Figi. They were happy, “easy” babies.<sup>11</sup> The twins were developing normally, but when Charlotte was around three months old, she had her first seizure, which was diagnosed as fever related, a “fluke.”<sup>12</sup> Soon thereafter, Charlotte began having more seizures, and, by age two, the seizures had become constant.<sup>13</sup> According to her mother, “she was slipping away.”<sup>14</sup> In addition to the crippling seizures and declining cognitive development, she began having behavioral problems—attention deficit, hyperactivity, and self-injury.<sup>15</sup> Charlotte was diagnosed with DS and began pharmaceutical regimens, dietary alterations, and even acupuncture, but nothing controlled the seizures.<sup>16</sup> In fact, some of the drugs she was prescribed almost killed her.<sup>17</sup> By age five, Charlotte was having three hundred seizures per week, approximately two every hour.<sup>18</sup> She was virtually catatonic, and, at one point, she was placed in a medically induced coma so her fragile brain and body could recuperate.<sup>19</sup>

Paige and her husband Matt had given up hope that modern medicine could save their daughter’s life.<sup>20</sup> While deployed in Afghanistan, Matt saw a video online of a young boy with DS being treated with marijuana.<sup>21</sup> The boy had been seizure-free for four

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11. *WEED: A Dr. Sanjay Gupta Investigation* (CNN television broadcast Aug. 11, 2013), available at <http://www.cnn.com/TRANSCRIPTS/1308/11/se.01.html> (broadcast transcript of Dr. Gupta’s interviews with the Figis and the Stanley brothers).

12. *Id.*

13. *Id.*

14. *Id.*

15. *Id.*

16. *Id.*

17. *Id.*

18. *Id.*

19. *Id.*

20. *Id.*

21. *Id.*

days.<sup>22</sup> Desperate for help, Matt and Paige took Charlotte to Colorado where medical marijuana had been legalized.<sup>23</sup> At that time, Colorado required a prescription for marijuana from two physicians, and the Figis had difficulty finding two physicians who would prescribe marijuana to a child of Charlotte's age.<sup>24</sup>

However, while in Colorado, they were introduced to Joel and Josh Stanley, two of six Stanley brothers, who had genetically cultivated industrial hemp that was high in CBD, the non-psychoactive component of the plant, and low in tetrahydrocannabinol (THC), the psychoactive component of the plant.<sup>25</sup> The Stanley brothers began their marijuana business in 2008, producing plants high in THC that were intended to produce the psychoactive effect typically associated with smoking marijuana recreationally.<sup>26</sup> They experimented with the high-CBD, low-THC variety of plant, producing an oil they called "Hippie's Disappointment" because of its non-psychoactive effect.<sup>27</sup> In 2012, they provided their CBD oil to Charlotte Figi and, after just a few doses, her seizures "all but stopped."<sup>28</sup> After approximately two years on a feeding tube, suffering more than 300 seizures a week, Charlotte began to walk, talk, and feed herself.<sup>29</sup> Currently, she takes drops of CBD oil daily and "is nearly free of seizures."<sup>30</sup>

After seeing the effects of their CBD oil on Charlotte Figi, the Stanleys renamed it "Charlotte's Web."<sup>31</sup> Soon thereafter, multiple television broadcasts detailing Charlotte's story were released, and families from around the country wanted to purchase Charlotte's

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22.*Id.*

23.*Id.*

24.*Id.*

25.*Id.*

26.Dave Phillips, *Bid to Expand Medical Marijuana Business Faces Federal Hurdles*, N.Y. TIMES, Aug. 23, 2014, at A14.

27.*Id.*

28.*Id.*

29.WEED, *supra* note 11.

30.*See* Phillips, *supra* note 26.

31.Joel Warner, *Charlotte's Web: Untangling one of Colorado's Biggest Cannabis Success Stories*, WESTWORD (Dec. 3, 2014),

<http://www.westword.com/news/charlottes-web-untangling-one-of-colorados-biggest-cannabis-success-stories-6050830> (last visited Mar. 5, 2016).

Web to treat epilepsy and other diseases.<sup>32</sup> Unfortunately, possessing CBD oil is, according to the DEA, a federal crime.

PART 2: THE FEDERAL PROHIBITION OF CBD OIL AND THE  
INCONSISTENCIES BETWEEN STATUTES, CASE LAW, AND POLICY

*The Botany of Industrial Hemp and the Prohibition on Its Domestic  
Growth*

DEA spokeswoman Dawn Dearden put it best when she said, “Any chemical that comes from the plant [*Cannabis sativa*] is still a controlled substance. When we get into hemp, it gets a little squishy, but it still is illegal.”<sup>33</sup> “A little squishy” is an accurate, if colloquial, description of the ambiguous legal status of products derived from industrial hemp. Moreover, Ms. Dearden touches on a point that mars the discussion of legalizing CBD oil at the federal level – its association with marijuana.

CBD oil, such as Charlotte’s Web, is derived from industrial hemp, not marijuana.<sup>34</sup> To be clear, both the marijuana plant and the industrial hemp plant come from the same botanical species, *Cannabis sativa*, which is within the broader genus, *Cannabis*.<sup>35</sup> The *Cannabis sativa* plant has trichomes, which are small hairs growing from the epidermis of the plant.<sup>36</sup> These hairs contain two organic compounds, phenols and terpenes.<sup>37</sup> “As phenols and terpenes migrate upward from the base of a trichome to the bud at its tip, a series of chemical reactions occur that convert these simple basic

32.*Id.*

33.Phillips, *supra* note 26 (internal quotation marks omitted).

34.*Id.* That is not to say that it cannot be produced from marijuana, but it does not have to be, and currently, it is being derived from industrial hemp.

35.Lyle E. Craker and Zoë Gardner, *The Botany of Cannabis*, in THE POT BOOK 35, 36 (Julie Holland, ed. 2010) (describing the genus, *Cannabis*); *see also* Robert C. Clark & David Paul Watson, *Botany of Natural Cannabis Medicines*, in CANNABIS AND CANNABINOIDS PHARMACOLOGY, TOXICOLOGY, AND THERAPEUTIC POTENTIAL 3, 10 (Franjo Grotenhermen & Ethan Russo, eds. 2002) (noting that while some experts recognize three species of *Cannabis* (*Cannabis sativa*, *Cannabis indica*, and *Cannabis ruderalis*), *Cannabis sativa* “represents the largest and most diverse taxon”).

36.DAVID E. NEWTON, MARIJUANA 6 (2013).

37.*Id.* at 7.

compounds into a large variety of more complex compounds. . . .”<sup>38</sup> While more than 400 chemical compounds can be extracted from *Cannabis sativa*, 66 of them are unique to that plant.<sup>39</sup> These 66 chemicals are called cannabinoids.<sup>40</sup> Psychoactive THC, and non-psychoactive CBD, are the most abundant cannabinoids.<sup>41</sup> Although the flowering portion of the plant does not contain trichomes, it nevertheless has a high concentration of cannabinoids, “probably because of the accumulation of resin secreted by the supporting bracteole (the small leaf-like part below the flower).”<sup>42</sup>

It is the near absence of THC that distinguishes the industrial hemp plant from the marijuana plant.<sup>43</sup> “Over the centuries, the hemp plant has been crossbred to have low concentrations of THC, presently about 0.3 percent. By contrast, cannabis plants raised for the production of marijuana have much higher concentrations of THC, ranging from about 2 to as much as 20 percent.”<sup>44</sup>

The significant difference in THC content in industrial hemp and marijuana plants is irrelevant to federal laws; plants containing any amount of THC are illegal.<sup>45</sup> The CSA, passed in 1970, defines marijuana as follows:

The term “marihuana” means all parts of the plant *Cannabis sativa* L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted

38.*Id.*

39.*Id.*

40.*Id.*

41. JANET E. JOY ET AL., MARIJUANA AND MEDICINE 3 (1999).

42.*Id.* at 25-26.

43. NEWTON, *supra* note 36, at 11.

44.*Id.* Industrial hemp has been called “marijuana’s sober cousin” because of its low concentration of THC. JONATHAN P. CAULKINS ET AL., MARIJUANA LEGALIZATION 225 (2012).

45. NEWTON, *supra* note 36, at 11.

therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.<sup>46</sup>

Despite its convoluted language, it is clear that this definition does not offer a distinction between high and low THC varieties of the *Cannabis sativa* plant.<sup>47</sup>

This has not stopped some from arguing that industrial hemp is excluded from this definition.<sup>48</sup> This argument was rejected in *Monson v. DEA*, in which the Eighth Circuit examined a North Dakota law enacted in 2007 permitting the cultivation of industrial hemp containing no more than 0.3 percent THC.<sup>49</sup> After obtaining a license to grow industrial hemp under North Dakota law, but before planting it, the plaintiffs sought a judicial declaration that the CSA does not apply to industrial hemp.<sup>50</sup> The court examined the CSA and stated: “The CSA establishes a comprehensive federal system to regulate the manufacture and distribution of controlled substances, making it unlawful to ‘manufacture, distribute, or dispense’ any controlled substance ‘[e]xcept as authorized by’ the Act.”<sup>51</sup> The term “manufacturing” also includes “production,” and “production” includes “planting,” “cultivating,” “growing,” or “harvesting” a controlled substance.<sup>52</sup> The court held that the CSA’s definition of marijuana includes *all varieties* of the plant *Cannabis sativa*, and, consequently, industrial hemp may not be grown domestically.<sup>53</sup> It follows that if *Cannabis sativa* may not be grown domestically, then

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46.21 U.S.C. § 802(16). The “L.” in the statute refers to Linnaeus’ system of botanical classification. *See* *United States v. King*, 485 F.2d 353, 360–61 (10th Cir. 1973).

47.21 U.S.C. § 802(16).

48.*See* Courtney N. Moran, *Industrial Hemp: Canada Exports, United States Imports*, 26 FORDHAM ENVTL. L. REV. 383, 406-07 (2015).

49.*Monson v. DEA*, 589 F.3d 952, 955 (8th Cir. 2009) (examining N.D. Cent. Code §§ 4-41-01–4-41-03 (2007)).

50.*Id.*

51.*Id.* at 956 (quoting 21 U.S.C. § 841(a)(1)).

52.*Id.* (quoting 21 U.S.C. § 802(15) (defining “manufacturing”) and 21 U.S.C. § 802(22) (defining “production”).

53.*Id.* at 964; *accord* *New Hampshire Hemp Council, Inc. v. Marshall*, 203 F.3d 1, 8 (1st Cir. 2000) (holding that the CSA prohibits the domestic growth of any form of *Cannabis sativa*, including industrial hemp). The DEA may issue a license for the growth of industrial hemp pursuant to U.S.C. §§ 822-832 (2012), but these licenses are rarely given. Moran, *supra* note 48, at 407.

CBD oil may not be produced domestically.<sup>54</sup> Hence, the DEA's position that all chemicals that come from the plant *Cannabis sativa*, including CBD, are illegal.

*Federal Government Nonenforcement with Regard to Domestic Growth of Cannabis Sativa and the Various Legislative Responses from the States*

If *Cannabis sativa* may not be legally grown domestically in any form, then why were the Stanley brothers not prosecuted for growing it and providing its oil to Charlotte Figi in 2012? The answer is a federal government policy of nonenforcement. The legal status of *Cannabis sativa* in any form “remains the same as it has been since 1970: Possession, cultivation, and distribution are categorically forbidden and subject to criminal penalties.”<sup>55</sup> While the federal government has not sought a statutory change, the Obama administration “has adopted a public position of tacit encouragement for state legalization, premised on a baseline of federal nonenforcement.”<sup>56</sup>

On October 19, 2009, Deputy Attorney General David G. Ogden issued a memorandum to “selected” United States Attorneys (the Ogden Memo) in which he stated: “The Department of Justice is committed to the enforcement of the Controlled Substances Act in all States.”<sup>57</sup> However, the Ogden Memo goes on to discuss the limited resources of the federal government and further provides:

The prosecution of significant traffickers of illegal drugs, including marijuana, and the disruption of illegal drug manufacturing and trafficking networks continues to be a core priority in the Department's efforts against narcotics and dangerous drugs, and the

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54.It was once legal to grow industrial hemp in the United States. Moran, *supra* note 48, at 403. Federal restriction did not begin until passage of the 1937 Marihuana Tax Act, which placed all *Cannabis sativa* under the control of the U.S. Treasury Department. *Id.*

55.Bradley E. Markano, *Enabling State Deregulation of Marijuana Through Executive Branch Nonenforcement*, 90 N.Y.U. L. REV. 289, 294 (2015).

56.*Id.*

57.Memorandum from David W. Ogden, Deputy Att'y Gen., U.S. Dep't of Justice, to Selected U.S. Att'ys 1 (Oct. 19, 2009), <http://www.justice.gov/usao/az/reports/medical-marijuana.pdf>.

Department's investigative and prosecutorial resources should be directed towards these objectives. As a general matter, pursuit of these priorities should not focus federal resources in your States on individuals whose actions are in clear and unambiguous compliance with existing state laws providing for the medical use of marijuana.<sup>58</sup>

In short, the Ogden Memo stated the government's intent to shift federal resources away from *Cannabis* prosecutions in states that permit its use.<sup>59</sup>

The DEA did not accept the Ogden Memo as a clear mandate. In April 2013, it issued the following position statement: "While some people have interpreted these guidelines to mean that the federal government has relaxed its policy on 'medical' marijuana, this in fact is not the case. . . . [The] DEA will continue to conduct its mission to enforce the CSA and other actions as so directed by the U.S. Attorney General."<sup>60</sup>

To clarify federal executive policy, on August 29, 2013, Deputy Attorney General James M. Cole issued a memorandum to all United States Attorneys (the Cole Memo).<sup>61</sup> The Cole Memo restated the federal government's objective – to target drug traffickers and not to interfere with states that enact "laws legalizing marijuana in some form and that have also implemented strong and effective regulatory and enforcement systems. . . ."<sup>62</sup> The Ogden and Cole Memos

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58.*Id.* at 1-2.

59.*Id.* "Generally speaking, federal and state governments not only share constitutional jurisdiction over drug crimes, but they have also criminalized largely the same behavior. As a practical matter, however, federal authorities play a decidedly secondary role. The overall ratio of federal to state and local law enforcement personnel in this country is roughly one to ten, and drug enforcement is not the priority it once was." Ernest A. Young, *Modern-Day Nullification: Marijuana & the Persistence of Federalism in an Age of Overlapping Regulatory Jurisdiction*, 65 CASE W. RES. L. REV. 769, 774 (2015) (internal citation omitted).

60.U.S. DEP'T OF JUSTICE, DRUG ENFORCEMENT ADMIN., THE DEA POSITION ON MARIJUANA 1 (2013), available at [http://www.dea.gov/docs/marijuana\\_position\\_2011.pdf](http://www.dea.gov/docs/marijuana_position_2011.pdf), archived at <http://perma.cc/Q4A7-S7RP>.

61.Memorandum from James M. Cole, Deputy Att'y Gen., to U.S. Att'ys (Aug. 29, 2013), <http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf>.

62.*Id.* at 3.

signaled to the states that the federal government would turn a blind eye to *Cannabis* legalization at the state level.

As of March 10, 2016, twenty-three states, the District of Columbia, and Guam have enacted laws that legalize *Cannabis* for medical use.<sup>63</sup> Colorado and Washington were the first to go a step further and legalize *Cannabis* for recreational use.<sup>64</sup> In the last several years, seventeen other states have passed laws allowing the possession of high-CBD, low-THC products (such as CBD oil) for various medical conditions.<sup>65</sup> The statutes allowing CBD products vary in scope from state to state.<sup>66</sup> For example, many states, like North Carolina, permit possession only for the treatment of epileptic conditions.<sup>67</sup> Other states, like Georgia, permit possession to treat a variety of conditions, such as Parkinson's disease and Crohn's disease.<sup>68</sup> Many state statutes either do not define how CBD oil is to be obtained, perhaps because those states do not want to set out in statute how individuals should violate federal law, or the statutes outline complicated and restrictive means of obtaining it.<sup>69</sup>

Although the Stanley brothers were violating the CSA by growing industrial hemp in 2012, they were in compliance with Colorado state law, which allowed dispensaries to grow a limited amount of

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63. These states are Alaska, Arizona, California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maine, Maryland, Massachusetts, Minnesota, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oregon, Rhode Island, Vermont, and Washington. NATIONAL CONFERENCE OF STATE LEGISLATURES, STATE MEDICAL MARIJUANA LAWS (Mar. 10, 2016), <http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx> (last visited Mar. 18, 2016); MARIJUANA POLICY PROJECT, STATE-BY-STATE MEDICAL MARIJUANA LAWS 1 (2015), available at <http://www.scribd.com/doc/264980279/State-by-State-Laws-Report-2015> (detailing the legality of *Cannabis* in all 50 states).

64. NATIONAL CONFERENCE OF STATE LEGISLATURES, *supra* note 63. Alaska, Oregon, and the District of Columbia also allow *Cannabis* for recreational use. *Id.*

65. These states are Alabama, Florida, Georgia, Iowa, Kentucky, Louisiana, Mississippi, Missouri, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Utah, Virginia, Wisconsin, and Wyoming. *Id.*

66. *Id.*

67. *Id.*

68. *Id.*

69. *Id.*

*Cannabis sativa*.<sup>70</sup> Understandably, they were not bold enough to grow the amount of industrial hemp needed to satisfy demands for the oil, or to distribute it across state lines.<sup>71</sup> In a desperate effort to obtain the oil, many families moved to Colorado so they could get it directly from the Stanleys.<sup>72</sup> These families were termed “marijuana refugees,” and despite their willingness to uproot their lives, many of them were placed on a waitlist because of the limited supply of the oil.<sup>73</sup> To assist families in navigating the convoluted process of obtaining Charlotte’s Web, the Stanleys started a nonprofit, Realm of Caring.<sup>74</sup> By the end of 2014, there were approximately 12,000 people nationwide on the waitlist for Charlotte’s Web.<sup>75</sup>

### *The Agricultural Act of 2014*

Enactment of the Agricultural Act of 2014, also known as the U.S. Farm Bill, marked a significant policy shift with regard to domestic industrial hemp cultivation, but it has by no means solved the legal conundrum because it does not alter the CSA.<sup>76</sup> The U.S. Farm Bill provides that industrial hemp may be grown by an institute of higher education or a state department of agriculture if:

- (1) the industrial hemp is grown or cultivated for purposes of research conducted under an agricultural pilot program or other agricultural or academic research; and (2) the growing or cultivating of industrial hemp is allowed under the laws of the State in which such institution of higher education or State department of agriculture is located and such research occurs.<sup>77</sup>

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70. See Warner, *supra* note 31.

71. *Id.*

72. *Id.* (claiming that, as of December 2014, approximately 250 families had relocated to Colorado to obtain Charlotte’s Web).

73. *Id.*

74. *Id.*; About Us, REALM OF CARING, <https://www.theroc.us/about-us> (last visited, Mar. 18, 2016).

75. Warner, *supra* note 31.

76. Agricultural Act of 2014, Pub. L. No. 113-79, § 7606, 128 Stat. 649, 912-13 (2014).

77. *Id.*

As of March 4, 2016, twenty-eight states have enacted laws related to industrial hemp.<sup>78</sup> However, some states require a change to the CSA or a waiver from the DEA before the programs may be implemented.<sup>79</sup> “Generally, states have taken three approaches: (1) establish commercial industrial hemp programs[;] (2) establish industrial hemp research programs[;] or (3) authorize studies of industrial hemp or the industrial hemp industry.”<sup>80</sup>

Coinciding with enactment of the U.S. Farm Bill, the Stanleys reported that they planned to grow 17 acres of industrial hemp in Colorado by the end of 2014, and an estimated 200 acres by 2015.<sup>81</sup> Colorado expanded its state laws to allow the cultivation of industrial hemp with few restrictions,<sup>82</sup> and, although allowing private companies to grow unlimited amounts of industrial hemp may not meet the plain language restrictions of the U.S. Farm Bill, the bill certainly offers a layer of protection. Additionally, because the current administration is turning a blind eye to *Cannabis* production, so long as it complies with state laws, the Stanleys feel confident that they will avoid federal prosecution for growing industrial hemp in Colorado.<sup>83</sup>

However, to satisfy the waitlist for Charlotte’s Web, the Stanleys have to ship the oil across state lines.<sup>84</sup> They are currently doing so, and this marks “the first time in decades anyone has tried to sell domestic hemp nationwide.”<sup>85</sup> Now, approximately four years after Charlotte Figi tried CBD oil, there is no longer a waitlist for Charlotte’s Web.<sup>86</sup> This good news is tempered by the fact that the Stanleys are violating the CSA by distributing a Schedule 1 controlled substance in interstate commerce.<sup>87</sup> While expressing

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78.NATIONAL CONFERENCE OF STATE LEGISLATURES, STATE INDUSTRIAL HEMP STATUTES (Mar. 4, 2016), <http://www.ncsl.org/research/agriculture-and-rural-development/state-industrial-hemp-statutes.aspx> (last visited, Mar. 19, 2016).

79.*Id.*

80.*Id.*

81.Phillips, *supra* note 26.

82.*Id.*

83.*Id.*

84.*Id.*

85.*Id.*; REALM OF CARING, *supra* note 74.

86.REALM OF CARING, *supra* note 74.

87.21 U.S.C. § 841(a)(1).

their hope that “the enforcement agencies have bigger fish to fry and don’t want to take a bunch of medicine away from sick kids,” the Stanleys also say that “[i]f you are going to be locked up, it’s a thing worth getting locked up for.”<sup>88</sup>

Moreover, to legally possess domestically produced CBD oil under the CSA, it must be extracted, sold, and acquired in a state that has enacted industrial hemp laws pursuant to the U.S. Farm Bill.<sup>89</sup> Consequently, pursuant to the CSA, it is lawful to possess Charlotte’s Web only in Colorado.<sup>90</sup>

Contrary to the provisions of the CSA, the 2016 omnibus Appropriations Act contains the following language:

None of the funds made available by this Act or any other Act may be used . . . to prohibit the transportation, processing, sale, or use of industrial hemp that is grown or cultivated in accordance with subsection section 7606 of the Agricultural Act of 2014, within or outside the State in which the industrial hemp is grown or cultivated.<sup>91</sup>

Fortunately, this act opens the door to the distribution of CBD oil across state lines; however, it is another method of federal government nonenforcement and does not alter the CSA.

Thus far, federal government nonenforcement has prevented prosecution for the distribution and possession of CBD oil, and, as discussed *supra*, many states have passed laws to prevent prosecution under state law. However, the CSA remains unchanged. DEA spokeswoman Dearden was right – that is squishy.

### *The Quandary of Imported Industrial Hemp and CBD Oil Derived from It*

To add another layer of confusion, while industrial hemp may not be grown domestically, except in the limited circumstances described

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88. Phillips, *supra* note 26 (internal quotation marks omitted).

89. 21 U.S.C. § 841(a)(1); Rod Kight, *Is CBD Legal?*, KIGHT LAW (Oct. 15, 2015), <http://kightlaw.com/is-cbd-legal/>.

90. *See* 21 U.S.C. § 841(a)(1).

91. Consolidated Appropriations Act, 2016 Pub. L. No. 114-113, § 763, 129 Stat. 2242 (2015).

above, hemp products may be imported.<sup>92</sup> Approximately thirty countries allow the cultivation of industrial hemp.<sup>93</sup> “Ironically, the U.S. is the largest importer of [industrial] hemp products in the world” with retail sales totaling more than half a billion dollars annually.<sup>94</sup>

In 2004, Hemp Industries Association (HIA) won a significant legal battle against the DEA.<sup>95</sup> HIA’s products were non-psychoactive hemp products containing trace amounts of naturally occurring THC.<sup>96</sup> The products were derived from hemp plants imported from Canada and Europe.<sup>97</sup> In 2003, the DEA amended the Code of Federal Regulations to include *all* naturally occurring THC in the definition of THC, a Schedule 1 controlled substance listed separately from marijuana.<sup>98</sup> The conflict centered around the following exemption in the CSA’s definition of marijuana:

Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.<sup>99</sup>

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92.Moran, *supra* note 48, at 408 (“At this time, there are no active federal licenses allowing commercial cultivation of industrial hemp. All commercial hemp products sold in the U.S. are imported or manufactured from imported hemp materials.”); see CBF Info. Ctr., *Importing Hemp Products into the U.S.*, U.S. CUSTOMS AND BORDER PROTECTION,

[https://help.cbp.gov/app/answers/detail/a\\_id/1751/~/importing-hemp-products-into-the-u.s.](https://help.cbp.gov/app/answers/detail/a_id/1751/~/importing-hemp-products-into-the-u.s.) (last visited, Mar. 20, 2016) (“Hemp products such as paper, rope, and clothing (which contain fiber made from the cannabis plant) and animal feed mixtures, soaps, and shampoos (which contain sterilized cannabis seeds or oils extracted from the seeds), etc. may be imported into the United States.”).

93.Moran, *supra* note 48, at 385.

94.*Id.* at 387.

95.Hemp Indus. Ass’n. v. DEA., 357 F.3d 1012 (9th Cir. 2004).

96.*Id.* at 1013 n.2.

97.*Id.*

98.*Id.* at 1014.

99.21 U.S.C. § 802(16).

The Ninth Circuit held that the plain language of the statute excluded non-psychoactive hemp products derived from the “mature stalks” or constituting “oil or cake made from the seeds” of the *Cannabis* plant.<sup>100</sup> The DEA was not permitted to enact rules that “regulate *naturally-occurring* THC *not* contained within or derived from marijuana—i.e., non-psychoactive hemp products—because non-psychoactive hemp is not included in Schedule I.”<sup>101</sup>

In reliance on this decision, manufacturers of CBD oil made from *imported* industrial hemp claim that their products are legal under federal law and in all 50 states.<sup>102</sup> Others dispute that claim and argue that the court in *Hemp Industries Association* did not consider whether CBD was excluded from the CSA.<sup>103</sup> The products distributed by HIA were derived from sterilized hemp seeds; they were not distributing CBD-rich products.<sup>104</sup> The case law does not clearly resolve this dispute, and the DEA’s position appears to be that all cannabinoids are prohibited under the CSA, including CBD.

Moreover, questions have been raised about the purity of CBD oil derived from imported industrial hemp.<sup>105</sup> Some claim that the mature stalks of imported industrial hemp contain little CBD, and the chemical process used to extract it leaves residual solvents that are not fit for human consumption.<sup>106</sup> When industrial hemp is grown domestically, using *Cannabis sativa* that has been genetically bred to have high-CBD, low-THC concentrations, the oil may be derived from the CBD-rich flowers, not just the mature stalks.<sup>107</sup>

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100. *Hemp Indus. Ass’n.*, 357 F.3d at 1017.

101. *Id.* at 1018 (emphasis in original).

102. Joy Beckerman, *The Curious Legal Status of CBD*, MARIJUANA VENTURE (Jan. 1, 2015), <http://www.marijuanaventure.com/curious-legal-status-cbd/> (last visited, Mar. 20, 2016); Hollie Thrasher, *Is CBD Oil Already Legal?* (Mar. 19, 2014), [http://www.waaytv.com/news/is-cbd-oil-already-legal/article\\_234af87a-afb7-11e3-8249-0017a43b2370.html](http://www.waaytv.com/news/is-cbd-oil-already-legal/article_234af87a-afb7-11e3-8249-0017a43b2370.html) (last visited, Mar. 20, 2016).

103. Beckerman, *supra* note 102.

104. *See Hemp Indus. Ass’n.*, 357 F.3d at 1013.

105. Beckerman, *supra* note 102; Kight, *supra* note 89.

106. Beckerman, *supra* note 102; Kight, *supra* note 89.

107. Kight, *supra* note 89. The Realm of Caring offers the following information on its website: “Colorado grown Charlotte’s Web™ hemp has been bred to be naturally rich in CBD while being very low in THC. This offers a significant advantage when compared to other CBD products on the market today - most of

Consequently, the uncertain legal status of CBD made from domestically grown industrial hemp may have created a market for a potentially dangerous imported product.

### PART THREE: LIMITATION ON RESEARCH EFFORTS

To date, the efficacy of CBD oil is largely anecdotal.<sup>108</sup> Most studies involve parental reporting of dosage and reduction of seizures.<sup>109</sup> In 2015, researchers at the University of California, Los Angeles (UCLA) reported that 85 percent of study participants claimed a reduction in seizure frequency after using CBD oil.<sup>110</sup> However, the researchers admit that the primary limitation in their study is that it was conducted via an online-administered survey, as opposed to a controlled study where dosage and seizure control could be monitored.<sup>111</sup> The report concludes by stating:

At face value, this study indicates that CBD-containing products might be effective and well tolerated in the treatment of multiple forms of refractory childhood epilepsy[,] . . . but enthusiasm must be tempered by the absence of controlled data supporting this view. Rigorous clinical trials are clearly warranted and supported by these findings to determine the efficacy and safety of CBD.<sup>112</sup>

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which are derived from imported foreign hemp pastes from industrial hemp strains that are very low in CBD. . . . Hemp is known to pull toxic heavy metals such as lead and arsenic from soils. In fact, hemp is sometimes used as a remediation crop to decontaminate polluted soils. By extracting CBD from industrial hemp strains that contain only trace levels of CBD, other manufactures are required to use potentially ten to twenty times the amount of plant material to obtain the same amount of CBD that could be extracted from a single Charlotte's Web™ plant. With ten times the plant material, you are also potentially ingesting ten times whatever else was in that soil. Because Charlotte's Web™ is proudly grown on the arid plains of Colorado on family farms, we are able to know the history of our farmland." REALM OF CARING, *supra* note 74.

108.The Realm of Caring website provides many success stories. REALM OF CARING, *supra* note 74.

109. See Shaun A. Hussain et al., *Perceived Efficacy of Cannabidiol-enriched Cannabis Extract for Treatment of Pediatric Epilepsy: A Potential Role for Infantile Spasms and Lennox-Gastaut Syndrome*, 47 *EPILEPSY & BEHAVIOR* 138, 138 (2015).

110. *Id.*

111. *Id.*

112. *Id.*

In another 2015 study, researchers conducted a retrospective chart review of children who had been treated at the Children's Hospital of Colorado.<sup>113</sup> The children had documented seizure frequency prior to taking CBD oil as a daily treatment.<sup>114</sup> The study states that, according to parental reporting, 57 percent of the children showed at least some reduction in seizures, and 33 percent had a greater than 50 percent reduction in seizures.<sup>115</sup> Like the UCLA researchers, the researchers in this study acknowledge challenges with parental reporting as opposed to controlled studies.<sup>116</sup> In conclusion, the report states: "We strongly support the need for controlled, blinded studies to evaluate the efficacy and safety of OCE [Oral *Cannabis* Extracts] for treatment of pediatric epilepsies. . . . This study provides . . . evidence that OCE is well tolerated by children and adolescents with epilepsy."<sup>117</sup>

As these studies indicate, additional research is needed. Controlled, blind studies are imperative to assess the efficacy of CBD oil and to create guidelines for CBD concentrations and dosage instructions.<sup>118</sup> However, in order to conduct federally sanctioned research, scientists must obtain approval from the Food and Drug Administration (FDA), the DEA, and the National Institute of Drug Abuse.<sup>119</sup> In 2014, Colorado set aside \$9 million to research the efficacy of *Cannabis*, and one of the proposed studies focuses on DS and the efficacy of CBD oil.<sup>120</sup> Colorado researchers acknowledge

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113.Press, *supra* note 2, at 49.

114.*Id.* at 50.

115.*Id.*

116.*Id.* at 52.

117.*Id.*

118.*See id.*

119.J. Herbie DiFonzo et al., *Divided We Stand: Med. Marijuana & Federalism*, 27 HEALTH LAW 17, 20 (June 2015). As of 2013, the DEA reported that "[t]here are 125 researchers registered with DEA to perform studies with marijuana, marijuana extracts, and non-tetrahydrocannabinol marijuana derivatives that exist in the plant, such as cannabidiol and cannabinol." THE DEA POSITION ON MARIJUANA, *supra* note 60, at 5.

120.John Ingold, *Colorado Medical Marijuana Research Grants Face Federal Uncertainty*, THE DENVER POST (Aug. 29, 2014), [http://www.denverpost.com/news/ci\\_26433404/colorado-medical-marijuana-research-grants-face-federal-uncertainty](http://www.denverpost.com/news/ci_26433404/colorado-medical-marijuana-research-grants-face-federal-uncertainty). The study is titled "Genetic Analysis Between Charlotte's Web Responders Versus Non-Responders in a Dravet

that getting DEA approval for *Cannabis* studies is a time consuming process.<sup>121</sup> “You can do it . . . but you have to jump through the hoops.”<sup>122</sup> Children suffering from DS do not have time for researchers to jump through hoops. This process needs to be streamlined by eliminating the Schedule 1 designation for industrial hemp.<sup>123</sup>

#### PART FOUR: RECOMMENDATION FOR FEDERAL LEGISLATION

*Cannabis* law is a patchwork of inconsistent federal and state laws, coupled with government nonenforcement of these laws, which creates instability in an area where lives are at stake. While federal nonenforcement has allowed better access to CBD oil, it is not a permanent solution. A new Attorney General could change the

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Population” and is being conducted at the University of Colorado, Denver.

CLINICAL TRIALS.GOV,

<https://www.clinicaltrials.gov/ct2/show/NCT02229032?term=dravet&rank=1> (last visited, Mar. 20, 2016).

121. Ingold, *supra* note 120.

122. *Id.*

123. This article is not intended to promote CBD oil produced from industrial hemp, such as Charlotte’s Web, over a pharmaceutical alternative. GW Pharmaceuticals has acquired orphan drug status and fast track designation for its drug, Epidiolex, “[a] liquid formulation of pure plant-derived Cannabidiol.” Therapeutic Areas, GW PHARMACEUTICALS, <http://www.gwpharm.com/therapeutic-areas.aspx> (last visited Apr. 18, 2016). GW Pharmaceuticals recently issued a press release, stating that in Phase 3 clinical trials, “patients taking Epidiolex achieved a median reduction in monthly convulsive seizures of 39 percent compared with a reduction on placebo of 13 percent[.]” Press Release, GW Pharmaceuticals, GW Pharmaceuticals Announces Positive Phase 3 Pivotal Study Results for Epidiolex (Cannabidiol) (Mar. 14, 2016),

<http://www.gwpharm.com/GW%20Pharmaceuticals%20Announces%20Positive%20Phase%203%20Pivotal%20Study%20Results%20for%20Epidiolex%20cannabidiol.aspx>. Epidiolex may seek FDA approval later this year. Julie Carr Smyth, *Medical Pot Activists Fear Epilepsy Drug Could Undercut Them*, ASSOCIATED PRESS, Apr. 17, 2016, 2016 WL AP Alerts 16:09:23 “Many medical marijuana activists fear Epidiolex approval will mark the beginning of Big Pharma’s takeover of the marijuana plant, undercutting patients’ ability to treat themselves as they see fit.” *Id.* To the contrary, this author is not a medical marijuana activist and hopes to see more options to treat DS. Epidiolex is promising, but does not eliminate the need for research into CBD oil produced from domestically grown industrial hemp, which has also shown promise in treating DS.

executive policy set by the Cole and Ogden Memos.<sup>124</sup> Even while the policy is in effect, it is only policy, not law.<sup>125</sup> A “disobedient” federal prosecutor may choose instead to enforce the letter of the federal law.<sup>126</sup> In fact, “there is tremendous variation in enforcement policy from one U.S. Attorney’s office to the next, including in the context of drug enforcement.”<sup>127</sup>

With varying federal policies, the landscape is unclear, even to law enforcement. In 2014, the DEA seized a shipment of industrial hemp seeds in route to Kentucky that the state contends was permitted under the U.S. Farm Bill.<sup>128</sup> Kentucky Agriculture Commissioner James Comer stated that the DEA was “interpreting the law a hundred different ways[.]”<sup>129</sup> The solution is a definitive change to the CSA that would permit uninhibited industrial hemp cultivation in this country and expressly exclude CBD from the definition of marijuana.

The Charlotte’s Web Medical Access Act of 2015 is currently pending in Congress and excludes “[c]annabidiol and cannabidiol-rich plants” from the definition of “marihuana.” The Act defines “cannabidiol-rich plants” as having not more than 0.3 percent THC.<sup>130</sup> It is unclear why the bill creates the new term “cannabidiol-rich plants.” To avoid confusion, the bill should use the term “industrial hemp.”

Additionally, the bill states that “[t]he Federal Food, Drug, and Cosmetic Act . . . shall not apply to cannabidiol or cannabidiol-rich plants. . . .”<sup>131</sup> Complete removal of FDA oversight of CBD oil is unwise. In 2015, the FDA sent letters to seven companies that sell CBD oil, warning them that the products were not recognized as safe

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124. Alex Kreit, *What Will Fed. Marijuana Reform Look Like?*, 65 CASE W. RES. L. REV. 689, 693 (2015).

125. *Id.* at 694.

126. *Id.*

127. Markano, *supra* note 55, at 312.

128. Ryan Grim & Matt Ferner, *DEA Seizes Kentucky’s Hemp Seeds Despite Congressional Legalization*, HUFFINGTON POST (May 14, 2014), [http://www.huffingtonpost.com/2014/05/13/dea-seizes-kentuckys-hemp\\_n\\_5318098.html](http://www.huffingtonpost.com/2014/05/13/dea-seizes-kentuckys-hemp_n_5318098.html).

129. *Id.*

130. Charlotte’s Web Medical Access Act of 2015, H.R. 1635, 114th Cong. (2015).

131. *Id.*

and that they were engaging in illegal interstate commerce.<sup>132</sup> Accompanying the letters were lab results showing that the CBD concentration in the oils was lower than advertised.<sup>133</sup> The FDA's enforcement efforts were welcomed by CBD oil advocates like Paige Figi, who said "[t]hey're cracking down on quality, which is extremely important, and I'm very happy[.]"<sup>134</sup> A more prudent approach, therefore, would be limited FDA oversight of quality measures, such as CBD concentration.

Although some adjustments to the bill should be made, this article supports its passage. This legislation has bipartisan support and its enactment will respond to the needs of families struggling with DS.

#### CONCLUSION

Discussing the legalization of CBD oil and industrial hemp should not evoke concerns that it will be a slippery slope leading to the legalization of recreational marijuana. The marijuana debate can and should be left for another day. Rather, the merits of CBD oil produced from industrial hemp should be considered in isolation as a distinct, non-psychoactive substance. The potential medical benefit is not merely speculative; it has been seen in the stories of Charlotte Figi and other children like her. More research is needed to assess its efficacy, but in order to engage in that research, the legal barriers must come down.

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132. Steven Nelson, *FDA Brings Down Hammer on CBD Companies*, U.S. NEWS & WORLD REPORT (Mar. 11, 2015), <http://www.usnews.com/news/articles/2015/03/11/fda-brings-down-hammer-on-cbd-companies>.

133. *Id.*

134. *Id.*