

AMERICAN CANNABIS REGULATION, THE
INTERNATIONAL HEMP MARKET, AND
TARIFF POLICY

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INTRODUCTION: THESIS AND PAPER DESCRIPTION 208

I. THE BACKGROUND OF THE INDUSTRIAL HEMP MARKET: THE UNITED STATES AND BEYOND 211

 A. *The United States’ Hemp Industry and Regulations Before 2014*211

 1. *Marihuana Tax Act*..... 211

 2. *The CSA* 212

 B. *Prior Legal Gaps Created by the CSA and Their Effects on Hemp and Hemp Products in the United States*212

 C. *Hemp Outside the United States*214

 1. *Hemp Cultivation in Europe/the EU* 214

 2. *Hemp Cultivation in China* 216

 3. *Hemp Cultivation in Canada* 217

II. HEMP CULTIVATION AND MANUFACTURING IN THE UNITED STATES AFTER 2014 217

 A. *The Farm Bills, the CSA Currently, and an Emerging U.S. Hemp Market*.....218

 1. *2014 and 2018 Farm Bills and Their Effects on the CSA* 218

 i. *Hemp: Market Projections, Current Uses, and Financial Potential for the United States* 219

 ii. *USDA Regulations and Federal Protection under Subtitle G of the AMA*..... 223

iii. <i>The FFDCA and its Enforcement through the FDA</i>	227
2. <i>The American Hemp Entrepreneur</i>	231
i. <i>Current Models for Federal Hemp Compliance</i>	231
ii. <i>Meeting Current American Consumer Demand for Hemp Products</i>	232
III. INTERNATIONAL CONSIDERATIONS: RULES OF ORIGIN AND HARMONIZED TARIFF SCHEDULES.....	234
A. <i>Rules of Origin: Definitions and Purpose</i>	234
B. <i>Tariff Scheduling: Definition and Purpose</i>	236
C. <i>Shortcomings of Rules of Origin and Harmonized Tariff Schedules Regarding the Hemp Industry</i>	236
IV. STREAMLINED AMERICAN HEMP PRODUCTION AND THE UNITED STATES' PARTICIPATION IN THE INTERNATIONAL HEMP INDUSTRY	238
A. <i>Establishment of Consolidated American Hemp Market</i>	239
B. <i>A Consolidated American Hemp Market on the World Stage: Trade with Countries and Other WTO Members</i>	240
V. CONCLUSION	242
APPENDIX I – PERTINENT REGULATORY ACTORS	244
<i>Actor and its Associated Function:</i>	244

INTRODUCTION: THESIS AND PAPER DESCRIPTION

A green wave is coming. The increasing amount of support in the United States and abroad for the cannabis industry has never been more salient. With thirty-three states and the District of Columbia, Canada, and soon, Mexico having legalized cannabis in some capacity, North America is seemingly reforming its

opinions on marijuana.¹ While marijuana's legalization in certain states has created a billion-dollar industry,² there is another industry affected by the legalization of cannabis that is also deserving of consideration. This consideration is the agricultural commodity known as industrial hemp.

Hemp has historically been used for a variety of purposes: fibers for textiles, pulp for paper, food, and so on.³ Cultivation of hemp throughout the world for these purposes has gone on for millennia, its prevalence coming to the United States.⁴ However, the use of hemp in the United States began declining in the early twentieth century, at which point the United States would not see industrial hemp cultivation for roughly one hundred years.⁵ Various pieces of legislation made the cultivation of hemp within the United States virtually impossible, so for decades, the hemp industry in the United States consisted primarily of imports.⁶ However, recent developments in American cannabis regulation have provided the United States an opportunity to be at the forefront of a reemerging industry.⁷

The current industrial hemp market in the United States is valued at several billion dollars, with the international hemp market projected to be valued exponentially higher by the year

1. Diego Ore, *Mexican Senate Set to Pass Bill to Legalize Marijuana in Next Few Days*, THOMSON REUTERS (Oct. 15, 2019, 2:16 PM), <https://www.reuters.com/article/us-mexico-drugs/mexican-senate-set-to-pass-bill-to-legalize-marijuana-in-next-few-days-idUSKBN1WU2Q9>; Darran Simon & Nicole Chavez, *Canada Just Legalized Recreational Pot. Here's What You Need to Know*, CNN (Oct. 17, 2018, 4:20 PM), <https://www.cnn.com/2018/10/17/health/canada-legalizes-recreational-marijuana/index.html>; *State Marijuana Laws in 2019 Map*, GOVERNING, <https://www.governing.com/gov-data/safety-justice/state-marijuana-laws-map-medical-recreational.html> (last visited May 27, 2021).

2. See Eric Rosenbaum, *Colorado Passes \$1 Billion in Marijuana State Revenue*, CNBC (June 13, 2019, 5:36 PM), <https://www.cnbc.com/2019/06/12/colorado-passes-1-billion-in-marijuana-state-revenue/html>.

3. Jerome H. Cherney & Ernest Small, *Industrial Hemp in North America: Production, Politics and Potential*, 6(4):58 AGRONOMY at 3, 5 (2016).

4. Courtney N. Moran, *Industrial Hemp: Canada Exports, United States Imports*, 26 FORDHAM ENV'T L. REV. 383, 400 (2015).

5. Cherney & Small, *supra* note 3, at 2; U.S. DEP'T OF AGRIC., INDUSTRIAL HEMP IN THE UNITED STATES: STATUS AND MARKET POTENTIAL 3 (2000).

6. Moran, *supra* note 4, at 406–08.

7. *Id.* at 385–87, 407–08.

2026.⁸ Despite existing hindrances, the demand for hemp and hemp-derived products is increasing rapidly.⁹ And with some adjustments in domestic and international policy, the United States and other members of the World Trade Organization (“WTO”) could continue benefitting from the green wave as it continues to become an international affair.¹⁰ Ensuring that member nations scrutinize the WTO’s rules of origin and tariffs is critical for ensuring the robust expansion of the international hemp market, and adherence to these measures is necessary for any trading nation to advance the WTO’s stated policy objectives.¹¹

The preamble of the General Agreement on Tariffs and Trade (“GATT”) states the purpose of the WTO; these goals are, in pertinent part: (i) increasing global economic well-being through the increase of international trade by (ii) “substantially reducing tariffs and other trade barriers” and (iii) “eliminating discriminatory treatment in international commerce.”¹² With these goals in mind, this paper will: (1) discuss the modern history of the hemp market, particularly in the United States; (2) analyze the projected future of the hemp market after recent hemp regulation reform in the United States; (3) display why the United States should modify/implement its regulatory oversight of industrial hemp due to the current regulatory obscurity of the industrial hemp market; and (4) make the argument that the United States, the WTO, and its members must reform their rules of origin and tariff schedule to fulfill the WTO’s stated goals, thus accommodating the growing international hemp industry.¹³ To

8. Fior Mkts., *Global Industrial Hemp Market is Expected to Reach USD 14.67 Billion by 2026: Industrial Hemp Market by Product (Seeds, Fiber, Shivs), Nature, Application*, GLOBE NEWSWIRE (July 8, 2019), <https://www.globenewswire.com/news-release/2019/07/08/1879566/0/en/Global-Industrial-Hemp-Market-is-Expected-to-Rich-USD-14-67-Billion-By-2026.html>.

9. *Id.*

10. See *Technical Information on Rules of Origin*, WTO, https://www.wto.org/english/tratop_e/roi_e/roi_info_e.htm (last visited May 27, 2020) (discussing the impact of rules of origin on international trade).

11. *Id.* (highlighting harmonization as the goal of rules of origin).

12. JOOST H.B. PAUWELYN ET AL., *INTERNATIONAL TRADE LAW* 89 (3d ed. 2016).

13. Many scholars and government officials believe that “massive support by non-farmers and politicians for legalization of hemp has less to do with it as it does with

begin illustrating these points, it is crucial to provide a description of the hemp market historically.

I. THE BACKGROUND OF THE INDUSTRIAL HEMP MARKET: THE UNITED STATES AND BEYOND¹⁴

A. *The United States' Hemp Industry and Regulations Before 2014*

For most of its history, the cultivation and utilization of hemp was prevalent in the United States.¹⁵ However, during the twentieth century, the U.S. Congress passed legislation that hindered and eventually stopped hemp cultivation and production, starting with the Marihuana Tax Act.¹⁶

1. *Marihuana Tax Act*

Congress passed the Marihuana Tax Act in 1937, seeking to prevent marijuana use while still receiving the benefits of industrial hemp cultivation.¹⁷ To achieve this goal, the Marihuana Tax Act defined the cannabis plant as a narcotic drug and required farmers growing hemp to have and maintain a

marijuana,” and that such individuals are “motivated by the prospect of legalizing marijuana.” Cherney & Small, *supra* note 3, at 15. While this argument does have some bearing on the effect of normalizing cannabis internationally, it is outside the scope of this paper. This paper does draw parallels between the hemp and legal marijuana industry but does so more to illustrate the need to differentiate hemp and marijuana for the sake of continually liberalizing trade and increasing global wealth.

14. Throughout this paper, market and economic projections largely center around the United States. There are two reasons for this centralization around the United States. First, the United States is both a major trading partner on the world stage and Earth’s largest economy. Caleb Silver, *The Top 25 Economies in the World*, INVESTOPEDIA (Dec. 24, 2020), <https://www.investopedia.com/insights/worlds-top-economies/>. Second, where other countries have cultivated hemp either continuously or provided recent models for the United States to emulate, the United States has had a checkered history with hemp; however, the recent reform of hemp regulation in the United States has major implications for international trade generally, as will be explained below. See Moran, *supra* note 4, at 400–01.

15. See Moran, *supra* note 4, at 400–03.

16. See *id.*

17. RENEE JOHNSON, CONG. RSCH. SERV., RL32725, HEMP AS AN AGRICULTURAL COMMODITY 13 (2018).

federal registration with a special tax stamp.¹⁸ Hemp cultivation continued through World War II.¹⁹ However, due to industry competition and public anti-drug sentiments, hemp cultivation declined rapidly, ceasing in 1958.²⁰ This anti-drug sentiment culminated in the passage of the Controlled Substances Act (“CSA”).²¹

2. *The CSA*

In 1970, Congress passed the CSA, effectively placing the control of select plants, drugs, and other chemical substances under federal jurisdiction.²² Using the definition in the Marihuana Tax Act,²³ the CSA effectively prohibited the use of the cannabis plant regardless of the psychoactive properties (or lack thereof) in its variants, hemp included.²⁴ While the language in the CSA’s definition of marijuana states exclusions for certain aspects of the cannabis plant (impliedly for hemp), the prior language within the definition created problematic legal conflicts, inhibiting any potential American hemp entrepreneur.²⁵

B. *Prior Legal Gaps Created by the CSA and Their Effects on Hemp and Hemp Products in the United States*

The CSA’s exception section for marijuana stipulates:

Such term does not include the mature stalks of such plant [*Cannabis Sativa* L.], fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound . . . or preparation

18. *Id.*

19. *Id.*

20. *Id.*

21. *Id.*

22. *Id.*

23. *Id.*

24. *Id.* It is important to note that the CSA, in its broad categorization of marijuana which incidentally included hemp, classified marijuana as a Schedule I drug. 21 U.S.C. § 812 sched. I(c)(10). Schedule I drugs are categorized as such due to them having, amongst other reasons, “no currently accepted medical use in treatment in the United States.” See 21 U.S.C. § 812(b)(1)(B) (2019).

25. See JOHNSON, *supra* note 1717, at 13.

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.²⁶

However, the prior definition section of the CSA specified that all parts of the *Cannabis Sativa* L. plant, growing or not, and its derivatives were considered marijuana.²⁷ This conflicting language implicates the larger issue people had to consider should they have desired to grow hemp in the United States and simultaneously comply with the drug policies stated in the CSA.

Put simply, plants grow through the placement of seeds in a nutrient-rich environment, resulting in germination and growth.²⁸ Under the CSA's definition of marijuana and prior to the Agricultural Act of 2014 ("2014 Farm Bill"),²⁹ the act of planting *Cannabis Sativa* L. seeds with the intent to grow and cultivate hemp without a permit constituted a crime.³⁰ The only seeds stemming from the *Cannabis Sativa* L. plant that would not violate the CSA would be the sterilized seeds of the plant, or seeds that cannot yield plants.³¹ Should a potential hemp farmer have desired to use live seeds, they would effectively be growing marijuana.³² There was, therefore, no way an American farmer could grow hemp without a permit and comply with the CSA.³³

Following the passage of the CSA, the United States Drug Enforcement Administration ("DEA") treated hemp and marijuana as the same plant,³⁴ effectively prohibiting (except in very limited circumstances) any farmer and agriculturalist from growing hemp.³⁵ Until the Agriculture Improvement Act of 2018

26. *Id.*

27. *Id.*

28. See *Seed and Seedling Biology*, PA. STATE EXTENSION, <https://extension.psu.edu/seed-and-seedling-biology> (last visited Dec. 18, 2019).

29. See JOHNSON, *supra* note 1717, at 13.

30. See 21 U.S.C. § 841 (2019); JOHNSON, *supra* note 1717, at 13–14.

31. JOHNSON, *supra* note 1717, at 13.

32. See *Monson v. DEA*, 589 F.3d 952, 955, 958, 964–65 (8th Cir. 2009).

33. See 21 U.S.C. § 841.

34. *Monson*, 589 F.3d. at 952; Cherney & Small, *supra* note 3, at 3.

35. Cherney & Small, *supra* note 3, at 16–17. The only context where cannabis cultivation was permitted prior to 2014 was for research, and until 2014, the only entity that was permitted to conduct such research was the University of Mississippi's School of

("2018 Farm Bill"),³⁶ hemp cultivation was heavily regulated and could only be conducted within the scope of commercial and market research.³⁷ Consequently, the domestic hemp market was severely limited, resulting in "[a]ll commercial hemp products sold in the U.S. [being] imported or manufactured from imported hemp materials."³⁸ The following section illustrates how foreign hemp producers participated in the hemp industry while the United States mostly abstained.

C. *Hemp Outside the United States*

For decades, the distinctions in hemp regulation between the United States and other industrialized countries meant the only way for American consumers to have hemp products was through the importation of such products from predominantly Europe/the European Union ("EU"), China, and Canada.³⁹ Consequently, the United States fell behind other industrialized countries in the international trade of hemp and hemp-derived products.⁴⁰

1. *Hemp Cultivation in Europe/the EU*

Cultivation of hemp in Europe spans over hundreds of years.⁴¹ Europe has traditionally, with few exceptions, permitted the cultivation and manufacturing of hemp and hemp products.⁴² Modern hemp legislation and regulation promulgated by the EU

Pharmacy. Evan Halper, *Mississippi, Home to the Federal Government's Official Stash of Marijuana*, L.A. TIMES (May 28, 2014), <https://www.latimes.com/nation/la-na-pot-monopoly-20140529-story.html>. See generally *Marijuana Research*, UNIV. OF MISS., <https://pharmacy.olemiss.edu/marijuana/history/> (last visited Dec. 18, 2019).

36. Agriculture Improvement Act of 2018, Pub. L. No. 115-334, 132 Stat. 4490.

37. See Moran, *supra* note 4, at 407.

38. *Id.* at 408.

39. See JOHNSON, *supra* note 17, at 6.

40. See *id.*

41. See Cherney & Small, *supra* note 3, at 2; Chris Hudock, *Hemp Cultivation in Europe*, NEW FRONTIER DATA (Sept. 2, 2019), <https://newfrontierdata.com/marijuana-insights/developed-global-markets-hemp-acreage-comparison/>; Stephen Kinzer, *Germany Lifting Ban on Hemp Growing, but not Marijuana*, N.Y. TIMES, Nov. 12, 1995 (§ 1), at 13, <https://www.nytimes.com/1995/11/12/world/germany-lifting-ban-on-hemp-growing-but-not-on-marijuana.html>.

42. Hudock, *Hemp Cultivation in Europe*, *supra* note 41, at 1.

specifies, amongst other things, methods of importation,⁴³ quality/control terms (such as clarifying the amount of permitted tetrahydrocannabinol (“THC”) in hemp similar to the 2018 Farm Bill),⁴⁴ and minimum yield amounts for calculating financial aid.⁴⁵ Given Europe’s hemp-friendly history, it is not surprising that an estimated twenty-five percent of the world’s hemp supply comes from European yields.⁴⁶ Along with the United States, Europe increased its harvesting of hemp for food and medicinal consumption, specifically revolving around cannabidiol (“CBD”).⁴⁷ However, there are issues regarding individual countries’ policies concerning the cultivation of the hemp plant, specifically within the context of developing CBD products.⁴⁸ Different European countries currently struggle with uniformly enforcing hemp regulations, leading to a crackdown in sales of CBD products in some countries, and a hands-off approach in others.⁴⁹ Because the EU has not provided uniform regulations and classifications of hemp derivatives, like CBD, the varying enforcement of hemp regulations will likely linger.⁵⁰

Regardless, Europe’s policies regarding hemp as a commodity have been significantly and continuously more stable than the United States’ policies. These policies allow Europe to have a traditionally secure industrial infrastructure for cultivating and processing hemp products.⁵¹ China is another major cultivator

43. See Council Regulation (EEC) 1430/82, 1982 O.J. (L 162) (restricting the importation of hemp in certain forms).

44. See Commission Implementing Regulation (EU) 2017/1172, 2017 O.J. (L 170) (amending prior regulations to better verify the THC content of hemp).

45. See Commission Regulation (EC) 452/1999, 1999 O.J. (L 54).

46. Hudock, *Hemp Cultivation in Europe*, *supra* note 4141.

47. *Id.* See *infra* Section III.A.1.i. (discussing the applications of CBD in further detail).

48. See Hudock, *Hemp Cultivation in Europe*, *supra* note 4141.

49. *Id.*

50. *Cf. id.* (explaining how the only present classification of CBD has led to confusion among European countries).

51. See JOHNSON, *supra* note 1717, at 8–9 (explaining how the infrastructure has developed for a long time through many EU countries lifting their bans on hemp production in the 1990s and the subsidized production of hemp under the EU’s Common Agricultural Policy).

and manufacturer of hemp with a history similar to that of Europe.⁵²

2. *Hemp Cultivation in China*

Hemp cultivation has continuously existed in China for thousands of years.⁵³ Today, China makes up roughly forty-eight percent of all industrial hemp fiber cultivation in the world.⁵⁴ China manufactures hemp for textiles and exports large quantities of raw hemp fiber for the global market.⁵⁵ Consequently, China supplies a large number of manufactured hemp products to the United States.⁵⁶ However, as both the domestic and international markets start expanding, “the questions you have to ask yourself regarding Chinese hemp are how much quality control is there, what are their crop regulations?”⁵⁷ If the international importation of Chinese hemp expands beyond textile development, concerns arise because “China’s crops have issues with pesticides and heavy metal control on the plants, and that can be a consumer issue for products consumed by humans. That said, China can cultivate hemp much cheaper without such oversight.”⁵⁸ Whereas China and Europe have traditionally allowed a hemp industry, Canada’s history is quite different. Canada’s historical hemp industry is prudent to examine, as it parallels the hemp industry in the United States in many ways.

52. See *id.* at 9 (“In 2016, China’s hemp was grown on about 20,000 acres.”). See also Stefano Amaducci et al., *Key Cultivation Techniques for Hemp in Europe and China*, 68 INDUS. CROPS & PRODS. 2, 3 (2015) (showing how both Europe and China have cultivated and manufactured hemp for thousands of years).

53. See Amaducci et al., *supra* note 5252, at 12 (“China has traditionally cultivated hemp for fibre and seed for more than 6000 years.”).

54. *Id.* (explaining how in the past decade China harvested 47.8% of the world total for fiber hemp).

55. *Id.* (“At present, the main end use destination of fibre hemp in China is for the production of textile fibre”); Moran, *supra* note 4, at 440 (“China is currently the largest supplier of raw and processed hemp fiber.”).

56. JOHNSON, *supra* note 1717, at 9.

57. Telephone Interview with Jacob Black, PhD, Organic Chemistry, CEO, Treehouse Hemp (Nov. 7, 2019).

58. *Id.*

3. *Hemp Cultivation in Canada*

Like the United States, Canada has a mixed history regarding hemp, with Canada outlawing industrial hemp cultivation for almost sixty years.⁵⁹ However, an increased interest in industrial hemp cultivation in the 1980s and 1990s led to Health Canada introducing and granting research licenses for industrial hemp cultivation; Health Canada's goal was to discern whether industrial hemp served a viable commercial market.⁶⁰ Following the success of this initiative, Health Canada permitted agriculturalists and industrialists to cultivate and manufacture hemp and hemp products in 1998.⁶¹ Since then, and under the regulations of Health Canada, Canadian hemp farmers and companies have produced a variety of hemp products including foods, edible oils, shampoo, conditioner, moisturizers, animal bedding, and home insulation.⁶² As of 2007, the majority of Canada's hemp and hemp-product exports went to the United States.⁶³ The United States has seemingly emulated Canada's regulatory model through its enactment of various pieces of legislation in 2014 and 2018.⁶⁴

II. HEMP CULTIVATION AND MANUFACTURING IN THE UNITED STATES AFTER 2014

2014 was a significant year for hemp in the United States. 2014 brought with it a piece of legislation that catalyzed the U.S.

59. Moran, *supra* note 4, at 393.

60. *Id.* See also *Hemp and the Hemp Industry Frequently Asked Questions*, GOV'T OF CAN., <https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/producing-selling-hemp/about-hemp-canada-hemp-industry/frequently-asked-questions.html#a7> (last visited Oct. 3, 2020) (explaining how the increased interest in the cultivation of hemp in the 1980s and 1990s led to permits for scientific research). See generally *Health Canada*, GOV'T OF CAN., <https://www.canada.ca/en/health-canada.html> (last visited Oct. 3, 2019) (providing information on the department of Canada's government broadly responsible for public health).

61. Moran, *supra* note 4, at 394.

62. *Id.* at 398.

63. *Id.* at 399.

64. *E.g.*, 7 U.S.C. § 5940(a) (2014) (allowing institutions of higher education or State departments of agriculture to grow or cultivate hemp for research purposes); 21 U.S.C. § 802(16)(B) (2019) (excluding "hemp" from the definition of marijuana).

government's reconsideration of hemp as an agricultural commodity.⁶⁵

A. *The Farm Bills, the CSA Currently, and an Emerging U.S. Hemp Market*

1. *2014 and 2018 Farm Bills and Their Effects on the CSA*

Congress passed, and Former President Obama signed, the Agricultural Act of 2014 (also collectively known as the "2014 Farm Bill") on February 7 of that year.⁶⁶ In effect, the 2014 Farm Bill allowed the respective State departments of agriculture and institutions of higher education to cultivate hemp for research purposes, provided certain conditions were met.⁶⁷ The passage of the 2014 Farm Bill brought with it various pilot programs, which furthered the understanding of industrial hemp cultivation and hemp market logistics.⁶⁸ The Agriculture Improvement Act of 2018 (colloquially referred to as the "2018 Farm Bill") was subsequently drafted to continue the goals of the 2014 Farm Bill.⁶⁹

Congress passed, and President Trump subsequently signed into law, the 2018 Farm Bill on December 20 of that year.⁷⁰ The 2018 Farm Bill overhauled over forty years of hemp cultivation prohibition.⁷¹ First, the 2018 Farm Bill provides a delineation of

65. See Moran, *supra* note 4, at 420 ("The inclusion of Section 7606 in the Agricultural Act of 2014 was a landmark step forward for the industrial hemp movement in the U.S.").

66. *Id.* at 418.

67. 7 U.S.C. § 5940(a).

68. See Telephone Interview with Andrew Livingston, Dir. of Econ. & Rsch., Vicente Sederberg LLP (Nov. 6, 2019); 7 U.S.C. § 5940 (allowing institutions of higher education or State departments of agriculture to grow or cultivate hemp for research purposes conducted under an agricultural pilot program).

69. See 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/> ("One of the goals of the 2014 Farm Bill was to generate and protect research into hemp. The 2018 Farm Bill continues this effort.").

70. Agriculture Improvement Act of 2018, Pub. L. No. 115-334, 132 Stat. 4490 (2018).

71. See Adam Drury, *Industrial Hemp is Now Included in the 2018 Farm Bill*, HIGH TIMES (Nov. 30, 2018), <https://hightimes.com/news/industrial-hemp-now-included-2018->

Cannabis Sativa L. into two categories: the federally illegal drug, marijuana, and the non-psychoactive agricultural commodity known as industrial hemp.⁷² Second, hemp no longer constitutes marijuana pursuant to the new definition of marijuana in the Farm Bill.⁷³ Third, the Farm Bill extends federal protection of hemp and hemp products in interstate commerce if the hemp is produced in a manner consistent with Subtitle G of the Agricultural Marketing Act of 1946 (“AMA”).⁷⁴

In effect, the 2018 Farm Bill legalizes all Cannabis Sativa L. that contains no more than 0.3 percent delta-9 tetrahydrocannabinol, albeit with caveats.⁷⁵ However, these caveats create tension between hemp entrepreneurs seeking to profit off of the now federally legal hemp and individual states who still classify all Cannabis Sativa L. as marijuana.⁷⁶ Despite this tension, the market potential for hemp and hemp derivatives is vast.⁷⁷ Therefore, an analysis of industrial hems current and potential uses will illustrate what the American hemp industry could look like within the next several years.

i. *Hemp: Market Projections, Current Uses, and Financial Potential for the United States*

To reiterate, in the United States, hemp is no longer a controlled substance so long as hemp contains less than “0.3

farm-bill/ (removing industrial hemp from the CSA opens the door for many more possible applications of hemp).

72. See 21 U.S.C. § 802(16)(A) (2019) (“[M]arihuana’ means all parts of the plant Cannabis sativa L.”); Agriculture Improvement Act § 10113, 7 U.S.C. § 1639o(1) (“[H]emp’ means the plant Cannabis sativa L. . . . with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.”).

73. 21 U.S.C § 802(16)(B) (excluding “hemp” from the definition of marijuana in 7 U.S.C. § 1639o).

74. Agriculture Improvement Act § 10114(a)–(b), 7 U.S.C. § 1639o note.

75. *Id.* § 10113, 7 U.S.C. § 1639o(1).

76. *E.g.*, Big Sky Sci. LLC v. Idaho State Police, No.1:19-cv-00040-REB, 2019 WL 2613882 (D. Idaho Feb. 19, 2019) (mem op.) (involving a dispute between a company shipping industrial hemp interstate and the state seizing the cargo whose state law still classifies industrial hemp as a controlled substance), *rev’d sub nom. on other grounds* Big Sky Sci. LLC v. Bennetts, 776 F. App’x 541 (9th Cir. 2019).

77. See *infra* Section III.A.1.ii.

percent [THC] on a dry weight basis.”⁷⁸ Although the legal gaps and contentions still lend themselves to a variety of issues, a legal consumer market for hemp products has been further established by the changes the 2018 Farm Bill provided.⁷⁹ This legal market lends itself to expansion as the market predictions for hemp-product demand referenced earlier have suggested.⁸⁰

The current value of the industrial hemp market is approximately \$4.41 billion U.S. dollars and is anticipated to grow to \$14.67 billion U.S. dollars by 2026.⁸¹ The textile industry is currently one of the largest consumers of industrial hemp (using industrial hemp for manufacturing apparel, fabrics, denim, fine textiles, etc.) and is valued at \$1.03 billion U.S. dollars.⁸² The market for CBD reached nearly \$600 million U.S. dollars in 2018,⁸³ with numerous projections suggesting that the CBD market will rise to \$22 billion U.S. dollars by 2022.⁸⁴ Both the multibillion-dollar value of these already-established hemp industries and their projected market value demonstrate substantial growth. However, the scope of this growth is limited

78. Agriculture Improvement Act § 10113, 7 U.S.C. § 1639o(1); 21 U.S.C. § 802(16)(B) (2019) (excluding “hemp” from the definition of marijuana); Telephone Interview with Courtney Barnes, Founding Partner, Barnes Caplan LLP (Nov. 6, 2019).

79. See Press Release, Edgar Ward, President/CEO, NutraFuels, Legalization of Industrial Hemp Positions NutraFuels for Market Expansion (Dec. 21, 2018) (explaining how the 2018 Farm Bill provides clarity against the lack of legal clarification and the longtime stigma around hemp).

80. See *id.* (“The new law provides clarity and the legal parameters to enable companies like NutraFuels to capitalize on a more efficient operating environment and market expansion.”). See also Fior Mkts., *supra* note 8 (“Increasing demand in application industries and growing legalization of hemp cultivation are the two factors which may boost the growth of the industrial hemp market.”).

81. Fior Mkts., *supra* note 8.

82. *Id.*

83. Elisabeth Garber-Paul, *Exclusive: New Report Predicts CBD Market Will Hit \$22 Billion by 2022*, ROLLING STONE (Sep. 11, 2018, 7:00PM ET), <https://www.rollingstone.com/culture/culture-news/new-study-cbd-market-22-billion-2022-722852/>. See generally *Cannabinoid*, MERRIAM-WEBSTER, <https://www.merriam-webster.com/dictionary/cannabinoid> (“[A]ny of [the] various naturally-occurring, biologically active, chemical constituents (such as cannabidiol or cannabinol) of hemp or cannabis including some (such as THC) that possess psychoactive properties.”).

84. Ward, *supra* note 79.

to known hemp products.⁸⁵ Various markets could potentially be equal to or more valuable than the products comprising the current hemp industry.

There are fifty thousand claimed applications for hemp and hemp products, with the most prominent uses traditionally revolving around fiber.⁸⁶ Hemp fiber is commonly utilized for both animal bedding and concrete for building construction, particularly in Europe,⁸⁷ while also serving as a prominent source of materials for manufacturing textiles in countries such as China.⁸⁸ China has numerous well-established textile facilities coupled with a cheap labor force, and Europe has had a stable hemp fiber market spanning over two decades.⁸⁹ These market traditions indicate that the financial potential in the hemp fiber market is likely occupied by China and Europe, thereby inhibiting the United States from receiving large market gains by entering these industries.⁹⁰ However, with the emerging CBD market and its projected growth being primarily centered in the United States,⁹¹ there is a lucrative potential use of hemp America could dominate: pharmaceuticals.⁹²

Current scientific consensus indicates that CBD and other cannabinoid variants have beneficial properties, including anti-anxiety, anti-psychotic, anti-depressant, and anti-inflammatory effects.⁹³ Such associated benefits have resulted in the United States Food and Drug Administration (“FDA”) approving the drug Epidiolex, which is CBD-derived and used to treat several rare

85. See Garber-Paul, *supra* note 83 (showing how many new applications of CBD are being discovered and used in recent years).

86. Cherney & Small, *supra* note 3, at 3.

87. *Id.* at 4.

88. *Id.* at 5.

89. *Id.*

90. See *id.*

91. See generally Andre Bourque, *As Competition Increases, CBD Companies Need the Right Mentors to Survive*, FORBES (June 24, 2019), <https://www.forbes.com/sites/andrebourque/2019/06/24/as-competition-increases-cbd-companies-need-the-right-mentors-to-survive/#26c9e81c7b00> (illustrating the potential growth in U.S. markets); Ward, *supra* note 79 (estimating that the CBD market will be worth \$22 billion by 2022).

92. See Cherney & Small, *supra* note 3, at 3.

93. See *id.* at 8.

and severe forms of epilepsy.⁹⁴ CBD is but one of many cannabinoids that have historically been under-researched in the United States due to the broad prohibitions against cannabis.⁹⁵ In fact, “there are over 100 known naturally occurring cannabinoids” that could be extracted from hemp and have potential medicinal properties.⁹⁶

While the beneficial properties of less famous cannabinoids are still not completely understood, the United States could profit greatly if any of the other ninety-eight known cannabinoids have effective medicinal features and can be successfully manufactured into prescription drugs like Epidiolex. Assuming more hemp research further reveals therapeutic possibilities of these other cannabinoids, the market potential for hemp and hemp-derivatives likely will grow larger. In particular, companies like Colorado-based Treehouse Hemp predict the continued expansion of hemp and hemp-derivatives in areas such as food, dietary supplements, and even cosmetics.⁹⁷ With the 2018 Farm Bill creating a landscape more conducive to future hemp research and product development, various hemp derivatives could wind up in cosmetics or over-the-counter treatments for “skin rashes, acne, even topical pain relief” due to the anti-inflammatory effects of cannabinoids.⁹⁸ This potential industry left largely unoccupied by Canada, Europe, and China is but the tip of the proverbial iceberg and could be an analogue to CBD’s substantial market expansion.

With the overall market for hemp and hemp-products likely increasing over the foreseeable future, and the emerging potential uses described above, there are currently gaping structural issues

94. Amy Abernethy & Lowell Schiller, *FDA is Committed to Sound, Science-based Policy on CBD*, U.S. FOOD & DRUG ADMIN. (July 17, 2019), <https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-committed-sound-science-based-policy-cbd>.

95. Press Release, Nat’l Acads. of Scis., Committee on the Health Effects of Marijuana, *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research* (Jan. 12, 2017) (on file with the National Academies Press (U.S.)).

96. Black, CEO, Treehouse Hemp, *supra* note 57. See Cherney & Small, *supra* note 3, at 7.

97. Black, CEO, Treehouse Hemp, *supra* note 57.

98. *Id.*

in domestic policy that the United States must address. Such policy issues include the needed United States Department of Agriculture (“USDA”) hemp regulations⁹⁹ and the FDA’s enforcement of the Federal Food, Drug and Cosmetic Act (“FFDCA”).¹⁰⁰

ii. *USDA Regulations and Federal Protection under Subtitle G of the AMA*

The passage of the 2014 and 2018 Farm Bills overhauled over forty years of legal problems regarding American hemp cultivation. While “hemp is no longer a legally taboo commodity since it’s no longer a controlled substance,” the laws and regulations governing hemp in the United States continue to evolve rapidly.¹⁰¹ The 2018 Farm Bill is predicated on a federal regulatory structure for governmental oversight of hemp cultivation.¹⁰²

Although the USDA will be the primary federal regulatory agency overseeing hemp production in the United States, [U.S.] states, U.S. territories, and Indian tribes desiring to obtain (or retain) primary regulatory authority over hemp activities within their borders are allowed to do so after submitting a plan for regulation to the USDA, and receiving approval from the USDA for the same. Hemp production in jurisdictions that do not submit their own plans (and do not otherwise prohibit hemp production) will be governed by USDA regulation.¹⁰³

99. See *infra* Appendix I.

100. 21 U.S.C. § 371 (2018).

101. Barnes, *supra* note 78.

102. See Agriculture Improvement Act of 2018 §§ 10113, 10114(b), 7 U.S.C. §§ 1639o–s, 1639o note (2018). See, e.g., Agricultural Marketing Act of 1946, 21 U.S.C. § 601 (2018) [hereinafter *Agricultural Marketing Act*]; Hudak, *supra* note 69.

103. Barnes, *supra* note 78. See also Agriculture Improvement Act § 10113(297C(a)), 7 U.S.C. § 1639q; Hudak, *supra* note 69.

Immediately following the passage of the 2018 Farm Bill, there were no such regulations. However, on October 31, 2019, the federal government released interim rules for hemp production.¹⁰⁴ As a result, the USDA will now begin reviewing state hemp production plans. Once a hemp production plan is approved by the USDA, the state can convert its 2014 Farm Bill research program into a 2018 Farm Bill commercial regulatory regime.¹⁰⁵ The interim rules notably mark a transition period, and it could be up to two years before a final ruleset is adopted.¹⁰⁶ Even so, “the interim final rule provides necessary legal protections and parameters for states to begin implementing commercial hemp programs.”¹⁰⁷ However, because the interim rules have not gone into effect, this transitional period does come with its own set of temporary problems.

The issues of affording federal protection to industrial hemp are two-fold: there are difficulties of delineating hemp from marijuana,¹⁰⁸ and individual states vary in terms of their controlled substances definitions.¹⁰⁹ The 2018 Farm Bill regarding protection of hemp in interstate commerce states:

No State or Indian Tribe shall prohibit the transportation or shipment of hemp or hemp products produced in accordance with subtitle G of

104. Interim Domestic Hemp Production Program, 7 C.F.R. § 990 (2019).

105. See Press Release, U.S. Dep’t of Agric., USDA Establishes Domestic Hemp Production Program (Oct. 29, 2019) [hereinafter USDA Establishes Domestic Hemp Production Program], <https://www.usda.gov/media/press-releases/2019/10/29/usda-establishes-domestic-hemp-production-program>. See generally 7 C.F.R. § 990.

106. 7 C.F.R. § 990; USDA Establishes Domestic Hemp Production Program, *supra* note 105.

107. Barnes, *supra* note 78. See Press Release, Agric. Mktg. Servs., U.S. Dep’t of Agric., Establishment of a Domestic Hemp Production Program (Oct. 31, 2019) [hereinafter Establishment of a Domestic Hemp Production Program], <https://www.federalregister.gov/documents/2019/10/31/2019-23749/establishment-of-a-domestic-hemp-production-program>; USDA Establishes Domestic Hemp Production Program, *supra* note 105.

108. Moran, *supra* note 4, at 413 (showing DEA’s traditional position and a primary concern in regulating hemp).

109. See generally *Big Sky Sci. LLC v. Idaho State Police*, No. 1:19-cv-00040-REB, 2019 WL 2613882 (D. Idaho Feb. 2, 2019) (mem op.), *rev’d sub nom. on other grounds* *Big Sky Sci. LLC v. Bennetts*, 776 F. App’x 541 (9th Cir. 2019).

the Agricultural Marketing Act of 1946 (as added by section 10113) through the State or the territory of the Indian Tribe, as applicable.¹¹⁰

But again, the AMA requires states to adopt a USDA-approved hemp cultivation plan if their own plan has not been approved under Section 297B in order to protect against any hindrances or interference in the interstate transportation of hemp.¹¹¹ This has not happened universally across the states.¹¹² Therefore, there will likely continue to be more instances of interference of interstate transportation of hemp (particularly as states and their actors may have hemp still defined as a controlled substance such as in *Big Sky Scientific LLC v. Idaho State Police*).¹¹³

This transitional period also means that the vast majority of American hemp companies are, by definition, not complying with the 2018 Farm Bill. Again, hemp entrepreneurs are required to abide by regulations promulgated or accepted by the USDA for the sake of compliance, but these regulations did not take legal effect until October 31, 2019.¹¹⁴ Under the 2018 Farm Bill, hemp entrepreneurs are not dealing with illegal commodities, but are operating in a space that effectively has no federally approved regulatory oversight for a nationally streamlined domestic hemp market.¹¹⁵ Hemp is, therefore, subject to the interpretation and execution of the laws on a state-by-state basis, theoretically allowing states to hinder hemp and hemp product manufacturing.¹¹⁶ This legal gray area inherently creates a

110. Agriculture Improvement Act of 2018 § 10114(b), 7 U.S.C. § 1639o note (2018).

111. Agricultural Marketing Act § 297, 7 U.S.C. § 1639q.

112. *Status of State and Tribal Hemp Production Plans for USDA Approval*, USDA, <https://www.ams.usda.gov/rules-regulations/hemp/state-and-tribal-plan-review> (last visited May 23, 2021) (listing the USDA approval status of hemp production plans in each state).

113. See generally *Big Sky Sci.*, 2019 WL 2613882, at *3.

114. Establishment of a Domestic Hemp Production Program, *supra* note 107.

115. See *id.*

116. “[T]here have been a number of local and state enforcement actions in states . . . [that] do not allow the sale of hemp and/or CBD products, or where enforcement has confused hemp-derived CBD with marijuana.” Shawn Hauser, *Hemp and Hemp-Derived*

chilling effect on people seeking to enter the American hemp industry, as the uncertainty with the domestic hemp industry subjects hemp entrepreneurs to potentially fifty varying interpretations of hemp.¹¹⁷ Consequently, both the domestic and international hemp markets are impaired; the execution of controlled substance laws in the United States can impede hemp entrepreneurs seeking to expand their business to a national and global scale.¹¹⁸ However, it is important to note that the domestic hemp industry's current issues concerning USDA regulations are temporary, and hemp entrepreneurs still exist and thrive in the present landscape (albeit not as much as they potentially could).¹¹⁹

The USDA has stated that it will accept or promulgate rules for states to be federally compliant with hemp regulations.¹²⁰ While the timeframe for the implementation of such hemp regulations has not always reflected what the USDA has indicated, the federal government has signaled it intends to provide such regulations.¹²¹ Hemp experts have stated as much, predicting that “in the next few years or so, the 2018 Farm Bill should be fully implemented and hopefully eliminate some of these concerns.”¹²² There are other considerations for the domestic hemp industry as products continue to be developed specifically within the context of products meant for consumption. While products intended for consumption do fall within the scope of the USDA, this scope overlaps with the FDA.¹²³

Cannabinoid Issues, in MASSACHUSETTS CANNABIS LAW MANUAL § 7.6.5 (Mass. Continuing Legal Educ., Inc. 2019).

117. See generally *Big Sky Sci.*, 2019 WL 2613882, at *3 (observing that “states and Indian tribes may choose to regulate industrial hemp on their own”).

118. *Id.*

119. 7 C.F.R. § 990 (2019) (noting the temporary nature of the current USDA regulations by stating the defined end date).

120. *Id.* § 990.4.

121. See Establishment of a Domestic Hemp Production Program, *supra* note 107; USDA Establishes Domestic Hemp Production Program, *supra* note 105.

122. Barnes, *supra* note 78.

123. See *infra* Appendix I.

iii. *The FFDCA and its Enforcement through the FDA*

Congress passed, and Former President Roosevelt subsequently signed into law, the FFDCA in 1938.¹²⁴ The stated objective of this legislation has been and continues to be the prevention of “fraudulent activity with respect to food, drugs,” and various other consumable products falling within interstate commerce in the United States for the benefit and safety of consumers.¹²⁵ While the FFDCA has been amended many times since its enactment, the FFDCA continues to be the primary law regulating the safety of most foods, supplements, prescription drugs, and cosmetics.¹²⁶ The FFDCA is primarily enforced by the FDA, endowing the FDA with broad powers and the ability to impose various civil and criminal penalties against actors violating the FFDCA.¹²⁷ Consequently, the FFDCA creates an expansive scope for the FDA to analyze and regulate food, dietary supplements, drugs, and cosmetics.¹²⁸

The FFDCA provides a framework where products fitting into various categories of food, drugs, dietary supplements, and cosmetics must be produced in what the FDA deems sanitary conditions.¹²⁹ Moreover, these products must comply with FFDCA labeling requirements.¹³⁰ Products are analyzed to determine whether they are “adulterated” or “misbranded,” depending on how the FDA and FFDCA categorizes them.¹³¹ Consumable products are considered “adulterated” if they contain, amongst other things, new dietary ingredient(s) “for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable

124. Hauser, *supra* note 116, § 7.8. See generally JENNIFER A. STAMAN, CONG. RSCH. SERV., R43609, ENFORCEMENT OF THE FOOD, DRUG, AND COSMETIC ACT: SELECT LEGAL ISSUES 2 (2018); *Franklin D. Roosevelt*, HISTORY (Oct. 29, 2009), <https://www.history.com/topics/us-presidents/franklin-d-roosevelt> (last updated Apr. 1, 2021) (noting that Franklin D. Roosevelt served as President from 1933 to 1945).

125. STAMAN, *supra* note 124, at 1.

126. *Id.* at 2–3.

127. *Id.* at 4.

128. *Id.*

129. *Id.* at 2–3.

130. *Id.*

131. *Id.* at 3.

risk of illness.”¹³² These same products are considered “misbranded” if in package form unless it is labeled with “(1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.”¹³³ These regulatory concepts are salient throughout the current American hemp market due to the FDA approving the CBD-based drug, Epidiolex.¹³⁴ Epidiolex created a tension between the enforcement of the FFDCA amongst hemp entrepreneurs seeking to cash in on the CBD craze and the FDA’s regulatory oversight.¹³⁵

Both the FDA and DEA have indicated that CBD not only can be safe for human consumption in specific contexts but also has distinct medical benefits.¹³⁶ While foods, drugs, dietary supplements, and cosmetics are all regulated by the FDA, the FDA regulates these products differently depending on the FDA’s relationship with them.¹³⁷ The FDA considers various compounds within “drugs” to be unsafe until proven safe, and compounds within supplements and cosmetics are considered to be safe until proven unsafe.¹³⁸ Consequently, where FFDCA requires drugs to be proven safe before being marketed, supplements and cosmetics are under no such obligation.¹³⁹ This paradigm creates a

132. 21 U.S.C. § 342(f)(B) (2005).

133. 21 U.S.C. § 352(b) (2018).

134. See *FDA Approves First Drug Comprised of an Active Ingredient Derived from Marijuana to Treat Rare, Severe Forms of Epilepsy*, U.S. FOOD & DRUG ADMIN. (June 25, 2018), <https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms>.

135. Scott Gottlieb, *The CBD Craze Is Getting Out of Hand. The FDA Needs to Act.*, WASH. POST (July 30, 2019), https://www.washingtonpost.com/opinions/the-cbd-craze-is-getting-out-of-hand-the-fda-needs-to-act/2019/07/30/94c8024c-b211-11e9-8f6c-7828e68cb15f_story.html.

136. Hauser, *supra* note 116, § 7.8.

137. *FDA Regulation of Drugs Versus Dietary Supplements*, AM. CANCER SOC’Y (Mar. 31, 2015), <https://www.cancer.org/treatment/treatments-and-side-effects/complementary-and-alternative-medicine/dietary-supplements/fda-regulations.html>.

138. *Id.* See also 21 U.S.C. § 321(f)–(g)(1) (2016) (provides and contrasts FDA’s definition of “drug” and “food or dietary supplement”).

139. *FDA 101: Dietary Supplements*, U.S. FOOD & DRUG ADMIN. (July 15, 2015), <https://www.fda.gov/consumers/consumer-updates/fda-101-dietary-supplements>; *FDA Authority Over Cosmetics: How Cosmetics Are Not FDA-Approved, but Are FDA-Regulated*, U.S. FOOD & DRUG ADMIN. (Aug. 24, 2020), <https://www.fda.gov/cosmetics/cosmetics-laws->

landscape where hemp entrepreneurs are attempting, and in some instances succeeding, in circumventing various aspects of FDA regulations concerning CBD by distributing hemp derivatives as cosmetics and dietary supplements.¹⁴⁰ These products are not subject to the same levels of regulatory and legal scrutiny facially.¹⁴¹ However, the FDA has stated that when these products are marketed with health claims associated with hemp derivatives like CBD, this marketing implicates that these products could be “adulterated” or “mislabeled” “drugs.”¹⁴² Consequently, hemp entrepreneurs could be subject to all the associated penalties of producing hemp derivatives, specifically CBD, that are “adulterated” or “mislabeled.”¹⁴³ However, in practice, the FDA has not enforced the FFDCA to the greatest extent possible.

Again, by approving the CBD-based drug Epidiolex, the FDA has conceded there are contexts where CBD consumption is safe, but the only context of CBD production that is marketed as a drug, food, or dietary supplement the FDA considers legal is the production of CBD for Epidiolex.¹⁴⁴ The FDA has stated:

Among other things, it is currently illegal to put into interstate commerce a food to which CBD has been added, or to market CBD as, or in, a dietary supplement. Essentially, the relevant statutory provisions prohibit these uses of CBD because CBD

regulations/fda-authority-over-cosmetics-how-cosmetics-are-not-fda-approved-are-fda-regulated#What_does_the_law.

140. *What You Need to Know (And What We’re Working to Find Out) About Products Containing Cannabis or Cannabis-Derived Compounds, Including CBD*, U.S. FOOD & DRUG ADMIN. (Mar. 5, 2015), <https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis>.

141. *Compare FDA 101: Dietary Supplements*, *supra* note 139, with *Summary of Cosmetic Labeling Requirements*, U.S. FOOD & DRUG ADMIN. (Aug. 24, 2020), <https://www.fda.gov/cosmetics/cosmetics-labeling-regulations/summary-cosmetics-labeling-requirements>.

142. *See What You Need to Know (And What We’re Working to Find Out) About Products Containing Cannabis or Cannabis-Derived Compounds, Including CBD*, *supra* note 140.

143. *Id.*

144. *See id.*

was the subject of substantial clinical investigations into its potential medical uses before it was added to foods (including dietary supplements), and, separately, because CBD is the active ingredient in Epidiolex, an FDA-approved prescription drug product to treat rare, severe forms of epilepsy.¹⁴⁵

This statement stipulates that when compounds like CBD have been subject to clinical investigations for medical use before any other FDA-approved use, using the compound as a drug, food, or dietary supplement is considered illegal.¹⁴⁶ The FDA has also signaled that it may crack down on hemp entrepreneurs operating outside its approval through the distribution of supplements with CBD, stating:

There is a significant interest in the development of therapies and other consumer products derived from cannabis and its components, including cannabidiol (CBD). FDA recognizes the potential opportunities that cannabis or cannabis-derived compounds may offer and acknowledges the significant interest in these possibilities. However, FDA is aware that some companies are marketing products containing cannabis and cannabis-derived compounds in ways that violate the Federal Food, Drug and Cosmetic Act . . . and that may put the health and safety of consumers at risk. The agency is committed to protecting the public health while also taking steps to improve the efficiency of regulatory pathways for the lawful marketing of appropriate cannabis and cannabis-derived products.¹⁴⁷

145. Abernethy & Schiller, *supra* note 94.

146. *See id.*

147. *FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)*, U.S. FOOD & DRUG ADMIN. (Oct. 1, 2020), <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd#relatedinfo>.

However, “federal enforcement of the FFDCA prohibition against CBD-containing products, to date, has been sporadic at best and is generally targeted at products that pose a risk to public health and safety.”¹⁴⁸ In worst-case scenarios, “FDA enforcement has generally been limited to the dissemination of cease and desist warning letters sent to product manufacturers and retailers making drug claims about their unapproved CBD products.”¹⁴⁹

This level of enforcement by the FDA bodes well for hemp entrepreneurs trailblazing the domestic hemp market. With numerous states constructing and implementing their hemp regulations, there are distinct models for what regulatory compliance and entrepreneurship could look like soon.

2. *The American Hemp Entrepreneur*

i. *Current Models for Federal Hemp Compliance*

There are various ways a person could enter the American Hemp Market presently, but broadly speaking, there are two, non-mutually exclusive methods that one must consider. The first avenue is to enter as a hemp farmer, while the second is as a hemp manufacturer.¹⁵⁰ If a potential hemp entrepreneur decided to be a vertically integrated company,¹⁵¹ that entrepreneur would still have to determine what product(s) they wish their hemp to end up as (food, plant fiber, pharmaceuticals, etc.) when applying for a license.¹⁵² The approval of a hemp cultivation and/or manufacturing license is crucial as Section 10113 of the 2018 Farm Bill allows the hemp entrepreneurship only if individual state departments of agriculture devise a plan that is accepted by the USDA (as discussed previously regarding Subtitle G of the

148. Hauser, *supra* note 116, § 7.7.

149. *Id.*

150. *2018 Farm Bill and Hemp in Kentucky*, KY. DEPT OF AGRIC., https://www.kyagr.com/marketing/program_id/70/documents/HEMP_OV_2018FarmBillHempinKY.pdf.

151. *Vertical Integration*, MERRIAM-WEBSTER, <https://www.merriam-webster.com/dictionary/vertical%20integration> (last visited Dec. 18, 2019).

152. See *2018 Farm Bill and Hemp in Kentucky*, *supra* note 150.

AMA).¹⁵³ These plans and instructions will either vary from state to state, or a state can choose to adopt the USDA's plan, but they further instruct hemp entrepreneurs as to how to comply with pertinent rules.¹⁵⁴ Such model regulations typically include various fees surrounding application(s) depending on the nature of the business or university, zoning plans, background checks, orientation training, renewals, and so on.¹⁵⁵ While this is where current American hemp regulations end, these model regulations have provided a foundation for the American hemp entrepreneur to meet consumer demand for hemp products.

ii. *Meeting Current American Consumer Demand for Hemp Products*

As suggested earlier, market analyses display a high consumer demand for CBD within the United States; such analyses also project a continued increase in consumer demand for CBD over the next several years.¹⁵⁶ Despite the chilling effect of a potential FDA crackdown on manufacturers of hemp derivatives (such as CBD), this current and projected landscape has led various hemp entrepreneurs to meet such consumer demands.¹⁵⁷ Treehouse Hemp is an example of such hemp entrepreneurs meeting consumer demands.¹⁵⁸

Founded shortly after the passage of the 2014 Farm Bill, Treehouse Hemp is a "manufacturer of hemp-derived ingredients," emphasizing the development of hemp products through "pioneering the chemistry and biochemistry of cannabinoids."¹⁵⁹ Treehouse Hemp offers a variety of hemp-derived products such as CBD isolate and extracts containing

153. Hudak, *supra* note 69.

154. *Id.*

155. *2018 Farm Bill and Hemp in Kentucky*, *supra* note 150.

156. Ward, *supra* note 7979.

157. *See id.*; 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>.

158. *About Us*, TREEHOUSE HEMP, <https://treehousehemp.com/about-us/> (last visited Dec. 18, 2019).

159. Treehouse, LINKEDIN, <https://www.linkedin.com/company/treehouse-hemp/about/> (last visited Dec. 18, 2019).

other minor cannabinoids.¹⁶⁰ As the understanding of and market for hemp and its derivatives expands, Treehouse Hemp looks to expand with it concurrently.¹⁶¹ With the contention regarding FDA regulation in the background, Treehouse Hemp's product development department and legal counsel's "day-to-day consists of figuring out how to compare [the] industry to industries offering similar products," such as cosmetics and supplements.¹⁶² Treehouse Hemp achieves this goal by analyzing how other companies selling cosmetics and supplements deal with the FDA's regulatory scheme concerning various product additives.¹⁶³ Treehouse Hemp then emulates these companies and develops products they believe are analogous to theirs but which contain hemp/hemp derivatives in lieu of other additives "to anticipate how the FDA could categorize these kinds of products in the future."¹⁶⁴ There is little certainty that Treehouse Hemp's current method for product development and compliance will ultimately hold up in the future. But, as the American hemp market continues to take shape, companies like Treehouse Hemp must and will take shape with it.

Compliance issues with hemp product categorization in American policy have yet to be fully overcome. However, these issues implicate a much larger problem that must also be addressed should companies like Treehouse Hemp wish to expand to an international market. The FDA has its standards for regulating products based on various categories, but so does the U.S. International Trade Commission ("USITC") and the WTO.¹⁶⁵ If both the United States and the WTO wish to have the hemp market scale internationally and maximize wealth, it is reasonable to analyze some prominent tools both the USITC and

160. *Our Products*, TREEHOUSE HEMP, <https://treehousehemp.com/hemp-products/> (last visited Dec. 18, 2019).

161. Telephone Interview with Casey Black, General Counsel, Treehouse Hemp (Nov. 7, 2019).

162. *Id.*

163. *Id.*

164. *Id.*

165. *About the USITC*, U.S. INT'L TRADE COMM'N, https://www.usitc.gov/press_room/about_usitc.htm (last visited May 30, 2021).

WTO use to streamline trade.¹⁶⁶ These tools are rules of origin and harmonized tariff schedules.

III. INTERNATIONAL CONSIDERATIONS: RULES OF ORIGIN AND HARMONIZED TARIFF SCHEDULES

A. *Rules of Origin: Definitions and Purpose*

Rules of origin “were first introduced to gather statistics, to enable governments to determine the provenance of goods entering and leaving their territory, and to enable the analysis of demand and supply” of certain goods.¹⁶⁷ Rules of origin began evolving as major trading nations began creating special trade arrangements, resulting in tariffs being applied differently to goods depending on their country of origin’s identity.¹⁶⁸ Today, rules of origin function as a set of criteria needed to determine where a product was nationally sourced to appropriately apply duties and restrictions on goods relative to where the goods were sourced.¹⁶⁹ The applicable duties and restrictions on goods relative to their country of origin are imposed through preferential and non-preferential trade arrangements (also referred to as preferential and non-preferential rules of origin).¹⁷⁰ Rules of origin policies are implemented by national governments but subject to oversight from the WTO.¹⁷¹

In its Agreement on Rules of Origin, the WTO defines preferential rules of origin as “those laws, regulations and administrative determinations of general application applied by any Member to determine whether goods qualify for preferential treatment under contractual or autonomous trade regimes leading to the granting of tariff preferences going beyond the

166. See generally *Harmonized Tariff Information*, U.S. INT’L TRADE COMM’N, https://www.usitc.gov/harmonized_tariff_information (last visited May 30, 2021).

167. EDWIN VERMULST ET AL., *RULES OF ORIGIN IN INTERNATIONAL TRADE* 8 (1994).

168. *Id.*

169. *Technical Information on Rules of Origin*, WORLD TRADE ORG. https://www.wto.org/english/tratop_e/roi_e/roi_info_e.htm.

170. *Id.*

171. VERMULST ET AL., *supra* note 167, at 8.

application of paragraph 1 of Article I of GATT 1994.”¹⁷² Essentially, preferential trade arrangements apply reciprocal trade preferences between members of the arrangement (generally regional trade arrangements and customs unions), which are not afforded to those states outside of the agreement.¹⁷³ An example of such an arrangement would be the North American Free Trade Agreement (“NAFTA”), where the United States allowed imports from other NAFTA members (Canada and Mexico) to enter the United States duty-free.¹⁷⁴ The formation of free-trade areas (“FTA”) like NAFTA, or customs unions like the EU, is allowed in spite of general policies against discriminatory treatment, provided the FTA does not increase trade barriers which negatively impact imports from other states.¹⁷⁵

The WTO defines non-preferential rules of origin as “those laws, regulations and administrative determinations of general application applied by any Member to determine the country of origin of goods provided such rules of origin are not related to contractual or autonomous trade regimes leading to the granting of tariff preferences going beyond the application of paragraph 1 of Article I of GATT 1994.”¹⁷⁶ Effectively, non-preferential rules of origin, specifically within the context of Article I, oblige states to offer (specifically in regard to today’s international trade landscape, WTO members) the treatment offered to any other state and outside the scope of trade regimes granting preference towards particular and stipulated parties.¹⁷⁷

Whether preferential or non-preferential, rules of origin permeate throughout international trade, helping parties in trade receive “treatment in accordance with the treaties and agreements between them.”¹⁷⁸ However, rules of origin are only

172. Marrakesh Agreement Establishing the World Trade Organization, art. 1, Apr. 15, 1994, 1867 U.N.T.S. 154 [hereinafter Marrakesh Agreement].

173. PAUWELYN ET AL., *supra* note 12, at 354.

174. *Id.*

175. *Id.* at 349, 354–55.

176. Marrakesh Agreement, *supra* note 172, art. 1.

177. *Id.* (giving a list of examples of this concept such as most-favoured-nation treatment, anti-dumping and countervailing duties, safeguard measures, and origin marking requirements).

178. VERMULST ET AL., *supra* note 167, at 8.

one component. The other element to consider is the applicable tariff laws relative to the product traded.

B. *Tariff Scheduling: Definition and Purpose*

Tariffs broadly function as a tax in the context of imports.¹⁷⁹ An importing country collects the amount relative to the stipulated tariff rate, and that amount is paid for by foreign exporters or domestic importers.¹⁸⁰ To more efficiently classify and apply pertinent tariffs specific to imported goods, entities codify tariff schedules, thereby creating streamlined tariff standards.¹⁸¹ Prominent examples of such codes are the Harmonized Tariff Schedule of the United States ("USHTS") and the WTO schedule of tariff concessions.¹⁸² The former applies to the importation of goods for the United States, while the latter functions as concessions from WTO members; when states join the WTO they agree to a tariff ceiling where goods they import can be equal to or lower to the WTO's stipulated tariff ceiling, but not higher.¹⁸³

Consequently, the relevant rules of origin, in conjunction with tariff schedules, ultimately decide what rate countries should tax goods being imported into them.¹⁸⁴ However, both the United States' and the WTO's current policies raise concerns for the future of hemp. The next section examines rules of origin and tariff classifications for industrial hemp in the United States and WTO as they exist currently.

C. *Shortcomings of Rules of Origin and Harmonized Tariff Schedules Regarding the Hemp Industry*

While rules of origin and tariff schedules have been and continue to be beneficial tools for international trade, the current setup of both the WTO's and the USHTS' are not conducive to an expanding international hemp market. To reiterate, the projected

179. PAUWELYN ET AL., *supra* note 12, at 181.

180. *Id.*

181. *Id.* at 182.

182. *See id.*

183. *Id.*

184. *Id.* at 184–85.

market for economically viable hemp and hemp derivatives centers around pharmaceuticals, oilseed, cosmetics, foods, and fibers.¹⁸⁵ Yet, within the USHTS, there is a discrepancy between these products and hemp.¹⁸⁶ An example of this is Chapter 30 of the USHTS, which references various organic compounds and derived chemicals in relation to pharmaceutical products, but mentions nothing related to cannabinoids despite the United States having an FDA-approved cannabinoid-based drug, Epidiolex.¹⁸⁷

The WTO's tariff schedule has a similar issue where hemp and hemp-derived products are classified within the context of hemp-fiber by-products, raw hemp, waste hemp, and the like, but not within the context of pharmaceuticals.¹⁸⁸ Whereas other commodities derived from plants such as coconuts are delineated amongst the prevalent uses of such plants (coconuts in the WTO tariff schedule are classified under vegetable oils, textile fibers, raw plant material for consumption, etc.), hemp is not lent such scrutiny.¹⁸⁹ Further, where certain compounds and derivatives, such as vitamin A and hydrocortisone, are delineated for uses in supplements and medication, the WTO fails to account for the cannabinoids in cannabis (like CBD) with known medicinal properties.¹⁹⁰ Consequently, as the domestic and international hemp market continues to increase and the list of products that even partially contain hemp/hemp derivatives correspondingly

185. See Cherney & Small, *supra* note 3, at 3, 6–7.

186. Harmonized Tariff Schedule of the United States, USITC Pub. 4862, ch. 30 (Jan. 2019), <https://hts.usitc.gov/view/release?release=2019HTSABASICA> (click on “Full Document” to download PDF).

187. See *id.*; Press Release, Food & Drug Admin., FDA Approves First Drug Comprised of an Active Ingredient Derived from Marijuana to Treat Rare, Severe Forms of Epilepsy (June 25, 2018), <https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms>.

188. See World Trade Organization, WTO Tariff Database, <http://tariffdata.wto.org/ReportersAndProducts.aspx> (in the “Products” field, scroll to “53 – Other Vegetable Textile Fibres; Paper Yarn and Woven Fabrics of Paper Yarn” and expand the section) (last visited Dec. 18, 2019).

189. *Id.* (type “coconuts” in the search bar of the “Products” field and click “find”).

190. See Matthias Helble, *More Trade for Better Health? International Trade and Tariffs on Health Products*, 3, 5, 16, 28–29, 33 (WTO Econ. Rsch. & Stat. Div., Working Paper ERSD-2012-17, 2012), https://www.wto.org/english/res_e/reser_e/ersd201217_e.pdf.

increases, the United States, its trading partners, and other WTO members could and likely will face issues with hemp importation.

Since the tariff categories are subdivided amongst numerous additives and components within goods to streamline and establish the tariff rate of goods, the configuration of tariff rates for hemp products could be very convoluted. Without reference to all the current and potential derivations of hemp integrated into tariff schedules, individual trading entities would likely have to speculate or make up their tariff analyses for hemp product importation, thereby complicating and disincentivizing such importation. The convolution of tariff rate configuration regarding hemp products is further exacerbated by the fact that the importation of goods is also subject to any and all applicable rules of origin.¹⁹¹ In conjunction with an antiquated and similarly problematic WTO tariff system, the international hemp trade becomes very difficult.

Consequently, the United States and other WTO members using both kinds of international trade tools will probably face extreme difficulty in supplying goods to meet demand. The result will likely be a need to reorganize and edit the tariff classification systems of both the WTO and various WTO members to meet such demand. The following section discusses how the international hemp market could theoretically function if both American hemp regulations and tariff schedules were successfully implemented and reformed.

IV. STREAMLINED AMERICAN HEMP PRODUCTION AND THE UNITED STATES' PARTICIPATION IN THE INTERNATIONAL HEMP INDUSTRY

To recapitulate, the ideal American hemp entrepreneur is, as of right now, just that: an ideal. Analyses conducted throughout this paper show the hurdles such entrepreneurs must overcome while operating in the United States' present-day environment. Still, the fact remains that American hemp entrepreneurs are currently supplying domestic consumer demand for hemp products¹⁹² and will continue to do so while profit incentives for

191. See PAUWELYN ET AL., *supra* note 12, at 359–60.

192. See, e.g., Garber-Paul, *supra* note 83.

hemp continue to exist. With the promise of a wholly regulated, hemp-friendly America likely coming to fruition soon, the implications on the United States' participation in the hemp industry are staggering. Such implications, as suggested throughout, are both domestic and international.

A. *Establishment of Consolidated American Hemp Market*

After the USDA finalizes its set of hemp regulations or accepts the various states' hemp regulation plans, issues concerning the interference of hemp and hemp products will seemingly vanish. Federal protection will be afforded to those hemp entrepreneurs whose goods enter interstate commerce under the 2018 Farm Bill and the AMA.¹⁹³ No longer will state-based definitions of controlled substances inhibit hemp entrepreneurs from transporting goods through those states without legal recourse, as with Big Sky Scientific.¹⁹⁴ With this federal protection, hemp entrepreneurs will be able to coordinate completely through the apparatuses of interstate commerce, thus letting the mechanisms of a market economy further take hold of the American hemp industry. This protection incentivizes various public and private actors to invest time, money, and thought into the development of an American hemp market at a scale that has historically not existed in the United States.

Companies will likely begin product development in markets left largely open in the United States for generations. These companies will then bring about products both in existence in the current American hemp market, such as pharmaceuticals like Epidiolex, foods, as well as products that have yet to be invented and marketed. Again, there are over fifty thousand claimed uses for hemp, and ninety-eight lesser-known, naturally occurring cannabinoids in hemp.¹⁹⁵ CBD's current prevalence displays a recent market opportunity that grew from an esoteric compound into both a drug known to help individuals with severe epilepsy

193. See Agriculture Improvement Act of 2018 § 10114(b), 7 U.S.C. § 1639o note (2018); Agricultural Marketing Act § 297, 7 U.S.C. § 1639 (1946).

194. *Contra* Big Sky Sci. LLC v. Idaho State Police, No. 1:19-cv-00040-REB, 2019 WL 2613882 (D. Idaho Feb. 19, 2019) (mem. op.), *rev'd sub nom. on other grounds* Big Sky Sci. LLC v. Bennetts, 776 F. App'x 541 (9th Cir. 2019).

195. Cherney & Small, *supra* note 3, at 3, 7.

and a popular supplement.¹⁹⁶ Provided research and development show a medicinal or market utility in cannabinoids and hemp not yet occupied by other nations/economic entities, another industry such as CBD could arise and be just as lucrative. Given the United States government's history of subsidies for similar industries,¹⁹⁷ the possibilities for hemp in America are endless.

With the financial incentives in place for hemp farmers, manufacturers, and state actors to capitalize on such possibilities, a consolidated American hemp industry is waiting to grow exponentially. This domestic economic growth in the American hemp industry has already implicated economic growth through international trade, as seen with CBD's anticipated national and international financial projections.¹⁹⁸ With various tariff reforms, American hemp and hemp products can continue to go beyond the borders of the United States into the international market.

*B. A Consolidated American Hemp Market on the World Stage:
Trade with Countries and Other WTO Members*

Staying with a concrete example for the sake of illustration, should other countries or companies outside the United States desire to purchase or trade hemp-based pharmaceuticals like Epidiolex, they are currently hindered by the current WTO tariff format. However, manufacturing, trading and/or selling such pharmaceuticals presents a large financial opportunity both for the United States and any country and/or WTO member wishing to import such pharmaceuticals for their consumers. A reform of the WTO's tariff schedule based on delineating not only on the

196. Abernethy & Schiller, *supra* note 94.

197. See Avik Roy, *Inside The Pharmaceutical Lobby's Campaign for More Government Subsidies Through Medicare Part D*, FORBES (July 19, 2019, 6:30 PM), <https://www.forbes.com/sites/theapothecary/2019/07/19/inside-the-pharmaceutical-lobbys-campaign-for-more-government-subsidies-through-medicare-part-d/#26574b96393c>.

198. Iris Dorian, *CBD Market Could Reach \$20 Billion By 2024, Says New Study*, FORBES (May 20, 2019, 12:49 PM), <https://www.forbes.com/sites/irisdorian/2019/05/20/cbd-market-could-reach-20-billion-by-2024-says-new-study/#20b237de49d0>; *Global Cannabidiol (CBD) Oil Market Trajectory & Analytics 2020-2027 with COVID-19 Impact Analysis of Production & Buying 2020-2021*, BUS. WIRE (Sept. 25, 2020, 5:24 AM), https://www.oaoa.com/news/business/global-cannabidiol-cbd-oil-market-trajectory-analytics-2020-2027-with-covid-19-impact-analysis-of/article_f6a90222-f212-561e-a649-f7ac121e75ae.html.

individual parts of the cannabis plant but also, the individual cannabinoids within hemp would then profit both the United States and other WTO members. This tariff reform would streamline applicable tariff rates for all the individual hemp compounds. The United States and other WTO members would not have to speculate about and deal with any unclear tariff rates in these sorts of transactions. This reform would also mitigate rules of origin issues, as detailed tariff rates for hemp would no longer inhibit rules of origin's application to tariff schedules. Consequently, the United States would be open to a global market where they had once been cut off, bringing in large swaths of capital, and other WTO members would receive revenue in the form of tariffs and profits from sales within those locations.

Aside from the international sale/trade of pharmaceuticals, the United States could receive similar benefits to that of other WTO members regarding hemp importation should the USHTS be reformed. By providing delineations for hemp and hemp derivatives like those discussed previously, the United States could receive an analogous streamlining effect and benefit. With such reforms, countries that have a well-established hemp sector (such as China with textiles or Europe with hemp-based concrete) would be able to import such products with less hindrance. Being able to not only export but also import hemp products to and from the United States more efficiently from this tariff reform would open the international hemp market up to any comparative advantage individual countries have with their hemp sector(s).¹⁹⁹ The natural consequence of such a paradigm would be greater wealth for the United States and all of its trading partners.²⁰⁰

199. See generally PAUWELYN ET AL., *supra* note 12, at 11–17. Comparative advantage broadly is an economic concept where an individual or group can carry out a particular economic activity (such as making a specific product) more efficiently than others. *Id.* at 11–14. At an international scale, comparative advantage allows countries to specialize in an economic activity in which they are efficient and when countries with such efficiency open their borders to trade, they increase production possibilities available to them. *Id.* at 15–16. Further, “[w]ith this new ability to trade, each country has an incentive to make more of the product in which it has a comparative advantage and then trade for other product[s]” where they do not have such advantage. *Id.* at 15. The consequence is that trading countries receive more wealth and lower producer and consumer prices for tradable commodities. *Id.* at 15–17.

200. See *id.* at 16.

Should these reforms take place, and these results ensue, the United States would help fulfill its obligations and roles as a WTO member. The United States would liberalize trade entering the international hemp market, maximize wealth for Americans by entering such market, and, through the global demand of hemp products, likely incentivize the WTO to update its tariff schedules to the benefit of its other members.

V. CONCLUSION

For decades the United States has missed opportunities to financially benefit from industrial hemp by abstaining from the market under America's former controlled substance laws. However, with the passage of the Farm Bills, the reform of the CSA, and the implementation of federal hemp regulation in the future, the United States has an opportunity to redeem itself and receive economic benefits it had previously disregarded.

Hemp has already begun to increase revenue in the United States with CBD alone.²⁰¹ Within the context of the already established American CBD market, revenue has been projected to continually increase over the next several years despite the other lucrative hemp enterprises that have yet to be established.²⁰² With an increasing domestic hemp market comes an increase in international market opportunities for the United States should it then seek to open its economy up to the global hemp trade.

Further, the United States would be fulfilling its obligations and role as a WTO member should it consolidate and open its market to other WTO members. America's newfound revenue from a consolidated hemp market would yield financial benefits for its citizens and other WTO members. Given that some of the most significant stated goals of the WTO are increasing global economic well-being through the increase of international trade by substantially reducing tariffs and other trade barriers,²⁰³

201. Chris Hudock, *U.S. Hemp Revenues 2nd to China's: New Frontier Data Projects \$5.7B in U.S. Hemp Sales by 2020*, NEW FRONTIER DATA (Feb. 11, 2019), <https://newfrontierdata.com/cannabis-insights/u-s-hemp-revenues-2nd-to-chinas-new-frontier-data-projects-5-7b-in-u-s-hemp-sales-by-2020/>.

202. *Id.*

203. PAUWELYN ET AL., *supra* note 12, at 89.

America's hemp market could incentivize the WTO to change its trade policies to follow the money.

The United States still might have tremendous obstacles inhibiting a hemp market of this scale. Regardless, should the United States choose to continue embracing the green wave, it is imperative that America looks at reforming its trade policies. The consequences of such foresight towards trade reform could significantly benefit America and the rest of the world.

APPENDIX I – PERTINENT REGULATORY ACTORS

Actor and its Associated Function:

- Drug Enforcement Administration (“DEA”) – The DEA is an American federal law enforcement agency under the United States Department of Justice.²⁰⁴ The DEA was founded shortly after passing of the CSA and is tasked with enforcing the controlled substances laws of the United States.²⁰⁵ The DEA seeks to prevent the cultivation, manufacturing, and distribution of illicit substances, particularly to inhibit the availability of illicit controlled substances in domestic and international markets.²⁰⁶
- Food and Drug Administration (“FDA”) – The FDA is an American federal agency under the United States Department of Health and Human Services.²⁰⁷ The FDA is responsible for developing and executing federal laws relating to food (except for meat from livestock, poultry, and some egg products), drugs, and cosmetics.²⁰⁸ The FDA, amongst other things, seeks to prevent the promulgation of unsubstantiated medical claims concerning the consumption of products unapproved by the FDA.²⁰⁹ The FDA achieves this purpose by ensuring:
 1. Foods are labelled correctly and manufactured in sanitary conditions,

204. See *Agencies*, U.S. DEPT OF JUST., <https://www.justice.gov/agencies/list> (last visited Oct. 12, 2020).

205. See *History, The DEA Years*, DRUG ENFORCEMENT ADMIN., 31–32, 34, <https://www.dea.gov/sites/default/files/2018-07/1970-1975%20p%2030-39.pdf> (last visited Oct. 6, 2020).

206. See generally *id.*

207. *About FDA, FDA Organization*, FOOD & DRUG ADMIN. (Jan. 17, 2020), <https://www.fda.gov/about-fda/fda-organization>.

208. *About FDA, What We Do*, FOOD & DRUG ADMIN. (Mar. 18, 2018), <https://www.fda.gov/about-fda/what-we-do>.

209. *FDA Basics, What Does FDA Do?*, FOOD & DRUG ADMIN. (Mar. 18, 2018), <https://www.fda.gov/about-fda/fda-basics/what-does-fda-do> (explaining that the FDA ensures safety and proper labeling of the products it regulates).

2. Medical products for humans and pets are safe and effective, and
 3. Cosmetics are safe and properly labeled.²¹⁰
- United States Department of Agriculture (“USDA”) – The USDA is an American federal executive department tasked with developing and executing federal laws pertaining to farming, forestry, rural economic development, and food.²¹¹
 - United States International Trade Commission (“USITC”) – The USITC is an American federal agency that provides trade expertise to the legislative and executive branches of federal government.²¹² The USITC publishes and is responsible for tariff schedules for goods being imported into the United States.²¹³
 - World Trade Organization (“WTO”) – The WTO is an intergovernmental organization that aids in facilitating trade between WTO members.²¹⁴ The WTO was created to facilitate trade in goods, services, and intellectual property.²¹⁵ Its predecessor, the General Agreement on Tariffs and Trade (“GATT”), facilitated international trade solely with goods.²¹⁶ The United States has been a member of the WTO since its creation in 1995.²¹⁷

210. *Id.*

211. *U.S. Government Agencies, U.S. Agency for International Development*, U.S. AGENCY FOR INT’L DEV. (Oct. 1, 2020), <https://www.usaid.gov/us-government-agencies>.

212. *About the USITC*, U.S. INT’L TRADE COMM’N, https://www.usitc.gov/press_room/about_usitc.htm (last visited Oct. 6, 2020).

213. *Id.*

214. *About WTO, The WTO*, WORLD TRADE ORG., https://www.wto.org/english/thewto_e/thewto_e.htm (last visited Oct. 6, 2020).

215. *About WTO, History of the Multilateral Trading System*, WORLD TRADE ORG., https://www.wto.org/english/thewto_e/history_e/history_e.htm (last visited Oct. 6, 2020).

216. *Id.*

217. *WTO Member Information, United States of America and the WTO*, WORLD TRADE ORG., https://www.wto.org/english/thewto_e/countries_e/usa_e.htm (last visited Oct. 6, 2020).

