

2. In August 2020, DEA published an interim final rule entitled *Implementation of the Agriculture Improvement Act of 2018*, 85 Fed. Reg. 51639 (the “IFR”). The IFR purports to implement amendments to the Controlled Substances Act (the “CSA”) made by the Agricultural Improvement Act of 2018, codified at 7 U.S.C. § 1639o *et seq.* (the “2018 Farm Bill”). However, the IFR’s regulatory changes do not track the 2018 Farm Bill’s amendments.

3. Through the 2018 Farm Bill, Congress acted decisively and drew clear regulatory lines. The 2018 Farm Bill defines hemp broadly to explicitly include any part of the hemp plant, including its extracts, derivatives, cannabinoids, isomers, acids, salts, and salts of isomers; carves out “hemp” from the CSA’s definition of marijuana; and removes “tetrahydrocannabinols in hemp” from the CSA’s list of Schedule I substances. The 2018 Farm Bill also delegates exclusive authority over hemp production to the United States Department of Agriculture (“USDA”), with only one narrow exception for the Food and Drug Administration (“FDA”).

4. Contrary to the plain language and intent of the 2018 Farm Bill, DEA through the IFR, now claims that the statutory amendments in the 2018 Farm Bill do not remove essential steps of hemp production from DEA’s purview.

5. Specifically, DEA’s faulty interpretation of the 2018 Farm Bill criminalizes key steps of hemp production by improperly making intermediate hemp material (“IHM”) and waste hemp material (“WHM”)—two necessary and inevitable byproducts of hemp processing—Schedule I substances.

6. DEA’s latest jurisdictional overstep threatens every stage of the hemp production supply chain and jeopardizes the entire hemp industry. If allowed to stand, DEA’s intrusion will undermine a lynchpin of the new hemp economy that has created tens of thousands of new jobs and provided a lucrative new crop for America’s struggling farmers.

7. Through this action, Plaintiffs seek a declaratory judgment to reset the lines Congress drew in the 2018 Farm Bill and confirm that the hemp production process does not violate the CSA. Plaintiffs and the hemp industry deserve basic regulatory clarity and should not be forced to operate under constant threat of DEA enforcement that would be both crippling and unlawful.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1343. This action arises under the Constitution and laws of the United States.

9. This Court has the authority to issue the relief sought pursuant to 28 U.S.C. §§ 1343(a), 2201, and 2202.

10. Venue is proper under 28 U.S.C. § 1391(e).

11. This Court has *Leedom* jurisdiction.

THE PARTIES

12. Plaintiff HIA is a 501(c)(6) trade association whose mission is to advance the hemp economy, educate the market about hemp, and maintain and defend the integrity of hemp products. HIA represents approximately 1,050 member-hemp businesses who cultivate, manufacture, process, store, transport, distribute, and/or sell hemp and hemp-derived products. HIA's members include approximately 300 hemp processors, all of whom manufacture, process, and/or store IHM and WHM. The majority of HIA's non-processing members transact with and/or rely on persons or businesses who manufacture, process, and/or store IHM and WHM.

13. Plaintiff RE Botanicals is a private corporation with its principal place of business in South Carolina. In 2019, RE Botanicals acquired Palmetto Synergistic Research LLC dba Palmetto Harmony ("Palmetto Harmony"). Founded by Janel Ralph, a mother of a child with

severe epilepsy, Palmetto Harmony manufactures and sells consumer products derived from hemp. RE Botanicals was founded by John Roulac, a pioneer of the hemp seed industry. Its mission is to produce and market lawful, high quality hemp products.

14. Defendant DEA is the federal agency that administers the CSA.

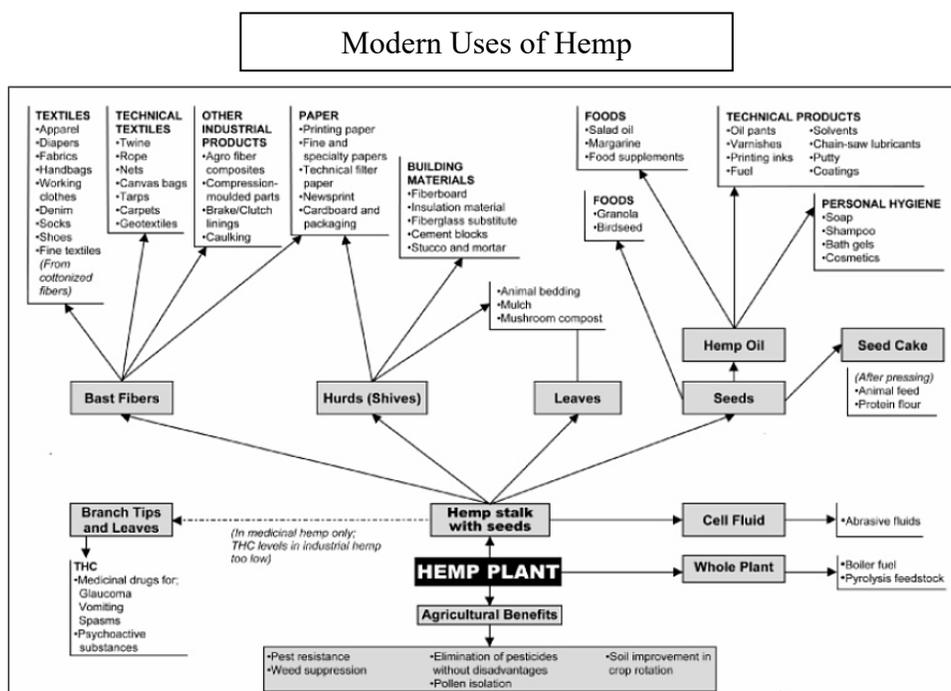
15. Defendant Timothy Shea is a government official serving as DEA's Acting Administrator.

FACTUAL BACKGROUND

I. Hemp is a Versatile, Non-Psychoactive Agricultural Commodity.

16. Hemp is a variant of the plant *Cannabis Sativa L.* with a delta-9 tetrahydrocannabinol ("Δ⁹-THC") concentration of not more than 0.3% on a dry weight basis. In sufficiently high concentrations, Δ⁹-THC can produce psychoactive effects. Such concentrations, however, are not present in hemp.

17. As an agricultural commodity, hemp has thousands of industrial and commercial applications. It can be grown indoors, outdoors, organically, and in a variety of climates; fits within typical crop rotation systems; and consumes nutrients similar to other agricultural crops, like corn. Hemp is used in fabrics and textiles; the woody cores of hemp stalks are used in animal bedding, papermaking, and oil absorbents; hemp seeds are used in a range of foods and beverages; and hemp extracts are used in a wide range of products, including soaps, shampoo, lotions, bath gels, and cosmetics. The following chart illustrates the modern uses of hemp:



II. Early Legislation Eliminates Domestic Hemp Cultivation.

18. Hemp has a storied place in our nation's history. It was introduced in America around 1545 and was cultivated in the Jamestown colony as early as 1611. Over a century later, many of our founding fathers, including George Washington, Thomas Jefferson, and Benjamin Franklin, cultivated and used hemp. George Washington spoke extensively about hemp in his diaries. Benjamin Franklin launched one of America's first paper mills making hemp paper. Thomas Jefferson invented a better "hemp brake" to separate hemp fibers from stalks. U.S. officials throughout the nineteenth century, including former House Speaker Henry Clay, cultivated the plant.

19. Although hemp forms an integral part of our nation's history, between 1937 and 2014, the hemp economy was dormant largely due to prohibitive tax schemes relating to the production of marijuana—another variety of the Cannabis plant—and, subsequently, the outright prohibition of marijuana.

20. In 1937, Congress passed the Marihuana Tax Act (the “MTA”). In the MTA, Congress recognized the difference between hemp and marijuana, as well as the usefulness of the hemp plant. The MTA’s definition of marijuana excluded the low $\Delta 9$ -THC portions of the plant:

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.

The MTA required all growers, sellers, manufacturers, importers, and distributors of marijuana to register with the U.S. Department of Treasury and imposed hefty taxes on those activities. Technological limitations prevented differentiating between hemp and marijuana variants according to $\Delta 9$ -THC levels, as we do today.

21. The MTA’s stringent requirements, and the technological limitations preventing differentiation between hemp and marijuana, caused American farmers to stop growing hemp, sweeping away America’s hemp economy.

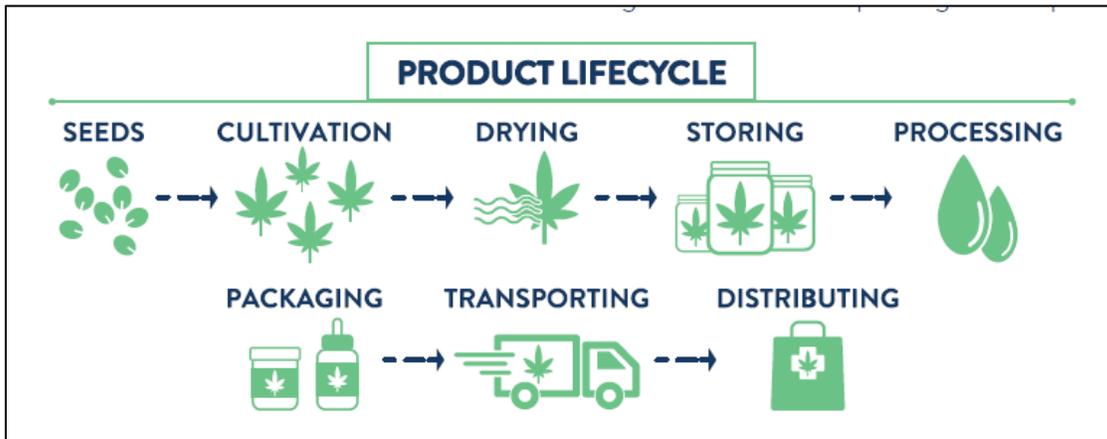
22. In 1969, the Supreme Court deemed a large portion of the MTA unconstitutional. However, the following year, Congress re-criminalized hemp cultivation by passing the CSA. The CSA adopted the MTA’s definition of marijuana, prohibiting the cultivation of hemp absent a DEA registration.

III. The Resurgent Modern Hemp Economy.

23. Today, thanks to the 2018 Farm Bill, hemp is making an American comeback. In 2017, approximately 41,000 acres of land were licensed for hemp cultivation in the U.S. That figure exploded to nearly 512,000 acres in 2019.

24. The multi-billion-dollar global hemp market consists of more than 25,000 products in nine submarkets: agriculture, textiles, recycling, automotive, furniture, food and beverages, paper, construction materials, and personal care.

25. Hemp’s product development cycle from cultivation to sale is complex and almost always requires some form of manufacturing or processing. The following chart illustrates a typical product development cycle for hemp-derived products:



26. Given hemp’s wide supply chain and multitude of uses, the hemp industry has—particularly since the passage of the 2018 Farm Bill—taken root and grown in the U.S., allowing farmers to grow a financially lucrative crop, thereby creating new jobs and economic activity throughout the supply chain.

27. This explosive growth has driven a dramatic increase in the number of state-licensed hemp processors, and accordingly, new jobs. A 2019 survey conducted by Vote Hemp found that of the states that issue hemp processor licenses, there are approximately 2,220 licensed processors; a more recent survey pegged that figure at more than 5,400 in 2020. While not capturing the full scope of hemp processors in the U.S., each of these 5,400 state-licensed hemp processors can employ dozens, even hundreds, of Americans.

28. Thus, in a time of declining employment, the hemp industry has created a new economy resulting in many new jobs and significant tax revenue. If permitted to blossom—as Congress intended through the enactment of the 2018 Farm Bill—the hemp economy will only continue to flourish.

29. Not surprisingly, politicians from both parties have lauded hemp and its economic potential. Senator Mitch McConnell (R-KY), one of the chief architects of the 2018 Farm Bill, declared his “commit[ment] to helping our farmers, processors, and manufacturers take full advantage of hemp’s potential.” Senator Chuck Schumer (D-NY) similarly described hemp as “an oyster with a pearl of opportunities that could mean millions in economic revenue while also helping to support new local jobs...”

IV. The Hemp Extract Submarket.

30. One of the most lucrative components of the modern hemp economy is the market for hemp-derived extracts, which are used as ingredients in a variety of products. Like the hemp plants from which they are derived, these extracts are not psychoactive and contain less than 0.3% Δ^9 -THC. The U.S. wholesale market for hemp extracts currently stands at \$2 billion U.S. dollars, while the wholesale market for products containing extracts exceeds \$5 billion U.S. dollars.

31. Part of this hemp extract market consists of cannabinoids. Cannabinoids are compounds that naturally occur in the hemp plant, primarily in the resins thereof. Scientists have identified over one hundred distinct cannabinoids, with cannabidiol (“CBD”) and Δ^9 -THC being the two most well-known.

32. Hemp grown for cannabinoid production is particularly profitable. For example, in 2019, hemp grown for its fiber generated approximately \$700 per acre. By contrast, hemp

grown for cannabinoids, such as CBD, can command over \$5,000 per acre. Without high-margin cannabinoid cultivation, many hemp farmers (and a large part of the new hemp economy) would crumble. In fact, recent surveys found that between 80%-85% of the hemp currently cultivated in the U.S. is grown for cannabinoids.

33. The process of making hemp extracts starts with the cultivation and harvest of hemp plants. Under the 2018 Farm Bill, USDA rules, and state regulations, prior to harvesting hemp, the hemp is sampled for its Δ^9 -THC potency.

34. If the sampled hemp measures at or below 0.3% Δ^9 -THC, it may then be harvested. Upon harvest, it is weighed and transferred to a third-party processor for “milling.” During the milling process, hemp flower is separated from sticks, stems and other adulterants captured as part of the sample. Although the milled hemp’s Δ^9 -THC content has *not* changed during the milling process, after removing the sticks and stems (and any adulterants), the remaining hemp flower material—which is naturally rich in resins and cannabinoids—is virtually certain to exceed 0.3% Δ^9 -THC, at least by percentage volume. This is because the portions of the hemp plant containing little or no Δ^9 -THC (i.e., the sticks and stems), which were previously present when the plant was initially sampled, are stripped away during the milling process.

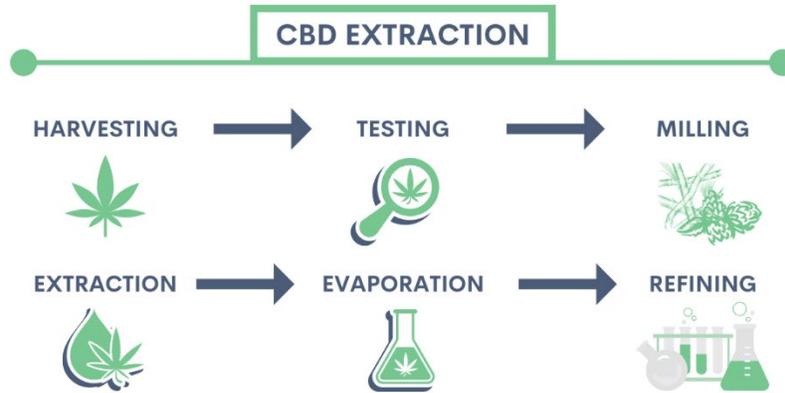
35. Next, the milled hemp is extracted. Milled hemp is soaked, (typically) mixed with an extraction solvent, and then fed into extraction equipment, where cannabinoids are separated from the raw hemp flower material. The processed raw hemp flower material is discarded, leaving an oil comprised of the extracted cannabinoids and the extraction solvent (if applicable).

36. This oil is then subjected to evaporation. Evaporation removes the processing solvent (if applicable), along with some fats and lipids present in the mixture. The output from evaporation is IHM, which contains concentrated levels of cannabinoids, because all other parts of the plant have been stripped away. As explained below, IHM itself is not added to, or used as an ingredient in, any consumer product; rather, IHM is refined into extracts or isolates containing not more than 0.3% Δ^9 -THC.

37. If the processor is creating isolates of specific cannabinoids, then another output from evaporation is WHM, which contains concentrated levels of cannabinoids. WHM is not added to, or used as an ingredient in, any consumer product.

38. Up to the evaporation stage, the actual Δ^9 -THC content in the harvested hemp has not changed at all. Each step of processing simply refines and strips away the non-resinous portions of the plant that contain few, if any, cannabinoids. By separating and refining the hemp, these steps concentrate the remaining compounds—predominantly the naturally-occurring cannabinoids, including CBD and Δ^9 -THC—by percentage volume. As a result, IHM and WHM naturally (and unavoidably) exceed 0.3% Δ^9 -THC.

39. Once IHM is created, special equipment is used to further refine IHM and create various types of hemp extracts and/or isolates of specific cannabinoids. These extracts and isolates, whose Δ^9 -THC concentrations are at or below 0.3%, are used as ingredients in a variety of products. The following chart illustrates the hemp production process for cannabinoids:



40. In sum, even when a harvested hemp plant contains 0.3% or less Δ^9 -THC, during processing, certain in-process hemp materials will inevitably exceed 0.3% Δ^9 -THC. These in-process materials are not added to or used as ingredients in any consumer products.

V. DEA Oversteps Statutory Authority to Unlawfully Regulate Hemp Products.

41. Although the CSA prohibited the *cultivation* of hemp, it has never categorically prohibited hemp products. Indeed, there has never been anything illegal about importing, manufacturing, selling, possessing, or consuming hemp-derived products, provided that those products were made with or derived from exempt portions of the cannabis plant.

42. As early as 1975, DEA itself recognized that parts of the cannabis plant (including certain hemp products intended for consumption) had been exempted under the CSA. *See* 40 Fed. Reg. 44164, 44167 (Sept. 25, 1975).

43. Relying on this exemption, U.S. businesses and individuals have for decades purchased and sold hemp products derived from exempt portions of the cannabis plant imported from abroad.

44. But beginning in the late 1990s and early 2000s, DEA attempted to sweep away the legal market for hemp products through rulemaking—despite express prohibitions from Congress to the contrary.

A. DEA Attempts to Bypass the CSA to Prohibit Legal Hemp Products.

45. On October 9, 2001, DEA issued a rule that attempted to classify all naturally-occurring THC—including THC found in exempt portions of the cannabis plant—under the CSA’s listing of THC, a Schedule I substance. *Interpretation of Listing of “Tetrahydrocannabinols” in Schedule I*, 66 Fed. Reg. 51530 (Oct. 9, 2001). That rule, DEA-204, purported to clarify that the listing of THC in Schedule I refers to both natural and synthetic THC—meaning that, according to DEA’s interpretation of the CSA and DEA regulations, any product containing any amount of THC was a Schedule I controlled substance, even if that product was made from portions of the cannabis plant that are excluded from the CSA’s definition of marijuana.

46. Following a lawsuit, the Ninth Circuit concluded that DEA-204 was inconsistent with then-existing regulations and was thus an invalid and unenforceable legislative rule. *See Hemp Industries Ass’n v. Drug Enf’t Administration*, 333 F.3d 1082 (9th Cir. 2003) (“*Hemp I*”).

47. After DEA’s issuance of DEA-204, DEA issued final rules—DEA-205F and DEA-206F—which together amended DEA regulations such that the listing of THC in Schedule I effectively included all products containing even naturally-occurring THC derived from exempt portions of the plant.

48. Following a second legal challenge, the Ninth Circuit issued an injunction and held that these final rules were “scheduling actions that would place non-psychoactive hemp in Schedule I for the first time,” contrary to Congressional intent, and failed to follow the procedures for scheduling actions as required by the CSA. *See Hemp Industries Ass’n v. Drug Enf’t Administration*, 357 F.3d 1012 (9th Cir. 2004) (“*Hemp II*”).

49. Despite the injunction in *Hemp II*, DEA never removed the enjoined rules from its regulations, and in publications continued to assert that its hemp rules still had the force and effect of law. Even after *Hemp II*, DEA’s official position was that *all* consumable hemp products were illegal. For example, in a November 2017 article in the Louisville Courier Journal, a DEA spokesman told the newspaper that the agency viewed all hemp products that can be consumed as illegal. DEA even asserted its unsupported position in its interactions with state agencies.

B. DEA Subverts the 2014 Farm Bill.

50. While DEA was attempting to tighten its grip over hemp production, several states passed laws permitting the cultivation of hemp subject to certain parameters. In 1999, for example, North Dakota legalized the cultivation of hemp if farmers complied with licensure and registration requirements. Montana passed a state law authorizing hemp production in 2001, and several other states, including Hawaii, Kentucky, Maine, Maryland, and West Virginia, adopted state hemp cultivation and research programs in the early 2000s.

51. Due to the rise of these various state laws and the growing interest in hemp across the country, Congress acted to enable this budding industry.

52. Congress began clearing the way for a renewed hemp economy with Section 7606 of the Agricultural Act of 2014, colloquially known as the 2014 Farm Bill. The 2014 Farm Bill legalized the cultivation and research of hemp,¹ defined as:

the plant *Cannabis sativa* L. and *any part of such plant*, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis” (emphasis added)—under certain conditions.

7 U.S.C. § 5940(a)(2).

¹ Although the 2014 Farm Bill defines the plant as “industrial hemp” and the 2018 Farm Bill defines the plant as “hemp,” these terms can be, and are, used interchangeably.

53. Consistent with federal law up to that point, the 2014 Farm Bill distinguishes between hemp and marijuana based on a cannabis plant's Δ^9 -THC concentration. A plant whose Δ^9 -THC concentration is 0.3% or less on a dry weight basis (and which is cultivated in accordance with the 2014 Farm Bill) is lawful hemp; any part of the plant whose Δ^9 -THC concentration exceeds 0.3% Δ^9 -THC is unlawful marijuana.

54. The 2014 Farm Bill removed hemp from DEA's purview. Although it did not expressly amend the language of the CSA to carve out hemp and its derivatives from the definition of marijuana, it expressly preempted the CSA: "Notwithstanding the Controlled Substances Act (21 U.S.C. § 801 et seq.), chapter 81 of title 41, . . . or any other Federal law . . .," hemp may be lawfully produced in accordance with the 2014 Farm Bill.

55. Twenty-nine members of Congress who drafted the 2014 Farm Bill confirmed its preemptive intent in an *amicus* brief submitted to the Ninth Circuit: "Congress clearly stated in the text of the [2014] Farm Bill that the dividing line between [hemp and marijuana is the THC level, see 7 U.S. Code § 5940(b)(2), and by its terms the [2014] Farm Bill's definition controls, 'notwithstanding' any conflicting definition that might apply under the CSA, see § 5940(a).]" "In enacting the [2014] Farm Bill," the members of Congress continued, "it was Congress's purpose that hemp and any derivatives, extracts, and uses thereof would be exempted from the definition of [marijuana] under the CSA. We know this because many of us helped draft the provisions and voted for them."

56. Despite clear Congressional intent to remove hemp and its derivatives from DEA control and enable the hemp economy, in the years following the enactment of the 2014 Farm Bill, DEA (i) pursued enforcement actions against institutions lawfully participating in hemp

pilot programs in compliance with the 2014 Farm Bill; and (ii) promulgated regulations designed to continue to treat hemp and its derivatives and extracts as Schedule I substances.

57. For example, in May 2014, DEA seized hemp seeds destined for use by farmers who complied with Kentucky's 2014 Farm Bill pilot program administered by the Kentucky Department of Agriculture ("KDA"). Senator Mitch McConnell (R-KY) and Representative Thomas Massie (R-KY), both of whom participated in the drafting of the 2014 Farm Bill, called DEA's actions "an outrage" and "ridiculous." The KDA similarly commented that the "DEA is trying to place...illegal restrictions on Kentucky...restrictions on the program that Congress doesn't allow." Later, in 2018, the Kentucky General Assembly petitioned Congress to enact measures that would prevent DEA from sending its agents onto farms and other sites where hemp is grown, stored, and processed. 164 Cong. Rec. S2438 (2018).

58. Forced to respond to DEA's flouting of the 2014 Farm Bill, Congress first turned to the power of the purse. Congress passed an appropriations bill prohibiting DEA, and any other law enforcement agency, from using federal funds in "contravention" of the 2014 Farm Bill or "to prohibit transportation, processing, sale, or use of hemp that is grown or cultivated in accordance with [the 2014 Farm Bill]..." Notably, this language has been repeated and re-adopted in each spending bill through 2020.

59. DEA, however, doubled down. In its "Statement of Principles on Industrial Hemp" published on August 12, 2016 (the "SOP"), DEA (with other federal agencies) attempted to narrow the 2014 Farm Bill's definition of hemp to include only "that [which] is used exclusively for industrial purposes (fiber and seed)" and limit the sale of "[hemp products]" in and among states with agricultural pilot programs. In response, Senator Mitch McConnell (R-KY) noted that, through the SOP, DEA had unlawfully attempted to narrow the definition of

hemp “beyond what Congress explicitly prescribed in the [2014 Farm Bill]” and that “Federal law...does not limit the ability to sell lawfully grown [hemp] products only to states with agricultural pilot programs.”

60. Similarly, in December 2016, DEA published the “Establishment of a New Drug Code for Marihuana Extract” (the “MER”), which stated that any extract “containing one or more cannabinoids that has been derived from any plant of the genus *Cannabis*, other than the separated resin (whether crude or purified) obtained from the plant” “will continue to be treated as Schedule I controlled substances.” The MER effectively purported to classify hemp-derived CBD as a Schedule I controlled substance.

61. In an *amicus* brief voicing disagreement with DEA’s expansion of its authority to control lawfully produced hemp products, the members of Congress explained that the “unduly broad” MER “encompasses lawful activity set forth under the [2014] Farm Bill”; “effectively repeals Section 7606 of the [2014] Farm Bill”; “subverts the Congressional definition of [hemp] contained in the [2014] Farm Bill”; inappropriately “subjects [hemp] extracts to DEA enforcement powers”; “cannot be justified in light of Congress’s express action in this area”; and “undercut[s] the legislative text of Section 7606 of the [2014] Farm Bill by prohibiting marketing research of hemp-derived extracts under an agricultural pilot program...”

C. Congress Passes the 2018 Farm Bill Removing Hemp from the CSA and Divesting DEA of Authority.

62. In light of DEA’s repeated intrusions, Congress and President Donald Trump took more decisive action in 2018. The 2018 Farm Bill, codified at 7 U.S.C. § 1639o *et seq.*, removes hemp and all its derivatives, extracts, and cannabinoids from the CSA. It also unequivocally divests DEA of its regulatory authority in the sphere of hemp production.

63. First, unlike prior legislation, Section 1639r of the 2018 Farm Bill places the *sole* federal authority to regulate hemp production under USDA. See 7 U.S.C. § 1639r(b) (the Secretary of Agriculture shall have “sole authority to promulgate Federal regulations and guidelines that relate to the production of hemp.”). The *one* exception to USDA’s sole federal authority is that the FDA commissioner retains authority to promulgate rules and guidelines relating to the production of hemp-related products under the Food, Drug, and Cosmetic Act (the “FDCA”). 7 U.S.C. § 1639r(c)(3).

64. There is no carve out for DEA, its Administrator, or the CSA. The Conference Report accompanying the 2018 Farm Bill makes the exclusive scope of the delegation clear: “The Secretary is required to consult with the Attorney General on the promulgation of regulations, but ultimately, the regulations shall *only* be issued by the Secretary of Agriculture.” (emphasis added) H.R. Rep. No. 115-1072, at 738 (2018).

65. Second, 7 U.S.C. § 1639o of 2018 Farm Bill (“Section 1639o”) contains a broader definition of “hemp,” expressly including “all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers” of the plant:

[Hemp is] the plant *Cannabis sativa* L. and any part of that plant, *including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers*, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.

(emphasis added).

66. The decision to expand hemp’s definition to expressly include these components was deliberate. In recent years, consumer demand for hemp-derived derivatives, extracts, and cannabinoids has grown exponentially. A Congressional report therefore concluded that the 2018 Farm Bill “intended to facilitate the commercial cultivation, *processing*, and marketing of hemp” (emphasis added). Replacing the term “industrial hemp” (which is used in the 2014 Farm

Bill) with the term “hemp” (which is used in the 2018 Farm Bill) further evidences Congress’ intent to legalize the full panoply of hemp-derived products and the associated supply chain.

67. In fact, during the legislative process, Senator Chuck Grassley (R-IA) had proposed a limiting amendment, seeking to strike the language emphasized above and add a provision stating that hemp does *not* include the derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers. That proposed amendment, however, never even came up for a vote in committee.

68. Third, Section 1639o distinguishes between lawful hemp and unlawful marijuana based on Δ^9 -THC concentration measured on a *dry weight basis*. Per the plain language of Section 1639o, the Δ^9 -THC concentration of *wet* hemp derivatives—such as extracts, oils, or other liquid forms of hemp—is not measured during its wet stage since *wet* derivatives cannot, by definition, be measured on a *dry weight basis*. By defining hemp (inclusive of its derivatives and extracts) based on its Δ^9 -THC concentration on a *dry weight basis*, the 2018 Farm Bill deems all hemp-derived materials as “hemp.”

69. When the 2018 Farm Bill was being debated, Congress knew and understood that the intermediate stages of hemp processing and extraction cause most wet IHM and WHM to exceed 0.3% Δ^9 -THC concentration. Indeed, many states operating under the 2014 Farm Bill (and the 2018 Farm Bill) regulate IHM and/or WHM. In addition, neither the 2018 Farm Bill nor USDA’s hemp regulations (see below) impose any post-harvest testing requirements for hemp, including derivatives, extracts, or cannabinoids thereof.

70. Finally, emphasizing Congressional intent to remove hemp and its derivatives from DEA’s purview, the 2018 Farm Bill expressly amended the CSA’s definitions of both marijuana and “tetrahydrocannabinols.” The CSA now states that “[t]he term [marijuana] does

not include...hemp, as defined in [7 U.S.C. § 1639o]” and excludes from Schedule I “tetrahydrocannabinols in hemp (as defined under Section 1639o of title 7)” from the list of substances controlled by the CSA. Thus, per Congress, “tetrahydrocannabinols in hemp” are not scheduled substances. Importantly, these amendments to the CSA were self-executing.

71. In sum, through the 2018 Farm Bill, DEA, whose *raison d’être* is to enforce the CSA, is divested of its authority to regulate hemp—an agricultural commodity now expressly removed from the CSA and under the sole federal regulatory authority of USDA and FDA. Indeed, DEA is not mentioned anywhere in the 2018 Farm Bill.

D. USDA Regulates Hemp Production.

72. Following the 2018 Farm Bill, USDA established the U.S. Domestic Hemp Production Program that sets forth comprehensive regulations governing hemp cultivation and production on October 31, 2019. *Establishment of a Domestic Hemp Production Program*, 84 Fed. Reg. 58522 (Oct. 31, 2019) (the “USDA Rule”).

73. The USDA Rule explains that “[h]emp is a commodity that can be used for numerous industrial and horticultural purposes including fabric, paper, construction materials, food products, cosmetics, production of cannabinoids (such as cannabidiol or CBD), and other products”; “[h]emp production in the U.S. has seen a resurgence in the last five years”; and the 2018 Farm Bill “require[d] USDA to promulgate regulations and guidelines to establish and administer a program for the production of hemp in the United States.”

74. The USDA Rule makes clear that distinguishing between hemp and marijuana occurs after harvest but before subsequent processing, consistent with the text and intent of Section 1639o and the 2018 Farm Bill. According to the USDA Rule, USDA developed its rule only “after extensive consultation with the Attorney General.”

75. Among other provisions, the USDA Rule requires that (i) all hemp be tested by a DEA-registered laboratory prior to being harvested, and (ii) a DEA-registered reverse distributor, or law enforcement, dispose of non-compliant plants (together, the “DEA-Related Provisions”).

76. The requirement that testing laboratories be DEA-registered met significant blowback from industry stakeholders, state officials, and members of Congress. For example, Sens. Ron Wyden (D-OR) and Jeff Merkley (D-OR)—two of the drafters of the 2018 Farm Bill—wrote a letter in November 2019 to USDA’s Secretary of Agriculture, Sonny Perdue, recommending that “the USDA remove the requirement that testing labs must be DEA-registered” because “[h]emp is a legal agricultural commodity and, like all other legal agricultural commodities, should not be subjected to prohibitive DEA regulations.” Similarly, the public comment submitted by the State of Colorado in response to the USDA Rule stated that through the DEA-Related Provisions, the USDA Rule “impermissibly exceeded the statutory authority set forth in the 2018 Farm Bill” and “expressly contradicts [Section 1639r] of the 2018 Farm Bill...”

77. In response to these and other comments, on February 27, 2020, USDA announced that it was exercising “enforcement discretion” and suspending enforcement of the unpopular DEA-Related Provisions until the earlier of October 31, 2021 or the publication of a final rule, which would supersede the USDA Rule. As a result, USDA does not enforce the DEA-Related provisions in the USDA Rule.

78. In the weeks following USDA’s announcement, Secretary Perdue attributed the DEA-Related Provisions to DEA: “[t]he [USDA Rule’s] testing and the limitations had a lot of impact from DEA...They were not excited about the crop as a whole anyway. We had some pretty serious constraints.” Days later, Secretary Perdue again testified that “in the [USDA

Rule], we had some pushback from DEA” because “the DEA really didn’t like the whole [hemp production] program to begin with.”

E. DEA Interprets the 2018 Farm Bill to Restore Its Divested Authority Over Hemp Production.

79. On May 19, 2020, Attorney General William Barr announced he was “pleased to appoint Tim Shea,” who had previously been appointed by the Attorney General to serve as Interim U.S. Attorney for this District under 28 U.S.C. § 546, “as DEA Acting Administrator.” Soon after the Attorney General’s appointment, the Acting Administrator began exceeding his authority.

80. Rather than work cooperatively with and through USDA to regulate hemp production—as the statute commands—DEA went at it alone. In August 2020, bypassing notice-and-comment, DEA issued its own interim final rule, effective as of its publication date, that purports to “merely conform[] DEA’s regulations to the statutory amendments to the CSA that have already taken effect [through the 2018 Farm Bill].”

81. The explanatory language accompanying the text of the IFR, however, reveals that DEA has an understanding of the definition of “hemp” that is contrary to the 2018 Farm Bill’s plain language (and Congress’ intent) and effectively sweeps hemp into DEA’s purview. DEA states, “the definition of hemp [in Section 1639] does not automatically exempt [from Schedule I] any product derived from a hemp plant, regardless of the Δ^9 -THC content of the derivative” and that “a cannabis derivative, extract, or product that exceeds the 0.3% Δ^9 -THC limit is a schedule I controlled substance, even if the plant from which it was derived contained 0.3% or less Δ^9 -THC on a dry weight basis.” The IFR also states, “entities no longer require a DEA registration or import and export permits to handle hemp extract that does not exceed the

statutory 0.3% THC limit.” Thus, DEA evidently believes that any hemp extract that exceeds the 0.3% Δ^9 -THC limit, including IHM and WHM, requires a DEA permit.

82. As discussed above, the creation of IHM—an extract whose Δ^9 -THC concentration fleetingly exceeds 0.3%, but which is further refined into an extract or isolate containing 0.3% or less Δ^9 -THC—is an inherent result of the hemp production process. The 2018 Farm Bill makes clear that IHM and WHM—inevitable byproducts of hemp processing—are not controlled substances and, moreover, that USDA and FDA have sole federal authority to regulate them.

83. Thus, DEA’s explanatory language preceding the text of the IFR evidences DEA’s intent to yet again overstep its authority, this time through statutory misinterpretation of Section 1639o. Specifically, DEA seeks to classify IHM and WHM as unlawful Schedule I substances. Given that these materials are inevitable results of the hemp manufacturing process, DEA’s misinterpretation criminalizes essential hemp processing and manufacturing operations and activities.

84. This newly disclosed DEA interpretation of Section 1639o has serious, immediate, and irreparable consequences: all hemp processors and manufacturers who work with and/or store IHM and/or WHM must now choose between ceasing to process, manufacture and/or store hemp; obtaining a Schedule I license from DEA; or risking criminal prosecution under the CSA. Given the centrality of hemp processing to the hemp industry’s supply chain, forcing processors to choose between the foregoing options would effectively destroy the entire hemp industry.

FIRST CLAIM FOR RELIEF
(Declaratory Judgment–Definition of Hemp in 7 U.S.C. § 1639o)
(Against All Defendants)

85. Plaintiffs repeat and reallege each preceding allegation of this Complaint as if fully set forth herein.

86. An actual controversy exists between the parties.

87. The 2018 Farm Bill was “intended to facilitate the commercial cultivation, processing, and marketing of hemp” and removes “hemp” and “tetrahydrocannabinols in hemp,” as defined in Section 1639o, from the CSA’s list of controlled substances.

88. Section 1639o of 2018 Farm Bill defines “hemp” as including “the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids...whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.”

89. As amended by the 2018 Farm Bill, CSA Section 202(c)(17) reads: Tetrahydrocannabinols, except for “tetrahydrocannabinols in hemp (as defined under 297A of the Agricultural Marketing Act of 1946).” 21 U.S.C. §812(c)(17).

90. By defining hemp, inclusive of derivatives and extracts, based on its Δ^9 -THC concentration on a dry weight basis, and by removing THC in hemp from control, Congress removed hemp-derived materials from the CSA that do not contain more than 0.3% Δ^9 -THC at points when Δ^9 -THC can be measured on a dry weight basis. IHM and WHM, two wet hemp extracts derived from plant material whose dry weight Δ^9 -THC concentration is at most 0.3%, fall within Section 1639o’s definition of hemp. IHM and WHM are not controlled substances under the CSA.

91. Through the explanatory language preceding the text of the IFR, DEA reaches a different conclusion. It claims “the definition of hemp does not automatically exempt [from Schedule I] any product derived from a hemp plant, regardless of the Δ^9 -THC content of the derivative” and any “cannabis derivative, extract, or product that exceeds the 0.3% Δ^9 -THC limit is a schedule I controlled substance, even if the plant from which it was derived contained 0.3% or less Δ^9 -THC on a dry weight basis.”

92. Plaintiff RE Botanicals, and Plaintiff HIA’s members, process, manufacture, and/or store hemp in accordance with the 2018 Farm Bill. Such processing and manufacturing naturally and inevitably yield IHM, whose Δ^9 -THC concentration temporarily exceeds 0.3% but which is subject to further processing and ultimately contains Δ^9 -THC equal to or less than 0.3% before being used in or added to or used as an ingredient in any consumer product. Accordingly, based on the language cited in the preceding paragraph, Plaintiffs (and/or their members) face the immediate dilemma of choosing between ceasing to process, manufacture and/or store hemp; obtaining a Schedule I license from DEA; or risking criminal prosecution under the CSA by DEA for conducting such activities.

93. There is a substantial controversy between DEA and Plaintiffs of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

94. Plaintiffs request a judicial determination that the definition of “hemp” as set forth in Section 1639o, includes IHM and WHM, and that IHM and WHM are not controlled substances.

SECOND CLAIM FOR RELIEF
(Declaratory Judgment—THC in Hemp Is not a Schedule I Substance)
(Against All Defendants)

95. Plaintiffs repeat and reallege each preceding allegation of this Complaint as if fully set forth herein.

96. The 2018 Farm Bill amended the CSA Section 202(c)(17), Schedule I (21 U.S.C. §812(c)(17)), to read: “Tetrahydrocannabinols, *except for tetrahydrocannabinols in hemp* (as defined under [Section 1639o])” (emphasis added).

97. The IFR amends Schedule I Section 1308.11(d)(31)(ii) to state: “Tetrahydrocannabinols does not include any material, compound, mixture, or preparation that falls within the definition of hemp set forth in 7 U.S.C. 1639o.”

98. Congress removed all THC in hemp from the CSA.

99. IHM and WHM are hemp-derived materials which contain THC. Therefore, the THC in IHM and WHM is not a controlled substance.

100. The IFR narrows the scope of the 2018 Farm Bill and improperly criminalizes THC in hemp.

101. There is a substantial controversy between DEA and Plaintiffs of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

102. Plaintiffs respectfully request a judicial determination that the THC in hemp, including THC in IHM and WHM, is not a Schedule I substance.

THIRD CLAIM FOR RELIEF
(Declaratory Judgment—Lack of Authority)
(Against All Defendants)

103. Plaintiffs repeat and reallege each preceding allegation of this Complaint as if fully set forth herein.

104. Section 1639r gives the Secretary of USDA “sole authority to promulgate Federal regulations and guidelines that relate to the production of hemp, including Federal regulations and guidelines that relate to the implementation of sections 1639p and 1639q of this title.” The lone exception to such exclusive authority is that FDA maintains its authority to regulate food, drugs, and cosmetics produced with hemp-derived ingredients through FDCA.

105. As used in the 2018 Farm Bill, hemp “production” necessarily includes both hemp cultivation, processing, and manufacturing.

106. As inevitable products of the hemp production process, IHM and WHM relate to the production of hemp. Accordingly, USDA and FDA are the only federal agencies conferred with any authority to regulate IHM and WHM. Section 1639r is clear and mandatory.

107. Although the 2018 Farm Bill clearly and exclusively delegated authority over hemp production to USDA (with only one narrow exception for FDA), DEA’s IFR (including the explanatory text) are regulations and guidelines that relate to the production of hemp.

108. Thus, the IFR is an “attempted exercise of power that had been specifically withheld.”² This improper act of regulating has had or will have chilling effects on the hemp industry.

109. There is a substantial controversy between DEA and Plaintiffs of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

110. Plaintiffs respectfully request a judicial determination that DEA lacks any independent authority to regulate any aspect of hemp production, including the production of IHM and WHM.

² *Leedom v. Kyne*, 358 U.S. 184, 189 (1958); *Ry. Lab. Execs’ Ass’n v. Nat’l Mediation Bd.*, 38 F.3d 1224 (D.C. Cir. 1994) (en banc).

FOURTH CLAIM FOR RELIEF
(Injunctive Relief)
(Against All Defendants)

111. Plaintiffs repeat and reallege each preceding allegation of this Complaint as if fully set forth herein.

112. Plaintiffs seek preliminary and permanent injunctive relief enjoining DEA from enforcing the CSA as to IHM and WHM and from classifying IHM or WHM as Schedule I substances under the CSA.

113. Unless and until Defendants are enjoined, RE Botanicals, and Plaintiff HIA's members, face the immediate dilemma of choosing between ceasing to process, manufacture and/or store hemp; obtaining a Schedule I license; or risking criminal prosecution. Plaintiffs will suffer irreparable harm if the Defendants are not preliminarily and permanently enjoined from enforcing the CSA with respect to IHM or WHM.

114. Plaintiffs also seek an injunction enjoining the IFR and enjoining DEA from promulgating rules that relate to the production of hemp.

115. Plaintiffs have no adequate remedy at law for the harm threatened.

116. Considering DEA waited more than 18 months from the passage of the 2018 Farm Bill to enact the IFR, and that the IFR will effectively destroy the burgeoning hemp industry, the balance of harms between the parties favors entering injunctive relief and an injunction in this case would serve the public interest.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

117. Declaratory relief, including but not limited to a declaration and judgment that (i) the definition of hemp in Section 1639o includes IHM and WHM; (ii) THC in hemp, including

THC in IHM and WHM, is not a Schedule I substance; and (iii) DEA lacks any independent authority to regulate any aspect of hemp production, including IHM and WHM.

118. Injunctive relief, including but not limited to an injunction enjoining DEA from enforcing the CSA as to IHM and WHM and to classifying IHM and WHM as Schedule I substances under the CSA;

119. Attorneys' fees;

120. Costs; and

121. Such other and further relief as the Court deems proper and just.

Dated this 12th day of October, 2020.

Respectfully submitted,

By: /s/ David Kramer

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