

WHAT DOES THE LEGALIZATION OF HEMP MEAN FOR SUPPLEMENTS AND FOOD?

Douglas MacKay

SVP, Scientific and Regulatory Affairs

CV Sciences

FDLI

March 21, 2019




AGENDA

- Background
- Hemp/CBD market environment
- Legal/regulatory considerations
- Predicting what's next

History of *Cannabis sativa* L extracts

CANNABIS AMERICANA
U. S. P.
Physiologically Tested

OUR American variety is the answer to the question which has so long troubled manufacturers. With our material a finished product can be turned out at a reasonable cost.



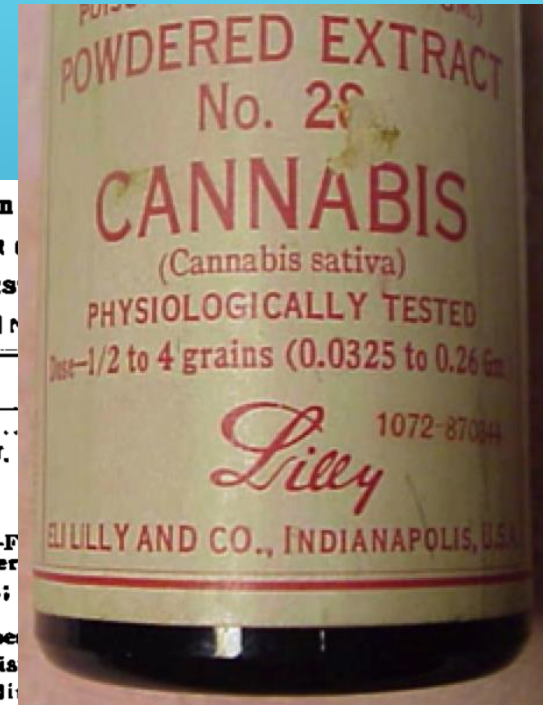
IT is no longer necessary to depend on the foreign variety which is of high cost and slightly superior. The uncertainty of further supplies of it is another factor favoring the American product.

J. L. HOPKINS & CO., 100 William St., New York

Cannabis Sativa—American
CONTAINS ALCOHOL 80 PER C
PHYSIOLOGICALLY TESTED
ELI LILLY & COMPANY, IN

CANNABIS INDICA.....
Strength—That of the U.
Physiologically tested.
Linna.
Indian cannabis U. S. P.—F
ish, Churrua, Bhang, Subjer
us, Persia, Northern India;
and the United States.

Habitat—Rich, moist soil of mountain slopes
Part used—The dried flowering tops of plant
Action and uses—Not poisonous according
though formerly so regarded. Antispasmodic, analgesic, anes-



Antispasmodic, analgesic, anesthetic, narcotic, aphrodisiac. Specifically recommended in spasmodic and painful afflictions; for preventing rather than arresting migraine: specific in that form of insanity peculiar to women, caused by mental worry or moral shock...in hysterical cases not calmed by opium it acts especially well.

till its effects are experienced.

ELI LILLY & COMPANY, LABEL REVISED 1908.

(12) **United States Patent**
Hampson et al.

(10) **Patent No.: US 6,630,507 B1**
(45) **Date of Patent: Oct. 7, 2003**

(54) **CANNABINOIDS AS ANTIOXIDANTS AND NEUROPROTECTANTS**

(75) Inventors: **Aidan J. Hampson**, Irvine, CA (US)
Julius Axelrod, Rockville, MD (US);
Maurizio Grimaldi, Bethesda, MD (US)

(73) Assignee: **The United States of America**
f
Health and Human Services,
Washington, DC (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/674,028**

(22) PCT Filed: **Apr. 21, 1999**

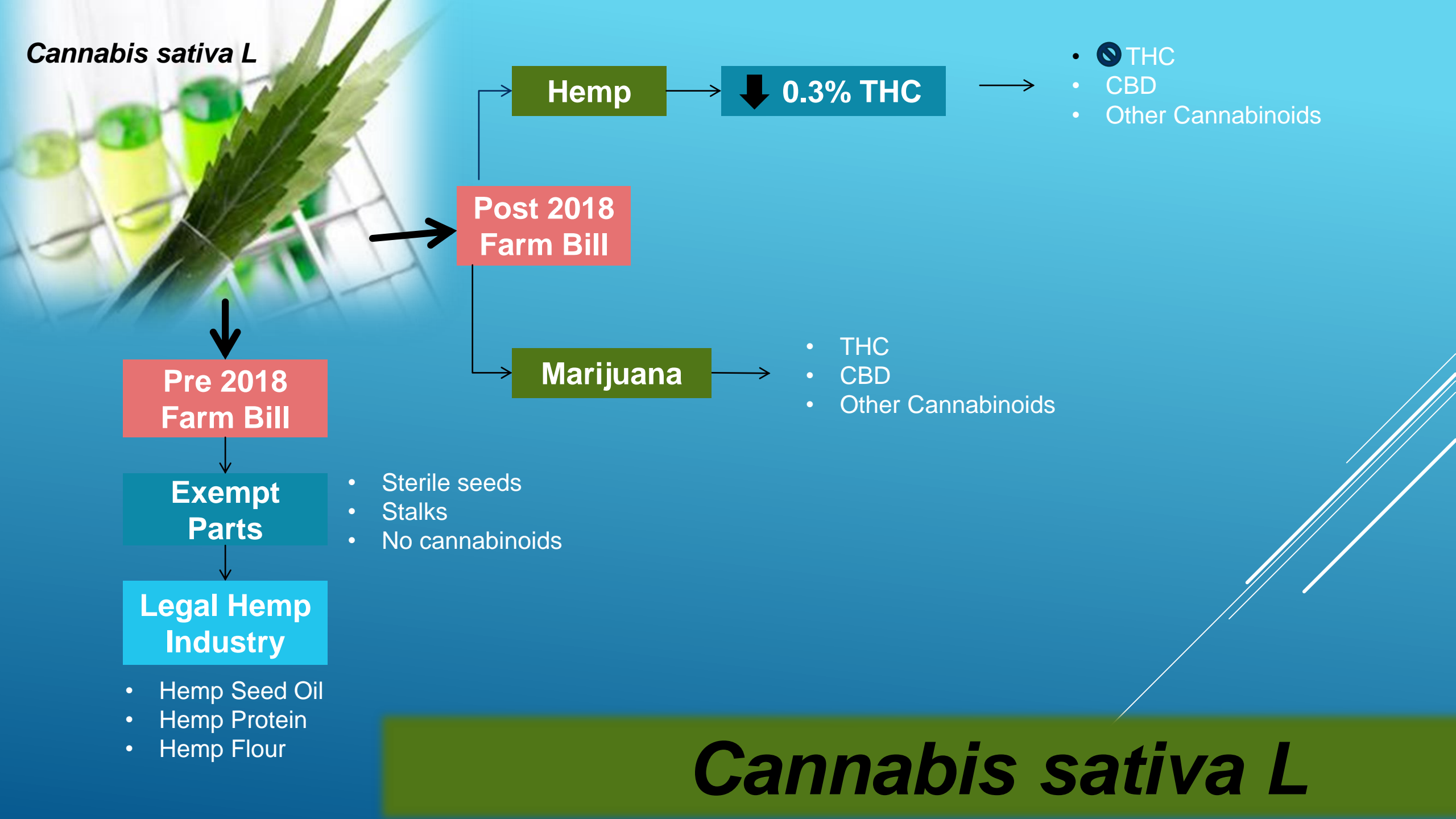
(86) PCT No.: **PCT/US99/08769**
§ 371 (c)(1),
(2), (4) Date: **Feb. 2, 2001**

(87) PCT Pub. No.: **WO99/53917**
PCT Pub. Date: **Oct. 28, 1999**

(57) **ABSTRACT**

Cannabinoids have been found to have antioxidant properties, unrelated to NMDA receptor antagonism. This new found property makes cannabinoids useful in the treatment and prophylaxis of wide variety of oxidation associated diseases, such as ischemic, age-related, inflammatory and autoimmune diseases. The cannabinoids are found to have particular application as neuroprotectants, for example in limiting neurological damage following ischemic insults, such as stroke and trauma, or in the treatment of neurodegenerative diseases, such as Alzheimer's disease, Parkinson's disease and HIV dementia. Nonpsychoactive cannabinoids, such as cannabidoil, are particularly advantageous to use because they avoid toxicity that is encountered with psychoactive cannabinoids at high doses useful in the method of the present invention. A particular disclosed class of cannabinoids useful as neuroprotective antioxidants is formula (I) wherein the R group is independently selected from the group consisting of H, CH₃, and COCH₃.

Cannabis sativa L



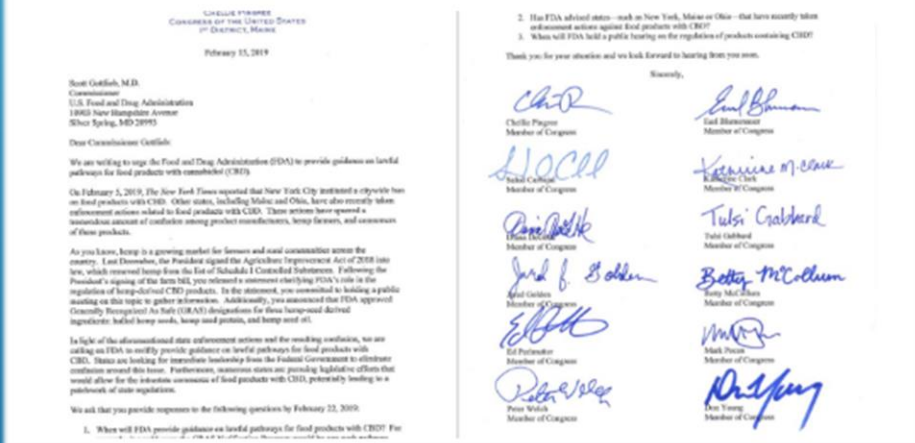
HEMP UPDATE



- 12/20/2018 - The Agricultural Improvement Act of 2018 legalizes hemp production and distribution under federal law
- 12/20/2018 - FDA Commissioner Scott Gottlieb released a statement reiterating FDA's position that federal laws prohibit CBD food or as supplements. However, statement signals FDA's willingness to explore a path to market for hemp derived CBD products

Hemp production is a growing market for farmers and rural communities across the country. We're urging Commissioner [@ScottGottliebMD](#) to provide lawful pathways for hemp-derived [#CBD](#) products. [#mepolitics](#)

Read our letter 



HEMP UPDATE

1/2019 – 2/2019 – Letters from Congress to FDA asking for action and clarity regarding CBD products

1/2019 – current – State enforcement varied, CBD product embargoes in news

2/28 – 2/29/2019 – Gottlieb public statements to agriculture officials and Congress reiterating willingness to explore FDA path to market; signals that legislation may be a preferred path; Gottlieb commits FDA to CBD public meeting in April 2019.

3/5/2019 – Gottlieb announces his retirement

3/13/19 – USDA hemp listening sessions

HOME / SHOP / HERBAL RENEWALS

How to Try CBD Oil for 7 Days — Absolutely FREE

★★★★☆ 549 Reviews

\$0.00

To purchase this product, login or create a Hemp Oil account here

Product

Free Sample

In stock

ADD TO CART

- ✓ Speedy Delivery Worldwide
- ✓ Third Party Lab Tested
- ✓ 90 Day Money-Back Guarantee



CBD MARKET

CBD in food and supplements = The New Wild West

- Wide-range of products
 - Range of starting materials (hemp/marijuana, yeast, synthetic)
 - Range of extracts (regular extract to 99% isolated to fully synthetic) and everything in between
- Wide range of legal/regulatory compliance theories and strategies
- Different interpretations of FDA's inaction
- Risk takers: low priority to quality and compliance
- Get rich quick scammers



PATH FORWARD – THE ISSUES

- USDA Issues – hemp growing and harvesting regulations; testing requirements; seed registration limited to agricultural varieties, disposal of non-compliant material, etc
- State Issues – States and tribes can issue unique hemp farming regulation. Patchwork of state cannabinoid laws (CBD and THC). Some tension between state-based products and dietary supplements.
- FDA issues
 - IND exclusion clause; proposed rule making and what CRN members want (hemp extract vs. isolate vs. synthetic)
 - Are all hemp extracts NDI's? What are companies doing to establish the products are safe? Free from adulterants (e.g., THC)
 - Will there be FDA enforcement?



Hemp production is a growing market for farmers and rural communities across the country. We're urging Commissioner [@ScottGottliebMD](#) to provide lawful pathways for hemp-derived #CBD products. #mepolitics

Read our letter 

CHARLIE PIERCE
CONGRESS OF THE UNITED STATES
1ST DISTRICT, MARYLAND

February 15, 2019

Scott Gottlieb, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20910

Dear Commissioner Gottlieb:

We are writing to urge the Food and Drug Administration (FDA) to provide guidance on lawful pathways for food products with cannabidiol (CBD).

On February 5, 2019, *The New York Times* reported that New York City instituted a citywide ban on food products with CBD. Other states, including Maine and Ohio, have also recently taken enforcement actions related to food products with CBD. These actions have opened a tremendous amount of confusion among product manufacturers, hemp farmers, and consumers of these products.

As you know, hemp is a growing market for farmers and rural communities across the country. Last December, the President signed the Agriculture Improvement Act of 2018 into law, which removed hemp from the list of Schedule I Controlled Substances. Following the President's signing of the Farm Bill, you released a statement clarifying FDA's role in the regulation of hemp-derived CBD products. In the statement, you committed to holding a public meeting on this topic to gather information. Additionally, you announced that FDA approved Cannabidiol (CBD) as a New Drug Application (NDA) designation for these hemp-sourced derived ingredients: hemp seed, hemp seed protein, and hemp seed oil.

In light of the aforementioned state enforcement actions and the resulting confusion, we are calling on FDA to swiftly provide guidance on lawful pathways for food products with CBD. States are looking for immediate leadership from the Federal Government to eliminate confusion around this issue. Furthermore, numerous states are providing legislative efforts that would allow for the interstate commerce of food products with CBD, potentially leading to a patchwork of state regulations.

We ask that you provide responses to the following questions by February 22, 2019:

1. When will FDA provide guidance on lawful pathways for food products with CBD? For

- Has FDA advised states—such as New York, Maine or Ohio—that have recently taken enforcement actions against food products with CBD?
- When will FDA hold a public hearing on the regulation of products containing CBD?

Thank you for your attention and we look forward to hearing from you soon.

Sincerely,


Charlie Pierce
Member of Congress


Earl Blumenauer
Member of Congress


Robert Calvert
Member of Congress


Kyrsten Sinema
Member of Congress


Thom Tillis
Member of Congress


Tulsi Gabbard
Member of Congress


Jared Polis
Member of Congress

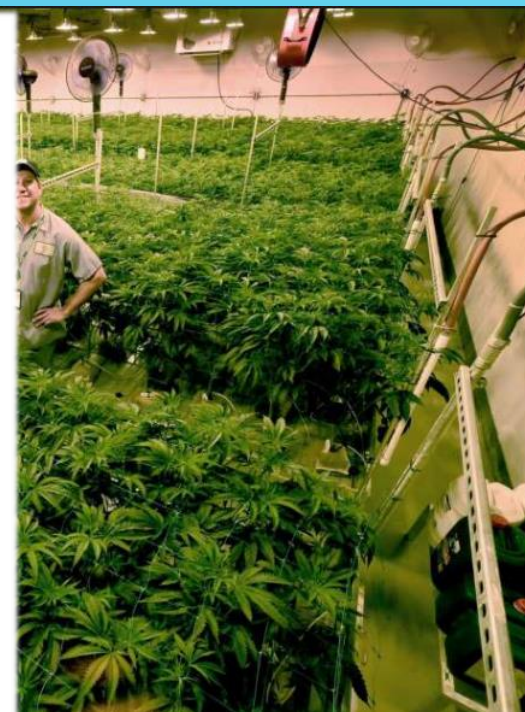

Kyrsten Sinema
Member of Congress


Ed Perlmutter
Member of Congress


Mark Pocan
Member of Congress


Peter Welch
Member of Congress


Kristi Noem
Member of Congress



CHEMICAL

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AGRICULTURAL HEMP

Federal law defines “hemp” as *Cannabis Sativa* plants that contain no more than 0.3% THC. *Cannabis Sativa* plants above 0.3% THC are classified as “Marijuana”.

ORIGIN, ANCESTRY, AVAILABILITY, AND AGRONOMIC CHARACTERISTICS

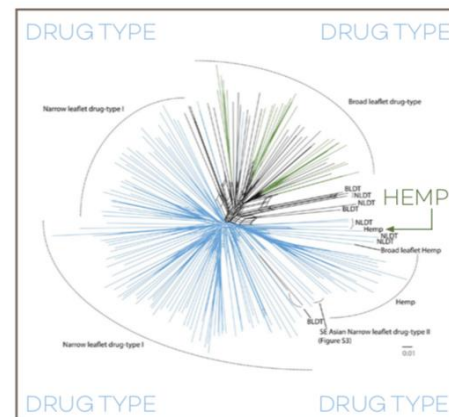
All strains within the genus *Cannabis* intercross readily and the pattern of variation for all morphological and agronomic traits is continuous. Hemp can be classified according to different attributes including: population type such as wild and naturalized populations, land races, and cultivars; plant-use as fiber cultivars (for long fibers or for pulp), seed cultivars, food/fiber, drug strains, and ornamentals.

De Meijer, 1995; D Meijer and Keizer, 1996

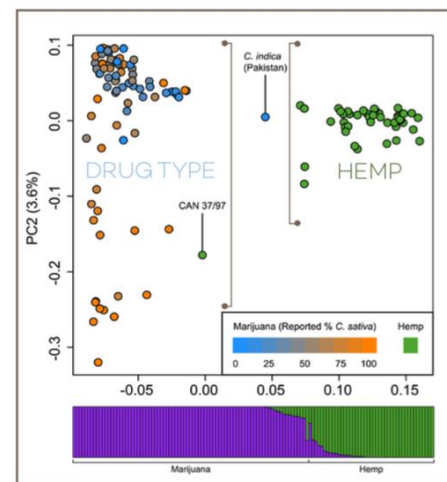
THE GENETIC STRUCTURE OF MARIJUANA AND HEMP

Marijuana and hemp are significantly differentiated at a genome-wide level, demonstrating that the distinction between these populations is not limited to genes underlying THC production....marijuana and hemp strain names often do not reflect a meaningful genetic identity.

Sawler, Jason & Stout, Jake & Gardner, Kyle & Hudson, Darryl & Vidmar, John & Butler, Laura & Page, Jonathan & Myles, Sean. (2015). The Genetic Structure of Marijuana and Hemp. PLoS one. 10. e0133292. 10.1371/journal.pone.0133292.



GENETIC DISTANCE AND HETEROZYGOSITY
FOR MAJOR CANNABIS GROUPS



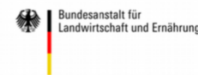
THE GENETIC STRUCTURE OF MARIJUANA AND HEMP



- Farm Bill – Hemp as *Cannabis sativa* L. below (0.3% THC) being discussed as a catch-all phrase
- USDA may require specific seeds to be registered as varieties of agricultural plants vs. drug types

Attachment 4

Stand: 35. complete issue

**INDUSTRIAL HEMP SEED TYPES WHO CAN BE SUPPORTED***

*For the support you can only use the Cannabis types which are till the 15th of march of this year listed in the common seed catalog for agricultural plants and published according to article 17 of the guideline 2002/53/EG.

Cannabis seed types for the regular farming

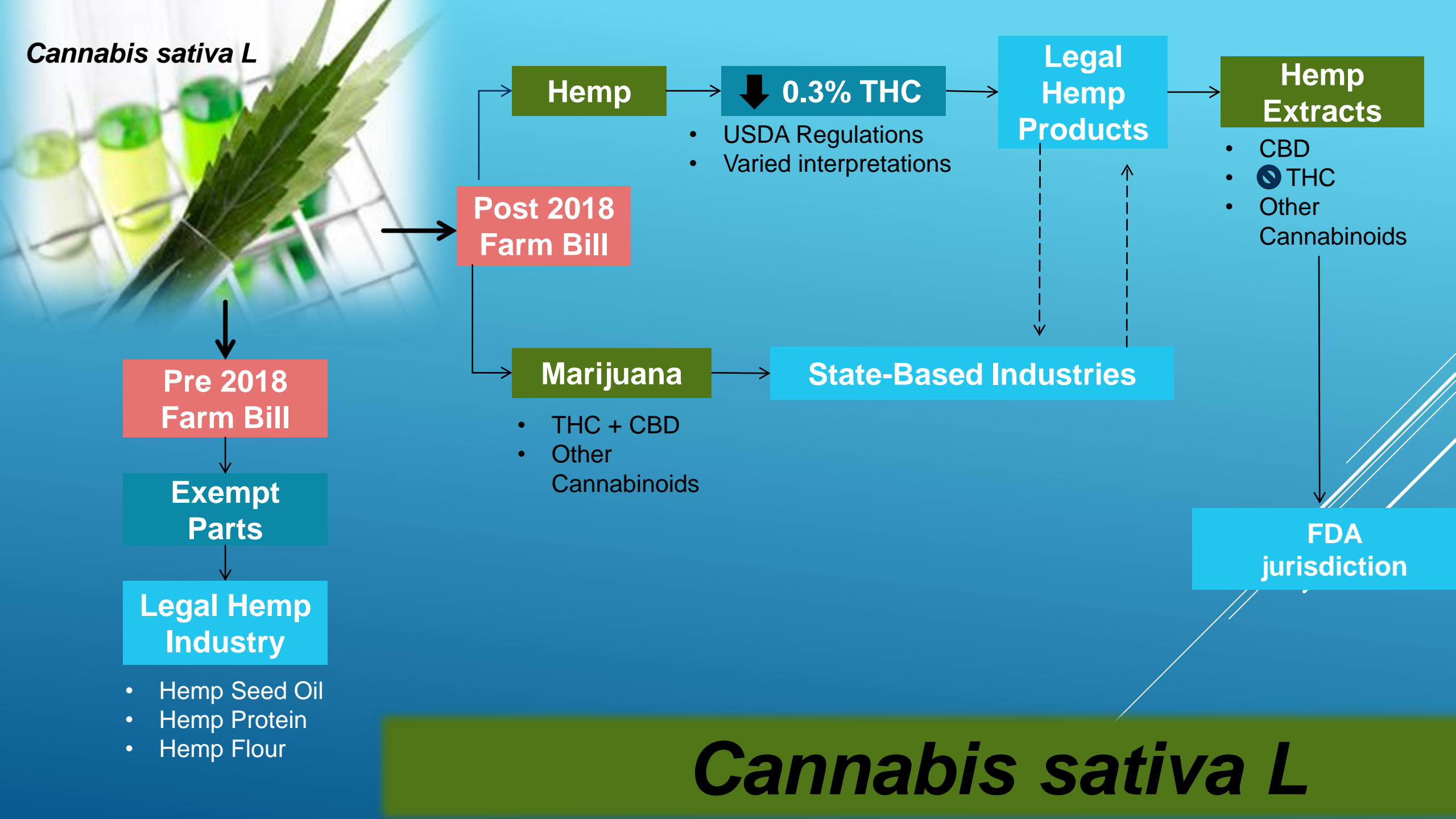
Antal	KC Dora
Armanca	KC Virtus
Beniko	KC Zuzana
Cannakomp	Kompolti
Carma	Kompolti hibrid TC
Carmaleonte	Lipko
Chamaeleon	Lovrin 110
Codimono	Marcello
CS	Markant
Dacia Secuieni	Monoica
Delta-Ilosa	Rajan
Delta-405	Ratza
Denise	Santhica 23
Diana	Santhica 27
Dioica 88	Santhica 70
Eletta Campana	Secuieni Jubileu
Epsilon 68	Silvana
Fedora 17	Szarvasi
Felina 32	Tiborszallasi
Ferimon	Tisza
Fibranova	Tygra
Fibrol	Uniko B
Finola	Uso-3 l
Futura 75	Wielkopolskie
Ivory	Wojko
KC Bonusz	Zenit

Cannabis seed types which are not allowed in Germany in 2017:

Bialobrzeskie	Carmagnola
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The average THC content of all samples of Bialobrzeskie and Carmagnola were above the allowed maximal concentration in two years.

Cannabis sativa L



Cannabis sativa L



Hemp
(0.3% THC)



Hemp = Botanical = D.I.
(whole plant)



Hemp Seed Oil

→ O.D.I.



Hemp Seed
protein/flour

→ O.D.I.



Hemp extract
(whole plant)

- ETOH
- CO2
- Other solvent



*** N.D.I.**

**parts of plant legally in food supply had almost no CBD or other cannabinoids and were not extracted for food use.*

FDA policy on
“articles” in
prior clinical studies
made public



- CBD/CBDa just there
- CBD concentrated
- CBD standardized
- CBD isolate



Each is unique

- safety
- legal/regulatory

* CBD synthetic or other source CBD – start over



Welcome to

EIHA

European Industrial Hemp Association

Industrial Hemp: Pulp & Paper, Insulation, Biocomposites & Construction, Food & Feed and Pharmaceuticals

PATH FORWARD

- **New Industry or New Ingredient?**
 - *MJ vs. Hemp - food, supplement, drug, medical food, and recreational – blurry lines that need clear and distinct lanes*
- **Food and Supplements - Regulatory Fix or Legislative Fix?**
 - *Misguided MJ advocacy; misguided cannabinoid drug advocacy*
 - *Does legislative fix turn into MJ free-for-all?*
- **Hemp-CBD in Limbo – What is the impact?**
 - *For How Long? Benefit or damage responsible industry's reputation (Drug and DS)?*

The logo for the Hemp Industries Association is overlaid on a close-up photograph of a green hemp plant. The logo consists of a stylized white "H" with a leaf-like flourish on the left, followed by the words "HEMP INDUSTRIES" in a bold, white, sans-serif font, and "ASSOCIATION" in a slightly smaller, white, sans-serif font below it.

HEMP INDUSTRIES
ASSOCIATION