



**Lost in the Weeds:
The Past, Present, and Future of
Hemp in Pain Treatment**

Stephen J. Ziegler, PhD, JD

Disclosures

- Drug & Health Policy Consulting, LLC
–CEO
- Advisory Board: Nebraska Hemp Association



Learning Objectives

- Describe the history and regulation of hemp in the United States
- Discuss the current legal and regulatory status of hemp and CBD at the federal and state levels
- Discuss the potential future of hemp in the treatment of pain



Where am I?



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Have any of your patients asked you about hemp or CBD?

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Accessing information



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Cannabis sativa L.:
Meet the controversial cousin: Marijuana



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Send in the Clones: Marijuana & THC



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Meet the other cannabis cousin:
Hemp (guilt by association)



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#1 Factor Impacting the Cannabis Space



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Result #1



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Result #2:

- Limited RESEARCH & S1:
- The classic CATCH-22

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National Academies of Sciences

- National Academies of Sciences, Engineering, and Medicine. The health effects of cannabis and cannabinoids: the current state of evidence and recommendations for research
- “One challenge was the volume of published work in this area and the paucity of high-quality data available to effectively address the topics of the study.”
–Piomelli et al., 2017, quoting Dr. Abrams, panel member).”

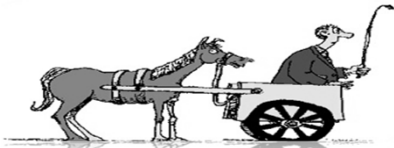
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**National Academies of Science Report:
Significant Barriers to Conducting Clinical Trials**

- “One of my mantras on the committee was that the absence of evidence of effectiveness does not equate to evidence of the absence of effectiveness!”
- We were quite selective and stringent in reviewing only the highest quality clinical trials and restricted our grading of evidence by using the careful criteria that the committee agreed upon. This coupled with the significant barriers that exist to conducting clinical trials of the potential therapeutic benefit of the plant material leave us with a handful of strong conclusions on therapeutic benefits of cannabis.
(Piomelli et al., 2017, quoting Dr. Abrams, panel member).”

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**Restricted research + direct democracy at
the state level = clinical challenges**

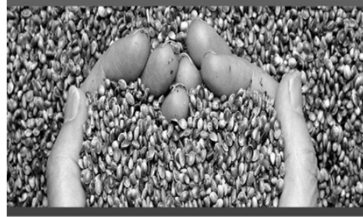


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Hemp: 25K uses and counting

- Seed (multiple uses)
- Fiber
- Oil
- Remediation
- Chemical derivatives
 - Medical use
 - Pain
 - Neurological disorders



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The Dynamic Duo: THC and CBD

- Derivatives
- Differences in law and chemistry. At least recently . . .
- Delta-9-tetrahydrocannabinol (THC)
 - Psychoactive
- Cannabidiol (CBD)
 - Derived from both MJ and hemp
 - Hemp by definition = 0.03% THC
- Extraction: It don't come easy

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Medical Cannabis in the Present: Marijuana & Hemp

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Medical MJ</p> <ul style="list-style-type: none"> ▪ States all over the place <ul style="list-style-type: none"> – Eligible conditions – Access, purchase, possession ▪ Multiple products ▪ Not your Grandpa's MJ ▪ THC and CBD; 1 or the other or both? ▪ Data (in the eyes of the beholder) <ul style="list-style-type: none"> – Anecdotal – Placebo – Limited clinical studies; but see, Israel ▪ Still illegal federally | <p>Hemp</p> <ul style="list-style-type: none"> ▪ Derivative source was an issue ▪ And source of confusion ▪ CBD oil <ul style="list-style-type: none"> – Uses, application, administration ▪ Dosing? ▪ Labeling? ▪ Data <ul style="list-style-type: none"> – Anecdotal – Placebo – Limited studies ▪ Now legal (sort of; the 2018 Farm Bill in a moment) |
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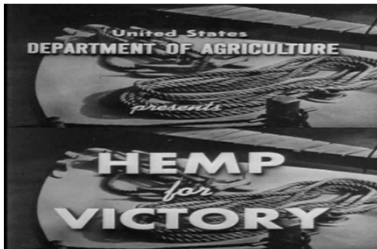
History and Use #25,001



▪ Marijuana Tax Act of 1937 & Harry Anslinger

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Hemp in World War II



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Hemp and the CSA



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Farm Bill 2014: University partnerships



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Federal Farm Bill of 2018: Can 80 Years of Prohibition be erased?



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Not yet.



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Who's on 1st?



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States need to submit their regulatory plans



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Say hello to the new boss,
same as the old boss?



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FDA press release post 2018 FB

- FDA expressed concern that “the number of drug claims being made about products not approved by the FDA that claim to contain CBD or other cannabis-derived compounds.
- Among other things, the FDA requires a cannabis product (hemp-derived or otherwise) that is marketed with a claim of therapeutic benefit, or with any other disease claim, to be approved by the FDA for its intended use before it may be introduced into interstate commerce.”[emphasis added]

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FDA press release post 2018 FB

- “Additionally, it’s unlawful under the FD&C Act to introduce food containing added CBD or THC into interstate commerce, or to market CBD or THC products as, or in, dietary supplements, regardless of whether the substances are hemp-derived.
- This is because both CBD and THC are active ingredients in FDA-approved drugs and were the subject of substantial clinical investigations before they were marketed as foods or dietary supplements.”
FDA Statement, Dec. 20, 2018

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Result of Press Release?

- The insanity continues
- “More restaurants and facilities nationwide report they can’t sell CBD anymore”
- “In the past week, enforcement letters and product seizures spread to new jurisdictions, a response to December comments from the U.S. Food and Drug Administration that CBD can’t be put in foods or nutritional supplements until the molecule gets an updated review.”
– <https://hempindustrydaily.com/cbd-crackdown-spreads-nyc-politician-vows-halt-overreaction/>

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Hemp Arrests!

- Farm Bill's guarantee: "no state or Indian tribe shall prohibit the transportation or shipment of hemp or hemp products."
- Four men working for a hemp-transportation company . . . were charged with drug crimes for allegedly carrying some 18,000 pounds of Kentucky cannabis destined for a CBD manufacturer in Louisville, Colorado
 - "We told them, 'We're hauling hemp, and here's our paperwork.' It was all there, certified by the state of Kentucky."
- An Oregon truck driver was arrested in Boise, Idaho, for carrying roughly 6,700 pounds of cannabis from Oregon to Big Sky Scientific, a CBD manufacturer in Aurora, Colorado
 - <https://bit.ly/2H1xB9Y>



**Congress to FDA:
We need CBD answers by Friday, February 22**

- "Saying that states need "immediate leadership" on CBD in foods, drugs and cosmetics, 12 members of Congress have asked the head of the U.S. Food and Drug Administration (FDA) to release updated guidance by Friday."
 - <https://hempindustrydaily.com/congress-to-fda-we-need-cbd-answers-by-friday/>



The future of hemp in pain treatment



The future of hemp in pain treatment

- It is all about the derivatives (CBD) – at least for now
- CBD derived from MJ used in epilepsy treatment
 - What about hemp?
- FDA will remain active (unless Congress says otherwise)
- Anecdotal data & the role of the placebo effect
- New studies in future
 - No longer S1 license (removes a hurdle)



A plant with a shady past but a bright future. Thank you!



- Contact information
- Stephen J. Ziegler, PhD, JD
- Purdue University, Professor Emeritus
- Sziegler@purdue.edu



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