

# ACCESS NOW

American Legion Conference

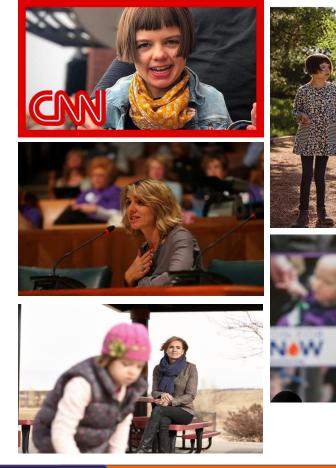
February 25, 2024

### COALITIONFORACCESS.ORG

## Paige Figi

### "Mother of the CBD Movement" and Founder of Coalition for Access Now

In 2010, Paige embarked on a journey when her daughter Charlotte, diagnosed with Dravet Syndrome, faced severe seizures with no relief from conventional treatments. Exploring alternative therapies, Paige turned to CBD research, collaborating with experts in Colorado to create a non-intoxicating hemp extract with high CBD and low THC, successfully alleviating Charlotte's seizures. Despite legal challenges due to federal categorization of CBD, Paige's success prompted her to establish the Coalition for Access Now, addressing outdated laws and advocating for CBD access. The nonprofit focuses on representing the American CBD consumer, public education, and collaboration with lawmakers for legislative change.



## What CBD <u>IS</u>

- One active cannabinoid that identifies in hemp that is safe and benign
- Supported by evidence to benefit the human endocannabinoid system
- Legal in 50 states
- A researched anticonvulsant as well as other medical properties

## What CBD is <u>NOT</u>

- Medical marijuana
- Intoxicating
- Toxic
- Addictive
- Controlled substance
- Unsafe

### What CBD SHOULD BE

- A dietary supplement
- Food
  - Medicine
  - Cosmetic
  - Pet Product
  - More

## **The Problem**

### 2018 Farm Bill

Bipartisan 2018 Farm Bill removed hemp from the statutory definition of marijuana, making CBD available in all 50 states but the FDA did not finish the job and regulate CBD as a dietary supplement.

### **FDA Authority**

FDA has the power to exempt a product from IND Preclusion but wants Congress to direct the agency.

### **Dangerous CBD Products**

Absence of federal regulation has led to the hijacking of the CBD category by intoxicating products masquerading as CBD

### **State Restrictions**

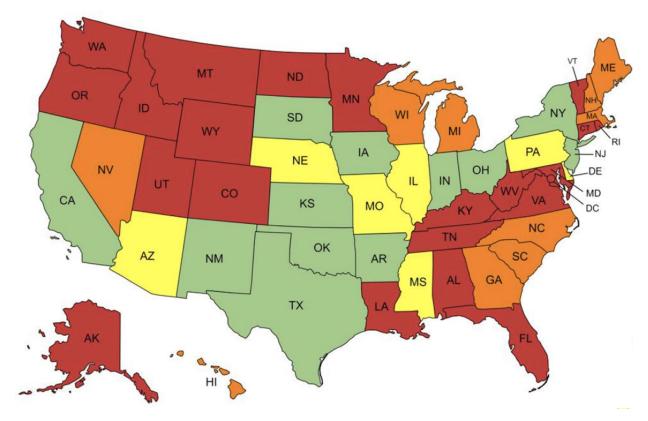
States are imposing overbroad restrictions on intoxicating "CBD" products, sometimes eliminating the CBD category entirely

### **FDA Regulation Necessary**

Regulating CBD products as dietary supplements will maintain access to CBD for millions, including veterans

45 million Americans – family caregivers, veterans, athletes and more – rely on the benefits of CBD

## **States Rolling Back CBD Access Laws**



Age restrictions, THC limits, and/or additional requirements apply Hemp/CBD restricted in food or supplements Unclear if Hemp/CBD products are permitted

Hemp/CBD products permitted if compliant with approved source, testing, labeling, packaging, and/or registration requirements

As of 12/31/23

## **Coalition for Access Now Objectives**

Differentiate what CBD is, what it is not, and tell the story of a robust, quality CBD industry and its impact as an alternative to opioids and other toxic medicines



Advocate for passage of legislation to provide authority to the FDA to regulate CBD as a dietary supplement

**H.R. 1629** – Griffith (R) & Craig (D) provides clear authority for the FDA to regulate hemp, cannabidiol derived from hemp, and any other ingredient derived from hemp, as a dietary supplement under the Federal Food, Drug, and Cosmetic Act. The bill is truly bipartisan. **S. 2451** – Wyden (D) & Paul (R) provides clear authority for the FDA to allow for hemp-derived cannabidiol and hemp-derived cannabidiol containing substances in dietary supplements and food. This bill is also bipartisan.

## **Coalition for Access Now Impact**



Coalition for Access Now and other top CBD experts briefed Congress on the need for FDA regulation of **CBD** products





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The Coalition for Access Now is engaging congressional champions and given them credit for their support.

The Coalition for Access Now partnered with U.S. Pain Foundation to advocate for the passage of legislation (H.R. 1629)

Ron Wyden and Rand Paul.

118TH CONGRESS S. 2451 1st Session

#### 118TH CONGRESS 187 SESSION H.R. 1629

The Coalition for Access Now is actively

consistently drafting letters to congressional members, urging their support for H.R. 1629

engaged in ongoing advocacy efforts,

introduced by Rep. Griffith, and Senate

version (S. 2451) sponsored by Senators

To allow for hemp-derived cannabidiol and hemp-derived cannabidio staining substances in dietary supplements and food

IN THE SENATE OF THE UNITED STATES.

JULY 20, 2023 Mr. WYDEN introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensio

#### A BILL

To allow for hemp-derived cannabidiol and hemp-derived cannabidiol containing substances in dietary supplements and food.

- Be it enacted by the Senate and House of Representa-2 tives of the United States of America in Congress assembled.
- 3 SECTION 1. SHORT TITLE.

This Act may be eited as the "Hemp Access and Con-5 sumer Safety Act"

- REGULATION OF HEMP-DERIVED CANNABIDIOL
- AND HEMP-DERIVED CANNABIDIOL CON-
- TAINING SUBSTANCES
- (a) INCLUSION IN DEFINITION OF DIETARY SUPPLE-
- 10 MENT.—Section 201(ff)(3)(B) of the Federal Food, Drug.

To make herap, cannabidiol derived from herap, and any other ingredient derived from herap lawfal for use under the Pederal Food, Drug, and Cosmetie Act as a dietary ingredient in a dietary supplement, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

- MARCH 17, 2023
- Mr. GRIFFITH (for himself, Ms. CRAIG, Mr. POCAN, Mr. COHEN, Mr. TRONE Ms. PINGREE, Mr. BLUMENAUER, Mr. NEWHOUSE, Mr. PANETTA, Ms. BARRAGÁN, Mr. JOYCE of Ohio, Mr. GROTHMAN, and Mr. GAETZ) intro duced the following hill: which was referred to the Committee on Energy and Commerce

#### A BILL

- To make hemp, cannabidiol derived from hemp, and any other ingredient derived from hemp lawful for use under the Federal Food, Drug, and Cosmetie Act as a dietary ingredient in a dictary supplement, and for other purnoses
- Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- **3** SECTION 1. SHORT TITLE.
- .4 This Act may be cited as the "Hemp and Hemp-De-
- 5 rived CBD Consumer Protection and Market Stabilization 6 Act of 2023"

## **Coalition Supporters**

U.S. PAIN FOUNDATION

REALM

CARING.





**IRAQ AND AFGHANISTAN** 

VETERANS OF AMERICA

Tox Strategies

LEGION

## **Current Situation**

- Bipartisan bills introduced in both the House and Senate
- Senate HELP and House Energy & Commerce Committees have jurisdiction
- Goal To move the bill by regular order, i.e., legislative hearing and markup
- House E&C Committee Chairwoman Cathy McMorris Rodgers recently announced she will retire at the end of the Congress
- No organized opposition identified
- FDA engaged with committees questions have been answered
- CBD industry united under umbrella of ONE HEMP coalition
- Election year calendar putting pressure on legislative calendar making the Spring 2024 a critical window for action
- Time is of the essence!!

### **CBD FOR VETERANS**



Too often our brave active duty and military Veterans suffer the physical and mental consequences of their service. Chronic pain that leads to opioid use, as well as mental health challenges due to anxiety, depression, and suicidality, can challenge these warriors. Increasingly they are turning to low-THC hemp-derived cannabidiol (CBD) products that are proving to provide benefits not previously achieved. Now, their access to CBD products is being threatened by FDA proposals that the Coalition is actively working to address in Congress.

### ADDRESSING ANXIETY AND DEPRESSION/SUICIDALITY

**Suicide rates** have been historically high among young Veterans and older Veterans as well, according to the Department of Veterans Affairs. Factors that play a role in the high suicide rate:

### Suicide among Veterans between the ages of 18 and 34 increased by 95.3% in the past 20 years.

- Acute psychosocial stressors
- Mental health conditions like anxiety disorder, manicdepressive disorder, depression, post-traumatic stress disorder (PTSD), and traumatic brain injury (TBI)
- Higher doses of opioid medications for pain control
- Substance misuse, especially heavy binge drinking
- Insomnia

### **CBD AS A SOLUTION:**

Research has shown that cannabinoids provide anti-anxiety, anti-depressant, anti-psychotic, and stress-reducing effects.

- Cannabidiol exerts fast antidepressant-like actions and may represent a novel fast antidepressant drug.<sup>1</sup>
- Relative to placebo in a clinical trial, CBD is associated with significantly decreased subjective anxiety, suggesting that CBD reduces anxiety in social anxiety disorder.<sup>2</sup>
- CBD, either as monotherapy or added to regular antipsychotic medication, improved symptoms in patients with schizophrenia, with particularly promising effects in the early stages of illness.<sup>3</sup>

### An Alternative for Chronic Pain - An Alternative to Opioids

U.S. military Veterans have been heavily impacted by the opioid overdose crisis, with drug overdose mortality rates increasing by 53% from 2010–2019.

- Opioids in particular have considerable side effects, including constipation, impaired sleep, and respiratory depression.<sup>4</sup>
- The rapid increase in opioid use and opioidassociated mortality is largely attributed to use of opioids in chronic pain treatment.<sup>5</sup>
- Opioid-associated mortality is largely attributed to use of opioids in chronic pain treatment.<sup>6</sup>

### **CBD AS A SOLUTION:**

- Rising prevalence of the non-psychoactive cannabinoid CBD presents an opportunity for the treatment of intractable chronic pain for which primary treatments are insufficient or not possible.<sup>7</sup>
- 53% of participants from a prospective cohort study published in Taylor & Francis in 2019 (Capano, et al.) reported reduced or eliminated opioid use within 8 weeks after adding CBD-rich hemp extract to their regimens.
  Almost all CBD users (94%) reported quality of life improvements.

## **Improving Quality of Life - Wellness - Sleep**

**Chronic pain and psychiatric disorders** often lead to a lack of sleep in Veterans, thereby leading to declining health.

- Sleep disorders are closely related to mental illnesses such as depression. Psychiatric disorders are one of the many causes of insomnia. Not getting enough sleep can have serious implications for our stress-response and high stress levels can contribute to poor sleep quality.
- 1. Linge, et al., Neuropharmacology, 2016 2. Crippa, et al., Psychopharmacology, 2010
- 3. Batalla et al., Journal of Clinical Medicine, 2019 4. NIH Library of Medicine study, 2015
- 5. NIH 2015 study 6. Chou, et al. Annals of Internal Medicine, 2022
- 7. Argueta et al., Frontiers in Pharmacology, 2020 8. Henson et al., Journal of Clinical Medicine, 2021

### **CBD AS A SOLUTION:**

- CBD provides a solution for sleep disorders, often caused by psychiatric disorders, including PTSD, leading to insomnia, through misalignment Veterans' circadian rhythm. A 2017 study published in Sleep Disorders concluded that CBD holds promise for REM sleep behavior and therapeutic potential for the treatment of insomnia.
- There have been seven double-blind placebo controlled clinical trials of CBD for stress on a combined total of 232 participants and one partially controlled study on 120 participants...

## All showed that CBD was effective in reducing the stress.<sup>8</sup>

## **Coalition for Access Now Briefs Congress**



## The Time to Act Is NOW

Despite Congress legalizing CBD nationwide, the essential task of establishing proper regulations for CBD products remains **unfinished**. There have been various studies and data that prove CBD products are non-intoxicating, non-addictive and nonpsychoactive. The danger lies in lack of regulation. Without regulation, bad actors are putting products on the market that contain contain harmful ingredients like pesticides or heavy metals putting Americans at risk. That is why, in the interest of public health, the House and Senate must work together to push for federally regulated CBD products

### How <u>YOU</u> Can Join the Fight for Access

- Make access to CBD a priority and activate voices in support
- Send a letter to Congress as an organization asking for a hearing and passage of H.R 1629 and S. 2451
- Utilize social media channels
- Encourage others to join the Coalition's efforts
- Identify veterans to join advocacy meetings on Capitol Hill

