Americans for Safe Access

To: The California Department of Public Health
Via email: regulations@cdph.ca.gov

From: Steph Sherer
Founder and Executive Director
Americans for Safe Access (ASA)

July 27, 2025

Re: **Regulation Package Identifier No. DPH-24-005**: **Serving Size and Age Industrial Hemp**
Proposal to make permanent sections 23000, 23005, 23015, and 23100 to Subchapter 2.6 of Chapter 5 of Division 1 of Title 17, California Code of Regulations in order to implement, interpret, or make specific sections 110045, 110085, 110095, 110100, 110390, 110395, 110398, 110400, 110660, 110680, 110760, 110765, 111920, 111921, 111921.3, 111922, 111925, 111925.2, 111926, 111926.2, 131095, and 131100 of the Health and Safety Code; Section 15731, Title 4 California Code of Regulations; and Part 101, Title 21 Code of Federal Regulations.

Dear Director Erica Pan and members of the California Department of Public Health,

I am writing to you on behalf of our thousands of members in California. First, let me say that Americans for Safe Access (ASA) fully supports the regulation of cannabinoid products as part of our mission to ensure safe access for patients. We want California to be successful in these efforts, as we have consistently called for federal oversight of these products. However, we request a minor yet crucial amendment to address a major issue affecting some of California's most vulnerable residents.

Urgent Concern: Unintentional Ban on Therapeutic Full-Spectrum Hemp Products

As currently written, the proposed regulations would inadvertently eliminate access to orally ingested, naturally derived, full-spectrum hemp CBD products containing small, non-intoxicating amounts of THC. These formulations—typically with ratios of 15:1 CBD to THC or higher—are critical therapies for patients with conditions such as epilepsy, autism, dementia, cancer, and chronic pain. These are not recreational products, nor do they carry abuse liability.

These products are uniquely effective due to the "entourage effect," where a small amount of naturally occurring THC enhances the therapeutic impact of CBD. Studies and clinical observations consistently show that isolated CBD is less effective than full-spectrum formulations.

Despite their proven medical utility and non-intoxicating nature, these products are not economically viable to produce under California's cannabis regulatory system. The high cost of cultivation and extraction under cannabis licensure forces patients to rely on the hemp-derived market for affordable access. The proposed regulations, if enacted without a carve-out, would eliminate these products almost entirely, even though they are not intoxicants and have no recreational appeal.

Proposed Amendment: Carve-Out for Non-Intoxicating, Therapeutic Hemp Products

To protect patient access while maintaining the intent of the regulation, ASA proposes a limited exemption from the zero-THC threshold for orally ingested hemp products intended for medical use. Specifically, we are requesting that the Department include the following language in the regulations:

> ***"Except for full-spectrum hemp cannabinoid oil-based products intended for medical use with a ratio of 15:1 CBD to THC (or higher)."***

This language establishes a pathway for the continued availability of life-saving therapies without compromising the Department's public health objectives. Additional language requiring these products to demonstrate compliance with California cannabis product requirements would be acceptable.

Supporting Evidence & Expert Testimony

Patients and providers alike attest to the critical role these products play. Bonni Goldstein, MD, a nationally recognized medical cannabis expert and ASA Advisor, shared the following insights:

> *"Banning naturally occurring, full-spectrum CBD hemp products would cause serious harm to vulnerable patients who already have achieved stability and symptom control using these specific formulations, some for over a decade with profound improvements in quality of life.*
>
> *Thousands of Californians, including children with intractable epilepsy, severe autism and advanced cancers, as well as adults with dementia and chronic pain* ***face a potential return of debilitating, and potentially life-threatening in the case of seizures, symptoms if they were to be cut off from their current CBD formulations.***
>
> *Many of these patients have been weaned off other medications, such as anticonvulsants, opioids and neuroleptics, replacing these with more effective and tolerable CBD-dominant*

hemp products. Continued use of these preparations, if outlawed, would criminalize desperate patients trying to maintain quality of life.

Naturally occurring, full-spectrum CBD-dominant hemp products with ratios over 15:1 have no appeal for recreational use and no abuse liability.

Treating naturally occurring, full-spectrum CBD-dominant hemp products as a public health threat is scientifically unfounded. The amount that one would have to take in order to achieve intoxication is both cost-prohibitive and
highly impractical compared to obtaining a less expensive THC-dominant product (natural or synthetic).

Eliminating access to effective medical therapy for patients who are nonverbal and/or disabled violates the spirit of disability rights protection under the ADA. In my opinion, the state will likely face a lawsuit from a patient or the parents of a patient harmed by this ban at some point.

ASA's proposed carve-out for 15:1 or higher naturally occurring, CBD-dominant products will ensure that vulnerable patients continue to have access to effective and affordable products while addressing safety concerns associated with unregulated intoxicating semi-synthetic products."

Clinical research supports these observations:

Studies demonstrate that naturally derived, full-spectrum CBD-dominant preparations with <0.3% THC by weight are clinically superior to CBD isolates (purified CBD) See:

> Pamplona, Fabricio A., Lorenzo Rolim Da Silva, and Ana Carolina Coan. "Potential clinical benefits of CBD-rich cannabis extracts over purified CBD in treatment-resistant epilepsy: observational data meta-analysis." Frontiers in Neurology 9 (2018): 392084;
>
> Gallily, Ruth, Zhannah Yekhtin, and Lumír Ondřej Hanuš. "Overcoming the bell-shaped dose-response of cannabidiol by using cannabis extract enriched in cannabidiol." Pharmacology & Pharmacy 6.2 (2015): 75-85.)

Respectfully, ASA requests that the Department consider the devastating harm inadvertently banning full-spectrum CBD products would cause to patients, particularly children with seizure disorders, and **urges the adoption of a simple, medically justified carve-out for full-spectrum, orally ingested hemp CBD products intended for therapeutic use**. This exemption will protect

patient access and preserve the integrity of California's public health mission without compromising the Department's goal of regulating intoxicating products.

Thank you for your consideration and for your commitment to the health and safety of all Californians. Should you require any additional information, please contact me directly at **steph@safeaccessnow.org**.

Sincerely,

Steph Sherer
Founder and Executive Director
Americans for Safe Access (ASA)

Founded in 2002, with over 150,000 active supporters in all 50 states, ASA is the oldest, largest national member-based organization of patients, medical professionals, scientists, and concerned citizens promoting safe and legal access to cannabis for therapeutic use and research.