



## Position Statement on Cannabidiol Products

Aimed Alliance is a nonprofit health policy organization that works to protect and enhance the rights of health care consumers and providers.

### I. Background

Food and supplement products containing cannabidiol (CBD) have risen in popularity over the past few years and have been misleadingly marketed as a cure-all for many medical conditions, including cancer, epilepsy, anxiety, depression, insomnia, pain, and diabetes.<sup>1</sup> At the same time, there is mounting pressure to legalize non-prescription CBD products,<sup>2</sup> which may pose significant safety risks to consumers.

#### A. U.S. Push to Legalize Products Containing CBD

Pursuant to the Food Drug and Cosmetics Act (FDCA), it is currently illegal to introduce or market food or supplements containing CBD, regardless of whether the substances are hemp-derived.<sup>3</sup> Yet, in December 2018, Congress passed the Agriculture Improvement Act of 2018 (Farm Bill), which required hemp to be removed from the Controlled Substances Act and allowed the marketing of hemp and derivatives of cannabis with extremely low (less than 0.3 percent) concentrations of tetrahydrocannabinol (THC). While Congress may have intended the Farm Bill to permit the sale of CBD products, the law did not change the FDA's regulatory authority.<sup>4</sup> As such, both the FDA and state officials have taken enforcement actions against the makers of CBD products over the past year.<sup>5</sup> Still, other states have introduced legislation that would allow for the sale of food and supplement products containing CBD, and some states have passed laws that encourage its use for medical purposes.<sup>6</sup> Additionally, members of Congress have called on the FDA to release guidance on lawful pathways for CBD products.<sup>7</sup>

Last year, the FDA announced that it may release regulations that would allow the sale of CBD in food products.<sup>8</sup> To solicit public input on those regulations, it hosted a public meeting, reopened a public comment period, and issued a report to Congress.

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<sup>1</sup> <https://www.marijuanabreak.com/conditions-cbd-oil-help>

<sup>2</sup> FDCA sec. 201(ff)(3)(B)(i), (ii);

[https://www.fda.gov/newsevents/publichealthfocus/ucm421168.htm#dietary\\_supplements](https://www.fda.gov/newsevents/publichealthfocus/ucm421168.htm#dietary_supplements)

<sup>3</sup> FDCA sec. 201(ff)(3)(B)(i), (ii);

<https://www.fda.gov/newsevents/newsroom/pressAnnouncements/ucm628988.htm>

<sup>4</sup> <https://www.fda.gov/newsevents/newsroom/pressAnnouncements/ucm628988.htm>

<sup>5</sup> [https://news.bloomberglaw.com/pharma-and-life-sciences/insight-fda-states-starting-to-enforce-bans-on-cbd-in-foods-supplements?utm\\_source=rss&utm\\_medium=HPNW&utm\\_campaign=00000169-10c6-d1d8-a5f9-53eedccd0002](https://news.bloomberglaw.com/pharma-and-life-sciences/insight-fda-states-starting-to-enforce-bans-on-cbd-in-foods-supplements?utm_source=rss&utm_medium=HPNW&utm_campaign=00000169-10c6-d1d8-a5f9-53eedccd0002)

<sup>6</sup> <https://medicalmarijuana.procon.org/view.resource.php?resourceID=006473>

<sup>7</sup>

[https://twitter.com/chelliepingree/status/1097874770799091714/photo/1?ref\\_src=twsrc%5Etfw%7Ctwcamp%5Etwetembed%7Ctwterm%5E1097874770799091714&ref\\_url=https%3A%2F%2Fnews.weedmaps.com%2F2019%2F02%2Fhouse-members-urge-fda-chief-to-issue-guidelines-for-cbd-food-products%2F](https://twitter.com/chelliepingree/status/1097874770799091714/photo/1?ref_src=twsrc%5Etfw%7Ctwcamp%5Etwetembed%7Ctwterm%5E1097874770799091714&ref_url=https%3A%2F%2Fnews.weedmaps.com%2F2019%2F02%2Fhouse-members-urge-fda-chief-to-issue-guidelines-for-cbd-food-products%2F)

<sup>8</sup> <https://insidehealthpolicy.com/daily-news/gottlieb-testify-budget-april-5-exit-forms-cbd-task-group>

Yet, all of this activity has created widespread confusion among consumers, many of whom believe food and supplement products containing CBD products are safe and legal.

## **B. Safety Concerns Regarding Food and Supplement Products Containing CBD**

The FDA defines a prescription drug as “a substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” that is prescribed by a health care practitioner and regulated by the FDA.<sup>9</sup> Prior to when a drug is marketed, it must meet stringent standards for safety and efficacy. Drugs must also uniformly meet standards regarding quality, purity, and dosage, thereby providing consumers with peace of mind.

In contrast, a dietary supplement is a product that is intended to supplement a diet, contains one or more dietary ingredient (*e.g.*, vitamins, minerals, herbs), and is intended to be taken orally.<sup>10</sup> The FDA does not review dietary supplements for safety or effectiveness before they are marketed in the U.S.<sup>11</sup> Additionally, there is no legal framework for the standardization of dietary supplements in the U.S.<sup>12</sup>

The lack of standards for quality, purity, and dosages have been particularly evident among CBD supplements. Given that supplement products containing CBD are poorly regulated, there have been frequent reports of adulterated products containing toxic substances, including dangerous, psychoactive compounds.<sup>13</sup> For example, the United States Army issued a public health warning in 2018 after approximately 60 people over the course of a few months presented with health issues linked to adulterated CBD products at medical centers at two bases in North Carolina.<sup>14</sup> Symptoms included headaches, nausea, vomiting, disorientation, agitation, and seizures.<sup>15</sup> A few months later, North Carolina health officials issued their own warning after approximately 30 people presented in the emergency departments with hallucinations, loss of consciousness, and heart irregularities linked to adulterated CBD.<sup>16</sup> Additionally, employees taking supplement products containing CBD have lost their jobs when their drug tests returned unanticipated positive results for THC,<sup>17</sup> and Child Protective Services have charged parents with “severe medical neglect” for administering supplement products containing CBD to their children.<sup>18</sup>

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<sup>9</sup> <https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100101.htm>

<sup>10</sup> [https://ods.od.nih.gov/HealthInformation/DS\\_WhatYouNeedToKnow.aspx](https://ods.od.nih.gov/HealthInformation/DS_WhatYouNeedToKnow.aspx)

<sup>11</sup> [https://ods.od.nih.gov/HealthInformation/DS\\_WhatYouNeedToKnow.aspx](https://ods.od.nih.gov/HealthInformation/DS_WhatYouNeedToKnow.aspx)

<sup>12</sup> [https://ods.od.nih.gov/HealthInformation/DS\\_WhatYouNeedToKnow.aspx](https://ods.od.nih.gov/HealthInformation/DS_WhatYouNeedToKnow.aspx)

<sup>13</sup> <https://www.chemistryworld.com/news/warnings-on-counterfeit-cbd-vaping-products-with-toxic-contaminants/3009771.article>

<sup>14</sup> [https://tonic.vice.com/en\\_us/article/zmk55a/everything-we-know-about-the-health-risks-of-vaping-cbd](https://tonic.vice.com/en_us/article/zmk55a/everything-we-know-about-the-health-risks-of-vaping-cbd);  
<https://phc.amedd.army.mil/topics/healthyliving/tfl/Pages/VapeOils.aspx>

<sup>15</sup> [https://tonic.vice.com/en\\_us/article/zmk55a/everything-we-know-about-the-health-risks-of-vaping-cbd](https://tonic.vice.com/en_us/article/zmk55a/everything-we-know-about-the-health-risks-of-vaping-cbd)

<sup>16</sup> [https://tonic.vice.com/en\\_us/article/zmk55a/everything-we-know-about-the-health-risks-of-vaping-cbd](https://tonic.vice.com/en_us/article/zmk55a/everything-we-know-about-the-health-risks-of-vaping-cbd)

<sup>17</sup> <https://www.ozarksfirst.com/news/man-fails-drug-test-from-cbd-oil/1850319693>

<sup>18</sup> <https://www.thedailybeast.com/parents-treating-kids-with-cannabinoid-oil-could-lose-them>

## **II. Aimed Alliance’s Positions on CBD**

Aimed Alliance supports the following actions to ensure that patients have access to safe and effective CBD products.

### **A. The FDA Should Establish a New Regulatory Pathway for Supplements and Food Products Containing CBD**

Without the FDA taking action to regulate CBD products, consumers cannot have confidence in the safety, quality, and purity of the products they are purchasing. Moreover, while states have taken the lead in establishing laboratory testing standards for cannabis, a national standard has not yet been adopted.<sup>19</sup> This patchwork of manufacturing standards leaves consumers in some states with greater certainty about the safety, quality, and purity of CBD products, while others are left in the dark. Without strong and consistent manufacturing standards, consumers will be susceptible to deception and fraud, as some CBD products make unsubstantiated therapeutic claims, lack the advertised ingredients, and have inconsistent potencies.<sup>20</sup> Until national standards are adopted to ensure that these products are properly manufactured and labeled, consumers are at risk. This environment is ripe for FDA intervention and regulatory clarity.

### **B. Federal and State Agencies Should Continue Engaging in Enforcement Actions Against Bad Actors**

Federal and state agencies must take action against manufacturers of CBD products that sell unsafe or misbranded products. To date, the FDA and the U.S. Federal Trade Commission have engaged in enforcement actions against companies that illegally market their products in violation of the FDCA, which has included sending warning letters to the responsible companies and requiring corrective action to be taken.<sup>21</sup> Alongside federal enforcement, some state attorneys general have enforced state consumer protection laws against companies engaging in deceptive marketing, which is frequently represented by companies making unsubstantiated therapeutic claims about their products.<sup>22</sup> Aimed Alliance recommends that enforcement actions be strong enough to deter CBD manufacturers from engaging fraudulent, misleading, and unsafe activities, including by levying financial penalties.

### **C. Patients, Providers, and the General Public Must Be Educated on CBD Products**

Following the enactment of the Farm Bill, consumer understanding of CBD products has not kept pace with the significant growth of the CBD market. A recently released report highlighted how 1) only one in four consumers is knowledgeable about the regulatory status of CBD; and 2) high percentages of consumers are using CBD to replace prescription medications

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<sup>19</sup> <https://www.leafly.com/news/industry/leaflys-state-by-state-guide-to-cannabis-testing-regulations>

<sup>20</sup> <https://www.cbs58.com/news/cbd-test-shocking-results>

<sup>21</sup> <https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products>

<sup>22</sup> [https://cannabisindustryjournal.com/feature\\_article/consumer-protection-laws-cbd-products-what-you-need-to-know-before-going-to-market/](https://cannabisindustryjournal.com/feature_article/consumer-protection-laws-cbd-products-what-you-need-to-know-before-going-to-market/)

for the treatment of medical conditions.<sup>23</sup> Similarly, a 2019 survey of health care practitioners revealed that more than 75 percent of clinicians do not feel equipped to answer patients' questions about CBD, and 86.2 percent feel they do not have the information necessary to answer patients' questions about CBD side effects and interactions with other drugs.<sup>24</sup> Additionally, as state and federal laws regarding CBD are complex and sometimes in conflict, consumers have received unclear information about the legality of supplement and food products containing CBD. Patient advocacy groups, practitioner associations, and health policy organizations should engage in efforts to inform the public about the legal status of CBD and the many unknowns about products containing CBD.

#### **D. States Must Pass Laws to Protect Public Health and Safety**

In the absence of a federal regulatory pathway for products containing CBD, consumers continue to be at risk of consuming unsafe and adulterated products that could place their health at risk.<sup>25</sup> A recent laboratory analysis of 250 top-selling CBD products revealed that 45 percent of all products, and 21 percent of products claiming to be free of THC, had detectable levels of THC.<sup>26</sup> A separate analysis by the same company found that 70 percent of CBD products are contaminated with heavy metals, herbicides, pesticides, bisphenol A, and toxic mold.<sup>27</sup> To protect public health and safety, states should enact and enforce laboratory testing and packaging standards to ensure that products containing CBD contain the advertised levels of CBD and that they do not contain adulterants or contaminants. They should also pass laws to ensure labeling and marketing materials are accurate and not misleading.

#### **E. Patients Should Have Access to Safe and Effective CBD Products**

Aimed Alliance supports access to safe and effective FDA-approved CBD medications prescribed by a licensed health care practitioner. Products that have obtained FDA approval have gone through rigorous safety and efficacy protocols, including clinical trials. To be prescribed, a licensed health care practitioner must determine that such treatment is medically necessary for the individual patient. To ensure that the patient is able to access such medication, health plans should provide adequate coverage of prescription CBD medications.

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<sup>23</sup> [https://www.digitalcitizensalliance.org/clientuploads/directory/Reports/DCA\\_CBD\\_Confusion\\_Report.pdf](https://www.digitalcitizensalliance.org/clientuploads/directory/Reports/DCA_CBD_Confusion_Report.pdf)

<sup>24</sup> <https://www.clinicaladvisor.com/home/topics/practice-management-information-center/we-surveyed-hcps-about-cbd-heres-what-we-learned/>

<sup>25</sup> <https://www.fda.gov/news-events/press-announcements/fda-warns-15-companies-illegally-selling-various-products-containing-cannabidiol-agency-details>

<sup>26</sup> <https://www.prnewswire.com/news-releases/ellipse-analytics-analyzes-over-250-top-selling-cbd-products-and-detects-thc-in-45-percent-300922779.html>

<sup>27</sup> <https://medicalcannabisnews.com/en/70-of-us-cbd-products-are-dirty/>