



September 19, 2019

Dear Senator:

The undersigned consumer organizations write to urge the Congress not to act on its own initiative to open a pathway to legalize cannabidiol (CBD) in dietary supplements or food products. Congress is not the right evaluator of the safety of products, and it should ensure that this critical job remains in the hands of the Food and Drug Administration (FDA), which should not be rushed to make a judgment about CBD that may impact the health and safety of millions of consumers, particularly when the science and risks are still unknown.

It is clear that the FDA currently lacks adequate legal authority to assure consumer safety and the consistency or quality of products containing CBD that may be sold as dietary supplements or in food. While we support additional resources for the agency, given the health risks and these regulatory deficiencies, CSPI urges Congress not to force the agency's hand on CBD, and not to set out an exceedingly tight timeline for its decisions. Instead, it should provide the agency additional authorities to ensure that CBD-containing products are safe for consumption.

Much is still unknown about the risks and safety of CBD and other cannabinoids. A recent analysis concluded that there is insufficient data to be able to reliably characterize CBD-specific risks, particularly for young children.¹ In clinical trials for drugs to treat Lennox-Gaust syndrome, involving relatively high doses of CBD, adverse effects included diarrhea, somnolence, loss of appetite and increased levels of liver enzymes.² Clinical trials for Epidiolex revealed that CBD doses of 10 to 20 milligrams per kilogram of body weight per day create a potential for liver injury.³

High potency CBD products, including products marketed for children, are currently available for sale. The company Hemp Bombs sells teddy bear-shaped CBD gummies with up to 25 mg CBD per gummy and up to 1500 mg CBD per unit of sale.⁴ The product's packaging bears no warning of liver injury and does not warn about use by children.

Moreover, many CBD products have been found to contain THC (tetrahydrocannabinol), a psycho-active cannabinoid, or other cannabinoids. Tests of 84 CBD products in 2016 found that 1 in 4 had CBD levels significantly higher than indicated on the label. Overall, 58 of the 84 products (69%) were inaccurately labeled, with higher or lower CBD concentrations. THC was detected at levels over 0.3% (with levels exceeding 6 mg/mL in one instance) in 18 of the 84 samples tested; cannabidiolic acid was detected in 13 of the 84 samples; and cannabigerol in 2 of the 84 samples.⁵

Mislabeled and adulterated is also common. Ingredients that are not listed on product labels, including synthetic cannabinoids, have been identified in cannabis products.⁶ Nine product samples purchased by investigators in Utah, labeled as CBD products, contained a synthetic cannabinoid, but no CBD.⁷ An 8-year old boy who consumed CBD oil for epilepsy was sent to the hospital according to a case report, and a subsequent analysis revealed synthetic cannabinoids in the product alongside CBD.⁸ A May 2019 study by CBS News and Ellipse Analytics found that 70 percent of hemp-derived CBD products were “highly contaminated” with metals like lead and arsenic, herbicides like glyphosate, and “a host of other contaminants including pesticides, BPA and toxic mold.”⁹

Current FDA policy is that CBD is not legal for use in supplements and food because it was the subject of a drug application (the so-called “exclusion rule” or “IND exclusion rule”), and ultimately of an approved drug product.¹⁰ Under the law, the FDA may waive the exclusion rule at the agency’s discretion, but only after issuing a regulation following notice and comment and finding that the article would be lawful under the Federal Food, Drug, and Cosmetic Act.¹¹ Such a waiver, then, must be consistent with the broad purposes of the FDA to assure and improve public health and safety.

As a practical matter, development of such a waiver would require FDA to develop a concrete, public-facing program to address each category of cannabis product within its jurisdiction, to take steps to specifically mitigate their risks, and to enforce standards that, over time, bring conflicting state and local programs into alignment with applicable federal laws supporting consumer health and safety. The report language would short-circuit this process by pressuring the agency to rapidly issue an enforcement discretion policy.

Committee Report or legislative direction from Congress that would require the FDA to hastily create a pathway that could lead to legalization of CBD in foods and supplements is deeply problematic:

- First, FDA currently lacks the needed authority and resources to effectively address the myriad problems that may arise from CBD use in supplements. Numerous improvements in the oversight of supplements are needed to address the product listing, quality, and lack of enforcement resources.
- Second, for food substances, by using “secret GRAS,” companies may self-determine that a substance is “generally recognized as safe” or GRAS, and use it in food without telling FDA. Given this loophole, FDA may never review the safety of many CBD uses in food.
- Third, dietary supplement manufacturers can first declare CBD is GRAS for food in secret, and thereby evade the FDA’s “new dietary ingredient” (NDI) safety review for supplements by exploiting an exemption that applies to “food ingredients.” An estimated 75-80 percent of new ingredients in supplements evade FDA safety review in just this way, according to the industry’s own admission at an FDA Public Meeting two years ago.¹²

This broken system will fail to assure the safety of CBD products. Forcing FDA to create a pathway that could lead to approval of CBD would mean that there would be no assurance of a

review for safety for most products. Instead, Congress should fix these systems so that both food additives and supplements containing CBD are safer for all consumers.

A safety pathway for food substances, including CBD, already exists at FDA

For food uses, as it did with partially hydrogenated oils (trans fat), FDA should be asked to report on whether it can and should issue a tentative determination that CBD is not GRAS. Also as it did for trans fat, FDA should allow currently manufactured products (but no new products) to remain on the market for a few years, pending the agency's final determination on their safety by a date certain.

Such a tentative determination would immediately make clear that FDA is asserting its role and oversight of food and would slow the unregulated advance of these products across the mainstream marketplace. If the agency took that step, it would end or prevent the practice of secret GRAS determinations for CBD in food or supplements and would clarify that self-determined GRAS is not an appropriate compliance pathway for such products.

FDA should then allow the industry to file food additive petitions to demonstrate with scientific evidence that CBD is safe for particular uses and at particular potencies, and to address any adverse effects or quality control and contamination concerns. This would incentivize serious study by the food industry of the risks and safe use of CBD products.

This process would also allow FDA to issue approvals for specific uses, including quality standards, and to ensure that any food companies making these products are visible to the agency. Such a process might identify doses and/or particular conditions of sale that would be legal to market. For example, as part of a condition of use for CBD, FDA could establish limits on CBD potency per serving for use, require a standardized symbol for CBD, and require that all CBD products be essentially THC-free and free of contamination. It could also bar uses that may appeal to children, such as candies, gummies, lollipops and the like, and determine packaging and labeling requirements, including for warnings, resealable, child-proof, plain and opaque packaging, and other measures as warranted.

For its part, Congress should appropriate additional funding for FDA to review the safety of these food uses and petitions.

Congress should provide more authority for FDA to ensure the safety of supplements containing CBD, and in general

For supplements, the safety standard and review process for “new dietary ingredients” (NDIs) is deeply flawed. A manufacturer is expected only to demonstrate to FDA that an ingredient will “reasonably be expected to be safe under the conditions of use.”¹³ This is a low bar. Moreover, the FDA can condemn a dietary supplement as adulterated only on a showing that it presents a “significant or unreasonable risk of illness or injury” under recommended, suggested, or ordinary conditions of use.¹⁴ In practice, this has meant that only a single substance—Ephedra—has ever been barred from use in supplements, but only after it was linked to more than 10,000 adverse events, including deaths.¹⁵

Problematically, many supplement makers have taken the position that a single NDI for a substance is a license for everyone to use it, which for CBD would mean that a single application could open the floodgates for every company. Moreover, troublingly, it is presently a bit unclear whether FDA's authority allows the agency to treat synthetic ingredients as distinct from those that are naturally derived.¹⁶

To compound these serious deficiencies, FDA's supplement office already has scant resources for enforcement matters, and because supplement products do not have to be listed with FDA, there is widespread non-compliance with the law. In fiscal year 2018, the Office of Dietary Supplement Programs (ODSP) conducted just 591 inspections of dietary supplement manufacturing facilities—an estimated 5 to 10 percent of all facilities in the United States.¹⁷ ODSP is ill-equipped to deal with the safety and quality issues that CBD supplements may present. As a consequence, the supplement marketplace is a “Wild West.”

Prior to any pathway for legalizing CBD, Congress should provide additional authority for FDA to regulate supplements, including those with CBD, including by requiring mandatory product listing, providing a stronger safety requirement (such as “reasonable certainty of no harm,” which applies to food) and clearer authority to recall dangerous products, closing the GRAS loophole (which is a misinterpretation of the law), and creating specific prohibitions on highly concentrated products. In addition, Congress should provide legislative support through directed rulemakings and statute for FDA oversight of supplements that includes:

- 1) A requirement warning labels regarding drug interactions with specific information;
- 2) A requirement for a 1-800 number on supplement labels for direct reporting to agency of adverse events experienced by consumers;
- 3) A post-market testing program to monitor the quality of “high-risk” categories of supplements known to be commonly adulterated, including CBD;
- 4) Mandatory adverse event reporting by companies for all (and not only “serious”) adverse events;
- 5) Much more robust funding for inspections and good manufacturing practices development and oversight; and specific authority to recall, seize, and levy penalties on products with synthetic adulterants, contaminants, mislabeling, and/or more than a trace amount of THC or other synthetic or natural psycho-active cannabis derivatives.

An interim enforcement discretion policy is urgent and warranted, but FDA should not be rushed

As an interim step, for both food and dietary supplement uses, FDA should publicly articulate its enforcement priorities, although not on an extremely short time-table pre-determined by Congress. The issues are just too complex.

As enforcement priorities, FDA should consider CBD products containing more than a specified amount of CBD per serving and per package or unit of sale (to be decided by the agency based on the available evidence of risk to public health) to be high risk and target enforcement actions at manufacturers of high potency CBD products, especially when individual servings are not clearly demarcated.

We encourage the FDA to exercise its additional authority by expeditiously developing a public-facing letter, later made into a guidance, making clear that the agency will take action against CBD products that pose the greatest public health risks. High-risk products warranting swift enforcement action include:

- products bearing health claims, especially for serious or life-threatening diseases for which FDA-approved alternatives are available, those that raise the possibility of serious side effects, or those that pose a hazard to vulnerable populations, including children and pregnant women;
- products that appeal to or that are marketed for children and youth;
- products containing high doses of either CBD or THC, products with higher concentrations than labeled, CBD products not labeled for THC content but that contain THC; and
- products found to be mislabeled or contaminated, particularly with FDA-approved drugs, synthetic cannabinoids, heavy metals, mold, high levels of pesticide residues, other dangerous chemicals, or pathogens.

We applaud the FDA for recently issuing warning letters to companies illegally selling CBD products that were intended to prevent, diagnose, mitigate, treat, or cure serious diseases, such as cancer.¹⁸ FDA appropriately recognizes that any products bearing claims to prevent, treat, or cure disease—especially serious or life-threatening diseases for which FDA-approved alternatives are available—should be prioritized as the agency exercises its authority to regulate products containing cannabis and cannabis-derived compounds based on risk to public health.

In sum, the FDA should be supported by Congress in doing its job, and the many serious shortcomings in its existing authorities that impact the safety of consumers of CBD products cannot be ignored. As we have seen from the recent serious incidents and deaths surrounding vaping, an uncontrolled rush into the marketplace can have serious consequences, including death, for both adults and youth.

We urge Congress not to erode—but instead to strengthen—the position of FDA to address these issues and protect health, as its mission requires.

Sincerely,

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Notes

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⁴ Hemp Bombs. *Certified Pure CBD Products*. 2019. <https://hempbombs.com/cbd-products/>. Accessed July 15, 2019.

⁵ Bonn-Miller MO, et al. Labeling Accuracy of Cannabidiol Extracts Sold Online. *JAMA.* 2017;318(17):1708-1709.

⁶ Poklis JL, et al. The Unexpected Identification of the Cannabimimetic, 5F-ADB, and Dextromethorphan in Commercially Available Cannabidiol E-Liquids. *Forensic Sci Intl.* 2019;294:e25-227.

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⁸ Rianprakaisang T, et al. Commercial Cannabidiol Contaminated with the Synthetic Cannabinoid AB-FUBINACA Given to a Pediatric Patient. *Clin Toxicol.* 2019.

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¹⁰ 21 U.S.C. § 331(II); 121 U.S.C. § 321(ff)(3)(B).

¹¹ 21 U.S.C. § 321(ff)(3)(B).

¹² Welch C. *Public Meeting to Discuss the Development of a List of Pre-DSHEA Dietary Ingredients*. October 3, 2017.

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¹³ U.S. Food and Drug Administration. When to Notify FDA and What is a New Dietary Ingredient. August 13, 2018. https://www.fda.gov/food/new-dietary-ingredients-ndi-notification-process/new-dietary-ingredients-dietary-supplements-background-industry#what_is. Accessed September 19, 2019.

¹⁴ 21 U.S.C. § 342(f)(1)(A).

¹⁵ Emery G. FDA Ban Nearly Wiped Out Deaths, Poisonings from Ephedra. *Reuters.* May 27, 2015. <https://www.reuters.com/article/us-fda-ephedra/fda-ban-nearly-wiped-out-deaths-poisonings-from-ephedra-idUSKBN0OC2SR20150527>. Accessed September 19, 2019.

¹⁶ U.S.A. vs. Hi-Tech Pharmaceuticals, Inc., Jared Wheat, D.C. Docket No. 1:13-cv-03675-WBH, Eleventh Cir Ct of Appeals, 2019. Available on-line at <http://media.ca11.uscourts.gov/opinions/pub/files/201713376.pdf>.

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¹⁸ U.S. Food and Drug Administration. Warning Letters and Test Results for Cannabidiol-Related Products. July 24, 2019. <https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products>. Accessed September 19, 2019.