Council for Responsible Nutrition
1828 L Street, NW, Suite 810 • Washington, DC 20036-5114
(202) 204-7700 • fax (202) 204-7701 • www.crnusa.org

January 22, 2021

Senator Dan Dawson
Commerce Committee
Iowa State Senate
1007 East Grand Avenue
Des Moines, Iowa 50319

RE: Iowa Senate File 43

Dear Senator Dawson,

The Council for Responsible Nutrition (CRN)[1] submits the following comments, along with our attached position paper: *Hemp-Derived CBD Dietary Supplement Position* in response to Iowa Senate File 43. Our position paper details CRN's support for a federal regulatory scheme for hemp-derived CBD dietary supplements. While we await clarity at the federal level, CRN also supports the promotion of state laws and regulations regulating hemp-derived CBD dietary supplements in a manner that is consistent with federal requirements for all dietary supplement products under the Dietary Supplement Health and Education Act (DSHEA).

CRN continues to work with Congress to support federal legislation (previously introduced as H.R. 8179, the Hemp and Hemp-Derived CBD Consumer Protection and Market Stabilization Act of 2020.) This legislation directs that CBD be recognized as a lawful dietary ingredient to be regulated by the Food and Drug Administration (FDA), irrespective of any other definitional hurdles in the federal Food, Drug & Cosmetic Act, and will require that hemp-derived CBD products adhere to the same legal requirements for manufacturing, labeling, promotion and usage as any other dietary supplement. The legislation provides a clear legal pathway to market for dietary supplements containing hemp-derived CBD and will help protect the health and safety of consumers by addressing many of the concerns that currently exist from an untamed market. We expect Congress to consider legislation addressing this critical issue early in the 117th session and strongly encourage states looking to adopt their own hemp-related regulatory structures to fashion ones that would be consistent with that federal framework. In anticipation of Congress's rapid consideration and enactment of this legislation and the current comprehensive federal

[1]The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington, D.C.-based trade association representing 190+ dietary supplement and functional food manufacturers, ingredient suppliers, and companies providing services to those manufacturers and suppliers. In addition to complying with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety, our manufacturer and supplier members also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Visit, www.crnusa.org. Follow us on: Twitter @CRN_Supplements, Facebook, and LinkedIn.

regulatory structure for dietary supplements, we propose the deletion of references to, "hemp products" and "consumable hemp products" in this bill.

Specifically, CRN encourages **deleting** this bill's proposed, "New Section 126.4 Hemp products and consumable hemp products –retail sales– claims" and references thereof (on page thirteen, the deletion of lines two through twenty-four and, on page sixteen, the deletion of lines ten through twenty-eight).

CRN's concerns with "New Section 126.4 Hemp products and consumable hemp products –retail sales– claims" and references thereof are as follows:

> **Senate File 43:** *"Unless a state or federal agency has substantiated and approved the efficacy and safety claims of a product based on competent and reliable scientific evidence …"*
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> **CRN Explanation:** Dietary supplements are regulated at the federal, **not** state level, by the federal Food and Drug Administration, and efficacy and safety claims are **not** "approved" by FDA nor any state regulatory agency, but rather there is an established notification process, described below.
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> The federal Food, Drug, and Cosmetic Act requires that manufacturers and distributors who wish to market dietary supplements that contain "New Dietary Ingredients (NDI)" notify the FDA about these ingredients. Generally, the notification must include information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing a new dietary ingredient will reasonably be expected to be safe under the conditions of use recommended or suggested in the labeling.
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> A new dietary ingredient (NDI) is a dietary ingredient that was not sold in the United States as a dietary supplement ingredient before October 15, 1994, prior to enactment of the Dietary Supplement Health and Education Act of 1994 (DSHEA). Manufacturers of NDI-containing dietary supplements must notify FDA of their intent to market a NDI-containing supplement at least 75 days before the supplement is marketed in the United States. The NDI Notification must thoroughly identify the NDI, how it is used in the NDI-containing supplement, and present the evidence the manufacturer relied upon to determine their use of the NDI in the supplement is reasonably expected to be safe. The NDI Notification requirement applies to every NDI-containing dietary supplement regardless of whether other firms have submitted NDI Notifications on the same substance.[2]
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> **Senate File 43:** ***"…****a person engaging in the retail sale in this state of a hemp product or a consumable hemp product as defined in section 204.210 that contains hemp-derived cannabidiol, shall include on the product's principal display panel, a statement that the product may or may not contain the ingredients stated on the label…"*
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> **CRN Explanation:** "A statement that the product may or may not contain the ingredients stated on the label" would be misleading and confusing to consumers. If the Senate is concerned with

[2] *See,* 21 CFR 190.6.

adulterated products, existing state and federal consumer regulations exist to protect consumers from products marketing and making false claims as to the ingredients in their products.

Senate File 43: ***"…****that the efficacy and safety of the product have not been substantiated or approved by a state or federal agency based on competent and reliable scientific evidence, and that the consumer should use the product at the consumer's own risk…"*

CRN Explanation: The FDA and the FTC already extensively regulate dietary supplements at the federal level in the United States. As indicated earlier, DSHEA established that federal regulatory structure for dietary supplements, and provides the FDA with substantial authority to protect consumers.

Current dietary supplement regulations cover all aspects of supplement manufacturing and distribution, from safety of ingredients, to manufacturing process requirements, to product claims. These comprehensive regulations ensure supplement products are safe and marketed to consumers in a truthful manner. Specifically, of importance and clarification for Senate File 43:

- **Labeling. Dietary supplements must be properly labeled to be marketed in the United States.[3] All dietary supplement labels must include a statement of identity; the net quantity of contents; nutrition labeling, including the Supplement Facts panel; a complete list of product ingredients; and the name and place of business of the manufacturer, packer, or distributor. Failure to include all the required information allows FDA to deem the product misbranded.**

  Structure/function claims have historically appeared on the labels of conventional foods and dietary supplements as well as drugs. DSHEA established some special regulatory requirements and procedures for structure/function claims and two related types of dietary supplement labeling claims, claims of general well-being and claims related to a nutrient deficiency disease. Structure/function claims may describe the role of a nutrient or dietary ingredient intended to affect the normal structure or function of the human body, for example, "calcium builds strong bones."

  In addition, they may characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function, for example, "fiber maintains bowel regularity," or "antioxidants maintain cell integrity." General well-being claims describe general well-being from consumption of a nutrient or dietary ingredient. Nutrient deficiency disease claims describe a benefit related to a nutrient deficiency disease (like vitamin C and scurvy), but such claims are allowed only if they also say how widespread such a disease is in the United States. These three types of claims are not pre-approved by the FDA, but the manufacturer must have substantiation that the claim is truthful and not misleading and must submit a notification with the text of the claim to the FDA no later than 30 days after marketing the dietary supplement with the claim. If a dietary supplement label includes such a claim, it must state in a "disclaimer" that FDA has not

[3] *See,* 21 USC §343(r)(6).

evaluated the claim. **The disclaimer must also state that the dietary supplement product is not intended to "diagnose, treat, cure or prevent any disease,"** because only a drug can legally make such a claim.

For more information about the difference between structure/function claims and disease claims, see 21 CFR 101.93, entitled "Certain Types of Statements for Dietary Supplements," and FDA's January 6, 2000 final rule entitled "Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body" (65 Fed. Reg. 1000).[4]

Companies that run afoul of these requirements can be subject to a host of repercussions, including injunctions halting business and product distribution, product recalls, product seizures, fines and criminal penalties, consumer redress mandates, and even prohibitions against future advertising and conduct in an entire product category or industry.

Senate File 43: "*…The statement required under this section shall be developed by the board of pharmacy and shall be consistent with the rules adopted by the department of inspections and appeals pursuant to chapter 204 and with applicable federal regulations promulgated by the United States food and drug administration. This section shall not apply to a medical cannabidiol manufacturer licensed pursuant to chapter124E."*

CRN Explanation: In states around the country, labeling requirements for hemp products are regulated by state departments of health and/or departments of agriculture. "Hemp products" and "consumable hemp products" are not drugs, nor is a public health or consumer interest served in attempting to regulate these products as such. Therefore, the state board of pharmacy should not have jurisdiction over any type of regulation over "hemp products" and "consumable hemp products".

We welcome any further discussions on this subject.

Thank you for your time and consideration.

Sincerely,

Amanda Darlington
Council for Responsible Nutrition

CC: Senate Commerce Committee
Chairman Jason Schultz
Senator Tony Bisignano
Senator Craig Johnson
Senator Zach Whiting

[4] *See,* U.S. Food & Drug Administration, Structure/Function Claims.