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CRN: The Short Report

A topline report from the Council for Responsible Nutrition (CRN), the leading trade association for the dietary supplement and functional food industry

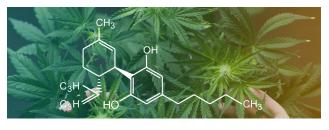
CBD Update: FDA promises 'pathway' to market, CRN provides thought leadership, science-based resources

FDA Commissioner Scott Gottlieb told a Congressional hearing on Feb. 27 that FDA is "deeply focused" on developing a pathway for hemp-derived cannabidiol (CBD) to be available in a variety of products. While insisting that currently "CBD cannot legally be put into the food supply" [including as a dietary supplement], he committed to a public meeting on the topic in April and offered that legislation may be necessary to address FDA's concerns. CRN has subsequently learned the FDA public meeting may be delayed until May.

Meanwhile, CRN is urging FDA to create a legal pathway to market hemp-derived CBD in dietary supplements and food and is working with Congressional allies to keep pressure on the agency to move quickly. CRN staff has advised several retailers on the legal status of CBD and recently authored these bylined articles appearing in industry trade press:

- <u>CBD and the 2018 Farm Bill—the legal status</u> of CBD supplements
- Science, CBD and the prisoner's dilemma
- <u>Will CBD Become a Shakespearean Tragedy?</u>

In addition, CRN is co-hosted a <u>webinar that looked at the</u> <u>science behind hemp-derived CBD</u>, now available on demand. CRN also developed a concise <u>FAQ on CBD</u> that the team is using on Capitol Hill in discussions with legislative staff, engaging members of the House Committee on Energy & Commerce to reach out to FDA.



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CRN embraces FDA's increased attention to dietary supplement regulation in the midst of leadership change

CRN welcomed FDA's promise of "one of the most significant modernizations of dietary supplement regulation and oversight in over 25 years," while applauding the agency's recognition of the dietary supplement industry's maturity in a <u>statement</u> released concurrently with Commissioner Scott Gottlieb, M.D.'s <u>announcement</u>. Since the Feb. 11 announcement, Dr. Gottlieb tendered his resignation, but his remarks that supplements have "become a routine part of the American lifestyle," and play an important role as "we strive to stay healthy," signal that FDA understands the importance of a level playing field for responsible companies who provide safe, beneficial products to consumers in its mission to protect the public health.

CRN President and CEO Steve Mister appeared on <u>CBS Evening News</u> and was quoted broadly in coverage of the FDA announcement. "We welcome additional enforcement actions to bring to justice those who would cynically trade on the halo effect of responsible industry to make a quick buck while ignoring the safety and health of consumers," Mr. Mister said.



In the wake of Dr. Gottlieb's resignation, CRN will continue to engage with FDA leadership on efforts to update FDA's oversight of the industry while balancing continued consumer access to these products with public safety.

CRN opposes legislation to put age restrictions on weight-loss and fitness supplements in Massachusetts

A bill to prohibit sales of weight-loss and bodybuilding dietary supplements to minors was reintroduced in Massachusetts recently. The legislation, similar to previous proposals submitted in past state sessions, would restrict access to products that are backed by science and have a long history of safe use.

CONTINUED ON BACK

CONTINUED FROM FRONT CRN opposes legislation to put age restrictions on weight-loss and fitness supplements in Massachusetts

House Docket 2883, an "Act Protecting Children from Harmful Diet Pills and Muscle-building Supplements," is the third iteration introduced in Massachusetts in recent years. CRN has worked diligently to defeat this legislation each time and will again push back, engaging its Government Relations State Subcommittee and Sports Nutrition Working Group. Without a clear public health objective, the bill could inspire similar motions in other states and would place significant economic burden on Massachusetts' 400 private retailers and 300 registered pharmacies that carry these products.

AER review supports safety of dietary supplements, highlights value of product listings, such as the Supplement OWL

Most adverse events related to dietary supplements are not serious, according to a <u>new study</u> co-authored by CRN staff, and those that are serious are often linked to weight loss products. The study, "<u>Serious Adverse Events Reported with</u> <u>Dietary Supplement Use in the United States: A 2.5 Year</u> <u>Experience</u>," published in the Journal of Dietary Supplements counters the <u>previously critiqued</u> assertion that 23,000 emergency room visits annually were related to dietary supplements in 2015. In fact, less than one percent of more than 40,000 adverse events associated with dietary supplement use were serious, the study found.

The research is ground-breaking data collection within the supplement industry, according to co-author Duffy MacKay, N.D. As quoted in Whole Foods Magazine's coverage, Dr. MacKay asks, "How many dietary supplements are out there? We don't even know. It's hard to refute news that slams the industry, because we don't have the data to do so. We're hoping that this study will encourage other data-collecting companies to publish their data, so we can get a clearer picture of the industry. We're hoping that more people will use the <u>Supplement OWL</u>..."

Indeed, the <u>Supplement OWL</u> dietary supplement label listing now has reached a milestone of 10K visible labels and more companies industry-wide are getting on board with the selfregulatory initiative. The <u>Commercial Data Exchange</u> (CDX) feature of the OWL is now being developed to allow manufacturers to showcase additional data about their products with retailers. Learn more about how retailers benefit <u>here</u>.



O. Council for Responsible Nutrition The Science Behind the Supplements

Dut
ts inCRN brief in ginkgo case argues conflicting
experts don't make a claim 'false'

Private plaintiffs should be required to show that advertising claims are actually false and not merely unsubstantiated, CRN explained in a "friend of the court" <u>brief</u> submitted in January in *Sonner v. Schwabe North America, Inc.* "Allowing a patchwork of conflicting private



actor-driven decisions on any single dietary ingredient stands to dilute the significance and authority of expert government ac-tors and discourage manufacturers from innovating in the nutrition space, or disseminating health benefit claims at all," CRN's amicus brief argued. The amicus brief was filed in support of Schwabe North America, Inc.'s petition for a rehearing of a case involving a dispute over cognitive health claims for ginkgo biloba supplements. The brief further noted, "Given the complexities of nutrition science and the unique expertise-and public health mindset-of regulators, this discrete group should continue to be the sole arbiters in weighing substantiation. If private actors are allowed to seize on any inconsistency or weakness that might be found in a complex body of research, both advertisersand consumers who rely on their products—stand to be harmed." Read more about this case and see other CRN amicus submissions in this CRN Members-only item. unlocked for recipients of The Short Report.

Dietary Supplement Caucus registered for 116th Congress

The Congressional Dietary Supplement Caucus (DSC) is officially registered for the 116th Congress. Under bipartisan leadership, the DSC currently includes 36 members of Congress and serves as a forum to exchange ideas and educate members and staff on legislative and regulatory issues related to health and wellness. CRN is an active partner with the DSC in hosting widely-attended lunch briefings for Capitol Hill staff. Learn more about the DSC here and encourage your representatives to join.

Special Edition: Supplement Facts Label Change

Supplement Facts

Council for Responsible Nutrition

Based on new science, "Daily Values" have been updated, so the percent provided on the new Supplement Facts label will change for some nutrients.

Like what you see? Have questions?

E-mail Emily Zavrel (<u>ezavrel@crnusa.org</u>) to be added to CRN's list to receive press releases and other news, or to ask a question about something you've read here.

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