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Unprecedented To Lawful: Regulatory Precedent Needed For Cannabinoids' Use In Supplements?

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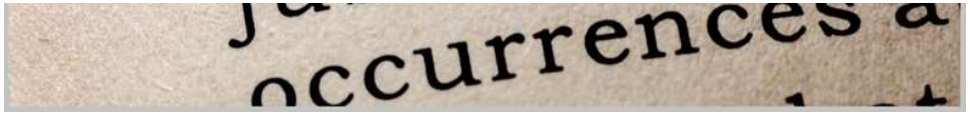
Executive Summary

"This is truly uncharted territory because we've never had this situation," says CHPA senior VP David Spangler. Asking Congress instead to instruct FDA to first determine a safe daily limit would be a threatening precedent for the supplement market, says CRN CEO Steve Mister. "That really turns DSHEA on its head."



Hemp-derived cannabinoids' existing uses in the US are without regulatory precedent, making a precedent-setting solution necessary for their lawful use as dietary ingredients, say the Consumer Health Products Association and the Council for Responsible Nutrition.

Moreover, they say bipartisan support is behind legislation introduced in Congress to exempt cannabidiols and other cannabinoids from the Food and Drug Administration's regulation prohibiting the use in dietary supplements and food of ingredients that have been studied as or are approved for use in drugs.

"This is truly uncharted territory because we've never had this situation," said David Spangler, CHPA's senior vice president for legal, government affairs and policy.

The drug preclusion provision of the FDA's regulations established under the Dietary Supplement Health and Education Act also excludes other ingredients from being used in supplements, Spangler said. "But we've never had something where prior to it first becoming a drug, it was a controlled substance and you couldn't possibly use it in a supplement."

"If there ever is going to be an exception, this is a special and unique case to make it for," he added.

The 2018 farm bill de-scheduled hemp – defined as cannabis or any part of the cannabis plant containing no more than 0.3% concentration, on a dry weight basis, of tetrahydrocannabinol.

However, the bill didn't remove cannabinoids from the FDA's oversight of their use in products subject to its regulation. That meant that because the agency already had approved synthetic cannabidiol ingredients as a drug as well as several cannabis-based drugs, its regulations still prohibited hemp's use in non-drug products.

"So, this really is unique," Spangler observed.

CRN president and CEO Steve Mister also spoke with HBW Insight in response to assertions by another trade group, the Natural Products Association, and its lobbyists that legislation specifically making hemp-derived cannabinoids lawful for use in supplements would signal to critics of the industry that Congress should propose other changes to DSHEA that would tighten regulation of the industry. (Also see "Legislating CBD As Lawful Supplement Ingredient: A Threatening Precedent For US Industry?" - HBW Insight, 18 Feb, 2021.)

CRN and CHPA also say NPA's recommendation that Congress should instead instruct the FDA to first determine a safe daily limit for cannabinoid use would be a threatening precedent for the US vitamin, mineral and supplement product market.

"That really turns DSHEA on its head," Mister said.

"FDA doesn't get to decide in advance of a product coming to market what is safe level of use. That's one of the fundamental tenets of DSHEA. If it's an herbal extract and it meets the definition of an herb, the burden is on FDA to show that it's not safe," he said.

DAVID SPANGLER, CHPA: "WE'VE NEVER HAD SOMETHING WHERE PRIOR TO IT FIRST BECOMING A DRUG, IT WAS A CONTROLLED SUBSTANCE AND YOU COULDN'T POSSIBLY USE IT IN A SUPPLEMENT."

Additionally, it's not their safety profile that makes cannabinoids unlawful for use in supplements.

"If this were any other ingredient that wasn't caught up in the drug preclusion language, the ingredient would come to market and it would be on FDA's watch to show that it's not safe," Mister said.

NPA's recommendation for cannabinoids would mean that "FDA gets to set the safe level before the ingredient ever comes to market," he added. "If you're worried about what precedent we may be setting, that worries me even more."

No Different From Other Dietary Ingredients

In addition to cannabinoids being unlawful as dietary ingredients under FDA regulations, NPA's recommendation would further separate them from other dietary ingredients, Mister said.

"Our feeling is that you treat CBD differently where CBD is different, but in ways there it's like any other ingredient you should treat it the way you would any other dietary ingredient."

Setting a safety profile, Spangler pointed out, wouldn't make cannabinoids lawful as dietary ingredients. "That still doesn't change that under the law, CBD still isn't allowed as a dietary ingredient," he said.

"That either has to change by FDA going through a notice-and-comment rulemaking process, which they could seek to do, or Congress doing it for them, which is what the Schrader-Griffiths bill would seek to do."

Bipartisan Support From The Top Down …

The Hemp and Hemp-Derived CBD Consumer Protection and Market Stabilization Act, H.R. 841, introduced in February by Reps. Kurt Schrader, D-OR, and Morgan Griffiths, R-VA, would make hemp and cannabinoids and any other ingredient derived from hemp lawful for use as dietary ingredients starting 90 days after enactment of the legislation. (Also see "CBD Regulation Bill Filed In US House Again; VMS In Pre-Tax Savings Accounts In First Senate Vote" - HBW Insight, 5 Feb, 2021.)

NPA's lobbyists described Capitol Hill's regard for the bill as opposition from the Democrat chairmen and the Republican ranking members in the two congressional committees with FDA oversight – House Energy and Commerce and the Senate Health, Education, Labor and Pensions.

CRN and CHPA don't agree with that description and note that H.R. 841 has more than 20 co-sponsors from across both parties.

"While you're entitled to your own opinion, you're not entitled to your own facts. In some cases what they're saying is just not true," Mister said.

Noting that committee leaders haven't stated "their unbridled support," Mister said nothing from either committee or other members in both chambers has indicated opposition to the bill. "We're building a bipartisan bill."

He pointed out that when Schrader and Griffiths introduced the same legislation in the previous session of Congress, it attracted 25 co-sponsors from across both parties. (Also see "US Bill For CBD Supplement Path Draws Mixed Industry Response" - HBW Insight, 12 Sep, 2020.)

… But Legislative Path Unclear

Bipartisan support for exempting cannabinoids from DSHEA's drug preclusion provision isn't a sign, though, that H.R. 841 will pass the House on its own or that similar legislation introduced in either chamber would pass Congress as a standalone bill.

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"Pretty much everybody who watches Congress thinks that to get something to move it needs to be in some of package. That seems to be the conventional wisdom," says Spangler.

Mister says H.R. 841 is in its early phase of being discussed and potentially changed by Energy and Commerce members. Making cannabinoids lawful as a dietary ingredient under FDA regulations could pass Congress on its own or part of broader legislation, he said.

"There are other possibilities," he said.

Among those would be legislation expected in Congress to legalize interstate commerce of cannabis as well as hemp and expunge criminal records for persons convicted of marijuana-related crimes and prohibit denying public program benefits to them.

Those changes were included in a bill passed the House in largely partisan voting in December, the Marijuana Opportunity Reinvention and Expungement (MORE) Act, H.R. 3884, introduced by Rep. Jerold Nadler, D-NY. (Also see "'Historic' Cannabis Legislation Passed By House Would Lift US Cannabinoids Business Roadblocks" - HBW Insight, 18 Dec, 2020.)

The bill made no progress in the Senate, then still with a Republican majority, and no similar legislation has been introduced so far in the current session of Congress. However, with a majority in both chambers, Democrats are expected to introduce and push for passage of the legislation during this session.

NDI Notification Language Needed

Mister emphasized that H.R. 841 is limited to making cannabinoids lawful for use as dietary ingredients. It doesn't relieve the ingredients of being subject to all other requirements and restrictions the FDA imposes, including the new dietary ingredient notification requirement.

In addition to being unlawful, hemp-based cannabinoids used in supplements available in the US are violative of the NDI notification provision of DSHEA – any dietary ingredient not in common use in the food supply when the bill passed in 1994 must be notified to the FDA with proof of a reasonable expectation of safety for its intended use.

It would be difficult currently to show cannabinoids' safety even if the agency accepted an NDI notification for one.

"Right now, if you send an NDI notification, FDA sends it back to you because of the drug preclusion. They say this isn't a dietary ingredient and we can't evaluate this," Mister said.

However, while H.R. 841 would make cannabinoids subject to NDI notifications, the current bill doesn't include language on how the FDA will impose the requirement on the industry, particularly on firms already marketing products.

Cannabinoid-containing supplements could be ordered off the market today due to containing unlawful ingredients, or should H.R. 841 pass as currently written, the FDA could enforce against those products for lack of NDI notifications.

"I think that's why there's been concern about having a certain grace period when the bill would be enacted," Mister said.

CRN supports allowing firms already marketing cannabinoid supplements a period of 90 days to submit NDI notifications to the FDA.

"That's something we are trying to figure out as the bill starts to move," Mister said.

The FDA is required under DSHEA to first determine whether an NDI notification has sufficient data and other information to be evaluated and then within 75 days evaluate the submission before advising a notifier whether it has questions that the information supports safety of an ingredient.

"We have to be sure that if the law is enacted that then there is an opportunity for people to get their NDIs in and have that 75-day waiting period We don't want to see FDA on day one come out and say we don't have NDIs and all these products have to come off the market," Mister said.

Enforcement of that nature would be averse the position the agency has held since the 2018 farm bill was passed. "They've turned a blind to them for the past two years. It seems like they can give companies another 75 days," Mister said.

The agency doesn't approve NDI notifications; it either refuses to evaluate, evaluates a notification and returns it with questions or files the submission without questions. NDI notifications must be submitted within 75 days of an ingredient becoming available in the US but firms aren't required to wait for an FDA response before selling products with an NDI.