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Schumer Includes Cannabinoid Pathway For Supplements In Cannabis Legalization Draft Bill

Joined by Wyden And Booker, Majority Leader Also Proposes Setting Safe Daily Level

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Executive Summary

Draft bill proposes rules not only on producing and marketing marijuana, but on using in supplements ingredients derived from cannabis plants classified as hemp. Some supplement industry stakeholders see draft as delivering on industry requests but others say it goes too far.



The US Senate majority leader leaves no stone unturned in draft legislation to change federal regulations on the commercial use of ingredients from cannabis plants.

Sen. Chuck Schumer's draft bill proposes rules not only on producing, marketing and possessing marijuana, but also on using in dietary supplements ingredients derived from cannabis plants classified as hemp.

The New York Democrat's draft circulated for discussion on 14 July is seen by some dietary supplement industry stakeholders as delivering on all the requests the industry has made for making hemp-derived cannabinoids lawful for use in their products. Others, though, say the draft goes too far.

Unlike other bills already introduced and assigned to committees in the House and Senate for lawful use of cannabinoids in supplements, Schumer's draft also de-schedules cannabis as a controlled substance and sets rules for business licensing and for competition in the sector and expunges sentences and records from convictions on federal charges linked to cannabis.

Schumer's draft, co-sponsored by Democrats Cory Booker, D-NJ, and Ron Wyden, OR, also differs from those bills by including a proposal to require the Food and Drug Administration establish a safe daily use level for cannabinoids along with changing an FDA regulation to allow the ingredients' use in supplements.

Room For Food On Plate?

S.1698, the "Hemp Access and Consumer Safety Act," includes both food and supplements as product categories it would direct the FDA to allow including cannabinoids. Authored by Oregon's two senators, Democrats Ron Wyden and Jeff Merkley,

Like the House bill, though, the draft includes a requirement requested by the FDA but not by the industry, all supplements including cannabinoids must be notified to the agency as new dietary ingredients with proof of a reasonable assurance of safety for their intended use. (Also see "Mixing Food In Legislation Changing US FDA Cannabinoid Rules Could Choke Its Progress" - HBW Insight, 25 May, 2021.)

The draft ties a safe daily level set by the FDA to the NDI notification requirement. It says the limit "shall be a threshold above which the [agency] may not accept new dietary ingredient notifications," though it also says the level "shall not be interpreted as a determination that lower amounts of cannabidiol are safe."

Setting Safe Level Needed Or Not?

The Natural Products Association, in a split with other supplement industry trade groups, supports directing the FDA to set a safe daily use level for cannabinoids, which most commonly are identified as cannabidiol, CBD.

"Setting a safe level of consumption for CBD products is long overdue, but it remains the best path forward for consumers and the industry," said NPA president and CEO Daniel Fabricant in a statement to HBW Insight.

"Unlike other federal bills, this one would do what NPA alone has long called for: it would direct FDA to expedite a rule that sets an upper limit for daily consumption," he added.

The Council for Responsible Nutrition, however, contends that a safe daily use level will be established as the FDA evaluates NDI notifications for cannabinoid supplements. A separate provision explicitly requiring it isn't needed for cannabinoids or any other dietary ingredient.

"As outlined in the existing House legislation, responsible CBD product manufacturers would comply with [DSHEA], the existing comprehensive framework that regulates dietary supplements, just as any other supplement. FDA must step up and better regulate the marketplace," said Julia Gustafson, CRN's vice president, government relations.

"In doing so, consumers could be assured that hemp-derived cannabinoid products are safe, properly labeled, and manufactured in compliance with good manufacturing practices (GMPs) as is required of all dietary supplements."

Gustafson added in a statement to HBW Insight that CRN supports the House cannabinoid legislation.

"That proposal directs FDA to establish a clear and robust federal regulatory framework for hemp-derived CBD and other non-intoxicating hemp ingredients to be lawfully marketed as dietary supplements. Such an approach promotes consumer safety while providing an economic boost to struggling farmers," she said.

and Kentucky Republican Rand Paul, it has been assigned to the Health, Education, Labor and Pensions Committee, where it could be amended to drop food as a category of products subject to the change. (Also see "US Senate Appetite For Lawful Use Of Cannabinoids Includes Food On Top Of Supplements" - HBW Insight, 19 May, 2021.)

H.R. 841, "Hemp and Hemp-Derived CBD Consumer Protection and Market Stabilization Act" introduced in by Reps. Kurt Schrader, D-OR and Morgan Griffith, R-VA, directs the FDA to end its prohibition against the use, which the agency currently suspends under enforcement discretion, only for supplements. It has been assigned to Health Subcommittee of the Energy and Commerce Committee. (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.)

The prohibition is required by a rule established in the Dietary Supplement Health and Education Act, passed by Congress in 1994 as the FDA's regulatory framework for the vitamin, mineral and supplement product industry and marketplace, that makes any substance studied or approved for use as a drug ineligible for use as a dietary ingredient.

Hemp was de-scheduled as a controlled substance under a provision in the 2018 farm bill, which defined it as containing less than 0.3% tetrahydrocannabinol by dry weight. However, the provision sustained the FDA's authority over use of hemp in products subject to its oversight.

The de-scheduling accelerated sales of supplements as well as food and topicals containing cannabinoids.

She also noted that CRN' in 2020 submitted a citizen petition urging the FDA to create a clear, legal pathway to market for hemp-derived CBD and other ingredients derived from hemp. (Also see "'Time Is Now' For FDA Rule On Lawful CBD Use In Supplements, CRN Says In Citizen Petition" - HBW Insight, 17 Jun, 2020.)



SEN. CHUCK SCHUMER: "AT LONG LAST WE ARE TAKING STEPS IN THE SENATE TO RIGHT THE WRONGS OF THE FAILED WAR ON DRUGS."

Chairman of the Finance Committee and Senator Booker, one of the foremost champions for justice and equity here in the Senate, we are all joining together to release draft legislation to end the federal prohibition on cannabis. This is monumental because at long last we are taking steps in the Senate to right the wrongs of the failed war on drugs," Schumer said in remarks made at the draft's announcement.

While the Senate previously hasn't moved bills on legalizing marijuana, the House in 2019 passed the "Marijuana Opportunity Reinvention and Expungement" (MORE) Act intended to boost the cannabis industry across the country and expunge criminal records for persons convicted of marijuana-related crimes and prohibit denying public program benefits to them. It also would legalize interstate commerce of cannabis as well as hemp, a designation important to the cannabinoids product market. (Also see "'Historic' Cannabis Legislation Passed By House Would Lift US Cannabinoids Business Roadblocks" - HBW Insight, 18 Dec, 2020.)

Rep. Jerold Nadler, D-NY, was chief sponsor of the MORE Act in 2019 and plans to sponsor similar legislation during the current session. Nadler, Judiciary Committee chairman, stated his intent with his opening remarks during a Crime, Terrorism and Homeland Security Subcommittee hearing in March.

A matching bill introduced in the Senate in 2019 by then-Sen. Kamala Harris, D-CA, was referred to the Finance Committee and wasn't considered further.

So far in 2021, the House has passed the Secure and Fair Enforcement "SAFE Banking" Act, H.R. 1996, sponsored by Rep. Ed Perlmutter, D-CO, to allow cannabis- and hemp-related businesses in states with some form of legalized marijuana to access financial institutions by creating protections for depository institutions that provide financial services to the companies. (Also see "US House Co-signs Banking For Hemp Industry" - HBW Insight, 20 Apr, 2021.)

Even though hemp no longer is a controlled substance, some states that still prohibit sales of products containing hemp-derived ingredients and also are known to prevent transportation of the ingredients, a practice that hinders businesses making and marketing the products.

NPA says setting a limit will help cannabinoid ingredient and product developers as the FDA gains authority to allow a clear path to introduce products in a regulated marketplace.

The association, in a second split with other groups, also supports allowing cannabinoids' use in food, which is included in the previously filed Senate bill but not in the House bill.

"While we still believe dietary supplements and foods should be under one piece of legislation, this is a positive development ... to ensure that we have clear federal guidelines and safety standards for CBD products," Fabricant added.

'End Federal Prohibition On Cannabis'

As majority leader, Schumer says he is making legalization of marijuana a priority. Under a Republican majority, Senate legislation to de-schedule cannabis was a non-starter.

"I as majority leader, Senator Wyden as the