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US FDA Doubts Hemp 'Derivatives Created From Scratch' Belong In Lawful Use Pathway

State 'Popularity Contests' Legalizing Cannabis Aren't Good Model For FDA Hemp Regulation

by Malcolm Spicer

States' histories with legalizing cannabis aren't good models for an hemp regulatory pathway, says FDA hemp and cannabis policy chief Norman Birenbaum. Influence from those models already seen in US with ingredients including delta-8 THC marketed as hemp as defined in federal law de-scheduling it as a controlled substance.

"Popularity contests" leading to legalizing cannabis in some states also led to markets opening without needed standards and safeguards, according to the US Food and Drug Administration's lead official on hemp and cannabis policies.

Those states' histories with legalizing cannabis aren't good models for determining whether using hemp ingredients in dietary supplements and food should be lawful, says Norman Birenbaum, senior public advisor in the FDA Center for Drug Evaluation and Research.

Influence from those models, however, already is seen in the US hemp market. Some substances which meet the definition of hemp set in a federal law de-scheduling it as a controlled substance – any part of the cannabis plant containing no more than 0.3% delta-9 tetrahydrocannabinol concentration by dry weight – are available in the US and already are known as not safe for use in supplements or food.

"Whether it's delta-8, delta-10, HC hydroxy-11, THC-acetate, all these different derivatives and derivatives of derivatives were created essentially from scratch with little to no history of human

use or experience. That is an issue," Birenbaum told HBW Insight.

"We're seeing a large increase of adverse events from the use of these products."

The agency's recent decision to turn to Congress for authority to establish a regulatory pathway for the use of hemp ingredients in non-drug products subject to its regulation will ensure not repeating the problems which emerged after some states legalized cannabis and when nationwide sales of hemp-containing products began spreading even before it was de-scheduled. (Also see "*US FDA 'Punt' On Hemp Rulemaking Frustrates, Confuses Supplement Industry*" - HBW Insight, 26 Jan, 2023.)

Birenbaum, who joined the FDA in September with experience in cannabis and hemp policy including as chief cannabis policy advisor to the governors of New York and Rhode Island, where he led agencies responsible for cannabis regulation and research, noted that some states have legalized sales of cannabis for medical use or also generally for adult use through elections. (Also see "*Heightening Focus On Hemp, Cannabis, US FDA Hires Norman Birenbaum As Public Health Advisor*" - HBW Insight, 30 Sep, 2022.)

"Nearly half of all state programs were ballot initiatives ... and went straight to the consumers, straight to voters. That is a popularity contest. It's not necessarily the best way to write legislation," Birenbaum told HBW Insight.

Through January, 39 states and the District of Columbia have legalized medical marijuana or adult possession or both. Idaho, Montana, Nebraska and South Carolina continue to prohibit any access to or use of cannabis, while Georgia, Illinois, Iowa, Kentucky, Tennessee, Texas and Wisconsin allow sales of CBD containing THC but not of

Solving Conflict Of 'Permissive' State Laws, Federal Prohibition

Four months into his FDA service, Birenbaum said establishing national standards for safe use of hemp and for using cannabis-based ingredients as drugs is the next step in his work to bring safety along with access to markets for the botanicals.

"I'm not sure that there are a lot of products that follow the same type of story in history, particularly looking at the conflict between states' permissive regulatory structures and federal prohibitions," he said.

"It's one of the reasons why this area is so interesting. It's one of the reasons why I'm so happy to be working with FDA. I've been working on how to solve these problems in a way that's responsible to safeguard public health and safety at the state level now for seven or eight years and have had the pleasure of working with FDA and other federal agencies on these issues over that time as well. I'm just grateful for the opportunity to

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cannabis.

take my experience and contribute now at the federal level."

Toothpaste Out Of The Tube

In states moving early in the trend, including Alaska, Colorado, Oregon and Washington, legal cannabis sales began "without basic standards in terms of packaging, labeling, serving and dose sizes," he added. "We saw a rash of adverse events related to that."

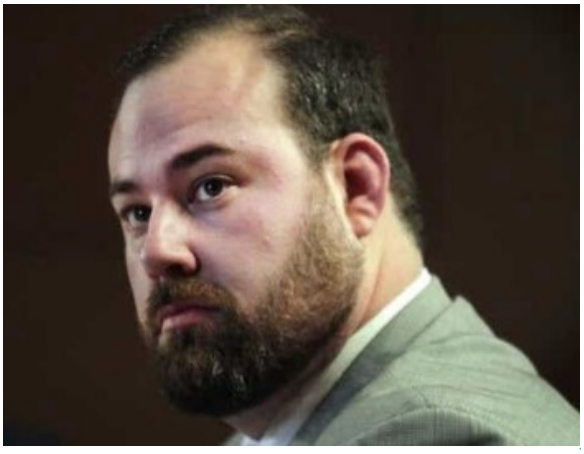
Regulators in those states have had to "engage in significant harm reduction, understanding that they weren't going to put the toothpaste back in the tube entirely."

Similarly, stopping sales around the country of supplements, food and personal care and other non-drug topicals containing cannabidiol (CBD) and other cannabinoids or other hemp-derived ingredients would have been next to impossible for the FDA.

"There are a lot of things that went into putting in place those programs" for cannabis sales in states, Birenbaum said. "Regulators have done a phenomenal job, given the lack of data, and utilizing real world data."

"I have a little bit of experience doing that myself at the state level and through the various associations and groups that state regulators have formed. But that's a path that looks very, very different from what we've seen, I think, with the proliferation of hemp-derived products."

However, the agency couldn't allow the hemp market to determine standards and set safeguards. The FDA also didn't expect the market to self-regulate—it created a still-open docket for information on the safety of CBD and other hemp and cannabis ingredients used in non-drug products.



NORMAN BIRENBAUM: "ALL THESE DIFFERENT DERIVATIVES AND DERIVATIVES OF DERIVATIVES WERE CREATED ESSENTIALLY FROM SCRATCH WITH LITTLE TO NO HISTORY OF HUMAN USE OR EXPERIENCE. THAT IS AN

Moreover, the 2018 farm bill provision de-scheduling hemp also maintained the FDA's authority over hemp's use in products subject to its regulatory oversight.

The agency in 2020 submitted for the Office of Management and Budget's review a draft guidance on its enforcement policy for hemp. However, the Trump administration didn't return the draft to the FDA and in January 2021 President Biden advised the OMB to

withdraw from the executive agency's review any pending rule or other regulatory item, including guidance documents, submitted by all federal agencies; the hemp enforcement draft guidance was among the FDA regulatory items withdrawn. (Also see "*Biden Administration Pause On Pending Trump-Era Rules Stalls FDA Cannabinoids Guidance Progress*" - HBW Insight, 27 Jan, 2021.)

ISSUE." *Source: Source: FDA*

The FDA hasn't published a draft or other guidance on its hemp policy since then. "We are evaluating options for efficiently communicating enforcement strategy," an agency spokesperson said.

'Address Safety Concerns' As Products 'Continue To Evolve'

While the FDA, under its ongoing de facto enforcement discretion policy allowing hemp product sales, has been active warning firms about making drug claims, it hasn't limited impact on slowing the expansion not only of sales, but also of types of hemp being used.

Birenbaum pointed out the same trend emerged as states allowed cannabis sales.

"One of the things that they have in common I'll say is they're constantly changing and innovating. That's one of the things that makes this area so difficult and one of the reasons why it is appropriate to have a new regulatory framework for these hemp-derived products, something that allows the federal government and FDA to address the safety concerns of these products as they continue to evolve," he said.

"We've seen products come into the market over the last six to 12 months that didn't even exist a year or two years ago. It was really important to make sure we have the proper regulatory structures to deal with these evolving markets and the various safety profiles of these products."

The proper structure likely will include a more detailed definition of hemp than stated in the 2018 farm bill. The FDA already has indicated it considers some cannabis ingredients containing no more than 0.3% delta-9 THC concentration as not safe for use in supplements or food. (Also see "*First US Warnings On Drug Claims By Delta-8 THC Supplements Also Describe Safety Concerns*" - HBW Insight, 4 May, 2022.)

The level of delta-9 THC isn't the only determinant of the potential intoxicating or psychoactive properties of an ingredient labeled as hemp.

"I think we're pretty clear now that the pathway forward is new authorities from Congress. In terms of the scope of those new authorities, that would be a tool to address what is probably the largest threat to public health and safety we've seen come out of the cannabis industry over the last few years," Birenbaum said.

“These products have less of a regulatory structure. If you can imagine that there's been CBD in most jurisdictions and the one thing that we've seen almost uniformly across the country, the states trying to expand their definition of THC to include these isomers in these other derivatives, or to just wholly prohibit them,” he added.

“This is certainly a growing public health and safety concern. We've seen an increase in adverse events related to these impairing and intoxicating cannabinoids. And new authorities would absolutely be an option in terms of a way to help address these and to safeguard public health.”