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HISTORIC HEMP HEARING ADDRESSES FDA INACTION ON HEMP AND CBD PRODUCTS

Congressional Leaders and Industry Experts Testify On FDA's Failure To Regulate Hemp-Derived Cannabinoids

WASHINGTON D.C. — On Thursday, July 27th at 2:00 PM ET, U.S. Hemp Roundtable General Counsel, Jonathan Miller, testified during a historic hearing on hemp and CBD before the House Oversight and Accountability Committee's Subcommittee on Health Care and Financial Services. The hearing, "Hemp in the Modern World: The Years long Wait for FDA Action," was the first time Congress has formally scrutinized the impact of the U.S. Food and Drug Administration's (FDA) failure to develop a regulatory pathway for the sale of ingestible hemp products such as CBD. Watch the recording here: https://www.youtube.com/watch?v=uGaYuP5EqwQ

Read Jonathan's full written testimony here: <u>2023-Hearing-Packet.pdf</u> (hempsupporter.com)

Hearing witnesses and members of Congress shared the same sentiments: 1) a regulatory framework for hemp-derived cannabinoids is urgently needed, 2) FDA has the existing data, tools, expertise and authority to regulate hemp-derived cannabinoids, and 3) a continued lack of FDA regulations for products containing hemp-derived cannabinoids poses a major consumer health and safety issue.

"Lack of a federal framework has led to the proliferation of unregulated products, some of which raise significant quality, safety, and other consumer protection concerns," said **U.S. Hemp Roundtable General Counsel, Jonathan Miller**.

"Whether through the Farm Bill or another priority piece of legislation, a broad regulatory framework is urgently needed to address hemp-derived cannabinoid products," said **Dr. Gillian Schauer Ph.D., MPH., Executive Director of the Cannabis Regulators Association**.

"Self-regulation is not sufficient; federal regulation is necessary to ensure that all products on the marketplace maintain the highest safety standards," said Mr. Richard A. Badaracco, President-Elect, Kentucky Narcotic Officers Association, (Retired) Assistant Special Agent in Charge, U.S. Drug Enforcement Administration.

Subcommittee leaders and members differed on which comes first: FDA or Congressional action. Rep. Katie Porter (D-CA) implied that Congress should direct the agency to regulate CBD products through legislation, while Chairwoman Rep. Lisa McCain (R-MI) stated they already had the authority granted under the 2018 Farm Bill.

"We should all be able to agree that the federal government needs to regulate hemp-derived products in a way that protects our constituents while also making safe products available to them," said **Sub-Committee Member, Rep. Katie Porter (D-CA).** Given the bipartisan interest, members of Congress should have no problem rolling up our sleeves, hell I don't even have any sleeves, and getting to work to establish the regulatory pathway that the FDA says it needs."

"The pathway already exists, Congress spoke in 2018, the FDA just needs to do the job that the American taxpayer is paying them for and if they can't do their job, maybe we should stop funding them or funding them at reduced levels. Again, the pathway already exists, "said **Subcommittee Chair Rep. Lisa McCain (R-MI).**

As <u>previously reported</u> by the U.S. Hemp Roundtable, the FDA continues to rely on incomplete safety data as the basis for its continued refusal to regulate CBD as a dietary supplement or food additive. The agency also <u>claims</u> a new regulatory pathway would benefit consumers by providing safeguards and oversight to manage and minimize risks related to CBD products. Hearing witnesses and committee leaders disagreed.

"FDA simply has not been transparent with the industry stakeholders or Congress in what scientific studies relies on and often moves the goal post for researchers attempting to satisfy the FDA's requirements through rigorous studies," said **U.S. House Oversight Chairman, Rep. James Comer (R-KY)**. "So even though we have more and more data available to regulators to make appropriate decisions about CBD in the marketplace, the FDA has taken no meaningful action to provide clear guidance and certainty in the market, refusing to regulate CBD products under existing lawful pathways. Without FDA regulations the good faith producers of these products are left with no path forward and consumers are left in the dark."

Dr. Rayetta G. Henderson Ph.D., Senior Managing Scientist, ToxStrategies, LLC said, "Based on my experience performing similar evaluations, the data available are sufficient for conducting a safety assessment of CBD following the same principles that we would apply for any ingredient proposed for use in foods or supplements."

"There are abundant consumer safeguards encompassed in the Federal Food, Drug and Cosmetic Act that would be applied to CBD products sold as dietary supplements," said Miller. For example, the law precludes manufacturers and distributors from selling mislabeled or adulterated products and it requires manufacture and sale of products consistent with good manufacturing product standards. The law also requires reporting of serious adverse events, and it mandates strict labeling, including if FDA desires, warnings against the use of products by children. Finally, the FDA with the Consumer Product Safety Commission could require child-proof packaging,"

Witnesses emphasized how the lack of FDA regulatory framework for hemp-derived CBD has also contributed to the proliferation of products containing intoxicating or impairing cannabinoids, most prominently delta-8 THC, which are being sold unregulated, sometimes to minors. While none of the witnesses support the criminalization of these products, they concur that strict regulations are needed for safety and to keep them out of the hands of children.

"In many states, including Kentucky, most delta-8 THC products are sold through unregulated market sources like convenience stores, smoke shops, gas stations, and even can be ordered online. These products are not reliably tested and have been found to contain many impurities," stated Badaracco. "Assuming these products remain legal, the optimal approach is following the lead of Kentucky, whose General Assembly this year passed legislation unanimously to strictly regulate these products and keep them out of the hands of minors," he said.

"These products served as a lifeline to U.S. farmers, and when manufactured properly, can be of considerable value to adult consumers. Accordingly, we oppose their ban or criminalization. However, they need to be strictly regulated for safety and kept out of the hands of children. Kentucky's General Assembly recently passed unanimously legislation to this effect – HB 544 -- it should be a model for the nation," said Miller.

"As an association of state regulators, CANNRA is not encouraging the re-criminalization of cannabinoid hemp products, but rather comprehensive regulation that accounts for the potential product risks and the existing markets that states have carefully architected for marijuana," stated Dr. Schauer. "States have demonstrated that thoughtful regulatory frameworks can protect consumers and public health and move us away from the harms of prohibition."

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ABOUT

The U.S. Hemp Roundtable is the hemp industry's national advocacy organization, a coalition of dozens of leading companies and organizations committed to safe hemp and CBD products. The Roundtable proudly works in partnership with the industry's leading national, regional and state grassroots organizations, and is leading the way forward for hemp and CBD products through education and action. More at <a href="https://example.com/hempsupporter.com/hempsupport