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Report on the FDA cannabis hearing: Passionate presenters urge clarity in regulation of complex industry

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On Friday, May 31, 2019, the FDA convened a public hearing to take comments from more than 100 presenters addressing a wide range of scientific, marketing, safety, and efficacy issues pertaining to products containing cannabis or cannabis-derived compounds. This day-long session was held at the U.S. Food and Drug Administration White Oak Campus in Silver Spring, Maryland.

Norman "Ned" Sharpless, M.D., the Acting Commissioner of Food and Drugs, began the day with welcoming remarks and offered perspective and purpose for the hearing. He commented on the widespread prevalence of CBD products available for sale in retail outlets and online.

He noted a general lack of scientific evidence with respect to the production, distribution, and use of CBD products. These gaps in data and knowledge, combined with unsubstantiated therapeutic claims about the use of CBD products — especially in vulnerable population groups such as the elderly, minors, and pregnant patients — has created an imperative for the FDA to investigate.

The Acting Commissioner noted that the FDA has created an internal working group to examine these issues and develop scientific-based policy for this fast-developing market. He noted that the public hearing was an important opportunity for the FDA to hear directly from stakeholders who could share vital perspectives and experiences about the cannabis and cannabis-derived products and industry.

HEARING FORMAT

The hearing consisted of a series of short remarks (2-5 minutes). The presentations, mostly oral but some supported with slide decks, were made by individuals who had registered in advance to present their views and perspectives. A distinguished panel of FDA representatives presided and posed questions to many of the speakers.

The Public Hearing Agenda identified the scheduled presenters.[1]

ISSUES AND THEMES

The presenters included academics, scientific researchers, state government regulators, physicians, hemp cultivators and distributors, product manufacturers, and retailers. Consumers, advocates, patients, trade group representatives, regulators (U.S. Pharmacopeia), and representatives of testing laboratories also spoke. Based on the prepared remarks and panel comments, many common themes emerged.

While the majority of presenters favor the CBD industry, there was a recurrent call for consistency and clarity in everything from regulatory oversight, permissible labeling claims, ingredient purity, and even the development of a consistent taxonomy to eliminate confusion in the use of terms such as "full spectrum," "broad spectrum," "synthetic CBD," "terpenes," and "isolates."

Companies engaging in this multibillion-dollar industry decried the harm caused by fraudsters, irresponsible marketers, and unpredictable regulations.

A common refrain was the need for a uniform and consistent regulatory landscape to reconcile the vagaries of federal and state laws and drive industry and support consumer confidence. Such regulation and standardization was welcomed by many speakers to help create reliable pathways to market.

Presenters and FDA panelists alike spoke of the essential need for reliable scientific research and studies to better understand the short-term and long-term accumulated exposure to cannabis-derived products and indications for use.

For researchers, this begins with a streamlined approach to sourcing research-grade CBD products in sufficient and reliable quantities for credible scientific research.

Companies engaging in this multibillion-dollar industry decried the harm caused by fraudsters, irresponsible marketers, and unpredictable regulations. Several speakers provided alarming examples of adulterated CBD-type products and demonstrated the blatant falsity between label claims and actual product content.

Permitting product "branding" also was mentioned as a way to enforce consistent product content and restore consumer confidence.

The FDA panel was keenly interested in speakers who referenced data collections, patient experiences, and adverse reaction reports. The panel asked repeatedly about evidence of use in children and limitations imposed on sales to minors. Similarly, it took note of references to CBD use in the elderly and in vulnerable patients.

The panel also asked questions about CBD dosing, serving sizes, routes of administration (ingested, inhaled, topical, vaping), absorption studies, drug-drug interactions, and the effect of cumulative exposures to CBD products over time.

> Several presenters described the desperate circumstances of family members who struggled with marijuana or cannabis addiction and committed suicide.

Several speakers, consumers, and physicians spoke of personal, patient, or anecdotal experience with CBD products and the asserted benefits in ameliorating pain, managing PTSD, and even providing an effective bridge to withdraw from opioid addiction — a comment that drew widespread applause from the audience.

There was obvious interest, from speakers and panelists alike, in CBD products for use in pets, farm animals, and food-producing animals.

Not all speakers favored the use of cannabis products. Several presenters described the desperate circumstances of family members who struggled with marijuana or cannabis addiction and committed suicide. They spoke of "Cannabis Use Disorder" and urged the FDA to enforce strict measures or outlaw these products altogether.

NEXT STEPS

Many of the speakers urged the FDA to act promptly to develop a regulatory framework, or at least issue guidance materials, to facilitate much-needed research and begin to set standards for some of the fundamental aspects of production, marketing, and distribution of cannabis-derived products.

The FDA acknowledged those requests, but at this time expressed no timetable for further regulatory activity.

Throughout the public hearing, the FDA panel asked many of the speakers to share their materials, additional research, and references on the FDA's open public docket, which allows interested parties to both post and review comments, data, and research.[2] The FDA will accept comments posted on the docket through July 2, 2019.

A recording of Acting Commissioner Sharpless's Opening Remarks and the entire public hearing is now available.[3] A transcript of the May 31, 2019 Public Hearing and slide decks is expected to become publicly available in July.

NOTES

1 https://bit.ly/2QDdYIg

2 https://bit.ly/2HFuILQ

3 See the FDA's post-hearing letter of June 7, at https://bit.ly/2LQvkkw, for details.

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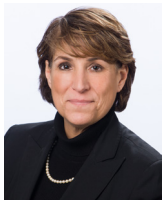

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