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FDA Hosts Long-Awaited Cannabis Public Hearing

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On May 31, 2019, the U.S. Food and Drug Administration ("FDA") hosted its much-anticipated public hearing titled "Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds" (discussed in our prior blog post). The day-long hearing presented an opportunity for FDA panel members to engage directly with stakeholders on the regulatory future of cannabis or cannabis-derived products within the scope of FDA's jurisdiction.

Acting FDA Commissioner Ned Sharpless, M.D., kicked off discussions, reminding the panel and stakeholders alike that it is "critical that we do all we can to support science to develop new drugs from cannabis." Commissioner Sharpless emphasized that some uncertainty remains regarding the safety of widespread cannabis use, a sentiment echoed by stakeholders throughout the day.

Panel members included Amy Abernathy, FDA's Principal Deputy Commissioner, and representatives from the Office of Foods and Veterinary Medicine and the Center for Drug Evaluation and Research. The panel heard from a diverse group of presenters, including members of academia, agriculture-focused groups, consumers, health care professionals, manufacturers of a variety of ingestible and topical cannabis or cannabis-related products, patients, retailers, and distributors, each offering various viewpoints on the safety, availability, and purity of cannabis products. Many presenters urged FDA to work quickly to develop and implement a regulatory framework, arguing that a protracted rulemaking process would unnecessarily delay the availability of helpful products. Overall, the stakeholders emphasized the need for a comprehensive regulatory framework that both protects consumers and eliminates current obstacles to the development of cannabis products. We provide a breakdown of key stakeholder and FDA perspectives below.

Expanded Research Initiatives

Representatives from academia and the health professional community advocated for lifting restrictions that currently apply to conduct of cannabis research because it is a Schedule I controlled substance, which means research must be approved by multiple federal and state agencies. They argued that, without the expanded ability to conduct research on cannabis products, the available data on the safety or quality of such products will be limited and it will be difficult to create appropriate quality control standards. Many speakers noted the need for more information about drug-drug interactions between cannabis products and other medications. Still others identified the need for research on dosing, as well as whether the route of cannabis administration impacts the safety of

such products. Skeptics stressed that cannabis product use and dosage is difficult to figure out on an individual patient scale, so widespread public use could prove too dangerous without data to support safety and quality.

Labeling and Marketing Restrictions

Consumers, providers, and members of academia raised significant concern about the adequacy and accuracy of the information disclosed by manufacturers and retailers of cannabis products. They argued that the current lack of a uniform regulatory framework and FDA oversight has led to poor quality cannabis products that put consumers in danger. Multiple presenters cited data showing discrepancies between product labeling and content. For example, one speaker reported that a cannabidiol ("CBD") product labeled as "THC-free" actually contained tetrahydrocannabinol ("THC") and also contained a different concentration of CBD than was stated on the label. A number of speakers discussing this topic argued that misrepresentations in labeling constituted "abuse" by the industry that must be addressed on a federal level.

Uniform Guidance for States on Legal Pathways to Market

Stakeholders at the hearing included those representing various state governments. These representatives discussed the increasing challenges for states to both meet economic needs and remain compliant with federal regulations as the consumer demand and market availability for these products grow. These representatives called for clarity and uniformity from FDA in a variety of contexts, including more guidance on which products are subject to regulation as Schedule I controlled substances in collaboration with the federal Drug Enforcement Agency and which are regulated by FDA alone, pathways to market for CBD dietary supplements and food products, and regulations for extraction and production of cannabis-related compounds. Some of the state representatives explained that such clarification from FDA would be helpful for their own legislatures that are working to develop state regulatory schemes for cannabis or cannabis-related products.

Distinction Between Psychoactive Cannabis Compounds and Non-Scheduled Cannabis Compounds

Some retailers and manufacturers identified certain cannabis-related compounds, which do not contain CBD or THC, as "low hanging fruit" for which FDA can clear a pathway to market. Examples included terpenes, a large group of organic compounds responsible for the taste and flavor of cannabis that are also found in other plants and fruits, as well as cannabis-free hemp products. Retailers and manufacturers urged FDA to acknowledge such products to be generally recognized as safe ("GRAS") as a first step in its regulatory scheme.

Adverse Event Reporting

Many presenters argued that CBD has been verified as safe, non-habit forming, and non-toxic. However, others disputed these claims, arguing that there is not enough evidence to demonstrate that CBD is not addictive or non-toxic, citing to research findings that suggest potential complications involving withdrawal symptoms and impaired liver function.

FDA panel members sought additional details regarding adverse events associated with CBD exposure, but presenters had limited information and focused on headaches and fatigue as reported physiological effects of ingesting CBD-containing products.

Panel Feedback

The panel questioned whether the industry has observed a lack of incentive by pharmaceutical manufacturers to develop drug products containing cannabis or cannabis-derived compounds because of CBD's broad availability. Most stakeholders recognized a need to distinguish between FDA-approved cannabis drug products necessary to treat serious medical conditions, and more widely available cannabis-derived dietary supplement or food products. As one stakeholder put it, FDA needs to "treat medicine as medicine," implying that therapeutic cannabis products should be regulated consistent with FDA's existing drug regulatory framework. Finally, throughout the hearing, panel members seemed keen on receiving detailed clinical study or testing data in comment form from companies that have already conducted this research.

Next Steps

FDA representatives did not give any indication of what, if any, regulatory changes the agency was considering, how the feedback from the hearing would be incorporated into the agency's decision-making, or the timing of any proposed regulatory changes. Stakeholders with an interest in developing, marketing, distributing, or purchasing consumer-focused CBD products—as well as in developing other hemp-derived cannabinoid compounds for the consumer market—can still submit comments for FDA's consideration via regulations.gov by July 2, 2019. Many stakeholders during the hearing requested an extension of this deadline, but it is unclear whether FDA will grant this request.

Lauren Petrin, a 2019 Summer Associate (not admitted to the practice of law) in the firm's Washington, DC office, contributed significantly to the preparation of this post.

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