What We Learned From FDA's Public Hearing On Cannabis

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The much-anticipated public hearing last week at the U.S. Food and Drug Administration on cannabis and cannabis-derived compounds drew a wide audience of participants, with strong views on how the FDA should (or should not) regulate the controversial plant.

In an amazingly short period of time, hemp-derived products, including those containing cannabidiol, have moved from the fringe to the mainstream, from state-licensed dispensaries to traditional brick-and-mortar retailers. And yet, the FDA's position has been clear — it is illegal to sell human food, pet food, dietary supplements and unapproved drugs that contain CBD.

Many comments submitted prior to the public hearing[i] were from individuals describing their personal stories using CBD, including for treatment of chronic pain, pediatric pain and more. Veterans also recounted compelling stories describing their use of CBD to relieve anxiety and symptoms of post-traumatic stress disorder.

Some comments, however, expressed significant concern over product quality and consistency (e.g., adverse events resulting from CBD levels that vary from the labeled amount), the accuracy of information in product labeling (e.g., undeclared or synthetic ingredients), and microbial contamination. Similar praise and concern about restricted access to CBD were echoed in public comments presented at the public hearing.

The hearing focused on the use of CBD in food and dietary supplements, which accounts for a large part of the market growth. Dr. Norman (Ned) Sharpless, acting commissioner of the FDA, stated at the outset that the FDA treats substances derived from cannabis "just like any other substances," meaning they are subject to the same premarket requirements and other authorities.

For example, any food additive must be approved by the FDA as safe before being put into the food supply, unless the substance is generally recognized as safe, or GRAS. Sharpless explained the current regulatory framework and reiterated the FDA's position that under current law, CBD cannot lawfully be added to a food or marketed as a dietary supplement. Sharpless commented that American consumers depend on the FDA to help make sure that the food they eat is safe, and that there are "many unanswered questions" related to the safety of CBD in foods and dietary supplements.

The FDA heard testimony from hemp business owners, scientists, farmers, industry associations, health care professionals and consumer advocates. As expected, the FDA

did not provide a strategy for regulating cannabis at the hearing or weigh in on specific questions. FDA panelists, however, asked questions that reveal the agency's concerns over the widespread use of CBD in the food supply, including the scientific evidence to support safe levels of CBD in various forms (e.g., food, oils, topicals), restrictions on youth access, the effects of CBD on food-producing animals, and data collection efforts by consumer product companies to identify adverse events experienced by the larger consumer base. The questions also revealed, on a more basic level, the lack of agreement on common terms that allow both industry and the agency to characterize the plant itself and any proven therapeutic benefits.

Top Takeaways From the FDA Public Hearing

FDA Does Not Intend to Exercise Enforcement Discretion

Sharpless opened the hearing with statements that affirmed the FDA's position on the illegal nature of CBD in foods and dietary supplements. Sharpless also stated that the FDA does not plan to exercise a policy of enforcement discretion with respect to any CBD products.

The FDA has garnered criticism from some for not aggressively pursuing marketers of online retailers of CBD gummies and edibles, despite the FDA's stated safety concerns. While the FDA has issued a handful of warning letters to companies making egregious therapeutic claims, such as those claiming to cure cancer or Alzheimer's, it has not initiated an aggressive pursuit of CBD marketers.

Much Is Unknown, and Industry Needs to Fill the Gaps

The FDA questions of public commenters, and the responses provided, revealed a lack of common understanding of CBD and delta-9-tetrahydrocannabinol, or THC, and the scientific bases for their therapeutic benefits. The FDA questioned commenters, for example, on how to properly define industry terms (e.g., full-spectrum versus broad-spectrum versus CBD isolate), and commenters' presentations appeared to provide inconsistent information.

Along with the basic lexicon for cannabis, the FDA asked pointed questions on the mechanisms of actions for CBD and its therapeutic benefits. While some patient advocates provided powerful stories of specific benefits, including for preventing pediatric seizures, many consumer advocates spoke of more qualitative effects, such as feelings of "overall well-being" and anxiety relief. It is clear that the FDA wants more data on CBD use in the consumer context, including scientific and empirical data regarding how cannabis-derived compounds affect the public. This included requests for both studies in healthy individuals and larger consumer populations. FDA panelists' questions focused particularly on understanding safe dosages, and routes of administration (e.g., inhaling versus ingesting versus topical application).

Commenters Largely Agreed That Some Regulatory Protections Would Be

Beneficial

Public commenters seemed to agree — at some level — that some FDA regulation is beneficial for the protection of consumers. Some consumers expressed concerns over the quality of CBD in products, including inconsistent purity levels and undeclared ingredients that contaminate the product.

Consumer advocates and business owners recommended, for example, that the FDA apply well-established protections in its current legal framework, such as labeling requirements and good manufacturing practice, or GMP, standards. Some manufacturers urged the FDA to adopt a GMP framework that reflects the natural variability of CBD compounds in the plant. When FDA panelists asked commenters if GMP standards were currently being followed, however, many stated no. These questions, and others, revealed the disparate state of manufacturing and quality controls currently implemented in the industry.

There Is Pressure on the FDA to Act Fast

The very recent explosion of CBD-infused foods, edibles (e.g., gummies, candy), and beverages in the marketplace, coupled with conflicting, lenient or nonexistant state laws on the sale of hemp-CBD products, puts pressure on the FDA to act quickly in an area that is squarely within its domain.

Multiple stakeholders urged the FDA to act fast — researches urged the FDA to move quickly so that cannabis could be more readily available for scientific studies; business owners asked for clarity so that they could understand their legal risks and opportunities; and consumer advocates sought clear post-market requirements, such as labeling and manufacturing standards, to protect consumers from contaminated products.

As in the past, the FDA will apply an evidence-based approach to regulation. The FDA will have to balance, however, the considerable time it will take to wade through the scientific data with industry and public demand for action.

Youth Access Is a Significant Concern

The FDA specifically requested information on how vulnerable populations, and in particular minors, would be affected by the proliferation of CBD products. The FDA asked companies selling CBD products to consumers how they were restricting sales to youth, including physical restraints in stores (for example, prohibiting minors from entering retail stores), and whether the age restrictions were determined based on scientific evidence. With the FDA's laser-like focus on preventing the marketing of electronic cigarettes to minors, industry can expect similar scrutiny on companies selling CBD products, and in particular those that may be inhaled/vaped.

Moving Forward — FDA Actions in the Near Term

In the near term, the FDA will be collecting and reviewing data from industry on the safety of cannabis and cannabis-derived compounds. If industry wants to move the needle, then it must present to the FDA as much supporting scientific data that it can muster on the safe, widespread use of cannabis-derived compounds. There is significant external pressure on the FDA to act quickly, and we can expect the FDA to remain focused on enabling a regulatory pathway.

The pathway, however, will be informed by a methodical and deliberate review of scientific information. And that process takes time. The FDA has asked the public to submit comments to the public docket by July 2, 2019; some commenters urged the FDA to allow more time. The FDA's internal working group on CBD, which has been tasked with exploring lawful pathways for dietary supplements and foods containing CBD, is expected to begin sharing their findings in summer 2019.

In the meantime, the FDA may continue its current enforcement strategy, which consists of targeting companies making egregious therapeutic claims. In his opening remarks, Sharpless signaled that the FDA will not take a "hands off" approach to retailers and manufacturers. The FDA also, however, may decide not take a more aggressive enforcement approach in the near term, given the disparate and heated stance on the availability of CBD products. While the FDA's current enforcement strategy is not a model of clarity for the marketplace, it would preserve the status quo while the FDA's internal working group explores legislative options for appropriate pathways.

The Existing Regulatory Pathways for CBD Products … And Why (Most of) Industry Is Ignoring It

Premarket Ingredient Review for Food and Dietary Supplement Ingredients

The FDA's legal framework for foods and supplements is premised on data-driven safety. By statute, any substance intentionally added to food is a "food additive," and is subject to premarket approval by the FDA.[ii] Food additive petitions must contain data on the safety of the proposed additive, including the additive's composition and technical properties, the amount typically consumed, immediate and long-term health effects, and more.

The FDA does not require food additive petitions for ingredients that are generally recognized as safe. A food ingredient can be shown to be GRAS either through scientific procedures (with notice to the FDA), or through experience based on common use in food prior to 1958. Similar to a food additive petition, a GRAS notice to the FDA contains detailed safety data on the substance. The FDA explicitly has stated that it is not aware of the presence of cannabis or hemp products in the food supply prior to 1958, so the GRAS experience path is not available for cannabis products

Three hemp seed ingredients — hulled hemp seed, hemp seed protein and hemp seed oil — have gone through the FDA GRAS notification process and may legally be

marketed in human foods for certain uses. No other cannabis-derived compound has been the subject of an FDA GRAS notice or an approved food additive petition.

A similar framework for premarket review of ingredients exists for dietary supplements. Companies that wish to market dietary supplements that contain a "new dietary ingredient" (i.e., a dietary ingredient that was not marketed in the U.S. in a dietary supplement before Oct. 15, 1994) must notify the FDA.[iii] The notification must include information demonstrating that the ingredient is reasonably expected to be safe under the conditions of use recommended in the labeling. CBD to date has not been the subject of a NDI notification.

The Statutory Hurdle — And a Novel Approach

While the requirements for premarket review of CBD as a food additive, GRAS ingredient or NDI seem surmountable, a more problematic statutory hurdle exists. Under the Federal Food, Drug, and Cosmetic Act, companies may not introduce into commerce any food (including animal food) or dietary supplement containing a substance that is an active ingredient in an approved drug product, or for which substantial clinical investigations have been instituted (and for which the existence of such investigations has been made public).[iv] In June 2018, the FDA approved Epidiolex, an oral drug that contains cannabis-derived CBD for the treatment of seizures associated with two rare and severe forms of epilepsy. As such, any food or dietary supplement containing CBD cannot be put into interstate commerce.

The statutory hurdle could be overcome if the FDA were to issue a regulation specifically approving the use of CBD in a food or supplement.[v] To date, the FDA has not issued such a regulation for any substance. This pathway may be appealing to the FDA, given the disruptive nature of CBD in the marketplace. On the other hand, such a regulation could take years to pass given the lack of data about cannabis products, and will seriously lag behind the market's demand for a clear pathway.

Marketplace Confusion (or Deliberate Avoidance)

How are CBD-infused edibles flooding the marketplace, given the FDA's position on their illegality? Some companies may think, incorrectly, that the Agricultural Improvement Act of 2018, or the 2018 Farm Bill,[vi] made hemp-derived CBD legal across the board. The 2018 Farm Bill removed hemp (with lower than 0.3% delta-9-tetrahydrocannabinol) from the Controlled Substances Act. While the 2018 Farm Bill removed many restrictions on the production of hemp, it did not alter the FDA's jurisdiction under the FDCA to regulate products containing hemp or CBD derived from hemp. Thus, while it is legal to grow hemp that is compliant with applicable state and federal regulations, it is not permitted to distribute hemp products regulated by the FDA across state lines.

Some companies may be following state law only, where state regulators may be less inclined to enforce state law equivalents of the FDCA regarding CBD in food. For

example, in California, the currently pending Assembly Bill 228 seeks to modify the state Sherman Food, Drug, and Cosmetic Law to declare that foods, beverages and cosmetics that include hemp-derived cannabinoids are not considered adulterated products (and hence permitted). In the interim, however, California's Department of Public Health has adopted the FDA's approach to hemp-CBD in food and beverages.

Also, Colorado law permits hemp in food products (under certain conditions). The FDA's jurisdictional hook is interstate commerce, and companies operating strictly within the state may be outside FDA jurisdiction. The FDA's slow approach to enforcement against companies selling gummies and other CBD edibles also may lead companies to think their products are legally permitted.

Some companies also may not want to put the resources into developing the technical and safety data required for the submissions to the FDA. Safety data, however, will be a key component of the FDA's regulatory approach to CBD, and companies that ignore the risks presented by their CBD products may find it more costly in the long run. History proves this out — companies that establish themselves as leaders in data collection often set the dialogue and help shape regulatory standards by working collaboratively with the FDA.

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[i] (Docket No. FDA-2019-N-1482).
[ii] See Federal Food, Drug, and Cosmetic Act (FDCA) §201(s) & 409.
[iii] See FDCA § 413(d).
[iv] See FDCA §§ 301(ll) & 201(ff).
[v] See FDCA §§ 301(ll) & 201(ff).
[vi] Public Law 115-334.