Concerns over Exaggerated Health Claims Prompt FDA Hearing on Effects of CBD Products

By CNN News

Cannabis-related products have flooded the market, making health claims about pain relief, immune function and anxiety and depression. On Friday, the US Food and Drug Administration is holding its first hearing to assess the safety and efficacy of these CBD products.

The goal of the hearing is to "identify and collate all available data to help us answer these questions in order to make sure that the American public is protected -- including to the extent CBD is being introduced into our food supply or other common consumer products," Michael Felberbaum, an FDA spokesman, said in an email to CNN.

CBD, also known as cannabidiol, is the ingredient in marijuana and hemp touted to have many medicinal benefits. It's different from tetrahydrocannabinol or THC, the main psychoactive component of cannabis.

'Only limited available information about CBD'

Last June, the FDA for the first time approved a cannabis plant-derived, CBD-based drug, Epidiolex, which is approved to treat two severe and rare forms of epilepsy: Dravet Syndrome and Lennox-Gastaut syndrome.

Dr. Amy Abernathy, principal deputy commissioner of the FDA and head of the agency's CBD working group, said in a tweet last week, "The FDA has not approved any other CBD-containing products. We want consumers to be aware that there is only limited available information about CBD, including about its effects on the body."

Witnesses from the supplement industry, researchers, doctors and patients are all expected to testify about their experiences with cannabis at Friday's hearing. The agency will also make a docket available for public comments that will close on July 2.

In April, then-FDA commissioner Dr. Scott Gottlieb warned in a statement that "open questions remain regarding the safety" of widespread use of CBD products. He also noted there are concerns about a lack of standards around CBD concentrations in products and the possible impacts of long-term CBD use.

"It's critical that we address these unanswered questions about CBD and other cannabis and cannabis-derived products to help inform the FDA's regulatory oversight of these products," he said. "Especially as the agency considers whether it could be appropriate to exercise its authority to allow the use of CBD in dietary supplements and other foods."

It is illegal to introduce CBD or THC into the food supply or market it as a dietary supplement. Marijuana remains illegal under federal law. However, at least 10 states have moved ahead and

legalized the purchase and possession of recreational marijuana while 33 states allow the use of medical marijuana.

Growing to a $15-20 billion market

As states have liberalized the use of marijuana, CBD-related products such as oils, lotions, chocolates and even dog food have stormed the market.

In December, President Donald Trump signed the Farm Bill into law, legalizing hemp, which also contains high levels of CBD. Market analysts expect the hemp-derived CBD market alone to hit between $15-20 billion in the next five to six years.

"The industry is exploding, it's growing in popularity every day. It's so important for the FDA to get a regulatory handle on this," said Jonathan Miller, general counsel for the US Hemp Roundtable, an industry-backed advocacy group. "There are bad products out there. There are products that make false claims. It's important that FDA develop standards."

Earlier this year, FDA sent warning letters to PotNetwork Holdings in Florida, Nutra Pure in Washington state and Advanced Spine and Pain in New Jersey for "making unsubstantiated claims related to more than a dozen different products and spanning multiple product webpages, online stores and social media websites." These companies made claims that CBD could help with cancer and dementia.

Since 2015, the FDA has issued 48 similar type letters about the marketing of CBD products.

Miller said the industry wants regulation. "Our biggest enemy isn't the FDA or the DEA, but CBD companies making false claims," he said.

'The genie' is 'out of the bottle'

"There needs to be clear steps in informing the public that there is no science behind the generic claims made about CBD," Dr. Yasmin Hurd, director of the Addiction Institute at Mount Sinai in New York and a cannabis researcher, wrote in an email to CNN.

But Hurd worries that the FDA is coming to the table too late.

"The market and the public have already let the genie out of the bottle and it will be difficult to put it back in without the FDA and government showing clear proof that there is evidence showing a negative health impact," she said.

While a timeline hasn't been set by the FDA, Miller is hopeful that the FDA will prioritize creating regulations for cannabis-based products. He anticipates that CBD can be regulated both as a drug and as supplement, potentially based on dosing and concentration.

Maintaining a distinction between a medical research pathway and a supplements pathway is key, Hurd said.

"It is critical that the FDA consider making a distinct pathway to expedite CBD research to thus make it possible to quickly inform policy makers, patients and physicians about the potential health impact, dosing regimens, adverse effects as necessary for the development of any medication. It needs to be clear that such a pathway would be different from recreational or nutraceutical/supplement market."