

**STATEMENT
OF
AMY ABERNETHY, MD, PHD
PRINCIPAL DEPUTY COMMISSIONER
FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**BEFORE THE
COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY
UNITED STATES SENATE**

“HEMP PRODUCTION AND THE 2018 FARM BILL”

JULY 25, 2019

RELEASE ONLY UPON DELIVERY

Introduction

Good morning, Chairman Roberts, Ranking Member Stabenow, and Members of the Committee. I am Dr. Amy Abernethy, Principal Deputy Commissioner of the Food and Drug Administration (FDA or the Agency), which is part of the U.S. Department of Health and Human Services (HHS). Thank you for the opportunity to appear before you today to discuss FDA's role in the regulation of hemp products. I am also pleased to appear with Greg Ibach from the U.S. Department of Agriculture (USDA) and Alexandra Dunn from the Environmental Protection Agency (EPA). FDA works collaboratively with USDA and EPA on a day in and day out basis across the Agency's programs to ensure coordination across the Federal government.

First, I would like to thank this Committee for explicitly preserving FDA's authority over hemp products in the Agriculture Improvement Act of 2018 (2018 Farm Bill, PL 115-334). We recognize the substantial potential that hemp has for our nation's farmers and agriculture sector. FDA's approach to cannabis and cannabis derived products, including hemp products, is to treat these products just like we do any other. FDA is committed to advancing hemp products through the Agency's existing regulatory pathways, and we are further exploring whether it would be appropriate to make additional regulatory pathways available to hemp products such as those containing cannabidiol (CBD). FDA believes taking this approach protects patients and the public health, fosters innovation for safe and appropriate products, and promotes consumer confidence.

The Current Regulatory State of Play

In December of 2018, the 2018 Farm Bill was signed into law. It removed hemp, defined as cannabis (*Cannabis sativa* L.) and derivatives of cannabis with extremely low concentrations of the psychoactive compound delta-9-tetrahydrocannabinol (THC) (no more than 0.3 percent THC on a dry weight basis), from the definition of marijuana in the Controlled Substances Act (CSA).

The 2018 Farm Bill explicitly preserved FDA's authorities over hemp products. Therefore, hemp products must meet any applicable FDA requirements and standards, just like any other

FDA-regulated product. For example, FDA’s existing authorities over foods, dietary supplements, human and veterinary drugs, and cosmetics apply to hemp products to the extent such hemp products fall within those categories. These safeguards help ensure that Americans have access to safe and accurately labeled hemp products, and, in the case of drugs, that patients can depend on the effectiveness of these products.

In late 2018, FDA advanced three hemp seed derived food products through the Agency’s Generally Recognized as Safe (GRAS) process.¹ Hemp seeds do not naturally contain cannabidiol (CBD) or THC, which are cannabinoid compounds that are found in other parts of the cannabis plant. The hemp seed products – hulled hemp seed, hemp seed protein powder, and hemp seed oil – can be legally used in the U.S. food supply. Any food products made with these hemp seed ingredients are subject to the same FDA requirements as any other food, such as those related to ingredient and nutrition labeling, as well as the risk-based, prevention focused Food Safety Modernization Act (PL 111-353) safeguards.²

The current regulatory state of play is more complex when it comes to hemp products that contain CBD.

It is unlawful under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to introduce into interstate commerce a food (including any animal food or feed) to which has been added a substance that is an active ingredient in an approved drug product or a substance for which substantial clinical investigations have been instituted, and the existence of such investigations has been made public.³ Similarly, these types of substances are outside of the statutory definition of a dietary supplement. These provisions in our statute exist to protect patients and to preserve American patients’ access to the most safe and advanced pharmaceutical system in the world. I think everyone on this Committee can understand why, in general, adding drugs like

¹ <https://www.fda.gov/food/cfsan-constituent-updates/fda-responds-three-gras-notice-hemp-seed-derived-ingredients-use-human-food>

² <https://www.govinfo.gov/content/pkg/PLAW-111publ353/pdf/PLAW-111publ353.pdf>

³ See FD&C Act Section 301(l) and Section 201(ff)(3)(B)

blood pressure medicines or chemotherapeutics to foods, or to products marketed as dietary supplements, may not be in the best interests of American consumers and patients.

In June 2018, FDA approved the drug Epidiolex⁴ for treatment of seizures associated with two very rare and severe pediatric diseases. The approval of this medicine was a significant milestone for these patients and their families. The active ingredient in this drug is CBD. Based on both the approval of this drug, as well as previous substantial clinical investigations of CBD, CBD cannot be marketed as a dietary supplement, and foods to which CBD has been added cannot be introduced into interstate commerce under the FD&C Act. The FD&C Act provisions that prohibit adding an active drug ingredient to foods or marketing an active drug ingredient as a dietary supplement contain an exception if the drug was marketed in foods or dietary supplements before the drug was approved and before it was subject to substantial clinical investigations. The Agency is not aware of any evidence that CBD was marketed in foods or dietary supplements prior to it being subject to substantial clinical investigation. Therefore, FDA has concluded this exception does not apply to CBD.

The FD&C Act further allows for the Agency to make an exception through notice and comment rulemaking to one or both of the provisions that prohibit adding active drug ingredients to foods or marketing them as dietary supplements. It is important to note that it can take three to five years to complete even an expedited notice and comment rulemaking process that complies with the Administrative Procedure Act and other requirements. Completing a rulemaking requires the Agency to develop a robust record to support the rulemaking, including economic analyses, and to consider public comments, which can be voluminous when rulemakings concern substantive topics for which there is extensive public interest, as in the case of CBD.

Creating an exception for an active drug ingredient to be used in either foods or dietary supplements would make sense only if we could determine that products would be able to meet the other relevant safety standards in the FD&C Act, such as the food additive safety standards for human or animal foods, or the New Dietary Ingredient standards for dietary supplements. If

⁴ <https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms>

we were to create an exception under one provision of the FD&C Act, but other provisions of the statute still barred products from coming to market, our action could end up generating additional confusion in the marketplace – a result the Agency believes all stakeholders would prefer to avoid.

FDA recognizes that three to five years is a long time to wait for regulatory clarity, particularly given the significant public interest in hemp products, and CBD in particular. That is why, as I discuss in greater detail later in my testimony, the Agency is exploring options to reach a resolution more quickly and efficiently.

Cannabidiol (CBD)

It has only been seven months since the 2018 Farm Bill removed hemp, which includes low-THC derivatives of cannabis, such as CBD products, from the definition of marijuana in the CSA. I cannot overstate how significant of a policy sea change this has been. Prior to the enactment of the 2018 Farm Bill, the CSA did not differentiate between marijuana and hemp, and all cannabis (with certain exceptions, e.g. sterilized seeds and mature stalks of the plant) was a Schedule I substance and therefore controlled by the Drug Enforcement Administration (DEA). Early interest in clinical research was focused on the development of drugs using THC rather than CBD. More recently, interest in CBD as a drug is increasing, and, as discussed above, FDA approved Epidiolex in 2018, a drug for the treatment of two severe forms of childhood seizures.

The passage of the 2018 Farm Bill has led to the misperception that all products made from or containing hemp, including those made with CBD, are now legal to sell in interstate commerce. The result has been that storefronts and online retailers have flooded the market with these products, many with unsubstantiated therapeutic claims. FDA has seen CBD appear in a wide variety of products including foods, dietary supplements, veterinary products, and cosmetics. As this new market emerges, we have seen substantial interest from industry, consumers, and Congress. However, in the midst of the excitement and innovation, FDA's role remains the same: to protect and promote the public health.

At present, any CBD food or purported dietary supplement products in interstate commerce is in violation of the FD&C Act due to the statutory provisions discussed above. However, FDA's biggest concern is the marketing of CBD products that make unsubstantiated therapeutic claims to prevent, diagnose, mitigate, treat, or cure serious diseases, but have not obtained new drug approvals. For example, FDA has seen various CBD products with claims of curing cancer or treating Alzheimer's disease. The proliferation of such products may deter consumers from seeking proven, safe medical therapies for serious illnesses – potentially endangering their health or life. FDA's commitment to protect consumers from these unsubstantiated therapeutic claims does not just apply to CBD products – it is a longstanding commitment of the Agency across all the products we regulate.

FDA has issued numerous warning letters to firms selling unapproved CBD drug products with claims to treat or prevent serious diseases, and in fact, the Agency began doing this in 2015, prior to the passage of the 2018 Farm Bill⁵. It is also worth noting that, while investigating these unapproved CBD drug products, FDA identified other concerns. For example, laboratory analysis of some of these products revealed they did not contain the amount of CBD that was claimed on a product's label, and/or the products contained other substances that were not on the product's label, such as other cannabinoids like THC.

Through the approval of the CBD-containing drug Epidiolex, which was based on adequate and well-controlled clinical studies, FDA has learned that CBD is not a risk-free substance. During our review of the marketing application for Epidiolex, we identified certain safety risks, including the potential for liver injury⁶. In that context, the risks are outweighed by the benefits of the approved drug to the particular population for which it was intended.

The drug approval process offers significant benefits to prescribers and patients, including those who seek to prescribe or use hemp products for therapeutic purposes. Drug approvals generally

⁵ <https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products>.

⁶ https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/2103651bl.pdf

are based on adequate and well-controlled clinical studies, which gives prescribers and patients confidence in the drug's safety and effectiveness for its indicated use. In addition, approved drugs have uniform strength and consistent delivery that support appropriate dosing needed to treat patients, particularly patients with complex and serious conditions such as the epilepsy syndromes that Epidiolex was approved to treat. Moreover, patients using an approved prescription drug are under medical supervision to monitor any potential adverse effects of the drug. But for consumers purchasing the types of CBD products that are proliferating throughout the marketplace, these protective factors are generally not present.

FDA's Commitment to Sound, Science Based Policy on CBD

Given the substantial public, industry, and congressional interest in CBD, FDA has formed a high-level CBD Policy Working Group, which I co-chair along with Lowell Schiller, who is the Agency's Principal Associate Commissioner for Policy. The goal of the CBD Policy Working Group is to coordinate the Agency's approach to CBD policy making, including considering the appropriateness of potential pathways for dietary supplements and/or conventional foods containing CBD to be lawfully marketed.

The first priority of the CBD Policy Working Group has been to obtain and assess safety data for CBD, given the Agency's public health mission. Although FDA has approved one drug, Epidiolex, that contains CBD, Epidiolex is approved for use in a limited population at a specific dose, was studied for safety and efficacy in rigorous randomized clinical trials, and is available only by a prescription from a licensed medical professional. When considering the use of CBD in non-drug products, such as conventional foods and dietary supplements, FDA must evaluate different factors than for a prescription drug product. CBD food and dietary supplement products would be directly available to a wide range of consumers, which could potentially include pregnant or nursing mothers, children, the elderly, those with chronic illnesses, and those taking medications that might interact with CBD. CBD products could also be given to a wide variety of animal species, some of which are used for food. These would also be available without discussions with a doctor or other medical professional. Given this, FDA must consider

the potential safety implications of long-term use of CBD by different human and animal populations.

FDA is wrestling with questions not only about the intrinsic safety of CBD, but also about potentially unsafe manufacturing processes for products containing CBD. FDA knows from CBD products it has tested that they may not contain the amount of CBD indicated on a label, or they may contain other potentially dangerous compounds that are not listed on the label. Therefore, FDA must consider questions related to good manufacturing practices for CBD products and potential labeling that might be appropriate for these products to address any potential risks to consumers.

FDA has made it a priority to address these questions, and we are working diligently to make progress. However, FDA will only consider creating legal pathways for CBD to be marketed as a dietary supplement or in a food if the Agency is confident that it can develop a framework that addresses safety concerns. Another issue that FDA plans to consider is whether allowing CBD to be marketed as a dietary supplement or in a food will deter clinical research to substantiate additional therapeutic uses for cannabis-derived compounds. Less research into the promise of cannabis-derived compounds and fewer drug approvals in this area would be a significant loss for American patients.

Listening to and Learning from Stakeholders

As part of the Agency's commitment to engage the public on cannabis products and their derivatives, we held a public hearing on May 31, 2019. The goal of the public hearing was to obtain scientific data and information about the safety, manufacturing, product quality, marketing, labeling, and sale of products containing cannabis or cannabis-derived compounds. The hearing was attended in person by more than 600 people, with over 2,000 more viewing it on line, and included presentations from more than 100 speakers, representing a broad and diverse array of stakeholders, including patients, consumers, and their advocacy groups; health care providers; academia; manufacturers, retailers and distributors; agricultural coalitions; and state, tribal, and local government representatives.

The public hearing raised many issues, including the need for more and better data regarding the benefits and risks of CBD, concerns related to manufacturing, adulteration, and unlawfully marketed products, and even as simple as the need for consistent terminology related to cannabis products. We opened a public docket to collect comments as part of the public hearing, and it just closed on July 16, 2019. We received 4,492 comments submitted to the docket, which we have been reviewing. As this issue progresses, we are committed to being transparent with the public about our path forward and providing information that is based on sound science and data.

We recognize that hemp producers, the food and supplements industry, the pharmaceutical industry, retailers, academic institutions, patients, and consumers all want and need regulatory certainty in this area. The Agency has also put out several statements since the passage of the 2018 Farm Bill to keep the public informed about the current regulatory landscape and our efforts to consider the appropriateness of potential new pathways for cannabis products⁷. We also maintain a Questions and Answers page on cannabis products to help address questions from the public and our stakeholders⁸. We are committed to keep the public updated on this evolving area.

Working with our Federal, State, Tribal, and Local Partners

FDA recognizes that our approach to regulating hemp products must occur in close collaboration with our Federal, state, tribal, and local regulatory partners.

First, I would like to thank my counterparts from USDA and EPA who are also testifying today. FDA has strong relationships with these agencies, and we are working closely with them as USDA and states implement the hemp provisions in the 2018 Farm Bill.

⁷ <https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-committed-sound-science-based-policy-cbd>; <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-advance-agencys-continued-evaluation>; <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-signing-agriculture-improvement-act-and-agencys>.

⁸ <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers>.

FDA and USDA staff and leaders have participated in numerous meetings and conversations regarding cannabis issues. These include a recent conference with senior leaders from the USDA Agricultural Marketing Service Specialty Crops Program to discuss the agencies' respective roles and responsibilities. FDA and USDA remain in close communication on this issue.

FDA and EPA are engaged in sustained information sharing. For example, earlier this spring, FDA provided EPA's Office of Pesticide Programs with information regarding FDA's regulation of cannabis and cannabis-derived products, including information regarding the recent public hearing. FDA and EPA remain in communication on this issue and plan to further discuss together moving forward.

FDA has been working closely with our state, tribal, and local partners to assist them in navigating the regulation of hemp products, including those that contain CBD. A number of states, tribes, and local jurisdiction have enacted various laws that decriminalize or allow different types of cannabis compounds or products under state law. FDA is also aware that products that contain CBD have become available in these jurisdictions, as well as in jurisdictions that have not enacted any cannabis legalization-related legislation

We remain committed to moving forward on the regulation of hemp products in close coordination with our federal, state, and local partners.

Preserving Incentives for Research and Drug Development

While FDA is considering the possibility of new legal pathways for CBD products, we know that it is important to maintain adequate incentives for drug research and development. Drugs have important therapeutic value and are approved after rigorous scientific studies that provide important new information about therapeutic uses. It is critical that we continue to do what we can to support the science needed to develop new drugs from cannabis. To date, FDA has approved four drugs that contain active ingredients that are cannabinoids found in or related to

the cannabis plant. In addition to Epidiolex, which contains plant-derived purified CBD, and was approved for treating two rare forms of pediatric epilepsy, FDA has approved three drugs containing other cannabinoids for treating the side effects of chemotherapy, such as nausea⁹. Among these three products, two contain synthetically-derived dronabinol, which is chemically identical to THC, and the third contains nabilone, a synthetic chemical analogue of THC, not naturally occurring in cannabis.

FDA has also received feedback from stakeholders interested in conducting research with cannabis and CBD. FDA is committed to doing what we can to facilitate and preserve incentives for clinical research. We are concerned that widespread availability of CBD in products like foods or dietary supplements could reduce commercial incentives to study CBD for potential drug uses, which would be a loss for patients.

To conduct clinical research that could potentially lead to an approved new drug, researchers need to submit an Investigational New Drug application to the FDA's Center for Drug Evaluation and Research. For use as an animal drug product, researchers would establish an Investigational New Animal Drug file with the FDA's Center for Veterinary Medicine.

Because the 2018 Farm Bill removed hemp from the definition of marijuana in the CSA, this change may streamline the process for researchers to study certain cannabis derivatives that have no more than 0.3% THC by dry weight, including cannabinoids such as CBD, which could advance the development of new drugs from those substances.

Conclusion

The 2018 Farm Bill made tremendous changes to the regulation of hemp products, and FDA is fully committed to the work that lies ahead in this space. We are, and will continue to work quickly and efficiently. We recognize the significant interest and potential this crop has for farmers across the United States. FDA looks forward to keeping Congress and stakeholders

⁹ <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers>.

updated on our work to bring appropriate hemp products to market through existing regulatory pathways, as well as our efforts to determine whether additional regulatory frameworks are appropriate for products containing CBD. Our work on hemp products will continue to be founded in our public health mission and our commitment to making sound, science-based policy.

Thank you for the opportunity to discuss FDA's regulation of hemp products. I would be happy to answer any questions.