



**STATEMENT**

**OF**

**DOUGLAS C. THROCKMORTON, M.D.**  
**DEPUTY DIRECTOR FOR REGULATORY PROGRAMS**  
**CENTER FOR DRUG EVALUATION AND RESEARCH**

**FOOD AND DRUG ADMINISTRATION**  
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**BEFORE THE**

**SUBCOMMITTEE ON HEALTH**  
**COMMITTEE ON ENERGY AND COMMERCE**  
**U.S. HOUSE OF REPRESENTATIVES**

**“CANNABIS POLICIES FOR THE NEW DECADE”**

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**RELEASE ONLY UPON DELIVERY**

## INTRODUCTION

Chairwoman Eshoo, Ranking Member Burgess, and Members of the Subcommittee, I am Dr. Douglas Throckmorton, Deputy Director of the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to be here today to discuss the important role that FDA plays in research involving cannabis and cannabis-derived compounds for potential medical uses in the United States, as part of FDA's mission to protect and promote the public health by ensuring the safety, efficacy, and quality of medical products, including drugs.

FDA has an important role to play in supporting scientific research into the medical uses of cannabis and its constituents in scientifically valid investigations as part of the Agency's drug review and approval process. As a part of this role, FDA supports those in the medical research community who intend to study cannabis by:

1. Providing information on the process needed to conduct clinical research using cannabis.
2. Providing information on the specific requirements needed to develop a human drug that is derived from a plant such as cannabis. In December 2016, FDA updated its Guidance for Industry: Botanical Drug Development<sup>1</sup>, which provides sponsors with guidance on submitting investigational new drug (IND) applications for botanical drug products.

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<sup>1</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/botanical-drug-development-guidance-industry>

3. Providing specific support for investigators interested in conducting clinical research using cannabis and its constituents as a part of the IND process through meetings and regular interactions throughout the drug development process.
4. Providing general support to investigators to help them understand and follow the procedures to conduct clinical research through the FDA Center for Drug Evaluation and Research (CDER) Small Business and Industry Assistance group.

To conduct clinical research that can lead to an approved new drug, including research using materials from plants such as cannabis, researchers need to work with FDA and submit an IND application to CDER. The IND application process gives researchers a path to follow that includes regular interactions with FDA to support efficient drug development while protecting the patients who are enrolled in the trials. An IND includes protocols describing proposed studies, the qualifications of the investigators who will conduct the clinical studies, and assurances of informed consent and protection of the rights, safety, and welfare of the human subjects. FDA reviews the IND to ensure that the proposed studies, generally referred to as “clinical trials,” do not place human subjects at an unreasonable risk of harm. FDA also requires obtaining the informed consent of trial subjects and human subject protection in the conduct of the clinical trials.

To date, FDA has not approved a marketing application for cannabis for the treatment of any disease or condition. The Agency has, however, approved one cannabis-derived drug product: Epidiolex (cannabidiol), and three synthetic cannabis-related drug products: Marinol (dronabinol), Syndros (dronabinol), and Cesamet (nabilone). These approved drug products are

only available with a prescription from a licensed healthcare provider. Importantly, FDA has not approved any other cannabis, cannabis-derived, or cannabidiol (CBD) products currently available on the market.

FDA has programs such as Fast Track, Breakthrough Therapy, Accelerated Approval and Priority Review that are designed to facilitate the development of and expedite the approval of drug products. In addition, FDA's expanded access (sometimes called "compassionate use") statutory and regulatory provisions are designed to facilitate the availability of investigational products to patients with serious diseases or conditions when there is no comparable or satisfactory alternative therapy available, either because the patients have exhausted treatment with or are intolerant of approved therapies, or when the patients are not eligible for an ongoing clinical trial. Finally, recognizing the unique challenges presented by products derived from plants such as cannabis, FDA has established a Botanical Review Team that is available to assist with the development of plant-based drugs.

FDA continues to believe the drug approval process represents the best way to ensure that safe and effective new medicines, including any drugs derived from cannabis, are available to patients in need of appropriate medical therapy. The Agency is committed to supporting the development of new drugs, including cannabis and cannabis-derived drugs, through the investigational new drug and drug approval process.

Under section 202 of the Controlled Substances Act (CSA), certain types and parts of the *Cannabis sativa L.* plant are controlled under the drug class "marihuana." Schedule I includes

those substances that have a high potential for abuse, have no currently accepted medical use in treatment in the United States, and lack accepted safety for use under medical supervision. Nevertheless, Schedule I substances, including drugs that are derived from botanical sources such as cannabis, can be and are the subject of clinical trials under the Federal Food, Drug, and Cosmetic Act, provided, among other things, that the sponsor successfully submits an IND to FDA and successfully registers with the Drug Enforcement Administration (DEA).

In December 2018, the Agriculture Improvement Act of 2018 (also known as the Farm Bill) 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 CSA. Because the Farm Bill explicitly preserved FDA's authorities over hemp and other low-THC cannabis products, including cannabidiol (CBD), these 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 and CBD products to the extent such 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.

Nonetheless, the misperception persists 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 those purporting to be foods, dietary supplements, veterinary products, and cosmetics. As this new market emerges, we have seen substantial interest from industry, consumers, and Congress. However, FDA's role remains the same: to protect and promote the public health.

At present, any food containing CBD or purported CBD dietary supplement product in interstate commerce is in violation of the FD&C Act under the statutory provisions discussed above.

FDA's biggest concern is the marketing of CBD products that put consumers at risk, such as by making unsubstantiated therapeutic claims to prevent, diagnose, mitigate, treat, or cure serious diseases, but that 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.

There are also many unanswered questions about the science, safety, and quality of products containing CBD. The Agency is working on answering these questions through ongoing efforts including feedback from a recent FDA hearing and information and data gathering through a public docket. Although FDA has approved one drug, Epidiolex, that contains CBD, it is only 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. 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 populations.

Consumers should be aware of the potential risks associated with using CBD products. Some of these can occur without awareness, such as:

- ***Liver Injury:*** During its review of the marketing application for Epidiolex, FDA identified certain safety risks, including the potential for liver injury. This serious risk can be managed when an FDA-approved CBD drug product is taken under medical supervision, but it is less clear how it might be managed when CBD is used far more widely, without medical supervision, and not in accordance with FDA-approved labeling. Although this risk was increased when taken with other drugs that impact the liver, signs of liver injury were seen also in patients not on those drugs. The occurrence of this liver injury was identified through blood tests, as is often the case with early problems with the liver. Liver injury was also seen in other studies of CBD in published literature. We are concerned about potential liver injury associated with CBD use that could go undetected if not monitored by a healthcare provider.

- ***Drug Interactions:*** Information from studies of Epidiolex show that there is a risk of CBD impacting other medicines a consumer takes – or that other medicines could impact the dose of CBD that can safely be used. Taking CBD with other medications may increase or decrease the effects of the other medications. This may lead to an increased chance of adverse effects from, or decreased effectiveness of, the other medications. Drug interactions were also seen in other studies of CBD in published literature. We are concerned about the potential safety of taking other medicines with CBD when the consumer is not being monitored by a healthcare provider. In addition, there is limited research on the interactions between CBD products and herbs or botanicals in dietary supplements. Consumers should use caution when combining CBD products with herbs or dietary supplements.
- ***Male Reproductive Toxicity:*** Studies in laboratory animals showed male reproductive toxicity, including in the male offspring of CBD-treated pregnant females. The changes seen include decrease in testicular size, inhibition of sperm growth and development, and decreased circulating testosterone, among others. Because these findings were only seen in animals, it is not yet clear what these findings mean for humans and the impact it could have on men (or the male children of pregnant women) who take CBD. For instance, these findings raise the concern that CBD could negatively affect a man’s fertility. Further testing and evaluation are needed to better understand this potential risk.

In addition, CBD can cause side effects. These side effects should diminish when CBD is stopped or when the amount ingested is reduced. Side effects may include changes in alertness, most commonly experienced as somnolence (sleepiness), but this could also include insomnia; gastrointestinal distress, most commonly experienced as diarrhea and/or decreased appetite, but could also include abdominal pain or upset stomach; and changes in mood, most commonly experienced as irritability and agitation.

FDA is actively working to learn more about the safety of CBD and CBD products, including the risks identified above and other topics, such as:

- ***Cumulative Exposure:*** The cumulative exposure to CBD if people access it across a broad range of consumer products. For example, what happens if you eat food with CBD in it, use CBD-infused skin cream and take other CBD-based products on the same day? How much CBD is absorbed from your skin cream? What if you use these products daily for a week or a month?
- ***Special Populations:*** The effects of CBD on other special populations (e.g., the elderly, children, adolescents, pregnant and lactating women).
- ***CBD and Animals:*** The safety of CBD use in pets and other animals, including considerations of species, breed, or class and the safety of the resulting human food products (e.g., meat milk, or eggs) from food-producing species.

FDA is considering 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 we have 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 do so. We are also working diligently to consider whether and how legal pathways might be established to allow the safe marketing of certain dietary supplements and/or food products containing CBD.

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.

FDA appreciates this opportunity to discuss our work in the regulation of cannabis for potential medical uses in the United States, which is a part of FDA's core mission to protect and promote the public health by ensuring the safety, efficacy, and quality of medical products, including drugs. FDA will continue to use its available authorities to ensure that any such new therapies are safe, effective, and manufactured to a high quality, applying the drug development paradigm

that continues to provide new medicines that meet these standards for patients. This paradigm, grounded in rigorous scientific research, is essential to determining any appropriate uses of cannabis and its constituents in the treatment of human disease. The drug approval process remains the best way to identify new treatments that are safe and effective for patients and to protect patients from products that are not what they purport to be.

Thank you for your interest in this important topic, and I am happy to answer any questions.