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# FDA approves cannabis-derived drug

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On June 25, the Food and Drug Administration (FDA) approved Epidiolex, the first drug derived from cannabis in the United States. Epidiolex, produced by GW Pharmaceuticals (in the United Kingdom), is derived from cannabidiol (CBD), a non-psychoactive part of cannabis, which is intended to treat patients with Dravet and Lennox-Gastaut syndromes, two rare forms of epilepsy. Clinical trials have demonstrated that patients taking Epidiolex experience 40% less seizures.

Having been approved by the FDA, Epidiolex will now have to be approved by the Drug Enforcement Administration (DEA) before becoming available in jurisdictions that have legalized medical cannabis use. While legislation has been and is being introduced to change cannabis's current classification as a Schedule I drug with no medical value, CBD, like cannabis, requires DEA reclassification, which is expected to occur within the next 90 days.

While other drugs have been approved to treat Lennox-Gastaut syndrome, Epidiolex is the first also specifically approved for Dravet syndrome. Analysts anticipate that Epidiolex will also be prescribed off-label (for purposes it has not been officially approved for) to treat many epileptic diseases besides Dravet and Lennox-Gastaut syndromes. Additionally, experts believe that Epidiolex's approval will increase patient safety because it provides a regulated medication with standard dosing and supply to patients who were previously being treated with CBD at home, some without dosage guidance.

FDA Commissioner Scott Gottlieb stated that he believes the FDA's approval of Epidiolex demonstrates that the FDA is willing to support the development of medical treatments derived from cannabis ingredients. But, Gottlieb also emphasized how stringent Epidiolex's development process was and that Epidiolex's approval was not "an approval of [cannabis] or all of [cannabis'] components. This is the approval of one specific CBD medication for a specific use[,] [and that Epidiolex] is . . . being delivered to patients in a reliable dosage form and through a reproducible route of delivery to ensure that patients derive the anticipated benefits."

Nixon Peabody will continue to monitor Epidiolex's status and the classification of cannabis and will provide subsequent alerts as developments in the cannabis industry continue. To learn about

our experience advising clients on the ever-changing cannabis regulatory landscape, please contact:


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