Health Care Alert: FDA Approves First Drug Derived From Cannabis

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CLIENT ALERT | 6.26.2018

On June 25, 2018, the federal Food and Drug Administration (FDA) approved the first drug derived from the cannabis sativa plant, commonly known as marijuana.

This approval follows the unanimous recommendation of an FDA advisory committee, which in April found that clinical trials demonstrated the drug's effectiveness in reducing otherwise uncontrollable daily seizures caused by two rare forms of epilepsy, Lennox-Gastaut and Dravet syndromes. Known as Epidiolex, the drug is an oral solution of purified cannabidiol (CBD) and does not contain tetrahydrocannabinol (THC), the primary psychoactive component of the cannabis plant. It is the first recognized treatment for Dravet syndrome.

The immediate effect of this approval is limited: because CBD is a component of the cannabis plant, it is currently classified as a Schedule I substance and cannot be marketed in the United States. By definition, a Schedule I rating indicates that a drug has no medicinal value and a high risk of abuse – however, given the FDA's findings, the agency has requested that the Drug Enforcement Agency (DEA) reclassify CBD. Reclassification is expected within 90 days.

This milestone approval is significant for physicians in Ohio, as the state's medical marijuana program is scheduled to become effective in September 2018. The Board of Medicine has been accepting and approving physician certificates to recommend medical marijuana since April, but physicians have faced difficult dilemmas in considering whether to apply. Specifically, many have concerns about their ability to verify the effectiveness and safety of treatments in the absence of clinical trials and FDA approval, as well as the legal implications of recommending what is still considered a Schedule I substance under federal law. The approval of Epidiolex and pending reclassification of CBD may help address at least some of these threshold issues.

Notably, post-reclassification, manufacturers and marketers of products containing CBD will be subject to FDA regulations governing the claims they can make about the compound's benefits. These

regulations apply to print materials, internet advertisements, and even social media, and the FDA has indicated that it intends to pursue enforcement actions against individuals and companies that fail to comply.

For more information about the FDA's approval of Epidiolex, Ohio's medical marijuana program, and/or FDA regulations governing the labeling and advertising of supplements containing CBD, please contact Jolie N. Havens, Elizabeth T. Smith, Mairi K. Mull, or your Vorys attorney.