

From the University of Mississippi Medical Center Division of Public Affairs

STATEMENT ON THE AVAILABILITY OF CANNABIDIOL OIL

The Mississippi Legislature passed legislation in April approving the University of Mississippi Medical Center to dispense cannabidiol oil (CBD) for the treatment of epileptic seizures in children. However, major regulatory requirements still exist before patients could receive the potential treatment in a carefully controlled clinical trial.

Those requirements fall broadly into three categories: Securing federal regulatory approval to grow the variant of low-THC, high-CBD marijuana from which the oil is extracted, process and transport it. Secondly, FDA approval for the manufacturing and clinical plan will require an investigational new drug approval. The third requirement is to initiate the clinical trial, with all the requisite safeguards, to enroll candidate children and test the oil's efficacy and safety.

Faculty and staff members at both the University of Mississippi and the Medical Center are moving forward on those three tracks simultaneously. For example, the National Center for Natural Products Research at the UM School of Pharmacy has recently gained approval from two federal agencies to grow a certain quota of the particular strain.

However many requirements remain ahead and meeting them could take a year or more. Anecdotal evidence suggests CBD oil may be effective for intractable epilepsy in children. However, rigorous and formal research studies in humans need to be conducted to establish the oil's effectiveness and safety.

Any such clinical trial established at UMMC would initially involve children with refractory or more serious types of epilepsy. There are no current plans to study the effectiveness of CBD oil or smoked marijuana on seizure activity in adults. Nor do neurologists at UMMC feel that smoked marijuana – whether medical or recreational – currently has a place in treating epilepsy.

The regulatory requirements for growth, production and use of CBD oil, and the safety measures involved in establishing a clinical trial are both significant and in place with good reason.

We understand the urgency and immediate need for improved treatments and are moving forward under that motivation. At the same time, our efforts are balanced by great measures of care, safety and compliance with current laws and the safety of the patients.

If and when regulatory requirements are met and clinical-trial setup is complete, enrollment of appropriate patients will begin.

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The University of Mississippi Medical Center, located in Jackson, is the state's only academic medical center. UMMC encompasses five health science schools, including medicine, nursing, health related professions, dentistry and graduate studies, as well as the site where University of Mississippi pharmacy students do their clinical training. The Medical Center's health-care enterprise includes five hospitals and University Physicians, the faculty group practice. The Medical Center's threefold mission is to educate tomorrow's health-care professionals, conduct innovative research to improve human health, and to provide the highest quality care available to the state's population. A major goal of the Medical Center is the improvement of the health of Mississippians and the elimination of health disparities. For more information, contact the Division of Public Affairs at (601) 984-1100 or click [here](#).