MRO ADVISORY:

DATE: November 26, 2018

FROM: Theodore F. Shults

RE: Report of Oral in-vivo Conversion of CBD to Delta9-Tetrahydrocannabinol

NOTE: MROs must follow the current DOT rules and HHS Mandatory guidelines

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Recent unpublished laboratory data and anecdotal reports indicate that a small but not insignificant amount of CBD oil can be converted in vivo to THC. This conversion appears to happen in the stomach due to its acidic environment. (see Chemistry). This issue is actively being studied by SAMHSA/CSAP in conjunction with John Hopkins University. It is also being studied by CBD manufacturers. The CBD-THC conversion appears to be simple and real. ***It is anticipated this information will quickly go viral and become the standard defense for all positive THC results.***

The new finding is also significant in a number of other ways. First, earlier this year the FDA approved the drug Epidiolex (CBD, cannabidiol) to treat seizures in people with Lennox-Gastaut syndrome and Dravet syndrome. DEA has subsequently rescheduled Epidiolex as a Schedule V chemical on the Federal Controlled Substances Act.

CBD remains on the Schedule I list but has been decriminalized in a number of states for treatment of a spectrum of medical disorders. Second, a number of lawsuits have been filed against manufactures of CBD oil from customers who relied on the labeling that the product contained only trace amounts of THC or none at all.

Federally Mandated Drug Testing:

MROs must follow the current DOT rules and HHS Mandatory guidelines.

There is inadequate information available at this time to establish data-based rules, thresholds and guidelines in the federal programs.

Following the federal regulations in respect to drug testing is an absolute defense to any allegations of negligence or malpractice.

There may be changes in guidelines and regulations in the future but right now the existing rules are in force. Keep in mind that CBD oil (which appears to be broadly used) is still a Schedule I drug; with respect to the recently approved Epidiolex, the only FDA approved use is in children with serious seizures. (However, like all other drugs it can be prescribed and used off-label).

Non-Regulated Drug Testing:

The MRO's defense of following federal regulations is not absolute one in non-regulated drug testing. Thus, in respect to a positive THC laboratory finding and a verified **Epidiolex** prescription, in the absence of any guidelines or employer policy to the contrary, **Epidiolex** drug should be treated like a Marinol prescription: report a negative result with the possibility of the MRO reporting a safety sensitive concern.

In respect to non-regulated CBD oil, the key issue is to allow the employer to address the policy issue of accepting of not accepting CBD as an alternative explanation for THC. Keep in mind that over a dozen states have authorized a variety of formulas of CBD for a variety of medical conditions.

Recently two MROs called to see if there were any new updates on CBD oil. The MROs were in the verification process for THC positives for non-DOT employees. In one case the donor was a maintenance supervisor and in the second case the donor was a senior police officer. Both jobs were safety-sensitive, and both donors claimed significant CBD use for appropriate conditions. Both reside in states that allow the use of CBD. Given the updated information, both MROs decided to report the laboratory results **"AS IS"** to the DERs. This means reporting the "positive lab results for THC" *with the explanation that CBD cannot be ruled out* as the cause of the positive results.

In a private employer drug-testing environment, an MRO with a positive THC and a donor's claim of using CBD oil, the MRO should consult with the employer. CBD oil is still a Schedule I compound, but state law and the employer should be considered. In the absence of any employer policy or guidance, the **"AS IS"** approach outlined above is recommended.

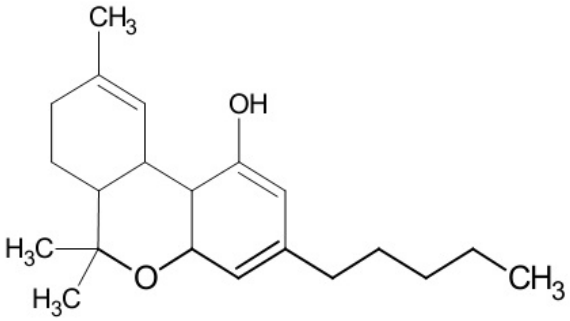
CBD oil has been decriminalized in many states, some of which do not have medical marijuana acts or recreational use statutes.

Chemistry of the CBD-THC Conversion

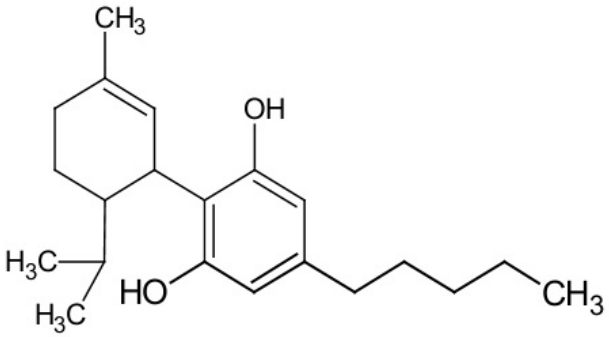
There has been speculation about the CBD-THC biochemical conversion for a number of years because THC findings were common with CBD use. But the ultimate issue remained unclear since most CBD products contain trace or residual levels of THC.

The new findings are significant and conclusive in that the laboratory study used pure synthetic CBD that contained no THC.

The organic chemistry is straightforward:



Tetrahydrocannabinol (THC)



Cannabidiol (CBD)

There are patents on how to convert THC to CBD. This involves the oxidation of THC. The reverse route simply involves hydrolyzing the hydroxide on the center ring and having it close up.

Keep in mind that this is CBD that is taken orally and that the level of THC in urine is relatively low and probably undetectable in routine blood and oral fluid tests, at least for the parent THC. This appears to be another strong argument for the implementation of Oral Fluid Testing (for parent THC).

There is also a lot of individual variability in the amount of THC detected in urine. This may be due to "how acidic" the stomach is or whether the CBD was consumed on an empty stomach or with food.

cc:

Substance Abuse and Mental Health Services Administration (SAMHSA)

Department of Transportation (DOT)

Nuclear Regulatory Commission (NRC)