

Mr. Chairman, members of the Commission on Narcotic Drugs, honored Guests, thank you for giving me this time to speak. I am John Redman CEO of CADFY, a drug prevention organization founded nearly 4 decades ago, that has been engaged in developing and supporting policies focusing specifically on reducing youth substance abuse. We are speaking to you today over concerns regarding the World Health Organizations recommendations on Cannabis.

In June and November of 2018, the WHO's Expert Committee on Drug Dependence (ECDD) conducted a critical review of cannabis and cannabis-related substances. Following ECDD's review in recommendation 5.5 it read: "Preparations containing predominantly cannabidiol and not more than 0.2 percent of delta-9-tetrahydrocannabinol **are not under international control.**" As grounds for its recommendation, the ECDD stated that cannabidiol is used to treat childhood epilepsy and ...is not psychoactive and there is no evidence of dependence or abuse."

While the time and effort ECDD has dedicated to its review is to be commended, recommendation 5.5 should be in question. The **ECDD should reconsider the scope of its proposed recommendation** given the current state of CBD research and evidence demonstrating important drug to drug interactions (DDI) and side effects such as liver toxicity. The ECDD should at least consider accompanying the proposed language with a recommendation that each of its Member States institute a comprehensive regulatory framework for the review, approval, and marketing of CBD products that will promote uniform interpretation throughout the Member States and prevent confusion and risks to public health and safety.

It is important to point out that ECDD's recommendation is based on the perception that CBD is generally a benign naturally occurring substance.

However, that perception is not supported by currently available research, which demonstrates that CBD is a drug not only with therapeutic effects, but with side effects and with drug interactions that should be acknowledged and addressed through appropriate controls, such as regulatory assessment for quality and safety and, in some instances, physician supervision.

The fact is that CBD is not a benign drug and has been shown to have numerous side effects. At issue is the balance of Benefit vs. Risk.

The National Library of Medicine yields at least 148 peer reviewed publications regarding cannabidiol in scientific journals. The current peer-reviewed scientific literature does not support the assertion that cannabidiol from these sources is free of side effects. In fact, it has been shown that there are a number of side effects including:

Anxiety, Weight gain, Insomnia, Vomiting, Nausea, Aggressive Behavior, Irritability, confusion, Fatigue, Somnolence, Gastrointestinal Disturbances...

And in 10% of cases...liver toxicity

In the United States, the only FDA-approved CBD drug therapy, Epidiolex[®], was studied in controlled trials, which revealed that CBD can cause drug-induced liver injury. Interactions with other drugs, such as warfarin, a commonly used anticoagulant, may occur, even at low doses.

Considering the known side effects of CBD and the need for continuing research, CADFY believes that a comprehensive regulatory framework is paramount to ensuring the safe utilization of pharmaceutical and non-pharmaceutical CBD products. Appropriate regulation of CBD will help ensure quality and consistency in CBD products, help mitigate risk associated with side effects, and ensure tracking and reporting of adverse events. A critical part of any regulatory framework is a pre-

market approval process for drug products by an appropriate regulatory authority, such as the FDA in the United States or the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom. These authorities ensure that safety and efficacy data support approval and marketing as a drug before pharmaceutical products reach patients.

Additionally, for non-pharmaceutical CBD products, other Member State regulatory bodies should act to ensure the quality, stability, and purity of each product by requiring Good Manufacturing Practices, including accurate testing and labeling; setting safe dosing and concentration levels; limiting therapeutic claims; and requiring reporting of adverse events. Absent this type of comprehensive regulatory framework, consumers purchasing non-pharmaceutical CBD will be at risk of using misleadingly marketed, unsafe, poor quality products that may contain excessive and potentially harmful amounts of THC.

CADFY Again strongly recommends that the **ECDD reconsider the scope of its proposed recommendation** given the current state of CBD research.