

To: Whom It May Concern

From: Kathleen Kennedy, PhD, MS

Date: February 3, 2023

Re: Maryland Recreational Use THC Dosing

By way of introduction, I am Dr. Kathleen Kennedy, former Director of Life Sciences Institute at the University of Maryland BioPark, Professor of Genetics, and retired Dean at BCCC. I am also a recent graduate of the University of Maryland School of Pharmacy's Master of Science degree in "Medical Cannabis Science and Therapeutics." I am currently a consultant to various licensed cannabis grow, process, and dispensaries. Finally, I created CannaWorkforce, a Maryland EARN Grant recipient company that trains persons, specifically minority women, for entry level jobs in the cannabis industry.

The purpose of this letter is to discuss the proposed dosing regulations for the Maryland recreational market (0.5mg/serving, 2.5mg/package). These amounts appear to be based on; a) an FDA approved synthetic cannabinoid Marinol at 2.5mg and b) a consensus-based paper (Bhaskar et al, 2021) on how to dose and administer medical cannabis in patients with chronic pain. While knowing synthetic dosing, and consensus dosing information is useful, these should not be considered definitive as; a) synthetics are not directly relational to natural compounds, and b) the study was intended solely for chronic pain and no other conditions (e.g., multiple sclerosis, nausea, vomiting, migraine, etc.).

A drug dose used in all FDA applications is the "LD50." This numerical calculation is the dose of a drug (e.g. THC) that is lethal in 50% of test animals. It is always expressed in milligrams per kilogram (mg/Kg) of body weight, and is especially useful when there is limited other toxicology data available. New drugs must be safe and effective at concentrations less than the LD50. The LD50 for THC (other than I.V.) ranges from 800 - 1270 mg/kg (Rosencrantz, 1974). This means the dose for a 165-pound person (75 Kg) should not exceed 60,000 - 95,250mg, or "30,000-times more than the proposed 2.5mg. In plain English, the LD50 demonstrates that "lethal dose" is so extremely high that for all practical purposes, it is not a medical concern. Therefore, in the same paper mentioned above, industry experts wrote that since the LD50 dose is extreme, they suggest "a maximum daily dose of 40mg/day of THC." This amount, which is "2,000-times less than the LD50, is still 16-times higher than the proposed 2.5mg.

The real concern is that the current proposed maximum doses are limiting and may be grossly insufficient to address the multitude of cannabis patient needs, as cannabis, unlike other drugs, affects people differently. Also, since reliable, rapid, and reasonably priced testing for all cannabinoids isn't available, limiting products to only naturally occurring is unrealistic. This was one of the very reasons the FDA has approved synthetic THC drugs.

In conclusion, please reconsider the THC dosing requirements, as well as requirements pertaining to synthetic vs naturally occurring.