MARIJUANA USED AS A MEDICINE

We only recognize medicines that are produced and distributed with standard best-practice pharmaceutical protocols and that are approved by the U.S. Food and Drug Administration (FDA). Unless a marijuana/cannabis product (including CBD) has been approved for marketing as a medicine by the FDA under the federal Food, Drug and Cosmetic Act (FDCA), it is neither safe or effective and puts patients at risk if it is intended "for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or because they are intended to affect the structure or any function of the body." [1]

When a medicine's benefits outweigh its known risks, the FDA considers it "safe" enough to approve. A drug is "effective" within meaning of FDCA if there is general recognition among experts, founded on substantial evidence, that the drug in fact produces results claimed for it under prescribed conditions. [2]

Marijuana products sold as medicines or treatments or marijuana infused food or supplements not approved by the FDA are black-market and are illegally trafficked and sold. AALM does not agree with applying the term "medical" when it comes to these black-market products that are not approved by the FDA. We consider black-market marijuana or CBD marketing and sales as illicit drug dealing.

The sale and dispensing of marijuana even when approved by medical care providers or state law should not be done unless there is FDA approval. Scientific evidence, research, double blind studies and FDA approval determine what is and is not medicine.

The US Surgeon General has stated that "There is no such thing as "medical" marijuana" unless and until it has been approved by the FDA. [4]

We oppose "legalizing" any of these products not previously approved by the FDA.

- $1.\ 21\ U.S.C.\ \S\ 321(g)(1).\ \underline{https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products}$
- 2. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321(g)(1) and (p); 21 U.S.C. 331 and 355(b)(1) (drug must be safe and effective in use). http://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis; http://www.fda.gov/news-events/press-announcements/fda-advances-work-related-cannabidiol-products-focus-protecting-public-health-providing-market
- 3. Gonzales v. Raich, 545 U.S. 1 (2005); United States v. Rutherford, 442 U.S. 544 (1979).
- 4. https://m.youtube.com/watch?v=YeVs7aTh9vw

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