## James L. Madara, MD





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The Honorable Robert M. Califf, MD Commissioner U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993 The Honorable Lina M. Kahn, JD Chair Federal Trade Commission 400 Seventh Street, SW Washington, DC 20024

Dear Commissioner Califf and Chairwoman Kahn:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing regarding updated AMA policy resulting from a recent meeting of the AMA House of Delegates, specifically concerning the marketing of cannabis for medical use. Marketing of cannabis for medical uses outside the context of a Food and Drug Administration (FDA)-approved or -cleared drug has long been a concern of AMA members, especially given the lack of federal regulation of these products. We would like to support and encourage any additional action that can be taken by either the FDA or Federal Trade Commission (FTC) to protect consumers and combat marketing of unapproved medical claims for cannabis.

As you know, cannabis is frequently marketed by the use of poorly substantiated health claims. Cannabis companies, whether operating in states where recreational use has been legalized or in those where the only legal use is for medical purposes, have frequently made claims that use of cannabis-based products can treat or cure conditions such as cancer, gastrointestinal disease, mental health disorders, chronic pain, chronic inflammation, and others. Unfortunately, there is currently little available evidence to demonstrate safe and effective use of these products for these purposes, and in some cases these claims are completely fabricated and with no supporting evidence at all. These same companies frequently rely on unregulated social media and internet-based blog posting to help disseminate these health claims in a manner more challenging to regulate.

Regardless of a product's legal/regulated status, the AMA has serious concerns regarding the proliferation of unsubstantiated health claims for unapproved drug products. Allowing for the marketing of evidence of health claims outside of those validated through robust clinical trials has serious impacts for all patients who may use cannabis and cannabis-based products. These concerns are obviously heightened when they concern a product currently not subject to any federal oversight or regulation.

At a time when trust in science and medicine is suffering, we must do everything we can to ensure the integrity of our regulatory system, the quality and safety of our drug products, and the safety of our patients. As such, we must ensure that individuals with financial interests in certain products are not allowed to make misleading or unsubstantiated claims that cannabis products can offer treatments or relief from symptoms that they do not have the evidence to substantiate.

We thank FDA and FTC for their work on this issue and strongly urge both agencies to continue to utilize all currently available authorities to regulate marketing of these products. Please do not hesitate to contact

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Shannon Curtis at <u>Shannon.Curtis@ama-assn.org</u> with any questions or if we can be of any assistance in this matter. We look forward to working with you both to ensure our nation's drug products are safe and effective for our patients.

Sincerely,

James L. Madara, MD