**OKLAHOMA STATE MEDICAL ASSOCIATION HOUSE OF DELEGATES**

 **Resolution 5: A-2023**

**Introduced by:** Woody Jenkins MD

**Subject:** Marijuana Product Safety

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**WHEREAS,** Physicians prioritize patient safety, and the American Medical Association Code of Medical Ethics underscores its commitment "to promote the art of medicine and the betterment of public health," and

**WHEREAS**, there are many legal implications due to the passage of state marijuana laws and the associated regulations passed by State Departments of Health; and

**WHEREAS**, current AMA policy, Cannabis and Cannabinoid Research H-95.952, calls for adequate and well-controlled studies of marijuana and urges that marijuana's status as a federal schedule I controlled substance be reviewed with the goal of facilitating the conduct of clinical research; and

**WHEREAS**, current AMA policy, Cannabis Legalization for Medicinal Use , D-95.969 states:  Our AMA (3) will develop model legislation requiring the following warning on all cannabis products not approved by the U.S. Food and Drug Administration: "Marijuana has a high potential for abuse. This product has not been approved by the Food and Drug Administration for preventing or treating any disease process."; and

**WHEREAS**, to date, the FDA has not approved a marketing application for cannabis for the treatment of any disease or condition (1); and

**WHEREAS**, the FDA has, approved one cannabis-derived drug product: Epidiolex (cannabidiol)(oral solution for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome), and three synthetic cannabis-related drug products: Marinol (dronabinol), Syndros (dronabinol), and Cesamet (nabilone)(1)(2); and

**WHEREAS**, the FDA is aware that some companies are marketing products containing cannabis and cannabis-derived compounds in ways that violate the Federal Food, Drug and Cosmetic Act (FD&C Act) and that may put the health and safety of consumers at risk(3); and

**WHEREAS**, the FDA is committed to protecting the public health while also taking steps to improve the efficiency of regulatory pathways for the lawful marketing of appropriate cannabis and cannabis-derived products (3); and

**WHEREAS**, under the drug application process, a sponsor of a nonprescription drug submits a New Drug Application (NDA) or an Abbreviated New Drug Application (ANDA) to FDA for approval with the sponsor not able to market the nonprescription drug until FDA approves the NDA or ANDA (4); therefore be it

**RESOLVED,** that the American Medical Association supports the policy against marijuana use, either medical or recreational, until such time scientifically valid and well-controlled clinical trials are done to assess the safety and effectiveness as any new drug for medical use, prescription or nonprescription; and be it further

**RESOLVED,** that the American Medical Association Council on Legislation draft state model legislation for states that have legalized “medical” or “recreational” marijuana that (1) prohibit dispensaries from selling marijuana products if they make any misleading health information and/or therapeutic claims, (2) to require dispensaries to include a hazardous warning on all marijuana product labels similar to tobacco and alcohol warnings and (3) ban the advertising of marijuana dispensaries and marijuana products in places that children frequent.

And be it further, **Resolved,** that this resolution be transmitted to the American Medical Association for consideration at the 2023 Annual Meeting.

**References**:

1. <https://www.fda.gov/news-events/public-health-focus/fda-and-cannabis-research-and-drug-approval-process>
2. <https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms>
3.
4. <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd>
5. <https://www.fda.gov/drugs/special-features/how-fda-strives-ensure-safety-otc-products>

**Relevant AMA Policy**

**Cannabis and Cannabinoid Research H-95.952**

1. Our AMA calls for further adequate and well-controlled studies of marijuana and related cannabinoids in patients who have serious conditions for which preclinical, anecdotal, or controlled evidence suggests possible efficacy and the application of such results to the understanding and treatment of disease.

2. Our AMA urges that marijuana's status as a federal schedule I controlled substance be reviewed with the goal of facilitating the conduct of clinical research and development of cannabinoid-based medicines, and alternate delivery methods. This should not be viewed as an endorsement of state-based medical cannabis programs, the legalization of marijuana, or that scientific evidence on the therapeutic use of cannabis meets the current standards for a prescription drug product.

3. Our AMA urges the National Institutes of Health (NIH), the Drug Enforcement Administration (DEA), and the Food and Drug Administration (FDA) to develop a special schedule and implement administrative procedures to facilitate grant applications and the conduct of well-designed clinical research involving cannabis and its potential medical utility. This effort should include: a) disseminating specific information for researchers on the development of safeguards for cannabis clinical research protocols and the development of a model informed consent form for institutional review board evaluation; b) sufficient funding to support such clinical research and access for qualified investigators to adequate supplies of cannabis for clinical research purposes; c) confirming that cannabis of various and consistent strengths and/or placebo will be supplied by the National Institute on Drug Abuse to investigators registered with the DEA who are conducting bona fide clinical research studies that receive FDA approval, regardless of whether or not the NIH is the primary source of grant support.

4. Our AMA supports research to determine the consequences of long-term cannabis use, especially among youth, adolescents, pregnant women, and women who are breastfeeding.

5. Our AMA urges legislatures to delay initiating the legalization of cannabis for recreational use until further research is completed on the public health, medical, economic, and social consequences of its use.

6. Our AMA will advocate for urgent regulatory and legislative changes necessary to fund and perform research related to cannabis and cannabinoids.

7. Our AMA will create a Cannabis Task Force to evaluate and disseminate relevant scientific evidence to health care providers and the public.

**CBD Oil Use and the Marketing of CBD Oil H-95.911**

Our AMA supports: (1) banning the advertising of cannabidiol (CBD) as a component of marijuana in places that children frequent; and (2) legislation and regulatory actions at the federal and state level to prohibit companies from selling CBD products if they make any unproven health and therapeutic claims.

**Cannabis Legalization for Medicinal Use D-95.969**

Our AMA: (1) believes that scientifically valid and well-controlled clinical trials conducted under federal investigational new drug applications are necessary to assess the safety and effectiveness of all new drugs, including potential cannabis products for medical use; (2) believes that  cannabis for medicinal use should not be legalized through the state legislative, ballot initiative, or referendum process; (3) will develop model legislation requiring the following warning on all cannabis products not approved by the U.S. Food and Drug Administration: "Marijuana has a high potential for abuse. This product has not been approved by the Food and Drug Administration for preventing or treating any disease process."; (4) supports legislation ensuring or providing immunity against federal prosecution for physicians who certify that a patient has an approved medical condition or recommend cannabis in accordance with their state's laws; (5) believes that effective patient care requires the free and unfettered exchange of information on treatment alternatives and that discussion of these alternatives between physicians and patients should not subject either party to criminal sanctions; (6) will, when necessary and prudent, seek clarification from the United States Justice Department (DOJ) about possible federal prosecution of physicians who participate in a state operated marijuana program for medical use and based on that clarification, ask the DOJ to provide federal guidance to physicians; and (7) encourages hospitals and health systems to: (a) not recommend patient use of non-FDA approved cannabis or cannabis derived products within healthcare facilities until such time as federal laws or regulations permit its use; and (b) educate medical staffs on cannabis use, effects and cannabis withdrawal syndrome.