AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 933
(I-19)

Introduced by: Maryland

Subject: Supporting Research Into the Therapeutic Potential of Psychedelics

Referred to: Reference Committee K

Whereas, Psychedelics are a class of drugs that produce mind-altering states, which includes psilocybin, lysergic acid diethylamide (LSD), and mescaline[1]; and

Whereas, Between 1950-1965, research into the therapeutic effects of psychedelics produced over 1,000 scientific papers and six international conferences, with promising results for alcoholism, depression, and a variety of other mental disorders[1]; and

Whereas, In the late 1960s, this promising research was halted when the FDA scheduled psychedelics as Schedule 1 drugs, due to both the dangers associated with their unregulated use and their association with the "counterculture" movement[1]; and

Whereas, There has been a recent resurgence of interest in the therapeutic application of psychedelics for patients with depression, anxiety, addiction, and a host of other psychiatric conditions[1]; and

Whereas, Despite their reported dangers in unregulated situations, such as accidental traumatic injuries, psychedelics have proven to be notably safe when administered in a regulated environment, with no long-term physical effects, tissue toxicity, or interference with liver function; scant drug–drug interaction[2]; and limited addictive properties[2-4]; and

Whereas, Studies have reported subjects who experience acute negative emotions after psychedelic use (paranoia, anxiety, etc), these emotions are short lasting and rarer in incidence than positive emotions[5]; and

Whereas, There is little evidence of adverse effects of psychedelics in habitual users, who use more often and use at a larger dose than experimental studies, and as of now, no evidence of persistent perceptual disturbances, known as 'hallucinogen persisting perceptual disorder' (HPPD)[5]; and

Whereas, A large population study in the USA found no link between the use of psychedelics and any mental health problems[6]; and

Whereas, The therapeutic index (TI) of both LSD and psilocybin is at least 1000, which is notably higher than that of morphine (TI = 70) and alcohol (TI = 10)[7,8]; and

Whereas, A number of prominent researchers and physicians have spoken out in support of expanding research on psychedelics[9]; and

Whereas, LSD led to a 22% reduction in STAI (State-Trait Anxiety Inventory) state anxiety at 2 months in patients with a life-threatening illness, and reductions was sustained through 12 months[10]; and

Whereas, Psilocybin has been associated with a 55% reduction in Beck Depression Inventory (BDI) scores at 3 months in patients with Major Depressive Disorder, remission of depression by BDI in 60-80% of patients with life-threatening cancer at 6.5 months, a 44% reduction in Yale-Brown Obsessive Compulsive score at 24 hours in patients with Obsessive-Compulsive disorder, an 80% abstinence rate at 6 months for smoking cessation and a 68% reduction in heavy drinking at 13-24 weeks for treatment of substance use disorders[11-15]; and

Whereas, In a randomized double-blind study of 51 participants with anxiety and depression associated with life-threatening cancer, a one-time psilocybin administration with guided therapy resulted in a 50% reduction in symptoms at 6 months post treatment in 78% of patients for anxiety, and 83% of patients for depression[16]; and

Whereas, Phase 2 trials testing MDMA with 107 participants with PTSD, 56% no longer qualified for PTSD after treatment with MDMA-assisted psychotherapy, and 12-months later, 68% no longer had PTSD[17]; and

Whereas, The current classification of psychedelic compounds as Schedule 1 means that their use is prohibited except for very limited scientific research studies requiring an extensive and costly approval process[4,6]; and

Whereas, Drugs are considered Schedule 1 if they meet three criteria: first, the drug or other substance has a high potential for abuse; second, the drug or other substance has no currently accepted medical use in the United States; and third, there is a lack of accepted safety for use of the drug or other substance under medical supervision[4]; and

Whereas, Current AMA policies regarding the regulation of “psychoactive” and “psychotropic” drugs only emphasize the health risks associated with such drugs and do not address the previously stated contemporary research showing their therapeutic potential, their limited addictive risk, and their limited risk when delivered in a controlled, regulated environment[1-17] (H-95.940); and

Whereas, Our AMA already has policy encouraging rescheduling of and research into other pharmaceuticals such as cannabis and cannabinoids (H-120.926 and H-95.952); and

Whereas, The AMA MSS has adopted this resolution into their policies; therefore be it

RESOLVED, That our American Medical Association work to establish a waiver process for psychedelics as Schedule 1 substances with the goal of facilitating clinical research. (Directive to Take Action)

Fiscal Note: Not yet determined

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RELEVANT AMA POLICY

Expedited Prescription Cannabidiol Drug Rescheduling H-120.926
Our AMA will: (1) encourage state controlled substance authorities, boards of pharmacy, and legislative bodies to take the necessary steps including regulation and legislation to reschedule U.S. Food and Drug Administration (FDA)-approved cannabidiol products, or make any other necessary regulatory or legislative change, as expeditiously as possible so that they will be available to patients immediately after approval by the FDA and rescheduling by the U.S. Drug Enforcement Administration; and (2) advocate that an FDA-approved cannabidiol medication should be governed only by the federal and state regulatory provisions that apply to other prescription-only products, such as dispensing through pharmacies, rather than by these various state laws applicable to unapproved cannabis products.
Citation: Res. 502, A-18;

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.
Citation: CSA Rep. 10, I-97; Modified: CSA Rep. 6, A-01; Modified: CSAPH Rep. 3, I-09; Modified in lieu of Res. 902, I-10; Reaffirmed in lieu of Res. 523, A-11; Reaffirmed in lieu of Res. 202, I-12; Reaffirmed: CSAPH Rep. 2, I-13; Modified: CSAPH Rep. 05, I-17; Reaffirmed in lieu of: Res. 434, A-19;

Harm Reduction Through Addiction Treatment H-95.956
The AMA endorses the concept of prompt access to treatment for chemically dependent patients, regardless of the type of addiction, and the AMA will work toward the implementation of such an approach nationwide. The AMA affirms that addiction treatment is a demonstrably viable and efficient method of reducing the harmful personal and social consequences of the inappropriate use of alcohol and other psychoactive drugs and urges the Administration and Congress to provide significantly increased funding for treatment of alcoholism and other drug dependencies and support of basic and clinical research so that the causes, mechanisms of action and development of addiction can continue to be elucidated to enhance treatment efficacy.
Citation: (Res. 411, A-95; Appended: Res. 405, I-97; Reaffirmation I-03; Reaffirmed: CSAPH Rep. 1, A-13)

Emerging Drugs of Abuse are a Public Health Threat D-95.970
Our AMA will participate as a stakeholder in a Centers for Disease Control and Prevention/U.S. Drug Enforcement Administration (CDC/DEA) taskforce for the development of a national forum for discussion of new psychoactive substances (NPS)-related issues.
Citation: CSAPH Rep. 02, A-17; Reaffirmed in lieu of: Res. 512, A-18;

Addressing Emerging Trends in Illicit Drug Use H-95.940
Our AMA: (1) recognizes that emerging drugs of abuse, especially new psychoactive substances (NPS), are a public health threat; (2) supports ongoing efforts of the National Institute on Drug Abuse, the Drug Enforcement Administration, the Centers for Disease Control and Prevention, the Department of Justice, the Department of Homeland Security, state departments of health, and poison control centers to assess and monitor emerging trends in illicit drug use, and to develop and disseminate fact sheets, other educational materials, and public awareness campaigns; (3) supports a collaborative, multiagency approach to addressing emerging drugs of abuse, including information and data sharing, increased epidemiological surveillance, early warning systems informed by laboratories and epidemiologic surveillance tools, and population driven real-time social media resulting in actionable information to reach stakeholders; (4) encourages adequate federal and state funding of agencies tasked with addressing the emerging drugs of abuse health threat; (5) encourages the development of continuing medical education on emerging trends in illicit drug use; and (6) supports efforts by federal, state, and local government agencies to identify new drugs of abuse and to institute the necessary administrative or legislative actions to deem such drugs illegal in an expedited manner.
Citation: Sub. Res. 901, I-14; Modified: CSAPH Rep. 02, A-17; Reaffirmed: Res. 503, A-18; Reaffirmed in lieu of: Res. 512, A-18