

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 917
(I-19)

Introduced by: Medical Student Section

Subject: Supporting Research into the Therapeutic Potential of Psychedelics

Referred to: Reference Committee K

Whereas, There is a complex cultural and political history regarding psychedelic drugs, which include, among others, mescaline, lysergic acid diethylamide (LSD), psilocybin, and NN-dimethyltryptamine (DMT); and

Whereas, The first legislative limitation of psychedelic use occurred through amendments to the Federal Food, Drug and Cosmetic Act in 1965; and

Whereas, Following this, the Controlled Substances Act (CSA) of 1970 was passed, which places "all substances which were in some manner regulated under existing federal law into one of five schedules"¹⁹; and

Whereas, Congress established Schedule I for drugs with (1) a high potential for abuse, (2) no accepted medical use in treatment in the United States, and (3) a lack of accepted safety for use under medical supervision¹⁰; and

Whereas, The major factor distinguishing substances in Schedule I from the others is established and accepted medical use in treatment in the United States⁶; and

Whereas, There is a D.C. Circuit Court precedent stating that a substance or drug with "no currently accepted medical use" should not automatically be placed into Schedule I⁹; and

Whereas, Despite finding in this court ruling, no changes were made as the ruling was filed in dicta, in other words, as an opinion from an authoritative body and not binding, exemplifying the power the Drug Enforcement Agency (DEA) holds over scheduling of substances and an explanation as to why and how the DEA has refused rescheduling of certain substances⁶; and

Whereas, It is argued that scheduling criteria that cannot be consistently followed and that is open to interpretation is fundamentally flawed, making the scheduling of substances by a political law enforcement agency at odds with those that want to study substances for their medical or scientific benefit⁶; and

Whereas, Upon close look at the socio-political environment in the United States at the time of passing the Controlled Substances Act, there is concern over the intention of the law and the consequences that result in limiting the study of psychotropics for medical and scientific purposes; and

Whereas, There is a large amount of evidence that psychedelics exhibit promise as therapeutics for a number of disorders including mood disorders, substance use disorders and headaches, among others; and

Whereas, One such study of more than 900 marginalized women who were at an increased risk of suicide, showed that subjects who used psychedelic drugs were at no significant hazard for suicidal ideation or attempt, while subjects with regular opioid use were at a three times great risk of suicidal ideation¹; and

Whereas, A systematic review of published clinical treatment studies using psychedelics showed that unipolar mood disorders, the current treatment for which is often suboptimal, can be improved by the psychedelic drugs lysergic acid diethylamide and psilocybin; and

Whereas, Other studies have shown, for example, that long-term ayahuasca use improves a subject's positive percept of health and correlates with health lifestyles, increased personal values, and reduced prescription drug use¹¹; and

Whereas, Both psilocybin and ayahuasca may be effective in treating treatment-resistant depression^{13,14}; and

Whereas, Ketamine psychedelic therapy may help with alcohol use disorder treatment⁷; and

Whereas, Cluster headaches may be effectively treated by both psilocybin and LSD¹⁸; and

Whereas, There is evidence that "micro-dosing" of psychedelics led to improved physical functions of connection, contemplation, focus, happiness, productivity and wellness¹⁵; and

Whereas, It should be noted that the preliminary results surrounding the therapeutic uses of psychedelics are promising, however, the studies done so far have had a limited number of subjects and have not been conducted over long enough time periods to firmly conclude the benefits of these substances; and

Whereas, Major concerns exist over the potential dangers associated with using these substances in research or patient treatment; and

Whereas, Symptoms of using these substances could include increased blood pressure, heart rate, body temperature, pupil size, cortisol, prolactin, oxytocin and epinephrine¹⁷; and

Whereas, Under current legal and procedural regulations, it is difficult to register to study psychedelic substances through the Drug Enforcement Agency (DEA); and

Whereas, Researchers must submit research protocols to conduct research on Schedule I drugs, and in this manner the DEA continues to be the authority on whether a substance maintains its classification and whether the researchers are allowed to conduct the studies outlined in their protocol pursuant to meeting certain criteria; and

Whereas, As the system currently stands, we are caught in an impasse even though investigators have published evidence to suggest that psychedelics are substances with (1) low potential for abuse, (2) measurable medical use in treatment in the United States, and (3) proven safety while used in clinical trials under medical supervision; therefore be it

RESOLVED, That our American Medical Association call for the status of psychedelics as Schedule I substances be reclassified into a lower schedule class with the goal of facilitating clinical research and developing psychedelic-based medicines (Directive to Take Action); and be it further

1 RESOLVED, That our AMA explicitly support and promote research into the therapeutic
2 potential of psychedelics to help make a more conducive environment for research, given the
3 high regulatory and cultural barriers (Directive to Take Action); and be it further

4
5 RESOLVED, That our AMA support and promote research to determine the benefits and
6 adverse effects of long-term psychedelic use. (Directive to Take Action)
7

Fiscal Note: not yet determined

Date Received: 10/01/19

References:

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8. McAllister, William B. "The global political economy of scheduling: the international-historical context of the Controlled Substances Act." *Drug and Alcohol Dependence* 76.1 (2004): 3-8.
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15. Polito, V. and Stevenson, R. J. A systematic study of microdosing psychedelics. *PLoS ONE*. 2019;14(2):e0211023. doi: 10.1371/journal.pone.0211023
16. Rucker, James JH, *et al.* "Psychedelics in the treatment of unipolar mood disorders: a systematic review." *Journal of Psychopharmacology* 30.12 (2016): 1220-1229.
17. Schmid Y, Enzler F, Gasser P, *et al.* Acute effects of lysergic acid diethylamide in healthy subjects. *Biol Psychiatry*. 2015;78(3):544-553. doi:10.1016/j.biopsych.2014.11.015
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19. The Controlled Substances Act. United States Drug Enforcement Administration. 1970.

RELEVANT AMA POLICY

FDA Recommendation on Scheduling of Hydrocodone Combination Products D-120.948

Our AMA will issue a public statement to the US Food and Drug Administration urging the FDA to maintain hydrocodone combination products as Schedule III of the Controlled Substances Act.

Citation: Res. 518, A-13;

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;

Modernization of the Federal Toxic Substances Control Act (TSCA) of 1976 D-135.976

Our AMA will: (1) collaborate with relevant stakeholders to advocate for modernizing the Toxic Substances Control Act (TSCA) to require chemical manufacturers to provide adequate safety information on all chemicals and give federal regulatory agencies reasonable authority to regulate hazardous chemicals in order to protect the health of all individuals, especially vulnerable populations; (2) support the public disclosure of chemical use, exposure and hazard data in forms that are appropriate for use by medical practitioners, workers, and the public; and (3) work with members of the Federation to promote a reformed TSCA that is consistent with goals of Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH).

Citation: Res. 515, A-12; Modified: Res. 907, I-13; Reaffirmation I-13; Reaffirmation I-16;