



The Florida Senate

Interim Project Report 2008-115

November 2007

Committee on Criminal Justice

SALVIA DIVINORUM AND SALVINORIN A AS CONTROLLED SUBSTANCES

SUMMARY

Salvia divinorum is a relatively rare sage plant. The main psychoactive component of the plant appears to be Salvinorin A. The recreational use of Salvia¹ to induce hallucinations or hallucinogenic-like effects has been reported in scientific literature on Salvia and its use. Salvia is effectively unregulated in Florida, so sale and use of Salvia is not restricted or prohibited. Salvia divinorum and Salvinorin A are listed as “Drugs and Chemicals of Concern” by the U.S. Drug Enforcement Administration.

The Florida Office of Drug Control and the Florida Department of Health recommend Salvia be added to Schedule I. At the local level, the Miami-Dade County Commission makes this same recommendation. The findings of this report are that Salvia appears to meet Schedule I criteria. Salvia has no accepted medical use in treatment in the United States. (Salvia cannot be added to Schedules II-V because those schedules require such accepted medical use.) There is also a “potential for abuse” because there is a substantial likelihood of Salvia being taken on the user’s own initiative rather than on the basis of professional medical advice. Proof of such use has been established. This “potential for abuse” is serious or ‘high’ because a designation of ‘low’ potential for abuse would suggest that Salvia is being taken on the basis of professional medical advice, which is not the case. Finally, it logically follows from these findings that Salvia cannot be used under medical supervision that meets accepted safety standards.

Other considerations may be relevant to the scheduling of Salvia. Numerous effects of Salvia use have been reported, ranging from dizziness to loss of consciousness (in high dosages). There are no reports in the United States of salvia use *directly* causing a death, though it has been reported that a Delaware

medical examiner listed Salvia use as a contributing factor in the death of a high school senior who committed suicide. Studies of human toxicity with Salvia have not been published, and the addictive potential of Salvia is still a matter of debate. The prevalence of Salvia use (number of Salvia users) in Florida and elsewhere has not been established by recognized surveys of drug use and drug trends but information indicates that several important survey instruments used to assess prevalence are not asking about Salvia use.

Products containing Salvia may be contaminated or adulterated and potency levels may not be as advertised by the seller. There is no regulatory authority checking claims made by the seller. While it appears that there are sellers who limit sales to adults, there is no statutory requirement to do so and there is no mechanism that can ensure that an Internet customer is an adult.

Scheduling Salvia would not preclude scientific research on Salvia. Florida law exempts lawful, scientific research on controlled substances.

If the Legislature determines that the current legal status of Salvia is inappropriate, staff recommends that the Legislature consider several different options for addressing Salvia use: (1) schedule Salvia in Schedule I with Schedule I penalties or lesser penalties (e.g., simple possession of Salvia could be punished as a misdemeanor); (2) schedule Salvia in Schedule I, but provide an exception to such scheduling for any drug that may be developed that contains Salvia or a derivative, if such drug is approved by the U.S. Food and Drug Administration; (3) leave Salvia unscheduled but punish possession, sale, etc., of Salvia; or (4) adopt any of an array of options (described in this report) provided by the laws of 8 states and legislation filed in at least 16 states to address Salvia use (e.g., penalties for possession for human consumption and fines for sales).

¹ The term ‘Salvia’ will be used throughout the report when referring to Salvia divinorum and Salvinorin A.

BACKGROUND

Salvia divinorum and Salvinorin A: Botany and Historical Use in Mexico

“Salvia divinorum is a perennial herb of the Lamiaceae (mint) family” and the Sage (*Salvia*) genus “that is indigenous to the Sierra Mazateca of Oaxaca, Mexico.”² *Salvia divinorum* “appears to be a cultigen, rarely if ever setting seed and possibly not occurring as a wild plant.”³ It does not grow naturally in the United States but can be readily cultivated.⁴ The main psychoactive component of the plant appears to be Salvinorin A.⁵ The Mazatec Indians of Oaxaca have used *Salvia divinorum* in “traditional spiritual and ethnopharmacological practices....”⁶

Effects, Toxicity, Addictive Potential, and Recreational Use in the United States

² Vortherms, T., & Roth, B. (2006, October). Salvinorin A: from natural product to human therapeutics. *Mol. Interv.*, 6(5), 257-265. Footnoted references in any cited resources are omitted.

³ Schultes, R. The plant kingdom and hallucinogens (part III) (1970, January 1) (retrieved from http://www.unodc.org/unodc/bulletin/bulletin_1970-01-01_1_page005.html#s170). Therefore, it does not appear that there would be a situation in which *Salvia divinorum* would be found by law enforcement growing uncultivated on private property. Section 893.101(2), F.S., provides that lack of knowledge of the illicit nature of a controlled substance is an affirmative defense to a violation of ch. 893, F.S. (controlled substances).

⁴ Halpern, J. (2004, May). Hallucinogens and dissociative agents naturally growing in the United States. *Pharmacol. Ther.*, 102(2), 131-138. The Florida Office of Drug Control states that there is considerable confusion regarding *Salvia divinorum* and *Salvia* plants used for landscaping. The genus *Salvia* consists of “around 900 species in the family Lamiaceae.” Imanshahidi, M., & Hosseinzadeh, H. (2006). The pharmacological effects of *Salvia* species on the central nervous system. *Phytother. Res.*, 20, 427-437. The Division of Plant Industry in the Department of Agriculture states that *Salvia divinorum* may not be used at all in Florida nurseries but is definitely not widely used in landscape businesses or the nursery trade. The Florida Nursery, Growers and Landscape Association states that it does not know of any Association member who grows or sells the plant.

⁵ Hoover, V., Marlowe, D., Patapis, N., Festinger, D., & Forman, R. (2007, October 9). Internet access to *Salvia divinorum*: Implications for policy, prevention, and treatment. *J. Subst. Abuse Treat.* (Epub. ahead of print).

⁶ Prisinzano, T. (2005, December 22).

Psychopharmacology of the hallucinogenic sage *Salvia divinorum*. *Life Sci.* 78(5), 527-531. Some *Salvia* users in the United States have asserted that their use of *Salvia* accords with these practices.

Salvia divinorum and Salvinorin A do not have an accepted medical use in treatment in the United States. The recreational use of *Salvia* to induce hallucinations or hallucinogenic-like effects has been reported in scientific literature on *Salvia* and its use.⁷ *Salvia divinorum* leaves can be chewed or smoked to extract Salvinorin A. Fortified extracts or tinctures can also be used. “When the leaves are dried and smoked, psychoactive effects typically appear rapidly and intensely, with potent effects lasting for 5-6 minutes, after which the effects subside over an additional 20-30 minutes.... When the leaves are chewed, psychoactive effects are typically felt in roughly 15 minutes and increase to a climax at approximately 30 minutes. This peak level can then be maintained for an additional 30-60 minutes, after which it typically declines over another 30-60 minutes.... When absorbed as a tincture held in the mouth, the effects generally emerge in 10-15 minutes and rapidly escalate to a peak intensity that can be maintained for 20-40 minutes....”⁸

Effects of *Salvia* use reported by the National Drug Intelligence Center include “vivid hallucinations – including out-of-body experiences, sensations of traveling through time and space, and feelings of merging with inanimate objects. Some abusers experience synesthesia, an effect that causes the abuser’s senses to become confused. For example, abusers may describe hearing colors or smelling sounds.”⁹ Some other effects that have been reported by *Salvia* users include feelings of panic, uncontrolled laughter, nausea, incoordination, slurred speech and awkward sentence patterns, decreased heart rate, chills, sweating, and fatigue or exhaustion.¹⁰ Short term

⁷ See e.g., the cited sources in footnotes 2, 5, 10, 11, 15, and 23.

⁸ Quoted remarks in this paragraph are from Hoover, Marlowe, Patapis, Festinger, & Forman, 2007.

⁹ U.S. Drug Enforcement Administration. (2003, June). *Microgram Bulletin*, Vol. XXXVI, No. 6. (retrieved from <http://www.usdoj.gov/dea/programs/forensicsci/microgram/mg0603/03jun-mb.pdf>).

¹⁰ Bucheler, R., Gleiter C., Schwoerer, P., & Gaertner, I. (2005, January). Use of nonprohibited hallucinogenic plants: increasing relevance for public health? A case report and literature review on the consumption of *Salvia divinorum* (Diviner's Sage). *Pharmacopsych.*, 38, 1-5. See also Hoover et al., 2007, and the Center for Substance Abuse Research (retrieved from <http://www.cesar.umd.edu/cesar/drugs/salvia.asp>). There does not appear to be any published research regarding the interaction of *Salvia* with other substances (many drug users are polysubstance users), or regarding gender specific effects of *Salvia* use or effects of *Salvia* use on persons with mental or physical

memory loss and loss of consciousness have been reported in high dosages.¹¹

“If high dosages are consumed stuporous states have been reported prompting users of the drug to recommend ‘sitters’ during the experience to prevent accidental injury.”¹² As with any agent (illegal or legal) that may incapacitate the user, there is the possibility that the user could be harmed from the incapacitation or from impaired judgment (e.g., sexual abuse or sexually transmitted diseases).

There are no reports in the United States of Salvia use *directly* causing a death, though it has been reported that a Delaware medical examiner listed Salvia use as a contributing factor in the death of a high school senior who committed suicide.¹³ At present, studies of human toxicity with Salvia have not been published. One study on rodents suggests that Salvia has relatively low toxicity;¹⁴ however, limitations to this study have been noted and “potential chronic toxicity linked to salvinorin A cannot be excluded.”¹⁵ “Additionally, to

disorders or illnesses, pregnant women, and children.

¹¹ Pichini, S., Abanades, S., Farre, M., Pellegrini, M., Marchei, E., Pacifici, R., et al. (2005). Quantification of the plant-derived hallucinogen Salvinorin A in conventional and non-conventional biological fluids by gas chromatography/mass spectrometry after *Salvia divinorum* smoking. *Rapid Commun. Mass. Spectrom.*, 19(12), 1649-1656.

¹² Mowry, M., Mosher, M., & Briner, W. (2003, July-September). Acute physiologic and chronic histologic changes in rats and mice exposed to the unique hallucinogen salvinorin A. *J. Psychoact. Drugs*, 35(3), 379-382. The authors of one study of Salvia users found that their volition subscale score, which reflects the users’ degree of incapacitation, was the highest ever observed by their group in clinical and survey studies. Gonzalez, D., Riba, J., Bouso, J., Gomez-Jarabo, G., & Barbanoj, M. (2006, November 8). Pattern of use and subjective effects of *Salvia divinorum* among recreational users. *Drug Alcohol Depend.*, 85(2), 157-162.

¹³ Chalmers, M. (2007, August 3). Parents sue over dead son’s Salvia use. *The News Journal*. (Wilmington, DE), p. B1. The finding of the medical examiner has been a matter of debate. The student’s death was the impetus for Delaware’s Salvia law. It is also reported in the cited article that the parents of the deceased filed a wrongful death action against two Salvia distributors.

¹⁴ Mowry, Mosher, & Briner, 2003.

¹⁵ Grundmann, O., Phipps, S., Zadezensky, I., & Butterweck, V. (2007, August). *Salvia divinorum* and Salvinorin A: An Update on Pharmacology and Analytical Methodology. *Planta Med.*, 73(10), 1039-46. It has been reported that “the duration of action [of Salvia] is so short that a patient who sought medical attention would

the present, no study has investigated a chronic or acute toxicity of the leaf extract of *Salvia divinorum*.”¹⁶

“The addictive potential of *Salvia divinorum* is still a matter of debate.”¹⁷ At present, there is no published study indicating that Salvia is physically addictive or that continuing use of the drug may lead to psychological dependence. However, there is research that suggests that “the dose [of Salvia] needs to be increased over time to get the same effect, which might be indicative of a potential addiction problem.”¹⁸

Various possible, though not indisputable, indicators of Salvia’s popularity or its potential for abuse have been cited: Internet search queries about Salvia;¹⁹ videos on the Internet of Salvia users and messages posted by Salvia users about their ‘trips’;²⁰ lack of significant

probably be lucid by the time help arrived.” Wolowich, W., Perkins, A., & Cienki, J. (2006, September). Analysis of the psychoactive terpenoid salvinorin A content in five *Salvia divinorum* herbal products. *Pharmacother.*, 26(9), 1268-1272. Additionally, some respondents to staff’s survey stated that it is possible that toxicology screens at hospitals are not detecting Salvinorin A, emergency physicians are not trained to detect Salvia use, and an acutely intoxicated person may not present for care. Although analytical methods have been developed for the detection of Salvinorin A in bodily fluids, it appears that further research is needed toward establishing [what Grundmann, Phipps, Zadezensky, & Butterweck, 2007, describe as] “a sensitive and practicable analytical method for the detection of salvinorin A or its metabolites in commonly analyzed bodily fluids.”

¹⁶ Grundmann et al., 2007.

¹⁷ Bucheler, Gleiter, Schwoerer, & Gaertner, 2005.

¹⁸ Grundmann et al., 2007.

¹⁹ Wolowich, Perkins, & Cienki, 2006. (“A Yahoo search for *Salvia divinorum* in 2003 yielded 100 hits; an identical Yahoo search in 2006 yielded 881,000 hits.”) Hoover et al., 2007, conducted Internet search queries from June 2005 through May 2006, and found that, on average, 78% of the sites were “pro-use.” Most of these sites “emphasized the legal status of *S. divinorum* and asserted that it was safe and enjoyable to use. Many sites misinterpreted the absence of scientific data on the possible toxicity or negative side effects of *S. divinorum* as evidence that there are no such effects.”

²⁰ According to one news report, “[c]urrently, *Youtube.com* has more than 3,000 videos of people, mostly teens, who recorded and posted their ‘trips’ while smoking salvia. There are 84 Facebook groups, and 11,900 on MySpace...” DiCosmo, B. (2007, July 22). Herb banned in Missouri shows up on Internet. *Southeast Missourian* (retrieved from <http://www.semissourian.com/story/1232598.html>).

regulation of Salvia,²¹ and the availability and relatively cheap cost of Salvia.²² The prevalence of Salvia use has not been established by recognized surveys of drug use and drug trends.²³ However, the National Drug Intelligence Center of the U.S. Department of Justice has stated that “[n]ational surveys conducted to estimate rates of drug abuse do not include questions regarding abuse of Salvia divinorum. Thus, current levels are difficult to determine.”²⁴ The Florida Department of Children and

²¹ Harding, W. Tidgewell, K., Schmidt, M., Shah, K., Dersch, C., Snyder, J., et al. (2005, July 7). Salvinicins A and B, new neoclerodane diterpenes from *Salvia divinorum*. *Org. Lett.*, 7(14), 3017-3020.

²² Bucheler et al., 2005. (“It can be easily ordered at an affordable price.”) Other possible indicators have been suggested. Imanshahidi & Hosseinzadeh, 2006, state that “a small investment in fertilizer and solvents, coupled with only a minimal mastery of laboratory techniques ... would make the cultivation of *S. divinorum* and the isolation of Salvinorin A potentially more attractive than synthesizing LSD or phencyclidine derivatives....” Hoover et al., 2007, state that “[i]t is an open question whether *S. divinorum*’s availability and positive portrayal are attributable to its legal status in most U.S. jurisdictions or whether it may be attributable to other factors, such as the relative ease with which it can be cultivated and the lack of clear scientific information about its potential side effect profile.”

²³ University of Florida researchers are currently conducting surveys on Salvia use but findings of those surveys were not available at the time this report was completed. It appears that the only available, recent research on the prevalence of Salvia use are findings from online surveys of 1,571 undergraduates at a large southwestern university. Lange, J., Reed, M., Ketchie, J., Clapp, J., & Homer, K. (2007, October 18-21). *College Student Use of Salvia Divinorum*. Poster session presented at the U.S. Department of Education’s 21st Annual National Meeting on Alcohol and Other Drug Abuse and Violence Prevention in Higher Education, Omaha, NE. The researchers found that the rate for past-year use of Salvia (overall, 4.4% of the combined sample reported such use) was comparable to past-year use rates for Ecstasy (5.0%) and cocaine (7.1%). Over 10% of the sampled students who reported past-year use of certain illicit drugs also reported past-year use of Salvia. Men, whites, fraternity/sorority members, past-two week heavy episodic drinking, and past-year drug use were all associated with the increased odds of past-year use of Salvia.

²⁴ See footnote 9. The Substance Abuse and Mental Health Services Administration of the U.S. Department of Health has provided notice that it is planning to route Salvia divinorum users into the questions on drug dependence and abuse in the 2008 National Survey on Drug Use and Health. 72 FR 24592-01 (May 3, 2007).

Family Services states that Florida’s Youth Substance Abuse Survey does not survey use of Salvia. The annual report of Florida’s State Epidemiology Workgroup appears to focus only on illicit drug use (except for legal use of alcohol and tobacco).

Sales and Cost

Salvia divinorum is sold on the Internet “as seeds, plant cuttings, whole plants, fresh and dried leaves, extract-enhanced leaves of various strengths (e.g., 5x, 10x, 20x, 30x), and liquid extracts purported to contain salvinorin A. These products are also sold at local retail shops (e.g., head shops and tobacco shops).”²⁵

Products containing Salvia may be contaminated or adulterated and potency levels may not be as advertised by the seller.²⁶ “Numerous Internet sources offer a mixture of esoteric advice, practical warnings and instructions on the use of the plant.”²⁷ There is no regulatory authority checking claims made by the seller.²⁸ While it appears that there are sellers who limit sales to adults, there is no statutory requirement to do so and there is no mechanism that can ensure that a customer is an adult.

Staff searched the websites of 10 sellers of Salvia and found that prices for the leaf ranged (based on weight and potency) from \$10 to over \$300 (one website seller

²⁵ Office of Diversion Control, U.S. Drug Enforcement Administration (retrieved from http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm).

²⁶ In their study of five herbal products containing Salvinorin A, Wolowich et al., 2006, found that the products were subpotent (actual concentrations of Salvinorin A did not coincide with claimed concentrations) and three contained adulterants: vitamin E or caffeine. The authors state that discrepancies between the products’ advertised Salvinorin A concentration and the actual concentration “may pose a risk of both misuse and overdose.” “For example, if a salvia user becomes familiar with effects from a mislabeled product and then ingests a more potent product that is correctly labeled, it may result in an unfamiliar and dangerous state of intoxication.”

²⁷ Bucheler et al., 2005.

²⁸ For example, one seller touts a color-coded system that the seller claims will ensure ‘uniformity’ (in quality and potency) without providing any evidence for this claim. Other sellers use scales “where the ‘trip’ [is] described in levels dependent on the amount ingested....” Dennehy, C., Tsourounis, C., & Miller, A. (2005, October). Evaluation of herbal dietary supplements marketed on the internet for recreational use. *Ann. Pharmacother.*, 39(10), 1634-1639. “The purveyors of salvia use nomenclature intended to imply standardization....” Wolowich et al., 2006.

sold leaves by the kilo) and from approximately \$8 to over \$900 for dry extract-enhanced leaves.²⁹

Research on Potential Medical Uses

“Although the psychotropic effects of *Salvia divinorum* have been widely known, the chemical component(s) responsible for these properties have not been extensively studied until quite recently.”³⁰ Research on Salvinorin A suggests it has a remarkable selectivity or affinity for the kappa-opioid receptors (KORs), a class of opioid receptors that are found in the brain, the spinal cord, and other sites. According to the authors of one study, “KORs and/or KOR signaling probably play a role in the modulation of human cognition and perception.”³¹ The authors of another study state that results of several research studies “imply that KOR selective agonists³² could conceivably represent treatments for diseases in which hallucinations are prominent, including schizophrenia, depression with psychotic features, and hallucinosis associated with certain dementias (Alzheimer’s, Huntington’s, and Pick diseases) and certain types of drug abuse (e.g., amphetamine and cocaine psychosis).”³³

²⁹ In comparison, in Miami, the retail price for one gram of powdered cocaine is \$13 to \$100, one gram of crack cocaine is \$50 to \$125, one gram of heroin (South American) is \$50 to \$125, one ounce of locally produced or hydroponic marijuana is \$200 to \$400 (\$60 to \$200 for commercial grade or imported), one ounce of powdered methamphetamine (Mexican produced) is \$30 to \$35, and one tablet of MDMA (Ecstasy) is \$20 to \$30. U.S. Department of Justice. (February 2007). *National Illicit Drug Prices: December 2006* (Product No 2007-L0424-002).

³⁰ Vortherms & Roth, 2006.

³¹ Sheffler, D. & Roth, B. (2003, March). Salvinorin A: the ‘magic mint’ hallucinogen finds a molecular target in the kappa opioid receptor. *Trends Pharmacol. Sci.*, 24(3), 107-109.

³² An ‘agonist’ is “[a] drug that binds to a receptor of a cell and triggers a response by the cell. An agonist often mimics the action of a naturally occurring substance.” MedicineNet.com. According to the authors of one study, “it has been suggested that ... salvinorin A is a [kappa] opioid receptor agonist, although there is no definitive evidence that hallucinations are mediated by [kappa] opioid receptors.” Capasso, R., Borrelli, F., Capasso, F., Siebert, D., Stewart, D., Zjawiony, J., et al. (2006, January). The hallucinogenic herb *Salvia divinorum* and its active ingredient salvinorin A inhibit enteric cholinergic transmission in the guinea-pig ileum. *Neurogastroenterol. Motil.*, 18(1), 69-75.

³³ Roth, B., Baner, K., Westkaemper, R., Siebert, D., Rice, K., Steinberg, S., et al. (2002, September 3) Salvinorin A: a potent naturally occurring nonnitrogenous

Legal Status

Salvia divinorum and Salvinorin A are effectively unregulated in Florida.³⁴ They are not controlled substances in Florida’s controlled substance schedules,³⁵ and sale, manufacture, distribution, and possession of *Salvia* are not otherwise specifically proscribed by the Florida Statutes.³⁶ *Salvia divinorum* and Salvinorin A are not federally scheduled controlled substances, and are not regulated by the U.S. Food and Drug Administration (FDA).³⁷ They are listed by the U.S. Drug Enforcement Administration (DEA) as “Drugs and Chemicals of Concern.” Limited information suggests that the DEA may be in the process of making a recommendation regarding *Salvia* scheduling.³⁸

[kappa] opioid selective agonist. *Proc. Natl. Acad. Sci.*, 99(18), 11934-11939.

³⁴ The Florida Department of Business and Professional Regulation (DBPR) states that, because *Salvia* sales are not proscribed, it is unable to regulate such sales at DBPR-licensed businesses. While information indicates that some sellers have sold *Salvia* products as herbal dietary supplements, staff is only aware of one instance (in 1996) when the Florida Department of Agriculture issued stop sale orders on herbal dietary supplements. These supplements contained ephedrine, which at that time was a non-regulated stimulant. However, the orders issued after the death of a tourist from an ephedrine overdose and the issuance of an FDA warning to consumers about the potential health risks of these products. The Florida Department of Health states that *Salvia divinorum* and Salvinorin A could be considered as “new drugs” under s. 499.023, F.S., if claims were made that these substances meet the definition of a drug in s. 499.003(17), F.S. This would subject these substances to approval by the FDA prior to marketing and distribution.

³⁵ *Salvia divinorum* and Salvinorin A do not appear to meet the criteria for classification as controlled substance analogues because Salvinorin A “is structurally unique and has no known analog among other drugs of abuse....” Hoover et al., 2007.

³⁶ Since *Salvia* is not a controlled substance or controlled substance analogue under ch. 893, F.S., or a substance listed in s. 877.111, F.S. (harmful chemical substances), which are the substances pertinent to Florida’s DUI law, an operator of a motor vehicle impaired by use of *Salvia* could not be prosecuted for DUI. Arguably, prosecutions relating to *Salvia* use, sales, etc., could be made in particular cases for careless or reckless driving, contributing to the delinquency of a minor, disorderly conduct, or disorderly intoxication.

³⁷ There are currently no FDA-approved or regulated drugs, including homeopathic drugs, that contain *Salvia* or *Salvia* derivatives.

³⁸ The Florida Office of Drug Control informed staff that, “[a]ccording to John Tolliver, Chief of the Drug and

Section 893.03, F.S., contains Florida's schedules for controlled substances. Scheduling a substance as a controlled substance can affect access to the substance as well as result in criminal penalties for sale, manufacture, distribution, and possession of the substance. A substance considered for scheduling in Schedule I must meet these criteria: (1) the substance has a high³⁹ potential for abuse; (2) the substance does not have an accepted medical use in treatment in the United States⁴⁰ (Schedule II-V substances have such an accepted medical use); and (3) in its use under medical supervision the substance does not meet accepted safety standards.

Section 893.02(18), F.S., defines "potential for abuse" as meaning a substance has properties of a central nervous system stimulant or depressant or an hallucinogen that create a substantial likelihood of its being: (a) used in amounts that create a hazard to the user's health or the safety of the community; (b) diverted from legal channels and distributed through illegal channels; or (c) taken on the user's own initiative rather than on the basis of professional medical advice. The definition is structured so as to provide for three equally acceptable meanings of the term.

Proof of potential for abuse can be based upon a showing that these activities are already taking place. Alternatively, it can be based upon a showing that the nature and properties of the substance make it reasonable to assume that there is a substantial

likelihood that such activities will take place, in other than isolated or occasional instances.

Section 893.13(9), F.S., authorizes lawful, scientific research on controlled substances.⁴¹

Laws have been passed in 8 states⁴² and legislation has been filed in at least 16 states (including Florida)⁴³ to

⁴¹ Federal law also authorizes scientific research on controlled substances, though such research is subject to restrictions. (2006, July 11). Magic Mushroom Drug Study Probes Science, Spirituality. *Forbes* (retrieved from <http://www.forbes.com/forbeslife/health/feeds/hscout/2006/07/11/hscout533738.html>).

⁴² Delaware and Illinois list Salvia divinorum in Schedule I. (Although Salvinorin A is not specifically listed, it may be covered by other provisions; similarly, if a state specifically lists only Salvia divinorum, Salvinorin A may be covered by other provisions.) Missouri and North Dakota list Salvia divinorum and Salvinorin A in Schedule I. Maine punishes unlawful transfer of Salvia divinorum and Salvinorin A to a minor (and provides an affirmative defense for transfer in reasonable reliance upon a fraudulent proof of age presented by the minor). Under Maine law, it is a civil violation for a minor to purchase, use false ID to purchase, and possess Salvia. In Oklahoma, prima facie evidence that a substance containing Salvia divinorum has been enhanced, concentrated or chemically or physically altered gives rise to a rebuttable presumption that the substance is a synthetic controlled substance. In Tennessee, it is a misdemeanor to knowingly produce, manufacture, distribute, possess, or possess with intent to produce, manufacture, or distribute an active chemical ingredient in Salvia divinorum (exceptions are provided for: (1) possession, planting, cultivating, growing, harvesting of Salvia divinorum for aesthetic, landscaping, or decorative purposes; and (2) a dosage form legally obtainable from a retail establishment with a prescription and recognized by the FDA as a homeopathic drug). Louisiana law punishes the same acts as Tennessee law when they are intended for human consumption of a "hallucinogenic plant," a term that includes Salvia divinorum.

⁴³ Recent legislation in Alabama, California, Florida (SB 340 by Senator Lynn; 2008 Session), Iowa, New Jersey, Ohio, Oregon, Pennsylvania, Texas, and Utah would list Salvia divinorum and Salvinorin A in Schedule I (an Alaska bill would list them in its Schedule IIA). Other Pennsylvania bills and a Wyoming bill would list Salvia divinorum in Schedule I (see comments in footnote 42 regarding the laws of Delaware and Illinois). A Florida bill (CS/SB 1718 by the Senate Judiciary Committee, Senator Crist, and Senator Saunders; 2007 Session) and a Virginia bill would list Salvinorin A in Schedule I. A Georgia bill would make it a misdemeanor to knowingly produce, manufacture, distribute, possess, or possess with intent to produce, manufacture, or distribute Salvinorin A

Chemical Control Unit at the U.S. Drug Enforcement Association, the DEA has completed their Eight Factor Analysis of salvinorin A, and ... will be sending the necessary documents to the U.S. Department of Health and Human Services to advance the scheduling process. According to Tolliver, there is no deadline for response from the Department of Health and Human Services, and it may take months for them to reply."

³⁹ The term 'high' as used in "high potential for abuse" (s. [893.03(1), F.S.] is undefined. The *Cambridge Advanced Learner's Dictionary Online* defines 'high' as including the meaning: "greater than the usual level or amount" (*accord Merriam-Webster Online*).

Dictionary.com defines the term as including: "of great consequence; important; grave; serious" (*accord Merriam-Webster Online*).

⁴⁰ The DOH states that "[t]he currently accepted medical use of substances listed in Schedules II-V is determined by the FDA. A drug must meet the requirements for approval under the federal Food, Drug and Cosmetic Act."

address Salvia use.⁴⁴ Countries that have reportedly initiated regulatory controls on Salvia include Australia, Belgium, Denmark, Estonia, Finland, Italy, South Korea, Spain, and Sweden.⁴⁵

METHODOLOGY

Staff sent surveys to the Florida Department of Law Enforcement, the Florida Department of Health, the Florida Office of Drug Control, and several researchers, doctors, and treatment providers to request information regarding Salvia divinorum and Salvinorin A and the possible scheduling or other regulation of these substances. Staff reviewed the responses to these surveys, as well as state and national drug use surveys, media articles and videos, research papers, reports from government agencies, state laws and legislation, and other information relevant to this report.

FINDINGS

The recreational use of Salvia to induce hallucinations or hallucinogenic-like effects has been reported in scientific literature on Salvia and its use. Salvia divinorum and Salvinorin A are effectively unregulated substances in Florida. They are listed as “Drugs and Chemicals of Concern” by the U.S. Drug Enforcement Administration. The Florida Office of Drug Control

(and provide horticulture and homeopathic drug exceptions). New York legislation would impose a fine for selling or offering to sell or giving away Salvia divinorum (and provide an exception for non-prescription over-the-counter drugs approved or regulated by the FDA and a defense that knowledge that the substance was Salvia divinorum was not reasonably discoverable). Another Texas bill would make it a misdemeanor to, with criminal negligence, sell, give, or cause to be sold or given Salvia divinorum to a minor (and provide a defense if the minor presented apparently valid proof of ID). A Wisconsin bill would impose a fine for manufacturing, distributing, or delivering Salvinorin A with the intent that it be consumed by a person (and provide a homeopathic drug exception).

⁴⁴ There are options to address Salvia use that have not been presented by laws or legislation. For example, the Legislature could leave salvia unscheduled and not punish sale, use, etc., of Salvia but address Salvia use through a drug prevention campaign. Also, some opponents of Salvia scheduling have proposed that Salvia be regulated like alcohol or tobacco, taxed, or both. However, if Salvia is eventually made a federal Schedule I substance, such legal but related use of Salvia would conflict with federal scheduling.

⁴⁵ Hoover et al., 2007, and the Office of Diversion Control, U.S. Drug Enforcement Administration (retrieved from http://www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm).

(FODC) and the Florida Department of Health (DOH) recommend these substances be added to Schedule I.⁴⁶ At the local level, the Miami-Dade County Commission has made this same recommendation.⁴⁷ The DOH states that “[t]hese substances have been identified as possibly the most potent naturally occurring hallucinogenic[s] giving them a high potential for abuse” and “[n]o valid argument can be made for not scheduling Salvia divinorum or Salvinorin A based on [their] current and potential abuse.” The DOH further states that this scheduling “is proactive protection of the health and safety of Florida’s citizens, especially our youth.”

The FODC supports initiation of action to schedule these substances in Schedule I. Regarding Salvia’s “potential for abuse,” the FODC states that “salvinorin A can indeed be ‘used in amounts that create a hazard to the user’s health or safety of the community.’” While noting that the “acute effects” of Salvinorin A are brief when compared to other drugs, persons “under the influence of salvinorin A certainly pose a risk to themselves and others.” The FODC states that this risk would be ‘considerable’ if Salvinorin A was used while driving, “situated at the top of a stairwell or ledge, or surrounded by sharp objects or open flames,” and is only one form of risk that use might entail. “The chronic effects of salvinorin A ... are, to the best of our knowledge, unknown.” With regard to the “substantial likelihood” that Salvia will be used in amounts that create these hazards, the FODC notes that this term is undefined and, therefore, is open to interpretation. These hazards might be minimized by having an experienced ‘sitter’ capable of physically restraining the user if necessary.

The FODC further states that potential for abuse can be established based on a substantial likelihood of Salvia being “[t]aken on the user’s own initiative rather than

⁴⁶ Counsel for the Florida Department of Law Enforcement (FDLE) states that the FDLE does not know if these substances meet Schedule I criteria but information has not been reported to its laboratories that would indicate more than isolated or occasional use of Salvia. However, counsel notes that the FDLE is not suggesting that potential for abuse cannot otherwise be established. The Florida Drug Policy Advisory Council has postponed consideration of any proposal to regulate Salvia in order to gather further information about Salvia and its use.

⁴⁷ Miami-Dade County Commission. *Miami-Dade Legislative Item/File Number: 070579* (retrieved from <http://www.miamidade.gov/govaction/matter.asp?matter=070579&file=true&yearFolder=Y2007>).

on the basis of professional medical advice.” Proof of “potential for abuse” can be established because these activities (use based on the user’s initiative rather than professional medical advice) are already taking place. “Since there is no currently approved medical use for salvinorin A, there is simply no way that current users could possibly take it any other way than under their own initiative. Thus, almost by default, or by virtue of the fact that medical research is nascent, salvinorin A has the potential for abuse.”

Salvia divinorum and Salvinorin A appear to meet the criteria necessary for scheduling as Schedule I substances.⁴⁸ There is no accepted medical use of Salvia for treatment in the United States. (For this reason, Salvia cannot be considered for scheduling in Schedules II-V, since such accepted medical use is required.)⁴⁹ There is also a “potential for abuse” because there is a substantial likelihood of Salvia being taken on the user’s own initiative rather than on the basis of professional medical advice. Proof of such use has been established. This “potential for abuse” is serious or ‘high’ because a designation of ‘low’ potential for abuse would suggest that Salvia is being taken on the basis of professional medical advice, which is not the case. Finally, it logically follows from

⁴⁸ While some laws or legislation specifically list only Salvinorin A in their Schedule I, Florida legislation to schedule only Salvinorin A would present a problem. In *Fiske v. State*, 366 So.2d 423 (Fla.1978), the Florida Supreme Court held that s. 893.03, F.S., was unconstitutionally applied to the appellant who was convicted for possession of psilocybic mushrooms. The statute scheduled psilocybin but did “not advise a person of ordinary and common intelligence that this substance is contained in a particular variety of mushroom.” The court concluded that the statute, as applied to the appellant, violated due process because it did not “give fair warning that possession of the mushrooms possessed by appellant is a crime.”

⁴⁹ The Legislature has, on occasion, provided exceptions from Schedule I scheduling for some FDA-approved drugs that would have fallen under the Schedule I designation of a particular controlled substance absent the exceptions. For example, the Legislature scheduled levon-alphaacetylmethadol (LAAM), which is used to treat opiate dependence, in Schedule II; this is an exception from the umbrella designation of alphaacetylmethadol, a Schedule I substance. Similarly, the Legislature scheduled gamma-hydroxybutyric acid (GHB) in Schedule I but provided a Schedule III designation for any FDA-approved drug product containing GHB (or its salts, isomers, or salts of isomers). Absent this Schedule III designation, a drug for treatment of narcolepsy would have fallen under the Schedule I designation of GHB.

these findings that Salvia cannot be used under medical supervision that meets accepted safety standards.

Other considerations may be relevant to the scheduling decision. Numerous effects of Salvia use have been reported, ranging from dizziness to loss of consciousness (in high dosages). There are no reports in the United States of Salvia use *directly* causing a death, though it has been reported that a Delaware medical examiner listed Salvia use as a contributing factor in the death of a high school senior who committed suicide. Studies of human toxicity with Salvia have not been published, and addictive potential of Salvia is still a matter of debate. The prevalence of Salvia use (number of Salvia users) in Florida and elsewhere has not been established by recognized surveys of drug use and drug trends but information indicates that several important survey instruments used to assess prevalence are not asking about Salvia use.

Products containing Salvia may be contaminated or adulterated and potency levels may not be as advertised by the seller. There is no regulatory authority checking claims made by the seller. While it appears that there are sellers who limit sales to adults, there is no statutory requirement to do so and there is no mechanism that can ensure that an Internet customer is an adult.

Scheduling Salvia would not preclude lawful, scientific research on Salvia because such research is authorized by s. 893.13(9), F.S.

RECOMMENDATIONS

If the Legislature determines that the current legal status of Salvia is inappropriate, staff recommends that the Legislature consider several different options for addressing Salvia use: (1) schedule Salvia in Schedule I with Schedule I penalties or lesser penalties (e.g., simple possession of Salvia could be punished as a misdemeanor); (2) schedule Salvia in Schedule I, but provide an exception to such scheduling for any drug that may be developed that contains Salvia or a derivative, if such drug is approved by the U.S. Food and Drug Administration; (3) leave Salvia unscheduled but punish possession, sale, etc., of Salvia; or (4) adopt any of an array of options (described in this report) provided by the laws of 8 states and legislation filed in at least 16 states to address Salvia use (e.g., penalties for possession for human consumption and fines for sales).