Legally High? Legal Considerations of Salvia divinorum[dagger]

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Legally High? Legal Considerations of Salvia divinorum[†]

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Abstract—The legal status of the hallucinogenic plant Salvia divinorum has been rapidly changing. Legal prohibitions on this plant native to Oaxaca, Mexico have emerged at the state level, a phenomenon that has not occurred since the passage of the Controlled Substances Act (CSA). Included will be a brief description of the plant that has only recently crept into the popular American consciousness, and a review of the different legal mechanisms through which states have controlled the plant and the pending legislation proposing controls. Lastly, the implications of various state laws are discussed.

Keywords—controlled substances, drug policy, drugs, hallucinogens, Salvia divinorum

In the past few years, there has been an apparent increase in the recreational use of Salvia divinorum. Its origins lie in the Mazatecan culture where its ceremonial use had historic ties to the traditional mystic religion and medicine practiced by its people. This psychoactive plant is native to the forest ravines of Oaxaca, Mexico—the area inhabited by the Mazatecs. It is a relative in the mint family, a family of plants that includes several psychoactive species. "The plant propagates itself by the decumbent branches fallen to the ground and rooting. It seems, however, to be in cultivation and to be absent in areas where it is not under the care of man. . . . [It] flowers only when the branches are about seven or more feet in length, at which time it is sprawling. The leaves are almost an iridescent green, and the stems are quadrangular with wings that are crenate" (Emboden 1979:

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93-94). The point in time when the plant was discovered as a recreational inebriant in the United States is unclear; however, it does seem that this change has been gradual and recent.

Aided by its availability in "head shops" and Internet sites (Halpern & Pope 2001), Salvia divinorum has indeed crossed over to recreational circles, but with only a few studies addressing prevalence, incidence, and continuance rates. The plant contains a highly potent hallucinogenic substance, salvinorin-A; researchers are only beginning to understand its effects (Grundmann et al. 2007). Smoking the leaves of Salvia divinorum or leaf material impregnated with tinctures of salvinorin-A extract results in a short-lived, intense intoxication (Gonzalez et al. 2006; Bucheler et al. 2005; Siebert 1994). Salvia divinorum can also be used by chewing the leaves or brewing the leaves into a tea (Halpern & Pope 2001; Valdes 1994). In fact, salvinorin-A has been labeled "one of the most potent naturally occurring hallucinogens" as small dosages can cause dramatic effects (Bucheler et al. 2005; Valdes 1994).

Despite the public realization by some that Salvia divinorum is being used for recreational purposes, the Drug

Volume 40 (2), June 2008

Griffin, Miller & Khey Legally High

Enforcement Administration (DEA) has thus far declined to place salvia on the list of controlled substances. On October 10, 2002 U.S. House Representative Joe Baca, proposed H.R. 5607 (known as the Hallucinogen Control Act of 2002) which proposed placing Salvia divinorum or any substance containing salvinorin A into Schedule I of the Controlled Substances Act (CSA). The bill was ultimately referred to the Subcommittee on Crime, Terrorism, and Homeland Security on November 12, 2002 and ultimately died in committee. This has resulted in leaving the legal regulation of the substance in the hands of the states, an interesting, and since the passage of the CSA, highly unusual situation. This article reviews the current state of knowledge and legal regulation of the substance as a case study of how state legislatures (and the military) respond to media and other reports of a "new" and "dangerous" substance on the scene.

BACKGROUND, EPIDEMIOLOGY, AND USE PATTERNS

While scientific research on Salvia divinorum and the salvinorins has been ongoing since the 1960s, a paucity of epidemiological work in the international scientific community has only recently been addressed as we proceed into the twenty-first century (See Babu, McCurdy & Boyer 2008; Braida et al. 2008; Capasso et al. 2008; Holden et al. 2007; Willmore-Fordam et al. 2007). Recently in the United States, reports of abuse and misuse by youthful experimenters have been sporadically included on local and national broadcast news programs and in various newspapers. Additionally, people have posted videos of people using Salvia divinorum on such websites as youtube.com and myspace.com. Only a handful of researchers have explored Salvia divinorum use in the general population outside of traditional ceremonial use. These studies typically explore a broader array of psychoactive natural medicinal products and preparations commonly marketed as dietary supplements on the Internet.

Halpern and Pope (2001) addressed hallucinogen information on the Internet by performing a Yahoo! search on the keyword "hallucinogen." These researchers were able to find Salvia divinorum for sale in late 1998 on the now defunct "Ethnobotany" website (http://www.ethnobotany. com) as part of their larger study. Hundreds of websites now exist in its wake that sell this natural product as well as preparations of Salvia divinorum laced with tinctures of salvinorin-A extractions to increase potency. At the time of publication, Halpern and Pope called for an increase in legitimate sources of information available on the web to counteract the bountiful underground information that existed on hallucinogen synthesis, extraction, identification, and methods of obtaining and ingesting these substances, both licit and illicit. To date, the imbalance still exists in favor of the underground.

Dennehy, Tsourounis, and Miller (2005) performed a similar study of Internet sites gathered from searching

Google, Yahoo!, AOL, and MSN using the keywords "buy herbal high" and "buy legal high." At the time of their search (February 2004), these researchers found Salvia divinorum to be the second most common substance available behind various ephedra products. Interestingly, during their study period, the Food and Drug Administration effectively banned products containing ephedra under its authority to regulate dietary supplements. With many websites complying with this ban by May 2004, one could surmise that Salvia divinorum products have taken the place of ephedra as the most common substance available via the Internet. Dennehy, Tsourounis, and Miller depicted the "safe legal high" and "street drug alternative" markets to be a potential public health concern, which coincided with a similar FDA warning released while the article was being written. This concern was based on the "desirable claims" of the products for sale on the reviewed websites versus their literature on adverse effects, contraindications, and interactions.

Specific to Salvia divinorum, Dennehy, Tsourounis, and Miller were particularly alarmed by a subjective scale of salvia's effects that is commonly published on websites that sell or promote its use: the SALVIA or S-A-L-V-I-A scale. This scale is utilized to gauge the various levels of effects produced by Salvia divinorum with increased dosage. Several variations exist on different websites and the origin of the term remains unclear. However, the blackouts that were uniformly described by level 6 (or the high-end A in the SALVIA scale) combined with a common call for a sober onlooker, or "sitter," to perform lifeguard-like duties for intoxicated users suggests that Salvia divinorum should be closely watched by healthcare professionals who counsel and treat recreational drug users and their families.

How this information available online is processed and utilized by Internet users remains unclear. Boyer, Shannon, and Hibberd (2005) began to shed some light on this topic in a sample of "innovative adolescent drug users." A total of 12 young adults aged 15 to 23-patients at the Adolescent Substance Abuse Program at Children's Hospital or those that were admitted to the Emergency Department at the University of Massachusetts-Memorial Medical Center—were interviewed and asked to respond to questions about the frequency of Internet use, which information about drugs has been sought, and what influence the onlineaccessible information had on the drug-taking behavior of the patient. Interestingly, these researchers found that their study participants developed new behaviors after exposure to the new information from the Internet. These behaviors included modifications in drugs of choice, desistance from drug use, and initiation of new drugs and/or drug combinations. Previous research has suggested that use of online drug encyclopedias (such as Erowid or Sagewisdom) promotes the initiation of recreational drug use (Wax 2002; Boyer et al. 2001). Boyer, Shannon, and Hibberd (2001) found that seasoned recreational drug users modified their drug-taking behavior by utilizing the resources available on the Internet, Griffin, Miller & Khey

Legally High

and a majority of their sample utilized the literature on the Internet in a manner consistent with harm reduction and risk minimization.

Since its introduction to the West (Wasson 1962; Epling & Jativa 1962), the United States has only recently seen an increase in recreational use of Salvia divinorum. Recreational use has differed from traditional use in the social context along with the quantity, potency, and method of administration. Halpern (2004) warns that recreational use of Salvia divinorum and other similar hallucinogens and dissociative substances may lead to adverse health effects. He emphasizes that the media popularity of Salvia divinorum could draw attention to other botanicals as well.

Studies of recreational users are relatively scarce in peer-reviewed scientific journals Bucheler and colleagues (2005) presented a case study of one 19-year-old man in Germany who was brought to a clinic by his concerned mother. He did not have a history of psychiatric disorders or current presentation of pathology or abnormality, and had no other history of drug use. The authors explained the young man's experiences with Salvia divinorum. The young man had been ingesting and smoking the dried leaves of Salvia divinorum twice a week for about six months. The study notes the individual's account of the experience and the intense but short-lived effects. According to the young man the drug produces a sensation of hovering, a disconnection from ones own body, and a new level of self-consciousness. These effects quickly wear off after 30 minutes, and for the next couple hours the young man reported shivering and a feeling of exhaustion preventing him from concentrating. The young man attributed this lack of concentration not to an effect of the drug, but rather the mental exhaustion of trying to make sense of his experience (Bucheler et al. 2005).

That study reflected an individual who used salvia for meditation purposes that closely resemble the spiritual and religious use prevalent in traditional usage of the plant. On the other hand, González and colleagues (2006) describe the use of Salvia divinorum in the more conventional concept of recreational use (e.g., to get high). In a sample of 32 drug users, the most common reason cited for the use of salvia was to experience "the trip" followed by "laughter, happiness, [and] well-being". The participants in this study were all habitual drug users and used a variety of different substances both licit and illicit. In a qualitative email survey of ten people who had used salvia, those surveyed were asked to provide as much information about their use and experiences as possible. From these surveys it appears that the experiences of salvia use vary from user to user and those that understand a "ritualistic setting" indicative of traditional use appeared to have a "fuller" experience (Dalgarno 2007). In a case study of a fifteen-year old who suffered from déjà vu, the author speculated that Salvia divinorum might have been the cause and noted that this could be a long term effect of salvia use. However, the young man had a family history of mental illness and admitted to using other drugs (Singh 2007).

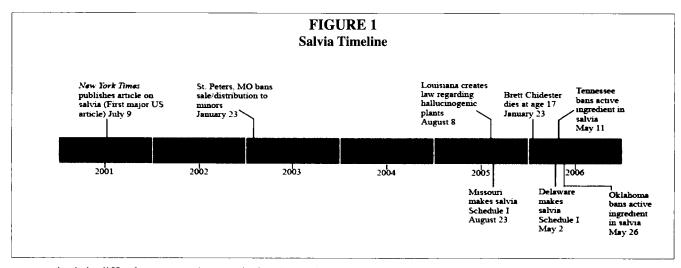
Two studies to date have sought to identify prevalence rates of Salvia divinorum use. In a general drug survey of 1.571 university students in a southwestern state where Salvia divinorum is not prohibited, the researchers found that 4.4% of those surveyed had used the drug within the previous year of completing the survey. Among those surveyed, White males were found to be the most likely to have used Salvia divinorum and other drug use seemed to be the best predictor of use (Lange et al. 2008). In a survey of 826 undergraduate students at a southeastern university in a state where Salvia divinorum was not prohibited at the time the students were surveyed, 6.7% of those surveyed reporting using Salvia divinorum. As in the study by Lange and colleagues (2008) White males reported higher rates of use than other demographic groups. Likewise, Miller and colleagues (Under review) found that specifically selfreported marijuana use was the highest predictor of Salvia divinorum use.

SALVIA IN THE MEDIA

In the past five years, the American media has presented salvia as a dangerous legal alternative to marijuana to which youths have ready access. A look at the media coverage on Salvia divinorum use reveals several key themes across the articles. Many of the articles cite specific experiences and descriptions of individuals who have used salvia. These articles often characterize the dissociative properties of the drug and make comparisons to illicit drugs such as LSD, mescaline, peyote, MDMA, psilocybe mushrooms, and marijuana. For example, In a KCNC TV report in Denver a salvia user characterized the experience as "... like taking acid and mushrooms and ecstasy and slamming a 40 and huffing a nitrous balloon all at the same time" (Blake 2006).

Another key focus of media attention has been on the increased use among college students and teenagers. Many local papers have cited increased use among university students at: Ohio State University, University of Kansas, Ball Sate University, University of Oklahoma, Northern Illinois University, Ohio University, University of North Dakota, and University of Florida. The Canadian media has had an increased focus on teen use.² Many of the articles and editorials express outrage that a potentially harmful substance is readily available to teenagers and sold in local stores. The Standard in St. Catharine's, Ontario notes a teen user's observation of a friend on salvia: "This girl, who smoked salvia, was banging her head against the wall. It was like she was having a seizure. She was snapping and pulling her hair out her head. It was a very nasty thing to see" (Spiteri 2006). The growing concern over adolescent use and unregulated sales has led to an outcry for increased legislation.

The story of a teenager in Delaware, Brett Chidester, whose suicide was officially linked to smoking salvia, has led to extensive media coverage. Although this death



was tragic, it is difficult to argue that one isolated case is sufficient to link salvia use to suicidal thoughts. In this case, the medical examiner revised the cause of death to include salvia as a contributing factor on the official death investigative report. This has been controversial because extant research (the little available) on salvia's psychoactive properties has been inconclusive, let alone suggestive that Salvia divinorum can lead to suicidal thoughts. In a stark contrast, well-established and conclusive evidence reveals that suicidal thoughts can be precipitated by a number licit substances; however, these pharmaceutical connections do not often appear on death certificates.³ Several other factors distort the clear connection of Chidester's death to the use of salvia. Even the teenager's mother, Kathy Chidester, indicated that there were more issues surrounding this suicide: "I just think, with all the things he had going on, and to add salvia to that mix, it was a lethal combination" (NBC 10 2006). Much of the media coverage has focused on a passage in Brett's journal. Brett's mother found an essay on his computer after his death where he wrote that the meaning of the universe "is nothing" (KATV 7 2006). Nevertheless, since this heightened coverage, state legislatures have taken the initiative to control Salvia divinorum. Figure 1 displays a timeline beginning with the first known popular media account of Salvia divinorum use and the dates of legislation passed prohibiting it prior to 2006.

THE LEGAL STATUS OF SALVIA DIVINORUM

Two states have placed Salvia divinorum within Schedule I of their state versions of the Controlled Substances Act. Missouri has placed Salvia divinorum within Schedule I of the state's Drug Regulations (Missouri Revised Statutes 2006; see also www.missouri.gov) with Missouri HB633. This bill scheduled Salvia divinorum and twelve other compounds within Schedule I. The state of Delaware added Salvia divinorum to Schedule I of its Uniform Controlled Substances Act with Senate Bill #259, also known as Brett's Law. In New Jersey, legislation on this issue (A3139)

is currently pending, and if passed, would place Salvia divinorum in Schedule I (New Jersey Legislative Digest 2006). In contrast, in Alaska, State Senator Gene Therriault has proposed Senate Bill 313, which if passed, will place Salvia divinorum in Schedule II of Alaska's list of illegal drugs (Alaska State Legislature 2006).

Other state lawmakers have sought innovative legislation separate from their controlled substances acts. By the beginning of 2007, three states had already passed laws prohibiting the possession or manufacture of Salvia divinorum in this manner. In Louisiana, the state legislature has passed a law prohibiting the production, manufacture, and distribution of hallucinogenic plant products in which fortyone hallucinogenic plants are mentioned, including Salvia divinorum. Persons convicted of manufacture, distribution, or possession with intent to distribute are subject to prison terms of no less than two years nor greater than ten years and are subject to a \$20,000 fine (Louisiana House Legislative Digest 2005).

In Tennessee, it is a Class A misdemeanor to knowingly produce, manufacture, distribute, or possess the active chemical ingredient in *Salvia divinorum*. As the statute notes, the prohibition does not apply to the possession of *Salvia divinorum* for aesthetic, landscaping, or decorative purposes. Furthermore, the prohibition does not apply to dosages of *Salvia divinorum* that can be legally obtained from a retail establishment without a prescription and are recognized for use as a homeopathic drug (Tennessee Code Annotated 2006).

In Oklahoma, Salvia divinorum was added into the subheading "synthetic controlled substances" of the Oklahoma Uniform Controlled Dangerous Substances Act. The statute defines synthetic controlled substances as "whether synthetic or naturally occurring, that is not a controlled dangerous substance, but which produces a like or similar physiological or psychological effect on the human central nervous system that currently has no accepted medical use in treatment in the United States and has a potential for abuse" (Oklahoma Code Annotated 2006). The Oklahoma statute

Griffin, Miller & Khey Legally High

does not prohibit the plant itself, but rather states, "Prima facie evidence that a substance containing Salvia divinorum has been enhanced, concentrated or chemically or physically altered shall give rise to a rebuttable presumption that the substance is a synthetic controlled substance" (Oklahoma Code Annotated 2006).

In January 2003, the city of St. Peters, Missouri passed the first, and thus far the only, local ordinance to regulate Salvia divinorum. As described by a National Drug Intelligence Center Information Bulletin, reports by local law enforcement indicating high levels of salvia abuse prompted politicians to pass a city ordinance that is explicated in Section 210.315 (DEA 2003). This ordinance outlawed the sale and distribution of Salvia divinorum and salvinorin-A extracts to minors unless done so by a family member on private property. The ordinance was later repealed in October 2005 in deference to the Missouri state law that placed Salvia divinorum and salvinorin-A extracts in its controlled substances act as Schedule I. "According to the city's Board of Aldermen, the enactment of the ordinance was necessary due to the high rates of abuse by adolescents and concerns the herb poses a threat to the health, safety, and welfare of residents of St. Peters" (DEA 2003: 2). It is unclear what, if any, empirical evidence was gathered in support of these assertions; however, enough concern was created to drive legislation to protect minors from using Salvia divinorum except under parental supervision or consent. This drastically differs from the State of Missouri's view on the legitimacy of salvia use two years later.

The military has been taking note of salvia use within its ranks. In a short article, Lance Corporal Holgersen (2005) reports that *Salvia divinorum* and salvinorin-A extracts are not explicitly controlled by the Uniform Code of Military Justice (UCMJ) in the controlled substances section of Article 112a. Alternatively, military personally can be charged under Article 92, entitled "Failure to Obey Order or Regulation" (Holgersen 2005). For Marines and Navy personnel, a section under the Secretary of the Navy Instruction 5300.28D entitled "Military Substance Abuse Prevention and Control," subsection 2c titled "Other Substance Abuse" justifies the Article 92 violation:

c. Other Substance Abuse. The unlawful use by persons in the DON [Department of the Navy] of controlled substance analogues (designer drugs), natural substances (e.g., fungi, excretions), chemicals (e.g., chemicals wrongfully used as inhalants), propellants, and/or a prescribed or over-the-counter drug or pharmaceutical compound, with the intent to induce intoxication, excitement, or stupefaction of the central nervous system, is prohibited and will subject the violator to punitive action under the UCMJ or adverse administrative action or both.

The Office of the Chief of Naval Operations' provisions in OPNAV instruction 5350.4C (OPNAVINST 5350.4C) entitled "Drug and Alcohol Abuse Prevention and Control" offers guidance on how to execute the Navy (and thereby

Marine) drug controls, monitoring, and treatment. Both instructions would be utilized by military prosecutors or superiors to handle personnel found in possession, using, or under the influence of salvia. LC Holgersen (2005) cites Colonel Mick McCue, the staff judge advocate for Marine Forces Atlantic who indicated that Salvia divinorum use is on the rise in the military and that this is not a new phenomenon. To date, it is unclear if any military personnel have been prosecuted, reprimanded, or have any mention of Salvia divinorum use in their personnel file (called jackets). Holgersen's sources revealed that no individual at Camp Lejuene has been caught (perhaps due to the lack of a toxicological screen for salvia). Thus, a reliable measure of the prevalence of this drug in the Marines and the military is not currently available.

SCHEDULING OF DRUGS

The Controlled Substances Act of 1970 (CSA) is the mechanism through which all drugs are to be regulated by the federal government. This law replaced all other legal mechanisms through which controlled substances were regulated. The CSA classifies individual substances into distinctive schedules based upon their potential for abuse, the safety of the drug, and its medical utility (Spillane 2004). For a drug to be placed into Schedule I of the CSA, the drug must fit three criteria: it must not have an accepted medical use; it must have a high likelihood of abuse; and it must have some potential for danger. Schedule II of the CSA is similar to Schedule I, the only difference being that it provides for an accepted medical use for controlled substances (Gahlinger 2004).

Although there are no currently accepted medical uses for Salvia divinorum, several scholars have been researching its potential medical utility. Thomas Prisinzano, (2005) a medical researcher at the University of Iowa, has indicated that the active ingredient (salvinorin A) might have some medical utility. He notes that it could potentially be used as a nonaddictive painkiller and might lead to a better understanding of how the brain works. If so, the possible medical utility of the substance might lead to treatments for Alzheimer's disease and other mental illnesses. Other researchers have indicated that salvinorin A might have medical utility as well. Among these uses are seen potential for combating depression, chronic pain, and kidney problems (Vorthems & Roth 2006). Furthermore, salvinorin A might be unique in its medical utility, since it is a highly specific kappa-opioid agonist which selectively binds to this single receptor in the brain. In comparison, LSD binds to about fifty different receptors in the brain. Although Roth doubts salvinorin A will be used as a treatment itself, he believes that the derivatives of the drug could be quite useful due to this unique property (Ubelacker 2006).

When considering the abuse potential of Salvia divinorum, the Drug Enforcement Administration (DEA) declined Griffin, Miller & Khey Legally High

to regulate the substance. In 2003, a published report from the NDIC reprinted by the DEA (2003) concluded that many users of Salvia divinorum indicated that they would not try the substance again after their first use. This is due to the common occurrence of negative experiences with salvia experimentation. Although the DEA stated that the abuse potential for Salvia divinorum was not known, they speculated that the drug would most likely not become popular. Indeed, they note: "Most likely, the abuser population is limited and primarily consists of young adults and adolescents who frequent 'head shops' or have been influenced by Internet sites promoting the drug" (DEA 2003). The DEA (2003) also noted that one Internet distributor of Salvia divinorum reported that approximately one in ten customers placed a second order for the drug.

Furthermore, the DEA states that Salvia divinorum will probably not become a "club drug." It notes that users generally become introspective and introverted, two states of consciousness that are not typically associated with rave culture (DEA 2003). The opinion of the DEA is also echoed by Paul Doering, a pharmacy professor at the University of Florida. According to Doering, users of Salvia divinorum generally describe the effects of the drug as unpleasant. Furthermore, he notes that many persons who have used Salvia divinorum indicated that they would not try it again and the main attraction of the drug was its legality (Davis 2006).

Daniel Siebert, an ethnobotanist and advocate of Salvia divinorum, states that the drug is not for recreational use. In his Salvia User's Guide, Siebert (2006) states that most people will not enjoy using Salvia divinorum. The guide suggests that those that use Salvia divinorum should do so to seek enlightenment. Moreover, he stresses that salvia should not be referred to as "legal pot" or "legal acid" (Siebert 2004).

When considering whether or not Salvia divinorum has a high potential for abuse, it is important to consider other Schedule I controlled substances and what properties or patterns of use of these substances have which resulted in their scheduling. For example, in February of 2000, former U.S. President William J. Clinton signed the Hillory J. Farias and Samantha Reid Date-Rape Prohibition Act of 2000. The two teenage girls that the law was named for had unknowingly ingested GHB and died as a result of ingesting the drug. This law placed GHB into Schedule I of the CSA. Although the recreational use of GHB was certainly a factor in placing it in Schedule I, the more nefarious use of GHB played a much larger role. As the law indicates, several persons have used GHB to render potential rape victims defenseless to their advances (DEA 2001).

Another Schedule I drug with contested abuse potential is MDMA. While at raves, partygoers will often dance for hours at a time. These individuals sometimes forget to consume fluids necessary to keep the body properly hydrated considering their level of exertion; as a result, they

suffer from varying levels of dehydration. In some cases, these levels of dehydration can be alleviated by consuming fluids. However, in some cases users of MDMA who have overexerted themselves have suffered from epileptic shock, coma, and in a few cases have died (DEA 2001). Furthermore, studies on rats and primates have shown that repeated doses of MDMA have led to deterioration of brain activity (Barnes 1988).

Considering how the DEA and the United States Congress defined a high potential for abuse in the cases of GHB and MDMA, it is hard to say that Salvia divinorum has the same potential for abuse. The effects of Salvia divinorum are generally reported to last anywhere between five minutes and one hour (Ubelacker 2006). No cases have been reported of persons overdosing on Salvia divinorum. Some have cautioned that persons could recklessly drive automobiles while under the influence of the drug (Gupta 2003). There have been no documented cases of such an occurrence. Furthermore, such a scenario may be unlikely given the culture of use and the brief effects. Medical science has only recently begun to study Salvia divinorum and its impacts on the body, mind, and faculties. At present, only the potent short-term dissociative effects of the drug have been uncovered as potentially dangerous (see Kerman 2006). What these dangers exactly entail is unknown.

It is important to note that some state legislators appear to be defining abuse liability solely in terms of the drug's potential to alter consciousness, which in and of itself is not and never has been the standard for assessing such liability. In Delaware, the state law that added Salvia divinorum to Schedule I of the Delaware State Code, known as Brett's Law, is based upon the circumstances surrounding one teenager's suicide. According to his personal journal, which was utilized by state lawmakers in the hearings to design the law, Brett Chidester mentioned that Salvia divinorum exposed him to different dimensions of reality that left him with an empty feeling about this world (Osborne 2006). It is difficult to argue that exposure to higher levels of consciousness alone justifies a label of having a high potential for abuse. In Tennessee, the legislator sponsoring the bill criminalizing Salvia divinorum expressed the belief that it was important to stop persons from using a substance that alters their state of consciousness. However, the lawmaker did not elaborate further on the potential danger of abuse (Davis 2006).

Implications of a Schedule I Label

It is difficult to ascertain what affect prohibitions will have on medical research within the states that have decided to craft separate laws controlling *Salvia divinorum* (rather than placing them in a particular controlled substance schedule). One of the main purposes of the CSA is to dictate the restrictions (or regulations) on research, based upon where a drug is placed into a particular schedule, and those states that have crafted these separate laws have made no provisions for

Griffin, Miller & Khey

Legally High

research exemptions or regulations. However, it is uncertain if these traditional guidelines will continue to apply as these atypical methods of prohibition do not have contemporary precedents. Indeed, a situation may occur where researchers will have to engage in forum-shopping among states with favorable laws if they are interesting in conducting research studies with Salvia divinorum.

The regulations concerning research of scheduled controlled substances are outlined in Title 21 Chapter II §1301 of the Code of Federal Regulations. To conduct research on a Schedule I controlled substance, a researcher must file an application with the United States Attorney General. Included in the application must be: the identity and background of the investigator, the institutional affiliation, qualifications of the investigator, the research project and a statement of its purpose, the individual names of controlled substances and the expected amount needed of each, a full description of the research including the number and species of research subjects, and the security provisions for protection of controlled substances. Furthermore, researchers hoping to investigate Schedule I substances must have their application approved by the Secretary of Health and Human Services as outlined in §1301.32—an additional bureaucratic oversight to which researchers of Scheduled substances II-V are not subject. Perhaps the most daunting of these requirements is found within the security protocols outlined in §1301.71. Although there are broad guidelines on what type of security is needed for approval of a research study, the language of the application requirements do not set any minimum requirements for the approval of an application.

An application must include a description of the building and its characteristics. Furthermore, the application must include "the type of vault, safe, and secure enclosures or other storage system." The "adequacy" of key control systems, lock control systems, electric detection and alarm systems, and the characteristics of any perimeter fencing must be included as well. The applicant must anticipate all potential unsupervised persons that will enter the facility, the adequacy of supervision of the facility and even the adequacy of police and/or private security protection in proximity to the proposed research site. The regulations also require strict screening of employees. Lastly, if an application for research is approved, the researcher must comply with strict inventory procedures which the DEA can review at any time. Successful applicants must renew their license every year and researchers must be in compliance with any additional state requirements.

Two recent examples of the hardships caused by a Schedule I label are telling. In 1986, Dr. Lester Grinspoon filed suit against the DEA arguing that the DEA had improperly scheduled MDMA. Among the many arguments that he made was that placing MDMA into Schedule I would effectively end scientific research due to bureaucratic regulations required to study Schedule I drugs. In order to conduct research on a Schedule I substance, a researcher is required

to receive approval from the FDA and must specially register with the DEA, as described previously. Furthermore, Grinspoon stated that there are problems obtaining participants in clinical trials and academic researchers often have trouble getting studies approved by institutional review boards when Schedule I drugs are involved (Grinspoon v. DEA 1987).

The sentiments of Grinspoon were echoed by Patti Engel of Orphan Medical when she testified before the U.S. House Commerce Committee when it was considering the Hillory J. Farias and Samantha Reid Date-Rape Prohibition Act in 1999. Engel testified that Orphan Medical was a small company in Minnesota that developed medicines to treat rare diseases. Among the medicines Orphan Medical was developing was GHB; Engel noted that it was the most effective way to treat narcolepsy. She stated that the FDA had actually approached her company about developing GHB as an orphan drug. Engel noted that many companies are unwilling to manufacture or synthesize Schedule I drugs, and that most sleep centers that would employ the drug experimentally would refuse to do so if the drug is Schedule I. Lastly, Engel said that to secure a Schedule I drug a twenty thousand square foot vault with eight-inch concrete would be required to store it. Her company had estimated the cost of construction of such a facility at \$20 million. As she stated, the economic disincentive of building such infrastructure would most likely prevent any company from producing a Schedule I drug (Engel 1999).

CONCLUSION

So far the DEA and the United States Congress has declined to regulate Salvia divinorum, choosing to leave the burden of regulating it upon the states. Currently six states regulate Salvia divinorum through a variety of legal mechanisms. Some branches of the United States Armed Forces and a few other states are currently debating what medico-legal actions to take without guidance of extant scientific and social scientific research. Although the media has portrayed Salvia divinorum as a drug of concern, states are only slowly following suit. Had it not been for one young man's suicide, perhaps the attention of state legislators would be even slower.

Since the passage of the CSA the federal government has usually taken the lead role in regulating and classifying controlled substances. Indeed, due to the supremacy clause of the United States Constitution, the states have essentially lost the ability to formulate regulations on controlled substances. However, since the DEA and the United States Congress have declined to take action on Salvia divinorum, the states are in a somewhat unique position since the passage of the CSA. As a result, a rare phenomenon within drug policy has occurred which the CSA was supposed to prevent: an anarchy of drug policy. This is problematic because states will have different laws regulating Salvia divinorum, which is antithetic to the design of the CSA,

and medical researchers may have to forum shop so that they can effectively maintain research projects. It will be interesting to see how many states and government entities will develop prohibitions against the substance or if the federal government will eventually take action as exposure increases.

NOTES

- 1. The term "salvia" is employed throughout this article to indicate the recreational ingestion of Salvia divinorum. The usage of "salvia" in this manner will reflect the drug culture and does not reflect all of the plants in the genus Salvia. The authors also use the taxon Salvia divinorum to properly refer to the psychoactive plant itself. These terms should not be confused.
- 2. In Canada, like the United States, there are no age restrictions on salvia use where it is legal.
- 3.I.e. Zoloft, Startera, Effexor, Lexapro, Accutane, and Prozac (see DeGrandpre 2006). It is important to stress that *therapeutic* rather than abusive or inappropriate use of these products are more likely to escape detection as a contrib-
- uting antemortem factor under the cause of death during the autopsy process. The variance in the protocol of death investigations across jurisdictions (namely, the differences between the traditional coroner and medical examiner systems) may further explain the low prevalence of these types of cases across the United States. Furthermore, the absence of a toxicological protocol for salvinorin-A in *any* matrix (blood, urine, vitreous fluid, etc.) creates additional problems for death investigators, coroners, and medical examiners. To date only two studies address the examination of salvinorin-A in body fluids, and neither study is comprehensive (see Grundmann et al. 2007). A decision to list *Salvia divinorum* as a contributing cause of death is thus very subjective by nature at this point in time.
- 4. Section 892, Article 92 of the UCMJ states: Any person subject to this chapter who—(1) violates or fails to obey any lawful general order or regulation; (2) having knowledge of any other lawful order issued by any member of the armed forces, which it is his duty to obey, fails to obey the order; or (3) is derelict in the performance of his duties; shall be punished as a court-martial may direct.

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Griffin, Miller & Khey

Legally High

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