

A Public-Health-Based Vision for the Management and Regulation of Psychedelics

Mark Haden, M.S.W.^{a,b}, Brian Emerson, M.D., M.H.S.C.^{c,d}, and Kenneth W. Tupper, Ph.D.^a

^aAdjunct Professor, School of Population and Public Health, University of British Columbia, Vancouver, Canada; ^bChair of the Board of MAPS (Multidisciplinary Association for Psychedelic Studies) Canada, School of Population and Public Health, Vancouver, Canada; ^cChair of the Psychoactive Substances Committee, Health Officers Council of British Columbia, Victoria, Canada; ^dMedical Consultant, Population and Public Health Division, Ministry of Health, Victoria, Canada

ABSTRACT

The Health Officers Council of British Columbia has proposed post-prohibition regulatory models for currently illegal drugs based on public health principles, and this article continues this work by proposing a model for the regulation and management of psychedelics. This article outlines recent research on psychedelic substances and the key determinants of benefit and harm from their use. It then describes a public-health-based model for the regulation of psychedelics, which includes governance, supervision, set and setting controls, youth access, supply control, demand limitation, and evaluation.

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The prohibition and criminalization of certain psychoactive substances generates harmful unintended consequences (Health Officers Council of British Columbia 2005, 2011). As a result, there is growing interest in alternative approaches to drug control (Canadian Drug Policy Coalition 2012; Global Commission on Drug Policy 2014; King County Bar Association: Drug Policy Project 2005; Rolles 2009). Psychedelic drugs are one class of substances garnering increased attention among scientists (Langlitz 2013), physicians (Tupper et al. 2015), spiritual leaders (Richards 2015), and the general public. These trends warrant discussion in terms of post-prohibition options for regulation and management of activities associated with these substances. For the purpose of this article, “psychedelic” substances include LSD, psilocybin, MDMA, DMT, ayahuasca, peyote, mescaline, and other psychoactive substances based on the tryptamine or phenethylamine classes of compounds.

Many frameworks can be used to understand concerns with the existing prohibitionist approach and to explore alternatives. For example, *religious freedom* has been a basis for one kind of psychedelic legalization, with accommodation of the importation and use of ayahuasca sacraments of the União do Vegetal and Santo Daime in the U.S. and some European countries. More broadly, the *human rights* model has been effective in supporting individual freedoms and can be applied to drug policy issues (Van Ree 1999). Discussions about *cognitive liberty* offer perspectives which

are likewise illuminating and constructive (Boire 2000; Walsh 2016). While these models have much to offer, the purpose of this article is to explore the management and regulation of psychedelics using the lens of public health.

Public health leaders have called for the development of post-prohibition models of drug control (Buxton, Haden, and Mathias 2008; Canadian Public Health Association 2014). This approach is organized, comprehensive, multi-sectoral, and directed at maintaining and improving the health of populations (Frank, Di Ruggiero, and Moloughney 2004; Last 2006). The public health perspective is based on an ethical framework (Wodak 2007), social justice (Mitchell 1986), human rights (Barrett et al. 2008), equity (Chambliss 1994), health promotion (World Health Organization 1986), harm reduction (Rhodes and Hedrich 2010), and evidence-informed policy and practice (Ritter 2009).

The Health Officers Council of British Columbia (HOC-BC), which represents the public health physicians of BC, proposed a public health framework for regulating psychoactive substances (Health Officers Council of British Columbia 2011, 2005). This framework has been used in the articulation of drug-specific, post-prohibition regulatory models for cannabis (Haden and Emerson 2014) and smokeable and injectable stimulants (Haden 2008). It is important to include psychedelics in regulatory discussions, as drugs in this class are among the top five psychoactive substances

used in Canada (Health Canada 2012), Europe (EMCDDA 2015), and the U.S. (Johnston et al. 2015).

Summary of current research on psychedelics

To contextualize the public health approach to regulating psychedelics, we first summarize recent scientific evidence about these substances, as there has been an international resurgence of interest in their potential medical and other benefits. Work by Mithoefer studying MDMA-assisted psychotherapy demonstrated positive effects on post-traumatic stress disorder (PTSD) symptoms (Mithoefer et al. 2010). Ten of twelve (83%) individuals who received MDMA no longer met the DSM-IV criteria for PTSD, whereas only two of eight (25%) of the participants who received only psychotherapy achieved this goal. Some participants who had been unable to work were able to regain employment. A follow-up study demonstrated that the therapeutic benefits were still evident for most patients years after the treatment (Mithoefer et al. 2013).

Grob et al. (2011) found that psilocybin-assisted psychotherapy was associated with reduced anxiety and improved mood among individuals with advanced cancer, corroborating findings from earlier research (Kurland et al. 1973), including a decrease in the fear of death in some participants (Pahnke 1970). Non-clinical use of psychedelics has been associated with significantly reduced psychological distress and suicidality (Hendricks et al. 2015), reduced recidivism for offenders under community supervision (Hendricks et al. 2014), and reduced arrests for intimate partner violence (Walsh et al. 2016). Moreno et al. (2006) observed psilocybin use to be associated with acute reductions in core obsessive compulsive symptoms. Sanches et al. (2016) reported rapid and sustained reductions in depression from the clinical administration of ayahuasca. Sewell, Halpern, and Pope (2006) found that patients suffering from cluster migraine headaches reported symptoms either terminated or attenuated by LSD or psilocybin.

The addiction treatment potential of psychedelic-assisted therapies has been observed in both historical and contemporary scientific research. Early psychedelic research in the 1950s and 1960s yielded intriguing evidence for psychedelic therapies to treat alcohol and opioid addiction (Abramson 1967; Savage and McCabe 1973). In a meta-analysis of six historical trials, Krebs and Johansen (2012) noted that, for alcoholism treatment, LSD-assisted therapies were associated with a decrease in problem drinking. This finding was supported by Bogenschutz et al. (2015), who observed that psilocybin-assisted psychotherapy for alcohol dependence was associated with reduction of craving and

increases in periods of abstinence. An open-label pilot study of psilocybin-assisted treatment for tobacco dependence showed abstinence rates which were more than double typical tobacco cessation interventions (Johnson et al. 2014). Thomas et al. (2013) demonstrated a reduction of problematic alcohol and cocaine use in members of a rural indigenous community who participated in ceremonial ayahuasca retreats. There is growing evidence that ibogaine could be effective in the treatment of addictions (Brown 2013; Schenberg et al. 2014). In the anthropological literature, a reduction of problematic alcohol use is reported in indigenous or spiritual communities who participate in ceremonial uses of peyote (Albaugh and Anderson 1974; Hill 1990; Stewart 1987) and ayahuasca (Grob et al. 1996; Halpern et al. 2008).

These findings may be partially explained by studies which explored the psychopharmacological effects of psychedelics in healthy human participants. Griffiths et al. (2006) documented the effects of a single dose of psilocybin in healthy volunteers taken in a supervised, supportive session. They found that this experience had a profound impact on participants' sense of personal meaning and spirituality, which had a positive impact on attitude and behavior. A 14-month follow-up found this effect to be persistent (Griffiths et al. 2008). MacLean, Johnson, and Griffiths (2011) observed that psychedelic use could affect domains of personality which are usually understood to be stable and fixed in adulthood; specifically, they found that the trait of openness was significantly increased by a clinically supervised experience with psilocybin. Carhart-Harris et al. found that clinically administered LSD in moderate doses, while producing acute psychosis-like effects, left participants with measurably increased openness and optimism, as well as overall improved psychological wellbeing in the mid- to long-term (Carhart-Harris et al. 2016).

The positive outcomes of psychedelic research need to be understood in context as, historically, the optimal clinical protocols for therapeutic uses of these substances have not always been understood or put in practice (Dyck 2008; Krebs and Johansen 2012). Today most researchers understand that psychedelic-assisted treatments require the context of a strong therapeutic relationship with a clinical practitioner who understands the importance of managing the environment to maximize positive outcomes (Grinspoon and Bakalar 1997; Johnson, Richards, and Griffiths 2008).

While recent clinical psychedelic research findings should be regarded as preliminary due to the small sample sizes, no serious or enduring adverse effects were observed when appropriate screening and safeguards were used (Johnson, Richards, and Griffiths 2008). Accordingly,

medical researchers have called for increased investigation into the potential benefits of psychedelics for mental illness and addiction treatment (Tupper et al. 2015). Further, a number of authors have offered a risk/benefit analysis of psychedelics and suggested that these substances be reclassified to reduce access restrictions for clinical and other scientific research (Nutt, King, and Nichols 2013; Rucker 2015; Sessa 2005; Winkelman 2007).

This renewed interest in psychedelic-assisted treatments (psychedelic medicine) is not unprecedented, as there was interest in their therapeutic and cognitive enhancement potentials before they were prohibited and criminalized (Dyck 2005; Grof 2008; Harman et al. 1966; Winkelman 2007; Winkelman and Roberts 2007). Early psychedelic research yielded insights that may be valuable today, especially since promising research avenues were prematurely terminated and unfulfilled for decades. The history of psychedelic medicine before criminalization is explored in detail by Dyck (2008) and Grinspoon and Bakalar (1997).

The reasons these drugs and plant preparations were criminalized had little to do with their pharmacological properties, but rather with the socio-political context of the 1960s. A prominent messianic figure of that decade, Timothy Leary, advocated for youth to “turn on, tune in and drop out” (Leary 1965), which was interpreted as an anti-social message linking psychedelics with disconnection from mainstream society (Cottrell 2015). This kind of message, with respect to psychedelics, was historically anomalous, as virtually all indigenous uses of psychedelics throughout the centuries have been pro-social and linked with spirituality, healing, and honoring seasonal and life transitions in the context of cohesive community (Coomber and South 2004; Dobkin de Rios 1990; Knipe 1995). The socio-political context of the backlash against Leary and others included the demographic shifts wrought by the coming of age of the Baby Boom generation, the loosening of sexual mores associated with the advent of the birth control pill, protests against militarism and the American war in Vietnam, and other artistic and cultural trends that seemed to challenge the foundational values of modern Western society. Psychedelic drugs were often portrayed as catalysts for changes that threatened the political and social status quo, and drug control mechanisms were established that effectively terminated all human research with these substances.

Set and setting: Determinants of benefits and harms

The prohibition of psychedelics, while stifling scientific and medical research, did not eliminate their illegal,

uncontrolled, non-medical use. As with other illegal drugs, the criminalization of psychedelics has generated significant harms, particularly as illegal markets produce and distribute psychoactive substances that range widely in quality and potency, resulting in unpredictable toxic effects. For example, drugs sold as “ecstasy” (presumed to be MDMA) are often adulterated with other substances, including paramethoxymethamphetamine (PMMA), which has resulted in a number of deaths (Nicol et al. 2015). In addition, the clandestine nature of drug use in a prohibition regime increases the risk of harm because prohibition interferes with the ability to implement “context of use” controls and cultivate social and other informal mechanisms that are important risk reduction measures.

The cultural regulation of psychedelics in non-prohibition contexts has a rich anthropological history from which to draw lessons. Many indigenous societies have traditionally integrated the use of psychedelic preparations using time-tested ceremonial safeguards to minimize adverse effects. They have utilized psychedelics as sacraments or “sacred medicines” in ancient ritualistic healing and spiritual practices (Calabrese 2013; Coomber and South 2004; Dobkin de Rios 1990; Durrant and Thakker 2003; Furst 1976; Myerhoff 1974).

The typical spiritual framework for the use of psychedelic plants in traditional indigenous contexts led early researchers such as Walter Pahnke (1966) to propose experiments with religious settings for modern psychedelic studies. Pahnke documented profound spiritual experiences in seminary students who were given psilocybin during a “Good Friday” sermon, the effects of which lasted for decades afterwards (Doblin 1991). However, Pahnke’s experimental “Good Friday” session also demonstrated, through an unexpected escape of a participant outside into public space, that careful supervision of people during psychedelic experiences is important (Doblin 1991).

The relative safety of psychedelics is evident in the significant numbers of indigenous cultural practices that include sacramental and ceremonial substance use with few adverse effects in hundreds or even thousands of years. One of the reasons that psychedelics are typically beneficial, rather than harmful, in these contexts is that “set” and “setting” are carefully structured. “Set” refers to an individual’s expectations and psychological profile. Culturally mediated beliefs, motivations, current life challenges, underlying mental health problems, and past traumatic experiences influence an individual’s set. The “setting” refers to the broader cultural, physical, and social environment in which the experience occurs. The range of settings varies

widely, as taking psychedelics in a peaceful, natural environment surrounded by supportive family, friends, or spiritual community is very different from taking them and wandering lost at a large dance festival in bad weather. Both are different from the experience of a psychedelic administered in a comfortable office of a skilled therapist. The importance of set and setting to create safe, non-problematic drug-using environments was explored in detail in Zinberg's (1984) analysis of controlled psychoactive substance use. Grund (1993) examined how drug use social rituals can result in self-regulation, which is associated with a reduction of problematic use and associated health and social problems. Carvalho et al. (2014) explored how set and setting are important for crisis intervention services at festivals where psychedelics are used in unsupervised settings.

Even in the absence of recognized safeguards, such as a ceremonial or clinical setting, psychedelics have low potential for health or social harms (Nutt, King, and Phillips 2010), as they are relatively non-toxic (Gable 2006) and have very low dependence potential (Gable 1993). Recent population health data analyses have revealed that non-medical uses of psychedelics are not linked to mental health problems (Krebs and Johansen 2013), or psychological distress or suicidality (Johansen and Krebs 2015). Some health harms from psychedelic drugs are reported in the medical literature, including the precipitation of psychotic breaks in individuals with psychotic disorders or a predisposition to these disorders, and Hallucinogen Persisting Perception Disorder (HPPD), sometimes known as “flashbacks” (Halpern and Pope 2003, 1999; Abraham, Aldrige, and Gogia 1996). However, the incidence of such adverse effects is low and, when they do occur, they are typically associated with illicit substances of unknown purity taken in uncontrolled settings without supervision. It is also important to note that, even within the generic classification of “psychedelic” drugs, there are a range of substances with differing pharmacological effects, potential harms, and potential therapeutic uses. Further, adverse reactions of individuals to particular substances may be a function of genetic or other risk factors for which future research may identify screening protocols. From the current research, it is increasingly apparent that the potential benefits of psychedelics, when used with appropriate supervision, are wide ranging with comparatively minimal risk (Sessa 2012).

Public health regulatory model

The following model is drawn from the lessons learned from the regulation of alcohol and tobacco, which were

used to develop a vision for public-health-based cannabis regulation (Haden and Emerson 2014). It articulates one model for regulating the production, distribution, and use of psychedelic substances, although other models are possible and deserve consideration. For example, the União do Vegetal church, whose members drink ayahuasca, and the Native American Church, whose members use peyote, have significant experiential history in the development of protective ritual safeguards.

Psychoactive Substance Commission (PSC)

A post-prohibition public health model for the regulation and management of psychedelics will require a governance structure. We propose establishing a Psychoactive Substance Commission (PSC), which would have government-delegated authority to regulate psychedelics and other currently illegal drugs (e.g., cannabis, opioids, cocaine), and potentially also alcohol and tobacco. The PSC would work with religious or cultural groups to cooperatively oversee the cultivation or importation of plant-based preparations (e.g., peyote, ayahuasca) used in specific spiritual/sacramental traditions, and would oversee production and distribution of substances used for medical or other non-religious purposes. The PSC would regulate the production, wholesale and retail trade of psychedelics and administer any taxation schemes established for commercial trade in these substances. The PSC statutory mandate would be explicitly guided by public health principles, goals, and objectives. Revenue generation would *not* be a primary function. The PSC would be given responsibility for administering the financial policies for wholesale and retail sales of psychoactive drugs and subsequent revenue streams. The net revenue generated from the sales, fees, and taxation would support the regulatory structure, scientific research on psychoactive substances, and public-health-related programs and other health and social initiatives.

College of psychedelic supervisors

As supportive oversight and compassionate guidance of the psychedelic experience are key to a beneficial outcome and prevention of harms, there is a need for trained, competent, experienced supervisors (e.g., ceremonial leaders, clinical psychedelic therapists, “trip-sitters” or guides) and quality assurance mechanisms.

To ensure that the health of the public is protected, a regulatory body with delegated authority from the PSC would be responsible for oversight of trained and qualified supervisors who manage and support the use of

these substances. This body would function like other regulatory health professional colleges and could be called the College of Psychedelic Supervisors. The function of the College would be to establish, monitor, and enforce standards of practice amongst its registrants. The College would be administered by individuals who had training and experience in psychedelic supervision, including indigenous, spiritual, and medical practitioners. It would be tasked with granting licences for new supervisors, dealing with complaints (e.g., psychological or sexual abuse) and developing and implementing best practices. This College would be responsible for licencing facilities or environments where psychedelics are administered, including inspection and certification to ensure that best-practice requirements have been met. They would develop regulations, performance standards, procedures, guidelines, and accreditation criteria which would be used to structure appropriate environments, and to ensure the delivery of high-quality, safe psychedelic administration and supervision.

There are two options for the regulatory status of psychedelic supervisors: licencing or certification. Certification is a process where individuals offering this service can prove that they have received basic training in this topic, and once certified, they can then supervise psychedelic experiences, but they would *not* be subject to oversight by a licensing body. Licencing is a process which results in a professional designation and the person licensed being subject to oversight by a licensing body.

The advantages of certification are that it would be less expensive and time-consuming and would allow a broader range of individuals to be involved. It would allow easier entrance for psychedelic users/sitters currently practicing outside the law to become supervisors within this new regulatory regime. Self-supervision or friends “sitting” for each other would be easier in the certification model, as the comparatively shorter time and financial commitments for the certification training would make it more convenient for individuals to undertake.

The advantages of licensure are that it would include a more rigorous training and evaluation process and would produce consistently trained professionals. The advantages of this model are the high standards of care, collegial or peer oversight, mechanisms to deal with complaints, and engagement of other professionals and mainstream society.

We recommend a model which allows for the benefits of both of these approaches. Our proposed model allows for a *required* basic certification, with a number of different *optional* advanced streams and levels which

would all involve obtaining a licence. The required basic certification would involve a core training package, including participating in supervised psychedelic experiences, and instruction in basic set, setting, safety, and dosage management. This training could be as short as a weekend course. This basic certification would allow self-supervision or supervision of friends. People with basic certification would not be allowed to offer commercial services for compensation, treat medical conditions, or conduct psychedelic psychotherapy.

Advanced training (i.e., licensure) would build on the basic certification skills (of set, setting, safety, and dosage) and lead to practitioners being granted a license as a psychedelic supervisor, as they develop a professional level of expertise and expand their skills and specialize. There would be a variety of types of specialization, as the skills required to facilitate psychedelic psychotherapy (Mithoefer 2013; Stolaroff 1997) are different from the skills required to structure ayahuasca (MacRae 2004), iboga (Fernandez and Fernandez 2001), or peyote (Calabrese 2013) ceremonies, which are again different from the skill of managing multi-day music festivals (Carvalho et al. 2014; Mojeiko 2007) where crisis intervention skills in a “calm tent” may be needed (Roberts and Everly 2006). Advanced psychedelic supervisors could take a variety of training programs at accredited institutions, pass standardized exams, undertake supervised practicums, and participate in a continuing competency program in order to maintain their licence.

The content and duration of certification and licensure training programs would be approved by the College of Psychedelic Supervisors, with input from clinical, academic, and public health experts knowledgeable about current evidence of the potential benefits and harms of psychedelics. It will be important that individuals who are supervisors as part of existing traditions for ceremonial/sacramental psychedelic experiences (e.g., peyote and ayahuasca communities) be part of this process at all levels. As many groups have significant history and extensive experience, their leadership in crafting best practices would be valuable. As the supervisors who are part of these groups have been demonstrating skills at managing set, setting, safety, dosage, and leadership, it would be reasonable that should they meet specific criteria established by the College, they could be “grandfathered” into this process and be granted a licence to continue supervising the experiences for which they are trained. The advantages of licensure of these supervisors to participants seeking experiences within an existing spiritual community are that there would be quality oversight and a complaint registration and resolution process which may not exist in the current tradition.

The circumstances of psychedelic supervision could vary widely, including psychotherapy, indigenous healing circles, dance events, music festivals, palliative care wards, or natural environments. Supervisors would be expected to offer prior orientation and ongoing monitoring and oversight during the experience. From both traditional indigenous knowledge and current scientific research, it can be expected that the supervisors' primary function would be to provide appropriate safeguards or set and setting controls for all participants for 8–10 hours after ingestion of a psychedelic. The set aspect would be managed by sharing accurate information and the creation of positive expectations and attitudes which facilitate spirituality, healing, connecting with people or nature. The setting aspect would be managed by creating a positive, attractive environment with carefully selected music. Clear boundaries within which the individual would be required to stay for the duration of the experience are important.

Psychedelic supervisors would create and maintain safe environments, including:

- (1) Screening individuals. For example, there may be age restrictions for youth and some mental illness diagnoses or pharmaceutical medication regimes may exclude some participants.
- (2) Obtaining informed consent from participants.
- (3) Involving participants in the choice of dosage, with guidance from the supervisor and clear information about different dosage effects and duration of substance action.
- (4) Understanding and communicating the different pharmacological profiles of the psychedelics. For example, LSD is long acting and has an extremely low risk for toxicity, whereas ayahuasca is shorter duration and may be contraindicated for people taking selective serotonin re-uptake inhibitors (SSRIs).
- (5) Preventing the operation of a motor vehicle or machinery while under the influence of the psychedelic, as impairment from any substance can involve risk to self or others.
- (6) Managing interactions between participants in group settings needs to be considered, recognizing that this is dosage dependent. High dosages need more controls, as everyone has different experiences and all participants have a right to not be intruded upon; for example, by an extroverted individual who is experiencing a difficult emotional process.
- (7) Ensuring the continuous presence of a responsible individual who can intervene if a participant experiences a difficult physical or emotional state.

Youth access to psychedelics

Another key issue in a public health regulatory approach to psychedelic substances is the matter of age of access. In some indigenous societies, youth are given access to psychedelic plant preparations as a normal part of community functioning, such as honoring ceremonial rites of passage (Coomber and South 2004; Furst 1976; Stewart 1987). This can encourage maturity, facilitate family and community bonding as a vehicle for intergenerational education, and bolster connection to cultural and spiritual traditions.

In exploring potential models of youth access to psychedelics, how youth currently receive some health services may be relevant. In Canada, provincial legislation allows youth to access health services confidentially when they are deemed mature. For example, a mature youth can consent to vaccination, or access birth control prescriptions or harm reduction supplies (e.g., sterile syringes) without parental approval. When receiving health services, youth are provided detailed information and obtain these services from trained adults.

We propose a model of psychedelic access for youth which borrows from the healthcare access model (Day 2007), which would allow youth to either access psychedelic experiences with their parent's or guardian's approval and/or participation, or independently if they are mature. In order to undergo psychedelic experiences, youth would be required to obtain basic certification (i.e., training in set, setting, safety, and dosage). Youth would only be able to access psychedelic experiences from adults with a licence that allows them to supervise youth. This requirement that adults guide the psychedelic experience is a reflection of indigenous experiences, where the supervision of youth is typically guided by experienced elders (Coomber and South 2004). An analogy is that of an airplane or helicopter pilot's license: before flying alone or flying with an inexperienced pilot, a novice must complete significant training and flying time under the supervision of an experienced pilot.

Supply control

Another key aspect of any regulatory model is supply-side controls over production and distribution of substances. In our model, pharmaceutical production of psychedelics, commercial growing, wholesale distribution, taxation, and retail sales would be controlled and monitored by the PSC. All formulations would be generic, and no commercial branding of the different psychedelics would be allowed. All products would be packaged plainly and without any proprietary formulations (e.g., no "magic mushroom" cookies or LSD-

infused “electric Kool-aid”) and therefore labelled with product and dosage information in plain packaging and appropriate content and warning labels. Importation of ayahuasca brews or peyote buttons would be monitored by the PSC, in partnership with respective spiritual community leaders or ceremonial practitioners receiving these substances. The PSC would be responsible for working with governments and community partners to ensure that vulnerable species like peyote (Labate and Cavnar 2016), iboga, and potentially ayahuasca (Labate and Feeney 2012) are protected, cultivated, harvested, and fairly traded in a way that ensures sustainability of the species.

Only certified or licensed psychedelic supervisors would be able to acquire a range of different psychedelics. They could either purchase the psychedelic from the PSC-controlled distribution outlet or grow their own (e.g., psilocybin mushrooms, peyote cactus, or plants that comprise ayahuasca). The risk of diversion from legal sources to illegal markets can never be completely controlled, but regulation of the supply chain and availability through legal sources, such as is the case with tobacco and alcohol (and, in some jurisdictions, cannabis), reduces interest in producing and purchasing illegally produced/diverted substances, and reduces the volume available through illegal channels.

Demand mitigation

An effective public health approach to regulating psychedelics would take an evidence-based approach to mitigating demand for such substances. We propose bans on activities promoting the commercial sale of psychedelic drugs, such as advertising, branding, and corporate sponsorship. The social, cultural, and spiritual norms of limiting use to specific settings conducive to a positive experience will be important demand mitigators. Demand mitigation would also be achieved by providing honest health-promotion-oriented psychoactive substance education in schools—perhaps incorporating lessons learned from sex education—regarding both risks and benefits (Tupper 2014), as fear-based prevention programs are ineffective (U.N.O.D.C. 2015). Similarly, fear-based anti-psychedelic media campaigns aimed at the general public would not be supported, as such drug prevention approaches are also of dubious merit (Werb et al. 2011).

Implementation, monitoring, evaluation, and research

Rigorous evaluation will be integral to monitor for potential harms and benefits of the new regulatory

system. Baseline measures of patterns of use, harms and benefits, and monitoring for changes will be critical for early detection of unanticipated effects and course correction. Close oversight of production, data on purchasing or other distribution patterns, and monitoring potential adverse consequences will provide assurance that the regulated market is functioning as intended, that harms are being minimized, and that anticipated benefits are accruing.

Research would be needed to broaden the scientific knowledge base upon which policies and programs are founded, including exploring the potential health-promoting beneficial effects, as well as studying the learning and cognitive enhancement potential of psychedelic substances used in varying settings, including explicitly educational contexts (Tupper 2003).

Conclusion

The increasing interest in psychedelic science, medicine, spirituality, and other related experiences is an important societal development. It coincides with a greater political legitimacy for drug policy reform, including alternative regulatory options. However, psychedelics are not panaceas, and no regulatory framework is flawless, as there will always be some risks and harms associated with any drugs or substances, including foods. The risk/benefit profile of psychedelics necessitates a thoughtful public health approach guided by both experiential and research evidence and anthropological insights in order to minimize the potential harms and maximize the benefits of this unique class of substances. This article provides a framework for the regulation and management of psychedelics based on public health principles, and we hope that it will promote further discussion about this and other regulatory options for all psychoactive substances.

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