The Legal Challenges of Ibogaine-Based Psychedelic Treatments for U.S. Military Veterans

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Introduction

- Ibogaine is a psychoactive substance produced by the *Tabernanthe iboga* plant (iboga), which is native to Central West Africa.
- Early clinical studies suggest that ibogaine may have potential to treat veterans with post-traumatic stress disorder (PTSD), traumatic brain injury (TBI), and substance use conditions (Davis et al., Cherian et al., Armstrong et al.).
- Because current treatments for these conditions have limited efficacy, it is crucial to determine whether ibogaine could be a partial solution.
- However, ibogaine's safety and effectiveness are poorly characterized. It poses serious physical and psychological risks, including potentially fatal heart rhythm abnormalities in susceptible individuals.
- Ibogaine is a Schedule I drug under the federal Controlled Substances Act, which means it is believed to have no currently accepted medical use and a high potential for abuse. The Schedule I classification renders ibogaine illegal in most cases.
- The social, legal, and economic effects of Schedule I status limit research opportunities and make scientific studies more complex and expensive (Marks and Cohen).
- This project evaluates the legal challenges of ibogaine research and treatment by analyzing existing regulations and proposing policy reforms.

Discussion

Early clinical studies show that ibogaine could potentially treat several conditions that are common in military veterans, with preliminary evidence showing reductions in suicidal ideation as well as fewer symptoms of PTSD, depression, and anxiety (Davis et al.). Some studies report that ibogaine creates a "dreamlike state of consciousness" and may improve TBI-related symptoms (Cherian et al.). However, there are legal and scientific barriers to conducting ibogaine research and increasing access to ibogaine-based treatments. Due to ibogaine's Schedule I status, it is generally illegal to possess, produce, or distribute, which makes obtaining federal funding challenging. In addition, serious potential health risks further jeopardize funding, requiring private philanthropy to fund most ibogaine research. This poster discusses potential ways of reducing these obstacles, including state-level decriminalization of ibogaine, promoting federally-funded ibogaine research, changing ibogaine's legal status under the Controlled Substances Act, or obtaining Food and Drug Administration (FDA) approval for ibogaine treatments (Marks).

Decriminalization reduces or eliminates criminal penalties for drug-related activities associated with personal use of drugs (Marks). In 2022, Colorado decriminalized ibogaine through the Natural Medicine Health Act, a voter-approved ballot initiative. This law decriminalized personal possession, cultivation, and use of plants or fungi containing five psychedelic substances, including iboga (Proposition 122). However, iboga grows in rainforest ecosystems of Central West Africa, making it difficult to produce elsewhere. In addition, it is illegal to import due to its Schedule I status. These circumstances make ibogaine inaccessible even if states decriminalize it. At the federal level, Congress recently enacted the National Defense Authorization Act of 2024. This law requires the Department of Defense to fund research on psychedelic treatments for armed services personnel with PTSD or TBI (Congress). The legislation could provide the funding required to research ibogaine and reduce reliance on philanthropic or commercial sources (Barnett et al.).

FDA approval is the standard path through which drug treatments are made available (Marks & Shachar). The FDA approves each drug formulation to treat a specific health condition. In making these decisions, the agency reviews data from clinical trials submitted by drug manufacturers. Currently, ibogaine is not approved for treating any health conditions. In fact, according to the FDA and the U.S. Drug Enforcement Administration (DEA), ibogaine has a high potential for abuse and no currently accepted medical use. Consequently, the DEA classifies it on Schedule I, the most heavily restricted of five controlled substance categories. Federal rescheduling ibogaine is possible, at least in theory. However, moving ibogaine to Schedule II or III would likely have little effect on research because, in most cases, ibogaine would remain heavily-restricted and

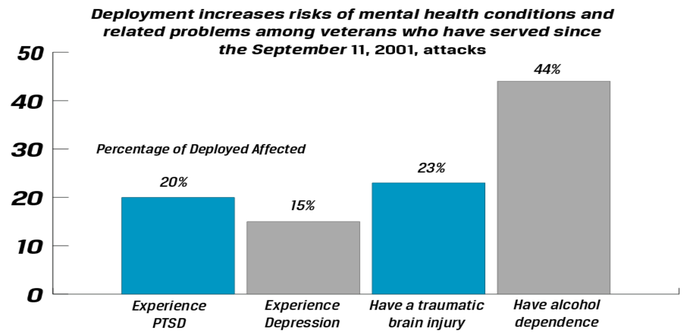

Figure 1: Percentage of Deployed Service Members with Mental Health Conditions Graph by Erin Anderson, https://ballardbrief.byu.edu/issue-briefs/untreated-mental-illness-among-veterans-in-the-united-states.

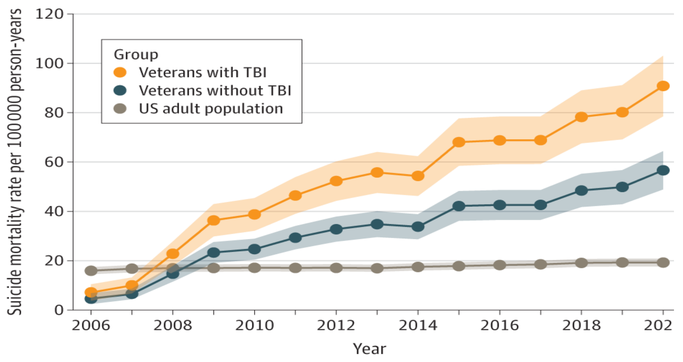

Figure 2: Adjusted Suicide Mortality Rates per 100 000 Person-Years From 2006-2020. Graph by Howard et al., https://jamanetwork.com/journals/jamaneurology/fullarticle/2808953.

Figure 3: *Tabernanthe iboga*. Photo by Marco Schmidt[1] CC BY-SA 2.5, https://commons.wikimedia.org/wiki/File:Tabernanthe_iboga_MS_4098.jpg.

Figure 4: *Tabernanthe iboga* root. Photo by Giorgio Samorini CC BY-NC-SA 2.0, https://www.flickr.com/photos/samorini/3835780963.

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Discussion Cont.

federally-illegal. Furthermore, members of Congress, the Department of Health and Human Services, and marijuana activists have failed to reschedule marijuana despite decades of attempts and dozens of congressional proposals. Rescheduling ibogaine could be even more challenging due to its documented heart-related risks. In addition, the lack of high-quality clinical trials of substantial size and control groups that utilize placebos inhibit researchers from accurately assessing ibogaine's safety and efficacy, which are necessary for FDA approval and would support rescheduling efforts.

Potential Limitations

Previous ibogaine studies have serious limitations. They lack large sample sizes and the use of control groups that utilize inactive placebos or active controls that approximate the subjective psychological effects of ibogaine (Cherian et al.). Consequently, the seemingly positive results of existing studies might be attributable to factors other than ibogaine treatment, including the high expectations of study participants, biased interpretations of study data by researchers hoping for positive outcomes, and other aspects of the studies such as the availability of alternative medicine modalities, such as yoga or meditation, and all-expenses-paid travel to exotic locations (Cherian et al, Davis et al.).

Conclusion

Ibogaine seemingly has potential to treat various mental health conditions. However, larger and more rigorous clinical trials are needed to determine its safety and efficacy, as well as ideal dosing regimens, conditions of administration, and other variables. Providing federal funding for ibogaine research could help reach these milestones, especially since past studies have relied on limited private funds. If more rigorous clinical trials confirm that ibogaine is safe and effective, then FDA approval may be possible, and one could argue more persuasively for rescheduling ibogaine.

The best way forward for evaluating ibogaine treatment safety and efficacy is to promote federally-funded research. Government-sponsored research would make studying ibogaine easier for public institutions, such as universities. It would reduce reliance on private donors (Marks & Shachar) and help researchers comply with the restrictions and expenses associated with studying Schedule I drugs (Barnett et al.) One of the main advantages of clinical research bills is that they "pose no conflicts with federal laws because they leverage existing federal regulations" (Marks). Robust clinical trials would also help establish the safety and applications of ibogaine, a crucial step toward potential FDA approval and rescheduling (Marks & Shachar).

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