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Comment for consideration of the President's Commission on Combating Drug Addiction and the Opioid Crisis prior to the Commission's first meeting on June 16th, 2017.

The Federal Government Should Fund Clinical Research into the Uniquely Effective Treatment Ibogaine to Treat Opioid Addiction[1]

I. Introduction

Per Executive Order 13784, it is the duty of the *President's Commission on Combating Drug Addiction and the Opioid Crisis* to make recommendations to the President to improve the capacity and response of the federal government in combatting the opioid crisis. Included within this duty is the task to "assess the availability and accessibility of drug addiction treatment services."[2]

Given this task, and given promising results from several studies which have strongly demonstrated that the naturally-occurring substance ibogaine is effective in treating opioid addiction, the Commission ought to recommend that the federal government fund further research and development of ibogaine as a clinical treatment to treat opioid abuse.

Ibogaine, a psychedelic alkaloid often extracted from the root bark of the Central African shrub *tabernanthe iboga*, possesses a unique ability to block the physiological symptoms of opioid withdrawal, and when combined with psychotherapy can stop or significantly reduce opioid use in the longer term. While the United States has placed ibogaine in Schedule I, ibogaine is not prohibited by the Convention on Psychotropic Substances of 1971, and it is used clinically or medicinally – often for treatment of opioid use disorder and other addictions – in countries like New Zealand, Mexico, Canada, Australia, Spain, Brazil, Costa Rica, and South Africa. Gabon has declared ibogaine's parent, iboga, an officially recognized natural treasure. The Bwiti religion, indigenous to Gabon, has used iboga as a traditional plant medicine for centuries.

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[1] Submitted on June 12, 2017 by the *Multidisciplinary Association for Psychedelic Studies* (MAPS), a 501(c)(3) research and educational organization that develops medical, legal, and cultural contexts for people to benefit from the careful uses of psychedelics and marijuana. Please contact MAPS Founder & Executive Director Rick Doblin, PhD (rick@maps.org) or MAPS Policy Fellow Ismail L. Ali, JD (ismail@maps.org) with any questions.

[2] Executive Order 13784, *Presidential Executive Order Establishing the President's Commission on Combating Drug Addiction and the Opioid Crisis* (March 29, 2017), Sec. 4(b). White House Office of the Press Secretary. Found at: https://www.whitehouse.gov/the-press-office/2017/03/30/presidential-executive-order-establishing-presidents-commission.

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II. Research into Ibogaine Demonstrates Efficacy in Treating Opioid Use Disorder

In May 2017, the *American Journal of Drug and Alcohol Abuse* published observational research from two studies of clinics in Mexico and in New Zealand that administer ibogaine to people struggling with opioid dependence. MAPS recently published a press release which provides an overview of both studies' findings.[3]

The Mexico study, conducted with participants who, prior to ibogaine, had unsuccessfully sought other means of treatment for oxycodone and heroin addiction an average of 3.1 times, observed significantly reduced physiological symptoms of withdrawal after using ibogaine.[4] Subjects were given a single dose of orally-ingested ibogaine and remained under clinical supervision for 3-6 days.[5] Notably, half of the thirty participants reported zero opioid use in the thirty days after treatment.[6] The study concluded that a single treatment reduced withdrawal symptom strength by over half on average, and achieved sustained cessation or reduction of opioid use over a twelve-month period for some patients who had previously been unsuccessful in treating their opioid addiction.[7]

The New Zealand study concluded that a single ibogaine treatment both reduced withdrawal symptoms and achieved either complete cessation or sustained reduction in opioid use over a twelve-month period.[8] A study participant wrote: "[Ibogaine] will give an opiate addict several months to half a year of freedom from craving and an expanded awareness… [ibogaine] will not do the work for you. However, it will help you do your own work."[9] Dr. Geoffrey Noller, the researcher who conducted the New Zealand study, stated that he believes the findings suggest that "for some people there appear to be significant and lasting benefits associated with ibogaine treatment for opioid dependence."[10]

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[3] *Two New Studies Show Ibogaine's Promise as Treatment for Opioid Addiction* (Press release June 7, 2017). Multidisciplinary Association for Psychedelic Studies. Found at: http://www.maps.org/news/media/6693-press-release-two-new-studies-show-ibogaine%E2%80%99s-promise-as-treatment-for-opioid-addiction.

[4] Thomas Kingsley Brown, PhD & Kenneth Alper, MD: *Treatment of opioid use disorder with ibogaine: detoxification and drug use outcomes*, The American Journal of Drug and Alcohol Abuse (2017). DOI: 10.1080/00952990.2017.1320802.

[5] *Id*.

[6] *Id*.

[7] *Id*.

[8] Geoffrey E. Noller PhD, Chris M. Frampton PhD, & Berra Yazar-Klosinski PhD, *Ibogaine treatment outcomes for opioid dependence from a twelve-month follow-up observational study*, The American Journal of Drug and Alcohol Abuse (2017), DOI: 10.1080/00952990.2017.1310218.

[9] *Id*.

[10] Personal communication (March 20, 2017) (email on file).

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The results of the New Zealand and Mexico studies support previous research into the efficacy of ibogaine treatment for opioid use disorder. A December 2016 literature review found that the results of eight studies that met established criteria supported the conclusion that "a single dose or a few treatments with ibogaine may significantly reduce drug withdrawal, craving, and self-administration in dependent individuals lasting from 24 hours to weeks or months."[11]

Currently-used treatment methods for opioid dependence, such as buprenorphine and methadone maintenance, stimulate and satisfy an addict's opioid receptors and typically require an extended period of use to gradually wean an addict from dependence.[12] In contrast, ibogaine appears to *reset* addicted receptors in the brain, though the exact biochemical nature of this mechanism is not yet known.[13]

Unlike buprenorphine and methadone which are known to perpetuate dependence, ibogaine has no history of being addictive and presents a very low potential for abuse, particularly as a clinical treatment administered one or several times. Ibogaine could provide a solution for individuals and communities struggling with opioid addiction across the United States.

To be sure, ibogaine requires further study to determine its safety. Ibogaine has been associated with cardiovascular risks, particularly for people with a pre-existing heart condition, but these risks are mitigated by adequate medical supervision. Ultimately, more rigorous studies would provide more information about ibogaine's risks.

III. NIDA Should Re-Allocate a Percentage of its Funds for Ibogaine Research

In the early 1990s, NIDA funded pre-clinical animal trials on ibogaine use, but declined to proceed or fund human studies.[14] In 2012, NIDA awarded a for-profit company a $6.5 million grant to develop 18-

[11] Raphael G. dos Santos, *et. al.*, *The antiaddictive effects of ibogaine: A systematic literature review of human studies*. Journal of Psychedelic Studies (2017), 1(1), pp. 20–28. DOI: 10.1556/2054.01.2016.001. Found at: http://akademiai.com/doi/full/10.1556/2054.01.2016.001.
[12] Angela L. Stotts, PhD, Carrie L. Dodrill, PhD, and Thomas R. Kosten, MD: *Opioid Dependence Treatment: Options In Pharmacotherapy*, US National Library of Medicine (2010), Expert Opin Pharmacother. 2009 Aug; 10(11), pp. 1727–1740. DOI: 10.1517/14656560903037168. Found at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2874458/.
[13] Kenneth R. Alper, Howard S. Lotsof, Charles D. Kaplan: *The Ibogaine Medical Subculture* (Section 1.4), Journal of Ethnopharmacology 115 (2008), pp. 9-24. Found at: https://www.myeboga.com/ibogaine/mechanisms-of-action.
[14] Global Ibogaine Therapy Alliance: Scientific Research - Clinical Trials (website). Found at: https://www.ibogainealliance.org/research/.

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MC, a non-psychedelic version of ibogaine, but no studies of 18-MC in people with opioid dependence have been announced.[15]

NIDA's current annual budget is just over $1 billion,[16] with about $43 million devoted to clinical trials of substance-abuse treatment methods.[17] The Multidisciplinary Association for Psychedelic Studies (MAPS), which has experience guiding clinical trials of Schedule I substances through the FDA drug development process,[18] estimates that $25 million would be needed over five years to fund an FDA-approved drug development program for ibogaine to treat opioid addiction. The first step of this process, two clinical studies to establish safety, would cost approximately $250,000.

Ultimately, developing ibogaine into a treatment for opioid use disorder would represent only a small portion of NIDA's annual research budget over the period of development. This is a modest price to pay compared to the total federal funding allocated to solve drug addiction generally and the opioid epidemic specifically, and the demonstrated efficacy of ibogaine suggests it could lead to a new paradigm in treating both.

Absent federal involvement and funding, ibogaine's Schedule I status presents a number of obstacles which would slow or even prevent ibogaine's healing potential from realization in the United States. The recent joint statement by NIH Director Francis Collins and NIDA Director Nora Volkow, announcing a commitment to accelerating opioid use disorder treatment,[19] indicates that the federal government is ready to take meaningful steps towards the development of effective new methods: ibogaine uniquely fits this bill. People suffering from opioid use disorder should not suffer because of the stigma surrounding Schedule 1 drugs and the associated barriers to researching them.

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[15] *Savant HWP Announces NIDA Funding for Pre-clinical Development of 18-MC as Potential Treatment for Addiction, Obesity*. Savant HWP (Press release Jan. 3, 2013). Found at: http://www.prnewswire.com/news-releases/savant-hwp-announces-nida-funding-for-pre-clinical-development-of-18-mc-as-potential-treatment-for-addiction-obesity-185528492.html.

[16] Fiscal Year 2017 Budget Information – Congressional Justification for National Institute on Drug Abuse (website). NIDA. Found at: https://www.drugabuse.gov/about-nida/legislative-activities/budget-information/fiscal-year-2017-budget-information-congressional-justification-national-institute-drug-abuse.

[17] *Id*.

[18] Dave Phillips, *F.D.A. Agrees to New Trials for Ecstasy as Relief for PTSD Patients*. New York Times (Nov. 29, 2016). Found at: https://www.nytimes.com/2016/11/29/us/ptsd-mdma-ecstasy.html?smid=tw-share.

[19] Lenny Bernstein, *Health officials vow to develop drugs to curb the opioid epidemic*. Washington Post (May 31, 2017). Found at: https://www.washingtonpost.com/news/to-your-health/wp/2017/05/31/health-officials-vow-to-develop-drugs-to-curb-the-opioid-epidemic/?utm_term=.edb7aa51767b.

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IV. The President's Commission Ought to Prioritize Ibogaine Research in the United States

The U.S. Department of Health and Human Services estimates that the opioid epidemic costs the American people upwards of $75 billion per year.[20] The epidemic – now a crisis – is killing 90 people per day[21] and the death toll continues to rise.[22] As long as the same strategies are being used, the same patterns can be expected to continue; in this time of dire circumstances and exhausted conventional remedies, the Commission should seriously consider integrating bold and creative solutions into the opioid treatment model.

The promising results of the aforementioned ibogaine studies indicate that investing in further research to develop clinical usage in the United States could lead to unprecedented success in treating the epidemic affecting communities across the nation. Legislation to support ibogaine research or treatment has already been introduced in Maryland, New York, and Vermont; however, none of the bills have been passed.[23] Although state-led models need not be abandoned, the federal government has the resources and authority to take the lead in eliminating barriers to accessing this promising treatment, beginning with allocating funding for clinical research.

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[20] *The Opioid Epidemic: By the Numbers* (fact sheet). Health and Human Services. Found at: https://www.hhs.gov/sites/default/files/Factsheet-opioids-061516.pdf.
[21] Opioid Crisis (website). NIDA. Found at: https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis.
[22] Josh Katz, *Drug Deaths in America are Rising Faster than Ever*. New York Times (June 5, 2017). Found at: https://www.nytimes.com/interactive/2017/06/05/upshot/opioid-epidemic-drug-overdose-deaths-are-rising-faster-than-ever.html.
[23] *See* Maryland HB1372: To establish a pilot ibogaine treatment program in MD; *see also* New York A 5459: Relates to requiring the office of alcoholism and substance abuse services to encourage, aid, and facilitate clinical research into the use of ibogaine in drug treatment; *see also* Vermont H741: An act relating to funding ibogaine clinical trials.