Senate Bill 58: Analysis and Recommended Changes

Prepared for: Chair Jim Wood
California Assembly Health Committee

Prepared by: Geoff Lawrence, Director

Date: July 11, 2023

Senate Bill 58 Proposes Constructive Reforms, But Could Go Further

Dear Chair Wood and committee members:

On behalf of Reason Foundation, I thank you for accepting these comments and making them part of the public record. Among other things, Reason Foundation is committed to ending the drug war and allowing discerning adults to safely and responsibly partake in substances they believe may enhance their life. Decades of academic research combined with the emerging results of large-scale clinical trials have shown that psychedelic substances, which have been used within many cultures since antiquity, may hold substantial value for improving mental health.

Over the past few years, the U.S. Food and Drug Administration (FDA) has recognized psychedelic substances as "breakthrough therapies" for post-traumatic stress disorder, major depressive disorder, and treatment-resistant depression. According to the FDA: "The criteria for breakthrough therapy designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy."[1] This designation is reserved for the treatment of "serious or life-threatening conditions."[2]

Although the FDA appears poised to approve certain psychedelic therapies within the next few years, the process of pharmaceutical approval is slow and costly. A study in the Journal of the American Medical Association reviewed drug approvals between 2009 and 2018 and estimated the average cost of bringing a pharmaceutical to market at $1.34 billion.[3] Once the FDA grants market approval for a drug, drug companies must recover this expense and compensate providers of capital for the time and risk involved in drug development through their pricing schemes. This means FDA-approved medications, even if they become available, are likely to be more costly than naturally occurring alternatives.

---

[1] U.S. Food and Drug Administration, "Frequently Asked Questions: Breakthrough Therapies," Accessed March 10, 2023: https://www.fda.gov/regulatory-information/food-and-drug-administration-safety-and-innovation-act-fdasia/frequently-asked-questions-breakthrough-therapies.

[2] Ibid.

[3] Olivier J. Wouters, Martin McKee and Jeroen Luyten, "Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018," *Journal of the American Medical Association*, Vol. 323, No. 9 (March 2020), pp. 844—853. Available at: https://pubmed.ncbi.nlm.nih.gov/32125404/.

DRUG POLICY PROJECT CONTACTS:
Geoffrey Lawrence, Director (geoff.lawrence@reason.org)
Michelle Minton, Sr. Policy Analyst
(michelle.minton@reason.org)

States can get ahead of this process by allowing for the cultivation, manufacturing or possession of psychedelic substances within their own regulatory frameworks. Oregon voters approved Measure 109 in 2020, which enacted a state-regulated market for psilocybin services, including state licensing for the commercial manufacture and distribution of psilocybin products. That market is expected to go live later this year. State legalization sidesteps the uncertain timeline involved in federal approval of pharmaceuticals, allows states to tailor their own policies, and could alleviate cost barriers for individuals seeking psychedelic therapy.

Senate Bill 58 would legalize the cultivation, preparation, possession and use of dimethyltryptamine, ibogaine, mescaline, and psilocybin or psilocyn in amounts reflecting personal use. In an earlier version of the bill, Sec. 4 and Sec. 9 would have also permitted "[t]he assisting of another person, 21 years of age or older" to complete these tasks. The current version forbids this assistance and any facilitated or supported use of psychedelic substances until a framework governing therapeutic use has been adopted. While this new language is obviously limiting for the immediate future, it signals a commitment from the legislature to consider a more comprehensive framework that will enable the emergence of a regulated marketplace in psychedelics. We consider this change encouraging because the original language would not have allowed a person to cultivate, harvest or prepare these substances in any amount exceeding the "allowable amounts," which are the per-person possession limits.

As Reason Foundation testified previously, that limitation would never have allowed anyone to specialize in the production of these substances so they could trade them with others. While the prior Sections 4 and 9 nominally allowed for the "facilitated or supported use" of these substances in supervised or group settings, they also expressly forbid the transfer of these substances between adults for financial gain. Each individual who seeks to use these substances would have been compelled to manufacture them independently, and in quantities that would not exceed possession limits.

To be sure, the current language still retains these limitations on cultivation and manufacturing, but it signals that the legislature will revisit these limitations in the future as it moves to establish a regulated market. As such, Senate Bill 58 represents a crucial first step into legalization, but it must be followed by subsequent legislation. If not, Senate Bill 58 will result in a highly inefficient marketplace wherein individuals will not gain equitable access to psychedelic therapies. Some individuals may not possess the skills, knowledge, wherewithal nor physical ability to safely produce these substances on their own. Likewise, growers would not be capable of achieving economies of scale that could reduce per-unit costs for members of a communal group. As Reason Foundation testified previously, only a real marketplace can solve these problems. The current language of Senate Bill 58 reflects that reality.

Geoffrey Lawrence
Director of Drug Policy, Reason Foundation

DRUG POLICY PROJECT CONTACTS:
Geoffrey Lawrence, Director (geoff.lawrence@reason.org)
Michelle Minton, Sr. Policy Analyst
(michelle.minton@reason.org)