Senate Bill 58: Analysis and Recommended Changes

Prepared for: Chairwoman Aisha Wahab
California Senate Public Safety Committee

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Senate Bill 58 Proposes Constructive Reforms, But Could Go Further

Dear Chairwoman Wahab and members of the committee:

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 from 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 through the FDA 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.

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[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/.

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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. Sec. 4 and Sec. 9 would also permit "[t]he assisting of another person, 21 years of age or older" to complete these tasks. In both cases, however, the language is constructed such that a person could not cultivate, harvest or prepare these substances in any amount exceeding the "allowable amounts," which are the per-person possession limits.

This language is a key limitation of Senate Bill 58 because it would never allow anyone to specialize in the production of these substances so they could trade them with others. Both Sec. 4 and Sec. 9 nominally allow for the "facilitated or supported use" of these substances in supervised or group settings, but they also expressly forbid the transfer of these substances between adults for financial gain. Every individual who seeks to use these substances would be compelled to manufacture them independently, and in quantities that would not exceed possession limits.

While the legalization of these substances is a step in the right direction, these restrictions will result in a highly inefficient marketplace. Some individuals may not possess the skills, knowledge, wherewithal nor physical ability to safely produce these substances on their own, or even with assistance. Growers would not be capable of achieving economies of scale that could reduce per-unit costs for members of a communal group.

California could address these problems by allowing for a regulated marketplace. This could take the form of a commercial licensing system, as Oregon has done for psilocybin services. Alternatively, California could allow registered caregivers to produce psychedelic substances safely and at scale, following the approach used for medical marijuana. Registered caregivers could then trade or provide these substances to other adults 21 years of age or older so that a functioning, regulated market can emerge.

Many Californians could potentially benefit from psychedelic therapies, but could find themselves unable to do so due to limitations resulting from age, health or skillsets. We advise that California allow some form of market to emerge so these Californians are not left behind.

Thank you,

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