

House Bill 228

**Regulation of FDA approved
psychedelic medicines**

Rep. Jennie Armstrong

This task force will not consider or take a position on the medicalization, decriminalization or legalization of psychedelic medicines.

The purpose of the task force

This task force will craft a set of policy recommendations for the 34th legislature to consider **in advance of the potential medicalization of certain psychedelic medicines by the FDA** so that we can be prepared if and when that happens.



Assess the potential use of psychedelic medicine in addressing the state's ongoing mental health crisis



Consider barriers to implementation and equitable access



Consider and recommend licensing and insurance requirements for practitioners in the state



Consider legal and regulatory changes that could be necessary in the state after federal medical approval of psychedelic medicines.

Why is this important?

The FDA approves about 43 novel drugs each year, but not all of them have the potential to make as big of an impact as psychedelic medicines.

“Popular media is inundated with overwhelmingly positive references to these drugs... The high degree of enthusiasm and anticipation is beyond anything we’ve ever seen with any unapproved psychiatric drug.”

Dr. Javier Muniz, a senior official at the F.D.A. division that evaluates new drugs

Alaska is suffering from an acute mental health and addiction crisis

MENTAL HEALTH

- 3rd highest **suicide rate** in the country

ADDICTION

- 35.6 drug **overdose deaths** per 100,000

VIOLENCE

- Highest rate of women killed by men for the 7th year in a row
- 58 out of every 100 women have experienced intimate partner violence, sexual violence or both

“If I hadn’t gone through it, my son would have a folded flag, and instead, he has a father. I think we need more mothers and fathers and less folded flags.”

–Jonathan Lubecky, Army Veteran who underwent psychedelic treatment

Alaska has the largest share of Veterans per capita in the U.S.

- Veterans have a 57% higher suicide rate than non-veterans
- ~2 of 10 Veterans with PTSD also have substance use disorder
- In the wars in Iraq and Afghanistan, about 1 in 10 returning Veterans seen by the VA have a problem with alcohol or other drugs.
- **In November 2023, the VA said it was committed to studying psychedelics for PTSD treatment**
 - **“There are several studies at VA facilities researching psychedelic-assisted therapy for mental health, and the department is closely monitoring outside research.”**

We can make sure Alaska is ready

By bringing together a diverse group of folks who will offer policy recommendations to the Legislature, we can make sure that Alaska is able to safely maximize the benefits these new medicines can provide to our state.

CLINICAL TRIALS MAP:

<https://psychedelics.berkeley.edu/clinical-trials-map/>

KEY DATES

- **2017:** FDA designated MDMA-assisted therapy for PTSD a Breakthrough Therapy.
- **2021:** MAPS PBC conducted two Phase 3 clinical trials for its MDMA therapy
 - Both showed that patients had “clinically significant improvements” in PTSD symptoms after receiving the treatment.
 - The results of the second Phase 3 trial, published in 2023 in Nature Medicine, showed that 71.2% of participants receiving the MDMA therapy no longer met diagnostic criteria for PTSD at the end of the study.
- **December 13, 2023:** MAPS PBC formally submitted a New Drug Application (NDA) to the FDA
 - If approved, would be the first new FDA-approved PTSD treatment in more than 20 years.
- **February 9, 2024:** FDA accepted the application and granted it Priority Review
- **August 2024:** FDA expected to announce its determination

Thank you!

Questions?
Thoughts?

Rep. Jennie Armstrong
rep.jennie.armstrong@akleg.gov
907-465-4968
