Ask MAPS Anything

Khea Morton

Since its inception in 1997, AskMAPS has answered thousands of inquiries about psychedelics, therapy, and research each year. Now Khea Morton is here to connect with the psychedelic community and provide educational resources.

Does MAPS have information on how each state handles the Schedule I substance? We are looking to conduct psychedelic trials and hope to find the best geographical areas which support these trials.

Thank you for contacting MAPS.

After posing this question to Policy & Advocacy Associate Leslie Booher, J.D., she suggested that the most relevant information for potential researchers is the licensing requirements at the state level (which, to the extent that they exist, are in addition to the federal regulatory hurdles).

The DEA (U.S. Drug Enforcement Administration) provides this list of states (**deadiversion.usdoj.gov/drugreg/reg_apps/pract_state_lic_require.htm**) where a second license is required, though that isn't the only potential state hurdle. Some states, like California, have provisions that may not require an additional license, but require some other type of additional oversight of research with Schedule I substances. Here's a link to a page about that California oversight body and it's organic statutory citations: **oag.ca.gov/research**

Additionally, if you are looking into conducting clinical trials with MDMA, we invite you to explore our Investigator-Initiated Trials program: iit.maps.org. You're also welcome to review our recent *Bulletin* article "**Investigator-Initiated Trials: From Process to Change**" by Valerie Ahanonu, with contributions from Michael Mithoefer and Hailey Gilmore.

I hope this is helpful!

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I am doing a review paper on the psychedelic treatment of PTSD and would like to include in it the assertion that the FDA is obliged to approve MDMA for PTSD, should the second part of the Phase 3 trial show comparable significance and safety profile. I have heard Rick Doblin say on a number of occasions that the process MAPS followed is an unusual one in which the FDA approves the study design and therefore binds itself to approval should the treatment be effective. Are there any resources or ways I can cite this? Our reviewer continues to push back against this even being possible. Thank you in advance for any assistance you can provide.

We sent this to Allison Coker, Ph.D., the Regulatory Affairs Manager at MAPS PBC, and she responded:

Thanks for writing! It is definitely not the case that the FDA is obligated to approve a drug.

The special protocol assessment (SPA) process that we completed is to help mitigate the risk of the FDA denying approval because of a flaw in the study design that caused the FDA to not consider it a valid study to demonstrate safety or efficacy. The communications we have with the FDA through the SPA and through the Breakthrough designated therapy process provide us excellent guidance from the Agency on the size and composition of the Phase 3 trials, as well as other data that we will include in our NDA, making our application much stronger and increasing the likelihood of approval, but this is certainly not a binding commitment or obligation on the FDA's behalf.

The AskMAPS article is for informational purposes only. MAPS cannot provide legal, medical, or mental health advice, nor do we advise on the use of any prohibited substance outside of the approved clinical study setting. Always seek the advice of your physician, mental-health professional, or other qualified health provider with any questions you may have regarding a medical condition. These emails have been edited for length and to protect the senders' anonymity. Visit ***maps.org/askmaps*** *for frequently asked questions about psychedelic healing, therapy, or research.*

Khea Morton is a Masters of Social Work Intern at MAPS. She obtained her Associate's degree in Human Services. She then transferred to Radford University where she completed her Bachelor's degree in Social Work and is now completing her Master's in Social Work from Tulane University. Khea is very passionate about advocacy, drug policy reform, and harm reduction. Khea wants her work to impact them to where they can find their light again, so they never lose it. She says, "Often, we dim our own light on the account of others. We can lose sight of our worth, our faith, and our drive, but with self-reflections and advocacy, individuals can find it again." In her free time she loves to cook, read, and spend time with friends.