A California panel is holding up studies on psychedelics: Some researchers want it gone

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At the Pacific Neuroscience Institute in Santa Monica, scientists are eager to explore whether a psychedelic chemical found in a toad could help people whose depression has not eased with typical treatments. Patients regularly call or send emails about joining clinical trials to test that and other compounds, but the research center is turning them away.

"We have to tell them we don't have any studies enrolling right now," said Dr. Keith Heinzerling, director of the institute's TRIP Center, which focuses on treatment and research on psychedelics. "We've been put on hold by the state."

Across the state, dozens of such studies are in limbo thanks to a little-known government panel that monitors research on federally restricted drugs and addiction treatment.

The holdup, tied to a state law requiring government meetings to be held in public, has dragged on since the fall and galvanized some scientists to push for the panel to be dissolved.

Lawmakers in Sacramento established the Research Advisory Panel of California more than half a century ago to vet studies involving cannabis, hallucinogens and treatments for "abuse of controlled substances," according to the state's health and safety code.

The panel, which includes representatives of state agencies and universities, has the power to reject studies if they are poorly conceived, would produce little of scientific value, or would expose Californians who sign on as research subjects to excessive risk. It also monitors ongoing research and can revoke its approval if studies veer from what it

approved.

Getting the panel's blessing is a crucial hurdle for researchers working in the state to find better ways to treat drug addiction, a crisis leading to more than 100,000 overdose deaths across the country each year. The panel also has oversight over research in the burgeoning field of psychedelics, which is developing potential treatments for depression, substance use disorder and other conditions.

The panel typically meets every other month, but gatherings scheduled for October and December were canceled with little explanation. Scientists waiting for the go-ahead to launch their studies say they've received no information about when meetings will resume.

Among those frustrated by the standstill is David, a 50-year-old grappling with post-traumatic stress disorder. The Los Angeles resident, who asked not to be identified by his full name to protect his medical privacy, reached out to the Pacific Neuroscience Institute to ask about upcoming clinical trials.

"I've been in search of a treatment that will alleviate symptoms of PTSD for a long time," David said. Some existing treatments "have worked pretty well, but there are still times where there's challenges and episodes that can be pretty destabilizing," including prolonged bouts of insomnia.

The potential of a psychedelic compound like psilocybin is appealing, but since he's in recovery for alcohol use, David only wants to try it if it's administered by medical professionals in a therapeutic environment. The Santa Monica center told him their next possible trial was being held up indefinitely.

"It just seems like the gears of bureaucracy conspire against meaningful solutions," he said.

At UC San Francisco, Dr. Josh Woolley said two of his planned studies on psilocybin are on indefinite hold. One of them is for young adults with anorexia, a disorder that can significantly ramp up the risk of death if left untreated. Now "we don't know when it will be approved," said Woolley, director of the Translational Psychedelic Research Program at UCSF.

The holdup has also interrupted plans for Dr. Charles Grob, a psychiatrist doing research with the Lundquist Institute at Harbor-UCLA Medical Center to examine whether psilocybin could help patients suffering existential anxiety and demoralization near the end of life.

"Just when things are ready to take off with more research, the field is frozen," Grob said.

Several current or former members of the panel declined to comment or did not respond to messages. Dr. Tanveer Khan, the panel's executive officer, referred questions to the California attorney general's office.

In a statement, the office said the panel was created to ensure that research involving addiction or certain controlled substances is tracked by the state and proceeds safely in line with "best medical practices and California law."

It attributed the interruption in its meetings to concerns about how a state law requiring public meetings might apply to the panel, but declined to clarify whether those concerns were prompted by recent changes to the Bagley-Keene Open Meetings Act or a new interpretation of existing rules.

Before it stopped meeting altogether, the Research Advisory Panel routinely convened behind closed doors. Scientists argued that meeting in public would be a nonstarter with funders who wanted to protect their

intellectual property.

"Realistically, the pharmaceutical companies are not going to allow their stuff to be reviewed in public, unless there's a very well-thought-out process that protects their interests," Heinzerling said.

The backlog of studies awaiting review and approval has ballooned since the panel last met in August. By December, 33 new proposals were on ice, as were 13 amendments to existing research projects, according to the attorney general's office.

The attorney general's office said it was working with lawmakers and the governor's office on a legislative solution to resolve the problem but declined to give specifics.

The impasse, first reported in the newsletter *Psychedelic Alpha*, has deepened longtime frustrations among scientists who argue that even when the panel is meeting normally, it is an outdated and unnecessary entity that slows down vital research.

Dozens of researchers in a newly formed consortium are now calling for the panel to be eliminated. They argue that studies involving controlled substances and addiction treatment are vetted by other oversight boards and that the California panel often rehashes issues that were already decided by other regulators.

Psychologist Steven Shoptaw, director of the Center for Behavioral and Addiction Medicine at UCLA, said there was a time when such experiments were conducted on people in jails and other settings who could not freely consent. But the rigorous scrutiny from institutional review boards, the Food and Drug Administration, the National Institutes of Health and others now make the California panel obsolete, he said.

"I've never understood why this was not dismantled decades ago," said Shoptaw, who has studied possible treatments for people who use methamphetamine.

Stanford University clinical psychologist Keith Humphreys said he was asked to join the panel years ago by then-Gov. Jerry Brown, but he declined "because I could see no purpose to it."

"I just thought, "We have an FDA. We have an NIH. Why is the state doing this?'" Humphreys said.

Even without hiccups, undergoing the state review can delay a study for upward of five months, researchers complained. That means wasting $100,000 or more on "unnecessary staff expenditures" during that time, they argued in a letter sent Thursday to Gov. Gavin Newsom and other decision makers.

Such delays can also shut Californians out of multi-state trials of emerging treatments, scientists argue. The lag time now looms larger as medication studies are expected to be run more quickly—within as little as a year instead of five, they said.

"If you're competing against other states where they don't have this delay, the industry is going other places," said Woolley of UCSF.

Dr. Phillip Coffin, director of the Center on Substance Use and Health at the San Francisco Department of Public Health, wanted to join a study on whether ketamine could help people struggling with methamphetamine addiction. But he said his site and others in California were excluded because of the panel's delays.

Losing out on the ketamine study and other research opportunities means that "I won't be able to hire or I will have to let go of staff," Coffin said.

Compass Pathways, a London-based biotech firm developing psilocybin treatments, decided not to establish a new "center of excellence" in San Diego. In an email sent in 2019 to a San Diego researcher, company co-founder George Goldsmith cited the "incredibly slow" state panel as a reason. (A Compass representative reached this week said the company's clinical trials for depression treatments underway in California had not encountered any delays.)

Many researchers are frustrated that the panel has been reviewing trials for addiction treatment even if they involve ordinary medications. For instance, the panel vetted a study Coffin undertook on mirtazapine—an FDA-approved antidepressant—as a treatment for people who use meth.

In 2022, the panel reviewed 52 new applications plus two submitted the previous year, according to its most recent available annual report. Among those 54 applications, three were either not approved or withdrawn. The reasons weren't given in the report.

By the end of that year, the panel was monitoring 132 ongoing research projects, including studies on whether cannabis use affects antiretroviral therapy and how psilocybin helps people suffering from phantom limb pain.

Michiel van Elk, who studies altered states of consciousness at Leiden University in the Netherlands, said he wasn't familiar with the California panel, but could understand the need for a specialized review board because assessing research procedures for psychedelics poses some unique challenges.

"It is really difficult to evaluate the risks of the drug itself, because it always interacts with the mindset of the person and also with the setting in which it's administered," Van Elk said. In general, "our current system is not set up for dealing with those type of challenges."

Not all researchers who interact with the panel are joining the calls to eliminate it. Grob said going through the panel is "extra work, but it's been positive," praising its members as astute and helpful.

"California has this extra layer of regulatory oversight, but the problem is not the committee itself," he said. "It's that the committee is unable to do its job."