Medical Xpress

KY commission hears from experts on promise of psychedelic to treat opioid addiction

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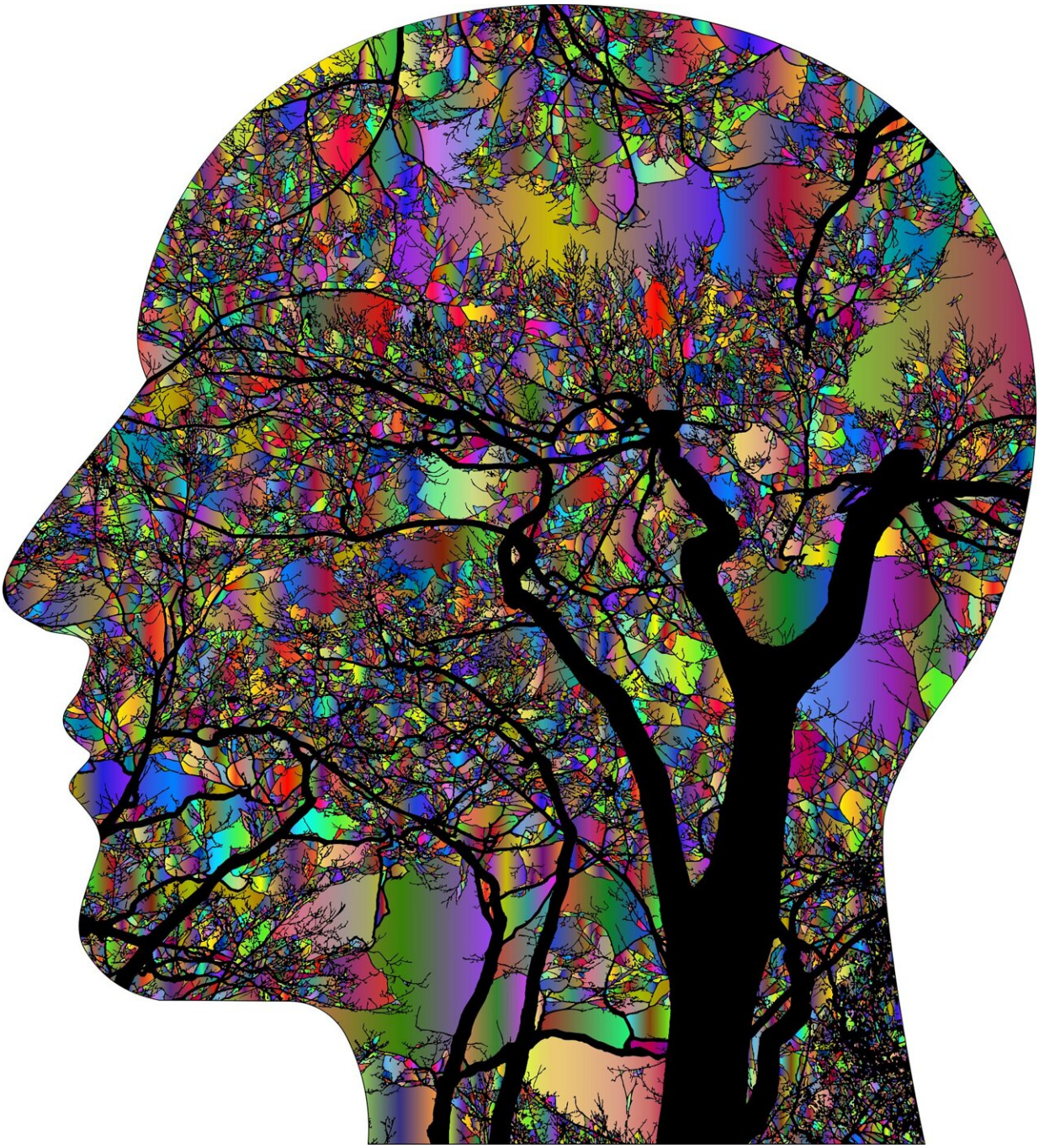

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Karen Butcher, whose son died in 2020 of an opioid overdose, asked a

panel of experts on Monday in Frankfort: If cost wasn't a factor, why shouldn't Kentucky explore the use of an illicit psychedelic drug as a treatment for opioid addiction?

"If money wasn't an issue . . . knowing this crisis has been around for so long, why would we not want to investigate this as a viable treatment?" Butcher said, seated alongside other members of the Kentucky Opioid Abatement Advisory Commission.

Butcher posed the question to Dr. Kenneth Alper, a neuropsychiatrist; Dr. Deborah Mash, a cellular and molecular pharmacologist; Dr. Srini Rao, a neurobiologist and neuropharmacologist; and Dr. Nolan Williams, a neuropsychiatrist and behavioral neurologist.

Butcher was asking about investigating the use of ibogaine, an experimental psychedelic drug illegal in the U.S., to treat opioid addiction. As opioids continue to drive Kentucky's fatal overdose rates—more than 9,000 people have died of a drug overdose since 2018—some state officials want the commonwealth to invest in the clinical exploration of ibogaine as another potential therapeutic to overcome addiction. And the commission chair has proposed paying for it, at least in part, with opioid lawsuit settlement money.

Though the psychedelic has a growing international following, it remains a Schedule 1 drug in the U.S. and is not approved by the Food and Drug Administration. Accessing it requires international travel. Commission Chair Bryan Hubbard, and the panel of experts he invited to Monday's hearing, are trying to change that.

To Butcher's question, Mash said there's no substantive reason not to explore ibogaine in a clinical setting, in hopes of getting FDA approval to distribute it widely.

"We want to investigate it," Mash said. Based on her decades of research, including a short-lived FDA-approved trial in the early 1990s, ibogaine "helps break the cycle of addiction and promote abstinence-based treatment," she said. Mash and her team at the University of Miami received initial approval from the FDA in 1993 to conduct the nation's first clinical trial for ibogaine. But after the National Institute of Drug Abuse revoked its funding to test the drug on humans, the trials were halted in 1995.

Along with Dr. Douglas Kramer, who previously worked in drug development and pharmaceutical risk management for the FDA and tuned into Monday's event virtually, the slate of experts were invited to the event by Hubbard, head of the state commission, appointed by Republican Attorney General Daniel Cameron.

Formed last year, Kentucky's commission is charged with dispersing a portion of the roughly $850 million Kentucky has secured in opioid lawsuit settlement money. Members vet applications from groups and organizations with evidence-based proposals for combating opioid use disorder. Since 2019, more than 9,000 Kentuckians have died of an overdose, over 90% of which were caused by opioids, according to state data.

In late May, Hubbard called a news conference to publicly propose an idea he hadn't yet presented to the commission: invest up to $42 million of settlement money into becoming the first state to clinically study ibogaine as a therapeutic to treat opioid addiction.

An alkaloid derived from the root bark of an iboga shrub native to West Africa, ibogaine has provided relief to veterans suffering from post-traumatic stress disorders and traumatic brain injuries. Panel experts have largely studied the use of ibogaine as a way to treat addiction, particularly to opioids, and they were invited to Monday's hearing.

When Hubbard did present his proposal to the 11-member commission at its June 13 meeting, it was met with skepticism and pushback from some members. The FDA has already granted approval to three drugs to help diminish cravings and reduce withdrawal from opioid addiction, said Dr. Sharon Walsh, then-commission member and director of the University of Kentucky's Center on Drug and Alcohol Research. "I'm not sure why we need other drugs to target opioid withdrawal," she said that day.

Still, a majority of commission members agreed to hold two public hearings on Hubbard's proposal, the first of which was Monday. The second is August 16.

The commission heard from panelists about the promise of ibogaine and its efficacy as a medication, the need for more clinical studies, the arduous and costly FDA approval process, and the need for alternative treatment options in addition to those already approved by the FDA, which include buprenorphine, methadone and naltrexone.

Anecdotes, case studies and clinical trials in other countries show ibogaine reduces opioid withdrawals and cravings in many people who take it. But it also carries a documented risk of "severe toxic adverse events" because of its impact on cardiac activity, as detailed in the Journal of Substance Use and Addiction Treatment.

The goal, panelists explained, is to administer ibogaine in a controlled, medical setting, where a variety of tests beforehand would give health care providers a good idea of the patient's risk level. This would help avoid many of those potential complications, they said.

If the commission does approve research into ibogaine and gets initial FDA approval for a clinical trial, each participant in that study would be screened by doctors and psychologists to randomize the trial. Then they

would be subject to extensive screenings, including a cardiogram, to ensure they were not at acute risk of adverse cardiac activity, Mash said.

From there, patients would take ibogaine orally, in pill form, from a hospital bed, monitored by providers. They would experience what Mash referred to as a "cognitive reflection" for several hours, during which they would vividly hallucinate. Patients would be kept overnight for monitoring and released the following day.

Panelists said ibogaine does not have to be a replacement for other available, FDA-approved drugs, but it could be an alternative for patients who have struggled to find success with current treatment options.

"I will never say we have a cure. For some it will work well and some it (may) not work at all," Dr. Rao said. "The brain is complex," and no singular treatment is "going to benefit everybody."

Jessica Blackburn and Juliana Mulligan provided testimony to that end on Monday.

Blackburn, who previously shared her ibogaine experience with the Herald-Leader, turned to the drug after exhausting all other available FDA-approved treatment methods. She says it saved her life.

Though she should've had acute withdrawals from taking oxycontin the day before her first ibogaine treatment in Mexico in 2008, Blackburn said she woke up feeling no semblance of a withdrawal or craving.

"At a time when I should've been puking, covered in cold sweats and having intense cravings, for the first time in so many years, (drugs) didn't enter my mind," she told the commission. "I did not have a single withdrawal symptom. I didn't think, how am I going to afford my drugs today. I didn't hate looking at myself in the mirror."

Blackburn said this August will mark eight years of sobriety.

Long-term recovery with the help of methadone, for instance, "will always have a place in addiction medicine," she said. "But it's important to work together to put every single treatment option we can on the table. More of the same is not what we need to move past this problem."

Cabinet for Health and Family Services Secretary Eric Friedlander, who pushed back against Hubbard's proposal at the commission's June 13 meeting, has questioned the sum of money Hubbard is asking for to study ibogaine—$42 million, to be matched by private partnerships over the next six years.

Hubbard said he determined the dollar amount based off another commission allocation: Senate Bill 90. Passed during the 2022 legislative session, SB 90 is a conditional dismissal program which aims to reduce incarceration and help with long-term recovery by diverting qualifying people with mental health and substance use disorders out of jail and into community support service programs. It's an 11-county, four-year pilot program funded by opioid settlement money.

Hubbard on Monday said if the commission can elect to spend $42 million on a four-year program involving only 11 of Kentucky's 120 counties, why not spend that same amount on a drug trial that, if successful, could have an impact far beyond just this state?

"It is my simple, personal, individual opinion that if this commission can pay for a highly consequential criminal justice initiative in 11 counties to the tune of $42 million over four years," Hubbard said, "then perhaps we can explore devoting $42 million . . . over the next six years to potentially revolutionize how we treat opioid use disorder for the people of this state, this country and for the people of this world."