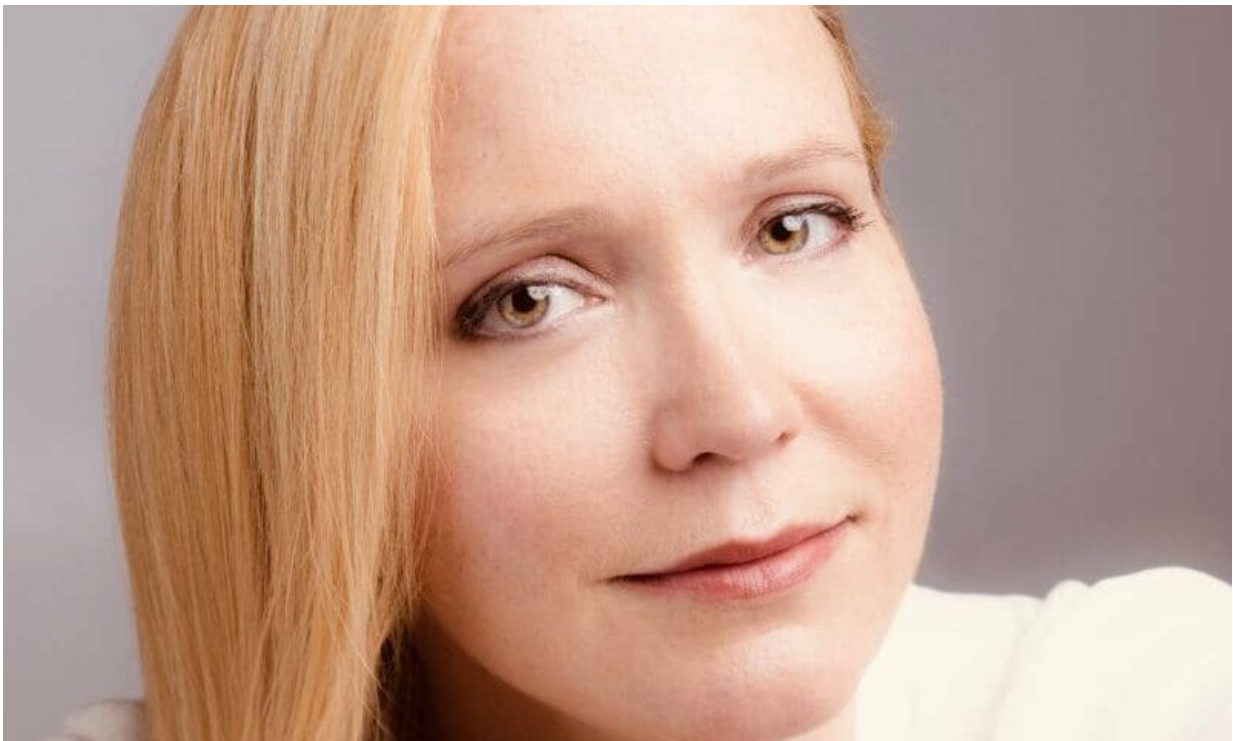


FDA poised to approve ketamine-like drug to ease depression

March 5 2019, by Carole Tanzer Miller And E.j. Mundell, Healthday Reporter



Jen Godfrey

(HealthDay)—The U.S. Food and Drug Administration could give its approval this week to esketamine—a relative of the "club drug" and anesthetic ketamine—against severe depression.

If that approval comes, it could be the first new class of medicines approved for years against an illness that plagues millions of Americans.

Approval couldn't be too soon for Jen Godfrey, who couldn't shake the "deep cloud" that lingered even after she found an antidepressant she could tolerate.

Then a string of stressors hit—five years of fertility treatment and an 80-pound weight gain during pregnancy that left her with persistent pain, a close relative's suicide, another who went missing, and her own divorce. It was all too much for Godfrey, a recovering alcoholic with a family history of depression.

"The life stuff just had a gravitational pull," said the 44-year-old stay-at-home mom from Reno, Nev. "I just thought: I don't drink, I'm a good friend, a good mother, a good spouse—I should be a lot happier."

Godfrey's search for relief pointed her to an unapproved and costly treatment for depression—[ketamine](#). An animal anesthetic best known as the addictive party drug "Special K," ketamine was approved for use as a human anesthetic in 1970. It's often used in emergency care to sedate kids and patients with breathing problems.

Low, intravenous doses have been found to boost mood and curb suicidal thoughts, but the FDA has not approved it as a treatment for depression. And the American Psychiatric Association (APA) warns patients about the potential for abuse and the lack of large, long-term studies of its effectiveness.

Even so, ketamine clinics like the one now treating Godfrey are springing up across the United States, prescribing the drug for "off-label" use against depression.

"The lack of information [on ketamine] is really quite dramatic when you look at the proliferation of use in certain communities," said former APA President Dr. Alan Schatzberg. He helped write an APA statement about ketamine urging caution.

A safer alternative?

Esketamine, the new drug seeking FDA approval, is meant to be a much safer version of ketamine.

Speaking this week with *National Public Radio*, Courtney Billington, president of Janssen Neuroscience, said esketamine will be marketed under the brand name Spravato.

Billington said numerous restrictions on Spravato's use will be put in place.

First, only patients who have failed at least two other antidepressants will be eligible for a prescription, and "Spravato will not be dispensed directly to a patient to take it home. It will only be available in approved and certified treatment centers," he said.

Also, unlike ketamine, "the amount of active ingredient that's in this product is at a very, very low dose," Billington told *NPR*.

That's important, because ketamine can trigger disturbing effects such as hallucinations and dissociation, a sense of being disconnected from one's body and the world. Spravato shouldn't carry those risks, Billington said.

In the meantime, clinics offering generic ketamine continue to do business.

It's not even clear exactly how ketamine works to improve mood,

Schatzberg said.

One common theory is that it affects the brain's response to the neurotransmitter glutamate. Neurotransmitters are chemicals that send signals from one part of the brain to another and from the brain to the body. Essentially, the thinking goes, ketamine rewires the brain.

But Schatzberg, a professor of psychiatry and behavioral sciences at Stanford University, was part of a small study published online in *The American Journal of Psychiatry*. It suggested another explanation—that ketamine somehow activates [opioid receptors](#) in the brain.

"We could be exposing people to untoward consequences from a drug that works through an opioid mechanism," he said. With an opioid addiction crisis in full swing across the United States, "we need to study [ketamine] more," he added.

When other treatments have failed

Dr. Robert Watson, Godfrey's doctor at Sierra Ketamine Clinics in Reno, agreed that more study is needed. He thinks researchers could learn much from clinics like his that offer ketamine as an off-label depression treatment.

Watson said he's seen the drug help many patients whose depression hasn't responded to other medications and/or talk therapy.

Since opening over a year ago, his clinic has treated about 500 patients—roughly 75 percent of them for chronic depression. It also uses ketamine to treat some other mental health problems, including post-traumatic stress, as well as chronic pain.

For depression, patients get four to six infusions, twice a week. Because

the treatment is not FDA-approved, insurance rarely covers the cost, which averages \$500 per dose. Patients go home with ketamine lozenges or nasal sprays to prolong the benefits. Some have gone six months or more without needing a booster infusion, Watson said.

Family members often notice a dramatic turnaround in mood after a patient's first 45-minute infusion, he said. Other patients only see the benefit after several IV doses. Most find treatment peaceful and relaxing, though it causes nausea in some, Watson said, and some dislike the feeling of being disconnected from their body and the world.

But he said he's seen no issues with abuse at the low and infrequent doses patients receive.

"There's still a lot we don't know, but even with what we don't know, it's proved to be the most efficacious and rapid-acting drug that we've ever seen for depression," Watson said. "It definitely needs to be looked at."

A 'game-changer'

Godfrey said ketamine has been nothing short of a miracle for her. Before that, she had tried a series of antidepressants before finding one that helped a bit, and everything from acupuncture to yoga and meditation. But her gloom and pain never seemed to go away.

During her first ketamine infusion, however, Godfrey felt an almost immediate sense of warmth and well-being, she said. Her second dose brought "the presence of a being that said 'everything is going to be OK.'"

"I didn't even realize how heavy the weight had gotten until it was totally lifted," Godfrey said. "Immediately following [an infusion], you have about 10 solid hours of no pain whatsoever, and it cut down my actual pain by about 75 percent in a lasting way."

She continues to take the antidepressant Lexapro (escitalopram) and sees a psychologist about once a month. When she needs it, she puts a ketamine lozenge under her tongue at bedtime, and she drifts off to sleep.

"I did not think that anything with this much relief and promise would come along in my lifetime, let alone now," Godfrey said. "It's a game-changer."

More information: The U.S. National Institutes of Health has more about [ketamine](#).

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