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FDA proposes to change regulation of ECT treatment

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For decades, people with severe depression, bipolar disorder, and other major mental health conditions have gotten help from the treatment known as ECT, when nothing else helped them.

Thousands of studies have shown its power to ease devastating, even life-threatening, symptoms.

Now, the U.S. Food and Drug Administration has proposed to change the way it regulates the devices that doctors use to deliver ECT treatment.

In some ways, the change could help make the treatment more accessible to people with some conditions.

But in other ways, a top ECT doctor says, the change could put the treatment out of reach for many more people - including some who have few other treatment options.

The FDA is accepting public comments on the proposed change until March 28, and will take them into account when writing its final decision about the devices.

Anyone who has undergone ECT, or seen a loved one experience its effects, can comment. So can people who work in mental health care. Find the comments form, and the full text of the proposed change, here: http://umhealth.me/ect-fda

But first, a bit more information, from Daniel Maixner, M.D., who directs the University of Michigan Health System's ECT program and treats hundreds of patients with ECT each year.

What is ECT?

The full name is electroconvulsive therapy, which doesn't sound pleasant. In fact, it may conjure up old movie scenes of psychiatric patients undergoing "shock therapy."

But in its modern form, with today's equipment and experienced treatment teams, it's a lot less off-putting.

Patients getting ECT today receive anesthesia and muscle relaxation before their treatments, so they're asleep the whole time. They receive an electrical stimulation to induce a brief brain seizure. It only takes a few minutes per treatment, and treatments occur every few days in the range of 6-12 sessions per course.

The brief seizures have numerous biological effects, but in simple terms may "reset" electrical activity between nerve cells in the brain. In each patient, doctors carefully target the symptoms that research has shown to be most involved in the patient's condition - whether that's crushing depression, uncontrolled mania, deeply disturbed thoughts, or catatonic states. All of these can make people candidates for ECT.

Doctors at U-M and other centers continue to refine ECT's use, to reduce the chance of side effects while boosting the effect it has on symptoms. A U-M team recently published an analysis of results from 32 studies, which reveals key factors that might help doctors better target the use of ECT to those who can benefit the most.

What is FDA proposing?

To make sure ECT happens safely around the country, the FDA regulates ECT equipment under its medical devices authority.

The new proposal would take ECT equipment out of a category of devices (called Class III) that it got "grandfathered" into decades ago, and put it alongside other devices in a lower-level category called Class II.

This move has been supported by many, including the National Network of Depression Centers. That's a network of research and treatment sites that began at U-M, and several years ago issued a formal statement in support of the move to Class II. Maixner was a co-author of that statement.

If ECT gear stays in Class III, manufacturers of the equipment would need to carry out very expensive large clinical studies as if the technology were completely new. That might keep them from innovating or even put them out of business.

And it's doubtful that university hospitals, where such studies would most likely take place, would agree to test ECT against a "sham" or fake form of the technology, because it wouldn't be ethical to let people with severe mental health conditions get randomly assigned to a placebo when there's so much evidence that ECT works.

If ECT equipment moves to Class II, there will still be safety oversight from FDA, including limits on who can provide the treatment, registration of machines, and labeling about safe use.

But it's how the FDA proposes to move ECT into Class II that has experts like Maixner, and mental health advocates, worried.

What does the proposal say?

It's pages and pages long, but in a nutshell: it says that the FDA is proposing to put ECT equipment into Class II for people over age 18 who have a ONLY a severe depressive episode related to major depression disorder and bipolar disorder.

And indeed, that covers a large portion of the people who receive ECT today, and whose insurance covers it.

But it leaves out a lot of others. And if FDA's final decision doesn't include the conditions they have, their insurance companies may have an excuse to stop covering ECT treatment.

"We worry that insurance companies that authorize payment may not approve it for other indications, where there is good evidence for its use - essentially making all other uses off-label," says Maixner.

Who's left out?

Maixner lists a few examples:

•Teens and tweens - For families at the end of their rope because their child's mental health condition hasn't responded to other treatments, ECT can be a lifeline. Families travel hundreds of miles to U-M and other major centers that offer ECT to people under age 18, to get treatment for kids and teens who have exhausted all other options.
•People who need repeated ECT - For many people who receive ECT, a single course of treatments can give results that last months or even years. But some people require a longer tapered course of treatment in a "maintenance" mode to keep their symptoms at bay.
•People with many other conditions - ECT has been shown to help people experiencing intense mania due to bipolar disorder or other conditions, and people experiencing psychosis or schizophrenia. But they're left out of the current proposed FDA reclassification. So are people in catatonic states due to their mood disorder or psychosis-causing condition - and for them ECT can be a life-saver, the only thing that "brings them back". Also left out: people with severe autism, of any age, for whom ECT can quell behaviors that cause them to injure themselves.

"If you look across the thousands of research citations on ECT, you see that numerous studies have been done in adults, and in children and adolescents, that provides evidence of usefulness in all these patient populations," says Maixner. "We're concerned that the FDA may not fully consider these results."

He points to a 2013 book co-edited by his U-M colleague Neera Ghaziuddin, M.D., and published by Oxford University Press, on ECT in children and adolescents. The first of its kind, it provides guidance on the use of the modern ECT technique in a subgroup of young people with severe psychiatric disorders.

What's more, Maixner says, if the FDA goes ahead with the narrow definition of ECT's treatment use, it would be extremely hard to get the definition expanded later to include these groups. Doing so would require major studies, which again would be costly and almost impossible to conduct because "sham" ECT is unethical.

What could happen?

Insurers don't have to follow the FDA classification when deciding what to pay for - but it's often used as a guide. And any change in a device's classification gives insurers a reason to look again at what they will and won't cover.

If an insurer, for example, doesn't normally cover a treatment for patients of a certain type, but a particular patient's doctor feels it could benefit them, the doctor can apply for a waiver to get coverage.

So moving ECT to Class II, with the current proposed limits on who it's recommended for, could open up a can of worms for patients and doctors alike.

Before that can opens, though, the public has a chance to share their thoughts. Until March 28.

Source:
University of Michigan Health System