

FDA bans shock device used on mentally disabled patients

March 4 2020, by Matthew Perrone



In this Aug. 13, 2014 file photo, a therapist checks the ankle strap of an electrical shocking device on a student during an exercise program at the Judge Rotenberg Educational Center in Canton, Mass. The student, who was born with a developmental disorder, wears the device so administrators can control violent episodes. On Wednesday, March 4, 2020, the U.S. Food and Drug Administration announced it is banning a class of controversial devices used to discourage aggressive, self-injurious behavior in patients with mental disabilities. (AP Photo/Charles Krupa)



Federal officials on Wednesday banned electrical shock devices used to discourage aggressive, self-harming behavior in patients with mental disabilities.

The announcement from the Food and Drug Administration follows years of pressure from <u>patient groups</u> and mental health experts who have called the treatment outdated, ineffective and unethical. The agency first announced its intent to ban the devices in 2016.

For years, the shock devices have been used by only one place in the U.S., the Judge Rotenberg Educational Center of Canton, Massachusetts, a <u>residential school</u> for people with autism and other psychiatric, developmental or mental disabilities.

School administrators have called the shocks a last resort to prevent dangerous behaviors, such as head-banging, throwing furniture or attacking teachers or classmates.

The FDA said Wednesday it estimates 45 to 50 people at the school are currently being treated with the <u>device</u>.

A woman who answered the phone at the center Wednesday morning said she could not comment on the FDA action.

Electric shocks and other painful or unpleasant treatments known as "aversive conditioning" were more widely accepted decades ago. But mainstream psychiatry now relies on behavioral modification, prescription drugs and other therapies that have proven more effective.

"Through advancements in <u>medical science</u>, there are now more treatment options available to reduce or stop self-injurious or <u>aggressive</u> <u>behavior</u>," said Dr. William Maisel, a director in the FDA's device center, in a statement.



The Rotenberg school has used shock devices carried in students' backpacks, which were attached to their arms and legs via electrodes. School staffers could trigger a two-second shock to a patient's skin by using a remote controller.



In this Aug. 13, 2014 file photo, a student wearing an electrical shocker device on her leg lines up with her classmates after lunch at the Judge Rotenberg Educational Center in Canton, Mass. Many students at the school, who were born with autism and development disorders, wear shocking devices to control violent outbreaks. On Wednesday, March 4, 2020, the U.S. Food and Drug Administration announced it is banning a class of controversial devices used to discourage aggressive, self-injurious behavior in patients with mental disabilities. (AP Photo/Charles Krupa)

Some patients from the Rotenberg center have compared the shocks to a bee sting or worse. The school has faced several lawsuits brought by



families who said their children were traumatized by the shocks.

Other parents reported that the technique was the only thing that prevented violent behavior linked to autism and other disabilities.

The FDA, echoing psychiatric experts, said in a statement that the therapy can exacerbate dangerous behaviors and lead to depression, anxiety and post-traumatic stress disorder. Patients have also suffered burns and <u>tissue damage</u> due to the device, the agency said.

Regulators said patients should instead receive treatments that focus on eliminating factors that trigger the behaviors or teaching <u>patients</u> coping skills to deal with them.

The FDA has only banned two other products in more than 40 years of regulating medical devices—powdered surgical gloves, which can cause allergic reactions, and fake hair implants, which caused infections and didn't work.

Typically, the FDA addresses safety issues by adding new warning labels or modifying instructions for devices. But the agency concluded that the problems with the <u>shock</u> devices could only be addressed by banning them.

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