FDA may ban electroshock devices used on some psychiatric patients

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Federal regulators are taking a second stab at banning the controversial

use of electroshock devices to manage the behavior of patients with intellectual and developmental disorders.

The devices deliver electric shocks to a patient's skin, in an attempt to stop them from harming themselves or lashing out physically at others, the U.S. Food and Drug Administration (FDA) said in its Monday announcement.

These devices—called electrical stimulation devices or ESDs—now are in use at just one U.S. facility, the Judge Rotenberg Education Center in Canton, Mass., the FDA said.

"We estimate around 50 individuals currently have a treatment plan that includes the use, or potential use, of" these devices, the FDA statement said.

A special United Nations report in 2013 concluded that the Rotenberg Center's use of the shock devices on students constitutes a violation of the U.N. convention against torture.

The FDA previously attempted to ban the use of the devices in 2020, but a federal court ruled that the agency didn't have the authority to enact its proposed ban.

"Since ESDs were first marketed more than 20 years ago, we have gained a better understanding of the danger these devices present to public health," Dr. William Maisel, director of the Office of Product Evaluation and Quality in the FDA's Center for Devices and Radiological Health, said in a news release at the time of the first ban.

"Through advancements in medical science, there are now more treatment options available to reduce or stop self-injurious or aggressive behavior, thus avoiding the substantial risk ESDs present," he added.

Congress has since revised the law to make clear that the FDA can, in fact, issue a ban for the devices.

The Rotenberg Center's website says that it provides treatment for both children and adults. Some students live at the facility, while others take day classes.

Those who have been court-approved to receive electric shock treatment wear a backpack with a battery inside, The New York Times has reported. Wires running from the backpack deliver shocks to students' skin, when triggered by a school employee.

Critics argued that the electrical shock devices were used excessively, causing lasting damage to students.

"Notably, some people who exhibit self-injurious or aggressive behavior have intellectual or developmental disabilities that make it difficult for them to communicate or make their own treatment decisions," the FDA said in its Monday announcement.

"These devices present a number of psychological risks, including depression, anxiety, worsening of underlying symptoms, development of post-traumatic stress disorder, and physical risks such as pain, burns, and tissue damage," the agency added.

However, the FDA noted that those exposed to this device may need treatment plan adjustments and time to gradually transition away from it.

"The FDA intends to consider the needs of these patients should we finalize the proposed ban," the agency said in its statement.

The proposed rule applies only to ESDs intended to be used for aggressive or self-harming behavior, the agency said. For example, it

would not apply to "aversive conditioning devices" intended for other purposes such as smoking cessation.

The agency will accept public comments through May 28. After reviewing them, it will decide whether to follow through with the ban.

More information: The U.S. Food and Drug Administration has more about its proposed ban on electrical shock devices.