



Autism Society of America
6110 Executive Blvd, Suite 305
Rockville, Maryland 20852

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Submitted Electronically at: <http://www.regulations.gov>

Docket Management Staff
5630 Fisher Lane, R, 1061
Silver Spring, MD 20852

Re: Comments on the Food and Drug Administration's Proposed Ban on
Electrical Stimulation Devices, Docket No. FDA-2023-N-3902

On behalf of the Autism Society of America, I write in strong support of the Food and Drug Administration's proposed ban on electrical stimulation devices (ESD) for self-injurious behavior (SIB) or aggressive behavior (AB).

The Autism Society of America is the nation's oldest and largest grassroots organization representing individuals with Autism and their families. From research and personal stories, we know that individuals with Autism are disproportionately subjected to electric shocks and other aversive treatments.

In 2020, after years of effort on the part of a broad coalition of disability advocates, the Food and Drug Administration (FDA) announced that it was banning the electric shock devices used at the Judge Rotenberg Center, yet these practices continue. The facility challenged the FDA's ban in court, and they won. The ban was never enacted, and this controversial method of behavior control continues to be used on vulnerable people today.

We agree with the FDA's determination that these devices present an unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated by labeling. When finalized, this rule will amend part 895 (21 CFR part 895) to designate ESDs for SIB or AB as banned devices.

It is essential to recognize the inherent dignity and rights of all individuals, regardless of their developmental or intellectual abilities. The use of electric shock and other aversive treatments, especially on the most vulnerable members of our society, is not only ethically questionable but also a violation of their basic human rights. As noted in the proposed rule, such practices are not in line with modern therapeutic and educational standards and can have long-lasting psychological impacts on the recipients.



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Research and evidence-based practices in developmental disabilities have shown that there are more effective, humane, and ethical approaches to supporting individuals with challenging behaviors. Techniques that emphasize positive reinforcement, skill-building, and compassionate care, such as positive behavioral support (PBS), are not only more effective, but also uphold the dignity and respect that every individual deserves.

Furthermore, the FDA properly finds the application of electric shock treatments, such as those used by the Judge Rottenberg Center, poses significant risks. These risks include physical harm, psychological trauma, and the potential to create an environment of fear and distress. This is counterproductive to any educational or therapeutic goals and can lead to further behavioral and emotional challenges.

The FDA rightly points out that this rulemaking will protect and promote public health by banning ESDs for SIB or AB, which would prevent individuals from being subjected to a device that poses a substantial and unreasonable risk of illness or injury. The FDA explains in the proposed rule that people who manifest SIB or AB often have intellectual and developmental disabilities including, but not limited to, Autism, Down syndrome, Tourette syndrome, as well as other cognitive or psychiatric disorders and intellectual impairment (including a broad range of intellectual measures) (see, e.g., 81 FR 24386 at 24389). Notably, some people with such intellectual and developmental disabilities may have difficulty communicating and may not be able to make their own treatment decisions because of such disabilities, making them more vulnerable.

The FDA also relied on evidence that most States have severely limited or banned the use of contingent electric shock and other painful aversive interventions. In 2015, the National Association of State Developmental Disability Directors (NASDDDS) surveyed States about their rules, policies, guidelines, contracts, or practices that governed aversive interventions. Of the 45 States responding, 82% reported that aversives are disallowed for use in service for people with I/DD. A more recent search has found that at least twenty-eight States have enacted prohibitions against the use of electric shock and other painful aversive procedures.

We are pleased that the FDA considered new information since the 2020 administrative record closed. As part of this proposed rule, the FDA conducted an updated literature survey, including published studies, articles, and policy statements related to the risks and effects of ESDs when used for self-injurious or aggressive behaviors. This record also incorporated a comprehensive literature review conducted as part of the 2016 and 2020 rule-making process. Results from the FDA's updated survey underscore the reliability of its past rulemaking and demonstrate that no further modification of the proposed rule is necessary.



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Regarding the FDA's request for comments on whether there should be a transition period of 180 days for the ban of all ESDs after the effective date of the rule, we believe the transition from ESDs should occur as soon as possible. We believe that the transition period should be no more than sixty days. In addition, the transition for these individuals should be done under the supervision of a qualified independent medical professional, trained in the provision of state-of-the-art behavioral support services. This must occur as soon as there can be appropriate functional assessments by qualified, independent medical professionals followed by positive behavioral support plans for each individual.

Thank you for the opportunity to provide comments. The Autism Society urges the FDA to move forward with approval of the proposed rule as soon as possible.

Sincerely,

A handwritten signature in black ink that reads "Christopher S. Banks".

Christopher Banks
President/Chief Executive Officer
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