



*For people with intellectual
and developmental disabilities*

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Leslie Kux
Associate Commissioner for Policy

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: 21 CFR Parts 882 and 895 Banned Devices; Proposal To Ban Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior

Docket No. FDA-2023-N-3902

Dear Associate Commissioner Kux,

The Arc of the United States appreciates the opportunity to submit comments on the Food and Drug Administration's (FDA) proposed rule banning electrical stimulation devices (ESDs) for self-injurious or aggressive behavior, published in the Federal Register on March 26, 2024.

The Arc of the United States is the largest national community-based organization advocating for people with intellectual and developmental (IDD) and their families, with nearly 600 state and local chapters across the United States. These chapters provide a wide range of services for people with IDD, including individual and systems advocacy, public education, family support, systems navigation, support coordination services, employment, housing, support groups, and recreation. The Arc has over seventy years of history promoting the human and civil rights of people with IDD and advocating for the rights of children and adults with disabilities to be free from harm and abusive treatment.

The Arc of the United States applauds the proposed rule and agrees with the FDA's assertion that these devices present an unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated by labeling.

The Arc agrees with the FDA's findings that ESDs are not only ineffective at reducing self-injurious or aggressive behavior but also pose an unreasonable risk of significant physical and psychological harm. It is precisely because of these harms that virtually every health provider in the nation rejects their use, which is practiced only by a single institution, the Judge Rotenberg Center (JRC) in Canton, Massachusetts. The Arc agrees with the FDA's finding that no evidence produced since the finalization of the 2020 rule banning the use of ESDs warrants any substantial revision of the FDA's prior analysis.

The Arc supports the conclusion that “the proposed ban would apply to devices already in commercial distribution and devices already sold to the ultimate user, as well as devices sold or commercially distributed in the future.” However, we encourage the FDA to go further, to also ban the use of such devices in future studies. The Arc agrees with the assertion that “the risk of illness or injury to individuals on whom these devices are already used is just as unreasonable and substantial as it is for future individuals on whom these devices could be used.” Therefore, any use, even in a study, must be banned.

The Arc agrees with the FDA’s assertion that ESDs are not being used as treatments of last resort, as JRC rarely conducts functional analyses of behavior. Without these analyses, it is not possible to implement alternative, less-intrusive treatments—undermining JRC’s assertion that the ESD is used only in times of last resort. Additionally, we agree with the FDA’s concern that individuals with IDD may not be able to communicate information to the device user—something that cannot be corrected or changed with labeling.

The Arc has long advocated for the use of positive behavioral support approaches. As is highlighted in the preamble to the proposed rule, research shows that positive behavioral supports are effective in reducing problem behaviors. Positive behavioral support (PBS) systems strive to understand the function of challenging behavior that prevents community participation. The systems focus on changing environmental factors so that challenging behaviors no longer are reinforced and instead offer individuals alternative behaviors that have been discussed collaboratively and explicitly taught that they can use to meet their needs.

The Arc has adopted position statements opposing the use of aversive procedures since at least 1984. Our current position statement on Behavioral Supports developed jointly with the American Association on Intellectual and Developmental Disabilities (AAIDD) and adopted by both organizations’ in 2021, states in part:

Research indicates that aversive procedures such as deprivation, physical restraint and seclusion do not reduce challenging behaviors, and in fact can inhibit the development of appropriate skills and behaviors. These practices are dangerous, dehumanizing, result in a loss of dignity, and are unacceptable in a civilized society. ...

The Arc and AAIDD are opposed to all aversive procedures, such as electric shock, deprivation, seclusion and isolation. Interventions must not withhold essential food and drink, cause physical and/or psychological pain or result in humiliation or discomfort.

Our position statement on Education, which was adopted by the Congress of Delegates in 2018, states in part:

In order to provide a free, appropriate public education for students with I/DD, all those involved in the education of students with I/DD must: . . .

- Prohibit the use of mechanical or chemical restraint, isolation, or aversives.

The Arc has a history of working to change practices used in large congregate facilities that deprived residents of their dignity and safety. As a pioneer in developing community-based programs for children and adults with disabilities, The Arc has been guided by the inherent value

and worth of every individual, creating programs and services that include monitoring and oversight to ensure quality and safety for the individuals served. In fact, The Arc participated in an amicus brief supporting the Commonwealth of Massachusetts in the case of Behavioral Research Institute v. Campbell before the Supreme Judicial Court of Massachusetts in 1996.

Additionally, in 2009, The Arc along with 29 other organizations, including most of the preeminent professional and consumer associations for people with intellectual and developmental disabilities (including, AAIDD, the Association of University Centers on Disabilities, Easter Seals, the Autism National Committee, the National Association of Councils on Developmental Disabilities, the National Disability Rights Network, TASH, the Syracuse University Center on human Policy, Law and Disability Studies, Self Advocates Becoming Empowered, the Autistic Self Advocacy Network, and United Cerebral Palsy) sent a letter to the federal Department of Health and Human Services, the Department of Education, the Attorney General, Congressional Committees, and Human Rights organizations calling for leadership in putting an end to the use of inhumane, painful aversive practices. As a result, the Department of Justice initiated an investigation into the use of electric shock at the Judge Rotenberg Center in 2010. In 2014, The Arc testified in front of the Neurological Devices Panel of the Medical Devices Advisory Committee of the FDA about the harmful effects of the ESD. Due to The Arc's long history of legal and public policy advocacy on this issue, we applaud the FDA's continued effort to eliminate these abusive practices.

The Arc believes this rule should take immediate effect—it should not be subjected to a 180-day transitional period. There is only one facility using these techniques, and they have sufficient notice with the 60-day comment period, as well as the time required to finalize the rule.

The Arc's overarching goal is to ensure that individuals with disabilities have all the supports needed in order to full participate in their communities free from harm or abuse. The FDA's proposed rule, when final, will greatly assist in ensuring each individual's right to be free from harm. The Arc maintains its strong in its belief that it is the responsibility of government to protect individuals with disabilities from mistreatment. Using aversive procedures to change behaviors of individuals with intellectual and developmental disabilities is dangerous, dehumanizing, a violation of civil rights, results in a loss of dignity, and is unacceptable in a civilized society. The Arc applauds the FDA in its effort to ban the use of devices that emit electric shock as a means of modifying the behavior of individuals with intellectual and developmental disabilities and encourages the FDA to finalize this rule without delay.

Respectfully Submitted,

Robyn Linscott
Director of Education and Family Policy
The Arc of the United States