

May 25, 2016

Dr. Robert M. Califf, MD  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

**RE:** 21 CFR Parts 882 and 895 Banned Devices; Proposal to Ban Electrical Stimulation Devices Used to Treat Self-Injurious or Aggressive Behavior

**VIA:** Electronic submission through the Federal eRulemaking Portal:  
<http://www.regulations.gov>.

Dear Commissioner Califf,

Thank you for the opportunity to comment on the proposed Rule to ban electrical stimulation devices (ESD) used to treat self-injurious or aggressive behavior published in the April 25 *Federal Register*. AUCD has also signed on in support of comments submitted by the Consortium for Citizens with Disabilities as well as those submitted on behalf of the Developmental Disabilities Act partners: NACDD, NDRN, and AUCD.

The Association of University Centers on Disabilities (AUCD) is a membership organization that supports and promotes a national network of university-based interdisciplinary programs. Network members consist of:

- 67 University Centers for Excellence in Developmental Disabilities (UCEDD), funded by the Administration on Intellectual and Developmental Disabilities (AIDD)
- 43 Leadership Education in Neurodevelopmental and Related Disabilities (LEND) Programs funded by the Maternal and Child Health Bureau (MCHB)
- 15 Intellectual and Developmental Disability Research Centers (IDDRC), most of which are funded by the National Institute for Child Health and Development (NICHD)

These programs serve and are located in every U.S. state and territory and are all part of universities or medical centers. They serve as a bridge between the university and the community, bringing together the resources of both to achieve meaningful change. AUCD strongly supports the FDA proposal to ban ESDs. ESDs are devices that apply a noxious electrical stimulus to a person's skin upon the occurrence of a target behavior in an attempt to condition the individual over time to reduce or cease the behavior. We agree with the FDA's findings that the risks far outweigh any possible benefit.

For many years AUCD has worked in concert with other advocates to ban the use of electric shock and other aversive techniques. Many of our members have worked over the past 40 plus years to return individuals with intellectual and other developmental disabilities from institutional care to the community. The treatment some of these individuals received in their institutional placements included painful aversive stimuli. Individuals who had the capacity to talk about their experiences described situations that were in no way

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Andrew J. Imparato  
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therapeutic or beneficial. Some spoke about being tortured by staff in mistaken attempts to control aberrant displays of behavior.

One need only look at the research on aversive stimuli to note that:

- 1) They act quickly but they are context bound;
- 2) The problem they were intended to address resumes once the aversive is no longer present;
- 3) Substantial data indicates the individual associates the aversive with the individual administering it, and;
- 4) It can cause learned helplessness, that is, complete passivity or withdrawal in the face of an aversive, not an adaptive behavioral change.

The information above does not include the human cost of aversive therapy. Individuals with intellectual and other developmental disabilities are historically a marginalized group within our society. Shuttered away in institutions where in many cases their basic human needs were (and are) barely met, use of aversive procedures exacerbate a dehumanizing environment, further indicating to the individual that they are “less than” those who are implementing aversive treatment, leading to conditions where these individuals are seen as less than human.

As one member from the Nebraska University Center for Excellence in Developmental Disabilities, Mark Smith explained:

“In my experience of returning individuals to community living, I worked with dozens if not hundreds of individuals with extremely challenging behavior, including life-threatening self-injury, high rates of aggression, and property destruction. Aversive procedures were never employed in any of these cases, yet an overwhelming majority of these individuals not only remained but thrived in community placements through persistent, positive approaches to addressing their behavior. We found that the more the individual could assume appropriate control over their lives in addition to effectively communicating, the less interfering problems were observed.”

AUCD believes that all aversive procedures, such as electric shock, deprivation, seclusion and restraints, are not therapeutic and are unnecessary and should be banned as an approach to dealing with difficult behavior. In addition, we believe that interventions must not withhold essential food and water, cause physical and/or psychological pain or result in humiliation or discomfort. As pointed out in the Rule, substantial research and evidence on the use of alternative positive behavioral supports and interventions and successful de-escalation techniques make these devices outdated and completely unnecessary.

AUCD believes it is time to include individuals with disabilities as participating members of our communities while providing supports where needed, including behavioral and mental health supports. This need not and should not include electric shocks. It is well past time to move beyond antiquated and destructive approaches when it comes to citizens of this country regardless of condition.

Therefore, AUCD fully supports the FDA proposed Rule to ban the use of Electrical Stimulation Devices. AUCD agrees that ESDs present a substantial and unreasonable risk of abuse and injury.

Thank you again for the opportunity to provide input into the proposed Rule. Please feel free to contact me with any questions.

Sincerely,



Andrew Imparato  
Executive Director, AUCD