



Committee, Docket No. FDA-2016-N-1111

To Whom It May Concern:

Thank you for the opportunity to comment on the proposed rule to ban electrical stimulation devices (ESD) that are used to administer electrical shocks to children, youth, and adults. The National Association of Councils on Developmental Disabilities (NACDD), Association of University Centers on Disabilities (AUCD) and National Disability Rights Network (NDRN) submit these comments in strong support of the proposed ban by the Food and Drug Administration (FDA). In 2014, NACDD, AUCD and NDRN all provided written and oral comments to the Neurological Devices Panel of the Medical Devices Advisory Committee which examined the safety and effectiveness of aversive conditioning devices that use a noxious electrical stimulus. At that time, NACDD, AUCD and NDRN all called for a ban of these devices. We are pleased to see the FDA has carefully weighed the evidence, and has issued the proposed ban of ESDs. We agree with the FDA's findings that the risks far outweigh any possible benefit, and that the substantial risks to illness or injury cannot be corrected or eliminated by labeling. As documented in the notice, there is more than sufficient evidence that exists to meet the standard for banning these devices.

NACDD, AUCD, and NDRN's position supporting the proposed ban is supported by federal policy, and other non-governmental organizations, as well as the professional academic literature. As the FDA states in the notice, the continued use of these devices is against the weight of the evidence for how to effectively provide treatment to individuals with self-injurious or aggressive behaviors. Current professional standards and use of evidence-based practices confirm that the use of ESDs fall outside the accepted standards of practice and the state of the art both within professional organizations and government entities at the state, national or international levels. It has been over twenty years since leading researchers in the disability community stated "[t]he routine use of procedures that deliver pain (shock, pinching, slaps), procedures that result in harm (bruises, cuts, broken bones), and procedures that are disrespectful or dehumanizing (facial sprays, shaving cream in mouth, foul smells) are no longer acceptable."¹

NACDD, AUCD and NDRN are the national membership associations for the three programs funded under the Developmental Disabilities Assistance and Bill of Rights Act (DD Act). These programs include the State Councils on Developmental Disabilities, University Centers for Excellence in Developmental Disabilities, and Protection and Advocacy Program for Persons with Developmental Disabilities. Each of these three programs are located in every state and territory. The DD Act charges these programs to "assure that individuals with developmental disabilities and their families participate in the design of and have access to needed community services, individualized

¹ Horner, R. H., Dunlap, G., Koegel, R. L., Carr, E. G., Sailor, W., Anderson, J., Albin, R. W., O'Neill, R. E. (1990). Towards a technology of 'nonaversive behavioural support, *Research and Practice for Persons with Severe Disabilities*. 15, 125-132.

supports, and other forms of assistance that promote self-determination, independence, productivity, and integration and inclusion in all facets of community life, through culturally competent programs”.²

The ongoing use of ESDs is in clear contradiction of the DD Act’s finding that “the goals of the Nation properly include a goal of providing individuals with developmental disabilities with the information, skills, opportunities, and support to... live free of abuse, neglect, financial and sexual exploitation, and violations of their legal and human rights.”³ The use of ESDs also disregards the Individuals with Disabilities Education Act’s (IDEA) clear preference for positive behavior interventions and supports. Furthermore, in a May 2012 Resource Document, the U.S. Department of Education stated that “any behavioral intervention must be consistent with the child’s rights to be treated with dignity and to be free from abuse.”⁴ A ban on ESDs is consistent with federal policy. Additionally, on March 4, 2013, the UN Special Rapporteur on Torture issued a report to the Human Rights Council in Geneva singling out the United States for sanctioning electric shock that had been categorized as torture.

As stated in the notice, ESDs are aversive conditioning 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. The only known entity to manufacture and use ESDs is the Judge Rotenberg Center (JRC) in Canton, Massachusetts. As the notice states, the current ESD that is in use at JRC is the Graduated Electronic Decelerator (GED)-3A and GED-4, and both are currently unapproved by the FDA.

The Disability Law Center, Inc. (DLC), the designated Protection and Advocacy agency for Massachusetts, has worked directly with individuals exposed to aversive behavioral interventions, such as the GEDs. DLC has previously submitted testimony that articulates the safety issues based on the pain inflicted by the device, the misfiring of the device, and the long-term traumatic effects. As discussed in the previous testimony of DLC, at any given time, residents may be wearing up to five GEDs simultaneously, so JRC residents are unaware of when, where, why and how many times they will be shocked. In addition, students are given shocks for minor incidents. DLC’s testimony chronicles the physical harm to one student:

...the burns and scars from being repeatedly shocked on her stomach. Electrodes had actually burned into her skin, and she experienced long-term loss of sensation, and numbness in the lower left leg after being shocked there. She describes feeling “searing pain all the way down to the bottom of her foot” and how she was “left with no feeling in her skin from the knee down for a year.” When electrodes were accidentally placed on students’ spines, she witnessed others being violently bent backwards.⁵

Moreover, JRC residents are subjected to misfirings and misuse of the GED. This news video about a prank phone call which resulted in 29 shocks to one student and 77 shocks to another is one such example with the result of first degree burns, see <http://www.youtube.com/watch?v=-aUIhWmDPeI>.

As the FDA notes, the use of ESDs are not consistent with proactive approaches or best practices in addressing the behavioral needs of students with disabilities. Behavioral supports should be person-centered, individually designed, positive, culturally appropriate, and allow for modifying or replacing the environment. There is significant research documenting that aversive behavior interventions are not effective long-term methods for

² The Developmental Disabilities Assistance and Bill of Rights Act of 2000, Sec. 101(b).

³ The Developmental Disabilities Assistance and Bill of Rights Act of 2000, Sec. 101(a)(16)(F).

⁴ U.S. Department of Education, Restraint and Seclusion: Resource Document, (May 2012) at <http://www2.ed.gov/policy/seclusion/restraints-and-seclusion-resources.pdf>

⁵ Written testimony of Richard Glassman and Christine Griffin, Disability Law Center, Inc., submitted to the Neurological Devices Panel of the FDA Medical Devices Advisory Committee, April 11, 2014

changing behaviors. The use of aversive behavioral interventions can also result in the unintended consequence of hindering the development of the very skills and behaviors necessary to counter the behaviors of concern.

It is critical to note that other states have found ways to work with students with the most significant behavioral needs without the use of aversive behavioral interventions, including conditioning devices, such as the ESDs. There are approximately 250 students enrolled at JRC. With few exceptions, other states have found other ways to serve students with the most significant behavior needs. For example, the Centennial School, located at Lehigh University in Pennsylvania is an approved private alternative school that serves students with the most significant emotional and behavioral disabilities. At a July 12, 2012 hearing in the Senate's Health, Education, Labor and Pensions Committee titled *Beyond Seclusion and Restraint: Creating Positive Learning Environments for All Students*, Michael George, the school's director, testified that students who enroll at Centennial have usually failed in other placements, and the common characteristic among the students is that their behavior is more severe than 99 percent of the population.⁶

Yet, Centennial has found a way to serve these students that does not rely on restraint, seclusion or aversive behavior interventions. Centennial is actually an instructive story of positive systems change. In 1997-98, the school had 76 students, who had been restrained 1,064 times. These high numbers of the use of restraint were accompanied by high rates of police involvement, suspensions, emergency hospitalizations, vandalism, truancy and staff absences. The following school year, Centennial underwent a major school-wide systems change effort by introducing positive evidence-based practices, including positive behavior interventions and supports, evaluating implementation, and making adjustments to improve outcomes. First and foremost, Centennial staff changed the way they viewed these students -- from students who were failures, unwilling or incapable of behaving -- to seeing the students as learners who were "works-in-progress," future successes, and as students that can meet the expectations if they are set for them. The school moved from the ineffective use of aversive behavior interventions to the use of positive behavior interventions and supports. For example, for a student who is cursing, a typical adolescent behavior, the focus shifted from administering a punishment to eliminating the cursing behavior by instead acknowledging polite statements made by students. Numerous other examples are documented in Mr. George's testimony. Centennial is one case study of a school that has found a way to address behaviors through positive evidenced based practices and without having to use aversive behavior interventions.

As the FDA found in the notice, substantial evidence exists which demonstrates that evidence-based positive alternatives to behavior modification, such as the use of positive behavior interventions and supports are safe and more effective long-term for use with students with the most significant behavior needs. We are pleased to see the substantial attention in the notice paid to the evolution from the use of aversive methods to the use of positive alternatives. The notice provides detailed information about the current state of the science and the overwhelming evidence that exists regarding the effectiveness of positive approaches. The notice also points out the reason why aversive conditioning devices, such as ESDs, has been found not only to be dangerous, but ineffective. The use of ESDs is inhumane, unnecessary, and deprives these children and adults of their civil rights.

Furthermore, given the history of the use of ESDs, and that only one entity that is known to use ESDs in the United States is also the sole manufacturer of them, and that the current device is being used despite not being FDA approved, NACDD, AUCD and NDRN request that the ban applies to all current devices, and any new devices that may be developed that are substantially similar to the current ESDs. Furthermore, the U.S. Department of Justice (DOJ) should closely monitor JRC to ensure that the device is no longer being manufactured or used on children and adults at JRC or at any other facilities. Lastly, DOJ should monitor to ensure that other aversive behavior interventions do not become a substitute for the use of ESDs. The video of Andre McCollins, a JRC resident from New York who was shocked 31 times, using the weaker GED for failure to take off his coat, is one example of the

⁶ <http://www.help.senate.gov/hearings/hearing/?id=28ddbd0d-5056-9502-5dea-7197eb6434c8>

very significant and serious concern that other aversive behavior interventions will be used once the ESD is ban in effective. Not taking off your coat is common adolescent behavior that does not rise to the level of needing this response. The video is available at <https://www.youtube.com/watch?v=ssc8mUqUEqE>.

Lastly, the DOJ and other applicable state entities must ensure that the children and adults subjected to use of ESDs receive trauma informed care, counseling and are transitioned to the use of positive approaches to behavior modification including positive behavior interventions and supports based on individual functional behavioral assessments.

Students deserve better. There is a significant risk to health and safety through use of aversive behavior interventions such as ESDs. In addition, the professional academic literature and practice among professionals in the field and government and non-governmental organizations supports this conclusion. There are more humane and effective alternatives. NACDD, AUCD and NDRN fully supports the proposed FDA ban on these devices.