



Honorable Sylvia Burwell, Secretary
U.S. Department of Health and Human Services

Robert Califf, MD, Commissioner
Federal Drug Administration

Shaun Donovan, Director
Office of Management and Budget

25 July 2016

Re: FDA Proposed Rule Banning Electrical Stimulation Devices [Docket No. FDA-2016-N-1111]

Dear Secretary Burwell, Commissioner Califf, and Director Donovan:

Disability Rights NC is North Carolina's federally mandated protection and advocacy (P&A) organization. We are a non-profit with unique authority and years of experience representing North Carolinians with disabilities and advocating for their legal rights. Our work focuses on numerous areas, including employment, education, housing, health care, voting, and abuse and neglect. We welcome the opportunity to comment on the FDA's proposed ban on the use of electrical stimulation devices (ESDs).

Disability Rights NC submits these comments to strongly support the Food and Drug Administration's (FDA) proposed ban on the use of electrical stimulation devices (ESDs) to treat self-injurious or aggressive behavior. In 2014, our national membership organization, the National Disability Rights Network (NDRN), provided written and oral testimony to the Neurological Devices Panel of the FDA Medical Devices Advisory Committee which examined the safety and effectiveness of aversive conditioning devices that use a noxious electrical stimulus. NDRN called for the ban of these devices during that meeting, we reiterate that call today. As the FDA states in the proposed ban, the continued use of these devices is against the weight of the evidence for how to effectively treat individuals with self-injurious or aggressive behaviors. The evidence has always been weak on the effectiveness of electrical stimulation to treat severe behavioral disorders, especially when considered against the significant harm caused by these devices. The FDA must therefore finalize the order to ban noxious electrical stimulus devices.

Based on available research, and the work of the national P&A and Client Assistance Program (CAP) system, Disability Rights NC fully agrees with the conclusion of the FDA that electrical stimulation devices (“ESDs”) are ineffective as treatment, and represent an unreasonable and substantial risk of illness or injury when used to reduce or cease self-injurious or aggressive behavior. As the FDA found, substantial evidence exists that positive behavioral supports, modification, and interventions are safe and more effective long-term for use with students and other individuals with the most significant behavioral needs than the use of ESDs.

As the FDA states in the comments to the proposed ban, the Judge Rotenberg Center (JRC) is the only known facility to use an aversive conditioning device that delivers a noxious electrical stimulus, called the Graduated Electronic Decelerator (GED), which JRC developed and manufactured.¹ In the proposed ban, the FDA found that use of ESDs, such as the GED, can trigger anxiety, panic, trauma, depression, and undesirable self-restraint. The FDA found that individuals subjected to ESDs experience varying degrees of pain, been subject to burns and ulcers, and most importantly that nature of the disabilities hinders the ability to assess the adverse effects of the use of ESDs. The FDA further notes the problems of the misfiring of the devices, and that trauma may occur when residents watch other residents be shocked by an ESD.

The Disability Law Center, Inc. (DLC), the designated P&A/CAP organization for Massachusetts, has worked directly with individuals exposed to the aversive conditioning devices used by the JRC. Testimony submitted by the DLC in 2014 is fully consistent with the findings of the FDA. The DLC noted in its testimony the safety issues based on the pain inflicted by the device, the misfiring of the device, and the long-term traumatic effects of ESDs. DLC’s testimony notes that, at any given time JRC residents may be wearing up to five GEDs simultaneously, so the residents are unaware of when, where, why and how many times they will be shocked. DLC’s testimony chronicles the physical harm to one student:

[T]he 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.

¹ BRI News, Winter 1991, Behavioral Research Institute, RI. (Note: The Behavioral Research Institute (BRI) changed its name to the Judge Rotenberg Center (“JRC”) in 1994. JRC is designated by the FDA as the manufacturer of the GED. See <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?lid=147131&lpcd=HCB>. JRC/BRI refers to itself as the manufacturer of the GED. See “A Comparison of Long Term Decelerative Effects”, JRC Pub. No. 93-2, available at <http://www.effectivetreatment.org/comp.html>, noting (at p. 3) that it manufactured 100 GED units from 12/90 and 3/93. DLC maintains that JRC engages in interstate commerce through the manufacturing process, and through the movement of students across interstate lines to attend JRC, and the use of the GED across state lines, when students are off-site. See *Barnes v. U.S.*, 142 F. 2d 648, 651 (9th Cir. 1944) (“Commerce so used in the statute is not confined in meaning to the actual transportation of articles across state lines, but includes the whole transaction of which such transporting is a part.”) (citations omitted). JRC previously maintained that it was exempt from FDA jurisdiction as engaging in the “practice of medicine,” it is no longer asserting this argument or contesting FDA jurisdiction.

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.²

Through a review of the literature and expert testimony, the FDA gathered more than sufficient evidence about the high risks and significant harm caused by the ESDs. Disability Rights NC agrees with the conclusion of the FDA that such substantial risks to illness or injury cannot be corrected or eliminated by labeling given the various individual reactions to ESDs, and most significantly the inherent high level of risk of these devices.

The FDA determined that the state of the art in responding to self-injurious and aggressive behavior has rejected the use of ESDs and turned to the use of alternative behavioral support. As NDRN stated in 2014 to the Neurological Devices Panel, current professional standards and evidence-based practices confirm that the use of aversive conditioning devices that deliver electric stimuli fall outside the accepted standards of practice and the state of the art both within professional organizations and government entities. More than twenty years ago 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.”³ Such research was correct then, and it is even more correct today.

It is critical to note that other states have found ways to work with individuals with the most significant behaviors without the use of aversive conditioning devices that use electric stimuli. Current JRC residents are predominantly from Massachusetts and New York, and with a few exceptions, other states have found ways to serve students with the most significant behavioral needs without resorting to ESDs. One such example comes from Pennsylvania.

The Centennial School located at Lehigh University is an approved private alternative school that serves students with autism and the most significant emotional disabilities. During a July 2012 hearing of the Senate Health, Education, Labor and Pensions Committee entitled *Beyond Seclusion and Restraint: Creating Positive Learning Environments for All Students*, the school’s director testified that students who enroll at Centennial have failed in other placements, and the students served by the school have behaviors more severe than 99 percent of the

² 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.

³ 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 behavioral support’, *Research and Practice for Persons with Severe Disabilities*. 15 , 125-132.

population.⁴ Centennial has found a way to serve these students without reliance on aversive behavioral interventions, restraints, or seclusion.

Centennial is an example of organizational and systemic change in the approach to students with disabilities and severe behavioral issues. During the 1997-98 school-year, Centennial's 76 students were restrained 1,064 times which resulted in high rates of police involvement, suspensions, emergency hospitalizations, vandalism, truancy and staff absences. The following school year, Centennial introduced positive evidence-based practices, evaluated implementation, and made adjustments to improve outcomes. Misbehaviors were seen as correctable errors instead of requiring punishment. By the 2012 school-year Centennial had reduced its total use of restraint or seclusion to 3 incidents.⁵

As emphasized by the FDA, the literature documents numerous studies showing the outcomes of using positive approaches to behavior and the limits of aversive behavioral interventions. For example, LaVigna & Willis (2012) reviewed 12 multi-element outcome studies that did not use punishment strategies. The 12 studies represented 423 cases. LaVigna & Willis concluded that positive behavior supports were effective with changing severe behaviors.⁶ Similarly, an affidavit filed in Probate and Family Court by the Commissioner of the Massachusetts Department of Developmental Disabilities reaches the same conclusions as Dr. LaVigna. The affidavit provides detailed support for the conclusion that aversive interventions including skin shock are not effective forms of treatment and are not best practices in the field.⁷

Looking at long-term outcomes, another study evaluated five adults with developmental disabilities who had been exposed to multiple, restrictive procedures including electric shock, food deprivation, and mechanical restraint in a residential treatment facility. Over a 24-month follow-up period after the five adults transitioned to a new habilitation setting where aversive procedures were terminated in favor of alternative methods of behavioral support, all of the participants were able to maintain clinically acceptable levels of challenging behaviors following the removal of the restrictive treatment procedures. Quality of life measures also revealed that

⁴ Available at <http://www.help.senate.gov/hearings/hearing/?id=28dcbd0d-5056-9502-5dea-7197eb6434c8>

⁵ Beyond Seclusion and Restraint: Creating Positive Learning Environments for All Students: Hearing Before the S. Comm. on Health, Education, Labor & Pensions, 112th Cong. (2012) (statement of Michael George, Director, Centennial School of Lehigh University).

⁶ LaVigna Gary, et.al., "The Efficacy of Positive Behavioral Support With the Most Challenging behavior: The Evidence and its Implications", *Journal of Intellectual and Developmental Disability*, (September 2012) 37(3), p. 185-195, available at <http://informahealthcare.com/doi/abs/10.3109/13668250.2012.696597>.

⁷ See Affidavit of Elin M. Howe (Massachusetts Commissioner of the Department of Developmental Services) ("Howe Affidavit"), appended as Attachment "E", at p. 3, para. 12 (Positive Behavioral Supports ("PBS") and closely related approaches are now the "overwhelmingly prevalent standard"); para. 13 (aversives are no longer accepted behavioral treatments for persons with developmental disabilities and specifically disallowed, banned or not permitted by public policy in many states); p. 20, para. 106 (evidence indicating use of GED promotes learned dependence which undermines ability to phase out GED use); and p. 21 para. 113 (2008 panel of expert psychologists convened by EOHHHS concluded aversive treatment for persons with disabilities was not the standard of care.)

the participants experienced greater independence, reduced supervision, and increased diversity in their living and work environments. The authors concluded that the study helped establish that positive adjustment can be sustained in the long-term without the continuation of restrictive treatment procedures.⁸ The FDA was thus correct to conclude that “the state of the art for the treatment of [self-injurious behavior] and [aggressive behavior] relies on multi-element positive methods, especially positive behavioral support. . . .”⁹

In addition to the evidence in the literature supporting positive alternatives to modifying behavior, numerous governmental entities and non-governmental organizations have issued statements or changed policies regarding the use of aversive behavioral interventions.

On April 12, 2012, the National Council on Disability (NCD)¹⁰ wrote to urge that the Department of Justice expedite an investigation of JRC and move forward with their findings.¹¹ NCD has long opposed aversive treatments. In its letter, NCD notes that as JRC accepts students from other states and the District of Columbia, NCD considers this to be a national issue. In the letter, NCD further quotes a 1995 report entitled “Improving the Implementation of the Individuals with Disabilities Education Act: Making Schools Work for All of America’s Children,” which addresses JRC’s efficacy claims, stating,

While it is possible to understand the desperation of these parents, to share their exasperation with ineffective programs and treatments, and to sympathize with them in their frustration to locate appropriate programs, there are limits to what society can permit in the name of treatment. There are those in our society who would advocate for severe physical punishment or even the mutilation of prisoners convicted of what everyone would agree are heinous crimes. Yet these prisoners are afforded protection under the law from this treatment, even though there are those who claim that such treatment would “teach them a lesson”. Students with severe behavioral disabilities are not criminals, and yet present law allows them to be subjected to procedures which cannot be used on the most hardened criminals, or in some cases, even on animals.¹²

In addition, the United Nations Special Rapporteur on Torture and other cruel, inhuman, or degrading treatment or punishment concluded that ESDs are not merely inappropriate and unacceptable treatment, but that use of these devices violates the rights of student at JRC

⁸ Bird, F.L. & Luiselli, J.K., “Positive Behavioral Support of Adults With Developmental Disabilities: Assessment of Long-Term Adjustment and Habilitation Following Restrictive Histories, 31 *Journal of Behavior Therapy and Experimental Psychiatry* 5 (2000).

⁹ 81 F.R. 24403 (April 25, 2016).

¹⁰ *National Council on Disability* (NCD) is an independent federal agency, statutorily created (29 U.S.C. 780 et seq.) and charged with advising the President, Congress, and other federal agencies regarding policies, programs, practices, and procedures that affect people with disabilities.

¹¹ See https://www.ncd.gov/rawmedia_repository/DOJ%20letter%20re%20%20JRC-1.pdf

¹² *Id.* citing to National Council on Disability, *Improving the Implementation of the Individuals with Disabilities Education Act: Making Schools Work for All of America’s Children* (1995), available at <http://www.ncd.gov/publications/1995/09051995>

under the Convention against Torture for which the United States is a party, as well as other international standards.¹³

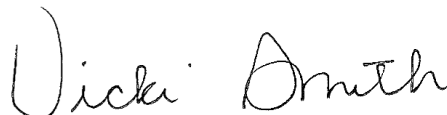
Lastly, as documented in DLC's prior testimony many of the states, including New York and Massachusetts with the most students at JRC, have taken action to shift away from the use of aversive interventions. In the fall of 2011, the Massachusetts Department of Developmental Services adopted new regulations restricting the use of the GED and other aversive-conditioning techniques employed at JRC.¹⁴ The Massachusetts regulations prevent the use of these devices on all entering residents, and only permit the GED to be used upon residents that were previously subjected to aversive treatment by court order. These regulations follow regulations adopted by New York State. Furthermore, a number of states have substantially limited or totally prohibited aversive interventions in schools and upon students. *See Bryant v. N.Y. State Educ. Dep't*, 692 F.3d 202, 212, fn. 4 (2nd Cir. 2012) (citing California, Pennsylvania, Montana, North Carolina, Nevada, Washington, Virginia, New Hampshire and the District of Columbia).

Students and individuals with disabilities deserve better. There is a significant risk to health and safety through use of aversive conditioning devices that use a noxious electrical stimulus. In addition, the literature and practice among professionals in the field, and government and non-governmental organizations supports this conclusion. There are more humane and effective alternatives, such as positive behavioral interventions and supports. Disability Rights NC thus fully supports the FDA ban on the use of ESD to attempt to reduce or eliminate severe behavioral issues. Please do not hesitate to contact me at 919-856-2195 or matthew.herr@disabilityrightsnc.org.

Respectfully,



Matthew Herr
Attorney, Policy Analyst



Vicki Smith
Executive Director

¹³ Juan E. Méndez, Report of the Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment, at 83 – 84. March 4, 2013. A/HRC/22/53/Add.4.

¹⁴ 115 CMR 5.14, available at <http://www.mass.gov/eohhs/docs/dmr/regs/reg-115cmr005.pdf>