July 25, 2016

Rebecca Nipper
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 66, Rm. 1540
Silver Spring, MD 20993–0002

Re: Comments on Proposed Rule to Ban Electrical Stimulation Devices Used to Treat Self-Injurious or Aggressive Behavior, Docket No. FDA–2016–N–1111

Dear Ms. Nipper:

The undersigned members and allies of the Consortium for Citizens with Disabilities (CCD) submit these comments in response to the FDA’s proposed rule to ban electrical stimulation devices used to treat self-injurious or aggressive behavior. CCD is a coalition of national disability organizations working for national public policy that ensures the self-determination, independence, empowerment, integration and inclusion of children and adults with disabilities in all aspects of society.

We strongly support the FDA’s proposed ban on these electrical stimulation devices (ESDs) used for aversive “treatment” purposes.\(^1\) We applaud the FDA for taking this critically important step, which we believe is long overdue. For too many decades, children with disabilities have been subjected to physical and psychological abuse through the use of these devices, and have experienced pain, trauma, suffering and long-term harms. Indeed, we are very concerned that the extended timeframe for submitting comments may further delay the issuance of a final regulation, and given the grievous harm that will continue until a ban is enacted, we urge you to

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\(^1\) As the FDA has explained, these devices administer electrical shocks through electrodes attached to the skin of individuals to attempt to condition them to stop engaging in self-injurious or aggressive behavior.
do everything in your power to ensure that a final rule is issued before this Administration comes to an end.

We agree with the FDA’s conclusions, based on its careful and thorough review of the scientific literature, expert opinions, and stakeholder input, that (1) there is a lack of evidence demonstrating that ESDs are effective in reducing self-injurious and aggressive behaviors on a long-term basis, (2) ESDs may even exacerbate or increase the targeted behaviors, (3) ESDs pose an unreasonable risk of significant physical and psychological harms, including depression, fear, escape and avoidance behaviors, panic, aggression, substitution of behaviors such as freezing and catatonic sit-down, pain, burns, tissue damage, and errant shocks from device misapplication or failure, and (4) effective alternatives exist—including positive behavioral approaches such as positive behavior supports that rely on a comprehensive functional behavior assessment to identify and address environmental and social triggers of the behaviors and teach the individual to replace those behaviors with others that do not cause harm. As the FDA states, “[t]he scientific community has long recognized that addressing the underlying causes of [self-injurious or aggressive behavior] rather than suppressing it with painful shocks, not only avoids the risks posed by ESDs, but can achieve durable, long-term benefits.”

We agree with the FDA’s observation that applying ESDs to “treat” self-injurious or aggressive behaviors also poses heightened concerns because the group of individuals with intellectual and developmental disabilities on whom ESDs are used for this purpose frequently have communication barriers that make it difficult to convey the pain and other harms that they are experiencing. In addition, as the FDA notes, the danger posed by these devices is compounded by the fact that providers administering the device may have difficulty distinguishing the negative effects of the device from the underlying symptoms of an individual’s disability.

The dangers of using these devices to address self-injurious or aggressive behaviors are even further heightened by the findings of state regulators that the Judge Rotenberg Center—the sole facility that continues to manufacture and use ESDs for this purpose—fails to adequately assess, monitor or address the collateral effects of their use on children with disabilities. As the FDA indicates, regulators have found that JRC does not appear to measure or treat collateral effects such as depression, anxiety, and/or social withdrawal, or symptoms associated with post-traumatic stress disorder. Massachusetts regulators concluded that staff failed to “monitor the residents in a manner that assured their health and safety.”

The FDA’s description of the Justice Department’s views of this use of ESDs is also important; as the FDA notes, the Justice Department must determine relevant standards of care in institutional settings as it enforces the Civil Rights of Institutionalized Persons Act (CRIPA). According to the FDA, the Justice Department has concluded that ESDs are outside of generally

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3 Id. at 24398.
4 Id.
accepted standards of care—which, for individuals with intensive behavior needs, require positive behavior supports implemented according to individualized plans—and are physically and psychologically harmful punishments with uncertain efficacy.\(^5\)

Further, 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 their use constitutes torture.\(^6\) As the FDA notes, this conclusion “suggests that there is great distance between these devices and state of the art for treatment of [self-injurious and aggressive behaviors].”\(^7\)

In light of the tremendous harm described above, we urge the FDA to apply the ban on ESDs not only to devices already in commercial distribution, devices already sold to the ultimate user, and devices sold or commercially distributed in the future, but also to the use of such devices in any future research.

For all of the reasons described above and documented by the FDA, we express our strong disagreement with one aspect of the proposed rule. The FDA states that “for certain individuals currently subject to ESDs, immediate cessation could possibly result in a significant increase of [self-injurious or aggressive behavior] before appropriate alternative therapies are in effect, and a more gradual reduction toward complete removal may be necessary for some patients, especially those who have been subject to ESDs for a considerable amount of time.” Accordingly, the FDA indicates that for a limited period of time, it will not enforce the ban with respect to ESDs “in appropriate circumstances” (such as when an individual “has a documented medical need for gradual transition to an alternative therapy, as determined by an independent psychiatrist, psychologist, or similar licensed behavioral expert”).

We do not believe that there are any appropriate circumstances for the use of a device that the FDA has determined to pose unreasonable risks of severe physical and psychological harm and to have uncertain efficacy, that the Justice Department considers far outside of generally accepted standards of care, and that the U.N. Special Rapporteur on Torture considers to constitute torture. The fact that children with disabilities have been subjected to torture by electric shocks for a prolonged period does not justify the continued use of such methods,\(^5\)

\(^5\) Id. at 24409.
\(^7\) Id.
particularly given the lack of evidence that they are effective. Children with disabilities deserve better.

Moreover, there is no reason why the implementation of positive behavior support cannot begin immediately for any person. Positive behavior support cannot be done simultaneously with the use of electric shocks. The continuation of electric shocks as punishment for targeted behaviors is entirely inconsistent with, and would actively undermine the effectiveness of, positive behavior support. In addition, the longer electric shocks are used, the more complex it will be for positive behavior support to undo the damage that has been done by such methods.

Accordingly, we urge the FDA to adopt its proposed ban and to enforce that ban immediately for all individuals subjected to ESDs for self-injurious or aggressive behaviors.

Thank you for the opportunity to comment on this important proposed rule.

Sincerely,

The Advocacy Institute
American Association of People with Disabilities
American Association on Health and Disability
American Association on Intellectual and Developmental Disabilities
American Foundation for the Blind
American Music Therapy Association
American Network of Community Options and Resources
American Occupational Therapy Association
Association of University Centers on Disabilities
The Arc of the United States
Association of Assistive Technology Act Programs
Autistic Self Advocacy Network
Bazelon Center for Mental Health Law
Brain Injury Association of America
Disability Rights Education and Defense Fund
Easterseals
Epilepsy Foundation
Lutheran Services in America Disability Network
Mental Health America
National Alliance on Mental Illness
National Association of State Directors of Developmental Disabilities Services
National Council on Independent Living
National Disability Rights Network
National Down Syndrome Congress
Parent to Parent USA

Allies of CCD:
Lakeshore Foundation
National Association for Rights Protection and Advocacy