

June 20, 2016

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: Docket Number FDA-2016-N-1111, Proposal to Ban Electrical Stimulation Devices Used to Treat Self-Injurious or Aggressive Behavior

Dear Food and Drug Administration,

The Autistic Self Advocacy Network (ASAN) submits the following comments on the Food and Drug Administration (FDA)'s Proposed Rule, "Banned Devices; Proposal to Ban Electrical Stimulation Devices Used to Treat Self-Injurious or Aggressive Behavior."¹ ASAN, a 501(c)(3), non-profit organization, is the nation's leading self-advocacy organization by and for autistic people ourselves. Our mission is to advance the social and civil rights of Autistic people and other individuals with disabilities.²

ASAN strongly supports FDA's proposed ban on the current and future use of electric skin shock devices (referred to in the Proposed Rule as "Electrical Stimulation Devices" (ESDs), particularly as a form of "treatment" for self-injurious behaviors (SIB) and aggressive behaviors (AB) in people with disabilities.³ ASAN has long maintained strong opposition to the use of electric skin shock.⁴ We agree with the FDA's findings that electric skin shock devices are not only ineffective at best at reducing SIBs and ABs, but also pose an

¹ Banned Devices; Proposed Rule to Ban Electrical Stimulation Devices Used to Treat Self-Injurious or Aggressive Behavior, 81 Fed. Reg. 24385, 24385-418 (proposed Apr. 25, 2016) (To be codified at 21 C.F.R. pts. 882, 895).

² For more information on ASAN, view our website at: <http://autisticadvocacy.org/>

³ Individuals who exhibit these behaviors include people with intellectual disabilities and/or developmental disabilities. People with psychiatric disabilities may also exhibit SIBs or ABs. ASAN's constituents, and most of its staff, fall into one or more of these categories. As a result, the proposed rule is of great importance to us.

⁴ For the purposes of this comment, we have elected to use the term "electric skin shock." We believe that this more fairly represents the true purpose of the devices, which are to inflict pain. We believe that this term also makes a clearer distinction between the devices covered by the NPRM and other therapies that use electricity for nerve stimulation, such as Electroconvulsive Therapy (ECT) or deep-brain stimulation devices, which are not covered by this NPRM.

unreasonable risk of significant physical and psychological harm. Considering nearly every health provider in the country has already rejected the use of these devices, banning them will not place a significant financial or regulatory burden on most behavioral health care providers or the administration.⁵

ASAN also reiterates the written testimony of Shain Neumeier, Esq., submitted on behalf of ASAN in advance of the FDA's hearing on electric skin shock devices in April 2014. That testimony is attached as Exhibit A. We also submit the following additional comments.

Electric skin shock devices present an unreasonable and substantial risk of injury that cannot be rectified by labeling.

The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes the FDA to ban any device intended for use on humans if it finds that the device presents "substantial deception" or "an unreasonable and substantial risk of illness or injury."⁶ When considering what kind of illness and injury is "substantial" and "unreasonable," the FDA examines how likely the device is to harm people (i.e. the likelihood of the device having "adverse effects") when compared with state-of-the-art treatment and research knowledge on the population affected and on any available alternative treatments.⁷ "Adverse effects," such as injuries caused by the device, can be physical or psychological in nature.⁸

As the FDA reports in its proposed rule, countless psychological and physical adverse effects have resulted from the use of ESDs. These include, but are not limited to, nightmares and traumatic revisiting of memories of ESD use; a pseudo-catatonic freezing up of the body or inability to engage in any kind of behavior; tissue damage or burns on the skin; and heightened risk of multiple psychiatric disabilities including depression, anxiety, and posttraumatic stress disorder (PTSD). The shocks may even lead to death if they are used frequently. Investigations of several deaths at the only facility known to use the devices, the Judge Rotenberg Center (JRC), uncovered evidence suggesting that a combination of the use of aversives and abusive treatment led to the deaths.⁹

⁵ See 81 Fed. Reg. 24385 at 24413 (describing economic impact of proposed rule).

⁶ Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C.S. § 360f.

⁷ 81 Fed. Reg. at 24388.

⁸ *Id.*

⁹ Gonnerman, Jennifer. "The School of Shock." Mother Jones. 20 Aug. 2007. Web. 10 Jun. 2014, available at <http://www.motherjones.com/politics/2007/08/school-shock>.

ASAN itself has heard reports from many people with developmental disabilities who have had an ESD used on them.¹⁰ Their stories are chilling. The survivors report that the devices cause severe pain, akin to torture. After repeated exposure to shocks, the survivors became anxious, depressed, and fearful. Many have developed symptoms of post-traumatic stress disorder. The United Nations Special Rapporteur on Torture specifically condemned the current use of electric skin shocks at the only facility at which they are still in use as violating the Convention Against Torture.¹¹

These adverse effects alone would constitute an unreasonable and substantial risk of injury even when the device is used as intended. Nevertheless, there is also ample evidence that these devices are frequently used as a form of punishment - contrary to proponents' claims that the devices are used solely to reduce self-injury and aggressive behavior. In one example captured on videotape, one student was shocked over 30 times in seven hours by the device while restrained. He was initially shocked merely for saying "No" and refusing to take off his jacket, and then received additional shocks for "tensing" his muscles in anticipation of pain.¹² Another student who has spoken about their experience reports being shocked repeatedly for a wide variety of harmless behaviors.¹³ The only facility in which these devices are used has thus for decades continued to administer skin shocks in response to minor disciplinary infractions, despite numerous government investigations, reports of misuse by students, former employees, and reporters who have visited the facility, and repeated promises by the facility to implement heightened safeguards against misuse. As a result, we must conclude that these devices inherently carry a high risk of use beyond their intended purpose.

These facts, and those presented in the FDA's report, support the FDA's finding that the devices pose a substantial and unreasonable risk of harm.

¹⁰An excellent resource that collects such reports, among other information on the facility that uses ESDs, is Autistic Hoya's Judge Rotenberg Center Living Archive, available at: <https://autistichoya.net/judge-rotenberg-center/>

¹¹ The United States has ratified the UN Convention Against Torture, with several reservations that do not apply here. United Nations Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, Jun. 26, 1987, 1465 U.N.T.S. 85 (ratified by the United States Oct. 21, 1994), available at http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session22/A.HRC.22.53.Add.4_Advance_version.pdf.

¹² To view ASAN's coverage of this event and the subsequent malpractice lawsuit, start at this article: <http://autisticadvocacy.org/2012/04/the-judge-rotenberg-center-on-trial-part-one/>

¹³ <https://autistichoya.net/2016/04/26/jennifer-msumbas-jrc-behavior-sheet/>

The FDA correctly concluded that there are effective, positive behavioral interventions available for use that reduce self-injuring and aggressive behaviors. Electric skin shock devices are not necessary or effective in treating these behaviors.

When the FDA determines whether or not it should ban a device, it weighs the benefits the public might gain from the device's continued use against the likelihood that the device will harm individuals as currently used.¹⁴ In order to determine whether the risks outweigh the benefits, the FDA compares the risks and benefits posed by the device with the risks and benefits posed by state-of-the-art alternative treatments for the same disease or symptoms.¹⁵ The FDA found that the state of the art in approaches to SIBs and ABs has moved away from the use of aversives like electric skin shock and toward the use of positive behavioral support and, where appropriate, medication or other pharmacological interventions.¹⁶

Positive behavioral supports encompass a wide range of approaches, some more effective than others. Effective positive behavioral supports focus on the causes or triggers of SIBs and ABs.¹⁷ These may include lack of appropriate communication supports, pain or sensory stressors, or emotional concerns. A strong body of research literature shows that these supports are more effective than approaches that use aversives.¹⁸ As the FDA notes in its comments on functional communication training, the most effective interventions consider the perspective of the person with a disability and emphasize the development of communication skills and cognitive strategies that allow people with disabilities to address and express their needs.¹⁹ There is simply no need for painful aversives that cause needless pain and suffering to children with disabilities when effective positive interventions are available.

The FDA should move promptly to enforce its ban.

Although we support the FDA's decision to ban electric skin shock devices, we are troubled by the FDA's announcement that it would defer enforcement of this ban for a "limited period of time" while individuals "transition" to alternative interventions. The only facility that uses these devices, the JRC, has an extensive history of using litigation to obstruct efforts to protect its residents from electric skin shocks. Based on this history, there is every reason to believe that JRC will attempt to delay indefinitely any "transition" to alternative

¹⁴ 81 Fed. Reg. at 24388.

¹⁵ *Id.*

¹⁶ *Id.* at 24403.

¹⁷ *Id.* at 24404-405.

¹⁸ For more information, see Testimony of Shain Neumeier on behalf of ASAN at Appendix A.

¹⁹ 81 Fed. Reg. at 24404.

interventions. In addition, allowing a period of transition is inconsistent with the FDA's well-justified finding that these devices present an unreasonable and substantial risk of harm. It is especially troubling that the FDA proposes to defer enforcement of the ban with respect to children and adults who have been subjected to them over a long period of time. These individuals have already suffered great harm. One more day would be one too many.

JRC has already had ample time to investigate and develop alternative approaches for those who are currently subjected to electric skin shocks. It is already more than two years since the Neurological Devices Panel of the Medical Devices Advisory Committee of the FDA recommended a ban on electric skin shock devices. Moreover, any enforcement action will in itself take time and may incorporate warning letters or other measures that provide a specific time frame in which to comply with the ban.

ASAN applauds the Food and Drug Administration's thorough investigation and its move to ban electric skin shock devices. We fully support the FDA's decision to prevent their current and future use. For more information on our comments please contact Samantha Crane, Director of Legal and Public Policy at ASAN, at scrane@autisticadvocacy.org. More information is also available via our website at <http://autisticadvocacy.org/tag/aversives-and-judge-rotenberg-center/>.

Sincerely,

A handwritten signature in black ink, appearing to read 'Samantha Crane', written in a cursive style.

Samantha Crane
Director of Legal and Public Policy, Autistic Self Advocacy Network