AUTISTIC SELF ADVOCACY NETWORK

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 No. FDA–2023–N–3902 for "Banned Devices; Proposal to Ban Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior."

Dear Food and Drug Administration,

The Autistic Self Advocacy Network (ASAN) is grateful for this opportunity to provide comment on the proposed rule from Food and Drug Administration (FDA), "Banned Devices; Proposal to Ban Electrical Stimulation Devices Used to Treat Self-Injurious or Aggressive Behavior."[1]

ASAN is a national, autistic-led disability rights organization that serves autistic adults. We advocate for policies that support the needs of autistic individuals, including access to health care and support services that meet our needs, and to ensure that public policymaking includes the voices and addresses the needs of autistic individuals. Since its founding, ASAN has been a prominent advocate for the rights of autistic individuals to receive services free of restraint, seclusion, and coercive practices, particularly those that rely on pain and other forms of abuse to affect behavioral compliance.

ASAN strongly supports the proposed rule to ban the use of Electronic Stimulation Devices (ESDs) for self-injurious behavior (SIB) and aggressive behavior (AB). ASAN has long advocated for ending the use of painful, harmful electric skin shocks as a form of aversive for behavioral conditioning, and provided comment on the FDA's prior rulemaking banning these devices in 2016.[2] In addition to the unreasonable risks of physical and psychological harm identified by the FDA, we note that the use of these devices remains a fringe practice within the field of behavioral intervention, being widely condemned by professional organizations including the American Academy of Pediatrics, the American Academy of Developmental Medicine and

[1] Banned Devices; Proposal To Ban Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior, 89 Fed Reg 20882, 20882-20897 (proposed Mar 26, 2024) (to be codified at 21 CFR 882 & 21 CFR 895

[2] Reproduced at https://autisticadvocacy.org/2016/06/asan-comments-on-fdas-proposed-ban-of-electric-shock-devices/

Dentistry, the American Association on Intellectual and Developmental Disabilities, the International Association for the Scientific Study of Intellectual and Developmental Disabilities, the National Association for the Dually Diagnosed, the National Association of State Directors of Developmental Disabilities Services, and the National Association of State Directors of Special Education.[3] As the FDA notes these devices are used by only one facility in the United States, which is also the sole facility that manufactures these devices, which were designed and developed by its founder, Matthew Israel.[4]

ASAN has long maintained vehement opposition to the use of electric skin shock. The use of electric skin shock as a pain compliance method of behavioral control has been rightly condemned by professional and civil rights organizations nationwide, including the American Academy of Developmental Medicine and Dentistry, American Association on Intellectual and Developmental Disabilities, American Association on Health and Disability, American Civil Liberties Union, American Occupational Therapy Association, the Arc of the United States, Association of University Centers on Disabilities, Autism Society of America, NAACP, National Alliance for Direct Support Professionals, National Alliance on Mental Illness, National Association of Councils on Developmental Disabilities, National Association of State Directors for Developmental Disabilities Services, National Association of State Directors of Special Education, National Association of the Deaf, National Council on Independent Living, National Disability Rights Network, National LGBTQ Task Force, and many others.[5] We have previously provided comments in support of the ban on these devices, including comments to the Notice of Proposed Rulemaking issued by the FDA in 2016, which we reiterate here, as well as 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, and attached as an exhibit with our prior comments.[6]

We agree with the FDA's findings that electric skin shock devices are not only ineffective at reducing SIBs and ABs but also pose an unreasonable risk of significant physical and psychological harm. It is precisely because of these harms that virtually every health provider in the nation rejects their use, which is practiced only by a single institution, the Judge Rotenberg Center (JRC) in Canton, Massachusetts. We agree with the FDA's finding that no evidence produced since the

[3] No. 20-1087 JRC v FDA, Brief of Amici Curiae (Jan. 22, 2021), https://www.iassidd.org/wp-content/uploads/2021/02/As-filed-Amicus-Brief.pdf
[4] Nisbet, J., & Weiss, N. R. (2021). Pain and shock in America: Politics, advocacy, and the controversial treatment of people with disabilities. Brandeis University Press
[5] Banned Devices; Proposal To Ban Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior, 81 FR 24386 (proposed April 25, 2016).
[6] *Id.*

finalization of the previous rule banning the use of electric shock devices warrants any substantial revision of the FDA's prior analysis.

The FDA correctly ascertains that 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."[7] This act was further amended in the Consolidated Appropriations Act of 2023 to clarify that this FDA authority extends to banning a device for a particular use.[8]

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.[9] In its proposed rule, the FDA also gives additional consideration to the fact that the behaviors these devices are used to target occur with disproportionately high frequency in people with intellectual and developmental disabilities (IDD). The FDA notes that individuals with IDD often have difficulty communicating and may not be able to make their own treatment decisions, including providing or withdrawing assent or consent, and on this basis identifies these individuals as a "vulnerable population."[10]

"Adverse effects," such as injuries caused by the device, can be physical or psychological in nature.[11] As the FDA notes, pain — in and of itself — is an adverse effect, and one that can cause additional psychological and physical harm. The fact that these devices are intended to deliver noxious stimuli does not provide a basis for discounting the physical and psychological harms associated with pain from these devices. As the FDA reported in its proposed rule, there is ample evidence based on research literature, expert and survivor testimony, and even the JRC's own operational manuals of a wide range of physical and psychological adverse effects associated with ESD use.[12] These include depression, post-traumatic stress disorder (PTSD), anxiety, fear, panic, substitution of other negative behaviors, worsening of

[7] Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C.S. § 360f
[8] Consolidated Appropriations Act of 2023, Pub. L. No. 117–328 § 3306 (2022), "Bans on Devices For One or More Intended Uses". https://www.congress.gov/117/plaws/publ328/PLAW-117publ328.pdf
[9] 81 Fed. Reg. at 24388
[10] 89 Fed Reg at 20891
[11] 81 Fed. Reg. at 24388
[12] 89 Fed Reg at 20888

underlying symptoms, and learned helplessness.[13]

As reported in the 2016 rule, advisory panelists noted that the manner in which shocks are delivered – "producing pain in people who have no control over the pain" – constitutes "a perfect paradigm" for producing learned helplessness. Learned helplessness is a behavior pattern associated with the development of depression and post-traumatic stress which arises when individuals are subjected to an aversive they can exercise no control over.[14] The same behavior is also observed in torture victims.[15] Individuals with IDD are at even greater risk of experiencing these harms due to the fact that they have little control over the use of the device, including limited means to communicate assent, little to no means to withdraw consent, and, based on survivor reports, are likely to experience additional shocks for speech or behavior that communicate distress, defensiveness or lack of consent. Survivors report receiving shocks for attempting to remove the device, for standing up, and for saying "no."[16] 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.[17]

ASAN has heard reports from many people with intellectual and developmental disabilities who have had an ESD used on them, and their stories remain 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 JRC as violating the Convention Against Torture.[18]

These adverse effects alone would constitute an unreasonable and substantial risk of injury even when the device is used as intended. However, there is also ample evidence that these devices are frequently used as a form of punishment – contrary to JRC claims that the devices are used solely on a "last resort" basis to reduce self-

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[13] *Id.*
[14] Seligman, M. E. P., & Maier, S. F. (1967). Failure to escape traumatic shock. Journal of Experimental Psychology, 74(1), 1–9. https://doi.org/10.1037/h0024514
[15] Putnam, F. W. (2013). The Role of Abusive States of Being in Interrogation. Journal of Trauma & Dissociation, 14(2), 147–158. doi:10.1080/15299732.2013.724344
[16] Neumeir, S. (2012, April 16). The Judge Rotenberg Center on Trial, Part One https://autisticadvocacy.org/2012/04/the-judge-rotenberg-center-on-trial-part-one/ (retrieved 5/16/2024)
[17] *Id.*
[18] Mendez, J. (2013) *Report of the Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment.* United Nations. https://www.ohchr.org/sites/default/files/Documents/HRBodies/HRCouncil/RegularSession/Session22/A-HRC-22-53-Add4_EFS.pdf (page 84)

injury and aggressive behavior.[19] In our above example, the individual discussed was shocked for behavioral noncompliance that did not constitute aggression or self-injury. Other survivors also describe their experiences of being shocked for a wide range of harmless behaviors.[20] Furthermore, the fact that individuals have received shock for protective or avoidance behaviors such as "tensing up" or attempting to remove the device underscores the fact that there are limited means for individuals subjected to this device to communicate distress or adverse effects. It also underscores the fact that – by being for communicating of distress – individuals on this device are being subjected to intense physical and psychological abuse through the use of this device.

The sole facility to use these devices has 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.

In addition, the FDA, its advisory panel, and many others have noted the severe risk of underreported adverse events from the use of these devices. In the current rule, the FDA discusses many of the sources of this underreport, among them being limited ability of those subjected to the device to communicate distress or other adverse effects, failure of practitioners to systematically monitor and report adverse effects, attribution of any adverse effects to the recipients' disabilities rather than the device, and provider bias in identifying whether an adverse effect was present. As the FDA notes, the confluence of these factors significantly limits much of the literature published by the JRC and affiliated researchers, which seldom reported or indicated monitoring for adverse effects. In the one JRC study that did identify adverse effects – a retrospective chart review – these were identified on a nonsystematic, anecdotal basis only. A lack of clear, systematic documentation of adverse effects from the sole facility employing these devices is a clear indicator that these adverse effects are severely underreported. As a result, we must conclude that these devices inherently carry a high risk of use beyond their intended purpose and a high risk of adverse effects even beyond the already substantial risks suggested in the available evidence. These facts, and those presented both in this Notice and in the FDA's 2020 rulemaking, support the FDA's finding that the devices continue to pose a substantial and unreasonable risk of harm.

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[19] 89 Fed Reg at 20892

[20] Jennifer Msumba's JRC behavior sheet (2016 April 2016) Jennifer Msumba's JRC behavior sheet https://autistichoya.net/2016/04/26/jennifer-msumbas-jrc-behavior-sheet/ (retrieved 5/16/2024). Additional information on the JRC may be found at Lydia X.Z. Brown's archival website, https://autistichoya.net/judge-rotenberg-center/

The FDA correctly concluded that effective, positive behavioral interventions are available to 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.[21] 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.[22]

Notably, this determination is based on the FDA's evaluation of the risks and benefits of this device compared to the risks and benefits of compared to alternative treatments used in current medical practice, not the substantially distinct question of whether ESDs themselves are conclusively proven to fall outside of the existing standard of care under current medical consensus. As such, the FDA correctly notes that Massachusetts state litigation from 2018 and 2023 – which argued on a far narrower question of whether a judge had abused their discretion in a 2016 ruling upholding a consent decree – is entirely irrelevant to the FDA's determination here, and should carry no bearing on the FDA's determination regarding this device's safety.[23]

The FDA found that the state of the art in addressing SIBs and ABs has for decades moved away from the use of aversives like electronic skin shock and toward the use of positive behavioral support and, where appropriate, medication or other pharmacological interventions. It noted many reasons for this. First and utmost among these are the ethical and humane considerations of applying painful aversives to vulnerable individuals who are unable to provide or withdraw consent. In addition, both the FDA in its proposed rule and many professional organizations focused on behavioral intervention note that the evidence supporting the use of electronic skin shocks is weak- shocking someone for noncompliance does not teach skills or coping mechanisms, does not help someone address underlying triggers or sources of behavior, and does not provide individuals with alternative means to communicate. In fact, as the FDA noted in its 2020 rule, among the many adverse effects that can be caused by ESDs are increases in the supposedly targeted behaviors due to psychological trauma.[24] As such, it is no surprise that the FDA found evidence that many individuals under this device remain so indefinitely, with no improvement in targeted behaviors. These are not individuals who are "uniquely

[21] 81 Fed. Reg. at 24388.

[22] *Id.*

[23] *Id.*

[24] Banned Devices; Proposal To Ban Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior 85 Fed. Reg 13328 (March 6, 2020)

refractory" – whose behaviors persist despite intervention – these are the signs of a treatment that is not only ineffective but harmful.

The FDA correctly notes that the state-of-the-art in behavior intervention primarily includes positive behavioral supports. These 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.[25] These may include a 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.[26] As the FDA notes in its comments, 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.[27]

There is simply no need for harmful shocks that cause needless pain and suffering to individuals with disabilities when effective positive interventions are available.

The FDA should move promptly to enforce its ban.

Although we strongly support the FDA's decision to ban electric skin shock devices, we continue to be troubled by the FDA's proposal to defer enforcement of this ban for 180 days for individuals currently on this device to "transition" to alternative interventions. As we have stated previously, the JRC – the only facility in the US that uses these devices – 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 take advantage of any transition period not to provide behavior assessment and transition of care for individuals receiving these harmful shocks but to impose further delays or obstruction to enforcement.

The intervening history since the last time we provided this feedback has been instructive as to these facts. While the JRC has challenged this rulemaking in federal court, it has done little, if anything, to provide residents with comprehensive behavior supports, including assessment, which would facilitate transition away from these devices. In addition, allowing a lengthy period for 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 those who have been subjected to them over a long period of time. These individuals have already suffered great harm. Each day that these individuals remain on these devices is

[25] 81 Fed Reg. at 24404-405.
[26] For more information, see Testimony of Shain Neumeier on behalf of ASAN at Appendix A of our 2016 comments, 81 FR 24386
[27] 81 Fed. Reg. at 24404.

another day they will continue to experience these harms. The FDA must ensure this ban is implemented with urgency. It should not permit any avoidable delay.

JRC has already had ample time to investigate and develop alternative approaches for those who are currently subjected to electric skin shocks. It has already been over a decade since the Neurological Devices Panel of the Medical Devices Advisory Committee of the FDA recommended a ban on electric skin shock devices. Further, we anticipate that any enforcement actions undertaken by the FDA would be accompanied by additional warnings and opportunities for the few providers using these devices to come into compliance with this ban. While we recognize a need to ensure the safe transition of individuals to safe and effective alternatives, no disabled person should be subjected to this torture any longer because of the JRC's intransigence.

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 Gregory Robinson, Deputy Director of Public Policy at ASAN, at grobinson@autisticadvocacy.org. More information is also available via our website at https://autisticadvocacy.org/tag/aversives-and-judge-rotenberg-center/.