

# Written Comment to the Food and Drug Administration on the Proposed Ban of Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior

The Autistic People of Color Fund  
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## I. Introduction

The Autistic People of Color Fund<sup>1</sup> supports the FDA’s proposed rule banning the use of electrical stimulation devices (ESDs) for self-injurious (SIB) or aggressive behavior (AB).<sup>2</sup> According to the procedures for banning a device, the FDA has the authority to ban a medical device if it presents “an unreasonable and substantial risk of illness or injury.”<sup>3</sup> ESDs such as the graduated electronic decelerator (GED), which the Judge Rotenberg Center (JRC) created and regularly uses<sup>4</sup>, meet this criteria. ESDs present a substantial risk of illness, injury, and even death.<sup>5</sup> The Autistic People of Color Fund strongly urges the FDA to reinstate its final rule as drafted in 2020 banning these devices in the treatment of SIB and AB, which is the only available means of protecting vulnerable people at the JRC and any other similar institution from torture in the name of treatment.<sup>6</sup>

Previously, the D.C. Circuit Court of Appeals overturned the FDA’s 2020 final rule banning electrical stimulation devices for self-injurious or aggressive behavior, finding that the agency’s enabling statute at that time did not allow the FDA to ban specific uses of a device.<sup>7</sup>

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<sup>1</sup> The Autistic People of Color Fund (The Fund) is a national nonprofit organization dedicated to advancing disability, racial, and economic justice for all autistic people of color and other disabled people in Black, Brown, Asian, Latine, and Native/Indigenous communities. Our work focuses on providing direct economic support to autistic people of color through microgrants and advancing systemic change to challenge structural ableism and racism while improving social, cultural, political, and economic conditions. One hundred percent of The Fund’s leadership, community partners, and staff are people with disabilities, and all of The Fund’s leaders are autistic people of color. Since our founding in 2018, we have supported hundreds of autistic people of color and their families, and we often serve as a front-line resource and referral source for many disabled people and families who are unable to find culturally responsive information and support for their most pressing needs. We also provide technical expertise on autism and related developmental disabilities, with a focus on intersections of disability with race, ethnicity, culture, and language.

<sup>2</sup> Banned Devices; Proposal to Ban Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior, 89 Fed. Reg. 20882 (proposed Mar. 26, 2024) (to be codified at 21 C.F.R. pts. 882 & 895) [Docket No. FDA-2023-N-3902].

<sup>3</sup> 21 C.F.R. § 895.21(a).

<sup>4</sup> Cynthia McFadden, Kevin Monahan & Adiel Kaplan, *A Decades-Long Fight Over an Electric Shock Treatment Led to an FDA Ban. But the Fight is Far from Over.*, NBC NEWS (Apr. 28, 2021, 7:55 AM), <https://www.nbcnews.com/health/health-care/decades-long-fight-over-electric-shock-treatment-led-fda-ban-n1265546>.

<sup>5</sup> See Cascades Islwyn, *The Judge Rotenberg Center: An Environment of Torture*, BEARING WITNESS, DEMANDING FREEDOM: JUDGE ROTENBERG CENTER LIVING ARCHIVE (2015), <https://autistichoya.net/judge-rotenberg-center/> (reporting that at least six students have died from JRC abuse and negligence since it opened).

<sup>6</sup> See Juan E. Mendez (Special Rapporteur), Rep. of the Human Rights Council, at 84-85, U.N. Doc. A/HRC/22/53/Add.4 (2013) (stating that electric shock behavioral modification therapy violates the United Nations Convention Against Torture).

<sup>7</sup> *The Judge Rotenberg Educ. Ctr., Inc. v. United States Food & Drug Admin.*, 3 F.4th 390 (D.C. Cir. 2021) (ruling that the FDA can either ban a device altogether or not ban it at all, as the FDA’s final rule would have

Congress then amended the enabling act with the Food and Drug Omnibus Reform Act of 2022 (FDORA), which “authorizes the FDA to ban specific intended uses of a medical device if that use presents an unreasonable or substantial injury risk.”<sup>8</sup> With this clarification, the FDA is no longer bound by the federal appeals court decision in favor of the JRC and should issue a final rule banning ESDs used for self-injurious and aggressive behavior by people with disabilities.<sup>9</sup>

## II. Factual Background

Only one treatment facility in the United States, the Judge Rotenberg Educational Center (JRC) located in Canton, Massachusetts, is known to use ESDs to allegedly treat self-injurious or aggressive behavior.<sup>10</sup> The JRC is a residential institution for children, youth, and adults with intellectual and developmental disabilities, mental health disabilities, and learning disabilities.<sup>11</sup> Many autistic people live in one of the JRC’s group homes<sup>12</sup>, and the majority of the population is non-white.<sup>13</sup> Black people and people of African descent comprise 45.3% of the student population, and Latine people comprise 28.1% of JRC students.<sup>14</sup> In comparison, at the time the JRC survey was conducted, only 26.5% of Massachusetts residents identified as people of color, which includes all non-white racial and ethnic categories.<sup>15</sup> While a specific racial/ethnic disaggregation is not available for the sub-population currently receiving shocks from ESDs, this publicly available information demonstrates that people with disabilities at the JRC are disproportionately from communities of color.<sup>16</sup>

The JRC is also the sole manufacturer of an ESD called a graduated electronic decelerator (GED).<sup>17</sup> JRC staff members attach GEDs to the more than fifty people they treat for so-called behavioral problems, and can shock them at will.<sup>18</sup> Many affected people wear the GED in a backpack with protruding electrodes taped to their bodies for twenty-four hours a day for most of the time they reside at the JRC.<sup>19</sup> Staff members have issued shocks to punish people with disabilities for ordinary and non-injurious behaviors such as standing, swearing, flapping their hands, making noises, reacting to being shocked, failing to follow orders, not answering quickly enough, interrupting others, asking to use the bathroom, and many other alleged offenses.<sup>20</sup> The JRC derives its treatment methodology from behaviorist B.F. Skinner’s psychological experiments with shocking rats, which established the operant conditioning theory

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permitted use of ESDs for smoking cessation while prohibiting their use for self-injurious and aggressive behavior by people with developmental disabilities)

<sup>8</sup> Consolidated Appropriations Act, Pub. L. No. 117-328 § 3306 (2022).

<sup>9</sup> *See id.*

<sup>10</sup> #StopTheShock, AUTISTIC SELF ADVOCACY NETWORK, <https://autisticadvocacy.org/stoptheshock/> (last visited May 24, 2024).

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> Islwyn, *supra* note 4 (reporting that only 21.1% of JRC students were white as of 2015; statistics reflect only the school-age population and not the total population).

<sup>14</sup> *Id.* (noting that statistics are accurate as of 2015).

<sup>15</sup> *Massachusetts Population by Race/Ethnicity*, Mass. Dep’t of Pub. Health, <https://www.mass.gov/info-details/massachusetts-population-by-raceethnicity> (last visited May 24, 2024).

<sup>16</sup> *See* Islwyn, *supra* note 4.

<sup>17</sup> *Id.*; McFadden, *supra* note 3.

<sup>18</sup> *See* McFadden, *supra* note 3.

<sup>19</sup> *See id.*

<sup>20</sup> Islwyn, *supra* note 4; #StopTheShock, *supra* note 9.

of behavioral modification – that treatment subjects can be taught to associate targeted behaviors with positive stimuli as incentives and aversive stimuli as disincentives.<sup>21</sup> However, unlike weak jolts to non-human animals<sup>22</sup>, the JRC uses two ESDs that deliver a shock which can be more than ten times stronger than a stun belt.<sup>23</sup> The original GED delivers a 15.5 milliamp shock for up to two seconds, and the GED-4 (the current iteration of the device in use) delivers a 45.5 milliamp shock to those whom the JRC’s treatment team has determined are less responsive to the lower voltage.<sup>24</sup> Additionally, the JRC does not seek meaningful consent for many people for use of the device, as many of those subjected to the GED are non-speaking and do not have access to reliable and accessible communication methods.<sup>25</sup> Even for people whose disability does not affect their communication, however, JRC does not seek their informed consent before subjecting them to the GED; rather JRC relies on the doctrine of substituted judgment to receive consent from a nondisabled petitioner (often a family member, a clinician, or a court-appointed guardian).<sup>26</sup>

### **III. The use of electrical stimulation devices for self-injurious or aggressive behavior presents an unreasonable and substantial risk of injury because there are effective and humane alternatives for behavioral modification.**

The FDORA clearly authorizes the FDA to ban medical devices both altogether and for specific intended uses such as behavioral modification, as long as it can show an unreasonable or substantial risk of injury.<sup>27</sup> The JRC is the only treatment facility in the country that uses ESDs for this purpose, and no other professional or scholarly association focused on research and practice for people with intellectual, developmental, or psychosocial disabilities condones their use; continued use of ESDs is unreasonable under all contemporary standards of care.<sup>28</sup> All other treatment providers are able to manage self-injurious and aggressive behaviors using humane treatment methods.<sup>29</sup>

The risk of injury from ESDs is also substantial. The JRC deliberately manufactured its GED to emit extremely painful shocks in order to fulfill its intended purpose as an operant conditioning device<sup>30</sup>, and many former residents have come forward with graphic stories demonstrating its long-lasting, severe ill effects.<sup>31</sup> Two prior United Nations Special Rapporteurs on Torture have stated that the JRC’s use of this device violates the United Nations

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<sup>21</sup> See Saul Mcleod, *Operant Conditioning: What it is, How it Works, and Examples*, SIMPLYPSYCHOLOGY (Feb. 2, 2024), <https://www.simplypsychology.org/operant-conditioning.html>.

<sup>22</sup> See *id.*

<sup>23</sup> See Islwyn, *supra* note 4 (referencing that stun belts deliver shocks which can range from three to four milliamps).

<sup>24</sup> See *id.*

<sup>25</sup> Proposal to Ban Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior, 89 Fed. Reg. at 20893-94 (contrasting it with ESDs intended for other purposes such as smoking cessation, in which the patient can give informed consent to treatment).

<sup>26</sup> *Id.* at 20894.

<sup>27</sup> Pub. L. No. 117-328 § 3306.

<sup>28</sup> See #StopTheShock, *supra* note 9.

<sup>29</sup> *Id.*

<sup>30</sup> See *AWN Condemns Court Ruling Upholding Use of Electric Shock Torture*, AUTISTIC WOMEN & NONBINARY NETWORK (July 7, 2021), <https://awnnetwork.org/awn-condemns-court-ruling-upholding-use-of-electric-shock-torture/>.

<sup>31</sup> See, e.g., McFadden, *supra* note 3.

Convention Against Torture and other international human rights and humanitarian law.<sup>32</sup> As such, the risk of harm outweighs any possible health benefit and the FDA should ban ESDs for this purpose.

Nationally, treating clinicians and disability services providers routinely respond to people with disabilities presenting with the same self-injurious and aggressive behaviors without subjecting them to painful electric shocks.<sup>33</sup> For example, dialectical behavior therapy, cognitive behavioral therapies, positive noncontingent behavioral reinforcement, and functional communication training can effectively treat many people with self-injurious and disruptive behavior – especially when treatment providers conduct a functional behavioral assessment.<sup>34</sup> The established clinical literature also focuses on addressing environmental triggers and other root causes of self-injurious and aggressive behaviors, rather than responding to such behavior solely with behaviorist operant conditioning tactics. Even when schools and facilities punish students, they are able to do so effectively without inflicting pain.<sup>35</sup> In contrast, corporal punishment such as using GEDs is an outdated approach that psychologists do not recommend.<sup>36</sup> Because of the reasonable alternatives available that science has shown to be as effective, if not more so, as treatment with ESD for behavioral problems, the use of ESDs for this purpose is unreasonable.

#### **IV. The use of electrical stimulation devices for self-injurious or aggressive behavior presents an unreasonable and substantial risk of injury because such devices have caused demonstrable and severe harm to many people.**

Using ESDs for treatment of SIB and AB also presents an unreasonable and substantial risk of injury that is not outweighed by any public health benefit. As a particularly powerful and painful device, the GED is particularly likely to cause injuries.<sup>37</sup> The GED's creator (and founder of the JRC), Matthew Israel, expressed pride in creating a powerful device with a strong electrical current.<sup>38</sup> Israel was forced to resign from his position at the JRC when he was indicted for obstructing justice by destroying surveillance videos depicting staff shocking a group home resident seventy-seven times in a single night in response to a prank call from a

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<sup>32</sup> Mendez, *supra* note 5.

<sup>33</sup> See #StopTheShock, *supra* note 9.

<sup>34</sup> Andrea Gottlieb, *How Dialectical Behavior Therapy Treats Self Harm*, SHEPPARD PRATT (Mar. 25, 2020), <https://www.sheppardpratt.org/news-views/story/how-dialectical-behavior-therapy-treats-self-harm/>; Gary Shkedy, Dalia Shkedy, & Aileen H. Sandoval-Norton, *Treating self-injurious behaviors in autism spectrum disorder*, 6.1 COGENT PSYCHOLOGY (2019), <https://doi.org/10.1080/23311908.2019.1682766>; Asit Biswas, Rohit Gumber, & Frederick Furniss, Management of self-injurious behaviour, reducing restrictive interventions and predictors of positive outcome in intellectual disability and/or autism, 29 BJPSYCH ADVANCES 337-341 (2023), <https://doi.org/10.1192/bja.2022.49>.

<sup>35</sup> Proposal to Ban Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior, 89 Fed. Reg. at 20892.

<sup>36</sup> See, e.g., *id.*; Elizabeth Gershoff & Robert Larzelere, *Is Corporal Punishment an Effective Means of Discipline?*, AM. PSYCH. ASS'N (2002), <https://www.apa.org/news/press/releases/2002/06/spanking#:~:text=There%20is%20general%20consensus%20that,physical%20maltreatment%2C%22%20Gershoff%20writes.>

<sup>37</sup> See, e.g., McFadden, *supra* note 3.

<sup>38</sup> See *id.*

former JRC resident.<sup>39</sup> JRC staff shocked another student, Andre McCollins, thirty-one times over seven hours on a four-point restraint board for refusing to remove his jacket, screaming in fear and pain, and tensing in anticipation of further shocks – none of which were forms of self-injury or aggression.<sup>40</sup> The eighteen-year-old Black autistic youth suffered severe abrasions, catatonia, brain damage, and post-traumatic stress disorder afterward, never fully recovering.<sup>41</sup> McCollins and his mother subsequently sued the JRC, resulting in public viewing of the effects of the GED for the first time in video footage played in open court.<sup>42</sup>

Several other survivors of electric shocks at the JRC have come forward, including Antwone Nicholson, Rico Torres, and Jennifer Msumba.<sup>43</sup> All three survivors, who are disabled people of color, experienced substantial physical harm and psychological trauma from electric shock behavioral modification treatment at the JRC.<sup>44</sup> Nicholson sued the JRC for medical negligence, although his case was ultimately dismissed.<sup>45</sup> Torres wore the GED from the time he was eight until he was eighteen.<sup>46</sup> One JRC employee subjected Torres to GED shocks in his sleep.<sup>47</sup> Msumba testified at the FDA’s 2014 advisory panel hearing exploring whether the neurological devices panel experts should recommend a on ban ESDs as used at the JRC over a decade ago.<sup>48</sup> She reported muscle cramps and burn marks caused by the GED, as well as frequent malfunctions of the devices resulting in people receiving shocks for no putative treatment reason at all.<sup>49</sup> These survivors’ accounts demonstrate that these dangerous devices pose a substantial risk of injury and must be banned.

#### IV. Conclusion

ESDs can cause severe and long-lasting harm, ranging from physical injuries such as burns to psychological injuries such as lifelong post-traumatic stress disorder, without any contemporary scientific literature and mainstream clinical practice finding any long-term efficacy. These well documented harms create a substantial risk of injury that is not outweighed by a public health benefit, even if ESDs had been proven to be effective in treating people with the most intense self-injurious and aggressive behavior. Those who support the JRC’s use of the GED or other potential developers of similar ESDs cannot show that even the most powerful ESD is more effective at treating self-injurious and aggressive behavior than alternative

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<sup>39</sup> *Id.*

<sup>40</sup> Lydia X. Z. Brown, *Survivor Andre McCollins’s 2012 Civil Trial Coverage*, BEARING WITNESS, DEMANDING FREEDOM: JUDGE ROTENBERG CENTER LIVING ARCHIVE, <https://autistichoya.net/judge-rotenberg-center/> (July 15, 2021).

<sup>41</sup> *See id.*; *Rotenberg Center and Shocked Autistic Student Reach Settlement*, LUBIN & MEYER PC (2012), <https://www.lubinandmeyer.com/cases/rotenberg-shock.html>.

<sup>42</sup> Brown, *supra* note 39; *Rotenberg Center and Shocked Autistic Student*, *supra* note 40; .

<sup>43</sup> *See generally* Lydia X. Z. Brown, *Living Archive & Repository on the Judge Rotenberg Center’s Abuses*, BEARING WITNESS, DEMANDING FREEDOM: JUDGE ROTENBERG CENTER LIVING ARCHIVE, <https://autistichoya.net/judge-rotenberg-center/> (July 15, 2021).

<sup>44</sup> *See id.*

<sup>45</sup> *Nicholson v. State of New York*, 23 Misc. 3d 313 (N.Y. Ct. Cl. 2008)

<sup>46</sup> *McFadden*, *supra* note 3.

<sup>47</sup> *Id.*

<sup>48</sup> Lydia X. Z. Brown, *Jennifer Msumba April 2014 Video Testimony*, BEARING WITNESS, DEMANDING FREEDOM: JUDGE ROTENBERG CENTER LIVING ARCHIVE, <https://autistichoya.net/2016/04/22/jennifer-msumba-april-2014-video-testimony/> (last visited May 24, 2024).

<sup>49</sup> *Id.*

treatment methods. The only research suggesting any efficacy for ESDs is compromised by conflicts of interest as it is published by JRC's current and former clinicians.<sup>50</sup> There are numerous effective alternatives available that do not cause such long-lasting harm and that are widely accepted and used among clinicians supporting people with intellectual, developmental, psychosocial, and learning disabilities, even those with intense self-injurious and aggressive behavior. Thus, any continued use of ESDs is unreasonable.

The recently amended FDORA allows the FDA to ban medical devices for a specific purpose. The FDA should exercise its authority to promulgate a final rule banning the use of ESDs as treatment for self-injurious and aggressive behavior in people with intellectual, developmental, psychosocial, or learning disabilities. This rule will not only provide long overdue relief to the people currently at the JRC, but will prevent any other facility, treatment provider, or clinician from subjecting any other disabled person to the same dangerous, harmful, and traumatizing treatment modality in the future. The Fund urges the FDA to adopt the proposed rule and prevent any further torture of disabled people in the name of treatment.

For more information on our comments please contact Lydia X. Z. Brown at [brown.ly@autismandrace.com](mailto:brown.ly@autismandrace.com).

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<sup>50</sup> For further background on available research and the JRC's history of deceptive marketing around the GED's alleged efficacy, see, Shain M. Neumeier, Autistic Self Advocacy Network, WRITTEN COMMENT TO THE FOOD AND DRUG ADMINISTRATION ON THE BANNING OF ELECTRICAL AVERSIVE CONDITIONING DEVICES (April 2016), <https://autistichoya.net/wp-content/uploads/2016/04/asan-written-comment-neumeier.pdf>.