Written Comment to the Food and Drug Administration on the Banning of Electrical Aversive Conditioning Devices
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I. Introduction

The Autistic Self Advocacy Network (ASAN) strongly urges the Food and Drug Administration to ban aversive conditioning devices that deliver noxious electrical stimuli to an individual in order to modify his or her behavior. Under 21 C.F.R. § 895.21, the FDA may ban a medical device if its continued marketing involves substantial deception or presents an unreasonable and substantial risk of illness or injury. Because of the nature and purpose of electrical aversive conditioning devices, as well as the circumstances surrounding the way in which they are currently used, both of these two criteria are met. The only way for the FDA to meaningfully protect the vulnerable populations on whom these devices are used is by means of an outright ban.

II. Factual Background

At this point the only manufacturer of, and the only facility to use, electrical aversive conditioning devices in the United States is the Judge Rotenberg Educational Center (JRC), a residential facility for people with developmental and psychiatric disabilities located in Canton, Massachusetts. As a result, it is impossible talk about risks and benefits of such devices independently of how JRC has used and continues to use them as part of its program. JRC, which utilizes a behavioral approach to the near-exclusion of other methods such as psychiatric medications and traditional counseling, abandoned the use of some of its earlier aversives, which required staff to make physical contact with students, in favor of contingent electric shock approximately 20 years ago. Shortly thereafter, it developed its own device, the Graduated Electronic Decelerator (GED), which delivers a stronger shock than the original model. It has since developed a number of additional devices, including the significantly more powerful GED-4, which is capable of a 45-millamp shock with a peak voltage of 91 milliamps; a “holster” that delivers a shock to the wearer’s hands if he or she attempts to remove them; and a GED “cushion” that shocks a student who tries to get out of his or her chair.

With the ability to deliver 15.5 milliamps of electricity to the wearer over a two-second period, the original GED was already three times as strong as its predecessor, the Self-Injurious Behavior Inhibition System (SIBIS), and anywhere between four to fifteen times more powerful than

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1 See Laurie Ahern & Eric Rosenthal, Mental Disability Rights International, Torture Not Treatment: Electric Shock and Long-Term Restraint in the United States on Children and Adults with Disabilities at the Judge Rotenberg Center 3 (2010) [hereinafter “MDRI”].
2 See Matthew L. Israel, Ph.D., Behavioral Skin Shock Saves Individuals with Severe Behavior Disorders from a Life of Seclusion, Restraint and/or Warehousing As Well as the Ravages of Psychotropic Medication: Reply to the MDRI Appeal to the U.N. Special Rapporteur on Torture 7, 10 (2010) (asserting that JRC’s behavioral programming has been able to “save” its students in ways that psychotropic medications and other forms of treatment were not); PolyaXane Cobb, A Short History of Aversives in Massachusetts 1-2 (2005) (JRC had abandoned some of its earlier forms of aversives in favored of electric shock as of 1992).
4 See N.Y. State Educ. Dep’t, Observations and Findings of Out-of-State Program Visitation: Judge Rotenberg Educational Center 7-8 (2006) [hereinafter “NYSED”]. Unless otherwise specified, “GED” will refer to all electrical aversive conditioning devices currently used at JRC for the purposes of this comment.
commercially-sold electrical “stun guns.”\textsuperscript{5} Nevertheless, the FDA cleared the GED for marketing in 1994 based on its similarity to the SIBIS.\textsuperscript{6} The FDA has not cleared any of JRC’s other aversive conditioning devices.\textsuperscript{7} None of the devices that JRC has designed, manufactured or used are fully FDA-approved.\textsuperscript{8}

Until recently, a settlement between the state of Massachusetts and JRC, and subsequent state regulations based off that settlement, allowed for the use of highly intrusive (“Level III”) aversives, including contingent electric shock, so long as specific conditions were met.\textsuperscript{9} Namely, in order to include the use of the GED or similar devices in an individual treatment plan, JRC was required to obtain the informed consent of a student or his or her parent or guardian; court approval obtained through a substituted judgment hearing; and the approval of the school’s peer review and human rights committees, and to undergo a review process on a yearly basis.\textsuperscript{10} However, since 2011, the Massachusetts Department of Developmental Services has passed regulations banning state-licensed facilities from using contingent electric shock on any student whose treatment plan did not already include it as of September 1 of that year.\textsuperscript{11} Even so, the revised regulations have allowed JRC to use the GED on approximately 80 of its students.\textsuperscript{12}

III. The continued “marketing” of aversive conditioning devices is substantially deceptive in a way that undermines the due process rights and compromises the wellbeing of JRC students.

The FDA may ban a device when the device’s continued marketing is substantially deceptive.\textsuperscript{13} A device’s marketing may be substantially deceptive even absent proof that the manufacturer or other responsible party had the intent to mislead or otherwise harm users of the device, or that any particular individual was deceived or harmed.\textsuperscript{14} Instead, the Commissioner of Food and Drugs must consider whether users of the device may be deceived or harmed by it.\textsuperscript{15} In addition, the FDA must determine whether the deception is “important, material, or significant in relation to the benefit to the public health from its continued marketing” enough for it to meet the standard for being substantial.\textsuperscript{16} While the GED is not available for purchase, the JRC markets its use of its device to parents, guardians, and judges. The JRC’s marketing includes misleading – if not outright false – information about the risks and benefits of the device. This deceptive marketing poses significant risk to its students.

One element of JRC’s deceptive marketing tactics are its claims that the GED’S shocks are only mildly painful and do not cause tissue damage. JRC staff and administrators have frequently compared the level of pain that the device inflicts to a bee sting, and have emphasized that the shock only lasts for

\textsuperscript{5} See id.; MDRI at 13-14 (comparing the power of the GED to commercially-sold “stun guns.”)

\textsuperscript{6} See COBB, supra note 2, at 2.

\textsuperscript{7} See NYSED, supra note 4, at 7, 8.

\textsuperscript{8} See id. Despite this fact, as of 2006, the JRC represented on its website that the GED was FDA-approved. Id. at 7.


\textsuperscript{10} Settlement Agreement, supra note 9, at 2-6, 9-10. See also NYSED, supra note 4, at 5 (making the requirement of a parent or guardian’s consent explicit).


\textsuperscript{12} See id.; ISAAC BORENSTEIN, REPORT BY MONITOR JUDGE ISAAC BORENSTEIN (RET.) FOR THE JUDGE ROTENBERG EDUCATIONAL CENTER (JRC) 126 (2013) (approximately 38% of JRC’s 213 students had treatment plans that allowed for Level III aversives as of February 2013).

\textsuperscript{13} 21 C.F.R. § 895.21(a) (2011).

\textsuperscript{14} Id. at § 895.21(a)(2).

\textsuperscript{15} Id.

\textsuperscript{16} Id. at § 895.21(a)(1).
two seconds with no lasting side effects. In particular, JRC administration and staff have repeatedly claimed that it does not cause burns. This is contradicted not only by existing photographic evidence, which shows the aftermath of a student’s having received approximately 30 shocks, but by JRC’s own practices. Specifically, JRC staff regularly rotate the electrodes that deliver the shocks, changing their position on students’ arms and stomachs in order to avoid burns caused by repeated shocks to the same part of the skin. In fact, in some cases, JRC has temporarily stopped using the GED on specific students altogether out of necessity in order to allow their burns to properly heal without being aggravated by further shocks. These so-called “GED vacations” have in some cases lasted for weeks at a time.

At the same time, JRC and its proponents have long argued that the use of painful aversives such as contingent electric shock are necessary to address the needs of the population it works with and their sometimes dangerous and even life-threatening behaviors. In order to demonstrate what it sees as the need for the GED, JRC has provided examples of the kinds of students it works with (who it claims are the most severe cases in the country), or rather the kinds of behaviors it works to eliminate – students pulling out their own hair, hitting their head against the wall to the point of blinding themselves, and assaulting residential staff and family members, for instance. However, JRC also routinely shocks students for minor behaviors that do not pose any threat to themselves or others. JRC’s purported justification for this practice is that these behaviors must be addressed as “antecedents” – either possible precursors to imminent dangerous behaviors or temporarily harmless forms of more serious behaviors that could resurface later if left unchecked. Nevertheless, it has applied shocks to students for such behaviors as asking for permission to use the restroom or having a

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18 See Judge Rotenberg Center, JRC Responses to Allegations in NYSED June 9, 2006 Report 31 (2006) (“No student has been burned by the GED or GED-4 devices.”) [hereinafter “Judge Rotenberg Center”]; Israel, supra note 2, at 58; Judge Rotenberg Center, Judge Rotenberg Center Head Nurse Baron – refutes various false allegations (2012), available at https://www.youtube.com/watch?v=zPldpoom2vM.

19 See attached color photograph of Andre McCollins’ leg. McCollins’ case is discussed below. See infra text accompanying notes 38-39.

20 See NYSED, supra note 4, at 21-22 (“The rotation of electrodes is necessary to prevent skin burns that may result from repeated application of the shock to the same contact point on the student’s body.”); Borenstein, supra note 12, at 52; Israel, supra note 2, at 110 (“The electrode site is checked each hour, when the electrode is rotated, and also after each application.”)


22 See id.

23 See Israel, supra note 2, at 7, 10; Gonnerman, supra note 17.

24 See id.

25 See Borenstein, supra note 12, at 26 (student “James Roe’s” behavior plan provided for use of the GED in response to behaviors including getting out of his seat without permission and stopping work for more than 5 seconds); NYSED, supra note 4, at 3 (students are shocked for behaviors including “nagging, swearing and failing to maintain a neat appearance”).

26 See, e.g., Judge Rotenberg Center, supra note 18, at 22-26 (defending the use of shock in responding to harmless “antecedent” behaviors, including nagging and getting out of one’s seat, and denying that students are shocked for stopping their work).
strong emotional reaction to observing other students being punished in his or her presence, which cannot reasonably be described as merely precursors to dangerous behavior.  

While Massachusetts’s recent regulatory changes prevent any new families from being deceived or pressured into consenting to the use of contingent electric shock, JRC’s misrepresentations are still relevant in that they have resulted in families providing consent to use of the GED on existing students, and enabled court approval of individual treatment plans through the substituted judgment process. As far as the former is concerned, JRC has engaged in a number of practices that compromise the ability of individuals and their family members to provide meaningful informed consent. For instance, despite the fact that the FDA has never approved any of the GED devices, the JRC has claimed in some of its marketing materials that they are “FDA approved." Additionally, parents have reported feeling coerced into giving their consent for the use of aversives by JRC’s failure to provide adequate alternative forms of treatment and threatening to send their children to less desirable placements, such as prison, unless parents consent to use of the GED. JRC’s use of pressure and misinformation about the risks of the GED and its true policies and practices when using these devices, particularly when marketing the use of the GED to families already in crisis, can only be considered substantially deceptive within the meaning of the regulations.

The JRC’s marketing activities have deceived not only parents, but state court systems as well. In order to include contingent electric shock in a student’s individual plan, it must have obtained the approval of the Massachusetts probate court through an adversarial substituted judgment hearing. Specifically, it must have demonstrated that, if the student in question had been competent to decide for him or herself, he or she would have chosen to undergo contingent electric shock. The court would have considered a number of factors in reaching its decision, including the possible side effects of the treatment; the student’s prognosis with and without it; and whether less intrusive or non-aversive treatment would be effective in addressing the target behaviors. Even after having initially approved a treatment plan, the court will continue to oversee its implementation and review it as necessary. This process was established for the specific purpose of protecting students’ due process right to be free of unnecessary intrusive and painful interventions. However, due to JRC’s misrepresentations regarding the GED’s risks, benefits, and use, these hearings resulted in approval of many plans based on information that is incomplete, inaccurate or both, and a lack of effective oversight of their

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28 See Fredda Brown & Dina Traniello, The Path to Aversive Interventions: Four Mothers’ Perceptions, 35 Res. & PRAC. FOR PERSONS WITH SEVERE DISABILITIES 128, 132-133 (2010); FOX BOSTON, Graphic video of teen being restrained, shocked played in court (2012), available at http://www.youtube.com/watch?v=ZtRGQRtwhzU (Cheryl McCollins, mother of Andre McCollins, testified in court that she didn’t know how students were treated, and never signed up for her son to be tortured, at the JRC).  
29 See NYSED, supra note 4, at 7.  
30 See id. at 5; Brown & Traniello, supra note 28, at 132-133, 134.  
31 Settlement Agreement, supra note 9, at 2-6. See NYSED, supra note 4, at 5. The settlement agreement and resulting regulations also required that JRC seek approval from two oversight committees. Settlement Agreement at 9-10. However, neither of these committees are independent from JRC, so they are not addressed for the purposes of this section. See BORENSTEIN, supra note 12, at 15.  
32 Settlement Agreement, supra note 9, at 2-6. See also ISRAEL, supra note 9 (mentioning general criteria for substituted judgment and how they were originally applied by the court in allowing the use of aversives at JRC).  
33 Settlement Agreement, supra note 9, at 5-6.  
34 Id. at 6-7.  
35 See MDRI, supra note 1, at 35.
implementation. This has undermined — and continues to undermine — the rights of the same students these hearings are meant to protect while at the same time legitimizing JRC’s use of contingent electric shock. Deceptive marketing of the GED is therefore important, significant and material. As a result of JRC’s substantial deception within the meaning of the regulations, the FDA both can and should ban the manufacture and use of the GED.

IV. The use of aversive conditioning devices poses a substantial and unreasonable risk of injury, particularly in light of current research and best practices in the fields of treatment and education for people with disabilities.

The FDA can also ban a device on the basis that it poses an unreasonable and substantial risk of injury or illness. As with the standard for deception, the Food and Drug Commissioner must determine whether the harm caused by the device is “important, material, or significant” enough to outweigh the extent to which it benefits the public health. Because the GED has purposely been made to be highly painful, with power enough to cause burns on a regular basis, and because it has a tendency to malfunction, the device itself inherently poses a substantial risk of injury to its students. This risk is unreasonable in light of researchers’ and professionals’ success at identifying non-punitive means of providing treatment and special education services to children with disabilities over the past twenty-five years. In light of these risks and the particular vulnerability of the JRC’s student population, the FDA should ban these devices.

Numerous lawsuits, reports and articles have established that the GED causes serious physical injuries and psychological damage to the students it is supposed to benefit. For example, in 2002, Andre McCollins, an 18 year old autistic student with intellectual disabilities, was restrained and shocked approximately 30 times over a seven hour period for offenses including refusing to take off his jacket, tensing up his body in apprehension of being shocked, and screaming in fear and pain. As a result, McCollins experienced burns and catatonia, and has ongoing difficulties caused by post-traumatic stress, including a permanent loss of skills that he had previously possessed.

In the case of Antwone Nicholson, a young man with Attention Deficit Hyperactivity Disorder and Oppositional Defiant Disorder, staff at one point removed his clothes, told him that they were “going to hang [him] up like Jesus Christ,” and proceeded to shock him while he was in the shower in response to his refusal to get ready for bed as directed. In addition to the physical harm he suffered from this and other acts of abuse at the program, Antwone experienced deep psychological harm: he

36 See id. at 34-35; FREDDA BROWN, PH.D., CONSULTATION REPORT: [NAME REDACTED] 2 (2000) (“This author does not intend any disrespect of the Court, but rather to highlight some pressing concerns that I have. It appears that, for reasons unknown to me, the process that has been followed to date has not provided the court with sufficient motivation to further question, challenge, or change the practices at JRC.”)
37 21 C.F.R. § 895.21(a) (2011).
38 Id. at § 895.21(a)(1).
41 This student’s identity was determined by comparing a couple of different sources that share a common story. See Gonnerman, supra note 17 (mentioning Antwone by name); Brown & Traniello, supra note 28, at 133 (referring to him by a pseudonym, “Andrew,” in telling the same story that appeared in the Mother Jones article).
42 See Brown & Traniello, supra note 28, at 129, 133.
came to believe that his mother did not love him anymore because she allowed him to be abused, when in fact she had not consented or known about the extent and manner in which he had suffered.\footnote{See Gonnerman, supra note 17.}

Two more students were woken up in the middle of the night on August 26, 2007 and, without any provocation whatsoever, repeatedly shocked on the order of a former student who prank-called the residence house posing as a member of senior staff.\footnote{See Gonnerman, supra note 12; Anonymous, supra note 21; BORENSTEIN, supra note 12, at 86-87.} One of the young men, referred to in an investigative report as “John Doe,” was shocked 30 times, while the other, “James Roe,” was shocked 77 times.\footnote{See BORENSTEIN, supra note 12, at 86-87.} John was found to have multiple red markings on his stomach after the incident, while James developed a stage II ulcer on his left leg as a result of the repeated shocks.\footnote{See BORENSTEIN, supra note 12, at 44-46, 82.} One of the students was later diagnosed with first degree burns in two places where he’d been shocked by the GED.\footnote{See Department of Developmental Services, Response to Testimony and Written Comments to Proposed Amendments to Behavior Modification Regulations: 115 C.M.R. 5.14 8-12 (2011) (quoting letters from experts and citing research of behavior modification experts).}

The GED continues to pose an unreasonable risk of injury despite JRC’s purported changes in policies and practices. Although staff are no longer permitted to activate a student’s GED while he or she is using the shower or in restraints, and measures have been put in place to verify the identity of outside callers,\footnote{See id. at 27; DEEC at 8-9.} students continue to experience up to 50 shocks per day for behaviors that pose no reasonable risk of harm, such as so-called “antecedent” behaviors and those which even the program classifies as merely “noncompliant” (such as stopping schoolwork for more than 5 seconds) or “verbally inappropriate” (such as by demanding to know why one was shocked without warning).\footnote{See id. at 26; DEEC at 126; Anonymous, supra note 27.} Students continue to experience constant fear and apprehension over whether they might at any point be shocked for a “behavior” that occurred as long as half an hour ago, and as a result of being forced to witness their peers being shocked while facing punishment themselves if they react.\footnote{See id. at 133.}

Moreover, no modifications to JRC’s policies surrounding when and how the GED can be used could change the fact that the devices’ shocks are, by design, incredibly painful, yet produce no lasting behavioral changes. The original GED was created as a more aversive version of its predecessor, the SIBIS.\footnote{See BORENSTEIN, supra note 12, at 44-46, 82.} The GED-4, which is approximately nine times as powerful as the SIBIS, causes significant pain and yet has evidently not been enough to effect long-term behavioral change in its wearers.\footnote{See BORENSTEIN, supra note 12, at 26, 126; Anonymous, supra note 27.} The devices also pose an unreasonable risk of harm through device malfunction. GEDs have been known to misfire or spontaneously activate, thus shocking a student who did nothing wrong even by JRC’s standards.\footnote{See id. at 26, 126; Anonymous, supra note 27.} As of 2013, JRC had still not successfully corrected this flaw in the GED’s design, and had only proposed modifications to it that would’ve reduced the frequency of, but not eliminated, such malfunctions.\footnote{See id.; Kix, supra note 3.}

The risk of harm posed by the GED is not justifiable by any supposed benefit that it confers. The fields of treatment and education have moved past the use of aversives entirely in the past 25 years, and in fact stress that such methods are ineffective.\footnote{See ORESTEIN, supra note 12, at 86-87.} As of this hearing, no other treatment facility in

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\begin{itemize}
  \item \textit{See id.} at 133.
  \item \textit{See BORENSTEIN, supra note 12, at 24, 31-33; MASS. DEP’T OF EARLY EDUC. & CARE, INVESTIGATION REPORT 3 (2007) [Hereinafter “DEEC”].}
  \item \textit{See BORENSTEIN, supra note 12, at 24, 33.}
  \item \textit{See id.} at 27; DEEC at 8-9.
  \item \textit{See DEEC at 3.}
  \item \textit{See BORENSTEIN, supra note 12, at 44-46, 82.}
  \item \textit{See id.} at 26, 126; Anonymous, supra note 27.
  \item \textit{See BORENSTEIN, supra note 12, at 82; NYSED, supra note 4, at 26; Anonymous, supra note 27; Miller, supra note 21.}
  \item \textit{See Gonnerman, supra note 17.}
  \item \textit{See id.; Kix, supra note 3.}
  \item \textit{See Gonnerman, supra note 17; Anonymous, supra note 21; BORENSTEIN, supra note 12, at 86-87.}
  \item \textit{See BORENSTEIN, supra note 12, at 86-87.}
  \item \textit{See DEPARTMENT OF DEVELOPMENTAL SERVICES, RESPONSE TO TESTIMONY AND WRITTEN COMMENTS TO PROPOSED AMENDMENTS TO BEHAVIOR MODIFICATION REGULATIONS: 115 C.M.R. 5.14 8-12 (2011) (quoting letters from experts and citing research of behavior modification experts).}
\end{itemize}
the United States uses a device like the GED. Furthermore, there has been no peer-reviewed research that supports the use of contingent electric shock as an effective means of treatment in the past several decades; in fact, one of its foremost proponents, O. Ivar Lovaas, has since repudiated it. Professionals who work with the populations that JRC serves have found that punishment has only a short-term effect and that it not only fails to teach but also inhibits the development of useful skills and appropriate behavior. Positive, non-punitive interventions that assess the function of existing behavior and teach adequate replacements for it as necessary have been proven to be more effective over the long term, and without endangering the well-being of students or patients. Contrary to JRC’s claims, these methods have been shown to work even for individuals who exhibit severely aggressive and self-injurious behaviors, including some of those who previously attended JRC.

Where, according to experts in the field, the GED has no health benefit and in fact is detrimental over the long term, there is nothing for the harm it causes to be weighed against in determining whether the risk it poses is “important, material or significant.” Therefore, it should be banned under the regulations on the basis that it presents both a substantial and unreasonable risk of injury.

V. Conclusion

Not only do the aversive conditioning devices used at JRC caused unreasonable and substantial harm to many of the students in its care, but the program has alternately downplayed and misrepresented the necessity of this harm to the public, including parents and court officials responsible for consenting to or authorizing their use. This deceptive marketing has continued even as experts in the fields of special education and the treatment of developmental and psychiatric disabilities have explored and increasingly identified effective and humane alternatives to the use of aversive interventions over the past two decades, negating any benefit that might outweigh these concerns.

A ban on electrical aversive conditioning devices designed to cause pain, and known to cause physical and long-term psychological harm, is not only reasonable in light of current research and practice, but necessary to protect the human rights, dignity and well-being of the approximately 80 students who still continue to be shocked at JRC.

that advocate against the use of punishment as a means of treatment and behavioral control and in favor of positive interventions); Freda Brown et al., Personal Paradigm Shifts Among ABA and PBS Experts: Comparisons in Treatment Acceptability, 10 J. of Positive Behavioral Interventions 212, 216-226 (2008) (showing decreased support for the use of aversives among both practitioners of positive behavioral supports and practitioners of applied behavioral analysis); Polyxane S. Cobb, A Discussion of Aversives: Why They Don’t Succeed and What Does 5-9 (2005); Freda Brown, Ph.D., Consultation Report: [NAME REDACTED] 2-6 (1999).

56 See MDRI, supra note 1, at 3.

57 See Gonnerman, supra note 17; NYSED, supra note 4, at 16; DEPARTMENT OF DEVELOPMENTAL SERVICES, supra note 55, at 8-12.

58 Cobb, supra note 55, at 7-8; DEPARTMENT OF DEVELOPMENTAL SERVICES, supra note 54, at 8-11; Brown, supra note 55, at 1-2.

59 Cobb, supra note 55, at 8; DEPARTMENT OF DEVELOPMENTAL SERVICES, supra note 55, at 8, 10-11, 14; BROWN, supra note 55, at 3-4.

60 See generally Frank L. Bird & James K. Luiselli, Positive behavioral support of adults with developmental disabilities: assessment of long-term adjustment and habilitation following restrictive treatment histories, 31 J. of Behavioral Therapy and Experimental Psychiatry 5, 14-18 (2000) (demonstrating long-term success of five individuals who previously had attended and been treated with aversives at JRC after they moved to a program that relied solely on the use of positive behavioral interventions). See also Cobb, supra note 55, at 9.
ATTACHMENT: Photograph of burns on the front of former JRC student Andre McCollins’ knee after he received 30 electric shocks from the GED on 25 October 2002.