WRITTEN STATEMENT OF
THE AMERICAN CIVIL LIBERTIES UNION

For a Hearing on

“The Safety and Effectiveness of Averse Conditioning Devices”

Submitted to the Neurological Devices Panel of the
Medical Devices Advisory Committee of the U.S. Food and Drug Administration (FDA).

[Docket No. FDA-2014-N-0238]

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Members of the Neurological Devices Panel of the Medical Devices Advisory Committee:

On behalf of the American Civil Liberties Union (ACLU), its over half a million members, fifty three affiliates nationwide and countless additional supporters and activists, we commend you for holding this hearing to examine the use of devices that are intended to modify behavior through a noxious electrical stimulus. We urge you to ban the use of a noxious electrical stimulus as a behavior modification tool. Such aversive devices create an unreasonable and substantial risk of injury, and have been promoted with substantial deception. In addition, the use of these devices is a violation of federal law.

Background

The Judge Rotenberg Center (JRC) in Massachusetts developed the “aversive conditioning devices,” called the Graduated Electronic Decelerator (GED). The device provides conductors that are strapped to the arms, legs, and torso of a student at the JRC, and worn both sleeping and waking hours, seven days a week. The student wears a backpack that carries the wires and charger for the electrical shock. In the first version of the GED, the electrodes emitted 60 volts and 15 milliamps of electricity for two seconds at a time. The latest version of the GED is three times more powerful and reportedly three times more painful.1

Employees at the JRC carry a transmitter and are instructed to send a shock whenever the student engages in undesirable behavior. The employees must continue to shock the student until the undesirable behavior has ceased.2 Some reports indicate that staff provide a series of shocks even when the behavior has stopped, and even when the student exhibited no undesirable behavior.3

There are reports of students being shocked 20, 30, even more than 70 times in one day.4 Because of significant public protest, and some private lawsuits, the school now limits those it shocks to students admitted prior to 2011, in which both a court and the parents agreed to the use of the aversive therapy.

The GED is used only at the Judge Rotenberg Center, a “residential education center” for students with disabilities. These are primarily young students, many of whom are non-verbal or

with limited speech. The range of disabilities is wide, from intellectual disabilities to autism, ADHD, Post-Traumatic Stress Disorder (PTSD), and other psychiatric disabilities.

The GED Meets the FDA Criteria for Banning a Product

For the FDA to ban a device, it must find that the device creates an "unreasonable and substantial risk of injury" or that the device is presented with "substantial deception." The Graduated Electric Decelerator (GED) meets both criteria.

The GED Creates an Unreasonable and Substantial Risk of Injury

Numerous credible reports show the GED causes both physical and psychological harm.

The GED is intended to cause pain – that is the aversive method of achieving compliance. But, the voltage is sufficient to also cause burns on the skin. Over time, electric shock may cause scarring of the skin, hair loss, tooth damage, and impotence. One former resident reports that the GED-1 burned scars into her stomach and that she was left with no feeling from her knee to her foot for a year.

More importantly, the GED causes emotional and psychological harm. The New York State Education Department’s report found that, as a consequence of JRC’s aversive techniques, many students they spoke with were suicidal, and that fear, anxiety, and widespread loneliness were “pervasive” among the students they interviewed. Repeated electric shock can cause “post-traumatic stress disorder, severe depression, chronic anxiety, memory loss and sleep disturbance.”

Letters and interviews with former residents of JRC testify to the physical and emotional harm of the GED. Perhaps the most publicized case is that of Andre McCollins, whose mother sued over his treatment. Andre was a 17-year-old student with intellectual disabilities, who was shocked for not responding promptly when told to take off his coat. Over the next several hours, he was shocked an additional 30 times strapped to a restraint board, with his arms and legs tied down. When his mother found him the next day, he was catatonic. He remained catatonic and hospitalized for five weeks.

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5 21 CFR Part 895.
6 Kix, supra note 1.
7 Laurie Ahern, Eric Rosenthal, Torture not Treatment: Electric Shock and Long-Term Restraint in the United States on Children and Adults with Disabilities at the Judge Rotenberg Center, Mental Disability Rights International (MDRI), p. 3.
8 Survivor’s letter, supra note 3.
9 NYSED supra note 3, p. 25.
10 MDRI, supra note 7, p. 3.
11 Gonnerman, supra note 1. The video of the 31 shocks was played at McCollins’ trial. Because the judge allowed reporters to re-broadcast the video, there was widespread outrage in response.
Finally, both Mental Disability Rights International (MDRI)\textsuperscript{13} and the United Nations’ Special Rapporteur on Torture have found the use of the GED to qualify as torture.\textsuperscript{14} In a report that MDRI wrote on the Judge Rotenberg Center, it found that the use of the GED met the four primary criteria of torture:

1) Pain is severe – “The subjective experience of the victim is critical to understanding what pain might cause the emotional terror and physical suffering that rise to the level of torture. The powerlessness and vulnerability of children or adolescents with mental disabilities, held in detention and subject to treatment against their will are all factors that contribute to suffering.”\textsuperscript{15}

2) Pain is inflicted intentionally – The JRC practices “fit within the definition because they are inflicted systematically and specifically to induce pain and inflict punishment. Pain is not the incidental side effect…”\textsuperscript{16}

3) Pain is inflicted for a prohibited purpose – The shocks are specifically meant as “intimidation and coercion.”\textsuperscript{17}

4) Acquiescence of a public official or other person acting in an official capacity – Because JRC is licensed by a state agency and funded by both state and federal agencies, its services are “sanctioned” by the government.\textsuperscript{18}

The GED Is Marketed with Substantial Deception

The Judge Rotenberg Center maintains that the use of the GED and aversive therapy are necessary to prevent self-harm.\textsuperscript{19} But, reports from staff, former residents of JRC and JRC’s own data show that shocks are administered in response to any “undesirable” behavior – from leaving a chair, to stopping work for 10 seconds, to flapping one’s hands, to slouching in a chair, to not taking off a coat.\textsuperscript{20} None of these behaviors are self-injurious. Further, the New York State Education Department found, in its site visit in 2006 that part of the “treatment program” for students is to intentionally create “unfair or mistaken” GED shocks to the students.\textsuperscript{21} “The student is expected to handle these unfair situations successfully and not ‘plead’ or appeal to a psychologist or clinician.”\textsuperscript{22}

In short, JRC shocks students deliberately, without cause. If they protest, JRC shocks them again in order to train them not to ask for help or fairness in their treatment.

The Judge Rotenberg Center describes the shock of the GED as if it were a “2 second bee

\textsuperscript{13} MDRI, \textit{supra} note 7, pp. 21-28;
\textsuperscript{14} Juan E. Mendez, \textit{Report of the Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment}, Human Rights Council, March 4, 2013, p. 84.
\textsuperscript{15} MDRI, \textit{supra} note 7, p. 23.
\textsuperscript{16} Ibid. p. 25
\textsuperscript{17} Ibid. p. 26
\textsuperscript{18} Ibid. p. 28
\textsuperscript{19}Matthew L. Israel, \textit{Aversives at JRC: A Better Alternative to the Use of Drugs, Restraint, Isolation, Warehousing or Expulsion in the Treatment of Severe Behavior Disorders}, \texttt{http://web.archive.org/web/20111025092649/http:/www.judgerc.org/}.
\textsuperscript{20} NYSED, \textit{supra} note 3, Gonnerman, \textit{supra}, note 2; \textit{Letter from Former Teacher at Torture Center, supra} note 2.
\textsuperscript{21} NYSED, \textit{supra} note 3, p. 18.
\textsuperscript{22}Ibid.
sting.” Former residents dispute that characterization. Significantly, the JRC does not allow the public, or journalists, to try the most powerful GED-4. A staff member will demonstrate the GED-1, but not the stronger GED-4.

In a lengthy review of JRC’s on-line materials, none indicate the frequency and randomness of the aversive electric shocks that students may be subjected to. None of the materials include video of a student being shocked. None of the materials show the four-point restraints used to hold a student in place, while being repeatedly shocked. Unless the JRC makes such details clear in its conversations and presentations to parents and judges, it seems fair to conclude that the JRC engages in significant deception toward those who must approve the use of the GED.

**Because the Aversive Conditioning Device Is Used Solely on People with Disabilities, Its Use Is a Violation of Federal Disability Rights Laws.**

As a recipient of federal funds, the Judge Rotenberg Center is subject to Section 504 of the Rehabilitation Act. As a residential school and a behavior modification facility, it is subject to the Americans with Disabilities Act (ADA). Under both the Rehabilitation Act and the ADA, discrimination against people with disabilities is prohibited.

Both the GED’s advocates and its critics refer to the GED as a part of a method of behavior modification. It is not a treatment for the underlying mental condition. In other words, the GED is not active treatment of an intellectual disability, or autism, or ADHD. The GED is used just to change behavior.

In the United States, we have hundreds of behavior modification programs, both voluntary and involuntary. We have programs to stop bad habits (such as smoking, drinking, or eating too much). We have incarceration programs to curb or punish harmful behavior (such as theft, assaults or murders). None of these programs – whether run by a private entity or by the government – employ a device, such as the GED to “treat” undesirable behaviors.

Drinking, smoking, and drug use may be just as self-injurious as hitting one’s head against a wall. A noxious electrical stimulus could be quite effective in curbing any behavior related to such bad habits and any “trigger” behaviors that could lead to it. Nonetheless, no behavior modification program employs such a device. Thefts, assaults, and murders cause clear harm to

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23 Judge Rotenberg website: [http://www.judgerc.net/whatisged.html](http://www.judgerc.net/whatisged.html)
24 Survivor’s letter, supra note 3.
25 Kix, supra, note 1.
26 42 USC 12132 Sec. 202. “… no qualified individual with a disability shall, by reason of such disability… be subjected to discrimination by any [public] entity.”; 29 USC Sec. 794, “No otherwise qualified individual with a disability in the United States… Shall, solely by reason of his or her disability, …be subjected to discrimination under any program or activity receiving Federal financial assistance…..”
27 The few that incorporate a mild aversive approach, such as snapping a rubber band on the wrist, are under the individual’s control, not a third party’s.
28 We do use noxious electrical stimulus to train animals, such as cattle prods on herds and electric collars on dogs. But treating a person with a disability as if he was a dog or a cow is precisely the type of discrimination that the Rehabilitation Act and the ADA were designed to prohibit.
others. Yet, no incarceration program uses a GED to “rehabilitate” or even punish those convicted of such offenses.

The United States also has thousands of schools. These schools work with students who have a range of disabilities and a range of behavior issues. But in no school is a noxious electrical shock used to modify behavior or maintain discipline.

It is only students with disabilities who are subjected to painful, repeated, and often arbitrary, shocks. Moreover, there is no individualized determination of the harm the shocks will cause. Students enrolled at the Judge Rotenberg Center are hooked up to the GED, regardless of their diagnosis, the Individualized Education Plan they arrive with, or the particular behaviors they exhibit. Whether the student is there because she has autism, an emotional disturbance, attention deficit hyperactivity disorder (ADHD), an intellectual disability, or Post-Traumatic Stress Disorder, the GED is used to teach compliance, to instill fear, and to maintain strict control.29 The students who are subjected to this noxious electrical stimulus have little in common except their disability status.

In no other population do we use aversive electric shocks to modify behavior, nor even to punish harmful acts. No students without disabilities are hooked up to a GED and forced to wear it 24 hours a day, seven days a week. No students without disabilities are repeatedly shocked until they are so cowed that they will not even protest the injustice of random and arbitrary punishment.

The use of the noxious electrical stimulus subjects these individuals with disabilities to treatment that is different from students without disabilities, treatment that is worse than that of students without disabilities, and treatment that is painful, dehumanizing, and random. In short, these students with disabilities experience discrimination, solely by reason of their disability.30

**Conclusion**

JRC staff has argued that their aversive methods are effective. The overwhelming weight of reputable medical and scientific research disagrees.31

The ACLU maintains that the efficacy of the GED is irrelevant.

The GED causes significant physical and mental pain to vulnerable students with disabilities, who are legally and physically held hostage. Whether the GED creates permanent or temporary behavior modification in some, many, or all of the students is immaterial. The use of a noxious electrical stimulus is inhumane. The fact that we consider using it on people with disabilities – and only people with disabilities – is evidence of significant bias and discrimination. Any

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30 29 USC Sec. 794; 42 USC 12132 Sec. 202; 28 CFR section 35.130 (a)(b)(1)(ii),(v),(vii).

participation by government entities, through licensing, contracting, referral, or funding, raises serious risk of federal disability rights violations.

Thank you for holding this hearing, and for your willingness to act in order to keep young people with significant disabilities from harm.

Sincerely,

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