Judge Rotenberg Educational Center, Inc.

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Neurological Devices Advisory Panel Meeting

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I. Introduction

This submission to Docket FDA-2014-N-0238 is hereby being provided as a follow-up to the April 24, 2014, meeting of the U.S. Food and Drug Administration's ("FDA" or the "agency") Neurological Devices Panel ("the Panel") regarding Electrical Stimulation Devices ("ESD") for Aversive Conditioning. The Judge Rotenberg Center ("JRC") submitted an initial packet to the docket on April 14, 2014 and actively participated in the panel meeting by providing oral testimony, and willingly participating in extensive Q&A from panel members. JRC understands that the purpose of the panel meeting was to obtain information on ESDs used for aversive conditioning as the agency considers whether to ban such devices, regulated under 21 C.F.R. § 882.5235, in accordance with Section 516 of the Federal Food, Drug, and Cosmetic Act ("FDC Act"). JRC also wrote a letter to Carlos Peña, Ph.D. on May 14, 2014. The purpose of that letter was to address the array of mischaracterizations and factually incorrect and unsubstantiated statements and claims made during the panel meeting about the graduated electronic decelerator ("GED"), the ESD that has been continuously in use at JRC for over twenty years. As noted in the May 14, 2014 letter to Dr. Peña, JRC, like the many parents of JRC students/patients who attended and/or presented at the panel meeting, is concerned with the influence that this misinformation about the GED and its safety and performance may have had on panel members, who were already charged with opining on what is admittedly a sensitive and politically charged issue. That letter also:

- Re-emphasized JRC's willingness to participate in a scientifically valid, prospective clinical evaluation of the GED.
- Re-extended JRC's invitation to FDA personnel to visit the school. As many unsubstantiated allegations, and opinions were presented to the panel by interest groups and others who have never been to the school, JRC continues to firmly believe that it would be prudent for agency representatives to see first-hand how the GED is used, and its lack of any harmful side effects, before making a decision to ban a treatment which is the only effective treatment available for this highly at risk population.

The May 14, 2014 letter to Dr. Peña was submitted to docket FDA-2014-N-0238 on June 20, 2014 (tracking number 1jy-8crx-wmd8).

As the only center in the United States which treats the most dangerous forms of behavior disorders in the nation and utilizes ESDs as a fundamental part of treatment of patients that exhibit the most severe self-injurious behavior ("SIB"), aggressive, and other seriously harmful behaviors, any ban of such devices, including JRC's Graduated Electronic Decelerator ("GED") devices, would have dire consequences on treatment, safety and well-being of this vulnerable population of patients and their care-givers to include potential permanent injury and death.

To address JRC's concerns regarding the many mischaracterizations and erroneous information provided to the agency regarding the GED, and to provide further support that the use of ESDs does not present a substantial and unreasonable risk of illness or injury, through this submission, JRC is hereby:

- Reiterating that the continued use of ESDs does not present an unreasonable and substantial risk of harm. There is a clear need for the continued use of ESDs on the small,

vulnerable population of people who exhibit uncontrolled self-injurious and aggressive behavior and for whom alternative treatments have proven ineffective. The benefits of ESDs far outweigh the perceived risks, most of which have never been seen at JRC and have never `been medically proven. A real safety risk to these patients and their care givers would result if these devices are banned.

- Providing background on the extensive training required prior to any JRC employee being allowed to administer a skin shock to a patient.
- Addressing concern with comments referencing the Statements made by the U.N. Special Rapporteur on Torture.
- Providing background and supporting data regarding the performance of the GED and the issue of misapplications.
- Responding to comments and mischaracterizations of JRC's Medical Device Reporting ("MDR") practices and obligations.
- Providing the chronology and current status of JRC's efforts to re-design the GED and obtain premarket notification ("510(k)") clearance for this enhanced version of the device.

Each of these issues is addressed in more detail below.

II. Background

Regarding the GED, JRC hereby incorporates by reference the background information provided in JRC's docket submissions submitted on April 14, 2014 (tracking number 1jy-8bjf-k0hb) and June 20, 2014 (tracking number 1jy-8crx-wmd8). Importantly, the GED devices continue to be used in the same way as when FDA originally cleared the device and does not present any new or different risks of safety or questions regarding the efficacy of the treatment as when the device was originally cleared by FDA. The standard of care for the intended use patient population remains the same. It is these refractory patients for whom the GED devices are indicated and have been demonstrated as sufficiently safe and effective.

JRC proactively filed the 510(k) notice for the device in 1991, and received clearance of the device in 1994 following multiple rounds of review by FDA and the provision of additional data include data on pain levels. Following clearance of the device, JRC made minor modifications to the device in accordance with the recognized memorandum to file process as the changes did not warrant the issuance of a 510(k) notice under the guidance documents in place at the time. In 2000, FDA visited JRC during a routine inspection. Following that inspection, correspondence from the agency clearly stated that no 510(k) notice for the devices is required as their use was within the practice of medicine. JRC continued to use the devices in the same manner, without any increase in safety risks associated with its use.

Only after certain anti-aversive individuals and organizations raised their philosophical and uninformed concerns based on misinformation to various governmental agencies did FDA decide to revisit the use of the GED device and aversive conditioning devices generally. The credence that the agency has placed on alleged "facts" provided by these uninformed sources without considering JRC's actual data on patients or FDA's visit to the institution, has been detrimental and detracts from the clear need for a small group of refractory patients to have access to this therapy. JRC and Panel

members maintain that patients need access to an alternative therapy where the positive behavioral support therapy and drugs are not adequately treating them.

JRC has repeatedly provided information to FDA to support the safety and efficacy profile of the GED devices and aversive conditioning devices generally since FDA raised concerns regarding the devices in 2010, which is 16 years after clearing the device and more than 10 years after concluding that the use of the devices were not subject to premarket notification. Sufficient safety and efficacy data exist to support the continued use of the GED devices in both their current form as well as the redesigned versions of the device that the agency requested. The redesigned devices incorporate additional safety features. JRC has further offered to collect additional clinical data regarding the device to further support the safety and efficacy data.

III. Clear Need for Continued Access to ESDs

As thoroughly discussed in the original docket submission (April 14, 2014, tracking number 1jy-8bjf-k0hb), and the May 14, 2014, letter to Dr. Pena (submitted to the docket on June 20, 2014, tracking number 1jy-8crx-wmd8), banning ESDs would subject patients to devastating physical and emotional harm. As previously detailed in the April 14, 2014, submission to the docket, the patients who are treated with the GED have failed numerous other therapies prior to treatment with the GED device. (See Attachment 2 of the April 14 submission which provides a summary of prior treatments and number of institutions for all patients currently receiving GED therapy). As confirmed by recent literature[1] and the Panel members during the April 24, 2014, meeting, there exists a refractory patient population who exhibit SIB for which other recognized forms of behavior and drug therapies are not sufficient.

This refractory patient population is the population currently treated with the GED devices.

The information provided by anti-aversive therapy organizations, and even FDA's own actions, seemingly ignore the significant adverse impact that removing the GED from their physician-approved and court-approved treatment plans would have. It would be a miscarriage of justice if these patients were prohibited access to this important treatment based on a philosophical beliefs and fabricated, unsubstantiated claims. Without an effective treatment, these patients will continue to severely injure themselves causing permanent damage and disfigurement, and cause harm to

[1]

- Carr, E.G., Robinson, F., Taylor, J. & Carlson, J. (1990). Positive approaches to the treatment of severe behavior problems in persons with developmental disabilities. In: *National Institutes of Mental Health Consensus Development Conference,* (pp. 231-341).NIH Publication No. 91-2410.
- Carr, E.G., Horner, R.H., Turnbull, A.P., Marquis, J.G., Magito McLaughlin, D., McAtee, M.L.,Smith, C.E., Anderson Ryan, K., Ruef, M.B., & Doolabh, A. (1999). *Positive behavior support for people with developmental disabilities: A research synthesis.* Washington, D.C.: American Association of Mental Retardation.
- Horner, R. H., Carr, E. G., Strain, P. S., Todd, A .W. and Reed, H. K. (2002). Problem behavior interventions for young children with autism: A research synthesis. *Journal of Autism and Developmental Disorders,* 32, 423-445.
- Matson, J.L. & LoVullo (2008). A review of Behavioral Treatments for Self-Injurious Behaviors of Persons with Autism Spectrum Disorders. *Behavior Modification, 32.* 61-76

their families and caregivers. Prior to finding an effective treatment with the GED devices, these patients had caused life-threatening injury and permanent disfigurement to themselves or others through their uncontrollable behaviors such as head banging, eye gouging, tearing their own flesh, biting off body parts, pulling out their own adult teeth, destroying furniture and school equipment, punching their fists through glass windows, running into traffic, jumping out of windows, and violently attacking family members, teachers, staff and others with punches, kicks, bites and sharp objects. These patients only began therapy with the GED devices after failing all other available treatment options, meaning that **all** other available therapies failed to either safely or effectively control their problematic behaviors. Other treatment options such as psychotropic medications and restraint have caused severe harm to many of these patients such as the dangerous side-effects of psychotropic medications and bodily injury from restraint. As is demonstrated in the various patient treatment summaries provided in JRC's June 24, 2014, docket submission, patients treated with ESD devices such as the GED have experienced great benefits from the treatment with the GED devices, namely the reduction of self-harm, in addition to educational, vocational and social benefits, with no harmful side-effects. Banning an entire category of devices would leave this vulnerable patient population without a safe or effective treatment option. The continued availability of the GED devices is imperative to maintain the health of individuals who receive life-saving therapy with these products.

IV. Device does not present an unreasonable and substantial risk of harm

JRC maintains that adequate safety and efficacy data exist on the GED device. Even in light of the panel's position with regards to evidence on the safety and efficacy is somewhat limited based on the lack of prospectively controlled data, there is no credible evidence to support that the GED device, or this category of devices as a whole, present an unreasonable and substantial risk of harm to patients.

This standard must be applied considering the specific intended use patient population. The data clearly show that the patient population indicated for this device cannot be adequately treated with positive behaviors support therapies alone and/or medications that did not present serious side effects. In fact, the patient records demonstrate that these patients have failed to be adequately and safely treated at numerous other well-known and respected institutions with therapies ranging from positive behavior support techniques to extensive combinations of medications, to seclusion and restraints.

As with any treatment, there are side effects that must be considered when evaluating the risk/benefit ratio of the device when a physician chooses to prescribe a specific therapy. JRC has observed only limited and temporary side effects with the device, such as avoidance response, temporary anxiety, and mild erythema at the site of the electrode. These side effects can hardly be considered a "substantial risk of injury." Notably, numerous of the potential risks identified by FDA and the panel members during the April 24 panel meeting have not been seen by the center or the families of these patients in the over 20 years of experience for the device. Rather, these other claims of injury, or risk thereof, are theoretical and anecdotal at best as no such data or evidence has been confirmed. Indeed, JRC is not aware of any confirmed diagnoses of such side effects as PTSD or otherwise, nor were any such confirmed cases presented or provided to the FDA panel or

docket. Rather, these are the same sensationalized and unproven stories that the anti-aversive community has been publicizing for years.

Moreover, even considering the potential for the risk of other side effects, as contemplated by the panel, these potential side effects may not be considered unreasonable in light of the risk/benefit ratio of the therapy. While there have been only minor side effects associated with the device, the GED therapy has significantly reduced hundreds of patients' self-injurious behaviors and aggressive behaviors. These reductions in behaviors, which are fully documented in the patient's medical records, have prevented patients from persistently continuing to mutilate and permanently harm themselves. Patients receiving therapy with the GED devices have significantly reduced their own frequency of destructive behaviors allowing them the opportunity to receive corrective medical procedures as well as educational benefits and integration into the community.

Should FDA believe that additional protections are necessary to ensure that this therapy is delivered in a safe manner, JRC strongly urges FDA to consider implementing required labeling to address issues such as the informed consent procedures, instructions regarding the patient population appropriate for treatment with the device, disclosure of potential associated risks, and/or instructions regarding the proper administration of the device. It should be noted that many of these items already are provided in the GED's User Manual and instructions for use.

JRC firmly believes that considering the safety and efficacy profile of ESD devices based on information in the literature, the patient summary information provided by JRC to FDA, the verification data for the newly developed GED-3B and GED-4B devices presented to FDA in the February 1, 2013, pre-submission material (Q130112), the potential for further clinical evaluation and revised labeling, FDA has not met its burden to enact a ban on ESDs devices.

V. Further information and corrections to statements at Panel Meeting

A. Evaluation of Patients

As has been noted by JRC, numerous protections already are in place to ensure that patients are not harmed and receive the best care possible. For example, the GED is only one aspect of each patient's comprehensive treatment plan. Regarding the use of the GED, in addition to the numerous steps required prior to use of the GED, following each activation of the GED device, a staff member must visibly check the area of the body on which the electrode is located immediately after administration of the GED therapy. Additionally, each patient is evaluated by a registered nurse within 24 hours. As with all medical records, these evaluations are fully documented in each patient's chart. A sample of nursing notes for five patients currently using the GED is provided in **Attachment 1**. These examples show how extensive and frequent these evaluations occur over each year. Moreover, as is demonstrated by the attached, each evaluation is documented and tracked by patient, date and outcome.

As discussed during the panel meeting, certain patients experience mild erythema at the site of the electrode which resolves within 1-2 days. The erythema has not presented with inflammation, pain,

or blistering and accordingly does not meet the definition of a burn. [2]/ As discussed with FDA in 1994 during the original 510(k) clearance of the device, JRC recognizes that it is possible that repeat exposure to the GED skin-shock could result in blistering, however, such effects have not been observed when the device is used in accordance with its instructions for use. Procedural safeguards to protect against misuse are in placed at JRC including frequent movement of the placement of the GED electrodes and extensive training of the staff. Further, the newly developed GED-3B and GED-4B include activation limits to limit the number of stimulations that can be applied.

Patients also are routinely monitored on a weekly basis for physical and mental well-being. At least twice weekly, JRC clinicians perform direct observation of each student/patient assigned to them. This may involve observing the student during the academic day, seeing the student during rewarding activities, or speaking with the student outside of the classroom. The clinician also reviews the student's recording sheets which include data on behavior frequencies, notes from staff, and the number of times GED skin-shocks were applied, among other data. In addition, the clinician will speak with the teachers and direct care staff who have worked with a particular student. This information is used by the clinician to determine if there are any issues (physical and/or psychological/behavioral) that need to be addressed. In addition, clinicians may utilize JRC's DVR monitoring and recording system which has cameras in all areas of the JRC school buildings and group homes, to examine applications of movement limitation or of the GED in order to assess collateral effects.

In addition to the evaluations of patients performed directly by JRC Direct Care Staff, registered nurses, and certified behavior analysts and psychologists, the use of the GED is transparent to entities outside of JRC. In this regard, the Center and its use of the GED devices, is subject to oversight and inspection by Massachusetts' state agencies and courts. The probate court prospectively approves the use of the GED device in the treatment of each and every patient. In addition, JRC also submits periodic reports to the court and various agencies regarding the use of the device. Specifically, each quarter JRC submits a progress report, which consists of a narrative analysis by the patient's attending clinician of the progress since the last report. The clinician considers behavior charts, tally sheets, and functional analyses in formulating each narrative analysis. For patients who have had supplementary court-authorized aversives for three years, a case conference review is done on the patient. Attending these case conferences are an independent psychologist, appointed by Massachusetts Department of Developmental Services "DDS", a consulting psychiatrist, the treating clinician, the classroom teacher, the parent and/or guardian, a nurse, and the case manager. A report is written and submitted to the Probate Court and DDS by the independent clinician which includes the rationale for continuing or discontinuing the court-authorized supplementary aversives. A copy of this report is sent to the Court, the patient's counsel, the Court Monitor, the Parent/Guardian and DDS. Each treatment plan with court-authorized supplementary aversives is reviewed annually by JRC's Human Rights and Peer Review Committees.

B. Training of Staff Responsible for Administration of GED Stimulus

One item that was the subject of much discussion and speculation at the April 24, 2014 panel meeting was the training required of JRC personnel prior to their ability to initiate an application of

[2]/ Stedman's Medical Dictionary defines a "superficial burn" (synonymous with "first-degree burn") as "a burn involving only the epidermis and causing erythema and edema without vesiculation."

the GED. Despite JRC's efforts to explain that all personnel who are authorized to deliver a skin-shock receive thorough and detailed training, comments made by panelists and the anti-aversive therapy organizations show a clear misunderstanding of the training programs in place at JRC, as well as FDA's regulatory requirements with respect to prescription devices. For example, one panelist stated, "The fact that individuals who are not licensed professionals are carrying out this is a visceral disgust, I think, that strikes in a lot of us, that people who aren't adequately trained are given the power to inflict pain on others. The first principle of medicine is do no harm. That's clearly being violated here."[3] These statements seemingly ignore or demonstrate a lack of awareness of the training programs and the many safeguards that are in place.

1. Labeling & Associated Personnel Training

The labeling of the cleared GED states that The GED should be used only by or under the supervision of an appropriately licensed professional as part of an overall therapy program. (see User Manual, page 3, provided in **Attachment 2.**]

21 C.F.R. §801.109 applies conditions for devices deemed to not be safe for use except under the supervision of a practitioner licensed by law to ***direct*** the use of such device, and hence for which "adequate directions for use" cannot be prepared. Specifically, these devices are exempt from FDA's requirements to provide adequate directions for use provided that the device is:

- In the possession of a person, or his agents or employees, regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device; **or**

- In the possession of a practitioner, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device […]

By use of the disjunctive word "or", FDA does **NOT** require that prescription use devices only be administered by licensed practitioners, such as physicians or nurses. Rather, the regulations allow that such devices to be used by manufacturers or their agents or employees.

As was briefly explained at the April 24, 2014 meeting, not all JRC personnel who are authorized to administer an application of the GED are licensed practitioners. However, per 21 CFR § 801.109, they are not required to be. Nonetheless, everyone who is authorized to activate the device is ultimately under the supervision of a Ph.D.-level clinician and the treatment is approved by a physician who is on call if needed. Indeed, there are many prescription use medical devices that are not administered directly by a physician or trained practitioner. Many are even authorized to be used by the patient in a home care setting. See e.g., bone growth stimulators, TENS devices, lasers for hair removal. Any statement or implication that JRC is putting the safety of its patients at risk by authorizing use of the GED by non-licensed practitioners is not only specious, it is based on misinformation and a lack of a basic diligence to obtain or understand JRC's training requirements. The following summarizes the training requirements for JRC's direct care personnel in order to be authorized to apply therapy with the GED:

[3] April 24, 2014 Neurological Devices Panel Meeting, Transcript, p. 309

- Per JRC Policy on Pre and Post Service GED Training (**Attachment 3**), newly graduated direct care staff are restricted from working with students who are court approved for the use of the GED as part of their treatment plan.

- During the employee's pre-service training, the employee receive 8 hours of instruction on the use of the GED, and must demonstrate, within the confines of Training Center, the ability to properly test and change GED batteries, and how to administer a GED application, and how to identify and verify a behavior that has been targeted by the clinician for treatment.

- In order to "graduate" from pre-service training, the employee must also successfully complete a written exam pertaining to the GED instruction received, and receive a score of 100%.

- Once the employee passes the exam, they are scheduled to work with students who do not receive GED as part of their treatment plan. During this time, the employee is evaluated daily on JRC policy and procedure, as well as their interactions with students and general performance. The employee primarily works with patients not receiving GED therapy during this time, though may assist in the care of patients using the GED. At the end of the three month period, supervisory staff will determine whether or not the staff member is qualified for additional training to become certified to use the GED device.

- After this three month period, with recommendations for several supervisors, the employee will receive an additional 8 hours of classroom training on use of the GED. This training includes instruction on the use of both the GED-3A and the GED-4.

- Per this training, the employee must demonstrate, within the confines of the Training Center, and with 100% accuracy, the ability to properly test and change GED batteries, identify and verify a behavior that has been targeted by the clinician for treatment, and administer a GED application.

- If the employee does not demonstrate the required skills with 100% accuracy, they will be placed on probation for one month and continue to work only with students who do not receive GED as part of their treatment plan. During this one month probationary period, the employee will be given two additional opportunities to demonstrate skills with 100% accuracy. If the employee is unable to meet the criteria after this probationary period, the staff's employment will be terminated.

- Each employee must also complete, with 100% accuracy, a written exam pertaining to the GED instruction received. If the employee does not score 100% on the written exam, they will be placed on probation for one month and continue to work only with students who do not receive GED as part of their treatment plan. During this one month probationary period, the employee will be given two additional opportunities to complete the written exam with 100% accuracy. If the employee is unable to meet criteria after this probationary period, the staff's employment will be terminated.

- Once the employee has completed the 8 hour training, and meets the required criterion, they will be scheduled to work with all students, including those who do receive GED as part of their treatment plan, on a probationary status.

- A trainer or designee (School Supervisor, Programming Director, or Director of Quality Control) must observe the employee for a minimum of one month and a minimum of 12 shifts. During this time, the employee will be allowed to observe and verify GED battery testing and changing procedures, identify behaviors that have been targeted by the clinicians for treatment, and observe and verify GED application procedures. The employee, under the supervision of a "GED Certified" staff, will also be allowed to test and change GED batteries, , and administer a GED application. .

- After above mentioned period of time, a trainer or designee will attest that the employee has demonstrated the competencies required to receive "GED Certification", which indicates that the employee is now able to test and change GED batteries, and administer GED applications. This training process takes at least 6 months to complete.

- If the trainer believes that an employee requires further supervision, the employee will be placed on probation for one month and continue to work, under the supervision of a "GED Certified" staff, with all students, including those who do receive GED as part of their treatment plan. During this one month probationary period, the trainer or designee will continue to monitor the employee. If, after this period of time, the trainer or designee still does not believe employee is ready to receive "GED Certification", the staff's employment will be terminated.

In addition, JRC requires annual recertification and training to use the GED. Specifically:

- Each employee must receive an annual 3 hour re-certification in which the employee will demonstrate, within the confines of the Training Center, the ability to properly rotate GED electrodes, test and change GED batteries, identify and verify the occurrence of a behavior targeted by the clinician for GED treatment, and, and how to administer a GED application.

- The employee must also complete a written exam with 100% accuracy. If, during annual re-certification, the employee does not score 100% on the written exam, they will be scheduled to come back in 1 week to take a second attempt. If they do not score 100% accuracy on the second attempt they will be placed on probation for one month. Employees who do not achieve 100% on the exam are not permitted to deliver GED therapy.

FDA's regulations (21 C.F.R. §801.109) also require that the device labeling bear information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended. This information also is to be provided in promotional pieces, which are considered to be device labeling. As noted above, JRC has not made this device available for sale and does not plan to do so. Nonetheless, pages 3-4 of the User's Manual identify all Warnings, Cautions and Contraindications associated with the use of the GED. *See* **Attachment 2**.

Based on the foregoing, JRC firmly believes that its personnel who administer applications of the GED are sufficiently trained to do so. This training is multi-step, involves significant oversight, requires demonstration of competency, and annual re-certifications. This training also goes well above and beyond the requirements of 21 C.F.R. § 801.109. The GED User's Manual also is fully compliant with FDA's labeling requirements for prescription use only devices. Nonetheless, as noted above, JRC would be willing to enhance its labeling to address any of FDA's concerns.

C. Prescribing and Utilizing GED Therapy

Certain panel members also appeared to have a fundamental misunderstanding regarding when a skin-shock was administered. The panel members heard anecdotal stories regarding the administration of skin-shocks related to minor actions such as a patient raising his or her hand, getting out of a chair, or talking out loud in class. JRC assures the agency that these instances are taken out of context and therapy with the GED device relates only to the patient's prescribed behaviors for self-injurious, aggressive, and other harmful behaviors.

As Nathan Blenkush, Ph.D., BCBA-D, described during the panel meeting, each patient has an individual treatment plan which is developed and supervised by JRC PH D-level clinicians. This treatment plan is based on the patient's health records from previous institutions and evaluation and assessments performed by JRC clinicians upon the patient's arrival at the Center. Each treatment plan is patient-specific based on their specific medical conditions, including any SIB, aggressive, and other seriously harmful behaviors. The treatment plan is designed based upon evidence-based principles of applied behavior analysis. As previous described, the vast majority of patients are treated at JRC with positive behavior support therapies alone. For patients exhibiting self-injurious, aggressive and other harmful behaviors that are not being sufficiently or safely controlled with positive behavior support therapies and medications, JRC clinicians may choose to introduce aversive therapy with the GED device to the behavioral treatment plan, provided that all procedural controls are met to begin this therapy, and only after other treatment therapies have been unsuccessful in treating SIB and aggressive behaviors. In these cases, the patient's treatment plan is revised to address how the GED device would be used to limit the patient's self-injurious, aggressive and other harmful behaviors, including identifying the specific behaviors that will be treated with the GED device. This treatment plan would be reviewed and approved by various persons including the patient's legal guardians, peer review committee, a human rights committee, school district or state agency that referred the patient to JRC, and a Massachusetts probate and family court. On average, patients are treated for 12 months with only positive behaviors support therapies at JRC prior to introducing therapy with the GED device

As the goal of the therapy with the GED devices is to limit occurrences of a patient's health dangerous behaviors, it is important to curb the actions prior to the patient causing harm to themselves or others. Based on clinical assessments of the patients and JRC's experience with the specific patient over the months at JRC receiving treatment based on positive behavior reinforcement, JRC treatment staff and clinicians are familiar with the specific precursor behaviors to their health-dangerous behaviors. Accordingly, the patient's treatment plans which involve therapy with the GED device prescribe delivery of the aversive stimulus upon the patient exhibiting one of

the identified precursor behaviors in addition to the aggressive and/or health-dangerous behavior which initially prompted prescribing treatment with the GED device.

A stimulus is delivered to the patient only when one of the clinician-prescribed behaviors or pre-cursor behaviors has been directly witnessed by a Direct Care Staff member and confirmed by another staff member. In order to ensure that the behavior is associated with the aversive stimulus, and therefore the patient becomes conditioned to learn to avoid this behavior, the staff member must deliver the stimulus quickly after witnessing and confirming the behavior. JRC's procedure manual explicitly states that no delayed stimulus may be delivered to a patient.

For certain patients, the GED-3A does not prove to be sufficiently effective in reducing the patient's aggressive or self-injurious behaviors to ensure his or her safety or the safety of others. The clinician may then choose to introduce the GED-4 device, which has increased output parameters to strengthen the aversive stimulus delivered to the patient. Importantly, the GED-4 is applied using to the same principles and procedures as the GED-3A, and has always been found to be more effective than the GED-3A in reducing the target behaviors without increased side effects. Moreover, any transition from the GED-3A to the GED-4 requires a court order. In other words, any such change is not just implemented by JRC or a treating physician. Rather, all parties required to approve initial use of the GED are apprised of and can object to a treatment plan with the GED-4.

While certain panel members raised some concern regarding increasing the level of stimulus for refractory patients, this is no different than common prescribing techniques for prescription medication. Physicians often increase dosages of medication where a patient does not respond to an initial limited dose or only demonstrates mild improvement. The increase in any dosage regimen, whether for a prescription medication or the GED device, is performed in the clinician's discretion under the practice of medicine and must be approved by the Court, parents and others, as indicated above. .

Notably, <u>all</u> patients who have been treated with the GED device have demonstrated a decrease in their self-injurious, aggressive, and other harmful behaviors. For patients receiving therapy with the GED-4 devices following treatment with the GED-3, there is a significant difference in the decrease of behaviors experienced with the two devices, demonstrating that an increase in 'dosage' is effective. Records for all 69 patients currently being treated at JRC with the GED devices are provided in a separate submission to the docket, submitted on June 24, 2014.

D. Pain Levels

Certain panel members also raised concerns regarding whether the GED device delivered a painful stimulus and further that pain levels can vary considerably across individuals. During FDA's review of the original 510(k) notice for the cleared GED1 device, JRC presented data on pain perception levels in order to support clearance of the device. FDA concluded that the device stimulation levels were acceptable and substantially equivalent to the predicates and cleared the device.

In addition to this data, further information is available in the literature to address the general range of pain levels associated with DC current, such as that delivered by the GED devices.

	DC	AC, 60 Hz
Perception of stimulation - Men - Women	5.2 mA 3.5 mA	1.1 mA 0.7 mA
Painful shock, muscle control maintained - Men - Women	62 mA 41 mA	6 mA 9 mA
Painful shock; "let go" range - Men - Women	76 mA 51 mA	16 mA 10.5 mA
Severe pain, difficulty breathing - Men - Women	90 mA 60 mA	23 mA 15 mA
Possible heart fibrillation after 3 seconds	500 mA	100 mA

- Tony R. Kuphaldt. Lessons In Electric Circuits, Volume1, Chapter 3, 2004
- Charles F. Dalziel, Deleterious Effects of Electric Shock, p. 24. Presented at a meeting of experts on electrical accidents and related matters, sponsored by the International Labour Office, World Health Office and International Electrotechnical Commission, Geneva, Switzerland, October 23–31, 1961

While JRC designed the device intending that it does not deliver severe pain, the GED device is intended to deliver an aversive stimulus. By its definition and for the treatment to be effective, the GED skin-shock must be unpleasant in order to have a deterrent effect. That being said, while the stimulation may be considered painful by some patients, the skin-shocks do not cause impairment to any body functions or damage to any bodily structures of the patient whereas, before treatment with the GED devices, the patient are causing themselves severe and ongoing pain, injury and disfigurement from their self-mutilation and aggression. Further, there are no confirmed reports or confirmed medical evidence that patients have any negative psychological side effects related to any discomfort experienced due to therapy with the proper use of the GED devices. There are, however, many reports of positive side-effects from the GED devices such as the elimination of pain and injury from self-abuse and dramatically improved affect due to the patient's ability to engage in education, independently spend time with family and friends and integrate into the community. These positive side effects have been readily apparent in all patients at JRC both communicative and non-communicative.

JRC further recognizes that literature discusses the impact of perception of control on reported pain levels. [4] There are recognized means to assess pain levels in individuals, including uncommunicative patients and children. For example, skin conductance has been demonstrated to be an evaluator of pain in uncommunicative patients, including children.[5,6] The Center is willing to discuss this issue further with FDA, in particular, how these assessments could be integrated into a clinical study of the devices.

[4] Delitto et al. A Study of Discomfort with Electrical Stimulation, PHYS THER. 1992; 72:410-421

[5] Hullet et al. Monitoring electrical skin conductance: a tool for the assessment of postoperative pain in children? Anesthesiology. 2009 Sep;111(3):513-7.

[6] Gjerstad AC, et al. Skin conductance versus the modified COMFORT sedation score as a measure of discomfort in artificially ventilated children. Pediatrics. 2008 Oct;122(4):e848-53

E. Misapplications and Spontaneous Activations of the GED

As explained by JRC representatives during the April 24, 2014 panel meeting, there have been rare instances where unintentional skin-shocks have been delivered to patients. These can come in the form of a misapplication by a JRC staff member (accidental application, or application to the incorrect patient); a spontaneous activation of a unit; multiple activations; or patient to patient activations.

The occurrence rate of these types of events is extremely low. Based on JRC trending data dating back to 1991, the overall occurrence rate of misapplications and spontaneous activations is less than 0.005 when compared to total contingent applications. Monthly data show that the highest occurrence rate in any given month (September 1991 – March 2014) was less than 0.012. Accordingly, even though such events have occurred, the occurrence rate is exceptionally low.

JRC also tracks and trends every occurrence of a misapplication and spontaneous activation. Moreover, JRC submits quarterly reports to JRC's court-appointed monitor, Dr. Daignault. In addition, a copy of the reports is sent to each of the attorneys representing JRC students/patients. These reports provide a narrative description of the events that have occurred in the subject quarter, as well as the results of JRC's investigation into the underlying event. The reports also provide charts that identify the trends for misapplications by JRC staff, accidental/multiple and spontaneous activations, as well as a chart depicting the number of multiple and spontaneous activations compared to contingent activations. The most recent quarterly report is provided as **Attachment 4**.

JRC also has procedures in place to address misapplications and spontaneous applications. For example, and as noted above, after any skin-shock is delivered to a patient, each patient is evaluated by a nurse within 24 hours. A staff member also must visibly check the area of the body on which the electrode is located immediately after administration of the GED therapy. And, as addressed in greater detail above, no patient has ever been injured or harmed as a result of a spontaneous activation, nor is such an event likely to result in a serious injury upon recurrence.

Regarding individual units involved in these types of events, per JRC's complaint handling procedure, after JRC becomes aware of any such event, it is promptly handled in accordance with JRC's complaint handling procedure, QMS-035, *Complaint Handling* (**Attachment 5**), and documented on QMS-035.2, the *Complaint Reporting Form* (**Attachment 5**). In addition, a complete investigation of each event, including a determination of the root cause is conducted in accordance with QMS-035 in tandem with QMS-013, *Root Cause Investigation* process (**Attachment 6**). Those procedures, which are intended to be used together, ensure that all GED related events, including misapplications and spontaneous activations are properly evaluated in accordance with the requirements of 21 CFR § 820.198, as well as 21 C.F.R. Part 803. Specifically, QMS-035 Section 2, *Complaint Evaluation*, describes the process used for evaluating complaints to determine the need for further investigation, and assessing the complaint for reportability. Section 2 of QMS-035 further describes how to document this evaluation on QMS-035.2, *Complaint Reporting Form*. If further investigation is determined to be required, QMS-035, section 3, Complaint Investigation, directs the investigator to QMS-013, *Root Cause Investigation*. Section 3 of QMS-035 further describes how to document this investigation on QMS-035.2, *Complaint Reporting Form*.

JRC is continually updating its procedures and manuals in order to further ensure the safety of its patients. From a technical perspective, and as is described in more detail below, JRC has retained a third party to re-design the GED. Among other things, the newly designed versions of the GED (GED-3B and GED-4B) have several design features that are intended to even further reduce the likelihood of misapplications and spontaneous activations. For example:

1. The modified GED Stimulus Generator performs a self-test immediately upon connecting the GED Stimulus Generator Battery. The self-test will validate the Stimulus Generator output voltage, current, and stimulus duration. A self-test failure will result in the system being permanently disabled.

2. The GED Stimulus Generator and Remote Activator utilize Bluetooth transceivers that are uniquely paired during manufacture. These components can only function as a pair and will not function with any other GED component. If a Remote Activator is lost the rest of that GED's components will not operate.

3. GED operation requires confirmation of an activation request to mitigate erroneous activations. When the "Activate" button is pressed on the GED Remote Activator, a stimulus is not delivered to the subject until the operator/therapist presses the "Confirm" button.

4. All connections of the GED Stimulus Generator, Remote Activator, and their corresponding Batteries are keyed and labeled to prevent improper connection between the components or to line voltages. Additionally, the connections are concealed after the Batteries have been properly assembled into both the Remote Activator and Stimulus Generator.

5. The GED Stimulus Generator contains a fuse to protect the subject in the event there is a short circuit or current overload caused by malfunction. <u>In ordinary operation, there should never be a short circuit or current overload.</u>

6. The modified GED system includes a Low Battery Lockout. In the event that the GED Stimulus Generator Battery or the Remote Activator Battery has been allowed to discharge to 10% of battery capacity the unit will disable and prohibit activations.

7. The GED limits the number of stimulus activations by temporarily disabling itself once the number of activations has exceeded a specified maximum for a given time period. Stimulation activation is limited according to the following table.

Frequency of Activations
5 Stimulations per Minute
10 Stimulations per Hour
20 Stimulations per Day (24 Hours)

8. The GED has the ability to identify when the activated stimulus was successfully delivered and will notify the operator/therapist with an indicator LED and an audible beeper.

Although a description of certain of these enhancements has been provided to FDA as part of a 510(k) pre-submission (Q130112) dated February 1, 2013, JRC unfortunately has not been able to implement these modifications due to FDA's delay in 510(k) discussions with JRC.

To address the issue of misapplications of the GED by JRC personnel, JRC has updated its procedures in response to past issues to prevent misuse. Specifically, in 2007 JRC updated its procedures for to include the following requirements for application of the GED:

- Prior to application of the GED stimulus, the applications must be verified with another staff member

- JRC staff members, including but not limited to, Video Monitoring staff, Case Managers, and Clinicians, are **not** authorized to direct another staff member to administer consequences if the person so directed did not witness the behavior.

- The DVR Monitoring office is **not** authorized to call staff and instruct staff to consequate GED behaviors.

- DVR Monitoring staff **cannot** authorize staff to give additional numbers of GED consequences.

- Only a JRC-authorized Clinician can authorize any GED application beyond increments of 10 per day (meaning that after the patient has received 10 applications the clinician must be notified and must authorize the administration of further GED applications, again after 20, etc.).

- Employees are not allowed to follow a direction from anyone, even if it is represented to be approved by a clinician or JRC senior management, if it is inconsistent with the policies and procedures that the employee has been taught during the orientation training period or through other means. Staff are instructed to call JRC's Executive Director immediately if they are given instruction which they believe to be inconsistent with JRC policy and procedure. Staff should be alert to the possibility of hostile persons making unauthorized calls to JRC and impersonating JRC supervisors. Staff should not assume that JRC supervisors or co-workers are always carrying out their duties in accordance with JRC policies.

- Students receiving GED therapy may only reside at designated residences staffed with licensed staff.

F. Comments Regarding Medical Device Reporting, 21 C.F.R. Part 803

JRC would like to address certain of the comments raised by Dr. Steven Miles regarding JRC's compliance with FDA's Medical Device Reporting ("MDR") requirements of 21 C.F.R. Part 803. Specifically, JRC is referencing the discussion on the panel related to misapplications of the GED and whether those events constituted MDR reportable events. Dr. Miles expressed his opinion that JRC was not in compliance with 21 C.F.R. Part 803 due the lack of MDRs listed in FDA's MAUDE database. Moreover, when the JRC Executive Director Glenda Crookes responded that JRC had

indeed evaluated such events and determined that they were not reportable, and that FDA previously agreed with these determinations, Dr. Miles explicitly stated, "I do not believe you." Transcript at p. 263. He further characterized JRC's alleged failure to report such events as MDRs as violating FDA regulations. These false statements were unfortunately repeated by Dr. Miles in a television interview conducted by local Boston television news station FOX25, which aired in the Boston area TV market on Thursday, June 5, 2014.

JRC is very concerned with the potential adverse and biased impact that these statements may have had on other panel members. JRC firmly believes that the comments are the result of the panel not being adequately or accurately apprised of JRC's complaint handling policies and procedures and a misunderstanding of FDA regulatory requirements.

1. Regulatory Standard

Under FDA's MDR regulation, medical device manufacturers are required to report to FDA within 30 days whenever any employee receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer:

1) May have caused or contributed to a death or serious injury; or
2) Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

Important to the assessment of whether an event is reportable are the regulatory definitions. FDA defines a Serious injury as an injury or illness that:

1) Is life-threatening,
2) Results in permanent impairment of a body function or permanent damage to a body structure, or
3) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

With respect to assessing whether an injury meets the reportability standard, the regulations define "Permanent" to mean irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.

FDA also defines the term "Malfunction" as the failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the intended use for which the device is labeled or marketed.

In addition, to add clarity to what constitutes a reportable malfunction, the preamble to the regulation states that FDA considers a malfunction to be "MDR reportable" if, among other things, the chance of a death or serious injury occurring as a result of a recurrence of the malfunction is not remote.

2. The GED Has Never Caused or Contributed to a Patient Death or Serious Injury

As JRC has previously communicated to FDA, there has never been a death associated with the use of the GED. Rather, the only death that JRC is aware of involved an incident resulting from the removal of the GED due to New York regulations. Information on this event was provided in the May 14, 2014, letter (submitted to the docket on June 20, 2014**,** tracking number 1jy-8crx-wmd8).

As presented during the April 24 panel meeting, JRC acknowledged that in rare cases, mild erythema of the skin may result. This erythema is essentially a temporary redness on the surface of the skin. However, this erythema disappears within an hour to a few days. It also should be noted that less than 1% of applications result in <1mm lesion. There also may be brief, temporary anxiety just prior to the delivery of the application as well as occasional harmless avoidance responses (*e.g.*, tensing of the body, attempts to remove the electrode in some cases). Despite JRC's observation of these events, none of these sequelae constitute reportable events. Specifically, the erythema, or skin redness, clears up within a couple of hours or days. By no means is the erythema permanent, or otherwise an irreversible impairment or damage to a body structure such as the skin. Neither is the temporary skin redness considered to be life threatening. Indeed, JRC is not aware of, nor has experienced any patient who has sustained an injury from the GED which meets either of the first two prongs of FDA's definition of serious injury.

Regarding the third prong, even though the JRC registered nurses evaluate each patient after a skin-shock is administered, such an assessment is performed prophylactically in an abundance of caution and in the best interest of the patient per JRC procedures. As previously explained to the agency, every application of the GED device is documented and such documentation is made available to the patient's treating clinician, parent and funding agency for analysis. In addition, the patient's physical health is closely monitored by JRC's Medical Department and other staff to ensure that the patient suffers no harm from treatment with the GED device: 1) direct care staff perform body checks on all patients each morning and evening; 2) all applications of the GED device are reported to nursing staff who perform within twenty-four hours a body check on the patient receiving an application; 3) the site of the GED electrode is checked each hour as well as after each application, at which point the electrode is moved to another part of the skin; and 4) nursing care is provided on a twenty-four hour, seven days per week basis. JRC requires these assessments in order to be transparent with patient parents as well as Massachusetts state agencies, including the Massachusetts Department of Developmental Services ("DDS"), Massachusetts Department of Early Educational Care, the Massachusetts Department of Children and Families, and the Disabled Persons Protection Commission. These assessments are conducted by JRC policy and not the result of necessitated medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

Regarding allegations of injuries by third parties, it is noteworthy to point out that no patient injuries or adverse events have been reported to FDA as voluntary MDRs by any current patients, former patients, current or former treating physicians or parents or physicians.

As noted during the panel meeting, JRC has indeed filed one MDR to FDA in an abundance of caution. In that case, it was ultimately determined that the patient's alleged injury could not have been the result of a GED application. In that case, what appeared to be a burn on a patient's arm

was investigated by JRC as a potential injury. JRC's evaluation of the reported injury recorded on Trouble Report #9938 on June 26, 2010 determined that, as the patient had not received any GED applications in the previous seven days, the "apparent" second degree burn could not have been caused by, and therefore was not related to a GED application. In response to concerns raised in FDA's June 29, 2012, Untitled Letter issued to JRC, a follow up investigation into this event was conducted. As part of JRC's follow-up investigation, the registered nurse who completed the first Nursing Note was interviewed. The nurse noted that a "dime-sized" burn or injury is not consistent with the size of an electrode; a dime is approximately 1.8 cm in diameter, and an electrode is approximately .9 cm in diameter, or ½ the size. The nurse further stated that in the seven years he has been at JRC (three as a nurse), he had never seen a GED application result in a second-degree burn.

3. Malfunctions

As addressed in more detail above, JRC is aware of, and has acknowledged to FDA, that in very rare circumstances, the GED may errantly deliver an unintended skin-shock to a patient. These misapplications have occurred when a trained JRC staff representative intends to deliver a skin-shock to one student and the GED for another student is activated. Other times, a unit may spontaneously activate.

Although JRC acknowledges that these rare misapplications meet FDA's definition of a product malfunction, they are in no way reportable malfunctions. These events due indeed constitute malfunctions as the GED is not intended to spontaneously activate or deliver a spontaneous skin-shock. Nonetheless, not all product malfunctions are required to be reported to FDA. Rather, only those malfunctions that are likely to cause or contribute to a death or serious injury upon recurrence are required to be reported as MDRs. In this regard, JRC does not consider these types of events to be reportable. Specifically, a misapplication has never led to a patient injury and therefore certainly not death or serious injury, as that term is defined by FDA. Moreover, for the reasons set forth in the serious injury analysis above, there is no reasonable likelihood of resultant death or serious injury from a misapplication of the GED (addressing the "upon recurrence" prong). Based on more than 20 years of patient data, and consistent with the reports in the medical literature regarding the risks of ESDs generally, the chance of a patient death or serious injury occurring as a result of a recurrence of a misapplication malfunction is remote, if not less than remote.

4. Impact of Statements

Based on the foregoing, JRC respectfully disagrees with the statements made by Dr. Miles at the April 24, 2014 panel meeting and publicly to the media as these statements are, without question, false. JRC is concerned that the FDA moderators at the panel meeting allowed Dr. Miles's comments and line of questions to proceed to the point that they did, even though FDA's inspections and subsequent compliance related correspondence have focused on the MDR reportability of events involving the GED. JRC respectfully points out that at other times during the panel meeting, FDA representatives advised panel members to not focus on issues that were the subject of ongoing compliance matters involving JRC. For example, discussion of FDA's 2000 inspection of JRC and practice of medicine determination were quickly terminated by the agency representatives. Accordingly, JRC is very concerned with the impact that Dr. Miles' comments and incorrect application of the MDR standard may have had on other members of the panel – particularly

because his statements were made during the panel's deliberations when members were voting/responding to FDA's questions pertaining to the safety of the GED.

Complaint/MDR Related Corrective Actions

To ensure that the record accurately reflects JRC's actions taken to address the MDR related issues identified in FDA's 2011 inspection, the following summary is being provided. During FDA's 2011 inspection, the agency indicated that JRC's complaint handling and MDR procedures may not have been sufficiently prescriptive from an FDA regulatory perspective. In JRC's various responses, it was explained that JRC indeed had processes in place with respect to how malfunctions and potential injuries were evaluated. Regarding the assessment of potential injuries resulting from the delivery of a skin-shock, these specific requirements are discussed above.

Nonetheless, JRC acknowledged that certain corrective and preventive actions would be implemented to address FDA's inspectional observations and concerns. Throughout JRC's various correspondences with FDA over the past two years, JRC has explained to the agency, and provided supporting documentation, regarding JRC's corrective actions and enhanced processes to handle complaints and assess them for MDR reportability. These actions include:

- Revision of JRC's Procedure for Medical Device Reporting to ensure compliance with the current requirements of 21 CFR Part 803.
- Revision of JRC's Complaint Handling procedure to ensure full compliance with the requirements of 21 CFR §820.198.
- Enhancement of QMS-013, *Root Cause Investigation* process
- JRC performed a retrospective review of performance complaints covering the period of time from January 2009 through September 2011. Per this review, JRC evaluated each complaint for reportability in accordance with the standards set forth in FDA's MDR regulations, 21 C.F.R. Part 803. Documentation of completion of this review was provided to the New England District on November 15, 2011, and is hereby provided again with this response. (**Attachment 7)** All complaints identified since this review have been handled in accordance with JRC's revised *Complaint Handling* and *Medical Device Reporting* procedures, QMS-035 and REG-001, respectively.

To date, JRC has completed the implementation of all of the foregoing corrective and preventive actions.

G. Chronology and Status of Redesigned GED and Associated 510(k)

JRC received 510(k) clearance for the first GED model on December 5, 1994 (K911820). As discussed above, and has been previously discussed with the agency, JRC implemented modifications to the cleared device design through the letter-to-file process, concluding that the modifications could not significant impact the safety or efficacy of the device.

FDA reviewed the modified devices during its on-site inspection in 2000 and concluded that the GED devices were not subject to FDA's 510(k) requirements, and the device is considered to be within the practice for medicine. However, FDA subsequently and arbitrarily changed its position, without any

explanation or opportunity for comment, that clearance of a new 510(k) is required for use of the GED-3A and GED-4.

JRC provided several submissions to the agency in response to the Untitled Letters and Warning Letter. Rather than challenge the agency's sudden change in policy, largely because this determination has yet to constitute a final agency action, JRC worked cooperatively with the agency and initiated a comprehensive corrective plan. Part of that plan included the re-design of the GED devices and commitment to submit a new 510(k) for the redesigned GED. In fact, FDA even suggested that JRC re-design the GED during a July 13, 2011 meeting at the Boston District Office (and during which other FDA representatives participated via telephone).

JRC undertook the redesign of the devices, at great expense, subsequent to these exchanges with FDA, to further enhance the safety profile of the device and to ensure conformance to FDA's current requirements, expectations and recognized consensus standards. However, a new 510(k) notice has not yet been filed for these updated devices in accordance with certain communications with FDA. While the 510(k) notice was ready for submission, at a January 9, 2013, meeting, the agency requested that JRC first file a pre-submission in order to discuss the content of the 510(k) notice. In an effort to work cooperatively with FDA, the Center filed this pre-submission (Q130112) on February 1, 2013. A meeting was scheduled by FDA for March 25, 2013. In advance of the meeting, the agency requested further detailed information regarding the device output, which the Center provided. However, this meeting was cancelled by the agency five days prior to the meeting. Despite additional requests from JRC to schedule this meeting, the agency never responded with a new meeting date and did not provide JRC with comments on the pre-submission materials in accordance with FDA's guidance document stating that feedback should be provided within 90 days. Since FDA had specifically requested that the company submit a pre-submission to provide the Agency with the opportunity to provide comments on the content of the 510(k) notice prior to filing such notice, and since the agency never provided such comments, JRC never filed the 510(k) notice to address the newly designed devices. It should be noted that JRC also has not used the modified devices that will be covered by the proposed 510(k) notice. No further communication from FDA was received regarding the GED devices at all until notification of the April 24, 2014, panel meeting was received.

JRC is prepared to file the 510(k) notice for these modified devices whenever it will be notified by FDA that the agency is now ready for such submission.

These newer models of the GED device retain the primary specifications as the originally cleared GED1 device, but have been designed to ensure full compliance with FDA's current requirements, expectations and recognized consensus standards and to incorporate additional safety features. More specifically, the redesigned devices have the same general output specifications and performance characteristics as the cleared GED 1 and the devices which are currently in use, as detailed in the following table.

	GED1	GED 3A	GED 4	GED3B	GED4B
Electrodes	Concentric electrodes or set of distanced spread electrodes	Concentric electrodes or set of distanced spread electrodes	distanced spread electrodes	Concentric electrodes or set of distanced spread electrodes	distanced spread electrodes
Skin contact area	Ring: 3.64 cm Spread: 4.30 cm			Ring: 22.2 mm Spread: 9.5mm	Ring: 22.2 mm Spread: 9.5mm
Amps	11.98 mA rms	15 mA	41 mA	12 mA	24 mA
DC voltage		13.88 V	13.37 V		
RMC AC voltage	60 V-RMS (Range: 51-69 V-RMS)	63.5 Vrms	64 Vrms	60 ± 9 V RMS	120 ± 15% V RMS
Waveform	Square	Square	Square	Square	Square
Frequency	80 Hz (Range: 78.5 Hz – 81.5 Hz)			80 Hz pulses	80 Hz pulses
Duty cycle	25% (Range: 23.5% – 26.5%)	23.5 – 26.5%	23.5 – 26.5%	25% ± 1%	25% ± 1%
Pulse repetition rate		78.5 – 81.5 Hz	78.5 – 81.5 Hz		
Duration of stimulus	1.75 – 2.0 seconds	1.75 – 2.0 seconds	1.75 – 2.0 seconds	1.75 – 1.95 seconds	1.75 – 1.95 seconds
Delay in activation	1 second delay			0.5 second minimum delay. Two step activation requires two separate buttons to be pressed in sequence	0.5 second minimum delay. Two step activation requires two separate buttons to be pressed in sequence
Range of remote activation	50 feet	300 feet	300 feet	10 meters (33 feet)	10 meters (33 feet)
Battery:	12 VDC	NiMH	NiMH	6 cell	6 cell

	GED1	GED 3A	GED 4	GED3B	GED4B
	Lead Acid			Lithium Ion, internal to the Stimulus Generator case	Lithium Ion, internal to the Stimulus Generator case
Stimulation Indicator:	LED remains lit for 1 minute			LED remains lit for 2 minutes	LED remains lit for 2 minutes
Safety Features	Stimulation alert LED	Stimulation alert LED Low Battery Alert	Stimulation alert LED Low Battery Alert	Stimulation alert LED Low Battery Alert Stimulation Activation Delay 2-step activation Activation limits Active current and voltage monitoring	Stimulation alert LED Low Battery Alert Stimulation Activation Delay 2-step activation Activation limits Active current and voltage monitoring

The GED3B and GED4B also include additional features, as follows, to further ensure the safety of the aversive therapy.

- Hardware fault detection and calibration upon startup
- 2-step activation to deliver stimulus
- Stimulation activations that are limited in frequency:
  - 5 stimulations per minute
  - 10 stimulations per hour
  - 20 stimulations per 24 hours
- Minimum off time of 10 seconds between activations
- Compliance with IEC 60601

JRC has previously submitted detailed information regarding the performance of the newly designed devices in a pre-submission (Q130112). This submission included detailed device descriptions, newly designed user manuals and extensive verification testing. JRC believes that the totality of the safety and efficacy data on the existing patients, the historical clearance of the previous version of

the GED device (K911820), and the detailed design and testing information submitted in the pre-submission (Q130112) provide sufficient evidence to support the safety and efficacy of the device in compliance with current FDA expectations.

However, given the discussions at the recent April 24, 2014, meeting of the Neurological Devices Panel, JRC is willing to participate in a clinical study to provide even further safety and efficacy information regarding the devices. JRC further proposes that any such study evaluate the new versions of the devices, the GED-3B and GED-4B, as noted in the May 14 letter to Dr. Pena.

H. Comments referencing the Statements made by the U.N. Special Rapporteur on Torture

During the April 24 panel meeting, many of the public presenters looked to statements by the U.N. Special Rapporteur on Torture as validation of their ideological beliefs against use of aversive therapy and the GED. Indeed, even the FDA's comments referred to statements made by the U.N. Special Rapporteur on Torture. JRC is deeply concerned with FDA's reference to the U.N. Rapporteur in its statement and presentation and is concerned with the impact bias that this reference may have had on panel members, and continues to have on the agency.

As noted by FDA, in 2010, Mental Disability Rights International, or MDRI, an international human rights group with no government affiliation or other indicia of credibility, published a report on the use of the GED at JRC. MDRI also called on the United Nations Special Rapporteur on Torture or other Cruel, Inhuman or Degrading Treatment or Punishment to initiate an enquiry into JRC practices. In response, the UN Special Rapporteur wrote a letter, dated June 11th, 2012, to the United States Department of State, expressing concerns about JRC's aversive conditioning program. Neither the MDRI nor the UN have ever visited JRC or evaluated the GED device. The UN does not have the jurisdiction to conduct investigations in the United States. It made no effort to interview the hundreds of parents, JRC clients and former clients who have stated publically many times that the GED devices save lives and have not caused any harm. Their so-called "reports" are nothing more than regurgitation of the false rumors about the JRC and the GED that circulate on the internet. This request was forwarded to the Justice Department. A follow-up investigation also was initiated by a second UN Special Rapporteur in 2012.

In light of the timing of FDA's sudden inspection of JRC in 2010 – more than ten years after advising JRC that the GED device did not require 510(k) clearance as its use was governed by the practice of medicine, it appears that FDA's enforcement actions undertaken against JRC have been triggered by false allegations of torture or otherwise at the direction of other U.S. governmental agencies. Not only was FDA's sudden change in regulatory policy regarding the GED arbitrary and capricious, nowhere in the statutory standard for banning a device is torture mentioned or even considered. Although JRC acknowledges that FDA is to look at information "from all sources", any reliance on the U.N. Rapporteur's comments is misguided due to the inherent bias and abundance of manipulated statements, misinformation, and lack of credible or verifiable evidence inherent throughout the underlying appeal filed by MDRI upon which the Rapporteur's comments are apparently based.

To ensure that the FDA Docket is balanced and complete with respect to the U.N. Special Rapporteur on Torture's comments, JRC hereby submits the following:

- The underlying appeal to the U.N by MDRI is full of misinformation, anecdotal and unconfirmed information, as well as grossly distorted comments taken out of context from JRC's website.

- Almost all of the persons listed as sources for the information in the MDRI Report have testified in Massachusetts for bills that would, if passed, ban the use of aversive therapy devices. After trying, unsuccessfully to pass such bills for many years, the proponents of these bills appealed to the United Nations Rapporteur on Torture for help with their political and philosophical cause.

- Because of MDRI's strong philosophical opposition to the use of the GED, what they refer to as an "investigation" was simply not that. Representatives from MDRI have never visited JRC, never sought to discuss their concerns with JRC's clinicians or staff, have never spoken to the hundreds of parents who are pleased with what JRC has been able to accomplish for their children, never advised JRC of their "investigation" or invited JRC to respond to their concerns, and have never interviewed current or former students who have been pleased with the results of their treatment at JRC, including the use of the GED.

- MDRI's "investigation" consisted largely of the following: finding and using unverified negative accusations available on the internet; taking selective quotations from the JRC website given by parents and students in support of JRC's use of aversives, and referencing sentence fragments out of context in order to make the authors appear to be negative toward JRC's treatment; soliciting information from an individual who, according to an August 29, 2006 police report, claimed to have placed a "whistle blower" inside JRC (none of the "insider's" allegations were ever confirmed); soliciting as many negative quotes as possible from persons who are opposed to JRC; accepting and publishing anonymous accusations without researching whether there was any truth to them; taking selective quotations from reports by a state agency that has a philosophical opposition to use of aversive therapy devices (and that is currently being sued by a group of JRC parents in the Federal District Court of Northern New York) without any reference to JRC's responses to those accusations, all of which are available on JRC's website; and presenting as facts, outdated, re-hashed, and long-since refuted accusations, some of which are now as much as 30-40 years old.

- As an example of the gross mischaracterizations, the appeal quotes one parent's statement on JRC's website as saying, **"I refused to allow the GED…" (p. 18)**. This is an example of MDRI distorting a very positive and supportive statement off of JRC's website and reciting it in isolation and thus out of context in order to make it appear to be saying something negative about JRC. This statement comes from the testimony of Ricardo Mesa, the father of a current JRC student. To illustrate how blatantly manipulated and out of context this quote is, the full testimony is reproduced

here and the words taken out of context are shown in bold font.[7] Notably absent from the words that the MDRI Report chose to quote are the words, "*What means something is that I have a daughter who has a life now…and is happy."*

> *I have a daughter, Nicole, who went to JRC in 2004. She's still at JRC in the adult services and she was diagnosed with autism and later Landau-Kleffner Syndrome. As the years went by she got progressively worse. She had brain surgery to remove the epilepsy, which helped with her receptive language. But her behavior continued to be extremely severe. To the point that she would constantly punch her eyes like this {demonstrates} constantly. And I used to be a martial Arts instructor and I used to block and there was no way you could block those punches. Those were hard punches to the eyes. She was doing about a thousand a week. We had to pad the entire room, in her bedroom, she lived with us, she still lives with us. We had to, um, we couldn't go anywhere, we couldn't go on vacation, we couldn't …. At nights we would hear her banging her head constantly, all night long. She would run out, pinching constantly, her face, her body her breasts, black and blue. You get the picture. She went to the May Center, she went to the LCDC Center, she went to Lighthouse, she went to Perkins School for the Blind, she went to the behavioral program, the neuro-behavioral program at the May Center. These are all excellent programs with very devoted teachers and excellent staff. They couldn't help her. They couldn't stop her. Finally, the Boston School District, the ETL suggested JRC because of some of the progress she had seen from some of the children and I went to see it. We decided to send her over there. And **I refused to allow the GED**. Because it just, it's so counter-intuitive, I love my daughter, so I refused to allow it. And they were fine with it. They allowed me to keep her in the school. They used other methods to try to keep her safe, the restraints, the arm splints and so forth. But Nicole was not making any progress. When she'd come home it was the same story. I agreed after a long time and the hardest day of my life was going before Judge Souten (sp) and asking for them to allow her to use the GED. I told my wife, "We will give them one month. If I don't see immediate progress, she's off it." They put her on the GED, she had a few applications the first day. A few days went by and she had one more. And from that point on she's had an application once every three months, two months and they were usually for very severe behaviors. I don't allow them to use it for any other type of behavior. That contradicts prior testimony {gesturing about someone behind him.} They are fine with it. They have not asked me to take her out of there. Because of that, now she gets one maybe once every year, six months. I mean it's been a long, long time. I can't even recall. She lives at home with us. At home she doesn't wear the GED. It's there in the house and I remind her, that if I see the antecedents, I tell her, "You're going to have to wear the*

[7] Testimony of Father of a JRC Student to Massachusetts Legislative Committee, October 27, 2009. Available in its entirety testimony at:
http://judgerc.org/StateHouseTestimonies/42.%20Ricardo%20Mesa%20State%20House%20Testimony%2011.4.09.wmv

> *GED." She's fine with it. She has to dress well to go to school. She takes really good care of herself. The staff is extremely loving to her. Always has been, that's one of the things I love. I know them well. My wife knows them very well. We've been able to go to a vacation to Florida every year and Virginia Beach, we are able to go to the movies, we are able to go to dinner together, we have a life. And she lives with us. And that's the way I want it. My biggest fear is that we'll lose all of this ground we've made. That she might return to those horrible days, when she was hurting herself so badly. She knocked out my wife a couple of times with headbutts, this was before the GED. And if she were to go back to that stage, it would be just a matter of time before we would have to put her in an institution, or, she wouldn't be able to live with us. So, you know, I really, I know there's a lot of emotion in all of this. A lot of these are articles that have been written, I spoke one time to a reporter all about my daughter and the Boston Globe and the only thing they did, was post "Torture Versus Love." Not one word about what I told them about my daughter was in that article. You can't believe everything you read. And there's a public outcry, against this and exaggerations about what they are doing at the school. I can't speak for anybody else, but I can speak for my daughter and for my life. And I am not a crazy person, or an uninformed person. I am an accountant and I am also an ordained permanent Deacon with the Archdiocese of Boston. I work very closely with Cardinal Law, I mean Cardinal Sean O'Malley. I studied psychology when I was in school. All of that doesn't mean anything. What means something is that I have a daughter who has a life now. I taught her how to ride a bicycle, who can go swimming, who can go on vacation, who goes to school and comes home and is happy.*

JRC's official response to the MDRI Report and appeal is provided as **Attachment 8**.

Contrary to the statements made by various persons and anti-aversive therapy organizations who spoke at the April panel meeting, the Special Rapporteur has NOT conducted an investigation of JRC. Indeed, the U.N. Rapporteur is not even authorized to conduct an investigation in the U.S. Rather, the U.S. Mission to the United Nations sought comment from the U.S. Department of State who appears to have requested that the U.S. Department of Justice address the issue.

On January 2, 2013, the U.S. Mission to the U.N. sent a letter to the Rapporteur on Torture apprising the Rapporteur of certain actions that have been undertaken in the U.S., both on the federal and state level. Specifically, that letter references actions undertaken by the Department of Justice, FDA, and the states of New York and Massachusetts. It is important to note that the responses sought, and provided back to the U.S. Mission do not appear to be based on an objective sampling. Rather, in addition to the FDA's December 6, 2012 Warning Letter to JRC, the only other information attached to the January 2, 2013 letter comes from a Massachusetts state Senator who is a long time and vocal opponent of JRC and the state of New York. Regarding the state of Massachusetts, it is unclear whether input was sought, or why information was not provided by any Massachusetts legislators who have previously supported the mission of JRC and opposed efforts to ban the use of aversive devices. In addition, even though 10 states currently send students to JRC for treatment –

including states that have banned the use of aversive therapy - the only other state from which information is provided is New York – a state that is currently involved in litigation against involving ESDs due to the state's efforts to cease use of the GED on its students. In that case, JRC has obtained court approved injunctions which allow the continued use of the GED on students sent to JRC from the state of New York.

Based on the foregoing, JRC believes that any reliance upon the U.N. report is misguided due to the inherent bias and lack of credibility and accuracy of the appeal itself and the apparent lack of balance provided in the official US response. Moreover, as noted above, any reliance on these statements and determinations falls outside of the standard to ban a device set forth in 21 U.S.C. § 360f (a) and should only serve only as anecdotal evidence of the philosophical, political, and controversial nature of the issues involved in the use of ESDs.

VI. Invitation to Visit JRC

As many unsubstantiated and speculative allegations and opinions were presented to the panel by interest groups and others who have never been to the school, JRC believes that it would be prudent for agency representatives to see first-hand how the GED is used, before making a decision to ban the only effective treatment available for this highly at-risk, refractory patient population. JRC welcomes FDA to come at any time and unannounced. It would be arbitrary and capricious for the FDA to ban a treatment device without visiting JRC, the only program using the devices, without reviewing over twenty years of medical and behavioral data on the devices' safety and efficacy and interviewing all of the JRC parents, students and former students, JRC consulting physicians, psychiatrists, psychologists, nurses and other licensed professionals who want to inform the FDA of all the life-saving benefits of the GED devices and how these students have never been harmed by the device in any way. There will be no legal justification for the FDA to intentionally avoid reviewing this evidence if it makes a decision to ban these devices.

List of Attachments

Attachment 1	Sample of Patient Nursing Notes
Attachment 2	GED-3A User Manual
Attachment 3	JRC Policy on Pre and Post Service GED Training
Attachment 4	Quarterly Report on GED Misapplications
Attachment 5	Complaint Handling Procedures QMS-035, *Complaint Handling* QMS-035.2, *Complaint Reporting Form*
Attachment 6	QMS-013, *Root Cause Investigation*
Attachment 7	Retrospective Review of Complaints Related to GED
Attachment 8	JRC's Official Response to the MDRI Report and Appeal

Attachment 1

Sample of Patient Nursing Notes

Attachment 2

GED-3A User Manual

Attachment 3

JRC Policy on Pre and Post Service GED Training

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Attachment 5

Complaint Handling Procedures
QMS-035, *Complaint Handling*
QMS-035.2, *Complaint Reporting Form*

Attachment 7

Retrospective Review of Complaints Related to GED

Attachment 8

JRC's Official Response to the MDRI Report and Appeal