ECKERT SEAMANS
ATTORNEYS AT LAW

Eckert Seamans Cherin & Mellott, LLC
Two International Place
16th Floor
Boston, MA 02110

TEL: 617 342 6800
FAX: 617 342 6899

Michael P. Flammia
617.342.6854
mflammia@eckertseamans.com

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VIA FEDERAL EXPRESS AND E-MAIL

Elizabeth H. Dickinson, Esq.
Chief Counsel
Office of the Chief Counsel
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Elizabeth.Dickinson@fda.hhs.gov

RE: Docket No. FDA-2016-N-1111;
Proposal to Ban Electrical Stimulation Devices Used to Treat Self-Injurious or Aggressive Behavior

Dear Ms. Dickinson:

We are writing on behalf of the Judge Rotenberg Educational Center, Inc. ("JRC") in connection with the above-referenced matter. On April 25, 2016, the U.S. Food and Drug Administration ("FDA" or "the Agency") proposed banning electrical stimulation devices ("ESDs") used to treat self-injurious behavior ("SIB") or aggressive behavior ("AB") (hereinafter, the "Proposed Ban"). In response, JRC submitted a comment (the "JRC Comment") objecting to the Proposed Ban.[1] JRC is writing this letter to provide the FDA with more information about the multiple factual and legal deficiencies that pervade the process the FDA has utilized in an attempt to ban ESDs, to address some of the specific procedural and substantive defects, to request

[1] *See* Comment from JRC, comment identifier FDA-2016-N-1111-1637 (Aug. 18, 2016) ("JRC Comment"). The JRC Comment shows, among other things, that the benefits of ESDs in a refractory SIB and AB client population far exceed the potential risks, which are minimal, and that the FDA has failed to meet the regulatory standard required to ban a device as set forth in the Federal Food, Drug, and Cosmetic Act ("FDC Act") Section 516 (21 U.S.C. § 360f) and 21 C.F.R. Part 895. *See* FDA-2016-N-1111-1637.

documents and information from the FDA, and to request an in-person meeting with your office to discuss this matter further. Shortly, and under separate cover, JRC will also provide a detailed response to a sample of the comments that were made in support of the Proposed Ban and which included erroneous, biased, misleading, and unreliable information.

In short, the Proposed Ban targets a single facility and manufacturer – JRC. It risks the lives and well-being of a very small, vulnerable population of severely disabled individuals, and continues a multi-year unfair, biased, and one-sided regulatory action. This proceeding is not the result of good faith, reasoned and scientifically sound agency decision-making – rather, it relies heavily on value/morality judgments, which the FDA lacks authority to make. It also targets a particular use of a medical device. As such, it interferes in the practice of medicine, exceeding a limitation that is set forth in the FDA's authorizing statute (commonly called the "practice of medicine exemption"). Further, it exceeds the FDA's statutory authority to promulgate a regulation banning a particular device, in that the FDA is proposing to ban a healthcare professional's particular use of a medical device.

An adjudicatory hearing before a neutral arbiter is required even if the FDA had the authority to implement the Proposed Ban. The Proposed Ban is the product of an informal rulemaking proceeding, through which the FDA has collected information (most of which is specific to JRC's practices) from outside sources and individuals. The FDA's Proposed Ban opened the door to hundreds of comments that appear supportive of the Proposed Ban but, in fact, are untrue or misleading and, therefore, provide no support at all. Nevertheless, the FDA has already shown a willingness to accept and cite misleading or false information to support its

Proposed Ban.[2] The result is a record rife with errors, false statements, misinformation, and unsupported assumptions, and any resulting rule must be deemed unsupported by reliable evidence, arbitrary and capricious.

Because the FDA is not using an adjudicatory process, the FDA provides no mechanism by which JRC can test the veracity or reliability of factual claims, or correct the record. Given the large volume of misleading or mistaken comments, JRC cannot counter every falsehood without an adjudicatory process. However, by identifying in this letter a sampling of the numerous errors in the comments to the Proposed Ban, JRC is putting the FDA on notice of the dangers and legal errors of both uncritically accepting these comments, and of failing to establish a mechanism to differentiate unfounded allegation from fact. As described below, the FDA's process has resulted in the submission of hundreds of comments that contain false or misleading information. JRC is submitting this letter so that the FDA will not mistakenly and inappropriately rely upon the incompetent, invalid, and misleading comments that were submitted to the Agency.

JRC strongly opposes the Proposed Ban and requests that the FDA immediately withdraw it. Even if the FDA believes further consideration of the Proposed Ban is warranted, JRC requests that the FDA hold a regulatory hearing "to obtain additional information before making a decision or taking action" in accordance with 21 C.F.R. § 16.1 that meets all constitutional requirements, and give appropriate consideration to less restrictive alternatives to a ban, including more precise labeling, a post-market surveillance study, and/or the establishment of special controls.

[2] *See* JRC Comment; JRC's April 14, 2014 comment, comment identifier FDA-2014-N-0238-0065, tracking number 1jy-8bjf-k0hb; JRC's June 23, 2014 submission, comment identifier FDA-2014-N-0238-0085, tracking number 1jy-8cu2-q3xq.

I. BACKGROUND

A. JRC

JRC is a residential special education school and adult treatment center, formerly known as the Behavioral Research Institute, which has been serving mentally ill and developmentally disabled children and adults since 1975, and was licensed by the Massachusetts Office for Children (n/k/a the Massachusetts Department of Early Education and Care) in 1977.[3] JRC has a current population of 255 clients, which population includes individuals with the severest forms of behavior disorders in the nation. JRC employs for their care 4 licensed psychologists, 5 doctoral-level clinicians, and 13 Board Certified Behavior Analysts (9 of whom are licensed applied behavior analysts).[4] Clients at JRC are treated with standard of care clinical methods and provided educational and vocational opportunities and a safe learning and living environment.

It is JRC's goal not to turn away any individual due to the severity of his or her disability. As a result, JRC is often a place of last resort for clients who have been rejected or discharged from other institutions due to the severity of their SIB and/or AB and their failure to respond to treatment. These clients arrive at JRC exhibiting harmful and self-destructive behaviors such as head banging, eye gouging, tearing their own flesh, biting off body parts, pulling out their own adult teeth, punching their fists through glass windows, running into traffic, jumping out of windows, swallowing knives and violently attacking family members, teachers, staff and others with punches, kicks, bites and sharp objects. The clients come to JRC from psychiatric wards and other residential programs and have a long history of failed treatment.

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[3] *See* Attachment 18 to JRC Comment, Hearing Transcripts and Exhibits from *The Judge Rotenberg Educational Center Inc., et al. v. Commissioners of the Department of Developmental Services and the Department of Early Education and Care*; Docket No. BR86E-0018-GI; Tr., Ex. 83, at ¶ 35.

[4] This certification requires a masters or doctoral degree from a qualifying accredited institution with coursework covering the content outlined by the Behavior Analyst Certification Board, 1500 hours of supervised independent field work in behavior analysis, and a certification exam. *See* Attachment 18 to JRC Comment, Tr., Day 34, 105:14-19; 114:16-115-23.

Clients with untreated or inadequately treated SIB/AB are often forced to endure a succession of ineffective treatments, including: the prescription of powerful medications at high dosages and/or in dangerous combinations that have not been successful in treating their challenging behaviors, and which have either caused the client serious physical side effects, or have put the client at risk of such serious side effects (e.g., acute and chronic extrapyramidal syndromes [e.g., tardive dyskinesia, akathisia, dystonia, parkinsonism], neuroleptic malignant syndrome, obesity, sedation, sexual dysfunction, sudden cardiac death, addiction, diabetes, and life-shortening metabolic changes); use of physical restraint (which can lead to bruises, broken bones, and death), mechanical restraint (including helmets, facial screens, gloves, straitjackets), four- and five-point restraints, and/or chemical restraint (which function by sedating the client into compliance); and isolation or seclusion (which can be enforced for most of the day for years at a time). These ineffective treatments cause these clients to remain a danger to themselves and/or their caregivers, and expose the clients to long-term or permanent physical and emotional trauma, including death. Because of the frequency and intensity of their uncontrolled AB and/or SIB, these clients are denied the opportunity to: be educated and learn functional communication skills and positive behavioral skills to replace the dangerous and maladaptive behaviors; be involved in community activities and develop meaningful relationships with family, peers and caregivers.

JRC's effective behavioral treatment including the GED lowers its clients' behaviors to zero or near-zero levels.[5] Moreover, it allows its clients to discontinue powerful medications that have not been successful in treating their challenging behaviors, and which have either caused the client serious physical side effects, or have put the client at risk of serious side effects (e.g., acute and chronic extrapyramidal syndromes [e.g., tardive dyskinesia, akathisia, dystonia,

[5] *See* Attachment 6b to JRC Comment, Experience of JRC Client Group Receiving GED/GED-4 Treatment.

parkinsonism], neuroleptic malignant syndrome, obesity, sedation, sexual dysfunction, sudden cardiac death, addiction, diabetes, and life-shortening metabolic changes). JRC's behavioral treatment gives the client the opportunity to be educated and learn positive skills to replace the dangerous and maladaptive behaviors.

Many of the comments submitted to the FDA, as well as the Proposed Ban itself, portray JRC as a facility that is unaware of or uninterested in non-aversive options. That is simply incorrect. JRC provides its clients with positive behavioral procedures as well as multiple other forms of psychological and psychiatric treatments, such as counseling and medication. At JRC, each client's treatment begins with a non-intrusive treatment program that includes only positive behavioral therapies. For example, JRC clients receive carefully-selected rewards (e.g., treats, videogames, music, field trips) when they engage in targeted positive behaviors (e.g., academics) or refrain from targeted AB and SIB. JRC also employs, among many other things, a point/token system that enables clients to earn or lose points or tokens based upon their behaviors. Clients can use their accumulated points or tokens to earn rewards of their choice, including trips to favorite destinations such as sporting events, shopping malls, or restaurants. JRC provides individual and group counseling, family counseling, speech therapy, occupational therapy, and physical therapy according to their Individualized Educational Programs and Service/Habilitation Plans. When indicated, JRC's consulting psychiatrist provides treatment with medication.

Every client at JRC receives a comprehensive and ongoing functional assessment, so that JRC's treating clinicians can understand the stimuli that precede a particular individual's SIB/AB, and the stimuli that may maintain SIB/AB.[6] JRC uses an array of systems to monitor and analyze

[6] Many comments accuse JRC of being indifferent to learning what stimuli trigger AB/SIB. *See, e.g.*, Comment from American Academy of Pediatrics, comment identifier FDA-2016-N-1111-1513 (July 5, 2016) ("The scientific community has long recognized that it is imperative to address the underlying causes of SIB and AB, rather than to suppress symptoms and actions with painful shocks that only exacerbate a person's cumulative trauma, without

each client's SIB/AB, including 24 hour recording of behaviors via a digital video recording and audio system, comprehensive frequency charting, 24-hour data collection, databases tracking events associated with major behavioral incidents, and functional assessment questionnaires, among others. Clients meet with their case managers daily and with their clinicians on at least a weekly basis as part of providing treatment for their severe behavior problems and designing behavioral treatment plans. JRC also utilizes individual or group counseling, client questionnaires, and self-management programs tailored to the individual needs of each client. In addition, clients are provided with e-mail access and access to an online discussion board, and have frequent social opportunities with staff and clinicians. Moreover, JRC provides numerous methods and opportunities for clients with communication deficits to communicate with JRC staff and treating clinicians, including but not limited to through communication devices (iPads, dynavox speech-generating devices, communication boards), and communication training (through speech or applied behavior analysis services).

B. JRC's Treatment of SIB/AB Clients with ESDs

JRC has a subpopulation of treatment refractory clients who exhibit severe behavioral disorders involving SIB and AB and for whom the array of positive behavioral treatment options described above has not been adequately effective in treating their SIB/AB. JRC evaluates individuals in this refractory population to determine whether treatment with ESDs called the Graduated Electronic Decelerator ("GED") -3A and GED-4 devices (collectively, the "GED devices" or the "GED"), as a supplement to positive reinforcement behavior therapies, could

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proof of long-term benefits.") Those comments do not reflect actual clinical practice at JRC. This is not a situation where the FDA can say, "we have received conflicting information and treat either perspective as valid." As an evidence-based fact-finding process would show, these accusations are wrong. In effect, the claim is that the FDA and the commenters know better how JRC's clients are being treated and should be treated than the doctors, nurses, judges, and lawyers who make individualized treatment decisions for these clients based on their knowledge of each person.

provide a benefit. This evaluation is an exhaustive process, as described more fully below. Ultimately, only a portion (approximately 20%) of JRC clients meet the conditions for treatment with the GED. Contrary to what many commenters have claimed, this is a last resort option used only with clients who have failed multiple other therapies at multiple prior facilities, as well as at JRC.[7] For these clients, successful treatment with the GED can mean freedom from the pain and bodily injury caused by violent self-abuse, an ability to receive an education, gain living skills, develop meaningful relationships with family and friends, train to enter the workforce, and a materially better quality of life.

JRC has used the GED devices for over 26 years with hundreds of clients with no clinically significant adverse events. Based on JRC's constant evaluation of the safety and efficacy of the GED, there is no substantial risk of harm presented by the GED. JRC staff carefully monitor each application of a GED device in response to a client's SIB/AB. When staff determine that application of the GED is prescribed according to a client's court authorized treatment plan, the GED is used to send a two-second electric shock to an electrode on the surface of the client's skin, typically on the arm or the leg.[8] The locations are chosen to minimize the overall number of total GED applications the client receives and to avoid adaptation. After an application, the site of the electrode is examined and the electrode is moved to another spot on the body, and within 24 hours of a client's receiving a stimulus from the GED device, JRC's nursing staff carefully evaluate the client for any sign of physical or emotional harm.

JRC staff are also constantly monitoring clients to ensure their physical and mental well-being. Staff are instructed to carefully monitor any clients receiving treatment with the GED for

[7] *See, e.g.*, Comment of JRC Parents, comment identifier FDA-2016-N-1111-1570 (Aug. 12, 2016), pp. 4-16.
[8] Physicians and neurologists have approved as safe the following areas of the body for placement of the GED electrode: on the inner/outer forearm, upper arm, upper thigh, calf, torso/stomach, palms of hands, soles of feet, or upper/outer quadrant of the buttocks.

changes in behavior such as increases in aggression, escape behaviors, emotional reactions, sleep difficulties, and any other physical or emotional reaction or change which could be indicative of mental illness, including posttraumatic stress disorder. For 26 years, JRC has been monitoring for any of these types of harmful effects on hundreds of clients and has not found them to occur. Instead, the positive effects observed from the GED have included: dramatic reduction and elimination of SIB/AB behaviors; elimination of the severe pain and grievous injury caused by those behaviors; and an ability to integrate into the community, receive an education, vocational training, and safely enjoy the company of family and friends.

As of December 2016, of the 255 clients currently enrolled at JRC, only 53 clients are currently approved for ESD for SIB/AB. All current JRC clients receiving GED treatment are 20 years old or older. Additionally, 19 current clients at JRC have been successfully transitioned from GED treatment and are living their lives free of SIB/AB. All of the JRC clients who began GED treatment in or after 2000[9] experienced significant reductions in their severe SIB and AB.[10] In addition, after they received GED treatment, over 50% of these clients were able to leave JRC for a less intensive program or go home to their families.[11]

C. Regulatory and Judicial Process for Approving and Administering JRC's GED Treatment

JRC's use of the GED devices in treating clients is comprehensively regulated and closely monitored by the executive and judicial branches of the Commonwealth of Massachusetts. As described in more detail below, before treating clients with the GED, JRC must: (1) satisfy exhaustive regulatory requirements applicable to the facility as a whole; (2) satisfy exhaustive

[9] Additional clients were treated and successfully discharged prior to 2000.
[10] *See* Attachment 6b to JRC Comment, Experience of JRC Client Group Receiving GED/GED-4 Treatment.
[11] *See* Attachment 6a to JRC Comment, Summary of Experience of JRC Client Group Receiving GED/GED-4 Treatment.

regulatory requirements specific to each client treated with the GED; and (3) obtain permission from a Massachusetts Probate and Family Court judge after proving that the GED treatment is the "least intrusive, least restrictive" treatment that will be effective in treating the client's severe behaviors.[12] We are unaware of any other device that undergoes such rigorous and individualized review before and while it is used. Significantly, the FDA completely ignored this comprehensive, individualized review in proposing to ban the use of the GED.

The Massachusetts Department of Developmental Services ("MA DDS") oversees the use of aversive therapy for behavior modification in Massachusetts. MA DDS has promulgated detailed regulations (the "MA DDS Regulations") requiring that behavior modification treatment plans that include physical aversive interventions be used in a safe, well-documented manner.[13] JRC and MA DDS are also parties to a December 12, 1986 settlement agreement made a Judicial Order by agreement of the parties on January 7, 1987 (the "Consent Decree") (No. 86E-0018-GI), which authorizes JRC to use aversives such as the GED with its clients subject to a number of clinical requirements and approval on an individual basis by a Massachusetts Probate and Family Court Judge. In accordance with the MA DDS Regulations, treatment programs must apply for, and be specifically granted, a special certification by MA DDS to use aversive interventions.[14] The comprehensive certification process involves a thorough review of a facility's treatment program during which MA DDS has access to a facility's staff and clients as well as the records of the facility. Following the review, MA DDS will "provide for an inspection of the program by authorized Department representatives."[15] During the inspection the "authorized Department representatives", who typically include psychological and psychiatric experts in the field of

[12] *See* Attachment 18 to JRC Comment, Tr., Ex. 87 at §§ A(1-3).
[13] *See* 115 C.M.R. § 5.14.
[14] *See id.* § 5.14(4)(f).
[15] *See id.* § 5.14(4)(f)(5).

behavioral treatment, will "observe fully the treatment employed by the program and … review with the program's staff the procedures for which certification was granted or is sought and the manner in which such [aversive] procedures have been or are to be implemented."[16] In order to obtain certification, "the program or facility must demonstrate that it has the capacity to safely implement" behavior modification treatment involving the use of physical aversive treatment.[17] The program must apply for renewal of the certification and undergo the same rigorous evaluation by DDS every two years.[18] MA DDS has continuously certified JRC to use the GED devices for over 25 years. During that period, MA DDS has observed the GED being administered during its inspections. Meanwhile, the FDA has refused to even visit the JRC program and observe the treatment and treatment data first-hand.

The MA DDS Regulations set forth comprehensive procedures, including detailed consent procedures that all treatment programs must follow before implementing GED treatment. According to these procedures, JRC must develop a written behavior modification treatment plan for the client in question, specifying which behaviors will be treated with the GED devices and detailing the treatment's rationale, duration, conditions and goals, as well as a detailed monitoring plan for evaluating the treatment's efficacy.[19] The behavior modification treatment plan must be approved by a doctoral-level clinician with "a demonstrated history of experience and training in applied behavior analysis and behavioral treatment."[20] The plan must be approved by a Human Rights Committee composed of, among others: 1) a physician or nurse; 2) a clinician with expertise in mental retardation and developmental disabilities, mental illness, or applied behavior analysis;

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[16] *See id.* § 5.14(4)(f)(6).
[17] *See id.* § 5.14(4)(f)(1).
[18] *See id.* § 5.14(4)(f)(9).
[19] *See id.* §5.14(4)(c).
[20] *See id.* § 5.14(4)(d)(2).

and 3) an individual with relevant legal expertise.[21] In addition, the plan must be approved by a Peer Review Committee, which includes a licensed psychologist and other clinicians "with combined expertise in the care and treatment of individuals with needs similar to those served by the facility or program and in behavior analysis and behavioral treatment."[22] The plan must be reviewed by a physician or health care professional under the supervision of a physician,[23] and the physician or health care professional must examine the client and confirm that there are no medical contraindications to the use of the behavior modification treatment.[24] The school district or adult state agency that referred the client to JRC must also approve the behavior modification treatment plan and incorporate it into the client's Individualized Education Plan or Individual Service/Habilitation Plan.

In accordance with the MA DDS Regulations, the parents or guardians of JRC clients who seek access to ESDs must first request and obtain court approval of the treatment. Contrary to the impression of several commenters to the FDA's Proposed Ban, many parents of JRC clients are extremely sophisticated and well educated, and include physicians,[25] registered nurses, professors,[26] religious leaders,[27] financial professionals,[28] teachers, business owners, and IT professionals. These parents have pursued multiple other treatment options at other facilities – which failed to treat their child successfully – before requesting ESD.

The Massachusetts Probate and Family Court must approve ESD use on an individualized case-by-case basis and under "substituted judgment" criteria designed to protect the interests of

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[21] *See id.* § 3.09(1)(c).
[22] *See id.* § 5.14(4)(d)(5)(a).
[23] *See id.* § 5.14(4)(d)(4).
[24] *See id.* § 5.14(4)(d)(4).
[25] *See* Attachment 18 to JRC Comment, Tr., Day 23, 149:24-150:3, Testimony of M.S. (May 23, 2016).
[26] *See id.*, Tr., Day 34, 7:1-7, Testimony of Paul Peterson (June 13, 2016).
[27] *See id.*, Tr., Day 23, 12, Testimony of R.M. (May 23, 2016).
[28] *Id.*

people not able to make informed treatment decisions on their own behalf.[29] The court process involves assigning an independent attorney to represent the client's interest. This attorney can, and typically does, hire an independent clinical expert funded by the Court to evaluate the client and carefully review the proposed behavior modification treatment plan. In addition, MA DDS has the right to intervene in any individual case and to oppose the treatment. The Massachusetts Probate and Family Court holds a hearing and reviews issues such as the client's diagnosis, prior failed treatments,[30] and whether aversive treatment is necessary to effectively treat the individual's severe behavior disorder. In addition, as provided by the Consent Decree, a licensed psychologist appointed by the Massachusetts Probate and Family Court is responsible for the general monitoring of JRC's treatment and education program, including overseeing JRC's compliance with applicable state regulations, and is authorized to report any issues to the Court regarding the health, safety and well-being of JRC's clients.[31] The Supreme Judicial Court of Massachusetts has affirmed the Massachusetts Probate and Family Court's authority to approve aversive procedures such as use of the GED.[32]

D. The Massachusetts Motion to Vacate Trial

In 2013, MA DDS filed a motion to vacate the Consent Decree (the "Motion to Vacate"). In the Motion to Vacate, invoking arguments similar to those in the Proposed Ban, MA DDS claimed that ESD treatment is no longer within the standard of care for treating developmentally disabled individuals that exhibit SIB/AB, in light of advances in psychotropic medication and

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[29] *See* 115 C.M.R. § 5.14(4)(e).

[30] All current clients receiving GED treatment at JRC received alternative forms of behavior modification treatments prior to JRC, including treatment with Positive Behavior Supports, treatment with psychotropic medications, use of seclusion, use of protective gear, and/or use of physical or mechanical restraint; these treatments were ineffective in treating the SIB/AB of these clients.

[31] See Attachment 18 to JRC Comment, Tr., Ex. 87 (¶ B.2.).

[32] *Guardianship of Brandon*, 424 Mass. 482 (1997); *Judge Rotenberg Educ. Ctr., Inc. v. Comm'r of the Dep't of Mental Retardation*, 424 Mass. 430, 444-45 (1997).

positive reinforcement therapies. The testimony elicited at a trial in Massachusetts between JRC and MA DDS provides evidence refuting the FDA's conclusions in the Proposed Ban.

JRC and its clients, their parents and guardians ("Plaintiffs") opposed the Motion to Vacate. The trial on the Motion to Vacate (the "Trial") was conducted over 45 days from October 26, 2015 to October 17, 2016, and involved the examination and cross examination of 28 witnesses, including 11 expert witnesses. MA DDS argued that Positive Behavior Supports ("PBS") and psychotropic medication – the very treatments the FDA cites in the Proposed Ban as "state-of-the-art-treatments for SIB and AB"[33] – were an effective alternative to ESDs in treating the most severe forms of SIB and AB. Conversely, Plaintiffs argued that GED treatment is safe and effective, and that PBS, psychotropic medication and other alternative treatments do not safely and adequately treat JRC clients with the refractory types of severe SIB and AB who receive GED treatment at JRC.[34] Plaintiffs' witnesses included two former JRC clients who received GED treatment, five parents of current JRC clients, two Board Certified Behavior Analysts, JRC's consulting pediatrician, a Harvard psychiatrist and scientist practicing at McLean Hospital, a physician with expertise on electrical exposure and three psychologists, all of whom testified to the safety and effectiveness of the GED and the lack of effective alternative treatments.[35]

Many of the "conclusions" the FDA makes in the Proposed Ban were refuted by the Trial record, specifically by the cross-examination testimony of the MA DDS experts. For example, the FDA Proposed Ban claims that "state-of-the-art treatments for SIB and AB are positive-based behavioral approaches, sometimes alongside pharmacotherapy, as appropriate, and do not include ESDs."[36] Similar assertions were made by some of MA DDS' experts. Yet one of MA DDS's

[33] 81 Fed. Reg 24386 at 24410.
[34] *See* Attachment 18 to JRC Comment, Trial Record.
[35] *Id.*
[36] 81 Fed. Reg 24386 at 24410.

expert psychiatrists, Dr. James McCracken, acknowledged during cross-examination that, in a recent lecture before medical professionals, he stated that the only two drugs the FDA approved to treat behavior problems associated with autism, aripiprazole and risperidone, did not reduce self-injury compared to placebo in their research trials, and that this was a "big disappointment".[37] The best he could say about the efficacy of using psychotropic drugs in treating self-injury was that they "might work".[38] Dr. McCracken admitted that he was unable to help all patients with severe problem behaviors with medications.[39]

Plaintiffs also elicited cross-examination testimony from another one of MA DDS' purported PBS experts, Jennifer Zarcone, Ph.D., that PBS and psychotropic medication, even in combination, do not work for every patient with severe behavior disorders.[40] Dr. Zarcone testified that PBS is "an overtly value based technology" that is not based on scientific literature,[41] and that PBS is a "global perspective" and "not a treatment".[42] Dr. Zarcone also testified that professional standards issued by the Behavior Analyst Certification Board and the Association for Behavior Analysis International allow the use of skin shock to treat severe behavior disorders.[43]

The FDA Proposed Ban states that "[t]he studies in the literature suffer from serious limitations, including weak study design, small size, and adherence to outdated standards for study conduct and reporting."[44] At Trial, Plaintiffs offered into evidence a chart describing the extensive

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[37] *See* Attachment 18 to JRC Comment, Tr., Day 10, 62:15-63:3; 94:11-95:2 (Nov. 10, 2015); Tr., Ex. 375 (James McCracken, Drug Therapy in ASD 2014: What Works and What's Next?, PowerPoint); Ex. 376 (James McCracken, Drug Therapy in ASD 2014: What Works and What's Next?, YouTube).
[38] *See id.*, Tr., Day 10, 66:15-67:6 (Nov. 10, 2015); Ex. 375 (James McCracken, Drug Therapy in ASD 2014: What Works and What's Next?, PowerPoint); Ex. 376 (James McCracken, Drug Therapy in ASD 2014: What Works and What's Next?, YouTube).
[39] *See id.*, Tr., Day 10, 106:24-108:1 (Nov. 10, 2015).
[40] *Id.*, Tr., Day 14, Testimony of Dr. Jennifer Zarcone, 97:9-15; 191:8-12 (Nov. 17, 2015).
[41] *Id.* at 194:20-198:10.
[42] *Id.* at 190:13-191:3, 191:13-16. The Proposed Ban relies heavily on PBS. *See* 81 Fed. Reg. 24386 at 24403-24408; 24410.
[43] *Id.* at 219-222; 224-225, 227-228; Ex. 405, 406, 407.
[44] 81 Fed. Reg. 24386 at 24387.

support in the literature for ESD treatment in the form of over one hundred peer-reviewed articles, and Plaintiffs' experts testified at length regarding specific articles supporting ESD treatment.[45] Further, MA DDS' own expert, Dr. Zarcone, a widely published researcher in the field of Applied Behavior Analysis and the treatment of severe behavior disorders, testified that the study designs in the articles supporting skin shock are consistent with research standards in behavioral psychology:

> Q. And you would agree that all the research that has been done on [Applied Behavior Analysis] procedures that is considered evidence based has been single subject for science?
> A. Many of them involve single subject research, yes.
> Q. Would you say most of them do?
> A. Most of them probably, yes.
> Q. You consider single subject designs to be an acceptable form of research to be part of the support of an evidence-based treatment, correct?
> A. Yes, I do.
> Q. And single subject designs is generally accepted in applied behavior analysis as a form of research to support an evidence-based treatment, correct?
> A. Yes, it is.[46]

Also, during the discovery and evidence phases of the Trial, a number of psychologists who are current or former MA DDS employees or contractors testified that ESD treatment remains within the standard of care and is necessary, since alternative interventions cannot effectively treat all individuals with developmental and intellectual disabilities who engage in SIB and AB. For example, Philip Levendusky, Ph.D., a licensed psychologist and Chair of the Psychology Department and Co-Director of Training at McLean Hospital and the long-time head of the MA DDS team that evaluates whether JRC is qualified to offer treatment with the GED, testified that the GED has successfully treated patients who failed to respond to alternative interventions, and

[45] *See, e.g.*, Attachment 18 to JRC Comment, Testimony of Dr. Nathan Blenkush, Tr., Day 35, 170:17-182:18 (June 14, 2016); Tr., Day 41, 222:2-228:17 (June 22, 2016); Tr., Day 42, 11:12-54:9 (June 23, 2016); Ex. 721; Testimony of Dr. Michael Cameron, Tr., Day 33, 212:22-214:1 (June 10, 2016).
[46] *See id.*, Tr., Day 14, 78:21-79:12 (Nov. 17, 2015).

that the GED should remain available as a treatment.[47] Dr. Levendusky further testified about the dire physical and emotional condition of the clients entering JRC due to their severe behavior problems and the lack of effectiveness of all the alternative treatments that were tried with them, including many forms and high dosages of psychotropic medications.[48] He also testified about the dramatic and sustained improvement of these patients after JRC treated them with the GED devices.[49]

Edwin Mikkelsen, M.D., a MA DDS psychiatrist and a member of Dr. Levendusky's team, testified that he had patients who were unsuccessfully treated with psychotropic medications and that he had seen patients effectively treated with the GED.[50] Christopher Fox, Ph.D., a MA DDS employee and another member of Dr. Levendusky's team, testified that he believed contingent skin shock should be available as a treatment option.[51] Alfred Bacotti, Ph.D., a DDS licensed psychologist who served as MA DDS' representative on JRC's Peer Review Committee, testified at his deposition that he approved JRC treatment plans presented to the Peer Review Committee that included the GED and would not have done so if there were less restrictive, effective alternatives, and that contingent skin shock is within the current standard of care.[52] Susan Shnidman, Ph.D., a licensed psychologist approved by MA DDS to review JRC treatment plans at triennial case conferences,[53] testified that she recommended GED treatment because she knew from reviewing their records that JRC clients had previously received ineffective positive-only interventions and psychotropic medications from skilled providers at reputable institutions.[54]

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[47] *See id.*, Tr., Testimony of Dr. Philip Levendusky, Day 6, 95-96, 109-110 (Nov. 2, 2015).
[48] *See id.* at 89:1-17; 90-94, 99-101.
[49] *See id.* at 94-99, 107.
[50] *See id.*, Tr., Testimony of Dr. Edwin Mikkelsen, Day 7, 27-28, 198-206 (Nov. 3, 2015).
[51] *See id.*, Tr., Testimony of Dr. Christopher Fox, Day 40, 10-11 (June 21, 2016).
[52] *See* Attachment 20 to JRC Comment, Depo., Testimony of Dr. Alfred Bacotti, 83-84, 94-95, 101-102, 178, 184-185.
[53] MA DDS retains two independent psychologists to review triennially JRC clients with Level III treatment plans.
[54] *See* Attachment 18 to JRC Comment, Tr., Testimony of Dr. Susan Shnidman, Day 12, 146-147, 156.

Lewis Klebanoff, Ph.D., a licensed psychologist appointed by MA DDS to review JRC treatment plans at the triennial case conferences, testified at his deposition that GED treatment is necessary for some patients because there are no effective alternatives.[55]

These are just a few examples of how many of the Proposed Ban's "conclusions" were contradicted at the Trial through examination of Plaintiffs' experts and cross-examination of the MA DDS experts. This demonstrates a fatal shortcoming in the FDA's rulemaking process: the lack of an opportunity to subject claims to meaningful scrutiny. As shown by the Trial, some of the key assertions upon which the FDA has relied did not stand up under questioning. If the FDA were to conduct an adjudicatory hearing on the use of ESDs, JRC could directly refute the evidence on which the FDA relies for its Proposed Ban.

II. THE FDA LACKS AUTHORITY TO BAN USE OF A DEVICE

In its Proposed Ban, the FDA proposes to prohibit the use of ESDs, including the GED device, "for the purpose of treating aggressive or self-injurious behavior." The FDA admits that the Proposed Ban does not prohibit ESDs "intended for other purposes."[56] As such, the Proposed Ban is an impermissible intrusion into the practice of medicine that exceeds the FDA's statutory authority. Banning a specific use of a device violates the clear and unambiguous language of the FDC Act.

A. The Statute Clearly Precludes the FDA from Interfering in the Practice of Medicine.

Since its passage in 1938, the FDC Act has denied the FDA the authority to interfere in the practice of medicine. One of the Act's sponsors, Senator Royal Copeland, explained that "the bill is not intended as a medical practices act and will not interfere with the practice of the healing art

[55] *See* Attachment 21 to JRC Comment, Depo., Testimony of Dr. Lewis Klebanoff, 85-86, 121-122.
[56] *See* 81 Fed. Reg. 24387 at 24387 ("Some ESDs are intended for other purposes, such as smoking cessation; however, the proposed ban includes only those devices intended to reduce or eliminate SIB or AB.").

by [persons] in the States where they are licensed by law to engage in such practice."[57] This understanding was reinforced as the FDC Act was amended over years. For example, in 1969, a bill was introduced to clarify that the definition of "drug" did not include "medicine prepared and dispensed by a physician in the course of his professional practice," but was ultimately rejected as unnecessary because there is "nothing in the [FDC Act] which would interfere at all with the ordinary legal practice of medicine" under State law.[58] The FDA itself recognized its limitations under the FDC Act, explaining in the context of drug prescribing:

> the physician may, as part of the practice of medicine . . . vary the conditions of use from those approved . . . This interpretation of the Act is consistent with Congressional intent as indicated in the legislative history of the 1938 Act and the drug amendments of 1962. Throughout the debate leading to the enactment, there were repeated statements that Congress did not intend the Food and Drug Administration to interfere with medical practice . . . . Congress recognized a patient's right to seek civil damages in the courts if there should be evidence of malpractice, and declined to provide any legislative restrictions upon the medical profession.

37 Fed. Reg. 16,503, 16,503 (Aug. 15, 1972).

In 1997, Congress added the current language, further clarifying that the FDC Act is not intended to regulate the practice of medicine:

> Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.[59]

This provision is commonly called the "practice of medicine exemption."

Courts have recognized the FDA's limited authority under the FDC Act and practice of medicine exemption. In the seminal case of *Buckman Co. v. Plaintiffs' Legal Comm.*, the U.S.

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[57] S. Rep. No. 74-361, at 3 (1935).
[58] Peter Barton Hutt, *Regulation of the Practice of Medicine Under the Pure Food and Drug Laws*, 33 Q. Bull. Ass'n of Food & Drug Off. 1, 8 (1969).
[59] 21 U.S.C. § 396.

Supreme Court recognized that the FDA's "mission [is] to regulate in this area without directly interfering with the practice of medicine."[60] The Court further stated, "FDA is charged with the difficult task of regulating the marketing and distribution of medical devices without intruding upon decisions statutorily committed to the discretion of health care professionals."[61] Several courts have recognized that the FDA has the authority to "control the availability" of medical products, but not to regulate their off-label use as part of the practice of medicine. *See Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 56 (D.D.C. 1998) ("[O]ff-label use of FDA-approved drugs by physicians is an established aspect of the modern practice of medicine."), vacated in part on other grounds, *Wash. Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 2000); *United States v. Caronia*, 703 F.3d 149, 180 (2d Cir. 2012) ("Finally, a ban on off-label prescriptions would be no better. Indeed, it would constitute an unprecedented intrusion into the practice of medicine."); *Amarin Pharma, Inc. v. U.S. Food & Drug Admin.*, 119 F. Supp. 3d 196, 226 (S.D.N.Y. 2015) (rejecting FDA's narrow reading of *Caronia*).

Many other regulatory provisions are consistent with a prohibition on the FDA's intrusion in the practice of medicine. For example, section 360(g) of the FDC Act and 21 C.F.R. § 807.65 exclude licensed practitioners who develop or modify their own medical devices for treatment of their patients from annual registration requirements with the FDA. The FDA recognized that exemption in its recent *Mobile Medical Apps*[62] guidance, suggesting that licensed practitioners who develop a device for use in their professional practice and do not label or promote their product to be generally used by others would not be considered medical device manufacturers under 21 C.F.R. Parts 803, 806, 807, and 820, and therefore would not need to submit medical

[60] 531 U.S. 341, 350 (2001).
[61] *Id.*
[62] FDA Guidance for Industry and Food and Drug Administration Staff, *Mobile Medical Applications*, February 9, 2015.

device reports, notify the FDA of corrections, register their establishments, list their products with the FDA, or submit a premarket application for the device. In sharp contrast, the Proposed Ban seeks to regulate the practice of medicine by licensed physicians; clinicians would still be able to use ESDs for any purpose *except* for when treating clients diagnosed with SIB or AB. This creates ambiguity both for the clinician and the Agency, thrusting the FDA into the role of deciding whether a particular GED use is proscribed based upon the specific diagnosis that was rendered.

B. The FDC Act Prohibits the FDA From Banning a Particular Use of a Medical Device.

Consistent with the practice of medicine exemption, the FDC Act permits the FDA to restrict the availability of a medical device for use by medical professionals by (1) withholding approval of the device under certain circumstances,[63] or (2) issuing a regulation declaring the device a "banned device."[64] However, it *does not* permit the hybrid outcome: the device type remains on the market but the FDA restricts healthcare professionals' use of the device.

Importantly, the FDC Act provides that a device may be "banned" when the FDA finds, "on the basis of all available data and information," that the device presents "an unreasonable and substantial risk of illness or injury."[65] Here, however, the FDA is not seeking to ban a device, but has instead carved out a specific use of that device to ban. The "banned device" provision can only be interpreted to permit banning of a device in its entirety, rather than banning a particular use.

The FDA itself has previously only interpreted the "banned device" provision as permitting a complete ban on marketing a device.[66] And, in fact, the FDA has only previously banned two

[63] *See* 21 U.S.C. § 360e, 21 U.S.C. § 360f.
[64] 21 U.S.C. § 360f(a)(1).
[65] 21 U.S.C. § 360f(a)(1).
[66] 48 Fed. Reg. 25126.

medical devices. Neither action involved a particular *use* of the device. In 1983, the FDA issued a ban on prosthetic hair fibers, which banned *all* implanted hair fibers.[67] Similarly, in the FDA's Proposal to Ban Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove,[68] the FDA clarifies that it "is proposing these *devices* be banned" (emphasis added).[69] The final rule did, in fact, ban these devices.[70] The unprecedented proposal to ban a *use* of ESDs – rather than to ban ESDs themselves – cannot be squared with the FDC Act. As set forth above, this proposal directly intrudes into the practice of medicine. Congress gave the FDA the authority to ban a device, but not to tell doctors they could use a device for some purposes but were prohibited from using a device for other purposes.

In other cases, the FDA has issued warnings against particular uses which the Agency considered dangerous. For example, the FDA determined that use of laparoscopic power morcellator devices in hysterectomies or myomectomies in women with uterine fibroids risked spreading cancerous tissue – such as uterine sarcomas – beyond the uterus, thereby significantly worsening the patient's chances of long-term survival.[71] Rather than ban the use of morcellators, the FDA warned health care providers about their use, despite their significant and serious risk to patients and the availability of alternative treatments.[72]

In the case of infusion pumps used to provide pain medication following joint surgery, the FDA also chose to (1) issue a warning regarding the particular problematic use, and (2) seek additional warning language in the device labeling, rather than "banning" the use.[73] For infusion

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[67] 21 C.F.R. 895.101.
[68] 81 Fed. Reg. 15173.
[69] *Id.*
[70] 81 Fed. Reg. 91722.
[71] *See* FDA Safety Communication: UPDATED Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy (Nov. 24, 2014).
[72] *Id.*
[73] *See* Jared A. Favole and Alicia Mundy, Pain Device Warning, Wall Street Journal (Nov. 17, 2009).

pumps, the use in question resulted in substantial degradation of the affected joint, frequently requiring corrective surgery or complete joint replacement.

Similarly, the FDA recently warned health care providers about a use of the 3T Heater-Cooler System in patients who have undergone cardiothoracic surgeries. The FDA noted that use of the product in some patients had resulted in fatal Mycobacterium chimaera infections. Nevertheless, the FDA simply advised medical facilities to "[s]trongly consider transitioning away from the use of devices for open-chest cardiac surgery until the manufacturer has implemented strategies for these devices to mitigate the risks of patient infection."[74]

FDA's proposal to ban a use is unprecedented. It is striking that while the FDA has never sought to ban a particular use of a device that can cause death, it is seeking here to ban the use of a device even though it has not been demonstrated to cause any serious adverse events. A ban cannot be based on theoretical or possible risks.[75]

C. FDA's Interpretation of the "Banned Device" Provision to Permit Banning a Particular Use is Unreasonable.

Even if the FDA's interpretation of the FDC Act were permissible under the language of the Act, it is unreasonable in practice. Throughout the history of the FDC Act, the purpose of the practice of medicine exemption is to preserve the doctor-patient relationship and to ensure that the FDA does not interfere with or disrupt this important relationship. Regulation of the practice of medicine is reserved to the States. By trying to restrict the use of a device, rather than banning the device itself, the FDA is overreaching, implicating not just the FDC Act but constitutional principles of federalism.[76]

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[74] *See* FDA UPDATE: Mycobacterium chimaera Infections Associated with LivaNova PLC Stöckert 3T Heater-Cooler System: FDA Safety Communication (Oct. 13, 2016).
[75] *See* 81 Fed. Reg 24386 at 24389.
[76] The FDA's citations to *Medtronic v. Lohr*, 518 U.S. 470 (1996) and *Riegel v. Medtronic*, 128 S. Ct. 999 (2008), to support its federalism/preemption argument are unavailing; those cases pertain to federalism as it applies to the

Moreover, the FDA's Proposed Ban cannot be reconciled with Executive Order ("EO") 13132. The EO says, among other things, "that issues that are not national in scope or significance are most appropriately addressed by the level of government closest to the people." That is precisely what the FDA is not doing here. The use of the GED on several dozen individuals at a single facility is not one of national scope or significance. And the matter is being addressed by Massachusetts, "the level of government closest to the people."

The Proposed Ban clearly limits and interferes with a clinician's ability to treat his or her client and thereby explicitly intrudes upon decisions statutorily committed to the discretion of health care professionals. Imposing such a ban also would set a dangerous precedent, in that it would allow the FDA to ban any use of a device any time it disagrees with clinical practice or a certain school of clinical thought.

The FDA lacks knowledge of the specific needs of any client at JRC or any person who exhibits SIB and AB. The implementation of the Proposed Ban would only serve to overrule the judgments of the prescribing clinicians, as well as the parents, judges, government agencies, and legal representatives of the clients in addressing the individual needs and best interests of their clients. In fact, neither the FDA nor the commenters supporting the ban who profess to know what is best, have any firsthand knowledge about JRC's clients. The FDA's imposition of a ban in lieu of individualized client-specific treatment is the antithesis of respecting the practice of medicine exception.

D. The FDA Is Impermissibly Targeting JRC and the GED

There should be no doubt that this proceeding, although styled as a proposed regulation seeking to ban the use of a device, is targeted at the practice of medicine by one entity only, JRC.

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regulation of medical devices by the state, not the regulation by the FDA or the *use* of such devices in treating individual clients.

The FDA repeatedly makes that point in the Proposed Ban.[77]

The FDA's Proposed Ban does not ban ESDs categorically; it allows for the use of ESDs for "other purposes, such as smoking cessation."[78] The risks presented by the use of ESD devices for the treatment of other conditions[79] encompass some of the same risks presented by the use of the GED, as these other devices are still used to apply skin shocks to the client to modify behaviors. The FDA has not provided a rational basis for why the risks of shock treatment are appropriate for the treatment of these other behaviors (which do not necessarily place the patient's health at immediate risk) but not for the treatment of clients with severe SIB/AB who are at imminent risk of physical harm or death if not successfully treated.[80]

The FDA's purported distinctions between ESDs used to treat SIB/AB and ESDs used for other purposes – a person's "control over the shocks", and "difficulty communicating"[81] – do not withstand scrutiny. Many patient groups, such as infants, autistic and developmentally disabled

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[77] *See, e.g.,* 81 Fed. Reg. 24386 at 24409, and *passim*; *see also* Banned Devices; Proposal to Ban Electrical Stimulation Devices Used to Treat Self-Injurious Behavior; Proposed Rule – Preliminary Regulatory Impact Analysis, http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM497514.pdf

[78] 81 Fed. Reg. 24386 at 24387; see also Banned Devices; Proposal to Ban Electrical Stimulation Devices Used to Treat Self-Injurious Behavior; Proposed Rule – Preliminary Regulatory Impact Analysis, http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM497514.pdf

[79] *See, e.g.*, the commercially available Pavlok device – Which bad habits can I break with Pavlok? https://pavlok.groovehq.com/knowledge_base/topics/what-habits-can-i-break-with-pavlok?from_search=true (last accessed July 23, 2016); alcohol and drug treatment devices - *Medical Treatment for Alcohol Addiction*, available at, http://www.schickshadel.com/our-treatments/alcohol-addiction-treatment/medical-treatment/ and *Medical treatment for Marijuana Addiction*, available at http://www.schickshadel.com/our-treatments/marijuana-addiction-treatment/medical-treatment/; and Jan ter Mors, et al. "Evaluation of electrical aversion therapy for inappropriate sexual behaviour after traumatic brain injury: a single case experimental design study," BMJ Case Reports 2012; doi:10.1136/bcr-02-2012-5932; Franklin, Joseph C., Ph.D., "Conditioning an aversion to cutting stimuli: A new approach to nonsuicidal self-injury treatment." (*see* Attachment 18 to JRC Comment – Tr., Ex. 654).

[80] The FDA cannot make an informed benefit-risk decision – it admits that with respect to the impact of removing ESD treatment for clients, "it is impossible to say how much their utility would change due to rule-induced switches to other treatment programs." Banned Devices; Proposal to Ban Electrical Stimulation Devices Used to Treat Self-Injurious Behavior; Proposed Rule – Preliminary Regulatory Impact Analysis, http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM497514.pdf. Despite this professed lack of knowledge, FDA is prepared to overrule the judgment of the treating physicians who do know what the benefit-risk curve is for their patients.

[81] 81 Fed. Reg. 24386 at 24392.

individuals, coma patients, or anesthetized patients, lack control or lack the ability to communicate pain caused by FDA-approved medical devices and FDA-approved drugs. Neither lack of control nor inability to communicate differentiates the GED from other devices, some of which cause far more pain.

III. THE PROPOSED BAN IS NOT DATA DRIVEN

A. The Proposed Ban is Not Support by Sufficient Data or Other Evidence

The Proposed Ban departs significantly from the FDA's normal process. In this instance the FDA, a science-based agency tasked with making decisions based upon rigorous analysis of data, has deviated from its reliance on science. The Proposed Ban is not data-driven; it is not supported by sufficient data or other evidence that demonstrates, as the FDA claims, that the use of ESDs presents a substantial risk of illness or injury. The FDA's proposed dramatic action – a total ban of a particular use of a medical device – must be based on valid evidence. Yet the FDA has not even gone to the facility using ESDs to treat SIB and AB behaviors to review the treatment and the data firsthand.

The FDA has ignored or inappropriately discounted the data from JRC showing the benefits derived from the use of ESD devices in a refractory client population, and overweighted unsubstantiated allegations of harm. For example, the FDA condescendingly states that, for parents who spoke against the Proposed Ban, it "does not doubt their best intentions",[82] but nevertheless dismisses their testimony out of hand.[83] In sharp contrast, the FDA deems negative comments by parents of former JRC clients who oppose the use of ESDs to be fully and

[82] 81 Fed. Reg. 24386 at 24409.

[83] *See, e.g.,* 81 Fed. Reg. 24386 at 24409 (stating FDA "does not doubt their best intensions" in reference to family members of individuals with SIB/AB but noting that FDA "does have reason to question the information provided to these family members by JRC."). FDA never articulates its "reason."

unquestionably credible.[84] The FDA disregards supportive testimony by former clients,[85] but approvingly cites purported critical statements made by anonymous individuals to well-established critics of aversive therapy.[86] The FDA dismisses as unreliable any anecdotal evidence or non-peer reviewed research if it supports the use of ESD therapy,[87] but enthusiastically cites the same types of information if it favors the Proposed Ban.[88] The FDA never explains why the purported reports of a minority of users should outweigh the concrete experiences of the majority of users. The FDA dismisses patient data submitted by JRC,[89] despite the fact that this data has never been shown to be unreliable or inaccurate, and despite the fact that the data and information has been provided to, and relied upon, by multiple state agencies and state and federal courts, as well as published in peer-reviewed scientific journals. Yet the FDA accepts anecdotal, undocumented reports of harm. The FDA's use of only those data that supports its Proposed Ban is a classic example of what psychologists call confirmation bias.[90] In the world of rulemaking, the same behavior is deemed arbitrary and capricious, and demonstrates a total lack of objectivity.

In *Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 56–57 (D.C. Cir. 2015), the Court described an agency's obligations regarding the data on which it purports to rely as follows:

> To be clear, agencies do *not* have free rein to use inaccurate data. An agency is required to "examine *the relevant data* and articulate a satisfactory explanation for

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[84] *See, e.g.,* 81 Fed. Reg. 24386 at 24409 ("Once at JRC, none of the parents reported the development of prevention or antecedent strategies for their children."). Although JRC cannot respond to anonymous complaints like this, this statement is counter to JRC's policy. Where JRC was able to identify the parent or client referenced by the FDA, the characterizations made by those parents or clients to the FDA were incorrect. Further, the development of a treatment plan is a state issue, not an FDA issue.

[85] *Id.*

[86] *Id.* at 24400.

[87] *Id.* at 24406 (describing JRC's self-authored papers supporting refractory patients as "anecdotal reports"); *Id.* at 24412 (dismissing JRC's example of the effects to one individual after removing GED as "anecdote").

[88] *Id.* at 24393 ("In 2013 and 2014, FDA clinicians interviewed three individuals formerly on ESDs at JRC by phone.").

[89] *Id.* at 24402; *see* Attachment 2 and Attachment 3 to JRC Comment to Panel Meeting, tracking number 1jy-8bjf-k0hb (Summary of Patients Treated with GED Devices, Patient Behavior Tracking Charts). This patient data is primarily, if not entirely, drawn from information contained in routine medical records maintained and relied upon by JRC clinicians.

[90] Daniel Kahneman, Thinking, Fast and Slow (2011).

> its action including a rational connection between the facts found and the **214 *57 choice made." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, 103 S. Ct. 2856, 77 L.Ed.2d 443 (1983) (emphasis added; quotation mark omitted). If an agency fails to examine the relevant data—which examination could reveal, *inter alia,* that the figures being used are erroneous—it has failed to comply with the APA. Moreover, an agency cannot "fail[ ] to consider an important aspect of the problem" or "offer[ ] an explanation for its decision that runs counter to the evidence" before it. *Id.* These requirements underscore that an agency cannot *ignore* new and better data. *See Catawba Cnty., NC v. EPA,* 571 F.3d 20, 46 (D.C. Cir. 2009) (agencies "have an obligation to deal with newly acquired evidence in some reasonable fashion"); *see also New Orleans v. SEC,* 969 F.2d 1163, 1167 (D.C. Cir. 1992) ("an agency's reliance on a report or study without ascertaining the accuracy of the data contained in the study or the 'methodology used to collect the data is arbitrary" (quotation mark omitted)).

See also Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29 (1983) (concluding that the agency's explanation for its rescission of a rule "is *not* sufficient to enable us to conclude that the rescission was the product of reasoned decisionmaking" in light of "the limitations of this record in supporting the agency's decision.").

As described in more detail below, the FDA has ignored invitations by JRC to visit JRC and review the GED treatment and data first hand. In doing so, the FDA notably disregarded its own policy of gaining a first-hand understanding of the medical devices it regulates. The FDA's Center for Devices and Radiological Health ("CDRH") Experimental Learning Program ("ELP")[91] is "intended to provide CDRH staff with an opportunity to understand the policies, laboratory practices, and challenges faced in broader disciplines that impact the device development life cycle."[92] According to the FDA, these "formal training visits" are "an opportunity to provide CDRH review staff a better understanding of the products they review."[93] The FDA has conducted numerous ELP meetings because of its desire to learn about regulated devices. Yet the FDA has

[91] http://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm
[92] 81 Fed. Reg. 12737 at 12737.
[93] *Id.* at 12738.

refused to visit JRC and review the treatment and the data first hand, preferring instead to rely on hearsay and second-hand reports.[94]

This proceeding to ban certain uses of ESDs is not the result of good faith and reasoned agency decision-making. Rather, it relies heavily on value/moral judgments the FDA lacks authority to make. It is incontrovertible that the use of ESDs evokes strong emotions. Nevertheless, the FDA must disentangle moral, ethical, and political issues from this proceeding and engage in good faith, science-based decision-making to determine whether ESDs meet the statutory criteria for banning a device. Otherwise, any decision the FDA makes is arbitrary and capricious.

In another case in which emotional, political and moral issues came into play, *Tummino v. Torti*, 603 F. Supp. 2d 519 (E.D.N.Y. 2009), the Court found that the FDA's decisions regarding over-the-counter availability of the "Plan B" emergency contraceptive were arbitrary and capricious, noting:

> These political considerations, delays, and implausible justifications for decision-making are not the only evidence of a lack of good faith and reasoned agency decision-making. Indeed, the record is clear that the FDA's course of conduct regarding Plan B departed in significant ways from the agency's normal procedures regarding similar applications to switch a drug product from prescription to non-prescription use, referred to as a "switch application" or an "over-the-counter switch."

Id. at 523. The Court found that FDA officials were motivated by "improper concerns about the morality of adolescent sexual activity." *Id.* at 544. The Court further noted that "the mere existence 'of extraneous pressure'" would render an agency's decision invalid. *Id.* at 544-545; citing *D.C. Fed'n of Civic Associations v. Volpe*, 459 F.2d 1231 (D.C. Cir. 1971); *Latecoere Int'l, Inc. v. U.S. Dep't of Navy*, 19 F.3d 1342 (11th Cir. 1994), as amended (May 27, 1994).

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[94] *Id.* at 24403.

JRC does not doubt that many commenters may have a personal dislike for the idea of treatment with ESDs. However, that personal dislike is irrelevant under the FDC Act. Moreover, the issue is not the commenters' own subjective beliefs, but rather, what is clinically best for those individuals who have severe SIB/AB that has not been treated successfully with any other therapy.

B. The FDA Is Arbitrarily Applying Different Data Standards to JRC

It is also worth noting that the FDA has previously approved devices and drugs with far less supporting data than JRC has provided. For example, the FDA criticizes the lack of randomized, controlled clinical trials that have directly examined ESDs for SIB/AB.[95] Yet the FDA does not require applications for humanitarian use devices, medical devices "intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year,"[96] to contain the results of scientifically valid clinical investigations demonstrating that the devices are effective for their intended purpose,[97] as these devices are exempt from the FDA's effectiveness requirements of premarket approvals.[98] The FDA also admits that "[o]nly a small percentage of 510(k)s require clinical data to support the application."[99]

The FDA also attacked JRC's data for originating from one entity.[100] The FDA has previously approved premarket approval applications based on data from a single site.[101] In September 2016, the FDA approved the first drug to treat Duchenne muscular dystrophy, Exondys

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[95] 81 Fed. Reg. 24386 at 24389, 24400.
[96] 21 C.F.R. 814.3. Recent legislation has raised the ceiling to 8,000. JRC estimates the number of severe, refractory SIB/AB cases are below this threshold.
[97] 21 C.F.R. 814.102(b)(4)(i).
[98] 21 C.F.R. 814.20(b)(3)(v)(B), (b)(3)(vi), and (b)(6)(ii).
[99] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/
[100] 81 Fed. Reg. 24386 at 24406 (criticizing JRC's "anecdotal reports in two of JRC's self-authored papers").
[101] *See* Summary of Safety and Effectiveness Data, Kremer Excimer Laser; Summary of Safety and Effectiveness Data, Dishler Excimer Laser System; Summary of Safety and Effectiveness Data, Birmingham Hip Resurfacing (BHR) System.

51, despite the paltry evidence of treatment efficacy from drug manufacturer Sarepta Therapeutics.[102] Sarepta Therapeutics provided evidence from only 12 patients and did not use a controlled trial that involved the use of a placebo. The FDA stated that it had considered "the potential risks associated with the drug, the life-threatening and debilitating nature of the disease for these children and the lack of available therapy."[103] In approving this drug, the FDA went against the advice of a panel recommending against its approval, and justified its decision as follows: "[i]n rare diseases, new drug development is especially challenging due to the small numbers of people affected by each disease and the lack of medical understanding of many disorders."[104]

The FDA failed to apply this same logic before seeking to ban JRC's use of the GED devices – a treatment for a small number of individuals with "rare" and "life-threatening and debilitating" behavioral disorders for whom no other treatment has proved effective. Notably, panel members at the April 24, 2014 Neurological Devices Panel (the "Panel") of the Medical Devices Advisory Committee of the FDA (the "Panel Meeting") unanimously concluded that there is a sub-population of individuals exhibiting SIB and AB for whom other treatments are inadequate.[105] The data provide ample evidence of the safety and efficacy and favorable benefit-risk profiles of these devices, including over one hundred peer-reviewed articles, case studies, client case summaries, analysis of data trends for hundreds of clients treated at JRC with ESDs, and the testimony of physicians, psychiatrists, psychologists, Board Certified Behavior Analysts,

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[102] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm521263.htm
[103] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm521263.htm
[104] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm521263.htm; *see also* Robert Weisman, *FDA regulator defends decision to OK Sarepta drug*, BOSTON GLOBE, November 16, 2016, available at https://www.bostonglobe.com/business/2016/11/16/fda-regulator-defends-controversial-decision-sarepta-drug/L8E3GsPewXlCKbWz2FGofI/story.html.
[105] Advisory Panel transcript at pp. 281-285 (". . . it is unanimous amongst the Panel members that there seems to be a specific subpopulation of patients exhibiting SIB and aggressive behavior for which the above options are inadequate.").

former clients, and parents of current and former clients. Thus, the FDA has applied a different data standard here than for many other products.

IV. THE FDA RECORD IS FATALLY FLAWED

A. Pre-Panel Meeting History

As your Office evaluates the matter, we believe it is important that you be aware of the unusual regulatory background. This background strongly suggests there is a pattern of arbitrary and capricious conduct towards JRC that preceded the publication of the Proposed Ban.

JRC developed the GED devices for use in the treatment of clients enrolled at JRC. The GED devices are manufactured at JRC, and are used only for clients enrolled at JRC. They are not and have never been distributed or marketed for sale. JRC received 510(k) clearance for the first GED model on December 5, 1994. Subsequent to clearance, JRC developed newer versions of the first GED model – the GED-3A and GED-4. In 2000, following an FDA inspection of JRC and the GED-3A and GED-4 devices, JRC was advised by the FDA that the GED devices were not subject to the FDA's 510(k) requirements. Specifically, the FDA stated,

> After discussions with NEW-DO compliance branch and CDRH, it was determined that the firm is exempt from 510(k) notices, and the [GED-3A and GED-4] device is considered to be within the practice of medicine.[106]

An internal FDA e-mail sent during the FDA's 2000 inspection of JRC also noted that the FDA "did not observe any indications that the patients/clients were at risk."[107]

The FDA then unexpectedly and without prior notice or explanation reversed course. The FDA has never provided an explanation for the reversal despite JRC's inquiries, in contravention of the Administrative Procedure Act. *See Republic Airline Inc. v. U.S. Dept. of Transportation*, 669 F.3d 296 (D.C. Cir. 2012) ("One of the core tenets of reasoned decision-making is that 'an

[106] Attachment 14 to JRC Comment - FDA Letter to JRC that use of ESDs at JRC is within the Practice of Medicine.
[107] *See* Attachment A.

agency [when] changing its course . . . is obligated to supply a reasoned analysis for the change.'") (quoting *Motor Vehicle Mfrs. Ass'n v. state Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, 57 (1983) ("An agency's view of what is in the public interest may change, either with or without a change in circumstances. But an agency changing its course must supply a reasoned analysis . . . .")); *PREVOR v. Food & Drug Admin.*, 895 F. Supp. 2d 90, 97 (D.D.C. 2012) ("Where the agency has failed to provide a reasoned explanation, or where the record belies the agency's conclusion, [the court] must undo its action.") (internal quotation marks and citations omitted).

Starting in November 2010, the FDA inspected JRC and issued a 483 Notice of Observations, two Untitled Letters, and a Warning Letter related to JRC's use of ESDs. JRC responded to each of these documents. The FDA at that point took the position that the GED devices in use at JRC were medical devices under the jurisdiction of the FDA and required the submission of a second 510(k) notice for modifications made to the original GED model that the FDA cleared in 1994. JRC informed the FDA that the GED was not subject to FDA 510(k) requirements as originally determined in 2000, but that JRC would, without waiving its rights, seek 510(k) clearance. To comply, JRC then redesigned its GED devices to meet the current requirements of the FDA's Quality System Regulations, at considerable expense to JRC.

JRC then prepared a 510(k) notice. However, the agency requested during a January 9, 2013 meeting that JRC first file a pre-submission in order to discuss the content of the 510(k) notice before its submission. In an effort to work cooperatively with the FDA, JRC filed this pre-submission (Q130112) on February 1, 2013. The FDA scheduled a meeting to discuss the pre-submission for March 25, 2013. In advance of the meeting, the agency requested further detailed information regarding the device output, which JRC provided. However, on March 20, 2013, the FDA cancelled the upcoming meeting. Despite additional requests from JRC to reschedule this

meeting, the Agency never responded with a new meeting date and never provided JRC with comments on the pre-submission materials.[108] Because the FDA directed JRC to submit a pre-submission so that the Agency would have the opportunity to provide comments on the content of the 510(k) notice prior to filing such notice, and because the Agency never provided such comments, JRC never filed the 510(k) notice.[109] We are unaware of any other instance where CDRH received a pre-submission, scheduled a pre-submission meeting, canceled the meeting and refused to provide any feedback whatsoever, despite repeated requests.

Moreover, in a February 1, 2013 letter to the FDA, JRC also offered to submit an Investigational Device Exemption ("IDE") application to study the devices in a clinical trial. The FDA never provided an answer to this offer. In fact, JRC did not receive any further communications from the FDA after the FDA cancelled the pre-submission meeting.

B. Panel Meeting

On March 27, 2014, with no advance notice to JRC, the FDA issued a Notice of Meeting for the April 24, 2014 Panel Meeting. While a company may not normally expect notice of a panel meeting affecting a class of devices, JRC is the only company affected here. That being said, the FDA never communicated directly with JRC about the upcoming Panel Meeting. The notice disclosed that the Agency was considering whether to ban ESDs and that the committee was "seek[ing] clinical and expert opinion on the risks and benefits of certain aversive conditioning devices based on available scientific data and information."

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[108] The applicable guidance on pre-submissions say that the FDA should provide feedback within 90 days. http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf. The FDA's guidance does not contemplate the FDA will fail to respond at all.

[109] It should be noted that JRC has not used the modified devices that would be covered by the proposed 510(k) notice.

In preparation for the Panel Meeting, unbeknownst to JRC, the FDA spoke with individuals who were opposed to the use of ESDs, including three former JRC clients who purportedly received GED treatment at JRC. The FDA referenced these interviews and a large volume of other false and biased information on a variety of topics[110] concerning ESDs in a 122-page "FDA Executive Summary" which the FDA provided to Panel members before the Panel Meeting. The FDA never contacted JRC or any parents of current or former JRC clients for input in preparing the FDA Executive Summary. JRC is unaware of the FDA contacting any former clients or their parents who supported the therapy throughout this process.

JRC submitted a comment[111] on April 14, 2014, in advance of the Panel Meeting that provided information pertaining to JRC's programming, its client population, a description of the GED devices, a regulatory history of the GED devices, data concerning the safety and efficacy of the GED devices, and literature supporting the use of skin shock treatment. In this comment, JRC once again offered to conduct clinical trials under an IDE.

JRC does not know if the FDA provided JRC's comment to the Panel prior to the Panel Meeting. The FDA should have provided JRC's comment to the Panel, just as it would have done for a Premarket Approval panel meeting, given the adversarial nature of the proceeding, JRC's status as the only affected firm, and in light of the fact that the FDA never contacted JRC or any parents of current or former JRC clients for input in preparing the FDA Executive Summary.

During the Panel Meeting, the Panel heard presentations from the FDA, JRC, parents of JRC clients, former JRC clients, and anti-aversive groups and individuals, followed by Panel deliberations. The Panel unanimously agreed that there is a specific subpopulation of patients exhibiting SIB or AB for whom pharmacological and behavioral treatment options other than

[110] JRC discusses and refutes some of this erroneous information later in this letter. *See infra* at p. 46.
[111] Tracking number 1jy-8bjf-k0hb.

ESDs are inadequate.[112] Numerous Panel members acknowledged that treatments other than ESDs were insufficient in the treatment of all clients presenting with SIB and AB.[113] Many panel members suggested the need for more research on the use of ESDs to treat severe SIB and AB.[114]

Following the Panel Meeting, via a May 14, 2014 letter to Carlos Pena, Ph.D., who at the time was the Acting Branch Chief of the Restorative Devices Branch of the CDRH, JRC made its third offer to conduct clinical trials under an IDE. JRC submitted this letter to the regulatory docket on June 20, 2014.[115] JRC has also repeatedly requested a meeting with the FDA to discuss the GED devices and the data that support their safety and efficacy. Furthermore, JRC has, on numerous occasions, invited FDA's healthcare professionals to visit JRC to observe the GED treatment and the data first hand. The FDA refused to meet, and has in fact declined every opportunity for a meeting with JRC, either to discuss the 510(k) notice pre-submission or to visit JRC, despite JRC's multiple requests for such meetings, including in the February 1, 2013 pre-submission, the May 14, 2014 letter to Dr. Pena, and a letter to Dr. Ostroff, Acting Commissioner of the FDA, on June 19, 2015. Given the FDA's willingness to talk with and solicit the opinions of opponents of ESD treatment,[116] this consistent refusal to meet with JRC is arbitrary and capricious and demonstrates the FDA's bias against JRC.

On June 23, 2014, JRC submitted a post-Panel Meeting submission[117] which addressed the mischaracterizations and erroneous information presented at the Panel Meeting and provided further support that the use of ESDs to treat SIB and AB does not present a substantial and

[112] Advisory Panel Transcript at p. 285.
[113] Drs. Kim, Peavy, Connor, Goodman, Miles, Bickel, Dorsey, Fost, Reppas; Advisory Panel transcript at 273-280.
[114] Advisory Panel Transcript at p. 285.
[115] Tracking number 1jy-8crx-wmd8.
[116] 81 Fed. Reg. 24386 at 24393.
[117] Tracking number 1jy-8cu2-q3xq.

unreasonable risk of illness and injury. JRC again reiterated its request for a meeting with the FDA, but received no response.

C. Proposed Ban

The Proposed Ban, published on April 25, 2016, is premised upon a tainted record, including significant erroneous information disseminated for or during the 2014 Panel Meeting. The record is now further tainted by public comments that are also plainly wrong. It would be improper, arbitrary, and scientifically indefensible for the FDA to rely upon these statements. Many comments are riddled with errors, and the FDA cannot utilize them.

We highlight below some examples of the erroneous, biased, misleading, and unreliable information that has permeated the record created through the public comment process. This further demonstrates the need for an adjudicative proceeding. A more detailed and robust response to these and other select comments (hereinafter "JRC Comment to Comments") will follow shortly under separate cover.

1. The June 6, 2006 New York State Education Department Report

The FDA referenced a June 9, 2006 report from the New York State Education Department ("NYSED") titled "Observations and Findings of Out-of-State Program Visitation Judge Rotenberg Educational Center (the "2006 NYSED Report") in its Executive Summary and during the Panel Meeting, specifically with respect to its discussion regarding purported health and safety issues relating to the use of ESDs for aversive conditioning. The 2006 NYSED Report was subsequently cited in the Proposed Ban and in comments on the Proposed Ban.

The 2006 NYSED Report does not present an accurate appraisal of JRC's treatment and education program and JRC's use of the GED to treat SIB and AB. There is a long, complex history surrounding the 2006 NYSED Report, which the FDA has ignored.

JRC has been an NYSED-approved school since the 1970s. In September 2005, a team of NYSED special education officials visited JRC to conduct a periodic licensing review of the entire JRC program. On November 17, 2005, just seven months prior to NYSED issuing the 2006 NYSED Report, NYSED gave JRC an excellent evaluation, finding that JRC met all special education requirements for the New York students and that JRC met all of NYSED's health and safety requirements. In early 2006, a parent of a former JRC client sued NYSED, claiming that JRC had mistreated the client. The suit was followed by a media barrage in New York that was highly critical of NYSED. Subsequently, following brief site visits in April and May 2006, without warning or even a discussion with JRC or the JRC parents, NYSED officials attempted to ban the use of aversives, including ESDs, with students from New York State and remove JRC from its list of approved schools. The 2006 NYSED Report was created to conform with its newly stated policy position on JRC and aversives and to refute NYSED's own laudatory review of JRC conducted in September 2005. The 2006 NYSED Report is replete with false and misleading statements about JRC's program and the GED devices in order to attempt to legitimize the claim that GED devices are not safe and effective. Such false statements include, but are not limited to: 1) the GED devices cause burns; 2) the output of the GED devices is adjustable; and 3) in 2006, the FDA's regulations prohibited the use of GED devices. JRC sent NYSED a lengthy response to the 2006 NYSED Report, responding to and discrediting each false or misleading statement point-by-point.[118] Thus, any comment that relies on the 2006 NYSED Report must be disregarded.

The parents of JRC students from New York State filed a federal lawsuit against NYSED challenging NYSED's new regulations, which severely restricted the use of aversives. These parents sought an injunction against NYSED's regulatory restrictions as to their children. The

[118] *See* Attachment 17, JRC Comment.

Court, with full knowledge of the 2006 NYSED Report, issued such an injunction, which remains in effect today. See Memorandum-Decision and Order, Alleyne, et al. v. New York State Educ. Dep't, et al., No. 1:06-cv-00994 (GLS), (N.D.N.Y. Sept. 8, 2006) (Sharpe, J.). In a later decision, the Court acknowledged that it was "unreasonable" for NYSED to ban the use of aversives, including ESDS, on an emergency basis based on the 2006 NYSED Report, with the following reasoning:

> NYSED has conducted numerous visits, inspections, and reviews of JRC, and has approved JRC as an out-of-state school for decades. (See id. at ¶¶ 77-79.) During this time, no concerns were raised about the health and safety of JRC students or the use of aversives. (See id. at ¶¶ 82-83.) However, in early 2006, a parent of a former JRC student sued NYSED, claiming, inter alia, that JRC mistreated the student. (See id. at ¶ 84.) The suit was followed by sensation-seeking newspaper articles highly critical of NYSED. Shortly thereafter, NYSED proposed a complete ban on the use of aversives, and decided to conduct another review of JRC due to the lawsuit, despite having reviewed JRC in Fall 2005. (See id. at ¶¶ 80-81, 85.) While the group NYSED selected to conduct this "re-review" was experienced in educational matters, some members of the team were not familiar with aversive techniques and at least one member of the team was opposed to aversives under all circumstances. (See id. at ¶¶ 87-88.) In June 2006, NYSED released a report that was critical of JRC and its methods. (See id. at ¶ 89.) Plaintiffs contend that this report 'was littered with flaws and false statements' because it omitted information as to the effectiveness of JRC's program and relied upon conjecture, innuendo, and falsehoods. (*Id.* at 90.)

Alleyne, et al. v. New York State Educ. Dep't, et al., 691 F. Supp. 2d 322, 328-29, 337 (N.D.N.Y. 2010) (emphasis added).

Since the 2006 NYSED Report was issued, 457 New York residents have been admitted to JRC and funded by their New York school districts and NYSED, and new admissions from New York continue. The 2006 NYSED report cannot be taken at face value.

2. The Mental Disability Rights International Report and U.N. Special Rapporteur on Torture Report

In 2010, Mental Disability Rights International, an international human rights group, issued

a report (the "MDRI Report")[119] which alleged that use of aversive treatment at JRC violated the United Nations ("UN") Convention against Torture, and called upon the UN Special Rapporteur on Torture or other Cruel, Inhuman or Degrading Treatment or Punishment ("UN Special Rapporteur") to initiate an inquiry into JRC practices. In response, the UN Special Rapporteur wrote a letter, dated June 11, 2012, to the United States Department of State, expressing concerns about JRC's aversive conditioning program. Subsequently, the UN Special Rapporteur called for a ban on electroshock procedures in a "Report of the Special Rapporteur on Torture and other cruel, inhuman or degrading treatment or punishment" (the "UN Report"). During the Panel Meeting, many public presenters cited statements by the UN Special Rapporteur as validation of their opposition to the use of ESDs. The FDA's Proposed Ban relies upon the UN Report, and many of the comments reference the UN Report as well as the MDRI Report. The moral arguments are not legally relevant under the FDC Act. We would note that these reports do not address the moral issues posed by depriving individuals of the only effective therapy they have ever received.

The MDRI Report is a false, misleading, sensationalized and one-sided account of JRC drafted by individuals with a strong philosophical opposition to aversives and whose purpose was to generate negative allegations about JRC. MDRI's "investigation" used only biased and often-anonymous sources and second-hand, baseless allegations from other anti-aversive advocates. It contains falsified information, and distorted material from JRC's website. MDRI never informed JRC it was conducting an "investigation" and never asked to visit JRC to review the clients, treatment or the treatment data.

[119] Torture Not Treatment: Electric Shock and Long-Term Restraint in the United States on Children and Adults with Disabilities at the Judge Rotenberg Center, Urgent Appeal to the United Nations Special Rapporteur on Torture (2010).

For example, the MDRI Report claimed that a JRC video testimonial in support of GED on JRC's website states, "I was kept in a small room, isolated . . . one staff and me for a year and a half."[120] MDRI took words out of a JRC client's testimonial statement that was entirely favorable to JRC and supported GED treatment, and used those words to deceptively create a statement that the client never made and which appears to be negative toward JRC. The original statement (shown below) reveals the client never stated that he was "isolated," only that the room he was in with a staff member, was isolated. He noted that he was kept in that room with a staff member in order to prevent him from hurting others. He also never stated that he was "in a small room, isolated" for a year and a half; he only stated that after a year and a half he was approved for the GED treatment. JRC does not use, and has never used, isolation rooms. An accurate account of the February 16, 2006 statement of Chris Adonetto, as it has always appeared on the JRC website, is as follows (the words that were taken out of context by the MDRI authors, and inappropriately used to create statements the client never made, are shown in bold):

> And prior of me coming to JRC I was still aggressive during them times and I used to hurt people and try to hide objects, try to stab people and whoever was around me. To prevent from all that happening **I was in a small, isolated room** with one staff and me, try to do my academics, I didn't do it. And after **a year and a half** I was approved for electro shock treatment and when I went on I received a couple, like most likely twenty, once a week and after you know, I started realizing, you know, I wasn't hurting no one else but myself, I took the priority of, you know, the GEDs came a long way, cause I went almost 10 months already without aggression and prior to that when I was in the conference room I used to have over 2000, 2098 behaviors, problem behaviors and the GED has helped me because now I have zero, flat. I am a flat line. And, you know, and I felt that it helped and right now I have a job, I am faded, I don't wear them completely no more. Unless I exhibit a behavior that I would get a consequence for. And, you know, my goals are to become a chef and to receive my high school diploma, which I am going to be receiving in four months. And to show the people that I hurt in the past how much I came afar, a long way, you know. And that's pretty much about it.[121]

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[120] MDRI Report at pg. 3.

[121] Testimonial statement of JRC Client Chris Adonetto, February 16, 2006.

This is just one example of the many falsehoods contained within the MDRI Report.[122]

Neither the MDRI nor the UN Special Rapporteur visited JRC, evaluated the GED devices, or discussed a single of their concerns with any of JRC's clinicians for, or parents of, JRC clients, or with many of the current and former clients who had life-saving progress at JRC. Any reliance by the FDA on the UN Special Rapporteur's comments is misguided due to the lack of factual foundation.

It is also worth noting that the UN Special Rapporteur on Torture has also called for an absolute ban on restraint and seclusion, stating "any restraint on people with mental disabilities for even a short period of time may constitute torture and ill treatment" and that the imposition of solitary confinement "of any duration, on persons with mental disabilities is cruel, inhuman or degrading treatment." This is an extreme position, as: (1) restraints and seclusion are acknowledged to be appropriate in some circumstances by organizations such as the Association of Professional Behavior Analysts and the American Medical Association and are used in treatment programs across the country in the treatment of severe behaviors;[123] and (2) restraints remain classified medical devices under 21 C.F.R. § 880.6760.

The Proposed Ban cites to the findings of the UN Special Rapporteur at least three times. However, the very same report that attacked ESDs also attacks physical restraints. Thus, the FDA cannot simultaneously rely upon the UN Special Rapporteur's findings to support a ban of ESD therapy for SIB/AB and ignore the UN Special Rapporteur's criticism of restraints (and isolation,

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[122] As dedicated opponents of ESD therapy, MDRI has circulated misinformation. FDA should not reward organizations that utilizes or distortion and deception by relying on their disinformation.

[123] Association of Professional Behavior Analysts, *Position Statement on the Use of Restraint and Seclusion as Interventions for Dangerous and Destructive Behaviors: Supporting Research and Practice Guidelines*, 2010, available at http://www.apbahome.net/Support%20for%20APBA%20Pos%20Stmt%20-%20Restraint%20&%20Seclusion.pdf (last accessed July 23, 2016); American Medical Association, *Code of Medical Ethics, Opinion 1.2.7 - Use of Restraints*, available at http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion817.page. (last accessed July 23, 2016).

a practice at many institutions with SIB/AB patients). The FDA's own MAUDE database reflects the potentially fatal risks of restraints, as it includes numerous reports of patients dying while in restraint.[124] Asphyxial deaths from restraint have been documented in the scientific literature.[125]

3. James Eason

The Disability Law Center Inc. ("DLC") submitted a comment[126] prior to the Panel Meeting attaching an expert affidavit from Dr. James Eason,[127] a professor of biomedical engineering at California Polytechnic State University,[128] to support the assertion that ESDs may present a substantial risk of injury, and that ESDs may produce tissue damage and superficial skin burns. During the Panel Meeting, Nancy Weiss, an anti-aversive advocate, referenced a statement in a *New York Times* article attributable to Dr. Eason[129] that the lowest shock used by JRC is "roughly twice what pain researchers have said is tolerable for most humans."[130] This quote is also repeated in numerous comments in the record.

Dr. Eason has never been to JRC, examined a GED device, or tested the output of a GED device. Also, his scientific analysis contains major errors. Specifically, according to DLC's representations, he failed to distinguish between alternating ("AC") and direct ("DC") current. This is a critical distinction because DC is generally safer than AC, and the physiological effects are different at equivalent amperage. For example, according to DLC, Dr. Eason cites OSHA data

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[124] *See, e.g.*, sources cited in JRC's Comment, at 44.
[125] *Id.*
[126] Comment of Disability Law Center, comment identifier FDA-2016-N-1111-0070.
[127] While the DLC attached Dr. Eason's affidavit to its comment, it redacted the entirety of his affidavit. The DLC purportedly re-stated Dr. Eason's findings in its written testimony, but JRC has no way of verifying the truth or accuracy of DLC's statements. JRC provides later in this letter a request for documents or other information relied on by the FDA that were made available to JRC. *See infra* at p. 68-70.
[128] Many comments submitted to the docket refer to him as a Professor of Biomedical Engineering at Washington and Lee University. In fact, Dr. Eason has not worked at Washington and Lee for over eight years. He was an Assistant Professor of Physics and Engineering at Washington and Lee University from 2002 to August 2008. *See* his LinkedIn profile at https://www.linkedin.com/in/james-eason-6a383610.
[129] http://www.nytimes.com/2007/12/25/nyregion/25shock.html?_r=1
[130] Panel Hearing Transcript, pg. 168; 174; http://www.nytimes.com/2007/12/25/nyregion/25shock.html?_r=1

indicating that current at 17mA – 99 mA will result in "[e]xtreme pain, respiratory arrest, severe muscular contractions. Individual cannot let go. Death is possible."[131] However, this does not mention the type of current referenced by OSHA (AC at 60 Hz).[132] The GED devices use DC as opposed to AC, and do not result in the adverse effects described by Dr. Eason as claimed by DLC.

The table below[133] describes the differential effects of AC and DC current at equivalent amperages.

AC (60 Hz) (mA)	DC (mA)	Effects
0.5 – 1.5	0 – 4	Perception
1 – 3	4 – 15	Surprise (Reaction)
3 – 22	15 – 88	Reflex Action (Let Go)
21 – 40	80 – 160	Muscular Inhibition
40 – 100	160 – 300	Respiratory Block
>100	>300	Usually Fatal

The GED-3A has DC of 15.25 mA and the GED-4 has DC of 41 mA, thus falling far below the level of DC that could result in muscular inhibition, respiratory block, or death. The output of the GED devices fall within the FDA's recognized standards for nerve and muscle stimulators.[134] The GED devices have been evaluated and cleared for use by national medical and engineering experts in electrical safety. These experts have examined and tested the actual GED devices themselves, received GED-3A and GED-4 applications, examined all technical parameters

[131] Comment of Disability Law Center, comment identifier FDA-2016-N-1111-0070, at 9.
[132] https://www.osha.gov/SLTC/etools/construction/electrical_incidents/mainpage.html
[133] Neitzel, Dennis K. CPE. (2006). The Hazards of Electricity – Do You Know What They Are? Presented at the 2006 IEEE IAS Electrical Safety Workshop, February 7-10, Philadelphia, Pennsylvania.
[134] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard__identification_no=31290; http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm073783.pdf

associated with the GED devices, and determined that the devices are safe.[135,136] JRC informed the FDA of these findings prior to the Proposed Ban.[137] In other words, Dr. Eason's oft-cited statement and other information which DLC attributes to Dr. Eason is simply wrong. It does not become any more correct simply because numerous commenters report it.

Further, the FDA entirely disregarded the evidence JRC presented at the Panel Meeting and in its comment submitted prior to the Panel Meeting showing that the GED devices are not capable of causing skin injury. The FDA chose instead to credit inaccurate reports such as the 2006 NYSED Report,[138] literature[139] refuted by JRC[140] regarding burns allegedly caused by ESD application, and Eason's affidavit.[141] JRC has 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 is painless and disappears within an hour to a few days. Based on existing data, this erythema occurs in less than 1% of applications. Mild erythema does not support a ban on ESDs. Numerous devices cause erythema.[142]

Here, the only adverse effect of ESDs for which there is clinical evidence is erythema. On the other hand, in the FDA's powdered glove ban, the FDA found dangerous adverse effects.[143]

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[135] Durfee, D.A. (2009, November 18). Letter to the Judge Rotenberg Center. Copy in possession of The Judge Rotenberg Center.
[136] Miner, J.R. (2009, October 29). Letter to the Judge Rotenberg Center. Copy in possession of The Judge Rotenberg Center.
[137] January 16, 2013 Letter to Mr. William MacFarland ("All of these experts have concluded, upon review of the data, that the device operates safely and is highly effective in reducing problematic behaviors without serious side effects. See Letter from James Miner, MD, to JRC, dated October 29, 2009; BCA GED Electronics Report from David A. Durfee, Ph.D., to Glenda Crookes, dated November 18, 2009, copies of which are attached hereto as Attachment 2A-2B.")
[138] *See supra* at p. 37.
[139] 81 Fed. Reg. 24386 at 24395, Refs. 29, 30, 39, 41, 50, and 65.
[140] *See* Attachment 8 to JRC Comment, Analysis of FDA Cited References.
[141] 81 Fed. Reg. 24386 at 24410.
[142] See FDA Guidance for Industry and FDA Reviewers/Staff: Premarket Notification [510(k)] Submissions for Testing for Skin Sensitization To Chemicals In Natural Rubber products (Jan. 13, 1999)(discussing sensitivity testing measuring erythema reactions, based on the increased use of medical devices containing natural rubber); see also Summary of Safety and Effectiveness Data, P010061 (Photodynamic Therapy Light); Summary of Safety and Probable Benefit, H090002 (Hyperthermia System).
[143] 81 Fed. Reg. 91722 at 91723 ("the use of powder on medical gloves presents numerous risks to patients and

Also, the FDA found no significant benefit to powdered gloves.[144] The evidence here is that clients have benefited. The contrast between the two recent ban procedures is stark.[145]

4. Hearsay

The FDA has also elected to rely on hearsay and "second-hand accounts."[146] The "Scientific Literature" sections of the Proposed Ban are replete with totem-pole hearsay from articles citing to outside interviews, statements, and positions.[147] Innumerable comments also cite hearsay as well. For example, to support the Proposed Ban, the FDA approvingly cites an article by a known critic of GED citing unnamed individuals.[148] Because the critic's sources are anonymous, JRC cannot meaningfully respond to allegations made in the article.[149] The FDA's reliance on hearsay hamstrings JRC's efforts to meaningfully respond to and correct the record.

FDA discusses in the Proposed Ban the hierarchy of sources of valid scientific evidence.[150] Anecdotal information is among the lowest on FDA's list. FDA repeatedly cited even lower forms of evidence: hearsay relying upon anonymous sources. FDA is itself using information that it would not allow a company to use to support a marketing application.

5. Interviews

The Proposed Ban cites information from certain former JRC clients who have individually presented evidence to the FDA regarding harm they claim to have experienced as a result of

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health care workers, including inflammation, granulomas, and respiratory allergic reactions.").

[144] *Id.* at 91724 ("The benefits of powdered gloves appear to only include greater ease of donning and doffing, decreased tackiness, and a degree of added comfort, which FDA believes are nominal when compared to the risks posed by these devices.").

[145] *See PREVOR v. Food & Drug Admin.*, 895 F. Supp. 2d 90, 99 (D.D.C. 2012) ("An agency must treat similar cases in a similar manner unless it can provide a legitimate reason for failing to do so.").

[146] *Id.*, at 24403.

[147] 81 Fed. Reg 24386 at 24393.

[148] 21 Fed. Reg. 24386 at 24409.

[149] Given that the documentary evidence rebuts statements made by named former clients, this anonymous sourcing is not harmless to JRC.

[150] 81 Fed. Reg. 24386 at 24393.

treatment with ESD therapy. Treatment records for those clients, however, tell a very different story. For example, after leaving JRC, one of those clients maintained a cordial correspondence with JRC staff, enjoyed return visits, and even repeatedly in writing credited JRC, and the GED treatment that replaced her ineffective and harmful psychotropic medication, with saving her life.[151] Although the FDA cites her as a critic, in that former client's own words JRC "really did save my life from that state hospital."[152] Other JRC clients would have provided a similar perspective, had the FDA elected to hear perspectives that did not conform to the FDA's narrative.

Further, the identity of some of the individuals the FDA interviewed "off-the-record" is unknown, and the information with which they provided the FDA is not subject to verification. Thus, there is no way for JRC to respond to what they purportedly said. However, based on the unredacted client reports which are rebutted by the documentary evidence, it is likely that these anonymous individuals' reports are, at a minimum, incomplete and misleading.

D. Public Comments to the Proposed Ban

During the FDA's notice and comment period for the Proposed Ban, the FDA received 1,488 public submissions from various sources, including individual consumers, members of academia, healthcare professionals, well-known anti-aversive consumer groups, and state government agencies. It also received 181 anonymous comments. These comments include a potpourri of false and/or misleading statements, emotional opinions, and out-of-date statements based on hearsay, rumor, and unreliable or anonymous sources.

Many submissions are form comments containing identical language aimed only at JRC, indicating the existence of an organized campaign against JRC. For example, the Autistic Self

[151] Attachment 19 to JRC Comment.
[152] Attachment 19 to JRC Comment.

Advocacy Network issued an Action Alert[153] that encourages "self-advocates, our allies, and all those who oppose the inhumane use of electric shock to control the behavior of people with disabilities" to comment, provides instructions on how to do so, offers a template, and even warns that a failure to personalize the template with at least a few sentences could result in the FDA discarding the comment.[154] Similarly, commenter Gregory Miller posted a "sample comment" on www.change.org, which language is used in almost 200 of the comments to the FDA.[155]

The FDA's process for receiving public comments has resulted in a record full of false and/or misleading information which deprives JRC of any opportunity to adequately challenge the false information presented. If the FDA were to accept these erroneous comments at face value, any conclusions based on the comments would be unsupported by substantial evidence, arbitrary and capricious, and a miscarriage of justice. Comments that contain false or misleading information cannot support rulemaking, and opinions that rely on false premises must be afforded no weight. JRC provides below a few examples demonstrating the highly prejudicial and erroneous nature of the comments submitted. Shortly, JRC will submit JRC's Comment to Comments to the Office of Chief Counsel under separate cover, which will contain a more detailed discussion of JRC's objections to these and other select comments.

1. Comparison of GED Treatment with Torture

351 comments refer to GED Treatment as "torture." There is no basis for this assertion. The GED devices are not torture under human rights law. Under Article 1-1 in the UN Convention Against Torture, torture is defined as follows:

> [A]ny act by which severe pain or suffering, whether physical or mental, is intentionally inflicted on a person for such purposes as obtaining from him or a

[153] *See* https://www.change.org/p/1491487/u/16605134?fb_comment_id=1065917060114145_106
[154] *Id.* As FDA will note, many commenters did not heed this advice.
[155] *See* http://autisticadvocacy.org/2016/06/action-alert-tell-the-fda-ban-electric-shock-torture-of-people-with-disabilities/

> third person information or a confession, punishing him for an act he or a third person has committed or is suspected of having committed, or intimidating or coercing him or a third person, or for any reason based on discrimination of any kind, when such pain or suffering is inflicted by or at the instigation of or with the consent or acquiescence of a public official or other person acting in an official capacity.

The use of the GED devices as a supplementary component of positive behavior modification treatment that significantly reduces harmful and painful SIB/AB does not meet any of the elements in the definition of torture in the UN Convention against Torture. Behavioral skin-shock is applied to ameliorate a condition or illness pursuant to the proven scientific principles of Applied Behavior Analysis, which by itself rules it out as a form of torture. GED treatment does not inflict "severe pain and suffering." Many JRC clients view GED treatment as helpful or even life-saving. Aversive therapy is used to *end* pain, and to save, extend and enrich lives. The role of the "public official" – the independent third party reviewer – is to safeguard the client's rights and welfare. Aversive therapy is not administered for the purpose of applying retributive punishment to an individual. To call aversive therapy "torture" is as inappropriate as calling uncomfortable medical treatments torture or surgery "assault with a deadly weapon." Uninformed rhetoric should have no role in this regulatory proceeding.

Further, as described above, the MDRI Report, which contends that use of aversive treatment at JRC violates the UN Convention against Torture, and upon which the UN Special Rapporteur relied in his own report, is an uninformed, false, misleading, sensationalized, and one-sided account of JRC. It was authored by individuals who never visited JRC or discussed a single concern with any of JRC's clinicians or parents of JRC clients at the time of their "investigation", or with many of the current and former clients who made life-saving progress at JRC. It is polemic, not fact.

2. The 2002 Andre McCollins Video

Numerous comments reference a 14-year-old video of former JRC client Andre McCollins. As a threshold matter, this incident relates to the manner in which GED was used in one particular instance in 2002, not to the safety or efficacy of the device itself. Moreover, the video reflects the use of policies and procedures that JRC has since modified.[156] Thus, this single 2002 incident is of no probative value with respect to the FDA's 2016 Proposed Ban.

Nevertheless, because the FDA and numerous comments reference the video, we will discuss it in detail to illustrate the unfairness of relying on information taken out of context.

Mr. McCollins suffered from a behavior disorder which caused him to engage in severe SIB and AB. He was admitted to JRC in February of 2001 after expulsion and rejection by numerous schools due to his violent behavior that resulted in serious injuries to himself, other clients and staff.

At the request of his mother, and after JRC attempted to treat Mr. McCollins with positive programming and psychotropic medication, JRC sought and received court approval to add GED-treatment to Mr. McCollins' behavioral treatment plan. For seven months, Mr. McCollins received behavioral treatment at JRC supplemented with skin shock. This treatment proved extremely effective, bringing his dangerous and disruptive behaviors to near-zero levels and allowing him to make unprecedented academic, social, and behavioral progress. Mr. McCollins received a total of twenty-eight applications during this seven-month period.

On October 13, 2002, Mr. McCollins went for a one-week home visit with his mother. While Ms. McCollins was trained to use the skin shock device, as needed, and was instructed to

[156] In the Proposed Ban, the FDA says it changed its approach from 2000, when it told JRC it would not regulate GED. Similarly, JRC has changed its approach in the intervening years. The difference is that the FDA has offered no explanation for its change, while JRC has. The FDA cannot freely discard a prior position from 2000 but justify a ban by citing JRC procedures which were modified long ago.

continue the skin shock treatment during the home visit, she did not continue the treatment and, in fact, did not even have Mr. McCollins wear the device. Mr. McCollins began to regress during the home visit, and his dangerous and disruptive behaviors began to increase. Mr. McCollins returned to JRC, and dangerous and disruptive behaviors that occurred during the home visit again occurred during the early morning of October 25, 2002. On the bus from his group home to the school, Mr. McCollins punched a staff member and received a skin shock application. Once in the classroom, Mr. McCollins' dangerous and disruptive behaviors continued and he received a skin shock application after acting aggressively. Mr. McCollins was tensing-up (a serious self-injurious behavior where he would tense up his whole body with such intensity that he put himself at risk for a hyperintensive emergency during which his blood pressure could elevate to unsafe levels and result in damage to internal organs) and screaming, for which he also received a skin shock application. Mr. McCollins' assigned clinician became concerned that the physical restraints necessary to prevent Mr. McCollins from hurting himself or from hurting others were themselves agitating Mr. McCollins and exacerbating the situation. At that time, in an attempt to calm his outbursts, Mr. McCollins' clinician decided that it was best to move Mr. McCollins to the four-point restraint board to provide Mr. McCollins with relief from physical contact with JRC staff. After Mr. McCollins received thirty skin shock applications, the treatment was suspended.

Ms. McCollins retained an expert psychiatrist in connection with a civil trial related to this incident. This expert testified under oath that behavioral skin shock treatment is effective, is necessary for some cases of severe behavior disorders, and that the skin shock treatment was necessary for Mr. McCollins. His opinion was that JRC should have suspended Mr. McCollins' skin shock treatment on October 25, 2002 after the fifth application, not that Mr. McCollins should have received no shocks. Thus, while the tape of Mr. McCollins is repeatedly cited as proof that

ESD for SIB/AB should be completely banned, Mr. McCollins' own expert disagreed with that position.

Moreover, JRC has made numerous changes to its practices in the 14 years following this incident. For example, JRC now looks even more closely at the circumstances surrounding each GED application and conducts a more intensive analysis of the potential causes of the behavioral outburst, and will suspend treatment at the earliest possible signs of the treatment no longer being effective. JRC's policies now provide that only the client's specifically assigned JRC clinician can authorize any GED application beyond increments of 10 per day. However, it would be extremely unusual for any JRC patient to receive 10 GED applications in one day – as of May of 2016, the mean number of applications per week was less than 1.[157] Further, JRC's policies no longer permit staff to administer GED applications to clients while clients are on a restraint board.

The FDA's role is to address the device's safety and effectiveness, not to determine if a device is appropriate in a certain setting, for a certain client. This is true for not only the GED devices but also electrotranscranial treatments, TENS devices, or any other therapy, electrical or otherwise. The manner in which JRC used the GED on a client 14 years ago is irrelevant to whether the statutory criteria for a ban are met.[158]

Further, in an adjudicatory proceeding, this video footage could not be presented in a vacuum, as it was within the comments to the Proposed Ban. In the Trial, MA DDS introduced video clips showing JRC clients receiving GED applications, and MA DDS experts opined as to alleged deficiencies. JRC had the opportunity at the Trial to cross-examine MA DDS' witnesses, present additional video footage supporting the efficacy of GED treatment, introduce client-

[157] *See* JRC Comment, at Figure 1.

[158] That is particularly true given that the videotape has been divorced from the context, and JRC's treatment protocols have since been changed. The heavy reliance in the 2002 treatment of Mr. McCollins itself underscores the weakness in focusing on a particular use of a device, rather than its safety or effectiveness.

specific documents such as prior placement records, treatment plans and client charts, and elicit testimony from its own experts contextualizing the video footage introduced by MA DDS. By contrast, in the instant proceeding, the FDA has given JRC no ability to counteract such information, raising substantial procedural due process concerns.[159] Moreover, the question of whether treatment was properly administered in any particular instance falls within the purview of the states, not the FDA.

3. Comparison of GED Devices to TASER/Cattle Prod

Multiple comments erroneously use incorrect or incomplete information to make specious comparisons between the GED devices and other devices and treatments such as the TASER® device, a dog collar, a cattle prod, and Electroconvulsive Therapy ("ECT"). These comments demonstrate a fundamental misunderstanding of the various parameters associated with the GED.

Devices that deliver electrical current are designed for various purposes. The GED devices are designed to deliver a safe and localized stimulus to the surface of the skin that will serve as a decelerator for severe problem behaviors. The TASER® is a conducted electrical weapon designed to cause neuromuscular incapacitation by stimulating motor nerves that prevent coordinated movement.[160] The purpose of ECT machines is to induce a seizure by passing current through the brain.

Contrary to what some commenters claim, the GED devices are not "stronger" than a TASER® device.[161] [162] The TASER® has different characteristics than the GED devices. As described above, GED uses DC, whereas the TASER® device sends just under 4 mA of AC at

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[159] *See, e.g., Alaska Airlines, Inc. v. CA. B.*, 545 F.2d 194, 200 (D.C. Cir. 1976).
[160] Taser®. (2016). End-User Certification Course M26 Conducted Electrical Weapon. Version 20. Retrieved from: https://www.dropbox.com/sh/al8io78ytiq9etx/AACCgumyhWb3YkljQPbDBAYXa?dl=0
[161] Taser®. (2016). End-User Certification Course M26 Conducted Electrical Weapon. Version 20. Retrieved from: https://www.dropbox.com/sh/al8io78ytiq9etx/AACCgumyhWb3YkljQPbDBAYXa?dl=0
[162] Attachment 18 to JRC Comment, Tr., Day 26, at 21-24, 33 (June 1, 2016).

high voltage (25,000-50,000)[163] through the entire body and is designed to incapacitate a person by interfering with the activity of motor neurons. The TASER® transfers 77 times more electrical current per second than the GED-4 device.

The current from the GED-3A and GED-4 devices pass between two electrodes five centimeters apart over the surface of the skin, not through the entire body, and not through the heart or the brain. James R. Miner, M.D., who is an expert in the assessment and effects of human electrical exposure and who has published peer-reviewed articles on the TASER® device and has evaluated the GED and GED-4 devices, testified that GED devices are safe. Unlike the TASER® device, they transmit electricity across approximately five (5) centimeters of the surface of the skin; thus, the pain associated with the application of the GED is localized.[164]

Compared to other devices, the GED-3A and GED-4 deliver far less energy to a much smaller area of the body. For example, the GED-3A delivers less than 1% of the total energy than the TASER® M26. Compared to ECT, the GED-3A delivers less than .5% of the total energy. Further, the GED devices do not *continuously* pass current through the skin during an application. The GED devices have a duty cycle of 25%; thus, although the duration of the GED application is two seconds, the device only delivers current 25% of the time, or for .5 seconds.

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[163] TASER® Electronic Control Devices Electrical Characteristics – X26™. (2009). Retrieved on October 18, 2016 from http://www.ecdlaw.info/outlines/EC_02-01-09_%20X26_Elec_Char.pdf.
[164] Attachment 18 to JRC Comment, Tr., Day 26, 42:16-43:19 (June 1, 2016).

The properties of various devices that deliver electrical current are summarized in the table below:

Properties of Various Electrical Stimulation Devices

Device	Current Path	AC or DC	mA	Volts	Pulses per second	Duration (seconds)	Total Joules (energy) per Application
GED-3A	Surface of the Skin	DC	15.25	60	20	2	<0.45
GED-4	Surface of the Skin	DC	41	66	20	2	<1.353
Cattle Prod[165]	Surface of the Skin	AC	18.5	2400	50-500	~1	<44.4
TASER® M26[166]	The body	AC	<4	50,000[a]	20	5	50[b]
ECT (Thymatron System IV)[167]	The skull and brain	AC	900	450	variable	8 (max)	100 (max)
Defibrillator[168]	Through the Chest	DC	19400[c]	2425	-	.006	269

[a]50,000 Volts is the peak arcing voltage. The peak voltage across the body is reported to be 5000. See Taser® User Certification Course Version 18 Released July 2011.
[b]0.5 J per pulse * 20 pulses/s * 5 second duration = 50 J
[c] Maximum initial current at 125Ω

At the Trial, Dr. Miner testified about his research on the physiologic effects of the TASER® device.[169] Dr. Miner testified that comparing the pain experienced by the GED devices

[165] Geddes, L.A. & Roeder, R.A. (2005). Handbook of Electrical Hazards and Accidents. Tucson, AZ: Lawyers & Judges Publishing Company, Inc.
Foxx, R. M., McMorrow, M. J., Bittle, R. G., & Bechtel, D. R. (1986). The successful treatment of a dually-diagnosed deaf man's aggression with a program that included contingent electric shock. *Behavior Therapy, 17*, 170-186.
[166] Taser® User Certification Course Version 18 Released July 2011.
Taser®. (2016). End-User Certification Course M26 Conducted Electrical Weapon. Version 20. Retrieved from: https://www.dropbox.com/sh/al8io78ytiq9etx/AACCgumyhWb3YkljQPbDBAYXa?dl=0
[167] Somatics, LLC. (n.d.)The Streamlined Somatics Thymatron® System Saves Time and Effort. Retrieved from: http://www.thymatron.com/downloads/somatics_brochure.pdf
[168] ZOLL Medical Corporation. (2016). R Series® ALS Operator's Guide. Retrieved from: http://www.zoll.com/WorkArea/DownloadAsset.aspx?id=23899
[169] Attachment 18 to JRC Comment, Tr., Day 26, 21-24; 33-34 (June 1, 2016).

and the TASER® is "not even close" – the TASER® "hurts as much as something could possibly hurt" and rated it a "solid 11" on a 10-point scale.[170] He testified that the GED device as "moderately painful", the GED-4 device felt "[r]oughly the same" as the GED,[171] that both were around a 4 or a 5 on a 10-point scale,[172] and that there were no lingering effects.[173] Dr. Miner testified that the pain from the GED devices would be "very similar to the amount of pain from an anesthesia injection in terms of duration and intensity,"[174] and that patients generally "flinch or cringe" when they experience a brief, moderate pain and then "recover completely immediately afterwards".[175] Dr. Miner testified that, in his professional opinion and to a reasonable degree of medical certainty, GED treatment, as used at JRC, is safe[176] and, further, does not pose a risk or an unreasonable risk of illness or injury to a patient.[177]

The comparison of the GED shock to cattle prods is also entirely fallacious. Cattle prods send 18.5 mA at 5000 volts.[178, 179] Cattle prods deliver far more electrical energy than the GED devices. When all the electrical parameters are considered, a cattle prod delivers 100 times more energy (measured in Joules) than the GED-3A. The duration of the cattle prod is variable and depends on how long the prod is in contact with the skin. In comparison, the GED is set to fixed duration of two seconds, with current flowing for only 0.5 seconds.

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[170] *Id.* at 51:14-23.
[171] *Id.*, at 46:11-16; *see also* Tr., Day 26, 50:5-8 (June 1, 2016) (Dr. Miner testified that his experience the second time he received applications from the GED and GED 4 devices was comparable to his first experience.).
[172] *Id.* at 51:20-23.
[173] *Id.* at 46:20-22.
[174] *Id.* at 55:20-56:2.
[175] *Id.* at 56:19-57:9.
[176] *Id.* at 51-52.
[177] *Id.* at 53.
[178] Foxx, R. M., McMorrow, M. J., & Bittle, R. G. (1986). Increasing staff accountability in shock programs: simple and inexpensive shock device modifications. *Behavior Therapy, 17*, 187-189.
[179] Williams, D. E., Kirkpatrick-Sanchez, S., & Iwata, B. A. (1993). A comparison of shock intensity in the treatment of longstanding and severe self-injurious behavior. *Research in Developmental Disabilities, 14*, 207-219.

In sum, the FDA and opponents of GED treatment have wrongly depicted it as comparable to being TASERed or shocked with a cattle prod. The fact that multiple comments contain the same incorrect claim does not make it true. Indeed, the certainty with which commenters make these assertions undermines their credibility, given that the information they cite is so demonstrably false.

4. Errors Pertaining to The JRC Client Population

Over 250 comments claim that ESDs are currently used on minors at JRC, and commenters also claim that ESDs are used on over 200 clients at JRC.[180] These statements are false. The credibility of commenters making these assertions must be called into question because the authors of these comments made no effort to verify the accuracy of the statements they made therein. In fact, of the 255 clients currently enrolled at JRC, just 53 are indicated for use of aversive therapy and only 47 are currently utilizing GED devices. All JRC clients currently receiving GED treatment are 20 years old or older.

This is yet another example of how the FDA record is replete with erroneous comments made by individuals or groups unfamiliar with – or indifferent to – JRC's actual treatment and population. It further demonstrates the inherently flawed nature of this proceeding, and the need for an adjudicatory hearing in which false claims such as these may be properly addressed. Typically, the FDA could use third party comments in reaching its decision; however, to do so here would be to base a decision on falsehoods and to deny JRC due process. When comments are wrong on basic, objectively verifiable information such as the number of clients receiving GED devices, then all statements in those comments should be suspect.

[180] Comment from Massachusetts DD Council Anonymous, Massachusetts DD Council, comment identifier FDA-2016-N-1111-1405 (July 21, 2016).

5. Purported Deaths Related to GED Treatment

Several commenters have erroneously claimed that the use of ESDs at JRC has resulted in client fatalities. One commentator specifically named six clients whose deaths "have been attributed to the GED devices."[181] As JRC has previously told the FDA, these claims are false - the GED has never caused or contributed to a client death or serious injury.

JRC serves both children and adults with severe behavior disorders and offers life-long placement for clients with significant developmental disabilities rendering them incapable of living on their own. The current age range of the JRC clients is 8 years old to 57 years old. Since 1980, six JRC clients have died while enrolled in the JRC program. None of these deaths were related in any way to JRC's GED, aversive, or behavioral treatment. For example, one client, who never received GED treatment, passed away in 1985 from natural causes associated with tardive dyskinesia. Other clients, none of whom received GED, died from gastric perforation, jumping out of a moving vehicle, a seizure, and an intestinal issue. Another individual mentioned in a comment[182] who never received GED treatment at JRC did not die at JRC, but rather, is believed to have died from natural causes at a treatment program in Northridge, California. Once again, the FDA's process has resulted in the submission of unfiltered, baseless accusations.

It is also worth noting here that the FDA has received reports of hundreds of thousands of incidents of medical devices injuring (and potentially causing or contributing to the death of) individuals. The FDA has not proposed banning any of those devices, except for powdered gloves and the GED.[183]

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[181] Comment from Lee Tilson, comment identifier FDA-2016-N-1111-1681 (Aug. 23, 2016).
[182] *Id.*
[183] Joe Carlson and Jim Spencer, FDA rules allow medical device makers to keep injuries under wraps, Star Tribune, Oct. 16, 2016, http://www.startribune.com/fda-protocols-allow-medical-device-makers-to-keep-adverse-events-out-of-view/397256291/

6. Comments Directed at JRC

Many comments are directed specifically at JRC. Of course, the manner in which JRC cares for its clients is outside the FDA's purview and irrelevant to whether a device should be banned.

For example, Daniel Obejas, a representative of the Autistic Self Advocacy Network's Los Angeles chapter, claims that JRC's intent is to use ESDs to cause serious injury.[184] That is simply not true. Just like the parents or guardians of JRC clients and the Probate Courts that review and approve GED treatment, JRC's intent is to treat clients by reducing and eliminating SIB/AB and other behaviors that are causing them serious harm. There is no device in the United States that is subject to as many safeguards or as much oversight by independent third parties.

Another example is the comment by Kim Lawrence. Ms. Lawrence claims she worked at JRC as a home aide in a house that "was all boys, the youngest being five."[185] JRC has no record of having an employee by the name of Kim Lawrence. JRC also does not use the job title "home aide" and has never had a 5-year-old within its residential program. On its face, a comment from someone claiming to have been a former employee would appear credible. Yet Kim Lawrence's comment is a fabrication.

Another comment falsely states that "the devices are rarely re-calibrated."[186] In fact, GED-3A devices are calibrated every six months, and GED-4 devices are calibrated quarterly, per JRC's policies.

[184] Comment from Daniel Obejas, comment identifier FDA-2016-N-1111-0171 (April 25, 2016).
[185] Comment from Kim Lawrence, comment identifier FDA-2016-N-1111-0654 (May 13, 2016). Even if this were true – which it is not – it would have no bearing on whether GED should be banned.
[186] Comment from Gay Wilmerding, comment identifier FDA-2016-N-1111-0767 (May 13, 2016).

Comments such as these should be summarily dismissed. These comments further show that the Proposed Ban is specifically targeted at JRC's treatment practices, including its use of the GED devices, and further illustrates the need for an adjudicatory hearing.

i. Sweeping Assertions/False Information

Numerous comments make broad, unsubstantiated assertions, and patently false statements without citing any source. For example, many commenters use the repeated phrase "dozens of testimonies and documents"[187] to create the impression that evidence is unequivocal and irrefutable, without actually referencing any of these purported documents and testimony. Many commenters rely on unreliable sources, such as blog posts and YouTube videos, but cite to them in a manner that gives them the appearance of credibility.[188] The FDA should not rely upon these erroneous, sweeping assertions and unverifiable or false information.

ii. Mental Health Legal Advisors Comment

The comment of the Mental Health Legal Advisors Committee of the Supreme Judicial Court of Massachusetts ("MHLAC")[189] is riddled with false statements. MHLAC claims, without any substantiating data, that "[t]he effect of observing and hearing other students being shocked cannot be underestimated" and that it "immerses vulnerable residents in a culture of sorrow and

[187] *See* Comment from Cathy Terrill, comment identifier FDA-2016-N-1111-0221 (April 29, 2016); Comment from Tracy Mauk, comment identifier FDA-2016-N-1111-0918 (May 16, 2016) ; Comment from Gretchen White, comment identifier FDA-2016-N-1111-0934 (May 15, 2016); Comment from NADD, comment identifier FDA-2016-N-1111-1264 (May 19, 2016); Comment from Marian Frattarola-Saulino, comment identifier FDA-2016-N-1111-1426 (May 25, 2016) ; Comment from Danielle Dieterich, comment identifier FDA-2016-N-1111-1481 (June 24, 2016). These comments are form comments or otherwise repeat the same language for portions of their respective comments.

[188] *See* Comment from Noah B., comment identifier FDA-2016-N-1111-0968 (May 16, 2016) ("That approach has created PTSD in many, in addition to the physical injuries (https://stopjrc.wordpress.com/; https://www.youtube.com/watch?v=Ko-ip3MImik)". JRC psychiatrists have examined hundreds of clients receiving ESD treatment and have never found that ESD treatment caused an increase in PTSD symptoms.

[189] Comment from Mental Health Legal Advisors Committee of the Supreme Judicial Court of Massachusetts, comment identifier FDA-2016-N-1111-0255 (May 4, 2016).

fear." Such statements suggest that members of MHLAC personally made such observations. In fact, no members of MHLAC have ever visited JRC.

MHLAC also claims that JRC residents suffer "traumatizing events over and over, in insolation from one another and from the larger world." MHLAC further intimates that the GED somehow restricts community access. Nothing could be further from the truth. JRC clients often arrive at JRC having had no access to the community for years due to the dangerousness of their untreatable severe behavior disorders. Treatment with the GED devices and the resulting elimination of their problematic behaviors allows them to integrate into the community.

Neither the application of the GED nor witnessing its application is a traumatizing event as claimed by MHLAC, and as discussed in the Proposed Ban. JRC has not observed a negative impact on clients who receive GED applications or those who witness GED applications. Court orders approving GED treatment explicitly state that such treatment is "without the risk of any significant adverse side effects." Case conference reports – prepared by independent psychologists paid by the Commonwealth of Massachusetts – recommend continued GED treatment and do not state that the GED has had any negative impacts on the patients. Causing massive physical damage to one's self is traumatic. Having to live in a psychiatric ward because it is too dangerous to live in the community is traumatic. A two-second application shock to the skin (which based on the JRC data only occurs one time per week on average for the JRC clients) is not traumatic, particularly where the very infrequent skin shock eliminates acts of self-abuse and frees the client from locked wards.

JRC clients are integrated into the community – they live in group homes throughout the suburbs of southeastern Massachusetts, travel to and from JRC's day program on weekdays, attend community outings and home visits on weekends, and receive routine medical treatment in offices

throughout greater Boston, including the Harvard teaching hospitals. They work at jobs in the community and attend local colleges. For many clients, it is the effective treatment of their problem behaviors with the GED which has allowed them to access the community and attend regular home visits for the first time in years.

MHLAC's criticism inverts the truth. Clients who had been isolated at their prior facility due to their SIB/AB are no longer isolated after receiving the GED at JRC. The GED combined with other treatment interventions ends the need for restraints, hospitalization (many individuals arrive from locked psychiatric units), a lifetime of iatrogenic treatment, and community exclusion. For many clients, their SIB/AB once caused them to become isolated; GED has enabled them to return to the larger world.

At the Trial, a former JRC client, A.S., testified that treatment with the GED resulted in her integration into society, rather than her isolation from it. A.S. testified that before JRC, as a result of her severe SIB and AB, she was physically, mechanically, or chemically restrained about once per day for approximately a six-month period.[190] She was placed in juvenile detention,[191] was so "drugged up" that she felt "like a zombie",[192] was unable to function other than to hurt people,[193] and was admitted to JRC restrained on a stretcher because she was immobilized from the high dosages of psychotropic medication they were giving her.[194] After receiving only about 11 GED applications over the period of approximately one year,[195] GED treatment enabled her "to function as a human being",[196] earn her high school diploma,[197] work at a Friendly's restaurant in

[190] *See* JRC Comment, Attachment 18, Tr., Testimony of A.S., Day 38, 12-13 (June 17, 2016); *see also id.* at Attachment 18, Ex. 733, 2-3. Note that this practice arguably constitutes "torture" under the UN definition.
[191] *See id.* at p. 13.
[192] *See id.* at pp. 12, 15.
[193] *See id.* at p. 15.
[194] *See id.* at p. 16; *see also id.* at Attachment 18, Ex. 734.
[195] *See id.* at pp. 17-18.
[196] *See id.* at p. 21.
[197] *See id.*

the community,[198] and, after her successful discharge from JRC, live on her own in an apartment,[199] work in the medical services industry,[200] and raise her two children.[201]

The Trial witnesses whose children have received GED treatment testified that their children experienced similar dramatic improvements in their abilities to integrate with their families and the community. For example, M.S. testified that before his daughter received GED treatment for her severe SIB, his daughter: constantly wore a protective helmet and gloves;[202] was always drowsy and had tics and tremors from her psychotropic medications;[203] detached both of her retinas and blinded herself by striking her head at extremely high frequencies;[204] was unable to go on home visits or otherwise leave her residential program;[205] was not toilet trained;[206] and could not speak.[207] Her prior placements in New York tried all of the typical treatments referenced by FDA in the Proposed Ban, including psychotropic medications, and could not treat her SIB. Her successful GED treatment at JRC enabled her to: have the surgeries necessary to restore her vision;[208] interact with her caregivers, her family, and her peers;[209] go on home visits and field trips into the community with JRC and her family;[210] speak simple phrases and answer simple questions;[211] be toilet trained;[212] and dress and feed herself.[213] The other parents similarly

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[198] *See id.* at 21-23; *see also id.* at Attachment 18, Ex. 736.
[199] *See id.* at 6, 23-24.
[200] *See id.* at 6-7, 24.
[201] *See id.* at 6, 23-24.
[202] *See id.*, Tr., Testimony of M.S., Day 23, 196 (May 23, 2016).
[203] *See id.* at 162-163.
[204] *See id.* at 166-167, 184-186; *see also id.* at Attachment 18, Ex. 667, 1.
[205] *See id.*, Tr., Testimony of M.S., Day 23, 177 (May 23, 2016).
[206] *See id.* at 171.
[207] *See id.*
[208] *See id.* at 173-174.
[209] *See id.* at 174.
[210] *See id.* at 174-177.
[211] *See id.* at 175-176,
[212] *See id.* at 176.
[213] *See id.*

attributed their children's physical recovery and integration into the community to GED treatment.[214]

The Proposed Ban acknowledges that current therapies will not successfully treat all patients.[215] The examples presented at Trial illustrate the truth of that recognition. Imposing a ban would cause profound hardship for refractory individuals who failed multiple other therapies, and then achieved improvements through the GED. Depriving these individuals of access to the only successful therapy they have received would be unfair, unjust, and unwarranted. Contrary to what FDA said in its Preliminary Regulatory Impact Analysis, in this case it is possible to say how a client's "utility would change" if deprived of GED treatment.

It is notable that in banning powdered gloves FDA found that there were "suitable" alternatives.[216] FDA explicitly rejected comments saying that powdered gloves were essential. Here, the Panel members and the FDA both agree that for a small group of SIB/AB patients there are not suitable alternatives.[217] Thus, a key finding that supported the glove ban is not applicable to ESD for SIB/AB.

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[214] L.E. testified that, as a result of successful GED treatment, her daughter "has gone from a person that is isolated and medicated and injured and unhappy to a young person that is happy and able to live in [the] world and experience what other people experience." *See id.* at Attachment 18, Tr., Testimony of L.E., Day 24, 93. R.M. testified that GED treatment "stopped the madness of [his daughter] just being an eating, sleeping, hurting machine", thereby enabling her to become toilet trained, to have dinner with her family, to travel with her family to the mall, to parks, and on vacation, to spend time with friends, to go on field trips to the movie theater, bowling alley, and skating rink with JRC, and to use small sentences. *See id.* at Attachment 18, Tr., Testimony of R.M., Day 23, 60-64, 94-97. P.P. testified that before GED treatment, his son spent "many hours a day" in a strait jacket with mitts on his hands to prevent his severe self-injury, and that for the past decade of GED treatment, his son has not required any protective restraints and has become able to feed, dress, and toilet himself, speak short phrases, visit his family monthly at home, go on outdoor walks with his family, grocery shop with his family, and attend jazz festivals, Cirque du Soleil performances, and minor league baseball games. *See id.* at Attachment 18, Tr., Testimony of P.P., Day 34, 19-20, 34-38, 44. M.W. testified that the psychotropic medications that other programs had to administer to control her son's extreme AB put him "in a vegetative state" where "he couldn't keep his eyes open" and would not know that she was visiting him, whereas with GED treatment, he has been weaned from psychotropic medications, he works at JRC, and he goes out into the community with JRC staff, and he goes on interstate vacations with his parents. *See id.* at Attachment 18, Tr., Testimony of M.W., Day 43, 9-12, 19-21.

[215] 81 Fed. Reg. 24386 at 24406.

[216] *Id.* at 91725.

[217] *Id.* at 24406.

Additionally, there is no basis for the allegation that communication is somehow constrained at JRC.[218] Indeed, the contrary is true. The clients' guardians make the decisions about who can contact their child. There is a built-in system for collecting and responding to any complaint made by a client including a human rights officer, and JRC interviews each client weekly in order to solicit concerns. Many clients receive both individual and group counseling, and all clients meet regularly with their treatment teams. In addition, all clients have the ability to contact the Massachusetts Disabled Persons Protection Commission and the Massachusetts Department of Children and Families to report any concerns. For clients with communication deficits, JRC provides a wide range of communication options appropriate to the needs of each client, such as: teaching sign language and offering laminated communication icons; communication icons delivered via iPad; communication devices (*e.g.*, Tech Speak); functional communication tokens; 1:1 communication training; and speech and language services.

Thus, for the reasons described above, the FDA should not rely upon the MHLAC's comment.

V. THE FDA'S PROPOSED BAN IS ARBITRARY AND CAPRICIOUS REGULATORY ACTION, EXCEEDS THE FDA'S STATUTORY AUTHORITY, AND IS UNSUPPORTED BY SUBSTANTIAL EVIDENCE

The Administrative Procedure Act ("APA") provides, in relevant part, that a reviewing court shall "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law", "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right" and "unsupported by

[218] Comment from Mental Health Legal Advisors Committee of the Supreme Judicial Court of Massachusetts, comment identifier FDA-2016-N-1111-0255 (May 4, 2016) ("This harm is compounded by the rules at JRC where certain communications are discouraged and even forbidden.") Further, JRC's treatment practices with respect to client communications have no bearing on the issue of the Proposed Ban.

substantial evidence." 5 U.S.C. § 706. It is well-established that an agency's action is arbitrary and capricious where it:

> relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Motor Vehicle Mfrs. Ass'n of the U.S. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983); *Nat'l Cable & Telecomms. Ass'n. v. Brand X Internet Servs.*, 545 U.S. 967, 981-82 (2005) ("Unexplained inconsistency [with prior agency practice] is ... a reason for holding an interpretation to be an arbitrary and capricious change from agency practice under the Administrative Procedure Act."), *citing Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 46-57 (1983). *See also Fed. Commc'n. Comm'n. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) (observing that "[i]t would be arbitrary of capricious" for an agency to ignore a prior policy that rested upon factual findings that contradict those which underlay a new policy, or when its prior policy has engendered serious reliance interests that must be taken into account). To avoid running afoul of the APA, an agency must provide a "satisfactory explanation for its action including a rational connection between the facts found and the choice made"; the explanation must reflect the agency's consideration of "significant and viable and obvious alternatives." *FBME Bank Ltd. v. Lew*, 125 F. Supp. 3d 109, 123–24 (D.D.C. 2015).

Promulgation of the Proposed Ban would be arbitrary and capricious FDA action, would exceed the FDA's statutory authority, and is unsupported by substantial evidence. As described above, the FDA's Proposed Ban is fatally flawed. It discounts relevant data provided by JRC and the parents association for JRC clients, and relies heavily on false, misleading, biased, and cherry-picked data. It impermissibly bans one *use* of the ESDs rather than ESDs themselves while at the same time allowing for the use of ESDs for other purposes, thereby infringing upon the practice

of medicine. It specifically targets JRC, without giving JRC an adequate opportunity to respond. The FDA chose the most severe and rarely used action, a ban, and failed to give appropriate consideration to less restrictive alternatives to a ban, such as more precise labeling, a post-market surveillance study, or the establishment of special controls.[219] For example, before clearing a 510(k), the FDA is authorized to require medical device labeling that warns against use of a device for any purpose other than those specifically approved by the FDA (so-called "off-label use"), if the Agency believes that off-label use may present danger. [220]

The FDA has further failed to provide JRC with certain key documents and other information upon which it relied in the Proposed Ban. The FDA must immediately respond to the questions and information requests presented below, provide JRC with the documents requested below, and convene a "fair, expeditious, and impartial" adjudicatory hearing[221] with all the requirements of due process that allows JRC to present relevant oral and written information and cross-examine witnesses, before any further action is taken with respect to the Proposed Ban; failure to do so would constitute procedural error under the APA.[222]

VI. QUESTIONS/INFORMATION REQUESTS

JRC requests the following information from the FDA:

1. Provide the names of the "three individuals formerly on ESDs at JRC" FDA clinicians interviewed by phone, as referenced in 81 Fed. Reg. 24386 at 24393, the dates on which the FDA communicated with these individuals, and a description of the substance of each communication.

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[219] *See FBME Bank Ltd. v. Lew*, 125 F. Supp. 3d 109 (D.D.C. 2015) (enjoining implementation of FinCEN's Final Rule, finding that agency's Final Rule ran afoul of the APA as agency failed to consider obvious, viable, and less-punitive alternatives to full prohibition).

[220] 21 U.S.C. § 360c(i)(1)(E). *See also* Determination of Intended Use for 510(k) Devices; Guidance for CDRH Staff: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm082166.pdf (last accessed July 24, 2016).

[221] 21 C.F.R. § 16.60.

[222] *FBME Bank Ltd. v. Lew*, 125 F. Supp. 3d 109, 121 (D.D.C. 2015).

2. Provide a description of the criteria the FDA used in deciding to interview only the "three individuals formerly on ESDs at JRC" as referenced in 81 Fed. Reg. 24386 at 24393, and the methodology used during the interviews.

3. Provide the names of all former or current JRC clients and their family members with whom the FDA communicated about ESDs as used to treat SIB/AB, the dates on which the FDA communicated with these individuals, and a description of the substance of each communication. *See* 81 Fed. Reg. 24386 at 24393.

4. Provide the names of all agencies and government entities (state, federal, and international) with whom the FDA communicated about ESDs as used to treat SIB/AB, the dates on which the FDA communicated with these agencies and government entities, and a description of the substance of each communication. *See* 81 Fed. Reg. 24386 at 24393, 24409.

5. Provide the names of all disability rights groups with whom the FDA communicated about ESDs as used to treat SIB/AB, the dates on which the FDA communicated with these groups, and a description of the substance of each communication, and the methodology for selecting whom to contact. *See* 81 Fed. Reg. 24386 at 24393, 24409.

6. Provide the names of all behavioral psychologists with whom the FDA communicated about ESDs as used to treat SIB/AB, the dates on which the FDA communicated with these individuals, the criteria for choosing only them, and a description of the substance of each communication. *See* 81 Fed. Reg. 24386 at 24409.

7. Why did the FDA solicit the opinions of experts Dr. Gary LaVigna and Dr. Fredda Brown, who are known anti-aversive advocates? *See* 81 Fed. Reg. 24386 at 24393. Provide the names of all experts with whom the FDA communicated in connection with soliciting their opinions on the Proposed Ban, the dates on which the FDA communicated with these experts, a description of the substance of each communication, and the methodology used during these conversations.

8. Why did the FDA change its position from 2000 that JRC was exempt from 510(k) notices, and the GED-3A and GED-4 devices were considered to be within the practice of medicine? What was the basis of that decision?

9. Why did the FDA cancel the pre-submission meeting with JRC scheduled for March 25, 2013, and fail to respond with a new meeting date despite additional requests from JRC? Why did the FDA fail to provide JRC with comments on JRC's pre-submission?

10. Why did the FDA abandon the 510(k) process? Why did the FDA fail to provide JRC with notice that it was abandoning the 510(k) process in favor of pursuing a ban on ESDs to treat SIB/AB?

11. Why has the FDA refused JRC's multiple offers to visit JRC, review the data on ESDs, and observe JRC's use of ESDs first-hand?

12. Why did the FDA fail to contact JRC or any parents of current or former JRC clients for input in preparing the FDA Executive Summary or prior to publishing the Proposed Ban? Did the FDA provide JRC's April 14, 2014 comment to the Panel Meeting (tracking number 1jy-8bjf-k0hb) to the Panel prior to the Panel Meeting?

13. What process did the FDA use to evaluate the veracity and credibility of the conflicting comments on the safety and effectiveness of the GED and the effectiveness of PBS and medication to treat severe SIB and AB? *See, e.g.*, 81 Fed. Reg. 24386 at 24410. Please provide copies of any factual reviews FDA prepared of the literature and other information reviewed by the Agency.

14. Why are ESDs for smoking cessation or other purposes permitted under the Proposed Ban, but not ESDs to treat SIB/AB? *See* 81 Fed. Reg. 24386 at 24387.

15. Provide the factual basis for the statement in the Proposed Ban which states, "FDA has determined that labeling, or a change in labeling, cannot correct or eliminate the unreasonable and substantial risk of illness or injury." 81 Fed. Reg. 24386 at 24412.

VII. DOCUMENT REQUESTS

JRC requests the following documents from the FDA:

1. Affidavit of Dr. James C. Eason, Attachment 1 to the Disability Law Center Inc.'s public docket comment, comment identifier FDA-2014-N-0238-0038 (April 16, 2014); FDA-2016-N-1111-0070 (April 25, 2016), as referenced in the Proposed Ban, 81 Fed. Reg. 24386 at 24396.
2. All documents or other information concerning:
    a. the expert opinion(s) of Dr. Tristram Smith about ESDs as used to treat SIB/AB, including, but not limited to, minutes of meetings (in person, telephonic, or otherwise), all communications with Dr. Smith, documents and information provided to the FDA by Dr. Smith, and documents and information provided to Dr. Smith by FDA;
    b. the expert opinion(s) of Dr. Gary LaVigna about ESDs as used to treat SIB/AB, including, but not limited to, minutes of meetings (in person, telephonic, or otherwise), all communications with Dr. LaVigna, documents and information provided to the FDA by Dr. LaVigna, and documents and information provided to Dr. LaVigna by the FDA; and
    c. the expert opinion(s) of Dr. Fredda Brown about ESDs as used to treat SIB/AB, including, but not limited to, minutes of meetings (in person, telephonic, or otherwise), all communications with Dr. Brown, documents and information provided to the FDA by Dr. Brown, and documents and information provided to Dr. Brown by the FDA.

See 81 Fed. Reg. 24386 at 24393.

3. All documents or other information pertaining to the "three individuals formerly on ESDs at JRC" who FDA clinicians interviewed by phone, as referenced in 81 Fed. Reg. 24386 at 24393.

4. The Proposed Ban states, "With respect to ESDs for SIB and AB, FDA has weighed these factors based on consideration of information from a variety of sources, including the scientific literature, opinions from experts (including an advisory panel meeting), information from and actions of State agencies, information from the affected manufacturer, information from patients and their family members, and information from other stakeholders." 81 Fed. Reg. 24386 at 24387.

   Please provide all documents constituting, relating to, or referring to the "information from a variety of sources" as quoted above the FDA considered with respect to ESDs for SIB and AB, including but not limited to:

   a. the scientific literature;
   b. opinions from experts (including an advisory panel meeting);
   c. information from and actions of State agencies;
   d. information from the affected manufacturer;
   e. information from JRC clients and their family members, including former JRC clients and their family members; and
   f. information from other stakeholders (including but not limited to "government entities, disability rights groups, and members of the public" – see 81 Fed. Reg. 24386 at 24393).

5. The Proposed Ban states, "Information from other Federal agencies, behavioral psychologists, disability rights groups, and the United Nations corroborates FDA's conclusions regarding the risks of ESDs relative to the state of the art." 81 Fed. Reg. 24386 at 24409.

   Please provide all documents constituting, relating to, or referring to "information" as quoted above corroborating FDA's conclusions including information from:

   a. federal agencies;
   b. behavioral psychologists;
   c. disability rights groups; and
   d. the United Nations.

6. All documents or other information evidencing "the similar characteristics of the shocks delivered by [implantable cardioverter defibrillators] and ESDs" as referenced in 81 Fed. Reg. 24386 at 24395; and

7. All documents or other information concerning "reports of collateral effects" NYSED claims it received in its comment, as referenced in 81 Fed. Reg. 24386 at 24397; Comment of NYSED, comment identifier FDA–2014–N–0238 (April 14, 2014).

8. The Proposed Ban states, "FDA has determined that labeling, or a change in labeling, cannot correct or eliminate the unreasonable and substantial risk of illness or injury." 81

Fed. Reg. 24386 at 24412. Please provide all documents, analyses, and other information supporting this statement. Please also provide any benefit-risk analyses conducted by the FDA.

VIII. THE FDA MUST HOLD A REGULATORY HEARING PURSUANT TO 21 C.F.R. PART 16

As described above, the FDA's banning of the *use* of a medical device is improper. Even if the FDA were proposing to ban ESDs themselves, the FDA must hold a regulatory hearing prior to taking further action. Pursuant to 21 C.F.R. § 16.1, the FDA has the authority to "offer an opportunity for a regulatory hearing to obtain additional information before making a decision or taking action." Such a procedure would allow JRC to present relevant oral and written information, cross-examine witnesses, and allow a neutral arbiter to make findings on the credibility of witnesses, make factual determinations, and conduct a "fair, expeditious, and impartial hearing."[223] Following issuance of the Proposed Ban, JRC requested that the FDA hold a regulatory hearing under 21 C.F.R. Part 16 to discuss the Proposed Ban, address certain issues raised by the FDA in the Proposed Ban, and present additional information not previously considered by the FDA. The FDA summarily denied this request in a letter dated June 3, 2016.

The current forum is improper, and the process is inadequate. It deprives JRC of any meaningful opportunity to challenge and rebut a record riddled with errors and false, misleading statements. While this letter and JRC's Comment on Comments puts FDA on notice that the record is rife with errors, it is neither possible for JRC to address the myriad errors nor JRC's responsibility to do so. Nor, for the reasons noted above, is it possible for the FDA to sift through the comments and sort out truth from falsehood or exaggeration without an evidentiary hearing. The FDA should thus hold a regulatory hearing. As described above, the importance of an adjudicatory hearing is further illustrated by the Trial, in which JRC refuted many of the same

[223] 21 C.F.R. § 16.60.

conclusions made by the FDA in the Proposed Ban through cross-examination. The FDA's use of rulemaking has deprived JRC of the opportunity to test and rebut the assumptions and assertions made by the FDA and the commenters.

IX. CONCLUSION

For the reasons set forth above, JRC strongly opposes the Proposed Ban and requests that the FDA immediately withdraw the Proposed Ban. The FDA lacks authority to ban the use of a device. It also represents an improper and unprecedented intrusion into an area reserved for the states: the regulation of the practice of medicine. Even if the FDA believes further consideration of the Proposed Ban is warranted, JRC requests that the FDA hold an adjudicatory hearing in accordance with 21 C.F.R. § 16.1 that meets all constitutional requirements. The FDA must also give fair and thorough consideration to less restrictive alternatives to a total ban, such as more precise labeling, a post-market surveillance study, or the establishment of special controls.

JRC requests a meeting with the Chief Counsel's office as soon as possible to further discuss the issues outlined in this letter. This letter should be considered part of the administrative record.[224]

Sincerely,

Michael P. Flammia

Jeffrey Gibbs/MPF

Jeffrey N. Gibbs (Hyman, Phelps & McNamara, P.C.)

[224] *See* 5 U.S.C. § 706 ("the court shall review the whole record or those parts of it cited by a party."); *see also Am. Wildlands v. Kempthorne*, 530 F.3d 991, 1002 (D.C. Cir. 2008) (quoting Fed. R. App. P. 16(a)) (noting that record should include "the order involved, any findings or reports on which that order is based, and 'the pleadings, evidence, and other parts of the proceedings before the agency.'").

Exhibit A

To: Lynne Dwyer@NWE@fdaoraner, Domenic Veneziano@NWE@fdaoraner, Michael Kravchuk@NWE@fdaoraner, Gail Costello@NWE@fdaoraner
Cc: Frank Gesing@NWE@fdaoraner
From: Karen Archdeacon@NWE@fdaoraner
Certify: N
Priority: Normal
Subject: BRI/Judge Rautenberg CTR
Date: Mon Feb 07 12:59:00 2000
Attached: None

Update:

I spoke with Geaorge Wallace, attorney for BRI. He stated that they are acting in good faith with regard to the GED1 and GED4, however, they still believe they are exempt from premarket notification via 21 CFR 807.85, since they are "practicing medicine". He was very helpful and stated that they were willing to discuss these issues if we thought otherwise. I told him that we are still reviewing the issues and Lynne would be closing the inspection in a few days.

We would not be dealing with any investigational issues since the device has already been classified as class II, 21 CFR 882.5235. As long as this device is within the practice of medicine, changes may be made to the device by the physician.

I also spoke with Don Serra again this afternoon. He has spoken with a variety of folks at CDRH, including Eric Latish. He agreed that it appears that BRI would be exempt from registering and listing under 807.65(d) and would thus also be exempt from any 510(k) notices.

Therefore, it is my thinking that we would not exert any jurisdiction over this Center/EI at this time. The firm appears to be exempt from the registering requirements as well as the premarket notification requirements. It also appears that we did not observe any indications that the patients/ clients were at risk. They appear to have oversight via court orders issued by the Bristol County Probate Court. With this in mind, I do not see a need to even issue a FDA 483.

I will be working at home tomorrow, so perhaps, if you have any questions, lets chat.

Karen

Judge Rottenberg Center
Canton ma.
1/31/99, 2/1,3 2/10/00
LMD CFN 1222743
Attachment #3