



June 22, 2017

Electronic Submission (<https://www.regulations.gov>)

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. FDA-2017-N-0136 - Public Meeting on Client-Focused Drug Development for Autism: Comment on the Symptoms of Autism That Impact Patients Most and Current Approaches to Treating Such Symptoms

To Whom It May Concern:

I am in receipt of the U.S. Food and Drug Administration's ("FDA") Notice of Public Meeting on Client-Focused Drug Development for Autism in which the FDA seeks "client perspectives on the impact of autism on daily life as well as client views on treatment approaches for autism" (the "Public Meeting"). Specifically you seek "the perspectives of clients with autism and caregivers on (1) symptoms and the daily impacts of their condition, (2) current approaches to treatment, and (3) decision factors taken into account when selecting a treatment."

I represent the parents and legal guardians of patients at the Judge Rotenberg Educational Center, Inc. ("JRC") who have autism, severe behavior problems and currently receive Applied Behavior Analysis ("ABA") treatment, including the electrical stimulation device ("ESDs") known as the Graduated Electronic Decelerator ("GED") device for their harmful behaviors as part of their Massachusetts Probate and Family Court-approved treatment plans. I also represent the JRC Parents and Friends Association, Inc.,¹ the association that represents all of the JRC parents, including those whose children have autism and are currently receiving treatment with ESDs and those with autism who could be eligible to receive it if deemed necessary by their parents, medical professionals, and a court in a "substituted judgment" proceeding. This letter shall serve as the JRC Parents and Friends Association, Inc.'s comment on the symptoms of autism that impact their autistic children the most and the treatment approaches that have been the most effective in treating such symptoms.

I am writing this letter to the FDA to make your agency aware that for autistic patients who engage in treatment-resistant dangerous and destructive behaviors, it is these behaviors that have the most significant harmful impact on the lives of the patients and their families. Without

¹ Formally known as the B.R.I. Parents and Friends Association, Inc., but doing business as the JRC Parents and Friends Association.

effective treatment, these behaviors impact their daily lives by putting them at constant risk of physical and emotional harm and require their caretakers to isolate and restrain them by physical, mechanical or chemical means in order to protect the patient from life-threatening self-injury. These behaviors cause permanent physical damage and intense physical and emotional pain and prevent the patient from receiving an education and vocational training as well as accessing the community and their family and friends.

Typical forms of treatment for the behaviors in which autistic patients engage include medication, Positive Behavior Supports, behavioral therapy and talk therapy. For some autistic patients that have these severe behavior problems, the typical forms of treatments mentioned above are ineffective and the medication, in particular, exposes the patient to serious, and sometimes permanent, side effects, including death. For some of these treatment-resistant autistic patients, the best course of treatment is a positive programming supplemented with ABA punishment procedures such as skin shock treatment with the GED device. Without access to GED treatment, these patients would be: forced to receive the other available but ineffective treatments including cocktails of medication which can have life-threatening side effects and provide no benefit to severe behaviors, but rather sedate the patient; isolated from the community at large and denied meaningful relationships with family and friends; and at risk of catastrophic physical and emotional harm, including permanent injury and death. With GED treatment, however, the patient's dangerous behaviors are suppressed and they are: in good physical and mental health; happy receiving much needed education, rehabilitation, and other essential services; and able to engage in activities in the community, make friends and spend quality time with family.

Members of the JRC Parents and Friends Association, Inc. submitted comments to the FDA in connection with Docket No. FDA-2016-N-111, Proposal to Ban Electrical Stimulation Devices Used to Treat Self-Injurious or Aggressive Behaviors, and Docket No. FDA-2014-N-0238, the April 24, 2014 Meeting of the Neurological Devices Panel of the FDA's Medical Devices Advisory Committee. These comments were submitted in support of the availability of ESDs and against a ban of ESDs. These comments are directly relevant to this public meeting as they provide the perspective of the family caregivers of autistic patients who receive extraordinarily effective GED treatment for their otherwise treatment-resistant dangerous and destructive behaviors. Attached at Tab 1 are comments from the following family members of current and former autistic JRC clients who have received GED treatment: Jeanette Alleyne; Peter and Maureen Biscardi; Carlo Casoria; Esperanza Escorcia Castellon; Charles and Gail Cornish; Cornnis and Patricia Crawford; Angela DiSisto; Richard Doherty; Teresa Ellis-Brown; Lauren Emmick; Cheryl Lawler; Richard Levenson; Cheryl Lloyd; Alfred Lopez and Carline Riche-Lopez; Anaar Miller; Suraija Nasser; Paul and Carol Peterson; Edward and Pamela Prunckun; Bridget Reaney; Marie Rogers; Michael Sciannamea; Mitchell and Marcia Shear; James and Phyllis Shields; Ilana Slaff-Galatin; Lorraine Slaff; Leo and Claudia Soucy; Matthew and Holly Swenson; Carmen and Michael Torre s and Laura Gonzalez; Jenkin and Marie Washington; and Roger, Sharon and Jessica Wood. These comments describe how the GED device is safe and very effective in treating autistic patients with otherwise treatment-resistant



Todd & Weld LLP

June 22, 2017

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behavioral problems and I submit them to the FDA for the agency's consideration in connection with this public meeting.

Your thoughtful consideration of this comment and its attachments is greatly appreciated. If you would like more information on this topic or to discuss it further, then please contact me.

Sincerely,

Max D. Stern

MDS/pjm

Division of Dockets Management (DDM)
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

July 25, 2016

Dear: U.S. Food and Drug Administration;

My letter is to express that I am against to the new rule proposed that will prohibition the use of aversive therapy (GED). My son was a student at the Judge Rotenberg Center for ten years and he was treated with the GED. Prior to be admitted to JRC, he was diagnosed with Psychotic Disorder (not otherwise specified), Oppositional Defiant Disorder, Pervasive Developmental Disorder, Moderate Mental Retardation, Impulse Control Disorder (not otherwise specified), rule out Post Traumatic Stress Disorder and Rule out Bipolar Disorder.

He began receiving special education services at a young age. He attended a special education day program where he made some academic and behavioral progress. However, it was not enough and he was referred back to the CSE who placed him back in a specialized classroom in the public schools. While in school, my son became physically aggressive with teachers and other staff members and continued to exhibit other behaviors that were hard to control to the point where he was admitted into a hospital. He was admitted into Bronx Lebanon Hospital in May 2002 when he made a verbal threat to hurt one of his teachers and himself. Numerous medications were tried to control his behaviors, but none were very successful. The school district finally decided to put him in a residential program and he was admitted to Devereux in 2002. While he attended the program, he continued to have aggressive and self injurious behaviors. He continued to fight with teachers and peers, attempt to run away, run in front of cars and having suicidal gestures. Eventually, Devereux could not handle my son anymore and that was when I learned about the Judge Rotenberg Center.

He was admitted to the Judge Rotenberg Center on January 4th, 2005. At first he continued to have numerous behaviors, but under strong positive programming and supplemental aversive therapy he began to show improvement. He was able to go to school and receive an education that he deserves. He could interact appropriately with peers and teachers, and participated in things such as play basketball, go on field trips or attend a school dance. The Judge Rotenberg Center helped my son and my family in many different ways. Thanks to the GED, he made enough progress to be able to attend a less restrictive program, he is not on psychiatric medications and has a better quality of life. He is currently taking vocational training and has a pay job. I believe that without the aversive therapy, my son would have not made all these achievements. I appreciate you taking the time to read this letter.

Sincerely,

Ms. Alleyne

May 19, 2016

Division of Dockets Management (HFA-305)
Food and Drug
Administration 5630
Fishers Lane
Room 1061
Rockville, MD 20852

Re: Proposal to Ban Electrical Stimulation Devices Used to
Treat Self-Injurious or Aggressive Behavior

To Whom it may Concern:

This is in regard to Docket No. FDA-2016-N-1111 for "Proposal to Ban Electrical Stimulation Devices Used to Treat Self-injurious or Aggressive Behavior".

We are the parents of a 49 year-old student, Peter John Biscardi (P.J.), who is a client at the Judge Rotenberg Educational Center (JRC) who has benefited immensely from the use of the GED as part of his therapy. We are extremely disheartened by your decision to ban this device from use without ever accepting the invitations to come and visit this program personally, review all of the records of clients receiving GED, or speak with the parents and clients who have experienced life-saving benefits from the use of the GED. To take such a drastic step blindly is, in our opinion, incomprehensibly negligent of your responsibilities.

Our son has been a client at JRC since 1978 when he was eleven years old. He had been on the GED since its inception until the late spring of 2014, when the staff at JRC successfully weaned him off of the device.

Our son was diagnosed with autism when he was three years old. He is severely afflicted with this condition and an intellectual disability, and was violent and dangerously self-abusive. Prior to entering JRC, he attended several day programs that had successfully served other children with autism and an intellectual disability, but were unsuccessful in treating P.J. and eventually expelled him. The last program that he attended treated his hyperactivity with amphetamines, which caused him to lose his appetite, lose weight, and stop growing. Although he was of normal height and weight for his age before entering this day school, he was very small for his age when they expelled him. Despite the amphetamines and the school's efforts to control and teach him, his condition continuously deteriorated, and he became more violent and self-abusive.

To give you examples of the types of the dangerous and life-threatening behaviors he exhibited before he went to JRC: he sliced himself with a razor blade, and put Drano into his mouth, receiving severe chemical burns in his mouth as well as on his hands and legs. He drank shampoo, tipped over large pieces of furniture, ran full-force into walls, ran out into busy streets, and would bang his head and bite his hands. He developed large calluses on his hands and forearms from biting them so frequently.

When he was living at home, our other children (a girl one year older and a boy two-and-a-half years younger) were frequently in danger from his destructive behaviors. He managed to knock the top bunk off

his bunk beds, but thankfully, his brother was neither on the bed nor in the room at that time. He knocked over a large chest of drawers, but thankfully, his siblings were not in the room at the time. Our kids also suffered emotional anguish from the frequent sleepless nights and the added burden of having to help to watch him, due to his hyperactivity and habit of consuming inedible substances.

My husband and I were also in danger from his violence. At one time, when my husband leaned over to tie his shoe, P.J. grabbed a chunk of my husband's hair and dropped it, bloodied, to the ground.

Positive reinforcement did help somewhat to curtail these dangerous behaviors, but did not stop them, and as he grew, he became a continually more severe threat to his own safety and to that of others.

Since he has been at the JRC, and received a combination of reward and punishment therapy, he has improved drastically. He no longer runs into traffic, but instead, walks with us and follows directions. He no longer has any desire to "taste" foreign substances. The calluses on his hands are completely healed. He does not show any aggression toward his roommates or classmates. They and his teachers are safe when they are with him. When he comes home to visit, he is calm, relaxed, and happy. We no longer need the assistance of a staff member from the school to come with him when he comes home. He can go on field trips into the community; for example, he goes on hikes in the Blue Hills, meals at local restaurants, and bowling. Most importantly, he is happy.

When we were first told about the GED, we were reluctant to allow it to be used on P.J., but since his violent self abuse was still not completely under control, we thought it might be worth a try, especially since the use of the GED required court approval in a hearing during which P.J. had his own lawyer. We soon realized that the brief two-second skin shock is a minor price to pay to alleviate the self-mutilation, self-poisoning, and self-abuse that he previously exhibited. Also, P.J. has exhibited no side-effects from the GED, as he probably would have if we chose to use drugs to control his behaviors.

P.J. was taken off the GED for the last time in the Spring of 2014. It took many years of treatment with that device, but it did work! I think of the GED as more of an emancipator than a punishment. This program and the GED have not only saved his life, but have given him the quality of life that we find, and we think he finds, very rewarding.

Although P.J. is now off the GED, we are concerned that if the GED is banned, other students with violent behaviors will have to be suddenly taken off the GED, which raises extreme worry for the safety of our son both at school and in transit.

Please feel free to call us at any time at home, 781-937-9222, with any questions you have.

Please reconsider your decision to ban the GED, for the life and safety of so many students at JRC.

Sincerely,

Peter and Maureen Biscardi
7 Hawley St
Woburn, MA 01801
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THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION

PAGES 4 – 6 REDACTED

May 17 2016

Division of Dockets Management (HFA-305)
Food and Drug Administration 5630
Fishers Lane
Room 1061
Rockville, MD 20852

RE: FDA's Proposed Rule to ban GED

To Whom It May Concern:

My name is Esperanza Escorcia-Castellon and I am writing to you concerning my only son, Aldo. He is autistic and additionally, he suffers from severe mental retardation. He is my whole world and the object of all my love. These feelings could not be stronger, reaching as they do an intensity that hardly anyone could imagine. It has come to my attention that the US FDA is considering a ban on electrical stimulation devices used to treat aggressive or self-injurious behavior. My Aldo needs this effective treatment.

Since his most tender years, Aldo's aggressiveness has been evident. I still shudder to recall the time (when being only nine months old) he bit his grandmother's arm so violently that her arm bore a mark for a long time. Aldo's irritability and sudden mood swings (going from one extreme to the other) grew day by day, so much so that he injured himself and other people. He was also frequently breaking various objects such as toilet bowls, televisions, glasses, etc.

I, as well, as other close relatives have been tremendously affected by Aldo's behavior. His behavior has prevented us from sleeping in peace (as he suffered prolonged periods of insomnia accompanied by irritability) in which his only entertainment was to paint walls with his own excrement.

My son had a 42 day stay at Elmhurst Hospital, as he was completely out of control. Once he was "stabilized" there, he was transferred to a residential school in upstate New York where he remained for six years. This institution was considered to be one of the best in New York State and they were unable to cope with him. Aldo continued to be under medical treatment and was reinforced by psycho-pedagogic methods. He also had a person taking care of him on a one to one basis. Twenty-four hours a day and nothing proved effective to stop Aldo from having these uncontrollable behaviors.

As a rule, any new medicine he was given worked at the most, for one week. Not only did Aldo fail to improve in any way, but his weight went up to over 200 pounds even though he was only 15 and just over five feet tall. His behavior became worse, so much that I always noticed that some members of the staff (out of fear of being attacked by Aldo) avoided attending to him.

When he was at the upstate New York school, Aldo, was often out of control, endangering his life, and creating serious danger for members of the staff who several times had to call 911. The calls resulted on quite a few occasions in his interment at Saint Francis Hospital in Poughkeepsie. During one such incident he was taken to a hospital handcuffed.

The visits we paid him at Saint Francis Hospital were extremely painful for us, having in fact stamped on my memory and that of his father indelible marks of extreme sadness and frustration. We will never be able to forget the times we saw our son lying in bed, drugged from the strong doses of various medicines he had received half asleep and unable to sit. The effects of the drugs wore off and he became so aggressive that the hospital activated an alarm summoning members of the staff to Aldo's room to control him. Our emotions became so painful that we went outside to weep.

Finally the school at upstate New York officially informed us that they could not cope with Aldo and that we had to look for another institution that could care for him. When we were beginning to completely despair (and I started to think my name Esperanza, which means hope had become a cruel irony), we found out about the Judge Rotenberg Center, which is for me a veritable miracle school. Thanks to the methods used there Aldo is improving day by day. He is taking no medicine and his weight is normal for his age; nor does he injure himself or others. We actually enjoy the time we spend with him. During a recent visit, we were able to spend the day at the zoo. His behavior was exemplary.

As I already said, Aldo is my only son and the entire world to me. Nobody can protect and care for him better than me. However, my fears have once again become realized. Now we must contend with the possibility of losing access to his life-saving treatment, the GED. Loose the treatment that has taken him from a handcuffed out-of-control aggressor to a gentleman holding his mom's hand while walking thru the community. The medications he was prescribed did not control or change his behavior, but they did have serious side effects such as weight gain. His GED therapy has reduced his aggressive, destructive and self-abusive behaviors with no side effects. He wears the device as if it were part of his clothing. I have a son who looks me in the eye and places a gentle kiss on my cheek. When treated with other methods, I could not get physically close to him because he would hurt me and others.

Aldo is basically non-verbal. I am his voice. I have always been his voice. I choose this treatment for him after all other options failed him. It was a long process which included research and weighing the risks and benefits. A judge heard all the evidence and decreed it was in Aldo's best interest to try this treatment. Then it was incorporated into his program. Aldo is a changed man. He is calmer, relaxed, and able to be more independent. He has learned new skills. I don't dare to think of the consequences of a ban on this life saving therapy for Aldo. It has been the only therapy that has had this level of success with him. I invite you to meet me and Aldo at his program so you can see his progress first hand.

Sincerely,

Esperanza Escorcía Castellón

THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION

PAGES 9 – 12 REDACTED

May 19, 2016

Division of Dockets Management (HFA-305)
Food and Drug Administration 5630
Fishers Lane Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2016-N-1111 for "Proposal to Ban Electrical
Stimulation Devices Used To Treat Self-Injurious or Aggressive Behavior"

To whom it may concern:

We are writing to you regarding our adult daughter, Erin. Erin suffers from a developmental disability and has required special needs services all of her life. It has come to our attention that the FDA wants to ban "electrical stimulation devices used to treat aggressive or self-injurious behaviors."

While behavioral skin shock treatments may seem repugnant, what is much more repugnant is the sight of our daughter banging her head into a wall with so much force that she breaks the skin on her forehead and causes the wall to crack. She slammed her head down so hard on a school desk, in 1998, that she cracked a front tooth. She also broke her wooden bed frame during a home visit. She has taken more blows to the head and limbs than a seasoned prizefighter.

She has been prescribed various psychiatric drugs, starting in 1997 when she was ten years old: Tegretol (caused her to develop a rash), Depakote, Risperdal, Abilify, Concerta, Prednisolone (Pediapred) (caused her face to swell up so we stopped it), Lithobid, Aricept, Benadryl, Atarax, Thorazine, Ambien, Cogentin, Lamictal and Colace. She has had 1:1 crisis paraprofessionals both for the school bus and classroom, padded helmets, restraints, behavioral interventions like ABA, communication devices, and other less intrusive treatments, all of which have proved unsuccessful and have failed to reduce her Self Injurious behaviors.

It took us until 2005 to accept that our daughter needed residential treatment, despite our considerable struggles with her very dangerous behaviors. The last straw was when the Assistant Principal of her school tried to get her taken by ambulance a psychiatric hospital.

It was at this time in 2005 that we decided to place Erin at JRC. We want Erin to be protected from herself. Unfortunately, treatment of individuals with special needs can have little to do with what would be "nice" and a great deal to do with what is essential, which in this case is the GED. Judge Rotenberg Center and GED have given us the peace of mind we needed.

It is unfair to withhold an effective treatment just because it involves aversives. Certainly, it is wrong to let a person harm themselves when there are procedures that may effectively decrease or eliminate this behavior. Our daughter is now drug free. With the introduction of the GED, she

has tremendously reduced her health dangerous and aggressive behaviors. She is doing much better at the Judge Rotenberg Center. There have been several days, even weeks, with no major issues, and with Erin, that is a very great accomplishment. Our daughter, Erin, is a bright individual, whose needs far exceed what can be addressed by typical special needs services. In our daughter, there was a young lady trapped inside who was begging to be free, but her behaviors would not allow it; with the GED, we are now able to see that young lady.

Perhaps just as importantly, Erin likes being at the Judge Rotenberg Center. When we return from home visits, she does not put up a fuss. All she wants is to make sure that she has her MP3 and headphones before we leave. She always takes me to her classroom, on her own, which always surprises us.

Please give us the chance to continue with this method of treatment, and to follow our hearts, possibly saving our daughter's life, and allowing her to laugh, enjoy, and participate in JRC and community activities.

Sincerely,

Cornis and Patricia Crawford
225 Parkside Avenue apt. 5K
Brooklyn, NY 11226

Divisions of documents management (HFA-305) Food and Drug Administration 5630 Fishers lane Room
1061 Rockville MD 20852

My brother Luigi DiSisto is currently under care and a client of the Judge Rotenburg Center in Canton Ma. He is on the GED device and has been on it since entering the school. The school and staff along with the structure and support of the GED device has been a blessing in more ways than one. I have seen major improvements in my brothers autistic behaviors without the use of prescription medications. There is no specific medication for the treatment of autism. So what happens is that a bunch of psychotropic medications are tried to treat the behaviors associated with the disease this results in overmedicating and adverse side effects. I think this practice is inhumane.

I believe the alternative treatment involving the use of the GED is a much better and safer option as there are no side effects. I tried the device on myself several years ago to get a better understanding of what it feels like when its administered and I literally got a feel of what it is and does.

After my own experience and seeing my brothers behaviors go down I cant say enough about how detrimental it would be if he did not have it. My brothers physical outbursts towards himself and others have decreased significantly due to this device that I believe has been an absolute help to my brothers physical wellbeing. So I ask that you please reconsider taking this away and think of it in a different perspective. I would love the opportunity to speak with you and I can answer any questions you may have.

Sincerely,

Angela DiSisto 781-760-9802

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane - Room 1061
Rockville, MD 20852

May 17, 2016

Subject:

Docket No. FDA-2016-N-1111 (Proposal to Ban Electrical Stimulation Devices to Treat Self-Injurious or Aggressive Behavior)

Members of the FDA,

I would like to tell you about my son, Marc Doherty. As a parent whose child has been through the system and experienced various treatments I feel that there is a positive place for aversive intervention, specifically behavioral skin shock (GED). This is an effective treatment please don't let the recent media hype or politicians cloud your judgment.

I am a parent of an autistic person who is now a client at The Judge Rotenberg Center (JRC) in Canton, Massachusetts, this center has saved my son's life. Marc has been in residential placement since he was six years old, my wife Linda and I knew early on that Marc had severe problems and we took advantage of the "early intervention" programs on Long Island, as well as a three month admission to Bellevue Hospital Psychiatric in NYC. Marc was enrolled in several day programs on Long Island (DDI, Mary Haven, Kramer Learning Center) and was found not suitable for and too disruptive for other special need programs prior to his placement at the Anderson School. By the time Marc was age six we were told that none of them were a good fit for him. I can still remember the look on my wife Linda's face when I arrived home from work and she told me that she had been contacted by the Kramer Learning Center of Bayshore and informed that the bus would not be coming for him, we were at the end of our rope. Working with our school district in West Islip we started to look for an appropriate residential placement as we could no longer provide for Marc's needs or provide him around the clock safety, we were burned out. Marc was residentially placed in the Anderson School at Staatsburg NY in 1992.

Prior to being enrolled at JRC, my son Marc was on a variety of psychotropic drugs while he was at the Anderson School, although they were prescribed with best intentions they ended up not to be the best thing for my son. His needs were so intense that he required a 1:1 paraprofessional. The doctors on staff at The Anderson School for Autism, altered his medication regime on many occasions. This often included increasing/decreasing and starting/stopping multiple medications. At one time, Marc was taking as many as twelve different medications. Marc's response to being medicated was far from positive. A good portion of the time he was lethargic and zoned out. Any energy Marc did have manifested itself with his violent outbursts. At the direction of the Anderson School Psychiatrist and our permission my son Marc was admitted to the Westchester Medical center to detox from the many medications that he was on, even with the 24 hour Anderson staff member on hand his behavior was so unmanageable (self injurious & aggressive) that he had to

leave and return to the school. The purpose of the admission was to remove him from all drugs, some that may have been conflicting with each other so that medications could be effectively reintroduced.

. . My family and I struggled with our conscience while working with various professionals including psychologists/psychiatrists specializing in behavior modification techniques. Marc's self injurious behavior grew worse of the years while he was on medication. In addition to his self injurious behavior, he had become increasingly aggressive and his OCD's (obsessive compulsive disorder) increased. Marc has always been physically strong, staff at Anderson started wearing ball caps and tucking their long hair around Marc as he would grab their hair and violently pull the to the ground, he would also grab them and throw them, he injured several staff and even sent a few to the hospital. To my knowledge Marc never aggressed toward other students unless they had something that he wanted, his attacks on staff seemed random.

Eventually in 2004 the Anderson School requested that we find another placement as they were no longer able to care for and manage Marc. Every appropriate New York State placement that we were given turned us down after reading Marc's history. His information was sent to eighteen schools from Maine to Virginia. Only four of them called us for interviews. We went to screen these schools, looking to see what they had to offer. After various interviews and meetings, three of the schools sent representatives to the Anderson School to observe Marc. The administrators from one school in Delaware had told us they had never turned away an admission. After observing my son and talking to the Anderson School staff, we were told they could not afford the additional staff needed to serve Marc and he was subsequently not accepted.

After Marc was accepted at JRC his violent behavior manifested itself during transport by Anderson Staff from the Anderson School in Staatsburg NY to the Judge Rotenberg School in Canton MA in December 2004. As was the Anderson protocol he was administered a strong dose of Thorazine to calm him and get his behavior under control in this dangerous situation, this was in addition to scheduled dosage of Thorazine that he had received earlier in the day along with his other scheduled medications. Upon arrival at JRC Marc remained extremely agitated and went into physical distress that required his immediate emergency hospitalization. As a direct result of the additional administration of Thorazine Marc was diagnosed with Neuroleptic Malignant Syndrome (NMS), he went into a coma for eight (8) days and almost died. Believe it or not there was a Brightside, while Marc was in the coma he was finally able to successfully detoxify from the cocktail of medications that he was on without additional discomfort.

The use of aversive is a last resort, however, in extreme circumstances they can be a life saver. JRC has multiple safeguards in place to monitor the treatment of their students as well as their staff performance and I remain to have confidence in them and the GED to be the best treatment for my son. The Judge Rotenberg Center does not believe in psychotropic medication and Marc remains medication free, during his time at Anderson he experienced significant weight gain as result of his medications, in 2004 his weight had increased to over 240 pounds despite a regulated diet. His behavior and quality of

life has improved tremendously, along with his health after his admission to JRC. He has learned to work with the computers, ipad and can stay on task in the work shops on a regular basis. Marc is classically autistic with a full scale IQ of 41. He is non verbal, will most likely require residential placement for the rest of his life and he will need the use of the GED as well. Would you deny a diabetic their insulin? Why would you want to deny treatment to a thriving autistic person who has made so much progress?

I feel it is important to understand the treatment offered at JRC. When my wife and I went to the Judge Rotenberg Center to determine the suitability for my son Marc, I asked for and received a GED skin shock so that I could better understand the treatment. It left no burn or injury to my right arm but it defiantly got my attention, we hoped that this would be a better alternative to medication protocol offered in New York and it is.

Thank you for your time.

Richard T. Doherty
50 Arbour Street
West Islip, NY 11795

631-667-0073

Rtdoherty53@yahoo.com

cc: Congressman Peter King, NY
Senator Kirsten Gillibrand, NY
Senator Charles Schumer, NY

July 2nd, 2016

Division of Dockets Management (DDM)
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

To Whom It May Concern:

I received notice of a proposed new rule to ban the use of the GED that has been introduced by the FDA. I strongly oppose to this proposed rule that threatens to deprive children of the right to receive aversive therapy as a part of a behavior modification treatment program. It is my opinion that JRC should continue to utilize aversive therapy as long as they have professions to do the job and they use it only for dangerous behavior.

My son, Markey Ellis, was at the Judge Rotenberg Center for fifteen (15) years and I can say that aversive therapy really helped my son improve a lot. I think that the Judge Rotenberg Center should continue the aversive treatment because they have helped so many children and adults with Autism, intellectual disabilities, behavior problems and other disabilities. They have been there for families when there were no other place to get help for our children.

I would like to say at this time, I feel very fortunate that I was able to place my son at the Judge Rotenberg Center.

Sincerely,

Mrs. Teresa Ellis-Brown
Markey Ellis' Mother
99 Clinton Street, Apt. 2B
New York, NY 10002

Date: July 7, 2016

Division of Dockets Management (HFA-305)
Food and Drug Administration 5630
Fishers Lane
Room 1061
Rockville, MD 20852

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

To Whom It May Concern,

I am writing to express my deep concern about the proposed ban to electrical stimulation devices used to treat self-injurious or aggressive behavior. My daughter, Lian has been receiving treatment with electrical stimulation devices (GED's) for her aggressive and self-injurious behavior at the Judge Rotenberg Center for the past seven years. It has been a life-changing treatment for her. If the GED's are banned, I fear that she will return to a life of isolation, restraints, medications, injuries and hopelessness.

Below is a description of Lian's treatment history prior to JRC and her life at JRC, as well as my concerns about Lian's future if she doesn't have access to GED's. Also, attached please find a Diagnosis and Medication Summary, a Summary of School Placements and a picture of Lian and me.

My husband and I adopted Lian from China when she was 11 months. Her behavior problems began very early at age two when she started biting and scratching people, and she has been receiving various forms of treatment—therapy, medication, GED—ever since. Lian's aggressive and self-injurious behaviors prevented her from attending public schools past first grade. She attended the Community Therapeutic Day School for a few years until she was hospitalized when she was just ten years old because she was kicking glass and was a danger to herself and others. My husband and I were devastated when we came to the realization that we were no longer able to keep her safe, at which point we enrolled her in a full time residential program.

From ages ten to seventeen, she attended three different residential schools—Latham Centers, the Kolburne School, and the Protestant Guild—all of which were eventually unable to care for

her. Lian was hospitalized five more times during this period, with an average stay of 31 days. Each time she was hospitalized, we made every effort to get her into a Developmental Delayed Psychiatric Unit for each hospitalization because otherwise she would be placed in a unit that was not adequately prepared to handle her and that could be detrimental to her. Hospitals of this type were scarce, but we were able to secure New Hampshire's highly regarded Hampstead Hospital for her last four hospitalizations.

Lian's aggressive and dangerous behaviors have included screaming; throwing toys; hitting, kicking, biting and scratching people; pulling people's hair; attempting to bang staff's head against the wall; and unpredictable attacks on staff, peers, and family. Much of this behavior was exemplified during a car ride when I was taking her back to her residential school when she was 16. Without warning, she attacked me while I was driving on a four lane highway. She began pulling my hair from the roots and biting me hard all over. She then tried to jump out of the moving car. Fortunately, I was able to grab her and pull her into the car. To this date, both Lian and I no longer feel safe alone in a vehicle.

Because of her engagement in aggressive and impulsive behavior, Lian was frequently isolated from her peers in an effort to keep everyone safe. Consequently, she received little education and was rarely able to go out into the community. Lian spent many long hours in time-out rooms, with durations for as long as 19 hours a day. She also experienced years of physical restraints, and both of Lian's knees were severely injured due to these restraints. Knee surgery was not an option because she could not recover when she was constantly being on the floor being restrained.

Diagnoses by doctors were varied, often conflicting, and in the end, were ineffective in helping us find an effective treatment. Lian has been on at least 23 different psychiatric medications since she was five years old in an effort to help with her impulsive and aggressive behavior, including Ritalin, Zoloft, Clonidine, Lithium, Depakote, Cogentin, Clozaril (clozapine), Ativan, Klonopin (clonazepam), Risperdol, Tegretol, Topomax (topiramate), Haldol (haloperidol), Prozac (fluoxetine), Propranolol, Lamictal, Thorazine, Valium, Atarax, Trilafon, Zyprexa, Lexapro and Abilify. Not only were these medications ineffective, she experienced many side effects, including over-sedation, drooling, depression, confusion, weight gain, severe headaches and permanent hand tremors.

The Judge Rotenberg Center was the only school in the Commonwealth of Massachusetts that would accept Lian after she was dismissed from The Protestant Guild. She was enrolled at age seventeen. During her first six months at JRC, Lian was on the positive behavioral program, a program that at times is very effective. However, similar to her experience at prior institutions, Lian's aggression continued. During those first six months, Lian had 159 restraints, with a duration averaging 26 minutes. 11% of those restraints caused injuries to her or to staff members.

After six months of Lian's continued aggression, JRC asked us if we might be interested in considering the GED for Lian. We took this decision very seriously. I had the skin shock myself

before my husband and I made the decision. It hurt for two seconds, but when it was over, there was no pain and no other side effects. We agreed to approve the GED treatment because our daughter had not been successful in past programs, therapies, or medications, and plus she required surgery on her knees. JRC's data showed that their clients had great success with this therapy when nothing else had worked. I feared Lian would be upset about the GED treatment, but my husband and I also hoped and prayed that Lian would be one of the success stories and that her restraints and injuries would no longer continue. GED use also required approval in a court proceeding. Lian was provided her own attorney, and the GED treatment plan was approved by the court.

Lian started the GED treatment in February, 2009. The change was almost immediate. It helped her stop and think before she aggressed, which no other treatment had previously done. Over the past almost 7 years while on the GED, she has had only 59 applications (a mean of .72/month), a total of just 118 seconds of skin shock. During this time, she has not had any restraints. To put this in context, in just the six months prior to beginning the GEDs treatment, Lian had 159 restraints (a mean of 26.5/month for a total of 4,058 minutes).

JRC has been open and responsive about her treatment. They have cameras everywhere (except bathrooms), and when I requested to review tapes of Lian receiving a GED, JRC was happy to comply. At one time I had a concern about her treatment plan with the GED, and JRC listened and modified her program as I requested.

Lian now lives in a home with peers and has two roommates. Lian has worked at a variety of jobs at JRC and continues working on academics in a classroom setting. She is able to go into the community on field trips, go out to lunch with me every week and come home monthly. She's happy. She was able to have surgery on both knees and is now able to walk without braces. She is no longer on medication and as previously mention, has had no restraints since beginning the GED treatment.

Lian has told me multiple times that she is thankful for her program and for the GED devices. She once asked me why she didn't start this treatment when she was 10 years old. She never asked me to have this treatment stopped. She has never complained about pain, injury or illness associated with the GED, whereas prior to JRC she would complain about knee pain during restraints. Lian is very verbal and lets me know her complaints when she has them, and yet she has never indicated experiencing any of the side effects identified by the FDA. She comes home monthly and I have never seen any injuries when I am with her when she showers.

Lian has a challenging and difficult life. She works very hard every minute of every day. I love having her home for holidays, monthly overnight visits and weekly lunch dates. If the GED treatment is banned, all of this will likely stop, because her aggression will likely return. We have tried at least 23 medications and various forms of therapy and counseling without any measurable success. We fear that her life and our lives will become unbearable again.

I think Lian sums it up best. On April 12, 2013, she turned 22 years old. She started to worry that she would be leaving JRC as some students leave when they graduate at age 22. On April 27, 2013 I wrote down something she said to me. She said "If I went to an adult program before I am safe without GEDs, I'm afraid I will die or go to jail. I will refuse to take medicine. You can't make me." If the GED treatment is banned, how does one explain this to her? I am confident that isolation, restraints, injuries, medications and their side effects and hopelessness will return. And sadly, yes, jail is a possibility.

Those that oppose this treatment have never walked in our shoes. Before you make this final decision to ban the GED device, I strongly recommend that you come to JRC to meet the clients, parents and staff. This proposed ban is affecting a small population and could be life or death for them.

Sincerely,

Lauren Emmick, Parent

Llan Emmick

Diagnosis and Medication Summary

Age	Evaluator	Medications at Time of Admittance	Medications at Time of Release	Diagnosis at Time of Admission	Diagnosis at Time of Release
2 yrs, 5 mos	Children's Hospital Early Language Program- Sept 14, 1993	n/a	n/a	n/a	Difficult temperment including high activity level, distractibility, negative persistence, low sensory threshold and poor adaptability. Attention/concentration and impulsivity difficulties
2 yrs, 6 mos - 3 yrs	Early Intervention- toddler group and speech therapy to address speech, fine and gross motor skills, cognition and behavior				
2 yrs, 8 mos	Occupational Therapy Associates, P.C.- Wakefield, MA Evaluation dated Dec 6, 1993 and Dec 13, 1993	n/a	n/a	n/a	Difficulty with sensory modulation and discrimination. Underresponsive to movement processing as she craves proprioception and vestibular input. Experiences sensory defensiveness. These areas effect her attention to task, social relationships, behavior in school and fine motor development. Recommended neurological evaluation and OT therapy 2hr/week.
2 yrs 8 mos-3 yr, 4 mos	Occupational Therapy Associates, P.C.- Wakefield, MA Sensory Integration Therapy 2x wk for 60 minutes each. Note: Continued Sensory Integration therapy was continued at school programs				
2 yrs, 11 mos.	Children's Hospital Early Language Program - 2nd evaluation dated March 15, 1994	n/a	n/a	n/a	tempermental characterlists of a difficult child as defined by Stanley Turecki including difficulty adjusting to change, negative persistence, distractibility, overactivity, low sensory threshold and negative mood.
3 yrs, 4 mos 0025	Margaret L. Bauman, M.D., Pediatric Neurologist at Youville Hospital Pediatric Neurology O.P.D. Clinic - Evaluation dated Aug 19, 1994	n/a	na/	na/	Recommended EEG (done), continue Occupational Therapy and speech therapy. Also recommended behavioral psychologist.

Lian Emmick
Diagnosis and Medication Summary

Age	Evaluator	Medications at Time of Admittance	Medications at Time of Release	Diagnosis at Time of Admission	Diagnosis at Time of Release
3 yrs, 6 mos - 10 yrs	Richard Bromfield, PhD, Supervising Psychologist, Mass Mental Health Center, Harvard Medical School - weekly or biweekly therapy depending on needs.	n/a	n/a	n/a	Per treatment update dated 4/21/2001 (age 10) diagnosis is difficult. Reactive Attachment Disorder, possible PTSD, ADHD, Oppositional and Defiant Disorder. Possible Autism and PDD. At times her functioning appears to be psychotic or at least that consistent with burgeoning borderline personality structure. There is hardly a DSM-IV childhood diagnosis that can not be considered for Lian.
5 yrs, 1 mos - 10yrs	Elizabeth Childs, M.D., P.C. - Psychiatrist	Medications prescribed included Ritalin, Zoloft, Clonidine, Lithium, Depakote, Olanzapine, Cogentin, Clozapine, Ativan and Klonopin	Clozapine, Depakote and Ativan as needed.	Prior diagnosis were ADHD, Anxiety Disorder and Post Traumatic Stress Disorder to Bipolar Disorder and Post Traumatic Stress Disorder	Final Diagnosis was Psychotic Disorder NOS and Post Traumatic Stress Disorder
9 yrs, 10 mos	Charles Popper, M.D. Child and Adolescent Psychiatry and Psychopharmacology - Harvard Medical School, McLean Hospital - Evaluation dated Jan 23, 2001	See above	See above	ADD, Bipolar disorder, Psychotic disorder, NOS, Post Traumatic Stress Disorder, Separation Anxiety Disorder, Anxiety Disorder, Obsessive-compulsive disorder, Left Hemisphere dysfunction, Multiple developmental delays, Delayed language development, Autistic/PDD, Attachment Disorder	Post-traumatic reaction to abandonment, deprivation and neglect (probably not classical PTSD), Pseudo-Autism, Obsessive-compulsive disorder, Left hemispheric dysfunction due to abnormal sleep EEG (June, 1998- age 7)

0026

Lien Emmick

Diagnosis and Medication Summary

Age	Evaluator	Medications at Time of Admittance	Medications at Time of Release	Diagnosis at Time of Admission	Diagnosis at Time of Release
10 yrs, 0 mos 10 years 3 mos	Franciscan's Children's Hospital - Inpatient Unit for the period April 24 thru July 8, 2001	Risperdal, Depakote	While hospitalized, increased Risperdal, added Cogentin, tapered off Depakote and onto Tegretol. Tegretol trial was discontinued due to decreased WBC. Final Medication at discharge were Risperdal, Cogentin and Topomax	PTSD and psychotic disorder NOS	Provisional Diagnosis is Axis I: PDD, NOS and Mood Disorder NOS, history of Reactive Attachment Disorder and Post Traumatic Stress Disorder, Axis II: Question of borderline cognitive functioning and learning disabilities, Axis III: History of abnormal EEG, Axis IV: Difficulties with her social environment and educational setting and Axis V: 30
10 yrs, 3 mos	Rowland Barrett, PH.D. Director, Developmental Disabilities Program, Emma Pendleton Bradley Hospital, Rhode Island. Evaluation dated July 19, 2001				Axis I Asperger's Disorder, Axis IV: Neglect as Infant and Educational Problems, Axis V: Global Assessment of Functioning is 40.
13 years old	David S. Mishkin, Ph.D. Clinical Neuropsychologist, South Yarmouth, MA for Neuropsych Evaluation dated March 11, 2004				PDD, NOS, Cognitive Disorder, NOS, ADHD, Inattentive Type, Anxiety Disorder, NOS, Post Traumatic Stress Disorder and R/O Obsessive Compulsive Disorder
14 years old	Pembroke Hospital - Psychiatric Unit - From Jan 30, 2006 thru Feb 14, 2006		Risperdal, Abilify, Luvox, Topamax and Cogentin		Bipolar Disorder (296.50), Obsessive Compulsive Disorder (300.30) and PDD

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Llan Emmick
Diagnosis and Medication Summary

Age	Evaluator	Medications at Time of Admittance	Medications at Time of Release	Diagnosis at Time of Admission	Diagnosis at Time of Release
16 years old	Hampstead Hospital Developmental Disordered Psychiatric Unit from May 2, 2007 thru May 24, 2007	haloperidol, clozapine, cogentin, fluoxetine, topiramate, propranolol	clozapine and clonazepam	Axis I: Disruptive Behavior Disorder R/O Psychosis, PTSD, OCD, Axis II: Mild MR, IV: Severe and Axis V: 30	Axis I: Anxiety Disorder, NOS and Reactive Attachment Disorder, Axis II: Mild Mental Retardation, Axis III: PMS, Axis IV: Severe and Axis V: 55
16 yr, 2 mos	Hampstead Hospital Developmental Disordered Psychiatric Unit from June 13, 2007 thru Aug 3, 2007	clozaril and klonopin	clozaril, Klonopin and Lamictal	Axis I: Pervasive Developmental Disorder, ADHD. Rule out mood disorder. Rule out psychotic disorder. Reactive Attachment Disorder. Rule out PTSD. Axis II: Mild MR. Axis IV: Problems with primary support group. Problems with social environment, Educational problems	Axis I: Schizoaffective Disorder, PDD, Reactive Attachment Disorder and PTSD. Axis IV: Problems with primary support group, Axis V: 39
16 yrs, 11 mos	Hampstead Hospital Developmental Disordered Psychiatric Unit from March 31, 2008 thru April 14, 2008	Thorazine, Lysine, and Vallum	Perphenazine, Vallum, Topamax and Thorazine	Axis I: Schizoaffective disorder, PDD, Reactive Attachment Disorder. Rule out PTSD. Axis IV: Educational problems. Axis V: 25	Axis I: Schizoaffective Disorder, PDD and Reactive Attachment Disorder. Axis II: Mild MR. Axis III: Dislocation of left patella by history, Axis IV: Problems with primary support group and housing problems. Axis V: 38
17 yrs old	Hampstead Hospital Developmental Disordered Psychiatric Unit from May 19, 2008 thru June 13, 2008	Atarax, Trilafon, Valium, Thorazine, Zyprexa and Topomax	Lexapro, Zyprexa, and Vallum	Axis I: Disruptive Behavior Disorder NOS, Reactive Attachment Disorder by history, Schizoaffective disorder by history, Mood Disorder NOS. Rule out depression NOS. History of PDD NOS. Axis II: Mild MR. Axis IV: Severe. Multiple hospitalizations. Disruption. Possible loss of placement. Axis V: 23	Axis I: Schizoaffective Disorder. Axis II: Mild MR. Axis IV: Moderate. Multiple hospitalizations. Axis V: 54

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Lian Emmick
Summary of School Placements

Age	Dates	School	Reason for Discharge
3 - 5 yrs old	September, 1994 thru August, 1996	Steward Integrated Preschool with 1:1 aide, speech and sensory Integration therapy	Moved to local elementary school
5 - 6 yrs old	September, 1996 thru Aug, 1997 (Kindergarten plus summer program)	Harry Lee Cole School, Boxford, MA with 1:1 aide, speech therapy and sensory Integration therapy	Moved onto first grade at same school
6 - 7 yrs old	September, 1997 thru Aug, 1998 First Grade plus summer program	Harry Lee Cole School, Boxford, MA with a new 1:1 aide	Lian had difficulty transitioning into first grade. When Lian was aggressive, her mother was called and she was sent home. Her education was being disrupted for extended periods of time. Lian was working one on one with her aide in large emptied janitor's closet containing a desk. She was working on "art and related projects". In Dec, 1998, we started looking for a special therapeutic day school. The team agreed that the Community Therapeutic Day School (CTDS) in Lexington, MA seemed most appropriate but there was not an opening until Sept., 1998. We hired a behavioral specialist, supervised by CTDS, to train Cole School staff in new techniques to help Lian until her new placement at CTDS was available. Lian's aggression continued the remainder of the school year.
Age 7 - 10	September, 1998 - April 2001	Community Therapeutic Day School, Lexington, MA with 1:1 aide part time at school and part time at home. Lian received Integrated speech and Language and sensory Integration therapy, expressive therapy and Music/Movement Therapy.	Lian was becoming too difficult for the school to manage. She spent much time at home or in a separate classroom during times of significant aggression. In April, 2001, Lian was hospitalized as she was a danger to herself and others. Once hospitalized, we were told she could not return. A residential treatment facility was recommended.

0029

Lian Emmick
Summary of School Placements

Age	Dates	School	Reason for Discharge
Age 10 - 14	August 2001 - April 2006	Latham Centers, Inc., Brewster, MA. Lian received weekly social skills therapy and therapy sessions with social worker. Also, relaxation therapies including "brain gym".	Lian did relatively well for the first few years. Latham used a level system. She rarely went off campus unless with parents. Timeouts were used to calm Lian. The timeout procedure was for Lian to sit up against the back wall, on a mat with hands in lap or in "hook-up" position, with one leg straight out. The door was closed the entire time. If she soiled herself, she could clean up after she left the timeout room. Timeout began when Lian was quiet and lasted at least 45 minutes. During the last 2 1/2 months she was at Latham, she spent 16 nights sleeping in the timeout room (not sitting against the wall) and many hours/day in timeout to keep everyone safe. Her mother decided to find another school that had a better strategy to help Lian with her aggression.
Age 15 - 16	April 2006 - August 2007	Kolburne School, New Marlborough, MA. Lian had occupational therapy, speech therapy, therapy with clinician and a monthly meeting with their school psychiatrist. Lian was not able to have a roommate due to her behaviors	Lian was discharged due to her extreme aggression.

0030

Lian Emmick
Summary of School Placements

Age	Dates	School	Reason for Discharge
Age 16 - 17	August 2007 - July 2008	The Protestant Guild for Human Services, Inc., Waltham, MA. Lian received behavior management with behavior specialist, Speech and Language therapy and therapy with a social worker. Lian did not have a roommate. During her last months, Lian was living in the finished basement with staff supervision in her residence. This was done to keep the rest of the house safe.	Lian had injuries to both her knees from years of restraints. The aggression continued and Lian was discharged.
Age 17 - 25	July 2008 - to Present	The Judge Rotenberg Center	

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From: Alfred and Carline Lopez
12 Brookside Road
Unit 31
Westford, MA 01886

To: Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fisher Lane
Room 1061
Rockville, MD 20852

To Whom It May Concern:

Our son Jonathan is a twenty-three year old boy whom we love dearly. We struggled to teach and care for him since he was diagnosed with autism at the age of three. No parent is prepared to provide this kind of care and it would have been very helpful if there were more organizations like The Judge Rotenberg Center (JRC). As it stands, Jonathan has been subjected to countless medications, behavior treatments, examinations, evaluations and fad diets made popular by the autism community, desperate to find a "cure" or treatment that would give him a better quality of life.

Since 2004, we have dealt, not only with Jonathan's aggression, but with schools with inadequate resources to teach and handle a child such as Jonathan. To make matters worse, Jonathan has been put in handcuffs, both wrist and on his ankles by the public school system and "Baker Act" twice, with threats from the Sheriff's Department about pressing charges if he continues to hurt school staff. His aggression has caused destruction, lost of vision in one of his mother's eyes, scars from scratching and biting, concussions from head butting and facial injuries from punches, projectiles and kicks. He destroyed his room in our house and rental properties before that, by smashing his head through the dry wall, pulling down ceiling fans and breaking the windows. And if that weren't enough, the insurmountable costs incurred from my wife quitting her job to care for him, medications, treatments, etc. that left us in financial hardship. After exhausting all service in the State of Florida, we decided to look elsewhere. That's how we found JRC.

Jonathan has been attending JRC since April of 2010. By November 2010, Jonathan had sent at least 6 JRC staffs to the hospital. We opted for the aversive devices in November 2010 because all else had been tried and failed. Medications left him numb and unresponsive and it was difficult to redirect him when we needed to change his plans or when we saw that he was getting upset, which usually led to aggressive behavior, plus he incurred substantial weight gain as a result of the medications. It took a little while for the aversive therapy to work, but when it did, we saw more progress in his education and behavior than all the previous school years Jonathan had attended.

We did not make the decision for his current aversive plan without first gathering information on the treatment, reading and witnessing the success stories, and without trying it ourselves. We experienced the device for ourselves and found that the two second shock is no more painful than a strong pinch. The pain doesn't linger and it only last for those two seconds. Also, the fact that the trigger can only be used once in a 2-5 minute period, ensures that there's no abuse with the device.

Our primary goal was his own safety and health and being able to actually enjoy the things he wants to enjoy. Jonathan is an avid roller coaster rider and he's been visiting all the Florida theme parks since 2004, but his visits (which we incorporated in a reward system at that time for behavior modification) weren't always successful. He had to be flanked by both of us at all time, sit in certain chairs away from people in the ride just in case he became aggressive, and sometimes not ride at all because we couldn't trust him to ride alone in certain rides that required it. We've had to be escorted from several of the parks when Jonathan would beat me up in the middle of crowds where I would be bloodied and bruised from struggling to contain him. Now, he can walk by himself, meet and greet, and be with other people without the fear of injury to them or to himself. He's even able to sit in a five hour plane ride across the country.

As parents, we are always hopeful that Jonathan will someday be "normal", but we will also be very grateful for any improvement that will increase his quality of life. Since the placement of the aversive devices, he has been going on field trips every weekend, which he enjoys tremendously. He has been able to spend time with us without any aggression. When he comes home, he is cooperative, and eager to please. He even asks to do chores; something he always resisted.

Without the aversive treatment program at JRC, we would be lost; our lives would have to center around Jonathan, which would force us to stay home with him endangering his life and ours. This is not an exaggeration. Carlina is blind in one eye due to a sustained injury by Jonathan when he was twelve years old and 100 lbs lighter. No telling what he would do if he regresses and is left alone with his mother. I would have to take many days off from work when we suspect a "bad day" for him, which would jeopardize my job, medical insurance for my family and livelihood, in general. The public schools are not equipped nor is the staff trained to handle someone like Jonathan. Placing him in a group home where their methods are not up to the standards held by JRC, and the possibility that drugs and sedatives would be used to control him is unacceptable.

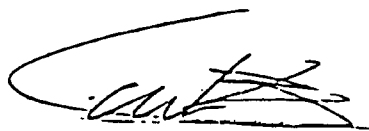
We get a report every day on Jonathan's progress and the number of applications, if any. It is very rare when Jonathan gets an application, and we haven't had any reason to do so ourselves at home in the time he's had them. It is aversive in the true sense: verbal direction is used first, which allows Jonathan to recognize what he did is unacceptable. If he stops the behavior, no application is administered. This works very well when he's at home with us or out and about.

For the first time in twenty years, we have hope for a desired quality of life for our son. So taking that away from him would actually be an inhumane thing to do.

Sincerely,



Alfred Lopez



Carline Riche-Lopez

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THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION

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May 20, 2016

To: The Federal Food and Drug Administration

From: Paul E. Peterson and Carol D. Peterson

Re: Proposed Regulation Docket No. FDA--2016-111 for "Proposal to Ban Electrical Stimulation Devices Used To Treat Self-Injurious or Aggressive Behavior."

We, the parents of David Peterson who resides at the Judge Rotenberg Center (JRC) in Canton, Massachusetts, request that the proposed regulation to ban electrical stimulation devices (ESDs) used by JRC to treat self-injurious or aggressive behaviors be withdrawn. In our view, the regulation is not compliant with the equal protection clause of the Fourteenth Amendment to the Constitution. The proposed regulation, if promulgated, would violate the equal right to effective treatment of our disabled son, David B. Peterson.

David has been at JRC since 1988. JRC serves a unique population, usually those students who have been rejected by every other school, and who have life-threatening habits or extremely aggressive, uncontrollable rages. Before he entered JRC, David had been in approximately 8 schools, all of which said they could not deal with him, and one (Devereux in Pennsylvania) gave us five days to come and pick him up. The director said, "I have to think about my staff, you know."

We have cared for David for 45 years now. He lived at home until age 13, when his self-injurious behaviors became so severe that he needed 24-hour care. Carol, his mother, spent full time attempting to help David while she raised two other children. Carol returned to work once her children were in college, and was the founding managing editor of an education journal. David's father is the Shattuck Professor of Government at Harvard University. (See Attachment

1 for CV.) David's sister is now a high-ranking administrator for the New York City Department of Education. His brother manages a team of computer programmers for a major software firm. We are closely engaged with the people at JRC and extremely supportive of the careful way they treat our son. We bring David home about once a month to enjoy birthdays and holidays with his parents, siblings, nieces, and nephews. These are special occasions both for David and his family.

Long-Term Side Effects

The FDA's proposed rule claims that individuals suffer serious, long-term side effects from treatment by ESDs. However, for David, the effects of ESD treatment have been nothing but favorable over the course of the 20 years he has been treated. David is in excellent physical health, and his sociability, curiosity, and ability to carry out basic tasks (such as dressing himself, eating, performing his toilet, etc.) has improved enormously. His mind is as clear as it can be, since it has not been altered by drugs. Nor is he physically restrained. He can attend events and go out into the community, which he does frequently.

Understanding Consequences

According to the proposed FDA regulations, the principal justification for distinguishing the use of ESD devices for "aversions to other conditions or habits" for those who are not mentally disabled is that "patients have control over the shocks." However, the ESD may be used only after certain conditions have been fulfilled, including consent by parents or guardians of the disabled patient and a clinical assessment of the need for treatment by an entity separate and independent from the ESD provider. In the case of David both those conditions obtain: We the parents have consented in writing to David's treatment, and David's treatment plan must be

affirmed by an officer of the Court of Massachusetts under a ruling Further, the administration of the treatment is closely monitored at the Judge Rotenberg Center, minimizing the risk of inappropriate treatment.

We add that, in spite of what the proposed regulations imply, David knows perfectly well what the ESD is and what it does. The device is important to him. It has a little box in the front that has a green or red light. If the light is green, the system is on. David checks the device periodically to make sure the green light is on, because he KNOWS it protects him from himself.

Immediate Adverse Effects

The proposed regulations argue that the immediate adverse effect of an electrical stimulus ("shock") constitutes a physical and psychological harm to be avoided. It reports that one experimenter said he definitely felt pain when he applied the ESD to himself. He described it like a dentist drilling on an unanesthetized tooth..." Another experimenter "observed a tremor in the thigh," a statement that suggests a notably lower degree of pain. We, too, have experienced an ESD shock – quite purposefully. We find the effects similar to those of the second experimenter. The report of the first one does not remotely resemble our experience.

The proposed regulations contend that the pain can vary from one condition to the next and from one individual to the next. If this is true, whatever the degree of variation, the FDA does not think the shock is so painful for anyone that an ESD or similar device must be banned from being used to "create aversions to ... smoking" and other undesigned behaviors. Apparently, the benefits from non-smoking are sufficiently large they offset any physical or psychological pain that accompanies the shock. But in our view, smoking effects, however harmful to health in the long run, are hardly as serious as the effects of non-treatment for our son, David.

It is worth emphasizing the seriousness of David's conditions. Prior to JRC's treatment, David gouged his rectum with his hands. He banged his head and damaged his ear. He stuck his hand down his throat so he could scrape his throat and bring up blood (as you see in the enclosed picture). He threatened to jump off our porch in Washington, D. C. in what would have been a life-ending fall. He was a run-away, and we found him many times in extremely dangerous situations. He has destroyed his gums with his fingernails. All of these behaviors are now under control as the result of ESD treatment. (By the way, David no longer has much in the way of gums. Dentists have used a product used for filling the teeth to create a bridge for him that holds the teeth in place for a while. He will eventually lose them, though. Nor are false teeth an option, since he has insufficient bone to hold them in place.)

Availability of Alternative Treatments

The proposed regulations suggest that alternative treatments are available for mentally disabled, autistic individuals who engage in self-injurious behavior. For some people such as our son, that is not the case. Our family traveled a long path before finding the treatment available at JRC. Before his placement there, David was enrolled in eight different programs for multiply disabled individuals, all of whom said they did not have an ability to help him.

In 1988, as a last resort, David entered the Autism and Developmental Disabilities Center at Johns Hopkins University, where experts explored a wide variety of treatment protocols, including various kinds of drug therapy, positive reinforcement therapy, and certain forms of aversive therapy, and ignore therapy (the option first tried). Their rules forbid a stay in excess of four months. At the end of this period of time the Center concluded that it had been unable to find a therapy that was effective. We told the staff that we had been simultaneously exploring

the possibility of a placement at the Behavior Research Institute, as JRC was previously known. They agreed that this was the best possible option for David.

Positive or Negative Therapy

The FDA's proposed regulations state that the effectiveness of the ESD device cannot be determined on the basis of individual case studies at the JRC, because the device is always combined with positive reinforcement therapy. The Commission states that the latter therapy might be the effective component of the treatment. However, in David's case, the positive reinforcement therapy has not been effective during those periods when the ESD was not used. As we noted above, David's treatment plan must be court approved. At times the legal situation has been such that ESD treatment must be withdrawn. This is an unhappy time for David and his family, because his self-abuse escalates. The one benefit of these situations is the demonstration in practice that ESD treatment—not other factors—is responsible for the remarkable improvement in David's overall well-being.

That said, it must be noted that JRC combines aversive therapy with a wide range of positive reinforcements. David has enjoyed a much more satisfying adult life than could ever have been imagined at the time he entered JRC. Nor is there any sign of psychological damage that could be attributed to ESD treatment. On the contrary, David loves to visit his family, and he is happy to return to his friends in the residence where he lives, and to go to school at JRC.

Enclosed you will find some pictures of David from 1988, when he began treatment at JRC (then called Behavior Research Institute or BRI). You see the seriousness of the situation. Then you can see the photo of David from this past Christmas, taken at the school. He is calm and happy.

In some cases, perhaps pictures speak more loudly than words. (See Attachment 2 for photographs.)

We urge you to withdraw this proposed regulation in consideration for the well-being of those very few and very unusual people who need extreme firmness in their lives in order not to harm themselves or others. When properly administered, as is the case at JRC, use of the ESD is an irreplaceable life-saving therapy. ■

ATTACHMENT 1

CURRICULUM VITAE

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EDUCATION

- B.A. Political Science, 1962, Concordia College, Moorhead, Minnesota (summa cum laude)
- M.A. Political Science, 1964, University of Chicago, Chicago, Illinois
- Ph.D. Political Science, 1967, University of Chicago, Dissertation: "City Politics and Community Action: The Implementation of the Community Action Program in Three American Cities"

PROFESSIONAL EXPERIENCE

- 2008 President Bush nominates Paul E. Peterson to the Board of Directors of the National Board of Education Sciences, U.S. Department of Education
- 2006 Named to Head Florida Education Transition Team by Florida Governor-Elect Charlie Crist
- 2005 Member, Education Research and Development Center Grants Peer Review Panel, U.S. Department of Education, Institute of Education Sciences
- 2003 - Member, Title I Independent Review Committee, Department of Education
- 2001 - Editor-in-Chief, *Education Next: A Journal of Opinion and Research*
- 2000 - Member, Koret Task Force on K-12 Education, Hoover Institution
- 2000 - Senior Fellow, Hoover Institution
- 1996 - 1997 Fellow, Center for Advanced Study in the Center for the Behavioral and Social Sciences, Stanford
- 1995 - Director, Program on Education Policy and Governance (PEPG), Harvard University
- 1989 - Henry Lee Shattuck Professor of Government, Department of Government, Harvard University

1988 - 2000 Director, Center for American Political Studies, Harvard University

1988 - 1989 Professor of Government, Department of Government, Harvard University

1987 - 1988 Benjamin H. Griswold III Professor of Public Policy and Director of Center for Study of American Government, Department of Political Science, The Johns Hopkins University

1983 - 1987 Director, Governmental Studies, The Brookings Institution

1981 - 1983 Chairman, Committee on Public Policy Studies, University of Chicago

1967 - 1983 Assistant Professor, Associate Professor and Professor, Departments of Political Science and Education and the College, University of Chicago

1978 - 1983 Research Associate, National Opinion Research Center

1979 - 1983 Member, Committee on Public Policy Studies, University of Chicago

1980 - 1981 Visiting Professor, School of Education and Department of Political Science, Stanford University

1977 - 1978 Academic Visitor, Department of Government, London School of Economics and Political Science

1973 - 1974 Visiting Associate Professor, Department of Political Science, University of Washington

1971 Visiting Assistant Professor, Department of Political Science, University of Illinois

1964 Research Assistant, National Opinion Research Center

SCHOLARSHIPS, FELLOWSHIPS AND HONORS

2010 Martha Derthick Best Book Award for *The Price of Federalism*, American Political Science Association

2003 The Thomas B. Fordham Prize for Distinguished Scholarship

1996 - 1997 Fellow, Center for the Advanced Study of the Social and Behavioral Sciences, Stanford, California

1996 Aaron Wildavsky Award for best book in public policy, Policy Studies Section, American Political Science Association

1996 Norton Long Career Achievement Award, Urban Politics Section, American Political Science Association

1996 Member, American Academy of Arts and Sciences

- 1994 Stephen Bailey Award for Outstanding Contributions to Politics of Education, American Educational Research Association
- 1990 Donald Stone Award for Lifetime Contribution to the Study of Federalism, American Public Administration Association
- 1984 Elected to National Academy of Education
- 1982 Woodrow Wilson Foundation Award, American Political Science Association Award for best book published in 1981 in politics, government or international relations
- 1977 - 1978 John Simon Guggenheim Fellowship
- 1977 - 1978 German Marshall Fund of the United States Fellowship
- 1977 Gladys Kammerer Award, American Political Science Association Award for best book published in 1976 on United States national policy
- 1968 - 1969 North Atlantic Treaty Organization Postdoctoral Fellowship
- 1966 Woodrow Wilson Dissertation Fellowship
- 1965 Russell Sage Foundation Fellowship for the Study of Urban Politics
- 1963 - 1965 National Opinion Research Center Training Fellowship
- 1962 - 1963 Woodrow Wilson National Fellowship
- 1958 - 1962 National Merit Scholarship

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59. "School Choice in Dayton, Ohio after Two Years: An Evaluation of the Parents Advancing Choice in Education Scholarship Program", with Martin R. West and David E. Campbell, Harvard University Program on Education Policy and Governance, PEPG01-04, August 2001.
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130. "Comparing Federal Education and Housing Programs: Toward a Differentiated Theory of Federalism" with Kenneth Wong, in Terry Clark ed. *Research in Urban Policy Analysis* I, pp. 301-324, 1985.
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134. "Urban Politics and Changing Schools: A Competitive View" in Ronald K. Goodenow and Diane Ravitch, eds. *Schools in Cities*, New York: Holmes and Meier, 1983, pp. 223-248.
135. "Inquiry and Social Function: Two Views of Educational Practice and Policy" with David J. Greenstone in Lee S. Schulman and Gary Sykes, eds. *A Handbook of Teaching and Policy*, New York: Longman, Inc., 1983.
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137. "Schooling in Democratic America: The Effects of Class Background, Education and Ability on Income" with Susan Sherman Kaplun, in John P. Crecine, ed. *Research in Public Policy Analysis and Management II*, Greenwich, CT: JAI Press, 1981, pp. 195-212.

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157. "Resolving Federal-State Issues through the Political Process," in Advisory Commissions on Intergovernmental Relations, *Is Constitutional Reform Necessary to Reinvent Federalism? A Roundtable Discussion*, Washington, D.C.: ACIR, 1987, pp. 27-30.
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159. "Foreword," in Jay D. Scribner and Donald H. Layton, eds. *The Study of Educational Politics*, Washington, DC: Falmer, 1985.
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163. "The Death of Maximum Feasible Participation" in Herrington J. Bryce ed. *Urban Governance and Minorities*, New York: Praeger, 1976.
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UNPUBLISHED PROFESSIONAL PAPERS

1. "School Reform in Philadelphia: A Comparison of Student Achievement at Privately-Managed Schools with Student Achievement in Other District Schools. Program on Education Policy and Governance Research Papers Series: PEPG 07-03.
2. "On the Public-Private Achievement Debate," co-authored with Elena Llandet, paper presented at the 2002 American Political Science Association annual meetings, New York, August 29 - September 1, 2006.
3. "The Efficacy of Choice Threats Within School Accountability Systems: Results from Legislative Induced Experiments," co-authored with Martin R. West, paper presented at the Annual Conference of the Royal Economic Society, University of Nottingham, March 2005, and Program on Education Policy and Governance Research Paper Series: PEPG 05-01.
4. "Participation in National School Voucher Program," Co-author with David Campbell and Martin West, paper presented at the 2003 Fall meetings of the Association for Public Policy Analysis and Management, Washington DC, November, 2003.
5. "Latest Results from the New York City Voucher Experiment," Co-author with William G. Howell, paper presented at the 2003 Fall meetings of the Association for Public Policy Analysis and Management, Washington DC, November, 2003.
6. "The Changing Politics of Federalism," Paper prepared for presentation at an International Seminar Series: 'Devolution and Democracy: Reconciling democracy, equity, and decentralization,' The Constitution Unit - School of Public Policy University College London, September 26, 2003.
7. "School Vouchers: Results from Randomized Experiments, with William G. Howell, Patrick J. Wolf, and David E. Campbell, paper presented at the 2002 American Political Science Association annual meetings, Boston, August 29 - September 1, 2002.

8. "Impacts of Vouchers on African-Americans." Co-author with William Howell, Conference on 'Closing the Gap: Promising Strategies for Narrowing the Achievement Gap Between White and Minority Students,' Brookings Institution Press, 2001.
9. "Randomized Experiments in Education: The Case of Vouchers," papers prepared for Conference on "the Economics of School Choice," Cambridge, MA: National Bureau of Economic Research, February, 2001.
10. "Implications of School Choice Experiments for Urban Education," prepared for Conference on "Education in Cities: What Works and What Does Not," Wingspread, Racine, Wisconsin, sponsored by Temple University Center for Research in Human Development and Education and the Johnson Foundation, November 1998.
11. "Devolution's Price," Paper presented before Symposium on Prospects for a New Federalism: Jurisdictional Competition and Competence sponsored by the Yale Law and Policy Review and Yale Journal on Regulation, New Haven, March 1996.
12. "American Federalism: A Test of Dual Sovereign Theory," paper presented before the Conference on Hyper-Federalism: Russian Decentralization in a Comparative Context, Center for International Studies, Princeton University, February 1996.
13. "Unemployment Compensation Policies in a Federal System," paper prepared for the Advisory Council on Unemployment Compensation. Washington, D. C., 1995.
14. "Vulnerable Politicians and Deficit Politics," paper presented before the meetings of the American Political Science Association, September 1995.
15. Block Grants: Intensifying the Race to the Bottom, presented before the National Academy on Aging, National Press Club, Washington, D.C., July 1995.
16. "The Milwaukee School Choice Plan: Ten Comments on the Witte Reply," Center for American Political Studies Occasional Paper, No. 95-3, March 1995.
17. "A Critique of the Witte Evaluation of Milwaukee's School Choice Plan," Center for American Political Studies Occasional Paper No. 95-2, February 1995.
18. "Modernization and Metropolitan Governance," paper presented as Keynote Speech delivered before the World Conference on Metropolitan Governance, Tokyo, Japan, April 1993.
19. "Purposes of the National Assessment for Educational Progress," prepared for the Study Group on National Assessment, Department of Education, September 1986.
20. "Exit, Voice and Equity in Education," prepared for the Educational Policy and Organization section of the National Institute of Education, November 1980.
21. "Incentive Theory and Group Influence: James Wilson's Political Organization and the End of the Group Theory," APSA Annual Meeting, San Francisco, 1975.

22. "An Overview of the Politics of Education in Post-War Europe and the United States," presented at the seminar on the changing European secondary school, Kent, Ohio, August 1969. This seminar was held by the Comparative Education Society under the sponsorship of the Office of Education.

MAJOR PROJECTS AND STUDIES

- 2005 "Reforming Education in Arkansas," a report prepared by the Koret Task Force on K-12 Education for the state of Arkansas and commissioned by Governor Huckabee.
- 2004 - Co Principal Investigator, "Center on School Choice, Competition, and Achievement" funded by the Institute of Education Sciences, U.S. Department of Education
- 2001 - Editor-in-Chief of *Education Next*
- 2000 - 2001 Principal Investigator, Evaluation of the Children's Scholarship Program
- 2000 - 2001 Principal Investigator, Basic Fund Scholarship Program in the San Francisco Bay Area, California
- 1998 - Principal Investigator, Evaluation of CEO-Horizon Program, San Antonio, Texas
- 1998 - Principal Investigator, Evaluation of Washington Scholarship Fund Program
- 1998 - Principal Investigator, Evaluation of PACE Scholarship Program, Dayton, Ohio
- 1997 - Principal Investigator, Evaluation of New York School Choice Scholarships Foundation Program
- 1995 - 1997 Principal Investigator, "Cognitive Skills and Public Policy," funded by the Russell Sage and Rockefeller Foundations
- 1996 - 1997 Principal Investigator, "Reanalysis of School Choice Evaluation," funded by Smith-Richardson Foundation
- 1994 - 1995 "A Study of the Milwaukee Choice Plan," funded by the Anne Casey and John Olin Foundations
- 1993 - 1995 "The Price of Federalism," a study prepared for the Twentieth Century Fund
- 1992 - 1994 Principal Investigator, Workshop on Race, Ethnicity Participation and Governance, Center for American Political Studies, sponsored by Ford Foundation
- 1989 - 1994 Principal Investigator, "Congress and the Making of Foreign Policy," study by the Center for American Political Studies, Harvard University, funded by the Olin and Bradley Foundations
- 1986 - 1987 Director, "Toward More Effective Government," Brookings Study funded by grants from the Ford and Dillon Foundations

- 1984 - 1986 Director, "When Federalism Works," Brookings Study funded by grants from the Ford and Exxon Foundations
- 1981 - 1982 Chairman, Conference on "The Future of Our City" sponsored jointly by the Committee on Public Policy Studies and the Law School, University of Chicago, funded by a grant from Mayer, Brown & Platt law firm
- 1981 - 1983 Rapporteur and Background Paper Author, Twentieth Century Task Force on the Future of Federal Education Policy
- 1980 - 1983 Director, "Federalism, Equity and Education Policy," funded by the National Institute of Education
- 1980 - 1982 Co-principal Investigator, "The Role of Diffuse and Specialized Interests in Education and Health Policy," funded by the National Institute of Education
- 1978 - 1981 Director, "Urban School Organizations and the American Working Class," funded by the National Institute of Education
- 1979 - 1980 Director, "Efficiency and Equality in Education," funded by the Spencer Research Committee, University of Chicago
- 1967 - 1972 Director, "School Board Decision-Making in Chicago," funded by the Danforth Foundation
- 1967 - 1971 Associate Director, "Citizen Participation in the War on Poverty," funded by the Russell Sage Foundation

ADMINISTRATIVE ACTIVITIES

- 1995 - Director, Program on Education Policy and Governance, Sponsored by the Center for American Political Studies, Department of Government and by the Taubman Center on State and Local Government, Kennedy School of Government, Harvard University
- 1988 - 2000 Director, Center for American Political Studies, Department of Government, Harvard University
- 1989 - 1993 Director of Graduate Studies, Department of Government, Harvard University
- 1979 - 1980 Member, Council of the University Senate, University of Chicago
- 1979 - 1980 Chair, Board of Pre-Collegiate Education, University of Chicago
- 1970 - 1973 Chair, Undergraduate Program in Political Science, University of Chicago

PROFESSIONAL ACTIVITIES

- 2009 - Member, Advisory Board, Center for School Reform, Pioneer Institute for Public Policy Research
- 2009 - Member, Interdisciplinary Advisory Board, University of Munich
- 2009 - Member, Center for American Political Studies' Executive Committee, Harvard University
- 2009 - Member, Steering Committee, Center for Education Policy Research at Harvard University
- 2006 Member, Visiting Committee, External Review for the School of Education, Boston University
- 2003-2004 Member, E. E. Schattschneider Award Committee, American Political Science Association
- 1996 - Member, Committee on Improving the Future of U. S. Cities Through Improved Metropolitan Area Governance," National Research Council, National Academy of Sciences
- 1993 - 1995 Chair, Committee on Highway Capacity and Air Quality, National Transportation Board, National Research Council, National Academy of Sciences
- 1992 - 1994 Member, Committee on Transportation Congestion Pricing, National Transportation Board, National Research Council, National Academy of Sciences
- 1992 Presenter, Conference on Social Policy, Organization for Economic Cooperation and Development, Paris
- 1988 - 1992 Chair, Committee on Urban Underclass, Social Science Research Council
- 1985 - 1991 Member, Committee on Urban Underclass, Social Science Research Council
- 1985 - 1995 Member, Advisory Committee, Program Evaluation and Methodology Division, United State General Accounting Office
- 1990 Chair, American Political Science Association Committee on the Ralph J. Bunche Award for Best Book in the Study of Ethnic and Racial Pluralism
- 1990 Panel Chair, The Urban Underclass, American Political Science Association
- 1989 Chair, American Political Science Association Committee on the William Anderson Award for Best Dissertation in Federalism
- 1990 Co-chair, Conference on the Urban Underclass, jointly sponsored by Social Science Research Committee and Center for Urban Studies, Northwestern University

1989	Panel Chair, The Political Dimensions of Urban Economic Development, American Political Science Association
1985 - 1988	Council Member, National Capital Area Political Science Association
1987	Panel Chair, The Local Politics of Federal Policy, American Political Science Association
1987	Participant, Roundtable Discussion of City Limits: A Critique in the Mid-Eighties, American Political Science Association
1986	Member, Local Government Research Advisory Board, U.S. Advisory Commission on Intergovernmental Regulations
1976 - 1986	Chairman, Users Task Force on Undergraduate Education, American Political Science Association
1975 - 1986	Member, Steering Committee on Undergraduate Education, American Political Science Association
1985	Guest Lecturer, Meiji University, Tokyo and Office of Management and Budget, Japan
1985	Member, Workshop on Demographic Change and the Well-Being of Children and the Elderly, National Research Council, National Academy of Education
1985	Section Chairman, Public Policy Analysis, American Political Science Association
1983 - 1985	Member, Committee on Mathematics, Science and Technology, National Academy of Science.
1982 - 1985	Member, Committee on Youth Unemployment, National Research Council, National Academy of Science
1982 - 1985	Member, Policy Council, Association of Public Policy and Management
1983	Chairman, Panel on Federalism and Educational Policy, American Educational Research Association, Montreal
1983	Member, Study Group on Law and Governance in Education, National Institute of Education
1983	Participant, Panel on the Pre-War Study of Urban Politics, Midwest Political Science Association, Chicago
1981 - 1983	Member, Committee on Vocational Education in Distressed Areas, National Research Council of the National Academy of Sciences.
1981	Chairman, Panel on Urban Service Delivery, American Political Science Association, September
1980	Chairman, Panel on Learning Analysis in Political and Social Science, Midwest

Political Science Association

1980 Discussant, Unionism in Education: Its Implications for Political and Organizational Theory, American Education Research Association

1980 Member, Committee to Award Gladys Kammerer Award for Best Book in American National Policy, American Political Science Association

1980 Participant, Democracy and Opportunity: The Effects of Education and Ability on Economic Success, American Educational Research Association

1980 Participant, Elite Reform and Working Class Responses in Urban Education, American Educational Research Association

1978 - 1980 Member, Board of Editors, American Journal of Education

1979 Discussant, Panel of Politics of Education, American Educational Research Association

1979 Participant, Conference on Community Studies, Columbia Teachers College, New York City

1978 Participant, Workshop on Policy Studies, Institute of Local Government Studies, University of Birmingham

1978 Participant, Workshop on Citizen Participation, European Consortium for Political Research, Grenoble, France

1977 Participant, Panel on Models of Decision-making in Education, American Educational Research Association

1976 Panel Chairman, State and Urban Politics, Illinois Political Science Association

1976 Section Chairman, Urban Politics, Midwest Political Science Association Convention

1975 Panel Chairman, Community Organizations, American Political Science Association Convention

1974 Panel Discussant on Decentralization and Community Control, American Educational Research Association Convention

1974 Panel Discussant on Comparative Educational Policy-Making, American Political Science Association

1974 Section Chairman, Urban Community Processes Panels, American Political Science Association Convention

1972 Panel Chairman, Interpretations of Urban Educational Politics, American Educational Research Association Convention

ATTACHMENT 2



BEFORE



AFTER TREATMENT





May 16, 2016

Division of Dockets Management (HFA-305)
Food and Drug
Administration 5630
Fishers Lane
Room 1061
Rockville, MD 20852

Re: Proposal to Ban Electrical Stimulation Devices Used to
Treat Self-Injurious or Aggressive Behavior

To whom it may concern:

We have been informed that you are proposing the prohibition of the GED procedure being used at the Judge Rotenberg Center in Canton, MA. We are distressed because eliminating the availability of this method would reverse the progress of students who have been helped by this treatment. Our son, Robert, is a student at JRC and is one of those who have been helped greatly. In this letter, we would like to describe how keeping the GED option in place is the humane choice for our son and many others.

We visited JRC in November 2004 as a possible placement for our son Rob, a resident of Delaware. We observed a number of students there who were being treated with GED and had achieved progress that astounded us once we learned where they had started.

Rob has been in private and institutional placements since age five because of his extreme and aggressive behaviors. He has jumped out of second story windows several times and broken bones in his ankles and pelvis. He damaged his cornea intentionally with a pencil, requiring a transplant. He has been aggressive toward and injured staff many times over the years. Some of the programs in these placements had excellent reputations, and we were very hopeful for them, but none was successful in reducing his behaviors or in leading to Rob being placed in less restrictive settings. Rob reached the age of 30 and still had the same behavioral problems. When Rob was in private placements (as opposed to state mental hospitals), without exception they invariably expelled him due to their inability to deal with his behaviors.

We were apprehensive about the aversives used at JRC until we saw the results of aversive treatments on other students and saw JRC's extremely disciplined approach to the use of aversives. We insisted on experiencing the GED applications ourselves and decided that the effect was mildly unpleasant but temporary compared to the constant drug-induced stupor that had become the preferred method of treatment for Rob. The comparison of GED to

"electroshock therapy" in any way is completely inaccurate.

We successfully enrolled our son at JRC on September 20, 2005, after a year of work on the part of Delaware and JRC.

The full program, including GED, at JRC could not be implemented until a hearing took place for the Court to decide whether the GED treatment was appropriate for Rob. It took almost four months to get onto the Court's calendar. JRC has a very consistent behavior program, but for those first four months without the GED, Rob showed no improvement in his aggressive behavior. We were pleased that he was being withdrawn from the antipsychotic drugs he had been on since 1991, which resulted in a reversal of the obesity that had been caused by the drugs, but he was still in mechanical restraints several times a day because of aggressive behavior. We thought that over time with JRC's consistent program, the rate of aggressions would go down, but it did not decrease until the GED program was initiated on January 31, 2006. The improvement was so dramatic that it was beyond our wildest expectations.

After the GED program started, Rob's Major Aggressive instances dropped from 10-90 per day down to 0 to 2 per day in only two months, a change that we have been able to monitor because JRC's charting staff provides daily progress reports online to parents and guardians. This program helps Rob to develop internal controls of his behavior rather than being subjected to chemical or mechanical "straightjackets."

He is now in a regular classroom and workshop – something we had hoped for in our dreams. He no longer needs to be placed in mechanical restraints, and he was once named "student of the week" for his outstanding progress. He is smart but his behavior has always interfered with his learning. In the past he was always drugged so he could be dealt with but no behavior program was ever successful until now with the GED. Rob's GED applications have become infrequent because he very quickly learned to avoid them by stopping the behaviors that cause them to be applied (which is the whole idea.)

Our son's days are also filled with positive rewards that he enjoys earning as part of the overall JRC program. Not only has Rob had no adverse effects from his GED treatment, but he is happy for the first time in his life, something he expresses frequently. If GED applications were prohibited from Rob's treatment, we expect that his treatment would revert to those that were used unsuccessfully in his prior placements – physical and mechanical restraints, and extensive use of antipsychotic drugs.

When considering whether the aversive aspects of JRC's programs are humane, one must realize that every non-aversive program at other facilities always includes chemical, mechanical, and physical restraints as techniques to deal with aggressive and destructive behaviors. We have witnessed the dehumanizing effects on our son from these methods, including drooling, falling asleep in his food, becoming grossly obese from medications, and all this without any positive effect on his behaviors.

We realize that it is a conceptual leap to admit that aversives have a role for some people who cannot be helped by positive-only treatment. I think the most apt comparison I have heard is that

denying the GED treatment to this small subset of handicapped people would be akin to withholding insulin from diabetics.

We hope that external pressures will not jeopardize this wonderful program. JRC is completely open to anyone visiting their facilities, where they will display any aspect of their program without hiding anything. Our son has been in many facilities where we couldn't see where he slept or ate. Please come see for yourself, and if you would like permission to see our son and review his progress, we would be happy to provide it.

Thank you and best regards,

Ed and Pam Prunckun
9 Forest Ridge
Newark, DE 19711
302-733-7930
email: prunckun@yahoo.com

THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION
PAGES 81 – 82 REDACTED

Marie Rogers
1455 Harrod Ave. Apt. 3C
Bronx, NY 10472

Division of Dockets Management (DDM)
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

To Whom It May Concern:

My name is Marie Rogers; I am the Grandmother and legal guardian of Terrence Ellis and I am writing to you concerning my grandson and the treatment he received at the Judge Rotenberg Center. Terrence was diagnosed, at the age of three, with Autism and Mental Retardation and his IQ is in the severe to profound range of functioning. Terrence began receiving special education services at the age of three and attended PS188 in New York, from age 5 until his placement at Judge Rotenberg Center (JRC) on February 1, 1999 at the age of 12.

While attending PS188, despite the use of medications, such as Mellaril, Clonidine, and Inipramine, Terrence required a one to one paraprofessional during the school day as well as a one to one transportation paraprofessional on the school bus.

Due to Terrence's range of functioning, his extremely limited vocabulary, and severe receptive difficulties, communication was frustrating and often led to uncontrollable temper tantrums as well as aggressive and self-injurious behaviors. Terrence has minimal frustration tolerance and when denied his own way, would often act out aggressively, especially towards his younger 7 year old brother, Frank.

Before placement at JRC, while living at home, Terrence would target his brother with aggression, throw temper tantrums, which included banging his head, defecate on the floor, and eat uncontrollably, to the point I had to padlock the refrigerator/freezer and lock all food cabinets. Terrence would also run into dangerous areas/situations in and around our home.

On arrival to JRC, Terrence required frequent restraint to control his behaviors, which were interfering with his social/emotional and educational well-being.

Once consents were signed, and approval received to begin level III treatment, the Graduated Electronic Decelerator (GED) was introduced into Terrence's treatment program.

Since the implementation of the GED into Terrence's program, he made great progress behaviorally, academically, and socially. Terrence was on a token system where he was able to earn tokens for appropriate behaviors and for task completion and exchange the tokens for preferred rewards.

Terrence was able to make excellent academic progress towards meeting his goals and objectives that were listed in his Individualized Education Plan (IEP). He learned to work, semi-independently, on computer tasks, such as, Basic Skills, Alphabet Skills, Receptive Vocabulary, Learning to Count and Learning to Tell Time. Terrence also obtained vocational skills and other daily living skills, as outlined in his IHP.

While at JRC, Terrence was able to participate in the Special Olympics and come home to New York, or stay with Frank and me at a hotel near JRC, for extended periods of time without staff supervision or exhibiting any inappropriate, uncontrollable behaviors.

JRC, and the use of the GED, significantly improved Terrence's quality of life, as well as that of our entire family. I am supportive of JRC policies and practices and grateful for the life they have given to Terrence. He was at JRC for 17 years and we are very thankful they were able to keep him safe and healthy during all that time.

Terrence had to leave JRC on March of this year and is still having a very rough transition. Terrence is displaying self-injurious and life threatening behaviors again. He had to be prescribed medication and gained more than twenty five pounds. During a recent outburst he had to be hospitalized and sedated. His current placement is not able to control him as he is a very strong young man. He is aggressive towards staff and constantly tries to hurt himself.

I will hate to see other disabled children and adults go through what our beloved Terrence and my family is going through at this moment. This is the result of denying an individual a treatment that is effective and that has improved their lives. I ask you to please take my story very serious. The life and progress of many children with disabilities is in your hands.

Sincerely,

Marie Rogers

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

June 21, 2016

To Whom It May Concern:

I am writing to you regarding the FDA's consideration of a measure to forcefully remove the use of GED from the Judge Rotenberg Center (JRC). I, along with my family, as well as the families of the other students/residents of the JRC, am vehemently opposed to this proposed action. Let me tell you why so you can clearly understand why this move will hurt my brother.

My brother is a 49-year-old student/resident at the Judge Rotenberg Center, and has been placed there since January 1978, when it was then known as the Behavior Research Institute (BRI). I believe I can lend a unique perspective to how his life (and my family's) has evolved over the past 38 years.

My brother was diagnosed as severely autistic when he was about two years old, and back then, there really was no defined way to "treat" him. Over the years, he was placed in different "special schools" and environments and treated with all kinds of medications for over 10 agonizing years. He was violent at times, and was hitting and biting himself to the point where my parents and I had to do all we could to keep him from harming himself.

In addition, the "special schools" in my home state were nothing more than a place for my parents to drop him off in the morning and pick him up in the afternoon. There was no concerted effort to modify his self-destructive behaviors. In addition, he would come home with bruises and sometimes lumps on his head from being stricken by other children as well as staffers – we have documented proof of that. I can't tell you how many tears my parents and I shed over this situation.

By the time my brother was 12 years of age, there was really no place that could care for him and help him overcome his difficulties. My family was literally at the end of their rope. There was no way we could care for him at home. My family lived in constant fear that he or someone would harm him to the point where he could die. That is NO WAY for anyone to live!

My parents then made the most difficult and heart-wrenching decision they ever had to make in their lives, as well as mine. They decided to place him at the BRI, which had a program that would wean him off the several medications he was on that were turning him into a walking zombie and would work on modifying his behavior so he could live in a structured environment.

As I said earlier, the decision to send a child to live many miles from home was the most painful thing I have ever witnessed in my entire life. The day my brother left for Providence, Rhode Island accompanied by my parents was the saddest day in our lives. After my parents left him in BRI's care, they were literally destroyed. When they got home, the three of us sobbed uncontrollably until we had nothing left in our bodies. But despite the tears, we knew it was the right thing to do.

It has been 38 years since that day, and now my brother is reaching his 50th birthday. He is still severely autistic and is almost non-verbal—no amount of behavior modification or wishing and hoping or praying is ever going to change that. However, he has progressed to the point where he can care for himself in a structured and supervised environment, and can manage to work in a small on-campus workshop where he can be productive and have some dignity in his life.

In addition, my family and I know that the staff of the Judge Rotenberg Center love and care for my brother as if he was a member of their own respective families. My parents know that he is well cared for and can rest easier knowing that he is OK.

My point in all of this is that the decision to send your child away because you can't care for them at home or that other so-called "educational programs" in their localities lack the abilities to help them is something I would not wish on anyone. For those critics who condemn the JRC in their use of aversive therapy on some of their students I simply say this to you:

Walk in my family's shoes for just one day and see what it's really like. You can read all the scientific journals in the Library of Congress and you can have your little discussion groups and theorize until the cows come home, but you have **NO CONCEPT** of the pain and anguish we went through.

For those who say this aversive therapy is "electric shock treatment", maybe you should do a little more research. This therapy **IS NOT** akin to having a student forced to place his or her hand into a bucket of water and then a JRC staffer throwing in a radio plugged into a wall socket. For you to call the actual GED therapy as "electric shock treatment", you should be ashamed of yourselves.

I would strongly suggest to you that visit the JRC so that you can observe my brother firsthand what he does there every day and how he functions in this environment. I also invite you to review his records so that you can see for yourself how the use of the GED device has benefited my brother and his way of life. You can visit the JRC at any time — you have my family's blanket permission to do so — in fact, you may contact us directly for any information you may so desire in order to gather all of the facts.

I ask you this — who are the people most qualified to discuss this issue with? Some bureaucrats in Washington or in Massachusetts who have never bothered to do the necessary research as to what is involved with aversive therapy, or the families of the

students/residents of the JRC who have had to deal with this issue since these children were born? You cannot be serious about taking these measures without at least talking to us!

For those of you who say that treatment is "wrong", then what is the alternative? Do you think that saying "Please don't do that" to a child who abuses himself and acts violently toward others is going to listen? Do you think that heavily medicating this child is going to work wonders and solve everything?

The students at JRC are there because their families had no other alternatives. There are many state bureaucrats who want to bring these people back to their home states so they can look good to their constituents, but they don't care for these people. They think these people would be better served being placed in a state-run facility far away from view from the public. NONE of the facilities in my state can adequately care for my brother. All these places do is nothing more than have them sit around all day and medicate them so they are "controllable".

Do you really believe my parents, who are in their late 70s, wouldn't want to be able to have their son live closer to them so they can spend as much time as they could with him in their remaining years? Don't you think that I wouldn't want to be able to see my younger brother more than just a couple times of year when I can make the trip to visit him?

Of course we would. And so would the families of the other students at JRC. But we live in the REAL WORLD, and not some fantasy one where those who are critical of this program believe that everyone should just hold their hands together and "wish" these problems away. I apologize for being so flippant, but this is a REAL issue and unless you have walked in our shoes, then you have NO RIGHT to disrupt our child's/sibling's life with your preconceived and ill-advised notions of what you believe is right for them.

Please, please, please, leave my brother alone. He IS NOT a political football. He is a human being who deserves to have a decent life. The Judge Rotenberg Center is the only place we know of that can provide him with the environment that he can thrive in. My family and I are sick and tired of having to fight against state bureaucrats who have no idea of what this situation is like. A government should help its citizens, not make them suffer any more than what they already have been subjected to.

As I've said before, walk in my family's shoes for just a few minutes before you judge the JRC and, most importantly, us. Until you do and truly understand what we have gone through, then leave us be. DO NOT take the action of forcibly removing GED therapy for our children/siblings. This is still the United States of America, and we are entitled to due process under the law, just like everyone else.

Sincerely,

Michael Sciannamea on behalf of the Sciannamea Family
32 Cotoneaster Court
Monmouth Junction, NJ 08852
(732) 406-0711
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5/26/16

Division of Dockets Management (HFA305)
Food and Drug Administration 5630
Fishers Lane
Room 1601
Rockville MD 20852

We would like to tell you about our daughter, Samantha, and how the Judge Rotenberg School and the GED saved her life.

We first discovered Samantha was different when she was about 2 years old. She would not relate well to others, had very little speech, and would stare at her hands or small objects for hours at a time. She also had frequent tantrums, and cried often. She began with early intervention, and over the next ten years, she went to four specialized schools for autistic children. In addition to her schooling, numerous therapists, and teachers came to our house to work with Samantha after hours, most of which was paid for out of our own funds. All these schools worked closely with her in small groups, and on a one to one basis, using learning trials, and positive reinforcement. In addition to this, Samantha was under the care of a psychiatrist, and given several different psychotropic medications.

Despite, all these well caring professionals working with our daughter, Samantha progressively deteriorated. Over the years, she became more violent. She would attack us, other children, and her teachers. She would bite, scratch, kick, hit, pinch, and head-butt. In addition she became more self-abusive. She would throw herself on the floor, hit herself, and throw herself against hard objects. She constantly had marks, and bruises on her from her own self abuse. We were also prisoners in our own home, as we could not take her anywhere, due to her behaviors; this had an impact on our other children as well. The final straw came when she hit herself in her head with such force, that she detached both retinas of her eyes, and was virtually blind. This has subsequently required 6 eye surgeries to repair, and her vision is still far from normal. The Anderson School, where she was at the time, told us they could not handle her, and asked us to find another school. This is when we learned about the Judge Rotenberg School (JRC), and the GED device.

Within several weeks of getting treated with the GED device, a miracle happened; Samantha stopped hitting herself, and stopped her violent behavior. She appeared much happier. She was able to be weaned off all of her psychotropic medications.

There was a period of deterioration. In June 2006, aversive treatment became a big issue in New York State. A law was passed prohibiting the use of the GED for antecedent behaviors, leading up to more aggressive behaviors. Samantha became more aggressive, and angry. Some of her old behaviors returned. An injunction to this law was obtained several months later, and the GED was then able to be applied as indicated in the JRC program. Samantha improved, and was happier, and no longer aggressive towards herself or others. This was proof that she needs an ongoing program that includes the GED.

Recently, Samantha had another challenge. Due to a congenital condition, she had to undergo complex orthopedic surgery on both legs to correct a balance problem, and prevent future arthritis. JRC was absolutely wonderful. They accompanied her to all her appointments at the Boston Children's Hospital. She remained in the hospital for 6 days after her surgery. JRC had staff members in her room 24 hours a day, during her entire stay in the hospital. In her post operative period, the staff was with her in her residence at all times, and met her every need. She non weight bearing for 6 weeks post op, and the staff helped her and transported her to school, and to all her post operative doctor's appointments.

One of the most remarkable things about her surgical experience, is through all her pain and all her frustration of not being able to walk, she remained calm, and pleasant. This proves the durability of this program at JRC. If she was anywhere else, surely her old behaviors would have returned, and may have affected her post operative outcome.

Sometimes, we feel that JRC is the most misunderstood place in the world. Samantha has now been at JRC for over 11 years, and we have seen nothing but love and affection for her on the part of the entire staff. They appear to have the same love for all the students at the school.

The GED is given only after the failure of positive reinforcement programs, and only after the approval of a judge. It is given carefully, and under strict protocols. Everything done at this school and in the residences is video monitored. The program is 100 percent transparent, and has nothing to hide.

The bottom line is that this program helped, and continues to help our daughter where all other programs have failed. Our daughter is a different person than 11 years ago. She is happy, able to concentrate and learn, and fun to be with. She is on no psychotropic medications.

JRC takes only the most difficult kids that have failed at other programs, and make successes of a large number of them. Many of these children have life threatening behaviors, before arriving at JRC. Everything there is done out of love, not cruelty.

The GED device has been instrumental in the success of the program. The device is safe. It gives only a 2 second shock, and leaves no burns or skin marks. She has not had any long term Psychiatric effects. Quite the opposite, she has gotten much happier after use of this treatment

The safety and efficacy of this device is comparable, and in many cases exceeds that of medications used to treat the same conditions. This device seems to be the only efficacious treatment in a very select group of children like Samantha, that have tried everything else (medication, therapy, and positive reinforcement). Please do not take this away from our daughter, and the many others that can benefit from this device. We have no doubt, that without this device, Samantha, and other children would be dead, or institutionalized by now. We of course wish she did not need the GED. When you think of banning this device, please try to stand in the shoes of the desperate parents, who have tried everything, only to see their children deteriorate before their eyes, before turning to this treatment.

Sincerely,

Mitchell Shear, MD, and Marcia Shear

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

May 16, 2016

To Whom It May Concern:

We are the parents of a young man currently receiving services at The Judge Rotenberg Educational Center (JRC) in Canton, Massachusetts. We live in Massachusetts and our son Michael is diagnosed with Autism and Severe Mental Retardation. The severity of Michael's behaviors is evidenced by the number of facilities that have ejected Michael. He was rejected by the following schools in Massachusetts: the Archway in Leicester; the League School in Newton; Efficacy Research Institute in Framingham and Crystal Springs in Assonet. Out-of-state rejections include Green Meadows in Vermont and Greenshire in Connecticut. All of these were before being placed at JRC in 1983 at the age of 18.

Since Michael entered this program, his progress has been amazing. He has progressed from exhibiting severe aggressive and self-abusive behaviors, including biting, hitting, kicking and head butting others, biting himself, banging his head, poking objects in his ears and slamming his body against the back of chairs and beds, to working in a workshop where he has gained valuable vocational training. Today, Michael attends the workshop daily and is extremely productive. He is engaged in recreational activities in the community and visits home frequently.

Our son's treatment has been successful through the use of the Graduated Electronic Decelerator (GED), a brief skin shock device, which is used as part of a comprehensive behavioral treatment plan. This plan is carefully designed by JRC clinicians and is approved and reviewed regularly by a court in Massachusetts. Thanks to this program, Michael was able to have surgery to correct his severe scoliosis, curvature of the spine. Prior to this treatment, he was unable to have this corrective surgery, since it required weeks of recovery. During his recovery, it was important that he remained still and cooperative, rather than having the tantrums he had before receiving the GED treatment. Previous to treatment with the GED, Michael was treated heavily with medication to manage his behavior. The medication had no effect on his dangerous behaviors and was accompanied by many negative side effects. There have been no negative side effects from the use of the GED and Michael's quality of life has improved enormously. Michael has also been able to work in his workshop setting, earning money. He has been able to enjoy outings in the community with his peers, something that would not be possible without the GED. Michael's behaviors are unpredictable and severe. With the use of the GED, he is able to control his behavior and access rewards and environments that we never dreamed he would be able to.

It is our greatest fear that the GED is removed from Michael's treatment plan and his behavior regresses. Prior to the GED, in order to control Michael's biting, another program used a helmet with wire mesh covering the mouth area, he would throw items at people and charge people to the extent that mechanical restraint was used daily. Michael has been on numerous medications in the past including Stelazine and Mellaril, with no reduction in his inappropriate behavior. He also had trials with Haldol, which he had a horrible reaction to, and Thorazine that did the opposite of what was expected. Due to the high frequency and intensity of his behaviors, no demands were placed on him, he sat in a room all day with nothing to do and was still extremely aggressive. That is not the life we want for our son. He is flourishing at the Judge Rotenberg Educational Center and with the use of the GED.

We are writing on behalf of the all of the students at JRC who also receive this treatment and those who could benefit in the future. We understand what a change in therapy could do to this type of student. We are asking, for the sake of Michael and the other clients at JRC that you do everything that you can to allow this life saving therapy to continue.

Sincerely,

James and Phyllis Shields

Ilana Slaff-Galatan, M.D.

79-29 213 St

Oakland Gardens, NY 11364

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May 12th, 2016

Division of Dockets Management

Food and Drug Administration 5630
Fishers Lane
Rockville, MD 20852

To Whom it May Concern:

I have identical twin brothers and a daughter with autism. I am also a practicing psychiatrist who completed a fellowship at the Seaver and New York Autism Center at Mount Sinai Hospital. I am extremely concerned about your proposed ban on my brother's skin shock treatment which saved his life.

I presented at the FDA's hearing on April 24th 2014. I have tried the shock myself and neither my brother nor I have ever experienced a side effect. The GED was approved by a court proceeding where my brother had his own attorney. The school never pressured my mother to consent to the device. What pressured my mother to consent was my brother's life-threatening behaviors. My brother has even asked to wear the device and also is on seven positive behavior contracts at once and earns preferred items throughout the day for being safe.

When living at home my brother banged his head into sharp corners. At home he also developed symptoms of neuroleptic malignant syndrome from haloperidol. When he required surgery to his head from self-injury, he was in the hospital for five and a half months and despite having a staff member present with him around the clock he continued to need repeated suturing for repeated head banging. This all occurred despite polypharmacy with five medications with their adverse effects of obesity, tardive dyskinesia, loss of ability to verbally communicate, drooling and excessive daytime sedation. The Board of Education told my mother that no educational facility would accept my brother and she was requested to waive his right to an education. She refused. Furthermore, the medical insurance was running out and my parents were told they could be held responsible for hospitalization costs. I remember my father wondering if the hospital could take our house. However, through my mother's physician she was informed about the Judge Rotenberg Center. He has been there for over twenty seven years and doing quite well without any head banging and is on no medication. We have taken him on trips to other states. He recently started working a job at the school. In

2011, when an attempt was made to remove the skin shock device he perforated both his tympanic membranes and had to go to the hospital, for the first time since entering the Judge Rotenberg Center. Initially, he had 200 applications of skin shock in the first year, but now has not needed any for over three years, although after engaging in a dangerous behavior, he sometimes needs to wear the device to prevent an escalation of life-threatening behavior. As have few other students, he did habituate to the less intensive skin shock device and the more intensive one, GED-4, was then used.

My other brother, who is not at JRC or on an aversive conditioning device, was functioning quite well in the past and as an adult had a full time job for about three years without any medication and was travel trained. He moved into a New York State Organization for People with Developmental Disabilities funded agency residence while holding this job. He lost his job after a fellow worker teased him, repeating to him that he had to work until 5PM when my brother had the fixed routine of working until 4 PM. My brother became agitated and grabbed the co-worker's butcher knife. Subsequently, my brother became obsessed with setting fires and has tried to set a peer and himself on fire. He has had numerous hospitalizations. Although the staff at the residence are kind and concerned, he has failed positive behavior supports with functional behavior assessment and has had at least fifteen medication trials which caused obesity, tardive dyskinesia, sedation and seizures. He is currently taking 20 medications, most of which are psychiatric medications or to treat the side effects of psychotropic medications. Last week, he had to go to the hospital for constipation due to his psychiatric medications. Once, at a family gathering he became agitated, obsessed with material, and he hit my grandmother who was then 99 years old in the face. He was too agitated to attend her 100th birthday party even though it was near his residence while his twin came in from Judge Rotenberg Center. We cannot get him the help he needs due to the aversives ban in New York. He was best friends with his identical twin and they cannot live together due to the refusal in New York to allow aversives. It is very sad that our family must live in different parts of the country due to politics.

Aversives and skin shock have been debated for decades. Eric Schopler, originator of the research based TEACCH program (which is used throughout the United States and internationally in public and private special education programs and adult day programs) discussed aversives in 1990. "He calls the critics 'self serving ideologues' who drastically oversimplify the issue with emotional arguments and 'are making a fortune going around doing workshops on how to never use aversives.'"¹ There are over 112 peer reviewed articles to support the efficacy of skin shock treatment for behaviors. In a literature analysis on punishment including skin shock, it was stated, "On the basis of these findings, numerous authors have recommended using moderate or high-intensity punishers to treat problem behavior and cautioned against increasing the intensity of

¹ What's holding up "Aversives" report C. Holden in Science, 1990 Aug 31; 249 (4972):980-1:

punishment gradually over time.”² Furthermore, the research on positive only treatments shows significant limitations, including defining "severe" behaviors, "in a chapter on hypothesis-based intervention for severe problem behavior (Carr et al., 1999). In both instances the behavior of concern- screaming, spitting at the teacher, grabbing another child's hair or throwing her school work off the desk- would be considered by many classroom teachers and practitioners to be fairly commonplace rather than severe.”³ This is not the behavior my brother had, banging his head into sharp objects requiring surgery. Furthermore, positive behavior supports are only effective in about half of cases to suppress the frequency of behavior by 90%⁴ which is not sufficient for a life-threatening behavior.

In practice, at least in NY, people are discharged or suspended from their day programs due to their behaviors, left alone with an elderly parent in a potentially very dangerous situation. Two prior students from Judge Rotenberg Center who were taken off the skin shock devices, returned to New York and died from their self-injury in their 20s. I do not want my brother to die too.

There are many problems with medication management for self-injury. For example, risperidone received FDA approval for autism. However, placebo controlled trials did not differentiate between mild and severe behavior in their outcome measures and there were no published line by line analyses of the Aberrant Behavior Checklist, as only three of the fifteen components relate to self-injury⁵⁶ and the sedation rate in the autism FDA registration trials was 49%.⁷ In addition, in the FDA registration placebo controlled trials

² Lerman DC, Vorndran CM, On the status of knowledge for using punishment: Implications for treating behavior disorders, *Journal of Applied Behavior Analysis* 2002, 35, p441.

³ Foxx, RM. "Severe Aggressive and Self-Destructive Behavior: The Myth of the Nonaversive Treatment of Severe Behaviors," in Jacobson, JW, Foxx, RM, Mulick JA. *Controversial Therapies for Developmental Disabilities*, Lawrence Erlbaum Associates, Publishers, 2005, pp 304-305

⁴ Carr EG; Horner RH, Turnbull RH, Marquis AP, Mc Laughlin JG, Magito D, McAtee, ML, Doolabh A, Braddock D. Positive behavior support for people with developmental disabilities: A research synthesis. American Association on Mental Retardation 1999)

⁵ McCracken JT, McGough J, Shah B, Cronin P, Hong D, Aman MG, Arnold LE, Lindsay R, Nash P, Hollway J, McDougle CJ, Posey D, Swiezy N, Kohn A, Scahill L, Martin A, Koenig K, Volkmar F, Carroll D, Lancor A, Tierney E, Ghuman J, Gonzalez NM, Grados M, Vitiello B, Ritz L, Davies M, Robinson J, McMahon D; Research Units on Pediatric Psychopharmacology Autism Network. Risperidone in children with autism and serious behavioral problems. *New England Journal of Medicine* 2002;347:314-21

⁶ Shea S, Turgay A, Carroll A, Schulz M, Orlik H, Smith I, Dunbar F. Risperidone in the treatment of disruptive behavioral symptoms in children with autistic and other pervasive developmental disorders, *Pediatrics* 2004, Nov; 114(5)

⁷ Goldberg, J M.D., M.S. Ernst CL, M.D., *Managing the Side Effects of Psychotropic Medications*, 2012, page 72

of aripiprazole, self-injury in persons with autism did not improve significantly more in aripiprazole treated children than in children in the placebo group.⁸ Furthermore, up to 60% of individuals with autism without clinical seizures have been reported to have epileptiform discharges on EEGs⁹ and the above medications will increase their risk for seizures. It also can be particularly dangerous to use medication in individuals who cannot communicate side effects and are unable to comply with prescribing guidelines such as blood pressures and blood tests. Using aversives decreases and even stops the need for psychotropic medications as it did in my brother. It has also allowed individuals with significant cognitive impairments who are unable to make risk benefit decisions to have physical exams. Your advisory panel did agree that there are no other effective treatments for life-threatening self-injury. It is unethical to take away the only treatment that has been proven to be effective for him.

When New York investigated the use of aversives, they did not obtain collateral information from the family or staff for reported symptoms. In fact, the Judge Rotenberg Center only found out through the New York State report that a student reported being suicidal. The psychologists who did the investigation never alerted staff or family. The United Nations who reportedly did an investigation has never visited the school or asked to speak with a family member.

Although your hearing discussed side effects, research on skin shock has shown positive side effects. In one study "Positive side effects indicating an improved affective state and increased interaction with the environment were documented. Treatment gains were maintained at a 1-year follow-up assessment. The consistent reports of positive affective side effects from successful treatment studies using SIBIS (self-injurious behavior inhibiting system) and contingent electric shock are noted".¹⁰ The child in this study even had an increase in self-initiated toy play. In another study, this one done at Judge Rotenberg Center "the side effects of contingent shock (CS) treatment were addressed with a group of nine individuals, who showed severe forms of self-injurious behavior (SIB) and aggressive behavior. Side effects were assigned to one of the following four behavior categories; (a) positive verbal and nonverbal utterances, (b) negative verbal and nonverbal utterances, (c) socially appropriate behaviors, and (d) time off work. When

⁸ Aman MG, Kasper W, Manos G, Mathew S, Marcus R, Owen R, Mankoski R. Line-item analysis of the Aberrant Behavior Checklist: results from two studies of aripiprazole in the treatment of irritability associated with autistic disorder. *Journal of Child and Adolescent Psychopharmacology* 2010 Oct;20(5):415-22

⁹ Spence SJ, Schneider MT. The role of epilepsy and epileptiform EEGs in autism spectrum disorders. *Pediatric Research*, June 2009; 65(6); 599-606

¹⁰ Linscheid, TR, Pejeau C, Cohen S, Footo-Lenz, Positive side effects in the treatment of SIB using the self-injurious behavior inhibiting system (SIBIS): Implications for operant and biochemical explanations of SIB, *Research in Developmental Disabilities*, Volume 15, Issue 1, January-February 1994, pages 81-80)

treatment was compared to baseline measures, results showed that with all behavior categories, individuals either significantly improved, or did not show any change. Negative side effects failed to be found in this study.”¹¹

It was discussed at the hearing that there needs to be placebo controlled trials with skin shock. First, it may be unethical to give someone a placebo with acute life-threatening behavior. Also, how could the observer really be blind to who is given a skin shock application when the person’s reaction would be observable. I did make a vocalization myself when I tried the shock. Furthermore, placebo controlled trials while important, have limitations. Even if results are statistically significant, there may be a large number of people to treat before finding a clinically meaningful response. In addition, if the sample size is large enough, there may be a statistically significant result even if the magnitude of change is small. That is not acceptable for a life-threatening behavior. Single case and multiple case studies with baselines reporting actual frequencies of a given behavior do have some utility to see individual clinically meaningful change and is often used in behavior analytic research including skin shock treatment.

I do not understand why the shock device is being held to a different standard than medication especially when the risk of no treatment can be death and off-label polypharmacy trials examining adverse effects have never been done on this population.

Just as New York does not approve the use of aversives, New York also does not approve one to one applied behavior analysis schools despite research evidence that with such intervention at a very young age self-injury may be preventable¹² as well as improve functioning.¹³ To obtain this treatment, I had to spend this year \$102,000 on my daughter’s autism school tuition and every year I have to file for an impartial hearing to seek reimbursement. By not having free and appropriate programs, this is causing more stress to families as well as resulting in economic segregation.

Furthermore, in 2011, New York State removed the minimum speech and language requirement of two half hours for thirty minutes for individuals who qualified for the service and they removed the daily language requirement for children with autism despite

¹¹ Van Oorsouw WMWJ, Israel ML, vonHeyn RE, Duker PC, Side effects of contingent shock treatment. *Research in Developmental Disabilities*, Volume 29, Issue 6, November–December 2008, Pages 513–523

¹² Williams BF, Williams RL, *Effective Programs for Treating Autism Spectrum Disorder: Applied Behavior Analysis Models*, chapter 14, *Observations and Reflections*, page 240

¹³ Ingvarsson ET, *Case studies in context: A review of triumphs in early autism treatment*, edited by Ennio Cipani. *Behavior Analysis in Practice* 2009 Fall; 2(2): 69-72

evidence that communication is vital. "For example, it appears that when communication skills are improved, the rate of inappropriate behaviors decreases,"

¹⁴ and "many of these extreme behaviors may be due large part to the child's defective language skills" and "language training needs to be a major component of programs for children with ASD." ¹⁵ If New York, is truly concerned about children with disabilities they would have never established such policies.

I also find it disturbing that the FDA has never visited the JRC and probably never visited a program that treats life-threatening behaviors with polypharmacy and routinely utilizes emergency medical services along with hospitalizations. I doubt the FDA ever observed a placement where individuals are so sedated, they cannot be safely evacuated in case of a fire. I have observed all of the above.

I have been working with a developmentally disabled population exclusively for ten years in New York. Like my brother who also lives in New York, there is no choice but to administer polypharmacy that makes these individuals sleeping much of the day to control their behavior. They have diabetes, heart disease, and liver toxicity among other ailments. Sometimes, they die very young from side effects sometimes early into adulthood due to adverse effects. When I see them, I think of my brother at JRC and how by banning skin shock he will be just like them, either sick or dead. Please rethink your ban on aversives and let my brother and others continue to live, function and have a quality of life.

Sincerely yours,

Ilana Slaff-Galatan, M.D.

Ilana Slaff-Galatan, M.D.

¹⁴ Williams BF, Williams RL, Effective Programs for Treating Autism Spectrum Disorder: Applied Behavior Analysis Models, Chapter 7, The Koegel Center Pivotal Response Training, page 125

¹⁵ Williams BF, Williams RL, Effective Programs for Treating Autism Spectrum Disorder: Applied Behavior Analysis Models, Chapter 8, Strategic Teaching and Reinforcement Systems: Verbal Behavior, page 147

Mrs. Lorraine Slaff

2567 Seymour Avenue

Bronx New York 10469

May 15, 2016

I have been informed that the federal drug administration is considering banning the use of the skin shock device also referred to as the G.E.D. citing that this device has serious side effects. My son Matthew has never had any of the side affects that F.D.A. States . He has had no depression, nor fear, nor avoidance behaviors. To the contrary, He has been happy, and engaged in his numerous interests. birds, studying maps, cartoons music, astronomy, and the internet.

Before the electronic skin device, he was on a cocktail of medications, klonopin, prolixin ,inderal, and artane. and had been in Lenox Hill Hospital for over 5 months with one to one staffing. He went to the hospital for plastic surgery to suture a deep gash in his forehead which was caused by his ramming his head into sharp corners. He had been on mellaril , and haldol before this hospitalization. Mellaril has now been banned, and he almost died from being given haldol during a weekend. During the hospital stay, a teacher came into his room, he banged her head, and she ran outside. I was also called many times by Lenox Hill for permission to give him stitches to close his newly self inflicted wounds.

No school in New York would accept him. A parent told me about The Behavior Research Center now known as the Judge Rotenberg Center. At this time, he was groggy, drooling, and shaking due to all the medications. He was initially given a consistent behavior program, but it failed to stop his dangerous behaviors. When he started to receive the skin shock, the dangerous behaviors began to decrease. Most of the side effects of the medication have now faded.

Matthew has had no psychiatric hospitalizations since being at the Judge Rotenberg Center for the past 27 years. He has not had a G.E.D. application for the past two years. His treatment is approved by a court proceeding.. I have considered the risks and benefits, and wholly approve of Matthew's treatment. I visit my son once a month.

I go alone now since my husband, who was his father passed away last year.

His identical twin brother Stuart is in a New York City group home. He had a supported work job, and needed no behavior medication when he moved there. There was no consistent behavior program. He lost the job when somebody teased him, and he threatened that person. Within six months his behaviors became dangerous in the home and the community. When a new job was found, he was already hospitalized for these behaviors, and had many medications to control them. It is now been about 15 years, and he has never had a job again, but many more hospitalizations. He currently takes 20 medications. He has had a grandmal seizure during a blizzard. He had never had any seizures before the medications. Stuart is unhappy, and tells me he wants to go to a strict home. Furthermore, his dangerous behaviors are not completely eradicated. I know he is uncomfortable because he cannot make his own boundaries.

I am astonished that the F.D.A. refuses to observe the program, and never spoken to any of the families, but is only listening to the side that in all probability has never known the experience of dealing with a life and death situation, and finally finding help being told that they can no longer access it. Without this treatment, there is a strong possibility my son would not be alive today.

Sincerely yours,

Lorraine Slaff

May 19, 2016

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville, MD 20852

Re: Proposal to Ban Electrical Stimulation Devices Used to
Treat Self-Injurious or Aggressive Behavior

Dear Administrators:

We are writing to express in opposition to your proposal to ban electrical stimulation devices used to treat self-injurious or aggressive behavior.

Our son, Brendon Soucy, attends the Judge Rotenberg Educational Center ("JRC"). He has been a student at JRC since he was 16. Brendon has been diagnosed as a self-abusive, hyper-active, non-verbal autistic person since his birth in 1967. When Brendon lived at home, a typical day began when we got up and let him out of his room. On many days we had to force our way into his room because he would tip over the furniture and mattress. Many nights he would be awake most of the night banging his head against the wall, and he would defecate in his pants and smear it all over the walls. Every single morning began by cleaning up his room. While we were cleaning, his hyper-activity would kick in and he would travel all over the house grabbing things, dropping them, and pulling curtains down. He would have what we called the "sorrowfuls," when he would lay on his back crying and banging his head against the floor and biting himself severely. He could go for days without sleeping, only taking little cat naps anywhere and anytime the spirit moved him. This activity would last for hours. We had to double lock the doors so that he wouldn't escape. He had no homing instinct, and if he got out of the house, he would just take off. Many times we had to mobilize the neighborhood to find him. By the time he turned seven years old, we were no longer capable of keeping him at home.

My husband and I are former Massachusetts residents and Brendon has been in the Massachusetts Mental Health system since he was two years old. All different treatments have been tried and exhausted. All of the autism programs that Brendon tried used behavior modification methods, and when those methods were not successful, they prescribed psychotropic medication. Medications caused Brendon to shake and moan and lay on the floor for days in his own waste. He was dangerous to himself and especially to his care-givers, and he had no quality of life. He has been "asked to leave" three or four different programs that could not handle his severely autistic, self-injurious, feces-smearing behaviors. The Hogan Center in Danvers, Mass., the May Center on Cape Cod, and the Spear Center in Framingham, Mass. (which later became the Efficacy Research Institute ("ERI") with autism founded by Vince Strully) all could not handle our Brendon.

When we first put Brendon in the Spear Center/ERI we saw that all the children who lived there had their own rooms with a bed, bureau, wall pictures, bed linens and bedspread. We thought this was wonderful. However, the next time we visited, Brendon's room had a single plastic covered mattress on the floor that was covered with feces. No furniture, pictures, blankets, spread, or anything. Everything had been removed from his room. The walls were painted concrete block and the little pours in the walls were filled with feces due to Brendon's smearing. The room smelled like feces. Brendon stayed at ERI for about seven years, during which time his behaviors worsened. He threw himself to the floor during transitions, destroyed property, stole food, frequently aggressed toward staff and students, slapped or banged his head, and defecated and smeared feces. The staff at ERI used behavioral interventions, but Brendon did not respond to them. Vince Strully admitted that the program could not handle him with these positive methods, and insisted that we put him on medication or he would have to leave. They treated him with psychotropic medications, including Mellaril and later Thorazine, but these reportedly only caused excessive sedation. Cogentin was added in 1983 to reduce fine tremors of the hands and head, presumably caused by the other medications. ERI discharged Brendon in 1984, saying that his safety and that of the other students and staff could not be assured. It is very significant that the director of one of the best programs in Massachusetts threw his hands up and admitted that he could not handle Brendon using positive behavior modification methods. Brendon was then placed at the Behavior Research Institute in Providence (now JRC).

At JRC, we researched the use of aversive treatments as well as the GED device. We were not enthusiastic, to say the least, but after personally visiting the school and learning more about it, we saw that this was a good method for Brendon that would allow him to live with dignity and maybe even learn. We went to court in 1986, with a lawyer representing Brendon and won a judgment to use this procedure to treat him. His treatment plan is now reviewed by a judge in Massachusetts on an annual basis. Because of the GED, he is able to have a life free of incapacitating drugs. His aggressive head banging and hand biting has diminished to almost zero. At most, he receives the GED one to two times per week for inappropriate defecation or urination, but often goes 2 to three weeks with no GED applications. He sleeps in a beautiful room with furniture, wall pictures, curtains, and personal affects all free from the smell of feces.

I was dumfounded to read the list of possible side effects of the use of GED identified by the FDA. Your list of 38 possible side effects, with the exception of a few, basically describes a severely autistic individual like our son. Prior to any treatment when he was a young boy still at home, he experienced depression, fear, escape and avoidance behaviors, panic, aggression, pain, tissue damage (due to self-injurious behaviors), PTSD, anxiety, chronic stress, neuropathy, heart palpitations, nightmares, insensitivity to fatigue or pain, changes in sleep patterns, loss of interest, difficulty concentrating, withdrawal from any activity, severe psychological trauma, catatonia, seizures, nerve damage (from self-injurious behaviors), etc., etc., etc. How can you suggest that by eliminating the use of the GED, Brendon will be saved from experiencing those listed side effects when in fact it is the GED that has saved him from those specific effects? Now he is a person who can enjoy his friends and his life in his own way, function in a happy and clean environment, and participate in community outings.

We feel that your argument that this procedure produces pain and therefore should not be allowed is not valid. All medical procedures produce pain with the hope of a positive outcome. The brief pain Brendon feels interrupts his self-abusive and dangerous behaviors long enough for corrective measures. I remember one time at the school, Brendon lifted a huge typewriter into the air over his head and was going to toss it through a plate glass window, but was stopped because of the GED!

I have been told that the FDA has refused to visit JRC, to see the use of the GED, to review all records of the students on GED for themselves or to interview parents. By not taking advantage of these opportunities, the FDA's decision-making is heavily skewed toward the anti-aversive advocates and away from parents of severely autistic persons who see the need for the GED on a daily basis. I question whether the "Civil Rights" of these disabled individuals are about to be denied.

Please, come to the school and meet Brendon and us. We want to personally show you around our school. We love this facility and especially its staff who work with these most difficult students. We would like the FDA to continue its good work by allowing this medical procedure to be used with a court order. As time goes on, maybe there will be different methods of treatment for his severe autism, but for now, Brendon needs this GED treatment to live a dignified and comfortable life where those who look after him, his caregivers, and Brendon, himself, are safe. We love our son and want the best life possible for him. And that is what the Judge Rotenberg Center & the use of the GED provides.

Sincerely,

Leo and Claudia Soucy
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THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION
PAGES 105 – 106 REDACTED

May 17th, 2016

Division of Dockets Management
(HFA-305) Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

To whom it may concern:

I am writing to you in regards to the FDA's proposal and attempts to ban the use of Aversive Treatment Procedures, targeting primarily the Graduated Electronic Decelerator (GED), which is and has the main reason for my son being able to achieve a more than adequate quality of life for the last several years.

My son, Angel Gonzalez, 21-year-old male who is diagnosed with Autism and currently attends JRC. Placing Angel on the GED, especially at such a young age was one of the most difficult decisions I have ever had to make, but it was by far the best decision for the safety and well-being of Angel. He has been at the Judge Rotenberg Center for thirteen years. JRC has been the only program that has provided effective treatment for my son without the use of harmful psychotropic medications. When Angel was at home, I had to be by his side all the time. He was constantly looking for ways to harm himself. This included having to sleep with him in same bed.

Angel would head bang on the wall or hit his head with his hands to the point of bleeding. He would slam his jaw against his shoulders so hard; you would think he would have broken it off. He would also kick his leg with the other, throw himself to the floor, and so on. He was always crying and barely slept. If I had to let Angel's hands go, I would have to resort to tying his sleeves together so the blows to his head were not as intense. He also had to be restrained and sedated at hospitals and during medical procedures.

Before going into the Judge Rotenberg Center, Angel was hospitalized many times, received in-home services and in the community but nothing was helping. The psychotropic medications were not helping him much and he had to be hospitalized due to negative side effects from these meds. My son was also rejected by other programs as they could not control his self

injurious behaviors. On his last psychiatric hospitalization the psychiatrist recommended Angel to be placed in a residential school. They did not believe he was going to live long if he continued in his self destructive path.

Angel has been on the GED for several years now. He no longer requires anyone to hold his hands, he no longer wear a helmet or special parts. He no longer requires arm splints. After Angel was placed on GED, it was the first time I had ever seen my son feed himself or drink without assistance. What a feeling of relief. He was successfully toilet trained and knows how to communicate his wants and needs by signs. The GED has allowed my son to focus his attention in learning, enjoying life and building a relationship with his family. Before JRC, Angel would not allow us to hug or kiss him and was very distant to the family. He has built a relationship with his sister, is affectionate to me and enjoys be hugging and kissing.

Without JRC, I do not know where Angel would be right now, maybe dead. If JRC no longer exists, I do not know what I will do. My family is happy and proud of Angel's progress. In your consideration about JRC, please do not forget about my son Angel and how well he has done.

I know that if the GED is banned, my son's life will become a living hell for him filled with trips and long stays at psychiatric hospitals; he will have to be kept in long hours of mechanical restraints, even when in psychiatric hospitals; and he will definitely lose the ability and or opportunity to enjoy outings in the community and public places to include movie theaters; parks, museums, restaurants; visits and trips with his family; being able to sleep in regular bed, versus a hospital restraint bed; being able to have his sister and nephews spend time with him at his home and school.

Without the GED, my son will become a zombie that is if any medication does not harm him as in the past.

With all that said, I am kindly asking you to think first before you act. What life for folks like my son will your decision to ban a treatment that has benefited them, will create? Do you think that it is appropriate or human for them to be stuck in hospitals and psychiatric centers, heavily medicated to the point that they are not able to even taste the food being offered or fed to them? What about their life in the community? Isn't every citizen of this world's right to the best quality of life? Well, please allow my son to continue to enjoy his as it has been, because any other will be life

threatening to him. My son's life is in your hand and trust that at the end of the day you will do the right thing.

Do not allow the biased and media opinion lead you to a significant life changing decision for folks like my son.

Thank you for your time,

Respectfully;

Carmen and Michael Torres
Laura Gonzalez (Angel's sister)
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Marie Washington
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June 16, 2016

Division of Dockets Management (HFA-305)
Food and Drug Administration 5630
Fishers Lane
Room 1061
Rockville, MD 20852

Re: FDA's Proposed Rule to ban GED

To Whom It May Concern:

I am writing in regards to the life -saving therapy for my son, Jacque Washington, is receiving at the Judge Rotenberg Educational Center, Inc. in Canton Ma. He has been on the GED therapy since 1992 after years of ineffective treatment with drugs which caused him to have severe side effects.

Jacque is diagnosed with Autism and Mental Retardation. He lived at home until he was 13 years old when his violent tantrums became too much for our family to handle. He was placed by New York Board of Education at the residential program call the Anderson School. Here, his treatment consisted of psychotropic medications which were not effective in reducing the number or intensity of his aggressive and other problematic behaviors. He then went to his present program, the Judge Rotenberg Center.

His father and I have been very pleased with the results of the skin shock therapy he receives. We visit him frequently and have not seen any negative side effects of this treatment. He is able to enjoy his life, has outings in his community and visits with his family members.

We have personally tried the GED device. We take an active role in the treatment plan of our son. To remove this behavioral program (the skin-shock) would be to revert back to ineffective psychotropic medication that cause serious health problems. He is healthy now and enjoys life. Please do not ban the GED.

Sincerely,

Jenkin and Marie Washington

THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION
PAGES 111 – 112 REDACTED