



April 10, 2024

Honorable James Comer
Chairman
Committee on Oversight and Accountability
United States House of Representatives
Washington, D.C. 20515

Honorable Jamie Raskin
Ranking Member
Committee on Oversight and Accountability
United States House of Representatives
Washington, D.C. 20515

Re: The Judge Rotenberg Educational Center, Inc. / FDA's Proposal to Ban Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior

Dear Chairman Comer and Ranking Member Raskin:

On behalf of the Judge Rotenberg Educational Center, Inc. ("JRC"), I write to express my appreciation for calling today's hearing entitled "Oversight of the U.S. Food and Drug Administration (FDA)." JRC is a state-licensed residential program and certified special education school located in Massachusetts that provides intensive Applied Behavior Analysis ("ABA") treatment and educational/vocational services to approximately 300 children and adults from across the United States with cognitive disabilities who engage in the most dangerous aggressive behaviors ("AB") and self-injurious behaviors ("SIB") in the nation.

Of particular concern to JRC is a continuing effort by FDA to engage in regulatory overreach and the practice of medicine by proposing to ban Electrical Stimulation Devices ("ESDs") for SIB or AB. FDA, since 2010, has been very publicly attempting to ban the use of ESDs for SIB and AB, even though only one program in the nation is using an ESD to treat the nation's most dangerous refractory patients, which is JRC's use of its Graduated Electronic Decelerator ("GED") device. The proposed ban, if finalized, will endanger the lives of the 54 patients receiving GED treatment at JRC.¹ These patients come from across the nation to receive this life-saving treatment because the other programs and treatments could not stop their life-threatening behaviors. The GED, by Massachusetts law, is only used at JRC when approved on an individual basis by a Massachusetts Probate Court and is reviewed yearly by the Court.

¹ Banned Devices; Proposal To Ban Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior, 89 Fed. Reg. 20,882-01 (Mar. 26, 2024) (to be codified at 21 C.F.R. pts. 882, 895).

Prior to their admission to JRC, these 54 patients caused life-threatening injury and permanent disfigurement to themselves and others through their uncontrollable behaviors, such as head banging, eye gouging, tearing their own flesh, biting off body parts, pulling out their own adult teeth, punching their fists through glass windows, jumping out of windows, jumping in front of moving vehicles, and violently attacking family members, teachers, staff, and others with punches, kicks, and bites. These 54 patients engaged in these dangerous behaviors while at some of the best treatment facilities in the nation, where they could not be effectively treated with all other forms of treatment, including Positive Behavior Supports; physical, mechanical, and chemical restraints; seclusion; time out; and massive dosages and combinations of powerful psychotropic medications, which cause dangerous and sometimes permanent side-effects, up to and including death. FDA admits that the patients' behavior disorders could be fatal, and that there is no other effective treatment capable of stopping their life-threatening self-abuse and aggression.² They are the only patients in the nation receiving ESD treatment for severe SIB and AB but FDA continues to refuse to meet these patients and study their ongoing successful treatment at JRC, despite numerous invitations and pleas from the families. FDA's proposal will only take away their treatment at JRC and patients elsewhere in the nation will continue to legally use skin shock to treat dangerous addictions and sexual dysfunction. FDA is improperly practicing medicine by deciding which patients can receive skin shock and which cannot. The families of all 54 patients advocate for continued access to GED treatment for their children. Attached are a few of the many letters/comments from these families to FDA when FDA first attempted to ban ESDs for SIB or AB in 2016. Ultimately, a 2021 D.C. Circuit Court ruling overturned the FDA's ban.³ These families have informed me that they intend to submit comments against this proposed ban and do everything else in their power to stop FDA as their children depend on this treatment to survive.

There is no scientific basis for FDA pursuing this ban. There is a long history of safe and effective treatment of hundreds of patients with the GED and there are no harmful side effects. The success of this treatment is documented in patient records and in the judicial findings of hundreds of individual aversive treatment cases decided by the Massachusetts Probate and Family Court. A 2018 Massachusetts court decision, which was affirmed by a unanimous Massachusetts Supreme Judicial Court in 2023, found that the GED treatment is humane, safe and highly effective for these patients and there is no alternative treatment.⁴ The GED rapidly decreases SIB and AB to zero and near-zero levels, which allows the patients to be free of painful and debilitating SIB and AB; receive successful medical treatment for their many severe injuries from SIB; be educated; learn positive behaviors to replace the harmful behaviors; learn daily living and other independence skills; and live in the community. The GED is so effective that the average number of applications needed is less than one per week. A 2020 study of 173 patients published in the *International Journal of Psychology & Behavior Analysis* shows that there is a 97% reduction in SIB and AB once GED is used.⁵ FDA admits that it has no scientific evidence or data that the GED device causes harmful side effects and acknowledges that the

² Banned Devices; Electrical Stimulation Devices for Self-Injurious or Aggressive Behaviors, 85 Fed. Reg. 13,312, 13,322 (Mar. 6, 2020) (to be codified at 21 C.F.R. pts. 882, 895).

³ *JRC v. FDA*, 3 F.4th 390 (D.C. Cir. 2021); *JRC v. FDA*, No. 20-1087 (D.C. Cir. Nov. 22, 2021) (order denying petition for rehearing en banc).

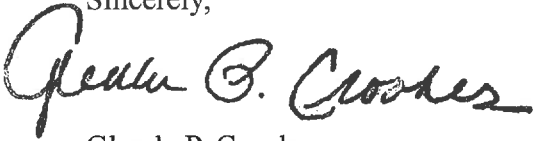
⁴ *JRC v. Comm'r of the Dep't of Dev. Servs.*, 492 Mass. 772 (2023).

⁵ Blenkush et al., *Contingent Skin-Shock Treatment in 173 Cases of Severe Problem Behavior*, 6 Int'l J. of Psychol. & Behav. Analysis 167 (2020).

published scientific research shows no harmful side effects.⁶ FDA is pursuing a ban as a result of political pressure from the U.S. Department of Health and Human Services, not because the device is harmful.

If FDA were to move forward with this rule, it would prevent critical treatment that gives these patients a life free from the constant pain, injury and isolation caused by self-abuse. I request that the Committee conduct further oversight of FDA's proposed rule to ban ESDs for SIB or AB – a rule that is politically motivated, contravenes the care recommended by medical professionals, is not based on sound science, and constitutes FDA unlawfully practicing medicine.

Sincerely,

A handwritten signature in black ink that reads "Glenda P. Crookes". The signature is written in a cursive, flowing style.

Glenda P. Crookes

Enclosures

⁶ Banned Devices; Proposal To Ban Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior, 89 Fed. Reg. 20,882–01, 20,8880–20,889 (Mar. 26, 2024) (to be codified at 21 C.F.R. pts. 882, 895).

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

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
2 yrs, 5 mos	Children's Hospital Early Language Program- Sept 14, 1993	n/a	n/a	n/a	Difficult temperament 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	temperamental characterists 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	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)

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
10 yrs, 0 mos - 10 years 3 mos	Franciscan's Children's Hospital - Inpatient Unit for the period April 24 thru July 8, 2001	Risperdol, 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

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
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 Valium	Perphenazine, Valium, 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 Valium	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

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 (Kindergarden 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.

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.

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	

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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169. "Federalism and Civil Rights," *Discourse* 7, Summer 1964, pp. 219-29.

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 Llaudet, 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





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