

July 19, 2016

VIA FEDERAL EXPRESS

Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Re: Expedited Freedom of Information Act Request for Information Regarding the Judge Rotenberg Educational Center, Inc./Electrical Stimulation Devices

Dear Sir or Madam:

Pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C.A. § 552, and the implementing regulations under 21 C.F.R. Part 20, I hereby request a copy of all agency records, including written communications between the CDRH Office of Device Evaluation and third parties and any records in the possession of the CDRH Office of Device Evaluation, including internal agency documentation, related to or referring to the Judge Rotenberg Educational Center, Inc. ("JRC"), aversive therapy, aversive conditioning devices, or electrical stimulation devices ("ESD"s). This request includes, but is not limited to, e-mail, memoranda, correspondence, meeting minutes, notes, and all other forms of communication sent or received or drafted from 1994 to the date of this request.

Agency records responsive to this request may include, but are not limited to, all communications, documents and other information concerning, constituting, relating to describing, evidencing or referring to (hereinafter, collectively referred to as "concerning") the following matters:

1. FDA inspection of JRC conducted from January 31 through February 10, 2000;
2. Form FDA 483 issued to JRC on November 23, 2010;
3. Untitled Letter issued to JRC on May 23, 2011;
4. Untitled Letter issued to JRC on June 29, 2012;
5. FDA inspections of JRC and all Establishment Inspection Reports;
6. FDA Warning Letter issued to JRC on December 7, 2012;
7. April 24, 2014, Neurological Devices Panel of the Medical Devices Advisory Committee; and
8. April 25, 2016, Proposal to Ban Electrical Stimulation Devices Used to Treat Self-Injurious or Aggressive Behavior.

In addition, agency records responsive to this request may include, but are not limited to, all communications, documents, and other information concerning the following parties as they relate to JRC, aversive therapy, aversive conditioning devices or ESDs:

1. All state, federal or international governmental agencies, and their present or former commissioners, officers, directors, employees, agents, attorneys, consultants, representatives and assigns, including, but not limited to:
 - a. The Massachusetts Department of Developmental Services (f/k/a The Massachusetts Department of Mental Retardation);
 - b. The Massachusetts Department of Early Education and Care (f/k/a the Massachusetts Office for Children and the Massachusetts Office for Child Care Services);
 - c. The Massachusetts Department of Elementary and Secondary Education;
 - d. The Massachusetts Department of Mental Health;
 - e. The Massachusetts Division of Professional Licensure;
 - f. The Office of the Attorney General of Massachusetts;
 - g. The Office of the Governor of Massachusetts;
 - h. The Massachusetts Executive Office of Health and Human Services;
 - i. The New York State Education Department;
 - j. The New York Office of the Attorney General;
 - k. The New York Office of People with Developmental Disabilities (f/k/a The New York Office of Mental Retardation and Developmental Disabilities);
 - l. Delaware Health and Human Services, Division of Developmental Disabilities Services;
 - m. The New Jersey Department of Education;
 - n. The New Jersey Department of Human Services, Division of Developmental Disabilities;
 - o. The Centers for Medicare and Medicaid Services;
 - p. The Department of Justice; and
 - q. The United Nations Office of the Special Rapporteur.
2. Present or former employees, agents, attorneys, consultants or representatives of any national, state or local disability advocacy organizations or human rights organizations including, but not limited to:
 - a. American Association on Intellectual and Developmental Disabilities, including its current and/or former employee Margaret NyGren, Ed.D.;
 - b. The American Civil Liberties Union, including its current and/or former employee Jennifer Bellamy;

- c. The ARC of Massachusetts, including its current and/or former employee Leo V. Sarkissian;
- d. The ARC of the United States, including its current and/or former employee Maureen Fitzgerald;
- e. Aspics for Freedom;
- f. The Association for Persons with Severe Handicaps;
- g. The Association of University Centers on Disabilities, including its current and/or former employee Kim Musheno;
- h. The Autism National Committee;
- i. The Autistic Self Advocacy Network, including its current and/or former employee Ari Ne'eman;
- j. Children Injured by Restraint and Aversives;
- k. The Church of Scientology;
- l. Coalition for the Legal Rights of People with Disabilities, including its current and/or former employee Polyxane S. Cobb;
- m. The Disability Law Center, Inc. in Massachusetts, including its current and/or former employees Matthew Engel, Esq., Stanley J. Eichner, Richard M. Glassman, Christine Griffin, and Alan Kerzin;
- n. Disability Rights International, including its current and/or former employee Eric Matthews;
- o. The Family Alliance to Stop Abuse and Neglect;
- p. Massachusetts Developmental Disabilities Council, including its current and/or former employee Daniel Shannon;
- q. The Massachusetts Governor's Commission on Intellectual Disability (f/k/a the Governor's Commission on Mental Retardation), including its current and/or former employee Cynthia Levine;
- r. Mental Health Legal Advisors Committee for the Supreme Judicial Court of Massachusetts, including its current and/or former employee Jennifer Honig;
- s. Occupy JRC, including its current and/or former employee Emily Minton;
- t. The Pass Group, including its current and/or former employees Nomita Ganguly and Deborah Thomson;
- u. The National Association of Councils on Developmental Disabilities, including its current and/or former employee Esme Grant;
- v. The National Association of State Directors of Developmental Disabilities, including its current and/or former employee Nancy Thaler;
- w. The National Disability Rights Network, including its current and/or former employee Curtis Decker, JD;

- x. The National Leadership Consortium on Developmental Disabilities at the University of Delaware, including its current and/or former employee Nancy R. Weiss, MSW;
 - y. The President's National Council on Disability, including its current and/or former employees Gary Blumenthal and Marylyn Howe;
 - z. TASH: Equity, Opportunity, and Inclusion for People with Disabilities, including its current and/or former employee Barbara Trader; and
 - aa. TASH: New England, including its current and/or former Board member Lydia Brown.
3. The Members of the April 24, 2014, Neurological Devices Panel of the Medical Devices Advisory Committee, including but not limited to:
- a. Daniel Armstrong, Ph.D., University of Miami, Miller School of Medicine;
 - b. Erika F. Augustine, M.D., University of Rochester, School of Medicine;
 - c. Warren Bickel, Ph.D., Virginia Tech, Virginia Tech Carilion Research Institute;
 - d. Jason Connor, Ph.D., Berry Consulting, LLC;
 - e. E. Ray Dorsey, M.D., M.B.A., University of Rochester Medical Center, Center for Human Experimental Therapeutics;
 - f. Norman Fost, M.D., MPH, University of Wisconsin, School of Medicine and Public Health;
 - g. Wayne K. Goodman, M.D., Icahn School of Medicine at Mount Sinai, Mount Sinai Institute of Mental Health;
 - h. Mark W. Green, MD, Icahn School of Medicine at Mount Sinai, Mount Sinai Institute of Mental Health;
 - i. Brian Iwata, Ph.D., University of Florida, Behavior Analysis Program;
 - j. Scott Y. Kim, M.D., Ph.D., National Institutes of Health Clinical Center;
 - k. Kristine R. Mattivi, MS, Colorado Foundation for Medical Care;
 - l. J. Stephen Mikita, J.D., Assistant Attorney General;
 - m. Steven Miles, M.D., University of Minnesota Medical School;
 - n. Guerry M. Peavy, Ph.D., University of California, San Diego;
 - o. John B. Reppas, M.D., Ph.D., Neurotechnology Industry Organization;
 - p. Donald E. Richardson, M.D., Tulane University Health Sciences Center, School of Medicine;
 - q. Glenn T. Stebbins, Ph.D., Rush University, College of Health Sciences;
 - r. Karen L. Weigle, Ph.D., University of New Hampshire, Institute on Disability/UCED; and

- s. Lynda J. Yang, M.D., Ph.D., University of Michigan, Department of Neurosurgery.
4. Vito Alvenese;
 5. Fredda Brown, Ph.D., Queens College Regional Center for Autism Spectrum Disorders;
 6. James Butler;
 7. Ian Cook;
 8. James C. Eason, Ph.D.;
 9. Diane Engster, JD;
 10. Gary W. LaVigna, Ph.D., The Institute for Applied Behavior Analysis;
 11. Cheryl McCollins;
 12. Gregory Miller;
 13. Jennifer Msumba;
 14. Shain Neumeier;
 15. Christopher Oliva, Ph.D., Gateways: Educational and Behavioral Consultation Services;
 16. Tristram H. Smith, Ph.D., University of Rochester Medical Center; and
 17. Maria Town, US Department of Labor's Office of Disability Employment Policy.

This request does not include a request for agency records that are publicly available in docket number FDA-2014-N-0238 or docket number FDA-2016-N-1111.

Under FOIA, agencies must expedite processing whenever it is demonstrated that there is a "compelling need," which includes circumstances where failure to obtain the records on an expedited basis "could reasonably be expected to pose an imminent threat to the life or physical safety of an individual" or at the agency's discretion. 5 U.S.C.A. § 552(a)(6)(E)(v)(I); *Id.* at § 552(a)(6)(E)(i)(II) (Westlaw through P.L. 114-143); 21 C.F.R. § 20.44(a)(1). I am requesting that this FOIA request be handled on an expedited basis. The following information is in support of my request for expedited processing and I certify that it is true and correct to the best of my knowledge and belief. My child, D.P., is a patient at JRC and undergoing treatment with an ESD device.

In light of the proposed ban on these types of devices, obtaining the requested information as soon as possible is crucial to understanding whether we will need to explore other treatment options for him in light of the agency's concerns regarding the safety and efficacy of this treatment as well as in the event that FDA does decide to ban the device and ESD devices are no longer an available treatment option. My child demonstrates severe self-injurious behaviors (e.g., shoving his hand down his throat to scrape his throat and bring up blood, banging his head with such force that it has permanently damaged his ear, gouging his rectum, destroying his gums with his fingernails) which place him at severe risk for his physical safety should these behaviors not be adequately controlled. Obtaining all information regarding his ongoing therapy and the facility at which he is being treated is crucial to maintain his physical safety.

I request that all agency records and correspondence be sent to my attorney, Max D. Stern, Esq., whose contact information is as follows: Todd & Weld, LLP, One Federal Street, Boston, MA 02110, (617) 388-1151. I agree to pay all reasonable processing and photocopying fees associated with this request up to \$1,000.00. If you reach costs and fees of \$1,000.00, please contact Mr. Stern for authorization of further charges.

If you deny any part of this request, please cite each specific reason that you think justifies your refusal to release the requested information. If a portion of a record is exempt from disclosure, please release the remaining portion(s) of the record in accordance with 5 U.S.C.A. § 552(b).

We look forward to receiving notice of your determination whether expedited processing will be provided within the next 10 days, as required by 5 U.S.C.A. § 552(a)(6)(E)(ii)(I). We also look forward to receiving processed records in a timely manner.

If possible, I request that we receive records as they become available instead of receiving a single response once all records asked for have been identified.

Please notify us of all appeal procedures available under law.

If you have any additional questions while processing this request, please contact Mr. Stern.

Sincerely yours,

Paul Peterson/da

Paul E. Peterson
5 Midland Road
Wellesley, MA 02482
ppeterso40@gmail.com

cc: Max D. Stern, Esq.