

August 23, 2016

**VIA FEDERAL EXPRESS**

U.S. 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") at 5 U.S.C.A. § 552, and the implementing regulations under 21 C.F.R. Part 20, I hereby request the following:

- 1. Documents relating to any in-person meetings between U.S. Food and Drug Administration ("FDA") employees and stakeholders or persons interested in electrical stimulation devices ("ESDs") as used to treat self-injurious behavior or aggressive behavior ("SIB/AB"), or with experience relating to the use of ESDs as used to treat SIB/AB, dating from January 2012 to the present;**
- 2. Communications, and any documents relating to communications, between Department of Health and Human Services officials and FDA employees regarding ESDs used to treat SIB/AB, dating from January 2012 to the present;**
- 3. Documents obtained, received, or created by FDA analyzing literature, whether published or unpublished, relating to ESDs as used to treat SIB/AB, or analogous devices, dating from January 2012 to the present; and**
- 4. Communications, including but not limited to records of telephone conversations or in-person meetings, and any documents relating to communications, between FDA employees and patients or former patients of the Judge Rotenberg Educational Center, Inc. ("JRC"), or parents of patients or former patients of JRC, dating from January 2012 to the present.**

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

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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.

In light of the proposed ban on ESDs, 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 ESDs 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. In the interest of receiving the requested materials as quickly as possible, we are happy to accept FDA's response on a rolling basis. I will pay all reasonable fees in supplying this information. If these fees should exceed \$250, please contact Mr. Stern for authorization to proceed.

I ask that you please adhere to the statutory and regulatory requirements governing access to public information (5 U.S.C.A. § 552; 21 C.F.R. § 20.41). 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.

Please notify me of all appeal procedures available under law.

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

Sincerely,

Paul Peterson /dal

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

cc: Max D. Stern, Esq.