UNITED STATES DISTRICT COURT
DISTRICT OF COLUMBIA

THE JUDGE ROTENBERG EDUCATIONAL CENTER, INC., THE J.R.C. PARENTS AND FRIENDS ASSOCIATION, INC., and PAUL E. PETERSON, PH.D., *Plaintiffs*, v. U.S. FOOD AND DRUG ADMINISTRATION 10903 New Hampshire Avenue Silver Spring, MD 20993 and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES 200 Independence Avenue, Southwest Washington, D.C. 20201, *Defendants.*	Civil Action No. 17-2092

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. This action is brought pursuant to the Freedom of Information Act (the "FOIA" or "Act"), 5 U.S.C. § 552, to compel the production of agency records improperly withheld from Plaintiffs the Judge Rotenberg Educational Center, Inc. ("JRC"), the J.R.C. Parents and Friends Association, Inc. ("Parents Association"), and Paul E. Peterson, Ph.D. ("Dr. Peterson") (collectively, "Plaintiffs") by Defendants U.S. Food and Drug Administration ("FDA" or

"Agency") and U.S. Department of Health and Human Services ("HHS" or "Department") (collectively, "Defendants") concerning FDA's Proposal To Ban Electrical Stimulation Devices Used To Treat Self-Injurious or Aggressive Behavior (the "Proposed Ban"), 81 Fed. Reg. 24386, and the Graduated Electronic Decelerator (the "GED"), the electrical stimulation device that JRC uses to treat the self-injurious and aggressive behaviors of some of its patients.

JURISDICTION AND VENUE

2. This Court has both personal jurisdiction over the parties and subject-matter jurisdiction over this action under 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331.

3. Venue is proper in the United States District Court for the District of Columbia pursuant to 5 U.S.C. § 552(a)(4)(B).

PARTIES

4. Plaintiff JRC is a non-profit corporation with a principal place of business at 240 Turnpike Street, Canton, Massachusetts. JRC provides care and treatment, including GED treatment, to patients who engage in self-injurious and aggressive behaviors. In connection with the FOIA requests at issue in this action, JRC is represented by Michael P. Flammia, Esq. ("Attorney Flammia"), a member of Eckert Seamans Cherin & Mellott, LLC, a law firm with an office at 2 International Place, 16th Floor, Boston, Massachusetts. Attorney Flammia submitted a letter on behalf of JRC to FDA's Chief Counsel about the Proposed Ban. FDA treated the letter as a FOIA request, and thus the letter is one of the FOIA requests at issue in this action.

5. Plaintiff Parents Association is a non-profit corporation with a principal place of business at 28 Mignon Road, Newton, Massachusetts. The Parents Association is doing business as the J.R.C. Parents and Friends Association, Inc. and is formally known as the B.R.I. Parents and Friends Association, Inc. The Parents Association represents all of the parents of JRC

patients, including those parents of patients who currently receive GED treatment. In connection with the FOIA requests at issue in this action, the Parents Association is represented by Max D. Stern, Esq. ("Attorney Stern"), a partner at Todd & Weld LLP, a law firm with an office at 1 Federal Street, Boston, Massachusetts. Attorney Stern submitted a letter on behalf of the Parents Association to FDA's Chief Counsel about the Proposed Ban that incorporated by reference JRC's letter, which FDA treated as a FOIA request and which is one of the FOIA requests at issue in this action.

6. Plaintiff Dr. Peterson is a resident of the Town of Wellesley, County of Norfolk, Commonwealth of Massachusetts. He is the father and legal guardian of D.P., an adult male who is receiving care and treatment, including GED treatment, for his self-injurious and aggressive behaviors at JRC. Dr. Peterson is a member of the Parents Association. In connection with the FOIA requests at issue in this action, Dr. Peterson is represented by Attorney Stern and Attorney Flammia. Dr. Peterson submitted under his own signature eight of the FOIA requests at issue in this action.

7. Defendant FDA is an agency within Defendant HHS. FDA is an agency within the meaning of 5 U.S.C. § 552(f)(1). FDA has possession, custody, and control of certain records that Plaintiffs seek through the FOIA requests at issue in this action.

8. Defendant HHS is an executive department in the Federal Government and includes Defendant FDA. HHS is an agency within the meaning of 5 U.S.C. § 552(f)(1). HHS has possession, custody, and control of certain records that Plaintiffs seek through the FOIA requests at issue in this action.

COUNT I: FOIA VIOLATION

LEGAL STANDARD

9. FOIA requires that "each agency, upon any request for records . . . shall make the records promptly available to any person." 5 U.S.C. § 552(a)(3)(A).

10. FOIA provides:

> "Each agency, upon any request for records . . . shall . . . determine within 20 [working] days . . . after the receipt of any such request whether to comply with such request and shall immediately notify the person making such request of . . . such determination and the reasons therefor; . . . the right of such person to seek assistance from the FOIA Public Liaison of the agency; and . . . in the case of an adverse determination . . . the right of such person to appeal to the head of the agency . . . ; and . . . the right of such person to seek dispute resolution services from the FOIA Public Liaison of the agency or the Office of Government Information Services [('OGIS')]".

Id. at § 552(a)(6)(A)(i).

11. Under FOIA, in "unusual circumstances", which include "the need to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the request", *id.* at § 552(a)(6)(B)(iii)(I), the twenty working day determination deadline "may be extended by written notice to the person making such request setting forth the unusual circumstances for such extension and the date on which a determination is expected to be dispatched", *id.* at § 552(a)(6)(B)(i). "No such notice shall specify a date that would result in an extension for more than ten working days", *id.*, unless the agency notifies the requester that the request cannot be processed within thirty working days and provides the requester "an opportunity to limit the scope of the request so that it may be processed within that time limit or an opportunity to arrange with the agency an alternative time frame for processing the request or a modified request", *id.* at § 552(a)(6)(B)(ii).

12. FOIA commands the agency to "promptly" produce the records to the requester upon making its determination to comply with the request. *Id.* at § 552(a)(6)(C)(i).

13. FDA's regulations implementing FOIA provide:

> "Within 20 working days . . . after a request for records is logged in at the Division of Freedom of Information [('DFI')], the [A]gency shall send a letter to the requester providing the [A]gency's determination as to whether, or the extent to which, the [A]gency will comply with the request, and, if any records are denied, the reasons for the denial."

21 C.F.R. § 20.41(b). Further, "[i]f any record is denied, the letter shall state the right of the person requesting such records to appeal any adverse determination to the Assistant Secretary for Health, [HHS]". *Id.* at § 20.41(b)(4); *see also id.* at § 20.49(c) ("A letter denying a request for records, in whole or in part, shall state the reasons for the denial and shall state that an appeal may be made to the Deputy Assistant Secretary for Public Affairs (Media), [HHS].").

14. HHS's regulations implementing FOIA provide that the Department's determination notification will include "whether any responsive records were located, how much responsive material was located, whether the records are being released in full or withheld in full or in part, . . . and [the requester's] right to seek assistance from the appropriate FOIA Public Liaison." 45 C.F.R. § 5.28(a). Further, if HHS denies any part of the request, then the Department's determination notification will also "explain the reasons for the denial, which FOIA exemptions apply to the withheld records, [the requester's] right to appeal that determination, and [the requester's] right to seek dispute resolution services from the appropriate FOIA Public Liaison or the [OGIS]." *Id.* at § 5.28(b).

15. HHS's regulations implementing FOIA additionally address the steps the Department must take to extend the twenty working day determination deadline in "unusual circumstances":

> "Whenever [HHS] cannot meet the statutory time limit for processing a request because of 'unusual circumstances,' as defined in the FOIA, and [HHS] extend[s] the time limit on that basis, [HHS] will notify [the requester], before the expiration of the 20-day period to respond and in writing of the unusual circumstances involved and of the date by which [HHS] estimate[s] processing of the request will be completed. Where the extension exceeds 10 working days, [HHS] will provide [the requester], as described by the FOIA, with an opportunity to modify the request or arrange an alternative time period for processing the original or modified request."

Id. at § 5.24(f).

FACTUAL BACKGROUND

THE PROPOSED BAN

16. On April 25, 2016, FDA published its Proposed Ban in the Federal Register. 81 Fed. Reg. 24386. According to FDA, the Proposed Ban targets only one treatment provider – JRC – and only one electrical stimulation device – the GED. *Id.* at 24390. FDA's Proposed Ban relies on inaccurate information, much of which is specific to JRC and the GED, and some of which is derived from publicly unavailable sources, including sources that have well-known anti-GED bias. Because FDA is proceeding by a rulemaking rather than an adjudicatory process, there is no mechanism – other than FOIA – for JRC, the Parents Association, and Dr. Peterson to examine the reliability of the factual allegations on which the Proposed Ban relies.

17. For example, the Proposed Ban states that "[i]n 2013 and 2014, FDA clinicians interviewed three individuals formerly on [electrical stimulation device]s at JRC by phone". *Id.* at 24393. FDA has never provided JRC, the Parents Association, or Dr. Peterson with information about how these individuals were selected, what these individuals were asked, and what these individuals told FDA.

18. As another example, the Proposed Ban states that FDA obtained "individual expert reports . . . from Drs. Tristram Smith, Gary LaVigna, and Fredda Brown". *Id.* Again,

FDA has not provided JRC, the Parents Association, or Dr. Peterson with information about how it selected these experts, the questions it asked them, or the reports that it received from them.

19. A further example is that FDA "reviewed" and "considered" the comments it received in connection with a panel meeting (the "Panel Meeting") it held in 2014 before publishing the Proposed Ban. *Id.* One commenter was the Disability Law Center ("DLC"), a long-time anti-GED advocacy group, whose comment included an expert affidavit. FDA-2016-N-1111-0070. While DLC claimed in its comment that the expert was highly critical of the GED in his affidavit, the publicly available version of the expert's affidavit is entirely redacted, *id.*, and FDA has ignored JRC's requests for an unredacted copy of the affidavit to assess the accuracy of the expert's statements.

20. On information and belief, FDA and HHS have thousands of pages of records concerning FDA's Proposed Ban and JRC's GED that were generated or received over many years in connection with the Panel Meeting, the Proposed Ban, and prior regulatory oversight that are responsive to the FOIA requests at issue in this action.

21. FDA could promulgate a final rule implementing the Proposed Ban at any time and without prior notice to Plaintiffs.

THE FIRST FOIA REQUESTS

22. On July 19, 2016, Dr. Peterson submitted six written FOIA requests (collectively, the "First FOIA Requests") under his own signature by Federal Express to FDA's DFI. The First FOIA Requests are incorporated herein and attached hereto as **Exhibits A-1**, **A-2**, **A-3**, **A-4**, **A-5**, and **A-6**.

23. The First FOIA Requests were substantively identical, seeking records concerning FDA's Proposed Ban and JRC's GED, from FDA and five of its components. Specifically, Dr.

Peterson sought "all agency records, including written communications between" FDA, its Office of the Commissioner ("OC"), its Office of the Chief Counsel ("OCC"), its Office of the Center Director in the Center for Devices and Radiological Health ("CDRH"), its Office of Compliance in the CDRH, or its Office of Device Evaluation in the CDRH "and third parties and any records in the possession of" FDA or its five components, "including internal agency documentation, related to or referring to . . . JRC . . . , aversive therapy, aversive conditioning devices, or electrical stimulation devices", including, but 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 the requests. In the First FOIA Requests, Dr. Peterson provided FDA and its five components with additional and extensive guidance about the particular records he sought, and the particular records he did not seek, namely, records that were publicly available in the Panel Meeting's docket (FDA-2014-N-0238) or the Proposed Ban's docket (FDA-2016-N-1111). Dr. Peterson advised FDA and its five components to contact Attorney Stern if any questions arose during processing of the First FOIA Requests.

24. Dr. Peterson explained in the First FOIA Requests that it was essential for him to receive the requested records in a timely manner. He wrote that his son, D.P., was a JRC patient undergoing treatment with an electrical stimulation device. He continued:

> "In light of the [P]roposed [B]an 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 [A]gency's concerns regarding the safety and efficacy of this treatment as well as in the event that FDA does decide to ban the [GED] and [electrical stimulation] 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."

Dr. Peterson concluded by stating that he looked forward to receiving the records in a timely manner and by requesting a rolling production of the records.

25. On August 15, 2016, approximately nineteen working days after Dr. Peterson submitted the First FOIA Requests, having received no records and no communications from FDA related to the First FOIA Requests, Attorney Stern, on behalf of Dr. Peterson, sent a letter to FDA's DFI, which is incorporated herein and attached hereto as **Exhibit B**. Attorney Stern requested a response to the First FOIA Requests, reiterating that "the treatment that the Peterson's child is receiving is vital to the overall care and safety of the child, and Dr. Peterson's interest in the requested information pertains to that treatment." Attorney Stern asked that "an open line of communication be established to process the request and get information as quickly as it becomes available", and that the records be produced on a rolling basis.

26. On September 2, 2016, approximately thirty-three working days after Dr. Peterson submitted the First FOIA Requests, by letter addressed to Dr. Peterson, FDA acknowledged receipt of the First FOIA Requests, docketed as number 2016-7308, and stated that the Agency would "respond as soon as possible". This letter is incorporated herein and attached hereto as **Exhibit C**. This letter did not include any records, and it did not constitute a determination, since it failed: to indicate that FDA had gathered and reviewed the records; to communicate to Dr. Peterson the scope of the records FDA intended to produce and withhold, and the reasons for withholding any records; to inform Dr. Peterson of his right to seek assistance from FDA's FOIA Public Liaison; and to provide Dr. Peterson with his appellate rights. 5 U.S.C. § 552(a)(6)(A)(i); 21 C.F.R. §§ 20.41(b), 20.49(c); *Citizens for Responsibility & Ethics in Wash. v. Federal Election Comm'n*, 711 F.3d 180, 188 (D.C. Cir. 2013) ("*CREW*").

27. On September 7, 2016, approximately thirty-five working days after Dr. Peterson submitted the First FOIA Requests, by letter addressed to Dr. Peterson, in "partial response" to the First FOIA Requests, an unidentified FDA component provided Dr. Peterson with twenty-three pages of records "that ha[d] previously been released under FOIA", thirteen pages or approximately fifty-seven percent of which were redacted under claims of "commercial confidential information". 5 U.S.C. § 552(b)(4). This letter is incorporated herein and attached hereto as **Exhibit D**. The component advised that Dr. Peterson's First FOIA Requests "remain[ed] open with other agency components," that he "w[ould] receive additional responses directly from those components", and that he "w[ould] receive appeal rights with . . . [his] final agency response." This letter did not constitute a determination, since it failed: to inform Dr. Peterson of his right to seek assistance from FDA's FOIA Public Liaison; to provide Dr. Peterson with his appellate rights; and to inform Dr. Peterson of his right to seek dispute resolution services from FDA's FOIA Public Liaison or the OGIS. *Id.* at § 552(a)(6)(A)(i); 21 C.F.R. §§ 20.41(b), 20.49(c); *CREW*, 711 F.3d at 188.

28. On September 28, 2016, approximately fifty working days after Dr. Peterson submitted the First FOIA Requests, by email addressed to Dr. Peterson, in "partial response" to the First FOIA Requests, the Office of the Executive Secretariat ("OES") in FDA's OC provided Dr. Peterson with a small record production. This email is incorporated herein and attached hereto as **Exhibit E**. The email advised that Dr. Peterson's First FOIA Requests were "still pending in other offices", that the other offices would "respond to . . . [him] directly with their release determinations", and that he would "receive appeal rights upon receipt of the final agency response." This email did not constitute a determination, since it failed: to inform Dr. Peterson of his right to seek assistance from FDA's FOIA Public Liaison; to provide Dr. Peterson with his

appellate rights; and to inform Dr. Peterson of his right to seek dispute resolution services from FDA's FOIA Public Liaison or the OGIS. 5 U.S.C. § 552(a)(6)(A)(i); 21 C.F.R. §§ 20.41(b), 20.49(c); *CREW*, 711 F.3d at 188.

29. OES heavily redacted the few records produced with the email. The production included only fifty-one pages of records. Four pages, or approximately eight percent of the record production, were partially redacted under claims of personal privacy invasion. 5 U.S.C. § 552(b)(6). Additionally, thirty-eight pages, or approximately seventy-five percent of the record production, were completely redacted under claims of deliberative process privilege. *Id.* at § 552(b)(5). OES's redactions under claims of deliberative process privilege were improper, since, on information and belief, not all of the redacted records were privileged, and since OES failed: to provide Dr. Peterson the reasonably segregable portions of the records, *id.* at § 552(b); to make the fullest possible disclosure of records, 21 C.F.R. § 20.20(a); to disclose all disclosable information in the records, *id.* at § 20.22(a); to issue the partial denial of the First FOIA Requests under the signature of the Assistant Commissioner for Public Affairs, *id.* at § 20.49(a); to attach a list of the name and title or position of each person who participated in the partial denial of the First FOIA Requests, *id.* at § 20.49(b); to state that Dr. Peterson could appeal the partial denial of the First FOIA Requests to the Deputy Assistant Secretary for Public Affairs (Media), HHS, *id.* at § 20.49(c); and to disclose all reasonably segregable factual information, *id.* at § 20.62.

30. As of the date of this Complaint, approximately 308 working days have elapsed since Dr. Peterson submitted his First FOIA Requests. During this time, FDA has not notified Dr. Peterson of its determination, and it has only produced seventy-four pages of records, fifty-five pages or approximately seventy-four percent of which were completely or partially redacted.

31. The failure of FDA to issue its determination within twenty working days of its receipt of the First FOIA Requests and to promptly produce the requested records is unlawful under the Act and the Agency's implementing regulations. 5 U.S.C. §§ 552(a)(3)(A), 552(a)(6)(A)(i); 21 C.F.R. §§ 20.41(b), 20.49(c); *CREW*, 711 F.3d at 188.

32. Dr. Peterson has constructively exhausted his administrative remedies with respect to his First FOIA Requests because FDA failed to comply with the Act's time limits for issuing its determination. *See* 5 U.S.C. § 552(a)(6)(C)(i) ("Any person making a request to any agency for records . . . shall be deemed to have exhausted his administrative remedies with respect to such request if the agency fails to comply with the applicable time limit provisions . . ."); *see also Oglesby v. U.S. Dep't of Army*, 920 F.2d 57, 67 (D.C. Cir. 1990) (holding that, under FOIA, a requester was excused from the administrative exhaustion requirement where an agency failed to provide his appeal rights with its response).

33. Pursuant to 5 U.S.C. § 552(a)(3)(A), Dr. Peterson has a statutory right to the records sought in the First FOIA Requests, which FDA has improperly withheld, including, but not limited to, the unproduced records and the produced records that were improperly redacted under claims of deliberative process privilege.

THE SECOND FOIA REQUEST

34. On August 23, 2016, Dr. Peterson submitted a written FOIA request (the "Second FOIA Request") under his own signature via Federal Express to FDA's DFI. The Second FOIA Request is incorporated herein and attached hereto as **Exhibit F**.

35. Dr. Peterson's Second FOIA Request, like his First FOIA Requests, sought records concerning FDA's Proposed Ban and JRC's GED. However, Dr. Peterson's Second FOIA Request was narrower than his First FOIA Requests, in terms of both subject matter and

time period. Dr. Peterson again advised FDA to contact Attorney Stern with any questions regarding the processing of his Second FOIA Request.

36. Dr. Peterson explained in his Second FOIA Request that it was essential for him to receive the requested records as soon as possible, reiterating the reasons that he had provided to FDA in his First FOIA Requests. Dr. Peterson expressed his preference to receive FDA's response on a rolling basis in the interest of receiving the requested records as quickly as possible, and he stated that he looked forward to receiving the processed records in a timely manner.

37. On September 1, 2016, approximately seven working days after Dr. Peterson submitted the Second FOIA Request, by letter addressed to Dr. Peterson, HHS acknowledged receipt of the Second FOIA Request, docketed as number 2016-7184. This letter is incorporated herein and attached hereto as **Exhibit G**. HHS indicated FDA had forwarded the Second FOIA Request to the Department in order to search for records. HHS claimed that it had already initiated a search for the records requested in the Second FOIA Request. HHS acknowledged that FOIA obligated the Department to respond to the Second FOIA Request within twenty working days of its receipt of the request. HHS claimed that certain "unusual" circumstances would impact its response time, including the "need to search for and collect records from components and/or field offices external to . . . [the processing] office". HHS advised that if the unusual circumstances prevented the Department from responding within twenty working days, it would utilize a ten working day extension.

38. HHS's letter did not include any records, and it did not constitute a determination, since it failed: to indicate that HHS had gathered and reviewed the records; to communicate to Dr. Peterson the scope of the records HHS intended to produce and withhold, and the reasons for

withholding any records; to inform Dr. Peterson of his right to seek assistance from HHS's FOIA Public Liaison; and to provide Dr. Peterson with his appellate rights. 5 U.S.C. § 552(a)(6)(A)(i); 45 C.F.R. § 5.28(a)-(b); *CREW*, 711 F.3d at 188.

39. HHS's letter did not properly extend the determination deadline by ten working days because the Department did not specify the date on which it expected to issue its determination, and, for that reason, its attempt to extend the determination deadline from twenty to thirty working days by claiming "unusual circumstances" was unlawful. 5 U.S.C. § 552(a)(6)(B)(i); 45 C.F.R. § 5.24(f).

40. HHS's letter did not properly extend the determination deadline for longer than ten working days because the Department did not notify Dr. Peterson that the Second FOIA Request could not be processed within thirty working days or provide him with an opportunity to limit the scope of his request or arrange an alternative time frame for processing his request, and, for those reasons, any attempt by HHS to extend the determination deadline beyond thirty working days by claiming "unusual circumstances" was unlawful. 5 U.S.C. § 552(a)(6)(B)(ii); 45 C.F.R. § 5.24(f).

41. On September 28, 2016, approximately twenty-five working days after Dr. Peterson submitted the Second FOIA Request, OES in FDA's OC emailed Dr. Peterson the partial response to the First FOIA Requests, *see supra* ¶¶ 28-29; *see also* Ex. E, which email also purported to be a partial response to the Second FOIA Request and which email also provided Dr. Peterson with a second small record production in response to the Second FOIA Request. This email did not constitute a determination, since it failed: to inform Dr. Peterson of his right to seek assistance from FDA's FOIA Public Liaison; to provide Dr. Peterson with his appellate rights; and to inform Dr. Peterson of his right to seek dispute resolution services from FDA's

FOIA Public Liaison or the OGIS. 5 U.S.C. § 552(a)(6)(A)(i); 21 C.F.R. §§ 20.41(b), 20.49(c); *CREW*, 711 F.3d at 188.

42. OES heavily redacted the few records produced with the email. The production included only two pages of records. One page, or approximately fifty percent of the record production, was heavily redacted under claims of deliberative process privilege. 5 U.S.C. § 552(b)(5). OES's redactions under claims of deliberative process privilege were improper, since, on information and belief, not all of the redacted record was privileged, and since OES failed: to provide Dr. Peterson the reasonably segregable portions of the records, *id.* at § 552(b); to make the fullest possible disclosure of records, 21 C.F.R. § 20.20(a); to disclose all disclosable information in the records, *id.* at § 20.22(a); to issue the partial denial of the Second FOIA Request under the signature of the Assistant Commissioner for Public Affairs, *id.* at § 20.49(a); to attach a list of the name and title or position of each person who participated in the partial denial of the Second FOIA Request, *id.* at § 20.49(b); to state that Dr. Peterson could appeal the partial denial of the Second FOIA Request to the Deputy Assistant Secretary for Public Affairs (Media), HHS, *id.* at § 20.49(c); and to disclose all reasonably segregable factual information, *id.* at § 20.62.

43. As of the date of this Complaint, approximately 283 working days have elapsed since Dr. Peterson submitted his Second FOIA Request. During this time, neither FDA nor HHS has notified Dr. Peterson of their determinations. FDA has produced two pages of records, one page or approximately fifty percent of which was extensively redacted, and HHS has not produced any records.

44. The failure of Defendants to issue their determinations within twenty working days of their receipt of the Second FOIA Request and to promptly produce the requested records

is unlawful under the Act and the implementing regulations of the Agency and the Department. 5 U.S.C. §§ 552(a)(3)(A), 552(a)(6)(A)(i); 21 C.F.R. §§ 20.41(b), 20.49(c); 45 C.F.R. § 5.28(a)-(b); *CREW*, 711 F.3d at 188.

45. Dr. Peterson has constructively exhausted his administrative remedies with respect to his Second FOIA Request because Defendants failed to comply with the Act's time limits for issuing their determinations. 5 U.S.C. § 552(a)(6)(C)(i); *Oglesby*, 920 F.2d at 67.

46. Pursuant to 5 U.S.C. § 552(a)(3)(A), Dr. Peterson has a statutory right to the records sought in the Second FOIA Request, which Defendants have improperly withheld, including, but not limited to, the unproduced records and the produced records that were improperly redacted under claims of deliberative process privilege.

THE THIRD FOIA REQUEST

47. On August 23, 2016, Dr. Peterson submitted another written FOIA request (the "Third FOIA Request") under his own signature via Federal Express to FDA's DFI. The Third FOIA Request is incorporated herein and attached hereto as **Exhibit H**.

48. Dr. Peterson's Third FOIA Request, like his First FOIA Requests and Second FOIA Request, sought records concerning FDA's Proposed Ban and JRC's GED. The Third FOIA Request was narrower than the First FOIA Requests, in terms of subject matter. Dr. Peterson again advised FDA to contact Attorney Stern with any questions regarding the processing of his Third FOIA Request.

49. Dr. Peterson explained in his Third FOIA Request that it was essential for him to receive the requested records as soon as possible, reiterating the reasons that he had provided to FDA in his First FOIA Requests and his Second FOIA Request. Dr. Peterson expressed his preference to receive FDA's response on a rolling basis in the interest of receiving the requested

records as quickly as possible, and he stated that he looked forward to receiving the processed records in a timely manner.

50. On August 29, 2016, approximately four working days after Dr. Peterson submitted the Third FOIA Request, by letter addressed to Dr. Peterson, FDA acknowledged receipt of the Third FOIA Request, docketed as number 2016-7106, and stated that the Agency would "respond as soon as possible". This letter is incorporated herein and attached hereto as **Exhibit I**. This letter did not include any records, and it did not constitute a determination, since it failed: to indicate that FDA had gathered and reviewed the records; to communicate to Dr. Peterson the scope of the records FDA intended to produce and withhold, and the reasons for withholding any records; to inform Dr. Peterson of his right to seek assistance from FDA's FOIA Public Liaison; and to provide Dr. Peterson with his appellate rights. 5 U.S.C. § 552(a)(6)(A)(i); 21 C.F.R. §§ 20.41(b), 20.49(c); *CREW*, 711 F.3d at 188.

51. As of the date of this Complaint, approximately 283 working days have elapsed since Dr. Peterson submitted his Third FOIA Request to FDA, FDA has not notified Dr. Peterson of its determination, and FDA has produced no records.

52. The failure of FDA to issue its determination within twenty working days of its receipt of the Third FOIA Request and to promptly produce the requested records is unlawful under the Act and the Agency's implementing regulations. 5 U.S.C. §§ 552(a)(3)(A), 552(a)(6)(A)(i); 21 C.F.R. §§ 20.41(b), 20.49(c); *CREW*, 711 F.3d at 188.

53. Dr. Peterson has constructively exhausted his administrative remedies with respect to his Third FOIA Request because FDA failed to comply with the Act's time limits for issuing its determination. 5 U.S.C. § 552(a)(6)(C)(i); *Oglesby*, 920 F.2d at 67.

54. Pursuant to 5 U.S.C. § 552(a)(3)(A), Dr. Peterson has a statutory right to the records sought in the Third FOIA Request, which FDA has improperly withheld.

THE FOURTH FOIA REQUEST

55. On December 27, 2016, Attorney Flammia submitted via Federal Express and electronic mail a letter, on behalf of JRC, to FDA's Chief Counsel about the Agency's Proposed Ban and JRC's GED (the "Fourth FOIA Request"). The Fourth FOIA Request is incorporated herein and attached hereto as **Exhibit J**. In the letter, JRC criticized the process FDA had pursued in promulgating the Proposed Ban, including the Agency's failure to provide JRC with key information and records on which the Proposed Ban relied. *See* Ex. J. at 67. JRC argued that, since the Proposed Ban targeted only a single provider, JRC had a due process right to view and comment on all of the information on which FDA relied, and FDA's failure to produce such information constituted procedural error under the Federal Administrative Procedure Act. *See id.* (citing *FBME Bank Ltd. v. Lew*, 125 F.Supp.3d 109, 121 (D.D.C. 2015)). JRC included requests for information and records concerning the Proposed Ban in the Fourth FOIA Request. *See id.* at 67-71.

56. On February 3, 2017, approximately twenty-six working days after FDA received the Fourth FOIA Request, FDA's Chief Counsel sent an email to Attorney Flammia, indicating that FDA was "reviewing" JRC's submission and "w[ould] be back in touch once [FDA] ha[d] assessed appropriate next steps." The email is incorporated herein and attached hereto as **Exhibit K**. This email did not include any records, and it did not constitute a determination, since it failed: to indicate that FDA had gathered and reviewed the records; to communicate to JRC the scope of the records FDA intended to produce and withhold, and the reasons for withholding any records; to inform JRC of its right to seek assistance from FDA's FOIA Public

Liaison; to provide JRC with its appellate rights; and to inform JRC of its right to seek dispute resolution services from the FOIA Public Liaison or the OGIS. 5 U.S.C. § 552(a)(6)(A)(i); 21 C.F.R. §§ 20.41(b), 20.49(c); *CREW*, 711 F.3d at 188.

57. On February 15, 2017, approximately thirty-four working days after FDA received the Fourth FOIA Request, FDA's DFI sent a letter to Attorney Flammia, indicating that FDA was treating JRC's letter as a FOIA request and acknowledging receipt of the Fourth FOIA Request, docketed as number 2017-1440. The email is incorporated herein and attached hereto as **Exhibit L**. FDA stated that the Agency would "respond as soon as possible". This letter did not include any records, and it did not constitute a determination, since it failed: to indicate that FDA had gathered and reviewed the records; to communicate to JRC the scope of the records FDA intended to produce and withhold, and the reasons for withholding any records; to inform JRC of its right to seek assistance from FDA's FOIA Public Liaison; and to provide JRC with its appellate rights. 5 U.S.C. § 552(a)(6)(A)(i); 21 C.F.R. §§ 20.41(b), 20.49(c); *CREW*, 711 F.3d at 188.

58. On February 27, 2017, Attorney Stern sent a letter on behalf of the Parents Association to FDA's Chief Counsel about the Agency's Proposed Ban. The letter is incorporated herein and attached hereto as **Exhibit M**. In the letter, the Parents Association incorporated JRC's letter by reference, thereby joining the Fourth FOIA Request as a requestor.

59. On March 6, 2017, Attorney Flammia sent a letter on behalf of JRC to FDA's DFI requesting that the Agency timely process the Fourth FOIA Request and explaining the reasons JRC needed to receive the requested records in a timely manner. The letter is incorporated herein and attached hereto as **Exhibit N**. Attorney Flammia informed FDA's DFI that:

> "The FDA has proposed banning electrical stimulation devices . . . used to treat self-injurious behavior . . . or aggressive behavior. . . *See* 81 Fed. Reg. 24386. I

> am an authorized representative of [JRC], a health care facility directly responsible for treating patients who engage in severe and life-threatening [self-injurious behavior] and [aggressive behavior] (e.g., head banging, eye gouging, tearing their own flesh, biting off body parts, pulling out their own adult teeth, punching their fists through glass windows, running into traffic, jumping out of windows, swallowing knives and violently attacking family members, teachers, staff and others with punches, kicks, bites and sharp objects). [Electrical stimulation devices] have proven to be the only effective treatment for these dangerous behaviors for these individuals, all of whom have been unsuccessfully treated with other therapies. These patients are currently receiving treatment with electrical stimulation devices at JRC and [electrical stimulation device] treatment is preventing them from engaging in severe [self-injurious behavior] and [aggressive behavior] that would otherwise threaten their health and put them at risk [of] death and disfigurement.
>
> "The implementation of a ban would threaten the lives and physical safety of the JRC patients receiving [electrical stimulation device] therapy. Now that the comment period has closed, the FDA could issue a Federal Register notice announcing a ban at any time. The patients and their famil[ies] would receive no prior notice that the FDA has imposed a ban that would deprive the JRC patients of the one treatment that suppresses their dangerous [self-injurious behavior] and [aggressive behavior], thereby putting them at risk of serious physical harm, including death. Many of the findings in the Proposed Ban about the safety and effectiveness of [electrical stimulation devices] are false, as explained in detail in a comment JRC submitted to the FDA on July 25, 2016. *See* FDA-2016-N-1111-1637. JRC needs the FDA's documents that purportedly provide the underlying support for its findings, which I requested in my December 27, 2016 letter, so that JRC will have the information for any needed judicial action and so JRC can further attempt to demonstrate to the FDA that the FDA's findings about [electrical stimulation devices] are inaccurate and based on false information. These document requests seek documents directly relevant to the FDA's key findings.
>
> ". . . The FDA's usual processing time of months (or sometimes years) would entirely frustrate the purpose of the FOIA Request because the FDA could issue a Federal Register notice announcing final agency action before JRC has received the requested documents. Receiving the documents after a ban goes into effect would be too late to protect the patients from the dangers that they would face immediately after the ban, before judicial relief can be sought."

Attorney Flammia concluded by requesting a rolling production of records.

60. On March 24, 2017, Attorney Flammia sent another letter on behalf of JRC to FDA's DFI, requesting to schedule a telephone call to discuss the Fourth FOIA Request. This letter is incorporated herein and attached hereto as **Exhibit O**.

61. As of the date of this Complaint, approximately 198 working days have elapsed since FDA received the Fourth FOIA Request, FDA has not notified JRC or the Parents Association of its determination, and FDA has produced no records.

62. The failure of FDA to issue its determination within twenty working days of its receipt of the Fourth FOIA Request and to promptly produce the requested records is unlawful under the Act and the Agency's implementing regulations. 5 U.S.C. §§ 552(a)(3)(A), 552(a)(6)(A)(i); 21 C.F.R. §§ 20.41(b), 20.49(c); *CREW*, 711 F.3d at 188.

63. JRC and the Parents Association have constructively exhausted their administrative remedies with respect to the Fourth FOIA Request because FDA failed to comply with the Act's time limits for issuing its determination. 5 U.S.C. § 552(a)(6)(C)(i); *Oglesby*, 920 F.2d at 67.

64. Pursuant to 5 U.S.C. § 552(a)(3)(A), JRC and the Parents Association have a statutory right to the records sought in the Fourth FOIA Request, which FDA has improperly withheld.

COMMUNICATIONS BETWEEN PLAINTIFFS AND FDA ABOUT THE FOIA REQUESTS

65. On April 6, 2017, Attorney Flammia, on behalf of JRC and Dr. Peterson, spoke by telephone with Sarah B. Kotler, J.D., Director of FDA's DFI ("Director Kotler"). Attorney Flammia informed Director Kotler that he, along with Attorney Stern, also represented Dr. Peterson in connection with the First FOIA Requests, the Second FOIA Request, the Third FOIA Request, and the Fourth FOIA Request (collectively, the "FOIA Requests"). Attorney Flammia

questioned FDA's delay in producing the records requested in the FOIA Requests, stressing the fact that the First FOIA Requests, the Second FOIA Request, and the Third FOIA Request were made by a JRC client's parent – Dr. Peterson – whose child engages in life-threatening behavior and requires for his continued health and safety the electrical stimulation device treatment that is the subject of FDA's Proposed Ban.

66. On April 13, 2017, Attorney Flammia sent a letter to Director Kotler. This letter is incorporated herein and attached hereto as **Exhibit P**. Attorney Flammia reiterated that he represented JRC and Dr. Peterson in connection with the FOIA Requests. Attorney Flammia pointed out that the First FOIA Requests, Second FOIA Request, and Third FOIA Request had been in FDA's hands for over seven months, and that FDA should have produced the requested records long ago. Attorney Flammia reiterated the reasons it was necessary for JRC and Dr. Peterson to receive the requested records as soon as possible. Attorney Flammia requested another telephone call with Director Kotler to discuss FDA's unreasonable delay in processing the FOIA Requests.

67. On April 21, 2017, Attorney Stern, on behalf of the Parents Association and Dr. Peterson, sent a letter to Director Kotler. This letter is incorporated herein and attached hereto as **Exhibit Q**. Attorney Stern reiterated that he and Attorney Flammia represented Dr. Peterson in connection with the FOIA Requests. Attorney Stern also stated that he and Attorney Flammia looked forward to a second telephone conversation with Director Kotler about the FOIA Requests.

68. On April 26, 2017, Attorney Flammia and Attorney Stern spoke with Director Kotler by telephone. During the call, Director Kotler admitted that FDA's Proposed Ban could be implemented at any moment and without prior notice. Director Kotler indicated that FDA's

OCC, CDRH, and Office of Regulatory Affairs ("ORA") likely had the requested records, and she offered to provide contact information and production timeframes for those components.

69. On May 1, 2017, approximately 196 working days after Dr. Peterson submitted his First FOIA Requests, Director Kotler sent Attorney Flammia and Attorney Stern an email. This email is incorporated herein and attached hereto as **Exhibit R**.

70. Director Kotler did not produce any records.

71. Director Kotler indicated that FDA's DFI and OES had "already responded" to the FOIA Requests. Notwithstanding Director Kotler's statement, FDA's DFI and OES had not issued determinations with respect to the FOIA Requests.

72. Director Kotler did not provide any contact information for FDA's OCC, CDRH, or ORA.

73. Director Kotler did not provide any information about the status of ORA's processing of the FOIA Requests.

74. Director Kotler indicated that FDA's OCC expected to begin releasing records in June 2017 and to "complete processing" the FOIA Requests "in the fall". Notwithstanding Director Kotler's assurances, Plaintiffs received no records from OCC at any time after Director Kotler's email.

75. Director Kotler also indicated that CDRH would "not likely be able to respond until 2018". Since FDA's OCC has neither issued a determination nor produced records, there is no reason to expect that Plaintiffs will receive a determination or records from CDRH before 2019.

76. The number of working days that have elapsed from the date Plaintiffs submitted their FOIA Requests to Defendants to the date of this Complaint is as follows:

FOIA Request	Working Days
First FOIA Requests	308
Second FOIA Request	283
Third FOIA Request	283
Fourth FOIA Request	198

77. Plaintiffs have received no records from Defendants since the last small production on September 28, 2016.

78. Pursuant to 5 U.S.C. § 552(a)(3)(A), Plaintiffs have a statutory right to the records sought in the FOIA Requests, including, but not limited to, the unproduced records and the produced records that were improperly redacted under claims of deliberative process privilege, and there is no legal basis for Defendants' refusal to produce such records in a timely manner.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Honorable Court:

1. Declare that the withholding of the records requested in the FOIA Requests by FDA and HHS is unlawful;
2. Order FDA and HHS to produce immediately and completely (including, but not limited to, unproduced records and unredacted copies of the produced records that were improperly redacted under claims of deliberative process privilege) the records requested in the FOIA Requests pursuant to 5 U.S.C. § 552(a)(4)(B);
3. Enjoin FDA and HHS from withholding the records requested in the FOIA Requests pursuant to 5 U.S.C. § 552(a)(4)(B);
4. Award Plaintiffs their litigation costs and attorney fees incurred in this action pursuant to 5 U.S.C. § 552(a)(4)(E)(i); and,

5. Grant such other and further relief as the Court deems just and proper.

Respectfully submitted,

THE JUDGE ROTENBERG EDUCATIONAL CENTER, INC. and PAUL E. PETERSON, PH.D.,

By their attorneys,

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Dated: October 10, 2017