UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE JUDGE ROTENBERG EDUCATIONAL CENTER, INC., *et al.*, *Plaintiffs*, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, *Defendants*.	Civil Action No. 1:17-cv-02092-BAH

JOINT STATUS REPORT

Pursuant to the Court's June 23, 2022 Minute Order in this matter, the parties, through their undersigned counsel, respectfully submit this Joint Status Report.

Procedural History

This action arises under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, and was brought by Plaintiffs, The Judge Rotenberg Educational Center, Inc. ("JRC"), The J.R.C. Parents and Friends Association, Inc., and Paul E. Peterson, Ph.D. (collectively, "Plaintiffs"), seeking to compel Defendants, the U.S. Food and Drug Administration ("FDA") and the U.S. Department of Health and Human Services (collectively, "Defendants"), to produce records responsive to Plaintiffs' nine detailed FOIA requests and concerning, among other issues: JRC; FDA's then-proposed rule banning electrical stimulation devices ("ESDs") used to treat self-injurious and aggressive behaviors; and the Graduated Electronic Decelerator ("GED") device, the ESD that JRC uses to treat the self-injurious and aggressive behaviors of some of its patients.

In 2018, this Court bifurcated the proceedings, separating those involving FDA's Center for Devices and Radiological Health ("CDRH") and all non-FDA components or agencies to

which Defendants had made a referral from those involving FDA's non-CDRH components [Feb. 2, 2018 Minute Order]. As to CDRH and the non-FDA components or agencies, the Court ordered Defendants to make a rolling production of no fewer than 5,000 pages per month every 60 days until production was complete [Feb. 2, 2018 Minute Order]. The Court further ordered the parties to file joint status reports with every production by Defendants [Feb. 2, 2018 Minute Order].

In 2019, the Court granted in part and denied in part the parties' respective cross-motions for summary judgment as to FDA's non-CDRH components [ECF Nos. 38-39]. After the Court issued its decision, the parties agreed that additional dispositive briefing would be required as to FDA's non-CDRH components [ECF No. 44 at 10], and Defendants later represented that CDRH and all non-FDA components and agencies to which a referral had been made had produced all records responsive to Plaintiffs' requests, which productions constituted the bulk of the productions made by Defendants to Plaintiffs [ECF No. 44 at 3-5; ECF No. 45 at 4].

In 2020, FDA published its final rule [ECF No. 48 at 2]. Plaintiffs and others petitioned for review of FDA's final rule in the U.S. Court of Appeals for the D.C. Circuit (the "Appeals"), and, in the Appeals, moved for discovery of certain records, including, but not limited to, unredacted copies of certain of the records at issue in this action (the "Discovery Motions") [ECF No. 52 at 2]. Plaintiffs, with the consent of Defendants, then moved to stay this action pending the resolution of the Appeals, explaining that the ultimate decision by the D.C. Circuit merits panel on the issues raised in the Discovery Motions and to be addressed in the merits briefs might obviate the need for or reduce the scope of further action by this Court [ECF No. 52 at 4]. The Court then stayed proceedings in this action [Aug. 24, 2020 Minute Order],

until fourteen (14) days after the D.C. Circuit's judgment in the Appeals became final [Sept. 22, 2021 Minute Order].

On July 6, 2021, the D.C. Circuit vacated FDA's final rule [ECF No. 54 at 3; ECF No. 54-1 at 2, 5-20]. The D.C. Circuit's judgment is now final [ECF No. 58 at 2]. Because the D.C. Circuit ruled in Plaintiffs' favor on the merits, it did not rule on the Discovery Motions in the Appeals.

On May 10, 2022, this Court extended the stay in this action through June 23, 2022, and directed the parties to file, by that date, a joint status report [May 10, 2022 Minute Order]. On June 23, 2022, the parties filed a joint motion to extend the time to file their joint status report, so that their counsel, including Defendants' newly re-appointed counsel, could discuss a comprehensive plan for the next phases of this litigation and, potentially, to reach an agreement as to some or all of those phases [ECF No. 60 at 1]. The Court granted the parties' motion, extended the stay in this action through July 14, 2022, and directed the parties to file, by that date, a joint status report advising the Court whether further proceedings are necessary and, if so, proposing a schedule to govern further proceedings in this matter [June 23, 2022 Minute Order].

Since the Court granted the parties' motion, their counsel have been in frequent communication via telephone and email, discussing and attempting to reach agreement on the recent developments and proposed schedule reported below.

Plaintiffs' Statement

Plaintiffs' Requested Further Review by FDA of 125 Redacted Records

On July 1, 2022, in an effort to narrow the issues in this action, Plaintiffs sent Defendants a list of 125 redacted records that Defendants had already produced in connection with this lawsuit, requesting that Defendants consider whether, in light of recent developments, they

would continue to withhold responsive information under Exemption 5 claims, 5 U.S.C. § 552(b)(5), which includes the deliberative process and attorney-client privileges. Specifically, Plaintiffs observed that Defendants initially withheld the redacted information at a time when FDA's proposed or final rule was pending, and, now that the D.C. Circuit vacated the final rule, Plaintiffs expected FDA to have a diminished interest in continuing to withhold records concerning that rule. Plaintiffs further observed that Defendants' redactions pre-date the Attorney General's recently issued FOIA memorandum, a copy of which is attached hereto as **Exhibit 1**, which instructs that, even if responsive information falls within a FOIA exemption, Defendants may only withhold it if they reasonably foresee that disclosure would harm an interest protected by a FOIA exemption, which harms do not include speculative or abstract fears or fears of embarrassment.

Defendants subsequently requested, and Plaintiffs agreed to provide by July 22, 2022, the redacted versions of the documents on Plaintiffs' list that are currently in Plaintiffs' possession. FDA has agreed to then review the documents on Plaintiffs' list for potential further releases of information. The parties have also agreed to file a further Joint Status Report concerning these documents by October 3, 2022.

Plaintiffs' 2022 FOIA Request and Motion to Amend

Plaintiffs understand that, after the D.C. Circuit issued its decision and judgment, FDA began lobbying Congress to legislatively reverse the D.C. Circuit's decision and grant FDA authority to ban ESDs used to treat self-injurious and aggressive behaviors and/or to enact a legislative ban. Thus, by letter dated March 28, 2022, JRC submitted a new FOIA request to FDA (the "2022 Request"), a copy of which is attached hereto as **Exhibit 2**. FDA has not yet produced any new records responsive to the 2022 Request.

For this reason, Plaintiffs believe they will once again require the assistance of this Court in compelling FDA to release records responsive to the 2022 Request in a timely manner. Plaintiffs view this FOIA lawsuit as a critical means of exercising their right to understand "what [FDA] is up to" now. Specifically, Plaintiffs believe this FOIA lawsuit will reveal that FDA is selectively sharing with Congress only certain records controlled by FDA and allegedly supportive of FDA's attempted ban while withholding information and evidence supporting the safety and efficacy of JRC's GED devices and demonstrating Defendants' bad faith regulatory actions against Plaintiffs.

Plaintiffs further believe that this Court, as the Court with the most comprehensive knowledge concerning the parties and the issues involved in Plaintiffs' requests and Defendants' responses, should review FDA's response to the 2022 Request. Rather than filing a new complaint concerning the 2022 Request and then moving to consolidate the new action with this one, it would be far more efficient for the Court and all parties if Plaintiffs were to move to amend their Complaint in this action. The 2022 Request is nearly identical to Plaintiffs' first six requests and seeks records for years subsequent to those six requests; it is directed to FDA and simply seeks more recent records concerning the same subject matters. Plaintiffs also expect that FDA will attempt to withhold significant portions of the records responsive to the 2022 Request by citing the deliberative process and attorney-client privileges, which were the primary bases Defendants cited to withhold records responsive to Plaintiffs' initial requests. For all of these reasons, Plaintiffs anticipate moving to amend their Complaint to include a claim concerning JRC's 2022 Request.

Defendants previously "request[ed] that summary judgment briefing be held in abeyance while [a possible] motion [to amend] is pending" and, if the Court granted Plaintiffs' possible

motion, that "the Court set a production schedule and defer all summary judgment briefing until the production is complete" because "proceeding in this manner is more efficient and avoids multiple rounds of summary judgment" [ECF No. 48 at 4-5]. Plaintiffs agree, as reflected in their below proposed schedule. While Defendants now take a different position, their proposed deadlines leave time for briefing a motion to amend in accordance with Plaintiffs' proposed schedule while Defendants review for possible further disclosures the 125 documents on Plaintiffs' list. Plaintiffs note that while Defendants essentially briefed their opposition to Plaintiffs' motion to amend below, Plaintiffs have simply provided a proposed timeline for the orderly briefing of that motion and reserve their arguments in support of that motion to the motion itself.

Because the D.C. Circuit has concluded its review of FDA's now-vacated final rule, Plaintiffs believe that it is now appropriate to end the parties' agreed-upon stay and that this matter is now ripe for a scheduling order to govern further proceedings. In view of these recent developments, Plaintiffs thus propose the following schedule, which accounts for the above-described recent developments and which would efficiently move this litigation forward in an orderly manner:

- July 22, 2022: Plaintiffs provide Defendants with their current copies of the 125 records on Plaintiffs' July 1, 2022 list of records.
- August 19, 2022: Plaintiffs serve and file a motion to amend their complaint and their amended complaint concerning JRC's 2022 Request.
- September 16, 2022: Defendants serve and file any opposition to Plaintiffs' motion to amend their complaint.

- September 30, 2022: Plaintiffs file any reply in support of their motion to amend their complaint.
- October 3, 2022: Defendants provide Plaintiffs with a response to Plaintiffs' July 1, 2022 request, including any less redacted copies of the 125 records that Defendants determine are now appropriate for release, and the parties file a Joint Status Report.

If the Court allows Plaintiffs' motion to amend their complaint:

- October 31, 2022: Defendants begin making rolling productions of no fewer than 5,000 pages per month to Plaintiffs every 60 days until production of records responsive to JRC's 2022 Request is complete. The parties begin filing joint status reports with every production by Defendants.
- After Defendants' production of records responsive to JRC's 2022 Request is complete: The parties will propose a consolidated summary judgment briefing schedule concerning all productions by Defendants responsive to all of Plaintiffs' requests.

If the Court denies Plaintiffs' motion to amend their complaint:

- November 30, 2022: Plaintiffs serve and file any dispositive motion or cross-motion and any opposition to Defendants' pending dispositive motion, and, if Plaintiffs have not already done so, up to 100 of the records included in the sample *Vaughn* index in the redacted form in which Defendants produced such records to Plaintiffs for *in camera* review (per the parties' previous agreement [ECF No. 44 at 10, 12]).
- January 13, 2023: Defendants serve and file any reply in support of their pending dispositive motion and/or any opposition to Plaintiffs' dispositive motion and/or cross-motion, and, if Defendants have not already done so, the original, unredacted versions of the records that Plaintiffs filed with the Court for *in camera* review.

- February 10, 2023: Plaintiffs serve and file any reply in support of their dispositive motion and/or cross-motion.

Defendants' Statement

The Purpose of FOIA Litigation is Not to Advance Plaintiffs' Lobbying Efforts.

This FOIA action was initiated by Plaintiffs to obtain records related to FDA's proposed, and eventual final, rule to ban ESDs used to treat self-injurious or aggressive behavior under FDA's authority to ban devices under 21 U.S.C. § 360f. After the D.C. Circuit ruled in Plaintiffs' favor on the merits (vacating FDA's ban of ESDs used to treat self-injurious or aggressive behavior), Plaintiffs' purpose for this FOIA action became compelling FDA into a "global resolution" of "various issues remaining between the parties." [ECF No. 58 at 3 ("If the parties are able to reach an agreed-upon global resolution, there will be no need for Plaintiffs to continue seeking in this action the responsive records that Defendants continue to withhold and thus no need for further proceedings in this action.")]. Plaintiffs sent to FDA "a letter proposing resolution" to those "various issues," [*id.*] and, while that letter addressed numerous issues, none related to the FOIA or specific exemptions asserted by FDA in this case. Because FDA did not agree to those terms or acquiesce to Plaintiffs' "global resolution" approach, Plaintiffs now have further distanced themselves from FDA's statutory duties, FDA's authority to regulate medical devices, the FOIA, or any judicial economies that might result from any "global resolution." Instead, Plaintiffs have shown they are utilizing this litigation to advance another purpose: as a "critical means of obtaining records necessary to defend against FDA's lobbying efforts." This is based on Plaintiffs' "understanding" that FDA "began lobbying Congress" related to that vacated ESD ban. Plaintiffs admit that they are using the FOIA not to better understand FDA's performance of its statutory duties but, instead, to probe Plaintiffs' "belief" that FDA did not

adequately represent Plaintiffs' interests to Congress. This new purpose is an improper use of FOIA and does not justify amendment of the Complaint.

Using FOIA to advance lobbying efforts "does not relate to 'the only relevant public interest in the FOIA balancing analysis'—the extent to which disclosure would shed light on the 'agency's *performance of its statutory duties*.'" *Nat'l Ass'n of Home Builders v. Norton*, 309 F.3d 26, 36 (D.C. Cir. 2002) (emphasis added). Indeed, the D.C. Circuit has recognized that a requester's desire to advance its lobbying efforts does not relate to a citizen's "right to be informed about 'what their government is up to.'" *Id.* (discussing *Dep't of Just. v. Reports Comm. for Freedom of Press*, 489 U.S. 749, 773 (1989)). Whatever lobbying efforts in which Plaintiffs may wish to engage as part of the current legislative process bear no relation to the FOIA requests at issue in *this* lawsuit. Moreover, neither Plaintiffs nor Defendants have any authority to decide what action, if any, Congress or other legislative bodies might take to regulate ESDs. Indeed, if Plaintiffs are concerned that Congress is mis- or ill-informed about their ESDs, Plaintiffs can submit information to Congress.

Amendment of the Complaint to Include the 2022 Request is Inappropriate.

Plaintiffs filed this litigation in October 2017. Nearly five years later, long after Defendants have produced all responsive records and filed their opening motion for summary judgment, Plaintiffs now want to prolong this litigation and delay any final resolution by amending their Complaint to include a new FOIA request. In their joint motion for extension of time filed on June 23, 2022, the parties represented they "require additional time to discuss the next steps in this litigation" [ECF No. 60 at 1]. Plaintiffs made no mention of seeking leave to amend their Complaint at that time. Instead, Plaintiffs' counsel raised the issue via e-mail on June 30, 2022, explaining that amending the Complaint was "necessary to compel further

disclosures by FDA" because Plaintiffs "understand that FDA is still engaged in efforts to have JDC's device banned." **Exhibit 3**. This is not the first time Plaintiffs have contemplated expanding the scope of this litigation to include FOIA requests that are not part of the case. [*See* ECF No. 48 at 3-5 & n.1 (addressing Plaintiffs' anticipated motion to compel production of records responsive to 2018 and 2019 FOIA requests)].

Plaintiffs' assertion that FDA has taken a different approach regarding whether to hold summary judgment briefing in abeyance pending Plaintiffs' possible motion to amend the complaint is misleading. In the parties' March 25, 2022, joint status report, Plaintiffs asserted a need to file a motion to compel records response to FOIA requests that were not the subject of this litigation but to which FDA had responded. [ECF No. 48 at 3 & n.1]. In response, FDA stated that because the FOIA requests subject to this potential motion to compel were not included in the complaint filed in this action, it would be improper for Plaintiffs to move to compel records in response to those requests and that, to the extent Plaintiffs attempted to add those requests to the case through a motion to amend the complaint, FDA reserved the right to oppose that motion. [*Id.* at 4]. However, given the uncertainty of what Plaintiffs would ultimately do, and with a May 4, 2020, summary judgment deadline approaching at that time, [*see, e.g.*, ECF No. 45 at 7], FDA made the reasonable request to stay this deadline pending the Court's consideration of any motion to amend filed by Plaintiffs. [*Id.*] This posture is vastly different than the present, where Plaintiffs want to amend the complaint years after this litigation was filed to add a new 2022 FOIA request to which FDA has not responded, after the government has already briefed summary judgment, and after the substantive issue (the ESD ban) has been vacated. The Court should reject Plaintiffs' latest effort.

Plaintiffs' asserted justifications for amending their Complaint at this late stage in the

proceedings and evading a response to Defendants' summary judgment motion—filed over two years ago [*see* ECF No. 50]—are devoid of merit. First, as discussed above, utilizing FOIA to advance Plaintiffs' lobbying efforts is not appropriate. Second, whether this Court has "the most comprehensive knowledge" of "the issues involved" in the FOIA requests at issue here is irrelevant. The Court's "comprehensive knowledge" of issues in this case has no bearing on any issues associated with Plaintiffs' 2022 Request, which constitutes a new request addressing different records. Instead, it suggests the appearance of forum shopping. If requesters were permitted to amend their pleadings each time they submitted a new FOIA request, then pending FOIA litigation addressing earlier, separate requests could continue indefinitely. Furthermore, Plaintiffs' conjecture that FDA may also invoke Exemption 5 in response to Plaintiffs' 2022 Request does not justify amendment to include Plaintiffs' 2022 Request simply because FDA previously invoked Exemption 5 with regard to different records that are currently at issue in this case. The application of any one or multiple FOIA exemptions in response to a specific request has no relationship to an agency's invocation of similar exemptions in response to any other request. Plaintiffs' desire to amend is contrary to how the Court adjudicates FOIA litigation and inconsistent with the mandate in Federal Rule of Civil Procedure 1 that the Court and litigants "secure the just, speedy, and inexpensive determination of every action and proceeding." Fed. R. Civ. P. 1. Briefing a motion to amend diverts the Court's limited resources from resolving the substantive issues in this case and unnecessarily increases the costs and inefficiencies of this litigation.

Third, Plaintiffs' suggestion that amendment is more efficient than "filing a new complaint concerning the 2022 Request and then moving to consolidate the new action with this one" is flawed. Consolidation is not available to Plaintiffs. The Court may consolidate cases

involving "common questions of law or fact." Fed. R. Civ. P. 42(a). When exercising its discretion to consolidate, courts weigh the risk of prejudice and confusion wrought by consolidation "against the risk of inconsistent rulings on common factual and legal questions, the burden on the parties and the court, the length of time, and the relative expense of proceeding with separate lawsuits if they are not consolidated." *Singh v. Carter*, 185 F. Supp. 3d 11, 18 (D.D.C. 2016). FOIA-related consolidation cases are uncommon. *Am. Oversight v. Dep't of Health & Human Servs.*, Civ. A. No. 20-0947 (TNM), 2020 WL 3469687, at *1 (D.D.C. June 25, 2020). Among the several factors identified by the *American Oversight* court that inform a consolidation determination is "whether the cases have a common procedural posture." *Id.* (citing *Nat'l Sec'y Counselors v. CIA*, 322 F.R.D. 41 (D.D.C. 2017)). That factor alone militates against consolidation.

Here, Defendants completed production of all responsive records and filed a summary judgment motion to which Plaintiffs have yet to respond. As Plaintiffs acknowledge, FDA has "not yet produced any new records responsive to the 2022 Request" that would be the subject of a separate lawsuit and consolidation request. Indeed, Plaintiffs ask this Court to delay indefinitely briefing on Defendants' summary judgment motion and instead order Defendants to make "rolling productions of no fewer than 5,000 pages per month to Plaintiffs every 60 days until production of records responsive to JRC's 2022 Request is complete." By Plaintiff's own admission, a new lawsuit addressing the 2022 Request would be in a completely different procedural posture that does not warrant consolidation. Consequently, Plaintiffs cannot make any showing that consolidation of any new lawsuit addressing the 2022 Request with this case is appropriate. There is no basis for consolidation.

In the event Plaintiffs desire to litigate their 2022 Request, Plaintiffs should file a

separate lawsuit and the parties can negotiate in that proceeding an appropriate schedule for processing and production of responsive records. How that theoretical case develops has no bearing upon these proceedings. Accordingly, the Court should decline Plaintiffs' invitation to litigate a motion to amend.

Plaintiffs' List of 125 Redacted Records

Although the Attorney General's FOIA memorandum "is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or equity by any party against the United States, its departments, agencies, instrumentalities or entities, its officers, employees, agents, or any other person," Mem. at 4 n.3, *available at* https://www.justice.gov/ag/page/file/1483516/download (last visited July 14, 2022), FDA is willing to review Plaintiffs' list of 125 redacted records as part of a good-faith effort to narrow the remaining issues in this case. Defendants are amenable to Plaintiffs' proposal that Plaintiffs provide current copies of these records by July 22, 2022. Defendants propose that they be afforded sufficient time to review these records and engage in further discussions with Plaintiffs. Accordingly, Defendants request that the parties file another joint status report by October 3, 2022.

Proposed Briefing Schedule on Defendants' Summary Judgment Motion

If any issues remain unresolved after review of Plaintiffs' list of 125 redacted records, then Defendants are amenable to the summary judgment briefing schedule Plaintiffs proposed above under the subheading "If the Court denies Plaintiffs' motion to amend their complaint."

Dated: July 14, 2022

The Judge Rotenberg Educational Center, Inc. and Paul E. Peterson, Ph.D.,

/s/ Edward J. Longosz, II
Edward J. Longosz, II (D.C. Bar No. 368932)
ECKERT SEAMANS CHERIN & MELLOTT,LLC
1717 Pennsylvania Avenue, Northwest,
12th Floor,
Washington, D.C. 20006
T: (202) 659-6619
F: (202) 659-6699
elongosz@eckertseamans.com

Michael P. Flammia (*Pro Hac Vice*)
ECKERT SEAMANS CHERIN & MELLOTT,LLC
2 International Place, 16th Floor
Boston, MA 02110
T: (617) 342-6854
F: (617) 342-6899
mflammia@eckertseamans.com

The J.R.C. Parents and Friends Association, Inc. and Paul E. Peterson, Ph.D.,

/s/ Max D. Stern
Max D. Stern (*Pro Hac Vice*)
TODD & WELD, LLP
1 Federal Street
Boston, MA 02110
T: (617) 624-4712
F: (617) 227-5777
mdstern@toddweld.com

Attorneys for Plaintiffs

Respectfully submitted,

MATTHEW M. GRAVES
D.C. Bar #481052
United States Attorney

BRIAN P. HUDAK
Chief, Civil Division

By: /s/ DRAFT

Robert A. Caplen, D.C. Bar #501480
Assistant United States Attorney
U.S. Attorney's Office, Civil Division
601 D Street, N.W.
Washington, D.C. 20530
(202) 252-2523
robert.caplen@usdoj@usdoj.gov

Attorneys for Defendants

CERTIFICATE OF SERVICE

I hereby certify that service of the foregoing joint motion has been made through the Court's electronic transmission facilities on this date.

/s/ Edward J. Longosz, II
Edward J. Longosz, II

Dated: July 14, 2022