376 F.Supp.3d 47 (2019)

JUDGE ROTENBERNG EDUCATIONAL CENTER, INC. et al., Plaintiffs,
v.
U.S. FOOD AND DRUG ADMINISTRATION and U.S. Department of Health and Human Services, Defendants.

Civil Action No. 17-2092 (BAH).

United States District Court, District of Columbia.

Signed March 21, 2019.

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William Mark Nebeker, U.S. Attorney's Office for the District of Columbia, Washington, DC, for Defendants.

MEMORANDUM OPINION

BERYL A. HOWELL, Chief Judge.

Judge Rotenberg Educational Center, Inc. ("JRC") is described as a non-profit treatment center for "patients who engage in self-injurious and aggressive behaviors." Compl. ¶ 4, ECF No. 1. For some patients, JRC's treatment regimen includes use of the Graduated Electronic Decelerator ("GED"), which is an "electrical stimulation device." *Id.* ¶ 1. In 2016, the Food and Drug Administration ("FDA"), a division of the Department of Health and Human Services ("HHS"), published a proposed rule that would ban use of the GED. *See* Proposal to Ban Electrical Stimulation Devices Used to Treat Self-Injurious or Aggressive Behavior ("Proposed Ban"), 81 Fed. Reg. 24,386 (Apr. 25, 2016). Following publication of the Proposed Ban, JRC, as well as JRC Parents and Friends Association, Inc. ("Parents Association"), and Paul E. Peterson, who is the father of an adult patient at JRC and himself a member of the Parents Association (collectively, the plaintiffs), submitted requests under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, to the FDA for records related to, among other things, the Proposed Ban, *see* Compl. ¶¶ 23, 35, 48.

Now, the defendants—the FDA and HHS—claim to have partially completed their response to the plaintiffs' FOIA requests by producing, with appropriate withholdings, all responsive records.[1] The plaintiffs, however, argue that the defendants have failed to justify, or misapplied, FOIA's production exemptions in withholding certain responsive records and have otherwise withheld documents without any statutory authority. Accordingly, the parties have cross-moved for partial summary judgment. Defs.' Mot. Partial Summ. J. ("Defs.' Mot."), ECF No. 25; Pls.' Cross-Mot. Partial Summ. J. ("Pls.' Cross-Mot."), ECF No. 30. For the reasons set forth below, both the defendants' motion and the plaintiffs' cross-motion are granted in part and denied in part.

I. BACKGROUND

This section summarizes the regulatory history of the JRC's GED, the plaintiffs' FOIA requests, the defendants' response to those requests, and the current litigation posture in this case.

A. THE FDA'S RULEMAKING FOR ELECTRICAL STIMULATION DEVICES

"JRC is a residential program" that treats patients "who engage in severe problem behaviors, including self-injurious behavior ... and aggressive behavior." Pls.' Statement of Material Facts As To Which There Is No Genuine Dispute ("Pls.' SMF"), ¶ 1, ECF No. 30 (citing Decl. of Glenda P. Crookes, Executive Director of JRC ("JRC E.D. Decl.") ¶ 3, ECF No. 28-1). Forty-eight of JRC's patients, "all of whom engage in life threatening 54*54 and treatment-resistant" self-injurious behavior, are treated with the GED, which is an "electrical stimulation device." *Id.* (citing JRC E.D. Decl. ¶ 3). For each patient, a probate judge has determined that electrical stimulation "is the most effective, least-restrictive treatment for [the patient's] severe behaviors." *Id.* (citing JRC E.D. Decl. ¶ 3).

JRC's treatment methods have been on the FDA's radar for nearly three decades. In 1991, JRC applied to the FDA for pre-market clearance, also known as 510(k) clearance, for the first version of the GED. *Id.* ¶ 3 (citing FOOD & DRUG ADMIN., *Premarket Notification 510(k),* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K911820 (last visited Mar. 21, 2019)). "A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device," and is required when a manufacturer intends to introduce a medical device into distribution for the first time, or to introduce a device that has undergone changes since the previous clearance that might affect the device's safety or effectiveness. FOOD & DRUG ADMIN., *510(k) Premarket Notification 510(k),* https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNoti fication510k/default.htm (last visited Mar. 20, 2019). JRC received that clearance in 1994. Pls.' SMF ¶ 3 (citing FOOD & DRUG ADMIN., *Premarket Notification 510(k),* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K911820 (last visited Mar. 21, 2019)). In 2000, after JRC had substantially modified the GED, the FDA, following an inspection of JRC's premises, advised that JRC need not obtain a new 510(k) clearance. *Id.* ¶ 5 (citing Decl. of Matthew D. Rodgers, plaintiffs' counsel ("Pls.' Decl."), Ex. 34, ECF Nos. 28-2 & 28-3).

A decade later, the FDA notified JRC that, although the FDA told JRC in 2000 that "GED devices were exempt from the 510(k) requirement ... [w]e have learned that this is not accurate." Pls.' Decl., Ex. 37; *see also* Pls.' SMF ¶ 8. The FDA explained that GEDs are "devices" under the Food, Drug and Cosmetic Act and must receive 510(k) clearance before marketing. Pls.' Decl., Ex. 37. Thus, the JRC was told to submit new 510(k) paperwork for the GED because of modifications made since 1994. Pls.' Decl., Ex. 37; *see also* Pls.' SMF ¶ 8.

At the FDA's request, JRC provided a "pre-submission" in February 2013 in anticipation of JRC's eventual 510(k) application. Pls.' SMF ¶ 13 (citing Pls.' Decl., Ex. 1). The parties set a meeting for March 25, 2013 to discuss the pre-submission, but the FDA cancelled the meeting shortly before the scheduled date. *Id.* ¶¶ 13-14 (citing Pls.' Decl., Ex. 2). Around the same time, the FDA met with "anti-aversive advocacy groups" and several former JRC patients. *Id.* ¶¶ 15-16 (citing Pls.' Decl., Ex. 12).

For the year between March 2013 and April 2014, the FDA and JRC representatives did not communicate. *Id.* ¶ 20 (citing JRC E.D. Decl. ¶ 7). In April 2014, JRC received notice that a committee of the FDA's Center for Devices and Radiological Health ("CDRH") had organized a panel on neurological devices, which panel convened on April 24, 2014, *id.* (citing JRC E.D. Decl. ¶ 7), and heard testimony, *inter alia,* from two former JRC patients and one former JRC employee, *id.* ¶ 21 (citing Pls.' Decl., Ex. 21). The panel was divided on the health benefits of the GED. *Id.* ¶ 22 (citing Proposed Ban, 81 Fed. Reg. at 24401).

Two years after the panel convened, the FDA, on April 25, 2016, published the Proposed 55*55 Ban, which, if finalized, would prohibit JRC's use of the GED. *Id.* ¶ 25 (citing Proposed Ban, 81 Fed. Reg. at 24,393). The FDA has not published a final rule. *Id.* ¶ 27.

B. THE PLAINTIFFS' FOIA REQUESTS

Nearly three months after the FDA published the Proposed Ban, Peterson submitted, on July 19, 2016, six identical FOIA requests to the FDA and five FDA components ("First Request"). Defs.' Statement Of Material Facts As To Which There Is No Genuine Issue ("Defs.' SMF") ¶ 2 (citing Compl., Exs. A-1-A-6, ECF Nos. 1-1-1-6). The First Request asked for records about, among other things, "FDA inspections of JRC; the Neurological Devices Panel of the Medical Devices Advisory Committee; and FDA's proposed ban of [electrical stimulation devices]." *Id.* (citing Compl., Exs. A-1-A-6, ECF Nos. 1-1-1-6). The FDA, consistent with internal regulations, consolidated these requests for processing. *Id.* ¶ 3 (citing First Decl. of Sarah Kotler, Division of Freedom of Information ("First DFOI Decl.") ¶ 15, ECF No. 24-2).

Peterson sent two additional FOIA requests to the FDA on August 23, 2016. One of these requests sought, among other things, records dating back to 2012 of meetings between FDA employees and stakeholders in electrical stimulation devices; of communications between the FDA and other divisions of HHS about electrical stimulation devices; of literature analyzing electrical stimulation devices that the FDA received or created; and of communications or records between FDA employees and former patients of JRC. *Id.* ¶ 4 (citing Compl., Ex. F ("Second Request"), ECF No. 1-11). The other request sought "materials related to expert opinions from three individuals about electrical stimulation devices." *Id.* ¶ 5 (citing Compl., Ex. H ("Third Request"), ECF No. 1-13).

Finally, on December 27, 2016, JRC submitted a letter that the FDA treated as a FOIA request ("Fourth Request"), in which JRC sought "information related to statements made in FDA's Federal Register notice announcing a proposed ban on electrical stimulation devices." *Id.* ¶ 6 (citing Compl., Ex. J, ECF No. 1-15). The Parents Association sent a letter

on February 27, 2017, joining the Fourth Request. Pls.' SMF ¶ 33 (citing Compl., Ex. M, ECF No. 1-8).

C. THE FDA'S PROCESSING OF THE PLAINTIFFS' FOIA REQUESTS

When the FDA receives a FOIA request, the FDA's Division of Freedom of Information ("DFOI"), the unit responsible for the FOIA compliance, directs the request to the FDA components most likely to possess responsive records. Defs.' SMF ¶¶ 7, 11 (citing First DFOI Decl. ¶¶ 7, 11). DFOI also is tasked with locating any responsive records that have been previously produced in response to separate FOIA requests. *Id.* ¶ 12 (citing First DFOI Decl. ¶ 11).

After receiving the plaintiffs' four FOIA requests, DFOI distributed the First, Second and Fourth Requests to four FDA components: the Office of the Chief Counsel ("OCC"), the New England District Office, the CDRH's Division of Information Disclosure, and the Office of Regulatory Affairs ("ORA"), so that each could search for responsive documents. *Id.* ¶¶ 16-19 (citing First DFOI Decl. ¶¶ 22-25). In addition, two HHS divisions outside the FDA agreed to produce records responsive to the First, Second, and Fourth Requests. *Id.* ¶ 20 (citing First DFOI Decl. ¶ 26). The Third Request was directed only to the CDRH's Division of Information 56*56 Disclosure. *Id.* ¶ 18 (citing First DFOI Decl. ¶ 24). From September 2016 through July 2018, HHS and multiple FDA components produced records to the plaintiffs, as summarized below.

DFOI made five separate productions to the plaintiffs: on September 7 and 28, 2016, *id.* ¶¶ 21, 23, 24 (citing First DFOI Decl. ¶¶ 31-34); on February 13, 2018, *id.* ¶ 30 (citing First DFOI Decl. ¶ 27); and on July 2 and 11, 2018, *id.* ¶ 28 (citing First DFOI Decl. ¶ 38). In total, DFOI produced roughly 10,000 pages of redacted records.

The OCC, for its part, made three productions of its own records to the plaintiffs on the following dates: December 4 and 22, 2017, *id.* ¶¶ 40, 45, 51 (citing Decl. of David Mednick, Office of the Chief Counsel ("OCC Decl.") ¶¶ 17, 24, 31, ECF No. 24-4); and March 5, 2018, *id.* ¶ 53 (citing OCC Decl. ¶ 33). All told, the plaintiffs received, with redactions, "a total of over 2,800 pages of OCC records." *Id.* ¶ 58 (citing OCC Decl. ¶ 38). Separately, the OCC produced, on March 19, June 13, and June 18, 2018, after consultation with the Department of Justice ("DOJ"), redacted records that had originated within DOJ. *Id.* ¶¶ 39, 41, 44, 46, 52, 55 (citing OCC Decl. ¶¶ 16, 18, 25, 32, 35). Likewise, the OCC released, on April 3, and May 14, 2018, after consultation with separate HHS divisions, 26 pages and 58 pages, respectively, of redacted records that originated within those divisions. *Id.* ¶¶ 41, 56, 73, 75 (citing OCC Decl. ¶¶ 19, 36; Decl. of Michael S. Marquis, Department of Health and Human Services ("HHS Decl.") ¶¶ 7, 8, ECF No. 24-3). Finally, the OCC provided, on February 13, 2018, after consultation with the Department of State ("State"), redacted records that originated with State. *Id.* ¶¶ 47, 54 (citing OCC Decl. ¶¶ 26, 34).

The New England District Office, too, had responsive records. That office made four productions to the plaintiffs on the following dates: on September 26, 2016, of 16 redacted pages, *id.* ¶¶ 60, 61 (citing First Decl. of Barbara A. Recupero, New England District Office

("First NE-DO Decl.") ¶ 11, 12, ECF No. 24-7); on May 2, 2018, of 562 redacted pages, *id.* ¶ 65 (citing First NE-DO Decl. ¶ 18); and on June 15 and June 20, 2018, totaling 10,205 redacted pages, *id.* (citing First NE-DO Decl. ¶ 18).

The ORA made two productions to the plaintiffs: on June 4, 2018, of 10 redacted pages, *id.* ¶ 71 (citing Decl. of Melissa Pickworth, Office of Regulatory Affairs ("ORA Decl.") ¶ 14, ECF No. 24-6); and on June 29, 2018, of 372 pages of redacted records, *id.* (citing ORA Decl. ¶ 14).

Two HHS divisions outside the FDA produced records to the plaintiffs beyond the records released in consultation with the OCC. The first division—the Office of the Secretary—released 756 pages of redacted records, identified through an internal search, on June 15, 2018. *Id.* ¶ 78 (citing HHS Decl. ¶ 14). The second division—the Administration for Community Living—provided the plaintiffs, on July 6, 2018, with 485 pages of redacted records. *Id.* ¶ 82 (citing First Decl. of Richard Nicholls, Administration for Community Living ("First Community Living Decl.") ¶ 11, ECF No. 24-5).

In total, HHS divisions, both inside and outside the FDA, but excluding the CDRH, have produced 24,241 pages of records to date. Pls.' SMF ¶ 39. Of those pages, approximately 12,642 pages were redacted in full, *id.* ¶ 42, and another 1,340 pages were redacted in part, *id.* ¶ 44.

D. THE LITIGATION HISTORY

The FDA now has produced over 24,000 pages, largely spurred on by the plaintiffs' instant lawsuit. Indeed, from the plaintiffs' submission of four FOIA requests between July and December 2016, to their initiation 57*57 of this lawsuit in October 2017, *see* Compl., the defendants had released only 92 pages of records, Pls.' SMF ¶ 35.

Shortly after the plaintiffs' filed their complaint, and after the Court instructed the parties to propose a briefing schedule to govern proceedings in this case, Min. Order (Dec. 7, 2017), the defendants started releasing records to the plaintiffs, as described *supra* in Section I.C. By January 2018, the defendants claimed that all FDA divisions other than the CDRH, which had not yet started releasing responsive documents, had responded in full to the plaintiffs' FOIA requests, *see* Suppl. Joint Meet & Confer Report at 8, ECF No. 16, a plainly erroneous claim given the productions subsequently made throughout 2018. At that time, the CDRH estimated that its search had uncovered roughly 60,000 pages of records responsive to the plaintiffs' requests. *Id.* at 9.

The apparent semi-complete nature of the production was too great an obstacle for the parties to agree on a schedule to govern proceedings in this case, *see generally id.,* prompting the need for a status conference to accomplish that case management task, Min. Order (Jan. 19, 2018) (scheduling status conference); Min. Order (Jan. 25, 2018) (re-scheduling status conference). Following the February 2, 2018 status conference, the case was bifurcated. "CDRH and any other HHS component to which a referral has been made" were ordered to "make a rolling production of no fewer than 5,000 pages per month to the plaintiffs, beginning on March 1, 2018, and continuing every sixty days thereafter until production is complete." Min. Order (Feb. 2, 2018). Separately, the Court entered a

scheduling order setting a deadline for the other defendants to file an index of documents withheld in full or in part—known as a *Vaughn* Index, *see* Vaughn v. Rosen, 484 F.2d 820 (D.C. Cir. 1973)—and deadlines for the parties to file dispositive motions "as to issues arising from the responses by each FDA component other than the [CDRH]." Min. Order (Feb. 2, 2018).

The defendants filed their first *Vaughn* index by the initial deadline. *See* Original *Vaughn* Index, ECF No. 19-1. By agreement of the parties, however, *see* Joint Mot. Revise & Extend Scheduling Order, ECF No. 20, the scheduling order was modified to set a new deadline for an updated *Vaughn* index and the filing of dispositive motions, *see* Min. Order (Mar. 29, 2018). After additional extensions, the defendants moved for partial summary judgment, *see* Defs.' Mot., and provided an updated *Vaughn* Index, *see* Updated *Vaughn* Index ("2nd Index"), ECF No. 24-9. That index, totaling 1,929 pages, gives a Bates-stamp number, description, date, author, recipients, the basis for withholdings, and the number of pages fully withheld, for all records withheld in full or in part. *Id.* The index confirms that the defendants have withheld records under three FOIA Exemptions: (1) FOIA Exemption 5's deliberative-process privilege and attorney-client privilege, 5 U.S.C. § 552(b)(5); (2) Exemption 6's shield for personnel, medical and similar files, "the disclosure of which would constitute a clearly unwarranted invasion of personal privacy," *id.* § 552(b)(6); and (3) Exemption 7(c)'s protection for law enforcement records that "could reasonably be expected to constitute an unwarranted invasion of privacy," *id.* § 552(b)(7)(C), a narrower category of records implicating personal privacy interests than Exemption 6.

After the plaintiffs filed their cross-motion for summary judgment, *see* Pls.' Cross-Mot., the defendants filed a third version of the *Vaughn* Index, 50 pages longer than the prior version, which corrected some problems that the plaintiffs 58*58 had identified. *See* Suppl. *Vaughn* Index ("3rd Index"), ECF No. 33-2. That index is 1,979 pages and, like the prior versions, gives for most withheld documents a Bates-stamp number, a description, the document's date, author and recipients, whether the document was withheld in part or in full, the basis for any withholding, and the number of pages fully withheld. *Id.*

The parties' cross motions for summary judgment are now ripe for resolution.[2]

II. LEGAL STANDARD

Under Federal Rule of Civil Procedure 56, summary judgment shall be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). "In FOIA cases, `summary judgment may be granted on the basis of agency affidavits if they contain reasonable specificity of detail rather than merely conclusory statements, and if they are not called into question by contradictory evidence in the record or by evidence of agency bad faith.'" *Judicial Watch, Inc. v. U.S. Secret Serv.*, 726 F.3d 208, 215 (D.C. Cir. 2013) (quoting *Consumer Fed'n of Am. v. U.S. Dep't of Agric.*, 455 F.3d 283, 287 (D.C. Cir. 2006)); *see also Students Against Genocide v. Dep't of State*, 257 F.3d 828, 833 (D.C. Cir. 2001) ("[A]n agency is entitled to summary judgment if no material facts are in dispute and if it demonstrates `that each document that falls within the class requested either has been

produced ... or is wholly exempt from the Act's inspection requirements.'" (quoting *Goland v. CIA*, 607 F.2d 339, 352 (D.C. Cir. 1978))). Most FOIA cases will be resolved on summary judgment. *Brayton v. Office of the U.S. Trade Rep.*, 641 F.3d 521, 527 (D.C. Cir. 2011).

FOIA was enacted "to promote the `broad disclosure of Government records' by generally requiring federal agencies to make their records available to the public on request." *DiBacco v. U.S. Army*, 795 F.3d 178, 183 (D.C. Cir. 2015) (quoting *U.S. Dep't of Justice v. Julian*, 486 U.S. 1, 8, 108 S.Ct. 1606, 100 L.Ed.2d 1 (1988)). To balance the public's interest in governmental transparency and "legitimate governmental and private interests that could be harmed by release of certain types of information," *United Techs. Corp. v. U.S. Dep't of Def.*, 601 F.3d 557, 559 (D.C. Cir. 2010) (quoting *Critical Mass Energy Project v. Nuclear Regulatory Comm'n*, 975 F.2d 871, 872 (D.C. Cir. 1992) (*en banc*) (alterations omitted)), FOIA has nine exemptions, set forth in 5 U.S.C. § 552(b), which "are explicitly made exclusive and must be narrowly construed," *Milner v. Dep't of Navy*, 562 U.S. 562, 565, 131 S.Ct. 1259, 179 L.Ed.2d 268 (2011) (internal quotation marks and citations omitted). "[T]hese limited exemptions do not obscure the basic policy that disclosure, not secrecy, is the dominant objective of the Act." *Dep't of Air Force v. Rose*, 425 U.S. 352, 361, 96 S.Ct. 1592, 48 L.Ed.2d 11 (1976).

FOIA authorizes federal courts to "enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant." 5 U.S.C. § 552(a)(4)(B). District courts must "determine *de novo* whether non-disclosure was permissible." *Elec. Privacy Info. Ctr. v. U.S. Dep't of Homeland Sec.*, 777 F.3d 518, 522 (D.C. Cir. 2015). When the sufficiency of "the release of information under the 59*59 FOIA" is challenged, "the agency has the burden of showing that requested information comes within a FOIA exemption." *Pub. Citizen Health Research Grp. v. Food & Drug Admin.*, 185 F.3d 898, 904 (D.C. Cir. 1999); *see also U.S. Dep't of Justice v. Landano*, 508 U.S. 165, 171, 113 S.Ct. 2014, 124 L.Ed.2d 84 (1993) (noting that "[t]he Government bears the burden of establishing that the exemption applies"). This burden does not shift even when the requester files a cross-motion for summary judgment because "the Government `ultimately [has] the onus of proving that the [documents] are exempt from disclosure,'" while the "burden upon the requester is merely `to establish the absence of material factual issues before a summary disposition of the case could permissibly occur.'" *Pub. Citizen Health Research Grp.*, 185 F.3d at 904-05 (quoting *Nat'l Ass'n of Gov't Emps. v. Campbell*, 593 F.2d 1023, 1027 (D.C. Cir. 1978)) (alterations in original).

III. DISCUSSION

The parties' cross-motions for summary judgment raise four categories of disagreements: (1) whether the defendants have impermissibly withheld non-responsive information contained in otherwise responsive records; (2) whether the defendants have properly invoked the deliberative-process privilege under FOIA Exemption 5, *see* 5 U.S.C. § 552(b)(5); (3) whether the defendants have properly invoked Exemption 6 to withhold medical and similar records to protect against any "a clearly unwarranted invasion of personal privacy," *id.* § 552(b)(6); and (4) whether the defendants have produced all reasonably segregable, non-exempt information.[3] These issues are considered *seriatim.*

A. WITHHOLDING OF NON-RESPONSIVE INFORMATION

The D.C. Circuit recently clarified that an agency in receipt of a FOIA request need not produce non-responsive records, but must nonetheless release non-responsive information within a responsive record. *Am. Immigration Lawyers Ass'n v. Exec. Office for Immigration Review* ("*AILA*"), 830 F.3d 667, 676-79 (D.C. Cir. 2016). The defendants agree that their initial production, which redacted non-responsive information within responsive 60*60 records, violated this rule. Defs.' Reply in Supp. of Mot. Partial Summ. J. & Opp'n to Pls.' Cross-Mot. Partial Summ. J. ("Defs.' Reply") at 38, ECF No. 33. To correct the problem, the defendants "re-reviewed their redactions of non-responsive material, and have unredacted and released non-exempt material within responsive records that was originally redacted on non-responsiveness grounds." *Id.* (citing Suppl. Decl. of Barbara A. Recupero, New England District Office ¶ 14, ECF No. 33-4). Yet, the defendants continue to withhold some non-responsive information because they deem that information to "so distinct in the document from the responsive material as to constitute a separate `record.'" *Id.* at 39. Fifty-one such records are at issue. *See* Suppl. Decl. of Sarah Kotler, DFOI, ¶ 8, ECF No. 33-6. The defendants' shift—now claiming to have withheld only non-responsive records—puts a spotlight on a variation of the question of what constitutes an "agency record" under FOIA that has become particularly relevant since *AILA:* when must information be grouped into a single "agency record" and when can information be separated into multiple "agency records"? *See* 5 U.S.C. § 552(a)(4)(B) (empowering district courts to order the production of any "agency records improperly withheld").

"Although FOIA includes a definition section, [5 U.S.C.] § 551, that section provides no definition of the term `record.'" *AILA,* 830 F.3d at 678; *see also* *Aguiar v. DEA,* 865 F.3d 730, 735 (D.C. Cir. 2017) (explaining that "[a]lthough FOIA does not define `agency records,'" the term has been limited to include "only [] those documents that an agency both (1) create[s] or obtain[s], *and* (2) control[s]... at the time the FOIA request [was] made")(internal quotation marks and citations omitted; alterations and emphasis in original). In practice, agencies "define a `record' when they undertake the process of identifying records that are responsive to a request," since defining the universe of responsive records is the first step an agency should take in response to a FOIA request. *AILA,* 830 F.3d at 677-78. Agencies have the flexibility to define "record" in a "range of possible ways," but some benchmarks inform that analysis. *Id.* at 678. DOJ guidance, which has been updated in response to *AILA,* instructs agencies to "use the definition of record found in the Privacy Act to guide their decisions as to what is a record for purposes of the FOIA. Thus, each `item, collection, or grouping of information' on the topic of the request can be considered a distinct `record.'" DEP'T OF JUSTICE, OIP GUIDANCE: DEFINING A "RECORD" UNDER FOIA (updated Feb. 15, 2017); *accord* 5 U.S.C. § 552a(a)(4). Generally, agencies should not define records "on less than a page-by-page basis." DEP'T OF JUSTICE, OIP GUIDANCE: DETERMINING THE SCOPE OF A FOIA REQUEST, FOIA Update, Vol. XVI, No. 3 (updated Aug. 13, 2014).

Here, if the defendants had committed to a consistent understanding of when information should be treated as a single agency record, or separated into multiple agency records, that understanding could have prompted focused judicial review. Yet, the defendants'

withholding of non-responsive information in this case suffers a more fundamental problem: midway through litigation the defendants reclassified collections of information that had been treated as one agency record as multiple agency records.

As the D.C. Circuit has said about an agency's determination of whether a document meets FOIA's definition of "agency record," courts must "be careful to ensure that `[t]he term `agency records'... not be manipulated to avoid the basic structure of the FOIA: records are presumptively 61*61 disclosable unless the government can show that one of the enumerated exemptions applies.'" *Consumer Fed'n of Am.,* 455 F.3d at 287 (quoting *Bureau of Nat'l Affairs, Inc. v. U.S. Dep't of Justice,* 742 F.2d 1484 (D.C. Cir. 1984)) (alterations in original). Although the question here is not whether information qualifies as an agency record in the first place, but rather about where one record ends and another begins, the admonition against record manipulation is no less applicable. Allowing the defendants to re-define the contours of a given record midway through litigation would invert the ordinary process of responding to a FOIA request, in which the first step is identifying the responsive records, *see AILA,* 830 F.3d at 677, just because the agency realized that, without the change, certain information would be subject to disclosure. That is precisely the sort of manipulation that undermines the purpose of FOIA.

That the defendants have altered their conception of what constitutes a single record is evident from comparison of the defendants' second *Vaughn* Index and third *Vaughn* Index. Recall that FOIA requires agencies to account for records only if they are responsive to a request. *See AILA,* 830 F.3d at 677 ("The statute thus sets forth the broad outlines of a process for agencies to follow when responding to FOIA requests: first, identify responsive records."). Agencies account for responsive records either by disclosing the record to the requester or claiming, and justifying, a statutory exemption. *Id.* Thus, "once an agency identifies a record it deems responsive to a FOIA request, the statute compels disclosure of the responsive record—*i.e.,* as a unit—except insofar as the agency may redact information falling within a statutory exemption." *Id.* Although the defendants now claim that multiple entries on the third *Vaughn* Index account for wholly independent, but non-responsive records, those records' inclusion in the indices signals that the defendants did not initially view the same entries as describing stand-alone records. If that was the agency's position all along, those records would not have been included in the indices.

For example, the third *Vaughn* Index entry for an email attachment, Bates-stamped JRC OES Supplemental 1 XXXXXX-XX, describes the email attachment as is its own record. *See* 3rd Index at 356-57. By contrast, in the earlier, second *Vaughn* Index, the agency described the same document as non-responsive, but "included in this production only because it is an attachment to an email that contains another attachment that includes responsive material." 2nd Index at 352-53. The second *Vaughn* Index reveals that the defendants viewed the email attachment as a piece of a single record that included the parent email and additional attachment. Otherwise, the record would not have been included in the index at all. Examples of a similar shift litter the indices. *Compare* 2nd Index at 335-36 *with* 3rd Index at 339-40; *compare* 2nd Index at 350-51 *with* 3rd Index at 354-55; *compare* 2nd Index at 352-53 *with* 3rd Index at 356-57; *compare* 2nd Index at 735-36 *with* 3rd Index at 752-53; *compare* 2nd Index at 781-82 *with* 3rd Index at 799-800.

The defendants' reclassifications are even more troubling because many were done to split emails and their attachments into multiple records. While emails and their attachments are not *per se* a single record, at a minimum "attachments should reasonably be considered part and parcel of the email by which they were sent" when the email "make[s] explicit reference to, or include[s] discussion of, the missing attachments." *Coffey v. Bureau of Land Mgmt.*, 277 F.Supp.3d 1, 8 (D.D.C. 62*62 2017); *see also Am. Oversight v. U.S. Gen. Servs. Admin.*, 311 F.Supp.3d 327, 340 (D.D. C 2018) ("[E]ven without `a *per se* rule that an email and its attachment must be treated as a single record,' ... the attachments to already-produced emails appear manifestly part of the `communications' between GSA and the PTT and, absent any agency explanation why not, `belong together.'" (quoting *Coffey*, 277 F.Supp.3d at 8; *Parker v. U.S. Dep't of Justice, Office of Prof'l Responsibility*, 278 F.Supp.3d 446, 452 (D.D.C. 2017))); *New Orleans Workers' Ctr. for Racial Justice v. U.S. Immigration & Customs Enf't*, No. 15-431 (RBW), 373 F.Supp.3d 16, 44, 2019 WL 1025864, at *11 (D.D.C. Mar. 4, 2019) ("`[A]ttachments should reasonably be considered part and parcel of the email by which they were sent' if `the emails ... make explicit reference to, or include discussion of, the [ ] attachments.'" (quoting *Coffey*, 277 F.Supp.3d at 8)); *Families for Freedom v. U.S. Customs & Border Prot.*, No. 10-cv-2705, 2011 WL 4599592, at *5 (S.D.N.Y. Sep. 30, 2011) (rejecting agency's separation of emails and attachments because "[t]he attachments can only be fully understood and evaluated when read in the context of the emails to which they are attached. That is the way they were sent and the way they were received. It is also the way in which they should be produced"). More than that, ubiquitous email practices suggest that agencies will struggle to justify separating an email and its attachments into multiple records. Of course, from time to time emails are sent with the wrong attachment, but in the ordinary course an attachment is included with the email because it relates to the body of the email. Though not a *per se* rule, ordinary practice leaves very little wiggle room in generally requiring an email with attachments to be kept together as a single record.

Here, however, the defendants need not be given the chance to explain why some emails and attachments should be considered as distinct records because reclassifying records midway through litigation is improper. Accordingly, the defendants must release all records currently listed on the third *Vaughn* Index as being withheld for non-responsiveness that are not also subject to a FOIA statutory exemption.

B. THE FDA'S EXEMPTION 5 WITHHOLDINGS

FOIA Exemption 5 permits agencies to withhold "inter-agency or intra agency memorandums or letters that would not be available by law to a party other than an agency in litigation with the agency." 5 U.S.C. § 552(b)(5). This exemption "incorporates the privileges that the Government may claim when litigating against a private party, including the governmental attorney-client and attorney work product privileges, the presidential communications privilege, the state secrets privilege, and the deliberative process privilege." *Abtew v. U.S. Dep't of Homeland Sec.*, 808 F.3d 895, 898 (D.C. Cir. 2015)).[4] Under the deliberative-process 63*63 privilege, an agency may withhold "documents reflecting advisory opinions, recommendations and deliberations comprising part of a process by which governmental decisions and policies are formulated." *Dep't of Interior v. Klamath Water User Protective Ass'n*, 532 U.S. 1, 8-9, 121 S.Ct. 1060, 149 L.Ed.2d 87 (2001). "The deliberative process privilege reflects the commonsense notion

that agencies craft better rules when their employees can spell out in writing the pitfalls as well as strengths of policy options, coupled with the understanding that employees would be chilled from such rigorous deliberation if they feared it might become public." *Judicial Watch, Inc. v. U.S. Dep't of Def.*, 847 F.3d 735, 739 (D.C. Cir. 2017).

"To qualify for the deliberative process privilege, an intra-agency memorandum must be both pre-decisional and deliberative." *Abtew*, 808 F.3d at 898 (citing *Coastal States Gas Corp. v. Dep't of Energy*, 617 F.2d 854, 866 (D.C. Cir. 1980)). "A document is `predecisional' if it precedes, in temporal sequence, the `decision' to which it relates," *id.,* or was "`prepared in order to assist an agency decisionmaker in arriving at his decision,' rather than to support a decision already made," *Petroleum Info. Corp. v. U.S. Dep't of Interior*, 976 F.2d 1429, 1434 (D.C. Cir. 1992) (quoting *Renegotiation Bd. v. Grumman Aircraft*, 421 U.S. 168, 184, 95 S.Ct. 1491, 44 L.Ed.2d 57 (1975)). Deliberative, in this context, means the record is "a part of the agency give-and-take—of the deliberative process—by which the decision itself is made." *Abtew*, 808 F.3d at 899. Requiring that a record be "deliberative" adds little to the requirement that the record be predecisional. *Nat'l Sec. Archive v. CIA*, 752 F.3d 460, 463 (D.C. Cir. 2014).

To gauge whether the deliberative-process privilege has been asserted appropriately, the government must explain, for each withheld record, at least, (1) "what deliberative process is involved,... (2) the role played by the documents in issue in the course of that process, ... and (3) the nature of the decisionmaking authority vested in the office or person issuing the disputed document[s], and the positions in the chain of command of the parties to the documents." *Ctr. for Biological Diversity v. U.S. Envtl. Prot. Agency*, 279 F.Supp.3d 121, 145 (D.D.C. 2017) (internal citations omitted). The government, not the requester, must identify the deliberative process to which any record relates. *100Reporters LLC v. U.S. Dep't of Justice*, 248 F.Supp.3d 115, 152 (D.D.C. 2017) (citing *Coastal States*, 617 F.2d at 868).

Broadly, the defendants withheld under the deliberative-process privilege two groups of records: (1) those reflecting deliberations about regulatory and enforcement decisions and (2) drafts of documents. 64*64 Defs.' Mem. P. & A. Supp. Defs.' Mot. Partial Summ. J. ("Defs.' Mem.") at 26-27, ECF No. 25. The first group of documents generally relate to the "appropriateness of different regulatory approaches as well as opinions and recommendations about how to best effectuate the regulatory approaches being considered." *Id.* at 27. The defendants enumerate the specific decisions to which the records relate as including "whether to propose a ban of electrical stimulation devices," First DFOI Decl. ¶ 44; "the regulatory strategy the agency should take with respect to JRC and [electrical stimulation devices]," First NE-DO Decl. ¶ 24; "discussion about how to respond to JRC's request for a part 16 hearing," OCC Decl. ¶ 43; "discussions about appropriate follow-up activity following the 2014 advisory panel meeting," ORA Decl. ¶ 19; "the status of inspections of the [JRC]," *id.*; the "FDA's draft proposed rule-making regarding [electrical stimulation devices]," HHS Decl. ¶ 21; and the decision to send a draft letter to the United States Special Rapporteur on Torture, Decl. of Nelson D. Hermilla, Department of Justice ("DOJ Decl.") ¶ 11, ECF No. 24-1. As for second group of records, drafts, although not deliberative *per se,* have been withheld to keep from public view editorial judgments that could be inferred from comparing a final record to a prior version. Defs.' Mem. at 27-28; *see also* First NEDO Decl. ¶ 24.

The plaintiffs attack the defendants' withholdings under the deliberative-process privilege from several directions. First, the plaintiffs argue the defendants' descriptions of the basis for Exemption 5 withholdings is deficient because the defendants have excluded dates of records. Pls.' Mem. Supp. Cross-Mot. Summ. J. & Opp'n Defs.' Mot. Summ. J. ("Pls.' Opp'n") at 11-12, ECF No. 30. Second, the descriptions are inadequate for describing too generally the deliberative processes to which withheld records contributed. *Id.* at 20-21. Third, the defendants have omitted the decisionmaking authority of the individuals related to a record. *Id.* at 21-22. Fourth, the plaintiffs maintain that, insofar as can be discerned, the defendants have impermissibly applied Exemption 5 to draft documents, *id.* at 23-26, and to records that are not predecisional or are purely factual, *id.* at 26-29.

The Court considers each of the ways in which the defendants' Exemption 5 withholdings are insufficiently explained, and then defendants' application of Exemption 5 to draft documents. Review of whether withheld documents are actually predecisional, however, is not possible at this point because for many records the defendants have not explained the basis of the exemption well enough to assess whether it has been properly claimed.

1. The FDA's Omission of Dates

The plaintiffs contend that the absence of dates associated with records is a problem that renders the defendants' *Vaughn* indices "structurally deficient." Pls.' Opp'n at 10. Although the plaintiffs press the view that every *Vaughn* index must contain certain information, including, among other things, record dates, *see id.* at 10-12, a *Vaughn* index serves a function: to "justify [an agency's] actions without compromising its original withholdings by disclosing too much information." *Judicial Watch, Inc. v. Food & Drug Admin.*, 449 F.3d 141, 146 (D.C. Cir. 2006). While a comprehensive *Vaughn* Index "typically" includes certain categories of information, *Ctr. for Biological Diversity*, 279 F.Supp.3d at 144, "there is no fixed rule establishing what a *Vaughn* index must look like," *ACLU v. CIA*, 710 F.3d 422, 432 (D.C. Cir. 2013); *see also Citizens for Responsibility & Ethics in Wash. v. U.S. Dep't of Justice*, 746 F.3d 1082, 1088 65*65 (D.C. Cir. 2014) ("[I]t is the function, not the form, of the index that is important."). Indeed, an agency need not even create a *Vaughn* Index to justify withholdings. *See Judicial Watch I*, 449 F.3d at 146.

Of course, when an agency uses a *Vaughn* index to justify withholdings, the index cannot be organized in a way that fails to "fulfill the purposes of ... providing sufficient information to the requester and the Court for a fair evaluation of the propriety of any withholding." *Ctr. for Biological Diversity*, 279 F.Supp.3d at 144-45. That might happen, for example, if the index has a "slapdash identification system seem[ingly] designed to create confusion," fails to account for changes made between versions, or documents "are listed on the... *Vaughn* index as withheld with no explanation whatsoever." *Id.* No such problems exist in this case.

At the same time, the defendants have applied Exemption 5 to some undated records. 2nd Index at 474-75, 732-33; 3rd Index at 481-82, 749-50.[5] Without a date, the plaintiffs claim that "there is no way of knowing when ... this email was generated, and thus whether this email is actually predecisional." Pls.' Opp'n at 11. Yet, the D.C. Circuit has never imposed a categorical rule against undated entries. *Judicial Watch I*, 449 F.3d at 151. Rather, "[d]ates are but one way to illustrate a chronology, and the FDA may have other ways to prove that

the undated documents were indeed predecisional." *Id.* The single dateless entry that the plaintiffs have identified establishes that the record is predecisional by stating that the email "occurred prior to FDA taking action regarding [electrical stimulation devices]." 2nd Index at 732-33; 3rd Index at 749-50. Another date-less entry is a draft of the Proposed Ban, which the *Vaughn* Index explains is predecisional because "it was drafted before the agency established its final position on the subject matter discussed in the document." 2nd Index at 474-75; 3rd Index at 481-82. Thus, the defendants have established chronology even without a date.

In the end, as discussed in the next section, the defendants' Exemption 5 justifications may be inadequate, but the absence of a date is not the problem.

2. The FDA's Descriptions of the Deliberative Process

Moving to the decision processes to which withheld records relate, an agency's "Exemption 5 claims must be supported with specificity and [in] detail." *Senate of Puerto Rico v. U.S. Dep't of Justice*, 823 F.2d 574, 585 (D.C. Cir. 1987). "To approve exemption of a document as predecisional, a court must be able to `pinpoint an agency decision or policy to which the document contributed.'" *Id.* (quoting *Paisley v. CIA*, 712 F.2d 686, 698 (D.C. Cir. 1983)); *Hunton & Williams LLP v. U.S. Envtl. Prot. Agency*, 248 F.Supp.3d 220, 241 (D.D.C. 2017) ("`To justify its 66*66 application of the deliberative-process privilege, an agency must address ... the nature of the specific deliberative process involved....'" (quoting *Nat'l Sec. Counselors v. CIA*, 960 F.Supp.2d 101, 189 (D.D.C. 2013))); *see also Trea Senior Citizens League v. U.S. Dep't of State*, 923 F.Supp.2d 55, 68 (D.D.C. 2013) ("[A] broad and opaque description of the deliberative process involved does not provide the Court with enough detail about whether these documents are deliberative and predecisional."); *Elec. Frontier Found. v. U.S. Dep't of Justice*, 826 F.Supp.2d 157, 168 (D.D.C. 2011) ("The Court finds this description inadequate because it fails to identify a specific deliberative process to which the withheld email messages contributed."). Indeed, the D.C. Circuit has said that "[t]he failure to specify the relevant final decision constitutes a sufficient ground for remanding [Exemption 5 claims] to the district court." *Senate of Puerto Rico*, 823 F.2d at 585. "Without a sufficiently specific affidavit or *Vaughn* Index, a court cannot decide, one way or the other, a deliberative process privilege claim." *Elec. Frontier Found.*, 826 F.Supp.2d at 168.

The plaintiffs assert that some of the defendants' descriptions of the deliberative processes to which records contributed are too vague to permit the necessary analysis of whether withheld records are predecisional. Pls.' Opp'n at 20. The plaintiffs are right. Emblematic of the problem, the *Vaughn* indices' descriptions of the deliberative processes to which records contributed include an "action being taken on electrical stimulation devices," 2nd Index at 2-3; 3rd Index at 2-3; "possible actions," 2nd Index at 4-5; 3rd Index at 4-5; "agency action," 2nd Index at 8-9; 3rd Index at 8-9; "action regarding [electrical stimulation devices] (such as proposing a rule)," 2nd Index at 732-33; 3rd Index at 749-50; "numerous matters being worked on," 2nd Index at 1749-50; 3rd Index at 1797-98; "regulatory action FDA is considering," 2nd Index at 1065-66; 3rd Index at 1090-91. Despite the defendants' numerous declarations generally describing the deliberative process undertaken by various FDA, in many cases the defendants fail to link those descriptions with entries on the *Vaughn* Indices, thus impeding review of whether the record is in fact predecisional.

Nevertheless, the defendants stand by their nebulous descriptions, commenting that "a government agency invoking the [deliberative-process privilege] may rely on a relatively broad deliberative process that covers many documents if that is, in fact, the relevant process." Defs.' Reply at 17. Permissive rules are needed, in the defendants' view, to "`encourage the candid and frank exchange of ideas' within agencies" and "to ensure that agencies do not have to `operate in a fishbowl.'" *Id.* (quoting *Nat'l Sec. Archive*, 752 F.3d at 462-63). In any event, the defendants reject that decisions here could have been defined any more specifically, *id.* at 17, highlighting entries on the second *Vaughn* Index that identified the deliberative processes as consideration of possible "compliance measures," Defs.' Reply at 19 (citing 2nd Index at 1065-66), a "possible response to a media inquiry," *id.* (citing 2nd Index at 687-88), or "preparations for an upcoming inspection of JRC," *id.* (citing 2nd Index at 1071-72). Finally, the defendants assert that the reality of this case is a large volume of documents relate to a single decisionmaking process—whether to issue the Proposed Ban. *Id.* at 19-20. Presumptively, the defendants mean to argue that any ill-defined reference to "agency action" refers to deliberations about the content of the Proposed Ban.

Each of the defendants' arguments is unavailing. First, referencing entries in which the deliberative process might have 67*67 been described with the requisite level of detail is not a response to the inadequacy of the remaining descriptions. Second, the defendants' claim that whatever records have not been connected to an identifiable decisionmaking process should be treated as related to deliberation about the content of the Proposed Ban is unacceptable. *See* *100Reporters LLC*, 248 F.Supp.3d at 153 ("Accepting DOJ and Defendant Intervenors' view of the deliberative process at issue would create a four-year umbrella effectively shielding all agency action from review without accounting for any subsidiary agency decisions."). If agencies could shield from review thousands of agency records because a years-long rule-making was underway, the deliberative-process privilege would be the exemption that ate the entire FOIA disclosure scheme. That simply will not do.

The defendants' effort to define the deliberative process so broadly is rejected because the withheld records may in fact pertain to a litany of subsidiary decisions that defendants fail to acknowledge. Indeed, although the agency, and not the requester, has the burden of justifying the exemptions, *Pub. Citizen Health Research Grp.*, 185 F.3d at 904, the plaintiff supplied several possible subsidiary decisions to which the withheld records may relate, *see* Pls.' Reply Supp. Cross-Mot. Summ. J. ("Pls.' Reply") at 8-9. ECF No. 35 (listing subsidiary decisions). The record supports the plaintiffs' list, which includes, though is not limited to, decisions such as the FDA's about-face as to whether JRC was exempt from the 510(k) requirement, Pls.' SMF ¶ 5; the determination that by 2010 "JRC made major modifications to the original GED device," Suppl. Decl. of Matthew D. Rodgers, plaintiffs' counsel, Ex. 8, ECF No. 35-1; the decision to cancel a March 2013 meeting with JRC's representatives, Pls.' SMF ¶ 13; and the decision to seat a panel on neurological devices, *id.* ¶ 14. Even the declarations submitted from the defendants appreciate the multitude of decisions to which "agency action" might refer. Those include "whether to propose a ban of electrical stimulation devices," First DFOI Decl. ¶ 44; "discussion about how to respond to JRC's request for a part 16 hearing," OCC Decl. ¶ 43; "follow-up activity following the 2014 advisory panel meeting," ORA Decl. ¶ 19; "the status of inspections of [JRC]," *id.*; the "FDA's draft proposed rule-making regarding [electrical stimulation devices]," HHS Decl. ¶ 21; and the decision to send a draft letter to the United States Special

Rapporteur on Torture, DOJ Decl. ¶ 11. Without the defendants acknowledging these subsidiary decisions or tying records to those specific decisionmaking processes, the Court cannot be sure that a record related to "agency action" or "agency work on particular topics" is in fact predecisional.

The defendants must update their *Vaughn* Indices to identify with adequate specificity the agency decision to which a record relates.[6]

68*68 3. The FDA's Descriptions of Decisionmaking Authority

As for decisionmaking authority, the plaintiffs observe that the defendants have wholly "omitted information about the positions and responsibilities of the authors and recipients (other than some attorneys) of the records." Pls.' Opp'n at 22. The defendants do not dispute their omission, Defs.' Reply at 10-12, but bemoan the "extraordinary burden" if required "to provide a job description for each and every person who authored, sent, and/or received a document listed on the nearly 2,000-page index," *id.* at 11. In the alternative, the defendants propose that descriptions of decisionmaking authority are unnecessary to resolve the propriety of defendants' withholding under the deliberative-process privilege because the defendants otherwise connect the records to "ongoing work" on a final rulemaking or to "contemporaneous thoughts and opinions about plans for work that should be done to support FDA's efforts." *Id.* at 12. Moreover, the defendants dismiss the necessity of identifying the relationship between the individuals connected to a record if the author is plainly in an advice-giving role. *Id.* (citing *Judicial Watch, Inc. v. U.S. Dep't of Justice* ("*Judicial Watch II*"), 20 F.Supp.3d 260, 271 (D.D.C. 2014)).

Contrary to the defendants' position, explaining decisionmaking authority is an essential ingredient to justifying withholdings under the deliberative process exemption. *See* *Access Reports v. Dep't of Justice*, 926 F.2d 1192, 1195 (D.C. Cir. 1991) ("A key feature under both the `predecisional' and `deliberative' criteria is the relation between the author and recipients of the document. A document from a junior to a senior is likely to reflect his or her own subjective opinions and will clearly have no binding effect on the recipient. By contrast, one moving from senior to junior is far more likely to manifest decisionmaking authority and to be the denouement of the decisionmaking rather than part of its give-and-take."); *Arthur Andersen & Co. v. I.R.S.*, 679 F.2d 254, 258 (D.C. Cir. 1982) ("To establish that documents do not constitute the `working law' of the agency, the agency must present to the court ... the nature of the decisionmaking authority vested in the office or person issuing the disputed document(s),... and the positions in the chain of command of the parties to the documents." (internal quotation marks omitted)). Even *Judicial Watch II,* the opinion which the defendants cite as hedging on the obligation to describe decisionmaking authority, in the paragraph after the one defendants quote, observed that "the agency `must describe the nature of the decisionmaking authority vested in the office or person issuing the disputed document(s), and the positions in the chain of command of the parties to the documents.'" 20 F.Supp.3d at 271 (quoting *Elec. Frontier Found.*, 826 F.Supp.2d at 168). *Judicial Watch II* appreciated that in some instances a record may reflect advice giving rather than decisionmaking "even if the relationship between the author and recipient of challenged

records is not one of subordinate and superior officials," 20 F.Supp.3d at 271, but did not relieve the agency of its duty to describe chain of command.

Lastly, the effort that the defendants must undertake to identify the authority of individuals attached to a given record is not as daunting as defendants fear. While the defendants express trepidation about needing to "provide a job description for each and every person who authored, sent, 69*69 and/or received a document listed on the nearly 2,000-page index," which surely would be a "Herculean" task, Defs.' Reply at 11, no such undertaking is necessary. The "key feature ... is the relation between the author and recipients of the document." *Access Reports,* 926 F.2d at 1195; *see also Judicial Watch II,* 20 F.Supp.3d at 270 (collecting D.C. Circuit cases explaining that critical information to justification of deliberative proves privilege is relationship between author and recipient). Marking, for example, a document as from a subordinate to a superior, from a superior to a subordinate, or as from peer to peer would communicate the needed information about the respective positions in the chain of command.

Thus, the defendants next *Vaughn* Index must explain the dynamic between the author or individual sending, and the individuals receiving, the withheld record at issue to meet the requirement that record was part of the deliberative process.

4. Withholding of Draft Documents

Finally, the plaintiffs also contend that the defendants have improperly withheld draft documents under Exemption 5. *See* Pls.' Opp'n at 23-26. Documents designated as "drafts" are not *per se* covered under the deliberative-process privilege, but rather must meet the same two criteria as any other record. *Arthur Andersen,* 679 F.2d at 257-58. In addition, a draft that was predecisional and deliberative when prepared may "lose that status if it is adopted, formally or informally, as the agency position on an issue or is used by the agency in its dealings with the public." *Id.* at 258. Additionally, "factual information which does not bear on the policy formulation is not subject to the deliberative-process privilege." *Heffernan v. Azar,* 317 F.Supp.3d 94, 125 (D.D.C. 2018).

The plaintiffs first argue that the "Defendants withheld drafts or parts of drafts that FDA ultimately adopted," or, at a minimum, the defendants have failed to establish otherwise. Pls.' Opp'n at 25; *see also* Pls.' Reply at 10 ("Defendants admit that information in several records `may... have been adopted in the government's final document.'" As examples, the plaintiffs cite: (1) three partially withheld drafts of letters subsequently sent to the United Nations Special Rapporteur on Torture, *see* 2nd Index at 139-40, 940-41, 963; 3rd Index at 140-41, 962-63, 985-86; (2) a partially withheld draft of "Key Messages and Responsive Q & A" which contained "talking points about the proposed rule," *see* 2nd Index at 288-89; 3rd Index at 290-91; (3) a fully withheld draft of the Proposed Ban, *see* 2nd Index at 474-75; 3rd Index at 481-82; and (4) a partially withheld draft of a Form 483, which captured observations made during an inspection of JRC's premises, *see* 2nd Index at 1607; 3rd Index at 1636-37. The defendants answer that "[a]t most, the plaintiffs show that some of the drafts contain views, opinions, or other material that was eventually reflected in the final agency document." Defs.' Reply at 23.

The defendants pick up on a nuance in the law governing FOIA's application to drafts that the plaintiffs skip past. A draft, as mentioned, even if once evincing deliberation, may "lose that status if it is adopted, formally or informally, as the agency position on an issue or is used by the agency in its dealings with the public." *Arthur Andersen,* 679 F.2d at 258. So, for the deliberative process to apply to a draft document, an agency must show that a document contains "`the ideas and theories which go into the making of the law' and not `the law itself.'" *Id.* (quoting *Sterling Drug, Inc. v. Fed. Trade Comm'n,* 450 F.2d 698, 708 (D.C. Cir. 1971)). In other 70*70 words, the agency's burden is "[t]o establish that documents do not constitute the `working law.'" *Id.* (quoting *Taxation With Representation Fund v. IRS,* 646 F.2d 666, 678 (D.C. Cir. 1981)); *see also Judicial Watch, Inc. v. U.S. Dep't of Def.,* 847 F.3d 735, 739 (D.C. Cir. 2017) ("[A] document can lose its predecisional character—and the protections of the privilege—if the agency adopts the documents as its own.... To adopt a deliberative document... the agency must make an `*express*[ ]' choice to use a deliberative document as a source of agency guidance." (quoting *NLRB v. Sears, Roebuck & Co.,* 421 U.S. 132, 161, 95 S.Ct. 1504, 44 L.Ed.2d 29 (1975)) (emphasis in original)). Thus, a draft does not lose its deliberative character by resembling the version that ultimately becomes the working law, but rather its deliberative character is lost if the draft—formally or informally—becomes the working law.

Applying these principles first to the early drafts of the Proposed Ban, so long as a draft contributed to the deliberative back-and-forth, and was not formally or informally the agency's working law, that draft does not lose its character because the Proposed Ban paralleled a draft in some measure. Indeed, for the withheld draft that the plaintiffs cite, the defendants state explicitly that the draft was "not in its final form." 2nd Index at 474; 3rd Index at 481-82. Similarly, regarding the draft talking points cited by plaintiffs, the defendants explicitly state this document "contains redline edits and comment bubbles" and was later turned into a version of the agency's final position. 2nd Index at 288-89; 3rd Index at 290-91. As for the draft letters to the United Nations, the Index is explicit that the withheld drafts "contain[ ] comments from government employees suggesting certain changes to the draft letter before it is finalized" and explain that the letter was "subsequently finalized." *See* 2nd Index at 139-40, 940-41, 963; 3rd Index at 140-41, 962-63, 985-86. Finally, the entry for the Form 483 references the existence of a separate, final agency position and explains that changes between this draft and the final version would disclose "editorial judgments of government staff." 2nd Index at 1607; 3rd Index at 1636-37.

Separately, the plaintiffs accuse the defendants have applying the deliberative-process privilege to "draft records simply because they are drafts" or to records that are not actually drafts. Pls.' Opp'n at 23-24. The plaintiffs provide a single example of each. Yet, the FDA's Executive Summary prepared for the April 24, 2014 panel, the record allegedly withheld simply because it is a draft, was withheld because "[t]his redline draft contains editorial comments of agency staff" to be considered before the document was finalized. 2nd Index at 992-93; 3rd Index at 1015. That application of Exemption 5 is proper. The record that plaintiffs allege is not actually a draft is a version of Power Point, prepared to "brief[ ] the FDA Commissioner about a possible Proposed Rule." 2nd Index at 531-33; 3rd Index at 538-40. Here, the defendants not only claim that the record is a draft, but that comparison of this version to the final version could reveal "editorial decisions of agency staff." 2nd Index at 531-33; 3rd Index at 538-40. Indeed, other entries in the *Vaughn* Index reference a final version of this Power Point. *See, e.g.,* 2nd Index at 142-44; 3rd Index at 143-45.[7]

71*71 The defendants are entitled to partial summary judgment for the draft records withheld under Exemption 5.[8]

C. THE FDA'S EXEMPTION 6 WITHHOLDINGS

The plaintiffs also contest the sufficiency of the defendants' withholdings under Exemption 6, which permits agencies to withhold "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." 5 U.S.C. § 552(b)(6). "FOIA's strong presumption in favor of disclosure is at its zenith in this Exemption 6 analysis." *Am. Oversight,* 311 F.Supp.3d at 345 (quoting *Jurewicz v. U.S. Dep't of Agric.,* 741 F.3d 1326, 1332 (D.C. Cir. 2014)).

Review of personal privacy withholdings under Exemption 6 proceeds in stages. Stage one requires the Court to "determine whether the [records] are personnel, medical or `similar' files covered by Exemption 6." *AILA,* 830 F.3d at 673. If the records are such files, in stage two, the Court must then "determine whether their disclosure would constitute a clearly unwarranted invasion of privacy." *Id.* (internal quotation marks omitted). Stage two embeds its own two-level review. *Id.* The first inquiry is whether "disclosure would compromise a substantial, as opposed to *de minimis,* privacy interest." *Id.* at 673-74. Next, if disclosure would infringe a substantial privacy interest, the privacy interest must be balanced "against the public interest in the release of the records." *Id.* at 674. Only one public interest matters: "the extent to which disclosure would serve the `core purpose of the FOIA,' which is `contribut[ing] significantly to public understanding *of the operations of activities of the government.*'" *U.S. Dep't of Def. v. Fed. Labor Relations Auth.,* 510 U.S. 487, 495, 114 S.Ct. 1006, 127 L.Ed.2d 325 (1994) (quoting *Dep't of Justice v. Reporters Comm. for Freedom of Press,* 489 U.S. 749, 775, 109 S.Ct. 1468, 103 L.Ed.2d 774 (1989)) (emphasis and alternations in original). "In other words, disclosure of government records under FOIA is meant to help the public stay informed about `what their government is up to.'" *AILA,* 830 F.3d at 674 (quoting *Reporters Comm.,* 489 U.S. at 773, 109 S.Ct. 1468). For Exemption 6, the D.C. Circuit has put the burden on the agency to establish that any withheld records meet the statutory balancing test. *Id.* at 673.[9]

72*72 The defendants have applied Exemption 6 to personal or medical files that identify JRC patients. Defs.' Mem. at 30; Defs.' Reply at 31.[10] As to step one, the defendants correctly state that Exemption 6 applies to those records because the statute explicitly covers medical files. Defs.' Mem. at 30; *see also* Defs.' Reply at 31. For step two, the defendants contend that releasing identifying information "would constitute a clearly unwarranted invasion of privacy," and the public has "no apparent interest in gaining access to the medical records of individual JRC patients." Defs.' Mem. at 30-31. Alternatively, the defendants assert that the public's interest in disclosure yields to the privacy interest. *Id.* at 31.

Relying on the D.C. Circuit's opinion in *AILA,* the plaintiffs answer that, at a minimum, the defendants have applied an impermissibly categorical approach to assessing the privacy interests implicated by records containing personally identifying information. Pls.' Opp'n at 33-35. In *AILA,* the requester had sought from the government records related to conduct of immigration judges. 830 F.3d at 669. The judges' names were redacted from all disclosed records because "[t]he government reasoned that, as a blanket matter, the privacy interest

of immigration judges in avoiding disclosure of their names necessarily outweighs the public's interest in learning any of the judges' names." *Id.* at 670. The Circuit remanded "for a more individualized inquiry," *id.,* explaining that the government had failed at step two of Exemption 6's tiered review because, in affording each judge the same privacy interest in her name, the government ignored that the "privacy interest at stake may vary depending on the context in which it is asserted," *id.* at 675; *see also* *Bartko v. U.S. Dep't of Justice,* 898 F.3d 51, 69 (D.C. Cir. 2018) ("On the privacy side of the balance, Wheeler's interest is substantially diminished. First, the allegations of misconduct during the Bartko trial are already a matter of public record, as is the referral to OPR published in the Fourth Circuit's decision, and the U.S. Attorney's public announcement that it too was referring the allegations of misconduct to OPR."); *Am. Oversight,* 311 F.Supp.3d at 347 ("GSA's Exemption 6 redactions obscure which of the publicly-named PTT members were referenced in, or included on, certain emails, even though those names are already `out of the bag' and are no longer subject to a significant, protectable privacy interest."). For the immigration judges, "[g]iven the variety in types of complaints and circumstances of individual immigration judges, not every judge has the same privacy interests at stake and not every complaint would 73*73 equally enlighten the public about `what their government is up to.'" *AILA,* 830 F.3d at 675 (quoting *Reporters Comm.,* 489 U.S. at 773, 109 S.Ct. 1468).

Sure enough, the plaintiffs have identified ways in which the government's assessment of the competing public and private interests papers over important context for records related to at least five people whose names have been redacted from the produced records. First, several withheld records identify former JRC patients. *See, e.g.,* 2nd Index at 93-94, 130-31, 132-33; *see also, e.g.,* 3rd Index at 94-95, 131-32, 133-34. Importantly for the privacy interests at stake, some former JRC patients have been very vocal about their experiences at JRC, including speaking with media outlets, testifying at the April 2014 panel meeting, and posting videos about JRC to YouTube. Pls.' Opp'n at 36; Pls.' SMF ¶¶ 17, 21, 23, 24. Yet, none of the index entries describing documents that identify former patients appreciates that the patients' public comments might diminish their interest in guarding their identity. That context must be considered.

Similarly, a fourth individual for whom the defendants have redacted identifying information submitted a consumer complaint to the FDA about JRC's use of the GED and declared an intent to share "this issue with social media such as Facebook to make the public aware of this issue." Pls.' Decl., Ex. 27. Yet, the *Vaughn* Index entry for this record says no more than that releasing the complainant's name "would constitute a clearly unwarranted invasion of personal privacy." 2nd Index at 1502-04; 3rd Index at 1531-32. Missing from that analysis is any acknowledgment that the complainant expressed an intent to publicize his or her views. While defendants need not scour the internet to determine what public comments an individual identified in a responsive record has made, the government cannot meet its burden under Exemption 6 by ignoring information sitting on the face of the record.

Finally, the defendants redacted the name of a former JRC employee who agreed to be interviewed for a piece that ran on CBS. Pls.' Decl., Ex. 30. The JRC employee's name is redacted from an email that references the employee's participation in the CBS story, yet the corresponding index entry does not discuss the individual's privacy interest, let alone account for how the invited publicity might affect that privacy interest. 2nd Index at 827-28;

3rd Index at 845-55. Although the defendants now concede this particular redaction was improper, Defs.' Reply at 34 n.15, the third *Vaughn* Index does not reflect that the error has been corrected, 3rd Index at 845-55. This information must be disclosed, and the plaintiffs are, consequently, granted partial summary judgment as to this record.

Despite failing to take a nuanced approach to the Exemption 6 balancing analysis, the defendants repeat that they have properly applied Exemption 6 because "an individual does not forfeit all privacy interest merely by making some public statements." Defs.' Reply at 34. That response misses the point. The defendants have not met their burden because they have forgone a necessary step in Exemption 6's balancing standard—properly defining the interests on either side of the equation. Redacting the identities of individuals who have publicly associated themselves with the very views that redaction intends to shield, without considering how that welcomed publicity changes the privacy interest, improperly ascribes a uniform privacy interest to one's identity and ignores a fact that minimizes any asserted privacy interest. That tack does not survive *AILA. See* 830 F.3d at 674-76; *see also* *Am. Over-sight,* 74*74 311 F.Supp.3d at 347. Nor does it matter that "the privacy interest at stake belongs to the individual, not the agency." Defs.' Reply at 32 (quoting *Amuso v. Dep't of Justice,* 600 F.Supp.2d 78, 93 (D.D.C. 2009)). Here, the unaccounted for conduct was taken by the individuals whose privacy is on the line. Factoring that context is consistent with the privacy interest belonging to the individual.

The defendants must also take a more nuanced approach to assessing the public's interest in the disclosure of identities. *AILA,* 830 F.3d at 675 (explaining the public interest in disclosure also "might vary in substantial measure" depending on context). In *AILA,* the Circuit explained that "the public interest likely would be more pronounced in the case of a sitting immigration judge, who continues to make decisions as an employee of the Department of Justice, than in the case of a former judge." *AILA,* 830 F.3d at 675; *see also* *Bartko,* 898 F.3d at 66-67 (explaining for both Exemption 6 and 7(c) that, as to the public's interest in records of investigations into a prosecutor's misconduct, "an unsubstantiated allegation that was dismissed as frivolous might implicate a greater privacy interest or a reduced public interest, while an in-depth investigation that exposed a pattern of abuses across numerous cases would trigger a different balancing of interests"). Applied here, the FDA, for example, included the testimony of "[t]hree individuals formerly on [electrical stimulation devices] at JRC" in the list of sources that the agency relied on in developing the Proposed Ban. *See* 81 Fed. Reg. at 24,393. The public interest in the identity of those people, given their role in the Proposed Ban, might be stronger than the interest in the identity of another JRC patient. While the Court is sensitive to the defendants' burden, this is what the law requires.

To say that the defendants have not conducted the necessary balancing is not to say that the agency will not, eventually, be able to "support redacting identifying information in all cases if its justifications for doing so were framed in a more targeted manner." *AILA,* 830 F.3d at 676. Indeed, as the defendants explain, the names of individuals who have provided information to the FDA might offer no insight into how the FDA performs it statutory duties. Defs.' Reply at 34. Perhaps the minimal public interest in the release of records will succumb to a properly articulated privacy interest because disclosure of any name risks divulging associated medical information that the individuals themselves have not

shared. *Id.* at 35. The defendants must provide the Court with the information needed to engage in that balancing inquiry. That has not happened.[11]

75*75 D. SEGREGABILITY

As for the last issue, segregability, FOIA requires that "[a]ny reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt under this subsection." 5 U.S.C. § 552(b). Producing segregable information is an essential ingredient to a sufficient FOIA production, and "[b]efore approving the application of a FOIA exemption, the district court must make specific findings of segregability regarding the documents to be withheld." *Sussman v. U.S. Marshals Serv.*, 494 F.3d 1106, 1116 (D.C. Cir. 2007). For those findings, "[a]gencies are entitled to a presumption that they complied with the obligation to disclose reasonably segregable material." *Id.* at 1117. Even with that presumption, "the agency must provide a `detailed justification' for its non-segregability" but need not "provide so much detail that the exempt material would be effectively disclosed." *Johnson v. Exec. Office for U.S. Attorneys*, 310 F.3d 771, 776 (D.C. Cir. 2002) (quoting *Mead Data Ctr., Inc. v. Dep't of the Air Force*, 566 F.2d 242, 261 (D.C. Cir. 1977)). Affidavits attesting to the agency's "line-by-line review of each document withheld in full" and the agency's determination "that no documents contained releasable information which could be reasonably segregated from the nonreleasable portions," in conjunction with a *Vaughn* Index describing the withheld record, suffice. *Id.*

The defendants here have provided a sufficiently detailed justification. The defendants have submitted eight affidavits, each certifying to the represented FDA or HHS component's performance of "a careful page-by-page, line-by-line review of all records." Defs.' Mem. at 33 (citing First DFOI Decl. ¶ 40; First NE-DO Decl. ¶ 20; OCC Decl. ¶ 39; DOJ Decl. ¶ 7; Decl. of Eric F. Stein, Department of State ¶ 11, ECF No. 24-8; ORA Decl. ¶ 15; HHS Decl. ¶ 15; First Community Living Decl. ¶ 15). The same affidavits confirm that all reasonably segregable information has been disclosed. *Id.* Corroborating those accounts, the defendants have partially released 1,340 pages of records. Pls.' SMF ¶ 44.[12]

Thus, the Court finds that as to draft records withheld under Exemption 5's deliberative-process privilege, records withheld under Exemption 5's attorney-client privilege, records withheld under Exemption 6 to conceal personal information about low-level JRC employees and the contact information of government employees, and records withheld under Exemption 7(c), the defendants have released all segregable information.

*** * ***

Through no fault of either party, this case is onerous. Indeed, the plaintiffs' massive FOIA requests returned over 24,000 76*76 responsive records, to say nothing of the 60,000 records that CDRH is in the process of producing. Such broad requests are understandable given that the records relate to the agency's regulation, and possible ban, of a treatment practice that the plaintiffs adamantly believe in. Of course, the volume of records is so substantial only because the defendants have been diligently considering the need for regulation for quite some time.

Nevertheless, issues relevant to this litigation have not been presented with clarity and neither party is blameless. On the defendants' side, too much has been painted with too broad a brush. While the end, at least for now, of the defendants' regulatory work is the Proposed Ban, the defendants have made an awful lot of intermediary decisions to get from the point at which JRC did not have to obtain 510(k) clearance for the GED to proposing a rule that would ban the GED altogether. In making those decisions, the FDA consulted with many individuals, including former JRC patients. Certainly, as a baseline, all JRC patients have a privacy interest in their medical history, but some individuals can exhibit behaviors reflecting a lesser interest in maintaining that privacy. The plaintiffs have done no better, identifying general problems with the defendants' production but offering only a smattering of examples of those purported problems, which fall short of their obligation under Federal Rule of Civil Procedure 56. *See, supra* n.5. Consequently, the plaintiffs have provided insufficient precision as to how many records, or which records, the plaintiffs are actually challenging, other than the relatively small number from the voluminous *Vaughn* indices that are specifically cited in the briefing.

Shortcuts, especially with such a large body of records, are tempting, and in this case both parties have taken some. FOIA litigation works best, however, when the defendants are clear about how and why exemptions have been applied and the plaintiffs are clear about where they believe the defendants have gone wrong. Of course, going forward, the remaining issues in this case may be narrowed by the parties conferring about the production, with this Memorandum Opinion providing some guidance. If the parties require another round of summary judgment briefing, they must do better focusing on which withholdings are still contested. To that end, any subsequent *Vaughn* Index must plainly identify the records in dispute.

IV. CONCLUSION

For the foregoing reasons, the defendants' Motion for Partial Summary Judgment, ECF No. 25, is GRANTED in part and DENIED in part. The defendants are granted partial summary judgment for withholdings under Exemption 5's attorney-client privilege, for withholdings of draft records under Exemption 5's deliberative-process privilege, for withholdings under Exemption 6 that conceal the personal information of low-level JRC employees or the contact information of government employees, and for withholdings under Exemption 7(c). As for the remaining withholdings under Exemption 5's deliberative-process privilege and under Exemption 6, the defendants must supplement their *Vaughn* Index and/or declarations consistent with this Memorandum Opinion.

The plaintiffs' Cross-Motion for Partial Summary Judgment, ECF No. 30, is GRANTED in part and DENIED in part. The plaintiffs are granted summary judgment with respect to the defendants' withholding of non-responsive information. The defendants must produce all such records not otherwise being withheld under one of FOIA's statutory exemptions. The plaintiffs 77*77 also are granted summary judgment as the record identifying the JRC employee who was interviewed by CBS, Bates-stamped JRC OES Supplemental 1 XXXXXX-XX. The plaintiffs' cross-motion is otherwise denied.

The parties are directed to submit, by April 19, 2019, a joint status report as to the progress, if any, the parties have made to narrow the issues in dispute and to propose a schedule to

govern further proceedings in this matter. If additional briefing will be required, the parties should provide their views on whether such briefing can be combined with any briefing that may be necessary regarding CDRH's response to the plaintiffs' FOIA requests.

An Order consistent with this Memorandum Opinion will be contemporaneously entered.

[1] On February 2, 2018, the case was bifurcated. *See* Min. Order (Feb. 2, 2018). "[E]ach FDA component other than the Center for Devices and Radiological Health (`CDRH')" was put on one production and briefing schedule; CDRH was put on another. *Id.* The pending motions relate only to the records released by components in the first group.

[2] The plaintiffs have requested a hearing, *see* Pls.' Cross-Mot. at 1, but that request is denied as unnecessary given the voluminous record in this case. LCvR 7(f) (authorizing oral hearings at "the discretion of the Court").

[3] The plaintiffs have also challenged the defendants' failure to produce roughly 150 email attachments to records from the New England District Office, Pls.' Reply Supp. Cross-Mot. Summ. J. ("Pls.' Reply") at 20, ECF No. 35, which attachments originated with FDA's CDRH, First NE-DO Decl. ¶ 19. Those attachments have been referred to CDRH to be included in a future production. *See* Suppl. Decl. of Barbara A. Recupero, New England District Office ¶ 5, ECF No. 33-4. The plaintiffs contend that referral to CDRH is no substitute for releasing the attachments because the New England District Office "remains responsible for producing these attachments." Pls.' Reply at 20. Yet, "agencies that receive FOIA requests and discover responsive documents that were created by another agency may forward, or `refer,' those requests to the agency that `originated' the document." *Elec. Privacy Info. Ctr. v. Nat'l Sec. Agency,* 795 F.Supp.2d 85, 92 (D.D.C. 2011). Referral is proper "when doing so does not constitute an improper withholding of agency records," as would be true if the referral's "`net effect is to impair the requester's ability to obtain the records or significantly to increase the amount of time he must wait to obtain them.'" *Id.* at 94 (quoting *McGehee v. CIA,* 697 F.2d 1095, 1110 (D.C. Cir. 1983), *vacated in part on other grounds,* 711 F.2d 1076 (D.C. Cir. 1983)). Here, "the CDRH and any other HHS component to which a referral has been made" are subject to a separate production schedule. Min. Order (Feb. 2, 2018). Allowing CDRH to complete production consistent with the prior scheduling order does not impair the plaintiffs' access to the requested email attachments. Accordingly, the plaintiffs' request that these email attachments be produced outside the Court-ordered schedule applicable to CDRH is denied.

[4] Although the plaintiffs' motion for summary judgment challenged the defendants' withholdings under Exemption 5's attorney-client privilege, *see* Pls.' Opp'n at 29-31, the plaintiffs did not respond to any of the defendants' counter-arguments, *see generally* Pls.' Reply. Consequently, the plaintiffs have conceded the defendants' arguments. *See Philipp v. Fed. Republic of Germany,* 248 F.Supp.3d 59, 69 (D.D.C. 2017) (treating argument to which the plaintiff failed to respond as conceded); *Cannon v. Wells Fargo Bank, N.A.,* 952 F.Supp.2d 1, 11 (D.D.C. 2013) (same); *Hopkins v. Women's Div., Gen. Bd. of Glob. Ministries,* 284 F.Supp.2d 15, 25 (D.D.C. 2003) (same). In any event, the defendants have sufficiently explained the basis for assertion of the attorney-client privilege, stating that "[r]ecords withheld under attorney-client privilege in this case include communications between FDA staff and agency attorneys within FDA's OCC." Defs.' Mem. P. & A. Supp. Defs.' Mot. Partial Summ. J. at 28, ECF No. 25. Those records reflect confidential communications "seeking and/or providing legal advice" or communications "among agency attorneys within OCC discussing legal advice that they would subsequently provide to agency staff." *Id.* at 28-29; Defs.' Opp'n at 27-28; *see also, e.g.,* 3rd Index at 55-56 (describing email as covered under attorney-client privilege because email was sent to agency for legal advice, with agency counsel identified as recipients of the email); 3rd Index at 100-02 (describing email as covered under attorney-client privilege because email was sent between agency counsel in response to client's request for advice); 3rd Index at 344-45 (describing draft of Proposed Ban as covered under attorney-client privilege because draft contained comments with legal advice from agency counsel). Accordingly, the defendants are granted partial summary judgment as to the records withheld under Exemption 5's attorney-client privilege.

[5] The plaintiffs claim that "many entries in the Updated Index lack dates," but cite only a single example, *see* Pls.' Opp'n at 11 (citing 2nd Index at 732-33), leaving to the Court the task of sifting through the extensive *Vaughn* indices to find evidence of the plaintiffs' point. The plaintiffs are cautioned that, in any future round of summary judgment briefing, they must point to specific entries in the *Vaughn* indices to sustain any particular challenge to the sufficiency of the defendants' response to their FOIA requests. *See* FED. R. CIV. P. 56(c)(3) ("The court need consider only the cited materials, but it may consider other materials in the record."); FED. R. CIV. P. 56(c)(1)(A) (directing that the "party asserting that a fact ... is genuinely disputed must support the assertion by ... citing to particular parts of materials in the record"). Failure "to properly address another party's assertion of fact as required by Rule 56(c)," may result in any records not specifically challenged to be "undisputed for purposes of the motion." FED. R. CIV. P. 56(e)(2).

[6] Given the volume of withheld records and the length of the defendants' *Vaughn* Index, for clarity of the analysis in any future summary judgment briefing, records may be sequentially numbered with a unique document number that would make reference simpler and location on the *Vaughn* Index more readily accessible, than use of only a Bates-stamp number, and will permit the parties and the Court to appreciate the total number of disputed records at issue. For those records withheld under the deliberative-process privilege, the defendants may employ efficient methods of describing the decisions triggering application of Exemption 5. For example, the defendants could submit an affidavit listing all decisions to which the responsive records relate and include in the *Vaughn* Index a cross-reference to that affidavit or group the records on the *Vaughn* Index by the specific decisions to which they relate.

[7] The plaintiffs also argue that this Power Point is unlikely to be predecisional because the presentation was organized more than a year after the FDA *started* drafting the Proposed Ban. Pls.' Opp'n at 24. By that logic, in which the relevant decision is the decision to initiate some process, the deliberative process would evaporate. Rather, the decision to which the Power Point contributed is the promulgation of the Proposed Ban, *see* 2nd Index at 531-33; 3rd Index at 538-40, a process which, at the time of the presentation to the FDA Commissioner, had not been completed.

[8] To facilitate review of contested records in any subsequent round of summary judgment briefing, the defendants are directed to indicate in some manner on a subsequent version of the third *Vaughn* Index, or in a separate index, the specific record entries withheld under Exemption 5's deliberative-process privilege for which the defendants have been granted partial summary judgment.

[9] The defendants stress that in *Carter v. Department of Commerce,* 830 F.2d 388 (D.C. Cir. 1987) and *Salas v. Office of the Inspector General,* 577 F.Supp.2d 105 (D.D.C. 2008), the plaintiffs bore the burden of establishing a public interest in disclosure more powerful than the countervailing privacy interests. Defs.' Opp'n at 32. Yet, *Carter* merely held that the requesters had not rebutted the agency's explanation of why disclosing certain identities would infringe a privacy interest that outweighs the public interest in disclosure. 830 F.2d at 391-92 & n.13. While in *Salas* a judge on this Court placed the burden on the requester "to articulate a public interest sufficient to outweigh an individual's privacy interest" and added that "the public interest must be significant," 577 F.Supp.2d at 112, the support for those propositions came from *National Archives and Records Administrative v. Favish,* 541 U.S. 157, 124 S.Ct. 1570, 158 L.Ed.2d 319 (2004). *Favish,* however, pertained to Exemption 7, which though narrower in scope than Exemption 6, is more protective of privacy interests than Exemption 6 and establishes a lower bar for withholding information. 541 U.S. at 165-66, 124 S.Ct. 1570. In light of the authority on which *Salas* relied—as well as the D.C. Circuit's *AILA* opinion—*Salas* is not persuasive.

[10] The defendants also withheld "the identities of lower-level employees of JRC and contact information of government employees in sensitive occupations," under Exemption 6. Defs.' Mem. at 31. The plaintiffs do not contest these withholdings. Pls.' Opp'n at 32-33 n.18. Thus, the defendants are granted partial summary judgment as to this category of Exemption 6 withholdings. To facilitate review of contested records in any subsequent round of summary judgment briefing, the defendants are directed to indicate in some manner on a subsequent version of the third *Vaughn* Index, or in a separate index, the specific record entries withheld under Exemption 6 to protect personal information about lower-level employees or contact information of government employees for which the defendants have been granted partial summary judgment.

[11] The defendants also withheld some records pursuant to Exemption 7(c). Rather than present any argument as to these withholdings, the plaintiffs simply "reserve their right to advance this argument in the future." Pls.' Opp'n at 16 n.9. Such reservation of argument does not suffice to preserve the objection. Now was the time to challenge the defendants' withholdings and to move this case to resolution. *See DeSilva v. U.S. Dep't of Hous. & Urban Dev.,* 36 F.Supp.3d 65, 70 (D.D.C. 2014) ("The plaintiff contests neither the applicability of the exemptions nor the defendant's segregability determinations, and the Court thus deems these matters conceded."). Without any specific objection from the plaintiffs to focus the dispute, but upon review of a sampling of the defendants' withholdings under Exemption 7(C), these withheld records appear appropriate. *See, e.g.,* 2nd Index at 6-8 (justifying Exemption 7(c) withholding of information in a string of DOJ emails as related to personal information about former JRC patient that had been gathered for law enforcement purposes); *id.* at 28-30 (justifying Exemption 7(c) withholding of information in a string of DOJ emails as related to personal information about former JRC patient who had contacted DOJ); *id.* at 44-46 (same); *see also* 3rd Index at 6-8, 28-31, 45-46. Accordingly, the defendants are granted partial summary judgment as to the information withheld under Exemption 7(c). Again, to facilitate review of contested records in any subsequent round of summary judgment briefing, the defendants are directed to indicate in some manner on a subsequent version of the third *Vaughn* Index, or in a separate index, the specific record entries withheld under Exemption 7(c) for which the defendants have been granted partial summary judgment.

[12] Largely, the plaintiffs' segregability arguments are repackaged from their arguments against the application of the deliberative-process privilege. For example, the plaintiffs argue that factual and background information contained within records withheld under the deliberative-process privilege should be released. Pls.' Opp'n at 41-42. Given that the Court is not issuing a ruling on the deliberative-process privilege expect as to draft records, segregability issues as to these withholdings cannot be resolved at this juncture.