

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

Informed Consent Action Network v. Food and Drug Administration

Informed Consent Action Network v. Food and Drug Administration · No. 22-3572 (CKK) · Decided March 3,
2026

OPINION

Informed Consent Action Network v. Food and Drug Administration

PER CURIAM.

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF COLUMBIA

INFORMED CONSENT ACTION

NETWORK,

Plaintiff, V. Civil Action No. 22-3572 (CKK)

U.S. FOOD AND DRUG

ADMINISTRATION,

Defendant.

MEMORANDUM ..., OPINION

(March 2, 2026) In this Freedom of Information Act ("FOIA") case, Plaintiff Informed Consent Action Network ("ICAN") argues that the U.S. Food and Drug Administration ("FDA") has unlawfully withheld records responsive to its request for copies of autopsy reports "concerning any [Vaccine Adverse Event Reporting System]-reported deaths following COVID-19 vaccination." See Compl., Dkt. No. 1, ¶ 5. The FDA contends that these records are entirely exempt from disclosure under FOIA's "Exemption 6," which exempts from disclosure "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). This Court previously granted partial summary judgment in the FDA's favor, concluding that the FDA conducted an adequate search for responsive records. However, the Court concluded that the FDA had not shown that the relevant statutory exemption supported withholding the relevant records in their entirety rather than segregating exempt and non-exempt information by producing redacted records. The Court therefore directed the FDA to file a Vaughn index identifying the portions of each record that it contends are exempt from disclosure and explaining how the agency decided that those portions could not reasonably be segregated from other, non-exempt material. The FDA has now filed its Vaughn index, and the parties have filed renewed motions for summary judgment. Upon consideration of the parties' submissions,¹ the relevant legal authority, and the entire record, the Court concludes that the FDA properly withheld the autopsy reports in their entirety. The Court shall GRANT Defendant FDA's renewed motion for summary judgment and DENY Plaintiff ICAN's renewed cross-motion for summary judgment.

I. BACKGROUND

This case is about access to autopsy reports for people whose deaths were reported through the Vaccine Adverse Event Reporting System (“VAERS”) in connection with a COVID-19 vaccine. VAERS is a national reporting system designed to help the FDA monitor vaccine safety by accepting reports of “adverse events”—that is, possible side effects—experienced by people who receive vaccines that are licensed or authorized for use in the United States. See Decl. of Narayan Nair (“Nair Decl.”), Dkt. No. 21-5, ¶ 7. The Emergency Use Authorizations (“EUAs”) for COVID-19 vaccines administered in the U.S. require vaccine providers and manufacturers to report certain “adverse events” to VAERS. Id. ¶ 8. When an individual dies after receiving the COVID-19 vaccine, a reporter may include the individual’s autopsy report as an attachment to the VAERS report. Id. ¶ 9. A federal contractor may also follow up with the requestor to request an 1

The Court’s consideration has focused on the following documents, including the attachments and exhibits thereto: • The Vaughn Index filed by Defendant FDA, Dkt. No. 28-1; • Defendant FDA’s Renewed Motion for Summary Judgment (“Def.’s Mot.”), Dkt. No. 30; • Plaintiff ICAN’s Renewed Motion for Summary Judgment (“Pl.’s Mot.”), Dkt. No. 31; • The Defendant Memorandum in Opposition to the Plaintiff’s Motion (“Def.’s Opp’n”), Dkt. No. 32; • The Plaintiff’s Memorandum in Opposition to the Defendant’s Motion (“Pl.’s Opp’n”), Dkt. No. 33; • The Defendant’s Reply in Support of its Motion for Summary Judgment (“Def.’s Reply”), Dkt. No. 34; • The Plaintiff’s Reply in Support of its Motion for Summary Judgment (“Pl.’s Reply”), Dkt. No. 35; In an exercise of its discretion, the Court concludes that oral argument is not necessary to the resolution of the issues pending before the Court. See LCvR 7(f).

2 autopsy report. Id. Reporters submit these autopsy reports with the understanding that they will be kept confidential to the fullest extent permitted by law. Id. ¶ 16. The FDA considers these autopsy reports, among many other data sources, when deciding whether a vaccine may be associated with a specific health risk. See id. ¶¶ 11–15. The Plaintiff in this case, Informed Consent Action Network (“ICAN”), describes itself as a “not-for-profit new media organization whose mission is to raise public awareness about vaccine safety.” Pl.’s Stmt. of Material Facts (“Pl.’s Stmt.”), Dkt. No. 31-4, ¶ 1. In November 2021, ICAN submitted a FOIA request to the FDA requesting “[c]opies of autopsy reports concerning any [Vaccine Adverse Event Reporting System (“VAERS”)]-reported deaths following COVID-19 vaccination.” Id. ¶ 2; Def.’s Resp. to Pl.’s Stmt. (“Def.’s Resp.”), Dkt. No. 33-1, ¶ 2. The FDA denied ICAN’s request in its entirety. Pl.’s Stmt. ¶ 3. In its response to ICAN, the FDA advised that it had located 539 potentially responsive autopsy reports, but it took the position that the autopsy reports were exempt from disclosure under 5 U.S.C. §§ 552(b)(3) (“Exemption 3”), which covers records “specifically exempted from disclosure by statute”, 552(b)(6) (“Exemption 6”), which covers “personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy,” the National Childhood Vaccine Injury Act of 1986, as amended, 42 U.S.C. §§ 300aa-10, et seq., and 21 C.F.R. § 20.63. Pl.’s Stmt. ¶ 3. ICAN filed an administrative appeal with the FDA

challenging the adequacy of its search and its decision to withhold the autopsy reports. Id. ¶ 4. The FDA acknowledged the appeal and stated that it needed to consult with another office to decide the appeal. See id. ¶ 5. About six weeks later, after receiving no further communication from the FDA, ICAN filed this action. Id. ¶ 6. In its Complaint, ICAN alleged three counts: failure to make a timely 3 determination of its appeal, failure to establish an adequate search for responsive records, and improper withholding of responsive records. Compl. ¶¶ 10–19. The FDA moved for summary judgment, arguing that its search was adequate and that it properly withheld the relevant records under FOIA’s exemption for “personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.” Def.’s Mot., Dkt. No. 21; 5 U.S.C. § 552(b)(6). ICAN opposed the FDA’s motion and filed a cross-motion for summary judgment, contending that the FDA should have segregated and redacted the exempt portions of the relevant records and disclosed the remainder. Pl.’s Mot., Dkt. No. 22. ICAN did not contest the adequacy of the FDA’s search. See id. This Court granted partial summary judgment to the FDA on the issue of the adequacy of its search. Mem. Op. & Order, Dkt. No. 26. However, the Court denied without prejudice the FDA’s motion for summary judgment on the issue of whether the FDA properly withheld the autopsy reports in their entirety. Id. The Court concluded that the privacy interests of decedents’ family members could support the application of FOIA Exemption 6 to withhold at least some parts of the autopsy reports, noting that family members “have a clear privacy interest in preventing the full disclosure of the autopsy reports.” Id. at 10. Although that interest could support withholding some information, the Court noted that “[t]here is also a public interest at stake in releasing the autopsy reports, to the extent that any of the reports conclude that a COVID-19 vaccine caused the adverse event.” Id. Recognizing that interest and the FDA’s duty to produce any reasonably segregable, non-exempt portions of the reports, the Court directed the FDA to file a Vaughn index and provide a “detailed justification” for its decision to withhold the reports in their entirety, rather than producing redacted versions. Id. at 10–12 (quoting *Mead Data Cent., Inc. v. Dep’t of Air Force*, 566 F.2d 242, 261 (D.C. Cir. 1977)). 4 In response to the Court’s order, the FDA conducted a “page-by-page, line-by-line review” of the autopsy reports to assess whether all of the information at issue was properly withheld under Exemption 6. Decl. of Elizabeth Teter-Gossmann (“Teter-Gossmann Decl.”), Dkt. No. 30-2, ¶¶ 9–

10. Based on this review, the FDA concluded that all substantive information in the autopsy reports is exempt from disclosure because releasing it would be reasonably likely to result in foreseeable harm to the decedents’ families by allowing the decedents to be publicly identified. Id. ¶ 13; see also Vaughn Index, Dkt. No. 28-1. The FDA explained that if this information were released, using a “mosaic theory,” individuals would be able to “piece together” this information from the autopsy reports and other sources to identify decedents, even if any single piece of information would not obviously be identifying. See Teter-Gossmann Decl. ¶ 13; see also Decl. of John Hyder (“Hyder Decl.”), Dkt. No. 21-4, ¶¶ 12, 14, 19; cf. *Halperin v. CIA*, 629 F.2d 144, 150

(D.C. Cir. 1980) (“[E]ach individual piece of intelligence information, much like a piece of jigsaw puzzle, may aid in piecing together other bits of information even when the individual piece is not of obvious importance in itself.”). Consistent with the Court’s order, the FDA then filed a Vaughn index documenting its determinations about which information was exempt, which information was non-exempt, and whether the non-exempt information could reasonably be segregated. See Def.’s Notice of Filing, Dkt. No. 28; Vaughn Index, Dkt. No. 28-1. The Vaughn index specifically identified the information in each autopsy report that is exempt from disclosure because it would result in a “clearly unwarranted invasion of personal privacy,” including the decedent’s full name, date of birth, address, date and place of vaccination, date and place of death, and medical history. See Vaughn Index, Dkt. No. 28-1; 5 U.S.C. § 552(b)(6). The index also identified the non-exempt information that would remain after redacting the exempt information: only “standardized form 5 language and headings” such as the contact information for VAERS and the labels for each of the fields on the report. See, e.g., Vaughn Index, Dkt. No. 28-1, at 2. After the FDA filed its Vaughn index, the parties filed renewed motions for summary judgment. See Def.’s Mot., Dkt. No. 30; Pl.’s Mot., Dkt. No. 31. In its motion, the FDA renews its argument that it properly withheld the autopsy reports in their entirety under FOIA Exemption 6. See Def.’s Mot. ICAN opposes the FDA’s motion renews its cross-motion for summary judgment, arguing that that Exemption 6 does not apply to all the information contained in the autopsy reports and the FDA is improperly withholding non-exempt portions of the reports. See Pl.’s Mot. Specifically, ICAN seeks the following information from each autopsy report: year of birth, race, sex, ethnicity, date when vaccine was given, list of medication, allergies, any non-identifying portions of the full medical history, chronic/long- standing health conditions, circumstances as to how decedent died, date and cause of death, toxicology test results, occupation, marital status, and any other information that is not personally identifying. Pl.’s Mem., Dkt. No. 31-1, at 8. However, ICAN represents that it is not seeking other information found in the autopsy reports, such as decedents’ names, addresses, full dates of birth, telephone numbers, email addresses, names of next of kin, and place of death. Id. The parties’ renewed motions for summary judgment are now ripe for decision.

II. LEGAL STANDARD

A party is entitled to summary judgment if it “shows that there is no genuine dispute as to any material fact” and that it is “entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). Summary judgment is the proper vehicle for resolving “the vast majority of FOIA cases.” *Brayton v. Off. of the U.S. Trade Representative*, 641 F.3d 521, 527 (D.C. Cir. 2011). An agency is entitled to summary judgment on a FOIA claim when the agency’s declarations “describe the justifications for nondisclosure with reasonably specific detail, demonstrate that the information withheld logically falls within the claimed exemption, and are not controverted by either contrary evidence in the record nor by evidence of agency bad faith.” *Larson v. Dep’t of State*, 565 F.3d 857, 862 (D.C. Cir. 2009) (quoting *Miller v. Casey*, 730 F.2d 773, 776 (D.C. Cir. 1984)). A reviewing court must decide de novo whether an agency correctly applied a FOIA exemption.

Mead Data Cent., Inc. v. Dep't of Air Force, 566 F.2d 242, 251 (D.C. Cir. 1977).

III. ANALYSIS

This Court previously concluded that the FDA conducted an adequate search and that it had a lawful basis to withhold at least some parts of the relevant reports. Now that the FDA has supplemented the record with further detail about the relevant exempt and non-exempt material in the responsive records and provided a Vaughn index, the Court agrees with the FDA that the relevant records do not contain any reasonably segregable material that is subject to disclosure. Accordingly, the Court shall GRANT the FDA's renewed motion for summary judgment and DENY ICAN's renewed cross-motion. A. The FDA properly supported its application of Exemption 6 to withhold information that could be used to identify individuals. FOIA Exemption 6, on which the FDA relies in this case, allows 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). This exemption is "intended to cover detailed Government records on an individual which can be identified as applying to that individual." U. S. Dep't of State v. Washington Post Co., 456 U.S. 595, 602 (1982) (quoting H.R. Rep. No. 1497, 89th Cong., 2nd Sess., at 11 (1966)). Deciding whether an invasion of privacy would be "clearly unwarranted" requires "balancing of interests between the protection of an individual's private affairs from unnecessary public scrutiny, and the preservation of the public's right to governmental information." Dep't of Air Force v. Rose, 425 U.S. 352, 372 (1976) (quoting S. Rep. No. 813, 89th Cong., 1st Sess., at 9 (1965)). Accordingly, a reviewing court "must weigh 7 the 'privacy interest in non-disclosure against the public interest in the release of the records in order to determine whether, on balance, the disclosure would work a clearly unwarranted invasion of personal privacy.'" Lepelletier v. FDIC, 164 F.3d 37, 46 (D.C. Cir. 1999) (quoting National Ass'n of Retired Fed. Employees v. Horner, 879 F.2d 873, 874 (D.C. Cir. 1989)). In this case, the FDA properly applied Exemption 6 to withheld information in the autopsy reports that could be used to identify individuals. As this Court previously concluded, "the decedents' family members have a clear privacy interest in preventing the full disclosure of the autopsy reports." Mem. Op. & Order, Dkt. No. 26. That same interest supports withholding all individual pieces of information that could be used to identify the decedents. See *id.* The record now before the Court shows that after a "careful page-by-page, line-by-line review" of the autopsy reports, the FDA concluded that disclosing any of the information that it withheld under Exemption 6 is reasonably likely to allow a reader to identify decedents by piecing that information together with other available data. See Teter-Gossmann Decl. ¶¶ 9, 13; Hyder Decl. ¶¶ 12, 14, 19. The Court is not persuaded by ICAN's argument that many pieces of information in the autopsy reports should be disclosed because, when considered in isolation, they are less readily identifying than names or dates of birth. See Pl.'s Mem. at 8–11.2 As ICAN's own evidence in this case shows, autopsy reports contain extraordinary amounts of information about a person, even when redacted to exclude the decedent's name and the other information that ICAN concedes is exempt from disclosure. See

Decl. of Elizabeth A. Brehm (“Brehm Decl.”), Dkt. No. 22-2, Ex. A (autopsy report with redactions applied by ICAN’s counsel). As the FDA explains, there is a substantial risk that, using a “mosaic” approach, an individual could combine that information 2 The FDA argues that ICAN waived its challenge to the withholding of this information by stating in the first round of summary judgment briefing in this case that it was not seeking “personally identifying information.” See Def.’s Opp’n at 3–8. Because the parties disagree about what information is in fact “personally identifying,” the Court resolves ICAN’s challenge on the merits rather than considering it waived. 8 with other information in the public domain to identify the decedent, even without a name or other directly identifying information. See Teter-Gossmann Decl. ¶ 13; Hyder Decl. ¶¶ 12, 14, 19; see also Def.’s Mem. at 11; Def.’s Reply at 8–13. The Court finds the FDA’s informed position on this issue to be persuasive and relevant to this Court’s de novo determination because of the agency’s experience and expertise in the complex and sensitive field of patient data protection. See *Mead*, 566 F.2d at 251; see also *SafeCard Servs., Inc. v. SEC*, 926 F.2d 1197, 1200 (D.C. Cir. 1991) (noting that agency declarations are “accorded presumption of good faith” in FOIA cases). ICAN’s arguments about the public interest in the information at issue do not tip the balance in favor of disclosure. See Pl.’s Reply at 6–8. Contrary to ICAN’s suggestion, the privacy interest of decedents’ family members is more than “minimal.” Cf. *id.* at 6. This Court previously described that interest as “clear,” crediting the FDA’s arguments that revealing the identities of the decedents may “subject the surviving kin to inquiries from the media or general public” and other unwarranted invasions of privacy. Mem. Op. & Order at 8–9 (citing Def.’s Mem., Dkt. No. 21-1, and collecting cases). Meanwhile, the countervailing public interest in disclosure is diminished by the fact that individual autopsy reports, devoid of other context, have only limited value in assessing either the role of a COVID-19 vaccine in an individual’s death or the safety of COVID-19 vaccines in general. See Nair Decl. ¶¶ 7, 10–15. That interest is further attenuated by the possibility that disclosure could harm a distinct public interest in encouraging the voluntary submission of future reports, which public health agencies might be less likely to share with the FDA if they cannot rely on the FDA’s assurance that the reports submitted will be kept confidential. See *id.* ¶ 16. 9 B. The remaining information is not subject to disclosure because it would have “minimal or no information content.” Having concluded that the FDA properly relied on Exemption 6 to withhold all of the identifying information found in the autopsy reports, the Court turns to the distinct question of whether it was proper for the FDA to withhold the reports in their entirety rather than producing redacted versions. For the reasons that follow, the Court concludes that it was proper for the FDA to withhold the entire reports. FOIA requires that “[a]ny reasonably segregable portion of [a responsive] record shall be provided to any person requesting such record after deletion of the portions which are exempt.” 5 U.S.C. § 552(b). Generally, if a document contains some exempt material, the statutory duty to segregate exempt and non-exempt material requires agencies to release redacted versions of documents unless the non-exempt portions are “inextricably intertwined with exempt portions.” *Mead*, 566 F.2d at 260. However,

FOIA does not require agencies to produce records that are so heavily redacted that no semantically meaningful content remains. If an agency may properly withhold parts of a document under FOIA's exemptions, it "need not disclose a redacted version of [the document] if the unredacted markings would have 'minimal or no information content.'" *Perioperative Servs. & Logistics, LLC v. United States Dep't of Veterans Affs.*, 57 F.4th 1061, 1069 (D.C. Cir. 2023) (quoting *Mead*, 566 F.2d at 261 n.55). The FDA's Vaughn index and supplemental declaration make clear that the autopsy reports at issue in this case would have "minimal or no information content" once all exempt, personally identifying information is redacted. See *Perioperative Servs.*, 57 F.4th at 1069. After redacting the information that the Court has agreed is exempt from disclosure, the only information that would remain unredacted is boilerplate form language such as headings and contact information 10 for VAERS. See Def.'s Mem. at 14. FOIA does not require agencies to expend their resources processing thousands of lines of redactions to produce documents in which nothing of value remains. As the FDA notes, an order to make such a production would further burden an office that is currently processing expedited requests for an extraordinary volume of records related to COVID-19 vaccinations that another district court has concluded are "of paramount public importance." See *Pub. Health & Med. Professionals for Transparency v. FDA*, No. 4:21-cv-1058- P, Dkt. No. 35 at 3 (N.D. Tex. Jan. 6, 2022); Def.'s Mem. at 14-15; see also *Informed Consent Action Network v. FDA*, No. 24-cv-1761, 2024 WL 4836405, at *1 (D.D.C. Nov. 20, 2024) (CJN) (describing the court-ordered production schedule for these records, under which the office must process hundreds of thousands of pages of records per month). This Court declines to add to that burden by requiring the FDA to produce records with "minimal or no information content" left unredacted. See *Perioperative Servs.*, 57 F.4th at 1069. Accordingly, this Court is of the opinion that the FDA has satisfied its burden to show that there are no reasonably segregable, non-exempt responsive records subject to disclosure here.

IV. CONCLUSION

For the foregoing reasons, the Court shall GRANT Defendant FDA's [30] Renewed Motion for Summary Judgment and DENY Plaintiff CAN's [31] Renewed Motion for Summary Judgment. An appropriate Order accompanies this Memorandum Opinion. Dated: March: i_, 2026 COLL~ J f ~ ~ ~ United States District Judge 11