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U.S. Department of Health and Human Services
Assistant Secretary of Public Affairs
VIA HHS online portal: https://requests.publiclink.hhs.gov/App/Index.aspx

February 13, 2025

Re: Administrative appeal of FOIA #61642

To Whom it May Concern:

With this letter, Children's Health Defense CHD) appeals the National Institutes of Health's (NIH) January 24, 2025 final response to Freedom of Information Act (FOIA) Request #61642. In response to the request, NIH provided CHD with 2498 pages of records, all of which are fully redacted. CHD requests that NIH lift the redactions, because the Agency has (1) failed to show that the redactions legitimately fall under any FOIA exemption; (2) failed to segregate non-exempt materials; and (3) failed to show how disclosure would foreseeably harm any interests protected by FOIA exemptions.

Background

A) The Request

On April 11, 2024, CHD submitted a FOIA request to the National Institute of Environmental and Health Sciences (NIEHS), directed towards the Division of Translational Toxicology (DTT). The request sought the following:

> All protocols, standard operating procedures, and other records describing the methods, procedures, and/or study goals of every study planned or conducted by DTT to follow up on the rodent studies previously conducted by the National Toxicology Program (NTP) and reported in NTP TR 595 and NTP TR 596.

The request is incorporated herein by reference.

B) The Response Letter and the Redactions

On December 3, 2024, the NIEHS FOIA office issued CHD a final response letter along with 389 pages of records; these records are not at issue in this appeal. The December 3 letter indicated that NIEHS sent the remaining 2,498 pages of records to the NIH FOIA office for review and final determination; these are the records at issue in this appeal.

On January 24, 2025, the NIH FOIA office issued a final response letter and provided 2,498 pages of records, all fully redacted. The records and January 24 response letter are incorporated herein by reference.

The January 24 response letter states, "portions of these records were withheld pursuant to Exemptions 4, 5, and 6 of the FOIA . . . and sections 5.32(d), (e), and (f) of HHS FOIA Regulations, 45 CFR Part 5."

The response letter does not indicate what the records consist of.

Each page of the records is fully redacted, bearing a stamp with a page number and this statement:

Withheld pursuant to exemption

(b)(4) ; (b)(5) ; (b)(6)

of the Freedom of Information and Privacy Act

The response letter does not indicate why these exemptions apply, or explain how it is possible that every page of records qualifies simultaneously as confidential financial information, an interagency deliberative communication, and a personnel, medical, or similar file.

Further, the response letter does not indicate that the foreseeable harm standard has been considered or met. Finally, the response letter does not indicate that any effort has been made to segregate and disclose non-exempt portions of the records.

Why the Redacted Material Is Not Exempt from Disclosure

When a federal agency like the NIH receives a properly formulated FOIA request, the Freedom of Information Act requires the agency to search for records responsive to the request, and promptly make those records available. *See* 5 U.S.C. § 552(a)(3)(A)-(D). When claiming that records are exempt from disclosure, the Agency has the burden of demonstrating that the claimed exemption applies. *See American Civil Liberties Union v. DOD*, 628 F.3d 612, 619 (D.C. Cir. 2011).

If any portion of a record is exempt, the agency must consider whether partial disclosure of the information is possible, and "take reasonable steps necessary to segregate and release nonexempt information." *See id*. at § 552 (a)(8)(A)(i) and (ii).

Even if a record is properly exempt, an Agency must still demonstrate that disclosing the record would foreseeably harm the interests protected by the claimed exemption. *See Reporters Comm. for Freedom of the Press* v. FBI, 3 F.4th 350, 361 (D.C. Cir. 2021).

A) The Material Does Not Qualify for Exemption Under (b)(4).

The NIH cannot meet its burden of demonstrating that any of the redactions fall under the (b)(4) exemption, which exempts from disclosure "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. §552 (b)(4).

When an agency withholds non-trade-secret information under Exemption 4,[1] it must demonstrate that the withheld information is "(1) commercial or financial, (2) obtained from a person, and (3) privileged or confidential." *Pub. Citizen Health Rsch. Grp. v. FDA*, 704 F.2d 1280, 1290 (D.C. Cir. 1983). Additionally, the Agency must demonstrate that the foreseeable harm requirement is met. *See* 5 U.S.C. § 552(a)(8).

The D.C. Circuit defines "commercial" to have its "ordinary meaning. And, in ordinary parlance, information is commercial if it pertains to the exchange of goods or services or the making of a profit." *Citizens for Resp. & Ethics in Washington v. United States Dep't of Just.*, 58 F.4th 1255, 1263 (D.C. Cir. 2023) (cleaned up).

According to the D.C. Circuit, "[g]iven the ordinary meaning of 'commercial,' Exemption 4 paradigmatically applies to records that a business owner customarily keeps private because they actually reveal basic commercial operations, such as sales statistics, profits and losses, and inventories, or [that] relate to the income-producing aspects of a business." *Citizens for Resp. & Ethics* 58 F.4th at 1263 (cleaned up).

To determine whether Exemption 4 applies, the court looks to whether information is commercial "in and of itself," meaning it "serves a commercial function or is of a commercial nature. [The D.C. Circuit has] read Exemption 4 to cover only information that, *in and of itself*, demonstrably pertains to the exchange of goods or services or the making of a profit." *Id*. at 1265 (cleaned up) (italics added).

Exemption 4 "does not make potential consequences of disclosure an explicit ground for withholding." *Id.* at 1264. Rather, "it is the nature of the information itself that is crucial, rather than potential commercial consequences of disclosure." *Id.* at 1265-67 (cleaned up).

In addition to demonstrating that withheld information is financial or commercial, to justify Exemption 4 withholding, the government must also demonstrate that the withheld information itself is "customarily and actually treated as private by its owner." *See Id.* at 1269 (citing *Food Marketing Institute v. Argus Leader Media*, 139 S.Ct. 2356, 2363 (2019)).

The redacted records are not exempt under (b)(4), because they do not appear to qualify as financial information. Additionally, they do not appear to meet the definition of "commercial," as they do not, in and of themselves, appear to relate to the exchange of goods or services or the making of a profit. Finally, the non-financial redacted records do not appear to be of a sort customarily and actually treated as private by its owner.

To the extent that any portion of the redacted material is truly exempt from disclosure, NIH must still segregate and disclose non-exempt portions. Finally, NIH has not shown that disclosure of the redacted material would foreseeably harm the interests protected by the exemption. Accordingly, all of the (b)(4) redactions should be lifted.

B) The Material Does Not Qualify for Exemption Under (b)(5)

The NIH cannot meet its burden of demonstrating that any of the redactions described above fall under the deliberative process exemption, which protects "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. . ." *See* 5 U.S.C. § 552 (b)(5).

[1] The D.C. Circuit defines a "trade secret" as "a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." See *Pub. Citizen Health Research Grp*., 704 F.2d at 1288. The redacted records at issue here do not appear to meet this definition.

The “deliberative process” exemption is designed to protect the decision-making processes of government agencies. *National Labor Relations Board v. Sears, Roebuck & Co*., 421 U.S. 132, 150 (1975). It exempts from disclosure “documents reflecting advisory opinions, recommendations and deliberations comprising part of a process by which governmental decisions and policies are formulated.” *Electronic Frontier Foundation v. U.S. Dept. of Justice*, 826 F. Supp. 2d 157, 165 (D.D.C. 2011) *(*quoting *Sears*, 421 U.S. at 150) (internal quotation marks omitted). The exemption shields “those documents, and only those documents, normally privileged in the civil discovery context.” *Sears, Roebuck & Co.,* 421 U.S. at 149.

Exemption 5 “does not authorize an agency to throw a protective blanket over all information.” *American Radio Relay League Inc. v. FCC*, 524 F.3d 227 238 (D.C. Cir. 2008). The exemption may be invoked only where an Agency can show that (1) a communication is pre-decisional, that is, “antecedent to the adoption of an agency policy,” and (2) the communication is deliberative, that is, a “direct part of the deliberative process in that it makes recommendations or expresses opinions on legal or policy matters.” *Vaughn v. Rosen*, 523 F.2d 1136, 1143-44 (D.C. Cir. 1975).

Moreover, the exemption may be invoked only where the release of records would *actually* inhibit the decision-making process. *See Southwest Center for Biological Diversity v. U.S.D.A.*, 170 F.Supp. 2d 931, 940 (2000) (rejecting application of exemption 5 where Agency only raised *possibility* that release of factual data would have adverse effect).

While the Agency need not identify a specific agency decision to meet its burden of showing that a record is “pre-decisional,” the Agency must at least describe the “nature of the deliberative process involved and the function and significance of the document in that process.” *See Public Employees for Environmental Responsibility v. EPA*, 213 F. Supp. 3d 1, 13 (D.D.C. 2016). It must also provide the “nature of the decisionmaking authority vested in the document’s author and recipient.” *Id*. at 18.

Notably, exemption 5 applies “only to the *deliberative* portion of a document and *not* to any purely factual, non-exempt information the document contains.” *Army Times Pub. Co. v. Department of Air Force*, 998 F.2d 1067, 1070 (D.C. Cir. 1993) (emphasis added); s*ee also EPA v. Mink*, 410 U.S. 73, 91 (1973). Non-exempt information must be disclosed if it is “reasonably segregable” from exempt portions of the record. *Army Times* 998 F.2d at 1070.

Here, there is no indication that the redacted material is deliberative or pre-decisional. To the extent that any portion of the redacted material is truly exempt from disclosure, NIH must still segregate and disclose non-exempt portions. Finally, NIH has not shown that disclosure of the redacted material would foreseeably harm the interests protected by the exemption. Accordingly, all of the (b)(5) redactions should be lifted.

B) The Material Does Not Qualify for Exemption Under (b)(6)

The NIH cannot meet its burden of demonstrating that any of the redactions fall under the personal privacy exemption, which protects “personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.” *See* 5 U.S.C. § 552b(6). “Similar files” includes “[g]overnment records on an individual which can be identified as applying to that individual.” *U.S. Dep't of State v. Wash. Post Co.*, 456 U.S. 595, 602 (1982).

Exemption (b)(6) leans heavily in favor of disclosure; indeed, the presumption to disclose is “at its zenith under Exemption 6.” *WP Company LLC v. U.S. Department of Defense*, 626 F.Supp. 3d 69, 78 (D.D.C. 2022).

When information in a record cannot be linked to a particular individual, the exemption does not apply. *See, e.g., Arieff v. Dep't of the Navy*, 712 F.2d 1462, 1467-68 (D.C. Cir. 1983) (holding that Agency must show more than a "mere possibility" that an individual's medical condition would be disclosed before the exemption would protect a list of drugs ordered by members of a large group).

If the information is linked to a particular individual, to determine whether the exemption applies, courts balance between "the protection of an individual's private affairs from unnecessary public scrutiny, and the preservation of the public's right to governmental information." *Id.* (cleaned up). Importantly, an agency may withhold personal information only if "disclosure would compromise a *substantial*, as opposed to a de minimis, privacy interest*." Nat'l Ass'n of Retired Fed. Emps. v. Horner*, 879 F.2d 873, 875 (D.C. Cir. 1989) (emphasis added).

Thus, the exemption does not apply merely because a record contains the names of individuals; rather, disclosure must significantly threaten the privacy of those individuals to justify the exemption. As the Supreme Court has noted, "we are not implying that disclosure of a list of names and other identifying information is inherently and always a significant threat to the privacy of the individuals on the list. Instead, we agree with the Court of Appeals for the District of Columbia Circuit that whether disclosure of a list of names is a "'significant or a *de minimis* threat depends upon the characteristic(s) revealed by virtue of being on the particular list, and the consequences likely to ensue.'" *United States Dep't of State v. Ray*, 502 U.S. 164, 176 n.12, (1991) (cleaned up).

Even when an identifiable individual has a privacy interest in the records, the interest must be weighed against the public interest in the disclosure of the records in order to determine whether disclosure would constitute a clearly unwarranted invasion of privacy. *NARA v. Favish*, 541 U.S. 157, 172 (2004) ("The term 'unwarranted' requires us to balance the . . . privacy interest against the public interest in disclosure.").

The public interest relevant to the balancing is "the extent to which disclosure of the information sought would shed light on an agency's performance of its statutory duties or otherwise let citizens know what their government is up to." *WP Co. LLC v. United States*, 626 F. Supp. 3d at 77 (citation omitted).

Here, there is no indication that any of the redacted information qualifies as personnel, medical, or similar files. Furthermore, to the extent that any of the redacted materials implicate privacy interests, the interests are not significant, and are outweighed by the public interest in the redacted material. Thus, none of the redacted material is exempt under (b)(6).

To the extent that any portion of the redacted material is truly exempt from disclosure, NIH must still segregate and disclose non-exempt portions. Finally, NIH has not shown that disclosure of the redacted material would foreseeably harm the interests protected by the exemption. Accordingly, all of the (b)(6) redactions should be lifted.

What We're Asking the NIH to Do:

In light of the above, we request that the NIH lift the redactions discussed above and provide the unredacted records to Children's Health Defense within 20 business days.

To the extent that any redactions are not lifted, we request that the NIH describe the redacted material in sufficient detail to clarify why the material is exempt—or, if redacted material is not exempt, explain why NIH cannot segregate and disclose it.

Finally, to the extent that any redactions are not lifted, we ask NIH to explain how disclosure of the redacted material would foreseeably harm the interests protected by the relevant exemptions.

Sincerely yours,

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