



September 25, 2023

Appeal No.: 2023-00173-A-PHS
Original NIH Case No: 58915

John Davidson

Dear Mr. Davidson:

This responds to your May 31, 2023, Freedom of Information Act (FOIA) appeal. On August 29, 2022, you submitted a FOIA request to the National Institutes of Health (NIH), which sought the following records, in pertinent part:

- “(1) All email communications between Eric O Freed and Oliver Schildgen for the time period 20th August 2021 to 31st May 2022; and
- (2) All email communications from/to Eric O. Freed containing the phrase ‘expression of concern’ or the name ‘Jiang’ in the body of the email.”

On August 31, 2022, you amended the second item of your request to “any emails containing the word ‘Jiang’ and any of the words ‘paper’, ‘expression’, ‘concern’, ‘retract’ or ‘retraction’.”

On April 14, 2023, NIH issued a final response to your request, which informed you that the agency had located 490 pages of records responsive to your request and that these pages were being withheld, in their entirety, under Exemption 4 of the FOIA and section 5.31(d) of the HHS FOIA Regulations, 45 C.F.R. Part 5.

On May 31, 2023, you submitted an appeal that challenged NIH’s decision to withhold the records responsive to your request, in their entirety, under Exemption 4. In your appeal correspondence, you stated that “[t]here is an important public health benefit to releasing these communications” and that NIH “has failed to give sufficient weight to the public’s interest in disclosure.”

You further stated that “MDPI is a non-profit business in Switzerland which operates a collection of scientific journals” and that “[t]he damage from exposed ‘review process’ trade secrets will be non-existent unless the communications reveal evidence of malfeasance.”

DISCUSSION

Exemption 4

Exemption 4 of the FOIA protects “trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential.”¹ Information other than trade secrets may be protected by Exemption 4 if it is 1) commercial or financial, 2) obtained from a person, and 3) privileged or confidential.² Here, the records responsive to your original request contain confidential commercial information that is protected under Exemption 4 and continue to be withheld on appeal.

For the purposes of Exemption 4, the terms ‘commercial’ and ‘financial’ are given their ordinary meanings and information is considered commercial so long as a party submitting the information to the government has a commercial interest in the information.³ Courts have recognized that the internal processes or procedures of an organization, including the organization’s quality control measures, are considered to be commercial in nature.⁴ In this case, the records withheld in response to your request are commercial in nature, and include information that reflects the editorial review processes of Multidisciplinary Digital Publishing Institute (MDPI), a publisher of open access scientific journals, and the processes and procedures MDPI uses to determine whether an article should be retracted.

The records that I am continuing to withhold under Exemption 4 have also been “obtained from a person”. The term “person” refers to individuals as well as to a wide range of entities, including corporations.⁵ The records withheld under Exemption 4 were obtained from MDPI, which is a private company that is registered in Switzerland, and is considered to be a person for the purposes of the Exemption.

The question then is whether the records that I am continuing to withhold under Exemption 4 are considered to be privileged or confidential. Commercial or financial information is considered “confidential” for purposes of Exemption 4 at least if it is (1) both actually and customarily treated as private by its owner and (2) provided to the government under an assurance of privacy.⁶

MDPI both customarily and actually treats the records withheld in response to your request under Exemption 4 as private. The records that continue to be withheld in response to your request under Exemption 4 include communications about MDPI’s editorial review process and the content of a post-publication investigation, which MDPI customarily treats as confidential and does not share with external parties. MDPI follows guidance from the Committee on Publication Ethics (COPE) and the International Committee of Medical Journal Editors (ICMJE), which specify that the confidential

¹ 5 U.S.C. § 552(b)(4).

² See *National Parks Ass’n v. Morton*, 498 F.2d 765, 766 (D.C. Cir. 1974); *Pub. Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1290 (D.C. Cir. 1983); *Herrick v. Garvey*, 200 F.Supp.2d 1321, 1324 (D. Wyo. 2000), *aff’d*, 298 F.3d 1184, 1193-95 (10th Cir. 2002).

³ *Pub. Citizen*, 704 F.2d at 1290.

⁴ See e.g., *Pub. Citizen v. HHS*, 975 F. Supp. 2d 81, 115 (D.D.C. 2013); *United Techs. Corp. v. Dep’t of Def.*, 601 F.3d 557, 564 (D.C. Cir. 2010); *M/A-Com Information Systems, Inc. v. HHS*, 656 F. Supp. 691, 692 (D.D.C. 1986); *Bowen v. FDA*, 925 F.2d 1225, 1227-28 (9th Cir. 1991).

⁵ See e.g., *Allnet Communication Servs. v. FCC*, 800 F. Supp. 984, 988 (D.D.C. 1992); *In Def. of Animals v. NIH*, 543 F. Supp. 2d 83, 101 (D.D.C. 2008).

⁶ *Food Mktg. Inst. v. Argus*, 139 S. Ct. 2356, 2366 (2019).

treatment of author manuscripts, review processes and related material is a fundamental aspect of scientific publishing, and that the sharing of information concerning the content, status or fate of a manuscript outside of the journal's review process is against principles of confidentiality.

The records withheld in response to your request in this case are also actually treated as confidential by MDPI. MDPI has made available certain information regarding the general process for investigating complaints about an article on its website⁷ and MDPI has attached a retraction notice to the article covered by the communications sought by your request that describes the retraction reasons, the form the investigation took and the approval of the editor-in-chief.⁸ However, beyond that, MDPI does not customarily nor has it in this case made any information about its review process public. This clearly indicates that the records that continue to be withheld under Exemption 4, on appeal, are actually and customarily treated as private by MDPI.

In this case, NIH has also provided assurances that the records that continues to be withheld under Exemption 4 would remain private. NIH's relationship with this and other journals would be harmed by disclosure here.⁹ NIH and the Department of Health and Human Services (HHS) have also provided such assurances by historically withholding information related to internal processes or procedures of an outside organization, including an organization's quality control measures, in so long as the information is considered privileged or confidential for the purposes of Exemption 4.¹⁰ Here, the records at issue reflect MDPI's internal processes and quality control measures for determining whether an article should be retracted. Because the records at issue are a type that have historically been withheld by NIH and HHS, there was an assurance that these records would not be released to the public.

On a final note, it is important to clarify that courts have expressly rejected the argument that, in applying Exemption 4, agencies "should gauge whether the [] harm done... by the public disclosure of confidential information is outweighed by the strong public interest" in its disclosure.¹¹ Congress has already determined that trade secrets and commercial or financial information that is obtained from a person and is privileged or confidential are exempt from release so long as the agency reasonably foresees that disclosure would harm an interest protected by Exemption 4 or disclosure is prohibited by law. Contrary to the arguments made in your appeal, there is no additional requirement in the FOIA statute requiring agencies to weigh the harm of releasing confidential commercial information against the public interest in the material.

With that said, because the records withheld under Exemption 4 contain confidential commercial information that MDPI actually and customarily treated as private and NIH provided MDPI with assurances that the information would be kept confidential, the information was properly withheld in response to your request and continues to be withheld on appeal. I have determined it is reasonably foreseeable that a prospective release of the information that continues to be withheld on appeal would cause the type of harm Exemption 4 is designed to protect against.

⁷ <https://www.mdpi.com/ethics#complaints>

⁸ <https://www.mdpi.com/1999-4915/14/5/1011>

⁹ See also, *Sejfe v FDA*, 43 F.4th 231 (2nd Cir, 2022).

¹⁰ See e.g., *Pub. Citizen v. HHS*, 975 F. Supp. 2d at 91; *M/A-Com Information Systems, Inc.*, 656 F. Supp. at 692; *Bowen*, 925 F.2d at 1227-28.

¹¹ *Pub. Citizen Health Research Grp. v. FDA*, 185 F.3d 898, 903-04 (D.C. Cir. 1999); see also *N.H. Right to Life v. HHS*, 976 F. Supp. 2d 43, 55 (D.N.H. 2013)

DECISION

After consideration of your appeal and a review of the administrative record, I uphold NIH's decision to withhold the records responsive to your request under Exemption 4 of the FOIA.

CONCLUSION

This letter constitutes the final decision of the Department in this matter. If you wish, you may seek judicial review in the district court of the United States in the district in which you reside, have your principal place of business, in which the agency records are located, or in the District of Columbia.

The 2007 FOIA amendments created the Office of Government Information Services (OGIS) to offer mediation services to resolve disputes between FOIA requesters and Federal agencies as a non-exclusive alternative to litigation. Using OGIS services does not affect your right to pursue litigation. You may contact OGIS via email at ogis@nara.gov.

Sincerely,

William H. Holzerland
Deputy Agency Chief FOIA Officer
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services