IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

RESTORE PUBLIC TRUST 1875 Connecticut Ave NW (Floor 10) Washington, DC 200009 Plaintiff, v. U.S. FOOD AND DRUG ADMINISTRATION 10903 New Hampshire Ave Silver Spring, MD 20993 U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES 200 Independence Ave SW Washington, DC 20201 Defendants.	)	Case No. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. This is an action under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, as amended, as well as agency FOIA regulations, 21 C.F.R. §§ 20.1 *et seq*., 45 C.F.R. §§ 5.1 *et seq.*, challenging the failure of the U.S. Food and Drug Administration ("FDA") and the U.S. Department of Health and Human Services ("HHS") to fulfill the requests for information made by Restore Public Trust.

2. Plaintiff seeks declaratory relief that defendants are in violation of the FOIA for failing to fulfill plaintiff's requests for records, and injunctive relief that defendants immediately and fully comply with plaintiff's requests under the FOIA.

JURISDICTION AND VENUE

3. This Court has both subject matter jurisdiction over this action and personal jurisdiction over the parties pursuant to 5 U.S.C. § 552(a)(4)(B) and 5 U.S.C. § 702, which gives the Court jurisdiction over agency actions where an aggrieved party has suffered a wrong "within the meaning of a relevant statute," here the FOIA. This Court also has jurisdiction over this action pursuant to 28 U.S.C. § 1331. Venue lies in this District under 5 U.S.C. § 703, 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391(e)(1).

4. Plaintiff Restore Public Trust is a public interest organization that promotes accountability and transparency in government to root out corruption and malfeasance. It is designed to serve as a critical resource for policymakers and elected officials investigating public corruption, members of the public looking for more information about what their government is or is not doing, and journalists examining the alleged malfeasance of government officials. It uses the information it gathers, and its analysis of that information, to educate the public through reports, press releases, and other media. Restore Public Trust also makes the material it gathers available on its public website.

5. Defendant HHS is an agency within the meaning of 5 U.S.C. § 552(f)(1). Defendant FDA, a component of HHS, is also an agency within the meaning of 5 U.S.C. § 552(f)(1). Defendants are the agencies with possession and control of the records responsive to plaintiff's requests and is responsible for fulfilling the FOIA requests of plaintiff.

STATUTORY FRAMEWORK

The Freedom of Information Act

6. The FOIA, 5 U.S.C. § 552, requires agencies of the federal government to release requested records to the public unless one or more specific statutory exemptions apply.

7. An agency must respond to a party making a FOIA request within 20 working days, notifying that party of at least the agency's determination whether or not to fulfill the request, and of the requester's right to appeal the agency's determination to the agency head. 5 U.S.C. § 552(a)(6)(A)(i).

8. In "unusual circumstances," an agency may delay its response to a FOIA request but must provide written notice to the requesting party and must also provide "the date on which a determination is expected to be dispatched." 5 U.S.C. § 552(a)(6)(B).

9. This Court has jurisdiction, upon receipt of a complaint, "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).

10. The FOIA provides a mechanism for disciplinary action against agency officials who have acted inappropriately in withholding records. Specifically, when requiring the release of improperly withheld records, if the court makes a written finding that "the circumstances surrounding the withholding raise questions whether agency personnel acted arbitrarily or capriciously," a disciplinary investigation is triggered. 5 U.S.C. § 552(a)(4)(F).

11. FDA has FOIA regulations mandating its requirements to respond to FOIA requests. 21 C.F.R. §§ 20.1 *et. seq*. HHS has FOIA regulations mandating its requirements to respond to FOIA requests. 45 C.F.R. §§ 5.1 *et seq*.

FACTS GIVING RISE TO PLAINTIFF'S CLAIMS FOR RELIEF

12. This case concerns four requests for records relating to Norman Sharpless and G1 Therapeutics, the biotech company he helped found before assuming his role as acting commissioner of the FDA. *See* Conor Hale, "With NCI Director Sharpless in as interim FDA Head, what does that mean for interagency cooperation?" FierceBiotech, March 12, 2019,

available at https://www.fiercebiotech.com/biotech/nci-director-sharpless-to-fill-as-interim-fda-head-and-a-potential-medical-research-go. In December 2018, G1's stock plummeted after its cancer drug trilaciclib failed to outperform placebo in a phase 2 clinical trial. *Id.* In April of this year, however, G1 announced that it planned to file for regulatory approval for the drug. *See* Todd Campbell, "Why G1 Therapeutics is Soaring 16% Today," The Motley Fool, April 30, 2019, available at https://www.fool.com/investing/2019/04/30/why-g1-therapeutics-is-soaring-16-today.aspx.

13. The integrity of the FDA approval process is paramount to ensure that only safe, effective drugs are brought to market. There is a strong public interest in learning the full extent of the involvement of FDA political appointees in the approval process for drugs and companies with whom they had a prior relationship.

The First Request

14. On May 3, 2019, plaintiff submitted a FOIA request via FDA's on-line request system. A copy of this request is attached as Exhibit 1. The request sought "any correspondence sent by, to, carbon copied ('CC'), or blind carbon copied ('BCC') Norman Sharpless, also known as Ned Sharpless, or his Executive Assistant or Scheduler, that contains the following keywords or phrases between and including April 5, 2019 and the date the search is performed:

- 'GI Therapeutics'
- 'GTHX'
- 'Trilaciclib'
- 'Mark Velleca.'"

15. Plaintiff sought a fee waiver, explaining that the request was made in the public interest. It explained that the disclosure of the information sought would "document and reveal

the operations of the federal government, including how public funds are spent and how officials conduct the public's business." Plaintiff also explained that its request for records is "primarily and fundamentally for non-commercial purposes," as it is a 501(c)(3) nonprofit organization with no financial interest in the records, and will use them to inform the public.

16. FDA acknowledged receipt of this submission by email dated May 3, 2017. A copy of this email is attached as Exhibit 2. On May 13, 2019, Sarah Kotler, Director of the Division of Freedom of Information, OES, U.S. Food & Drug and Administration denied plaintiff's request for expedited processing. A copy of this letter is attached as Exhibit 3.

17. As of the date of the filing of this Complaint, plaintiff has received no further communications from defendant concerning this request.

The Second Request

18. On May 3, 2019, plaintiff submitted a FOIA request via FDA's on-line request system. A copy of this request is attached as Exhibit 4. The request sought "access to and copies of calendars or calendar entries since and including April 5, 2019 for Norman Sharpless, also known as Ned Sharpless, including any calendars maintained on his behalf (e.g. by an administrative assistant)."

19. Plaintiff sought a fee waiver, explaining that the request was made in the public interest. It explained that the disclosure of the information sought would "document and reveal the operations of the federal government, including how public funds are spent and how officials conduct the public's business." Plaintiff also explained that its request for records is "primarily and fundamentally for non-commercial purposes," as it is a 501(c)(3) nonprofit organization with no financial interest in the records, and will use them to inform the public.

20. FDA acknowledged receipt of this submission by email dated May 3, 2017. *See* Exhibit 5 (attached).

21. As of the date of the filing of this Complaint, plaintiff has received no further communications from defendant concerning this request.

The Third Request

22. On May 10, 2019, plaintiff submitted a FOIA request via FDA's on-line request system. A copy of this request is attached as Exhibit 6. "The request sought "any correspondence sent by, sent to, carbon copying ('CC'), or blind carbon copying ('BCC') Ned Sharpless that makes references to the following terms between and including February 1, 2019 and the date the search is performed:

- 'GI Therapeutics'
- 'G1'
- 'trial' AND 'recus!'
- 'employ!' AND recus!'"

23. Plaintiff also sought a fee waiver, explaining that the request was made in the public interest. It explained that the disclosure of the information sought would "document and reveal the operations of the federal government, including how public funds are spent and how officials conduct the public's business." Plaintiff also explained that its request for records is "primarily and fundamentally for non-commercial purposes," as it is a 501(c)(3) nonprofit organization with no financial interest in the records, and will use them to inform the public.

24. FDA acknowledged receipt of this submission by email dated May 10, 2017. A copy of this email is attached as Exhibit 7.

25. As of the date of the filing of this Complaint, plaintiff has received no further communications from defendant concerning this request.

The Fourth Request

26. On May 31, 2019, plaintiff submitted a FOIA request via FDA's on-line request system. A copy of this request is attached as Exhibit 8. The request sought "copies of travel disclosures and gift disclosures filed by Ned Sharpless, or any other official acting on his behalf, between and including April 5, 2019 and the date the search is performed."

27. Plaintiff also sought a fee waiver, explaining that the request was made in the public interest. It explained that the disclosure of the information sought would "document and reveal the operations of the federal government, including how public funds are spent and how officials conduct the public's business." Plaintiff also explained that its request for records is "primarily and fundamentally for non-commercial purposes," as it is a 501(c)(3) nonprofit organization with no financial interest in the records, and will use them to inform the public.

28. On June 4, 2019, Director Kotler referred plaintiff's request to the U.S. Department of Health and Human Services ("HHS"). A copy of this email is attached as Exhibit 9. That same day, Michael S. Marquis, Director, Freedom of Information and Privacy Acts Division, HHS, acknowledged receipt of the request. *See* Exhibit 10 (attached).

29. As of the date of the filing of this Complaint, plaintiff has received no further communications from defendant concerning this request.

PLAINTIFF'S CLAIMS FOR RELIEF

CLAIM ONE

(Failure to Conduct an Adequate Search)

30. Plaintiff re-alleges and incorporates by reference all preceding paragraphs.

31. Plaintiff submitted requests that reasonably described the records sought and were made in accordance with FDA's and HHS's published rules.

32. In response, defendants have failed to conduct a search reasonably calculated to uncover all responsive agency records.

33. Therefore, defendants have violated the FOIA's mandate to search for responsive records. 5 U.S.C. § 552(a)(3)(A).

34. Plaintiff is entitled to injunctive and declaratory relief with respect to the search for the requested records.

CLAIM TWO

(Failure to Produce Records Under the FOIA)

35. Plaintiff re-alleges and incorporates by reference all preceding paragraphs.

36. Plaintiff properly asked for records within defendants' control.

37. Plaintiff is entitled by law access to the records requested under the FOIA, unless defendant makes an explicit and justified statutory exemption claim.

38. Defendants have not produced the records responsive to plaintiff's FOIA requests.

39. Therefore, defendants have violated the FOIA's mandate to release agency records to the public by failing to release the records as plaintiff specifically requested. 5 U.S.C. §§ 552(a)(3)(A).

CLAIM THREE

(Failure to Provide Fee Waiver)

40. Plaintiff re-alleges and incorporates by reference all preceding paragraphs.

41. Plaintiff properly asked for a public interest fee waiver.

42. Plaintiff is entitled by law to receive a public interest fee waiver. Restore Public Trust is a nonprofit organization dedicated to informing the public regarding issues of public concern. The integrity of FDA drug approvals is a matter of significant public concern. Plaintiff has no commercial interest in the information and will use it solely to inform the public.

43. Defendants did not provide a public interest fee waiver to plaintiff.

44. Therefore, defendants have violated the FOIA's mandate to grant fee waivers when the requests are made in the public interest. 5 U.S.C. §§ 552(a)(4)(A)(iii) and 20 CFR § 46(a).

PRAYER FOR RELIEF

WHEREFORE, plaintiff respectfully requests that this Court:

1. Declare that defendants have violated the FOIA and agency regulations by failing to conduct an adequate search for records responsive to plaintiff's FOIA requests;

2. Order the defendants to immediately conduct and document an adequate search for responsive records as dictated by plaintiff's requests;

3. Declare that the defendants have violated the FOIA by failing to lawfully satisfy plaintiff's FOIA requests;

4. Order the defendants to release all records responsive to plaintiff's FOIA requests;

5. Order the defendants to grant a public interest fee waiver for all records responsive to plaintiff's requests;

6. Award plaintiff its reasonable attorney fees and litigation costs in this action, pursuant to 5 U.S.C. § 552(a)(4)(E); and

7. Grant such other and further relief as the Court may deem just and proper.

Respectfully submitted,

By: /s/ Jonathan Massey

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