

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

LATHAM & WATKINS LLP
555 Eleventh Street, N.W.,
Suite 1000
Washington, D.C. 20004,

Plaintiff,

v.

U.S. HEALTH RESOURCES AND SERVICES
ADMINISTRATION
5600 Fishers Lane,
Rockville, MD 20852

U.S. DEPARTMENT OF HEALTH AND HUMAN
SERVICES
200 Independence Avenue, SW
Washington, DC 20201,

Defendants.

Case No. 1:21-cv-1862

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Latham & Watkins LLP (Latham) brings this complaint for declaratory and injunctive relief, and states as follows in support thereof:

PRELIMINARY STATEMENT

1. The Freedom of Information Act (FOIA), 5 U.S.C. § 552 *et seq.*, “was enacted to promote transparency and accountability in how the federal government discharges its numerous and far-ranging responsibilities.” *Shapiro v. U.S. Dep’t of Justice*, 153 F. Supp. 3d 253, 256 (D.D.C. 2016). FOIA provides a means for the public to access government documents and “mandates that an agency disclose records upon request, unless they fall within one of nine exemptions.” *Id.* at 257. FOIA also recognizes that the government cannot sit on its hands forever;

it must make timely determinations regarding what documents it possesses that are responsive to a specific request, and when it will produce them. *See* 5 U.S.C. § 552(a)(6)(A)(i).

2. Defendants the U.S. Department of Health and Human Services (HHS) and U.S. Health Resources and Services Administration (HRSA) administer, among other things, the federal government's statutory 340B drug discount program, which allows certain hospitals and other "covered entities" to purchase drugs from manufacturers at heavily discounted rates. *See* 42 U.S.C. § 256b.

3. On December 30, 2020, Defendant HHS's General Counsel issued an "Advisory Opinion" purporting to interpret the 340B statute. *See* Advisory Opinion 20-06 On Contract Pharmacies Under The 340B Program at 1 (Dec. 30, 2020). On May 17, 2021, Defendant HRSA issued determinations that six pharmaceutical manufacturers, including one of Latham's clients, have violated the 340B statute. HRSA reiterated that determination to Latham's client on May 28, 2021.

4. In order to fully understand the bases for HHS's Advisory Opinion and HRSA's determination concerning Latham's client, Latham filed FOIA requests with HHS and HRSA.

5. Latham urgently needs these records in connection with briefing in an Administrative Procedure Act (APA) case against HRSA and HHS about HRSA's determination concerning Latham's client. *See United Therapeutics Corp. v. Diana Espinosa et al.*, Case No. 1:21-cv-1686-DLF (filed June 23, 2021).

6. Neither HHS nor HRSA has made a determination on Latham's FOIA requests within the statutorily mandated 20 working days for such determination. 5 U.S.C. § 552(a)(6)(A)(i). As a result, HHS and HRSA are impeding Latham's access to these important records.

7. Administrative remedies under FOIA are deemed exhausted when an agency fails to comply with the statute's applicable time limits for making a determination on a given request. 5 U.S.C. § 552(a)(6)(C)(i). Having fully exhausted applicable administrative remedies for its request, Latham now turns to this Court to enforce FOIA's guarantee of public access to agency records. Accordingly, Latham asks this Court to declare that Defendants have violated FOIA, to order Defendants to provide Latham with legally compliant responses to its request, and to grant other appropriate relief, including attorneys' fees and costs.

PARTIES

8. Plaintiff Latham & Watkins LLP (Latham) is a private law firm with an office located at 555 Eleventh Street N.W., Suite 1000, Washington, D.C. 20004. Latham submitted the FOIA requests at issue here as part of its representation of a client and likewise brings suit to further that representation.

9. Defendant HHS is a department of the United States. Its headquarters and principal place of business are at 200 Independence Avenue, S.W., Washington, DC 20201. Its governmental activities occur nationwide.

10. Defendant HRSA is an agency of the United States and a division of HHS. Its headquarters and principal place of business is at 5600 Fishers Lane, Rockville, MD 20852. Its governmental activities occur nationwide.

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction over Latham's claims pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331.

12. This Court has authority to grant declaratory relief pursuant to 28 U.S.C. § 2201.

13. This Court has authority to award injunctive relief pursuant to 5 U.S.C. § 552(a)(4)(B).

14. Venue lies in this district under 5 U.S.C. § 552(a)(4)(B) (providing FOIA venue in the District of Columbia).

LEGAL BACKGROUND

15. FOIA “requires the government to disclose, upon request, broad classes of documents identified in 5 U.S.C. § 552(a),” unless the documents are exempt under 5 U.S.C. § 552(b). *See Prison Legal News v. Samuels*, 787 F.3d 1142, 1146 (D.C. Cir. 2015).

16. FOIA imposes strict deadlines on federal agencies when they receive a request for records pursuant to FOIA. First, an agency must acknowledge receipt of a FOIA request, in writing, within ten days of receipt of the request, exclusive of weekends and legal public holidays. 5 U.S.C. § 552(a)(7)(A).

17. Next, an agency must respond to a party making a FOIA request within twenty days of receipt, exclusive of weekends and legal public holidays, notifying that party of the agency’s determination whether 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). The D.C. Circuit has explained that to make a valid “determination” under the statute the agency must indicate “the scope of the documents it will produce and the exemptions it will claim with respect to any withheld documents.” *Citizens for Responsibility & Ethics in Wash. v. FEC*, 711 F.3d 180, 185-86, 188 (D.C. Cir. 2013); *see also Seavey v. Dep’t of Justice*, 266 F. Supp. 3d 241, 245 (D.D.C. 2017) (the agency must “(1) gather[] and review[] the [requested] documents; (2) determin[e] and communicat[e] the scope of the documents it intends to produce and withhold, and the reasons for withholding any documents; and (3) inform[] the requester that it can appeal whatever portion of the ‘determination’ is adverse”).

18. The agency may extend the statutory twenty-day deadline only in “unusual circumstances,” 5 U.S.C. § 552(a)(6)(B)(iii), and must then make the requested records

“promptly” available, *id.* § 552(a)(3)(A), (a)(6)(C)(i), except where it can establish that one of FOIA’s narrow exemptions listed at § 552(b) applies.

19. When an agency fails to make a timely determination with respect to a perfected FOIA request, a requester is deemed to have exhausted administrative remedies with respect to the request and may immediately file suit in district court. 5 U.S.C. § 552(a)(6)(C); *Citizens for Responsibility & Ethics*, 711 F.3d at 186.

FACTUAL BACKGROUND

20. On December 30, 2020, Defendant HHS’s General Counsel issued an “Advisory Opinion” purporting to interpret the 340B statute. *See* Advisory Opinion 20-06 On Contract Pharmacies Under The 340B Program at 1 (Dec. 30, 2020).

21. On May 17, 2021, Defendant HRSA issued determinations to six pharmaceutical manufacturers that they had violated the 340B statute. *See, e.g.*, Kristen Coppock, *HRSA Finds 6 Pharmaceutical Manufacturers in Violation of 340B Requirements*, PHARMACY TIMES (May 17, 2021), <https://www.pharmacytimes.com/view/hrsa-finds-6-pharmaceutical-manufacturers-in-violation-of-340b-requirements>. On May 28, 2021, HRSA reiterated that determination to one of Latham’s clients.

22. On June 9, 2021, Latham sent a FOIA request to HRSA by email to FOIA@hrsa.gov. *See* Exhibit A, attached.

23. The request sought all copies and related documents regarding (1) “complaints HRSA has received from covered entities” about Latham’s client’s policies regarding 340B drug pricing; (2) “specific complaints from covered entities regarding their inability to purchase several [of Latham’s client’s] covered outpatient drug products at or below the 340B ceiling price through the pharmacies that dispense medications to patients”; (3) “communications from covered entities to HRSA regarding” Latham’s client’s participation in the 340B program; (4) HRSA’s analysis

regarding two specific policies that Latham's client has announced it will adopt in relation to the 340B program; (5) emails, memoranda, or other documents related to the formulation of the May 17 and 28 determination letters that HRSA sent to Latham's client; (6) notifications HRSA has received since March 2010 from covered entities who discover 340B program violations, and HRSA's analysis of those notifications; and (7) certifications that covered entities have filed with HRSA since March 2010 about use of "contract pharmacies" and their compliance with the 340B program's regulatory requirements, and HRSA's analysis of such certifications. *See* Exhibit B, attached. Latham agreed to pay all necessary fees for this request.

24. A member of HRSA's FOIA office responded on June 10, 2021 that the agency was "reviewing [Latham's] FOIA request submission." *See* Exhibit C, attached.

25. As of the date of this filing, HRSA has not made a determination within the meaning of FOIA on Latham's FOIA request.

26. On June 9, 2021, Latham also submitted a FOIA request to HHS through HHS's FOIA portal at <https://requests.publiclink.hhs.gov/App/Index.aspx> by email to FOIA@hrsa.gov. *See* Exhibit D, attached.

27. That requested sought "All emails, memoranda, or other documents related to the formulation of 'Advisory Opinion 20-06 on Contract Pharmacies under the 340B Program' (Dec. 30, 2020)."

28. On June 9, 2021, HHS sent Latham an email confirmation that this FOIA requested was received. *See* Exhibit E, attached.

29. As of the date of this filing, HHS has not made a determination within the meaning of FOIA on Latham's FOIA request

30. Because HHS has not issued a determination within the statutorily mandated timeframe, Latham is deemed to have exhausted its administrative remedies. 5 U.S.C. § 552(a)(6)(C); *CREW*, 711 F.3d at 186.

31. Latham urgently needs these records for briefing in an APA case against HRSA and HHS. *See* Minute Order dated July 8, 2021, Case No. 1:21-cv-01686-DLF (D.D.C.).

CLAIMS FOR RELIEF

CLAIM I (Failure to Produce Records)

32. The foregoing paragraphs are incorporated by reference as if set forth in full herein.

33. FOIA requires agencies to make a determination regarding all requests within 20 working days, or 30 days where unusual circumstances are present and the agency sends a timely written notice of such circumstances.

34. Latham submitted its FOIA request to HRSA, which the agency received *no less than* 20 days ago (exclusive of weekends and legal public holidays). *See* Exhibits A-C.

35. Latham also submitted its FOIA request to HHS, which the agency received *no less than* 20 days ago (exclusive of weekends and legal public holidays). *See* Exhibits D-E.

36. Latham has a statutory right to receive a determination from both HRSA and HHS as to its FOIA requests within the time frames that Congress required through FOIA.

37. HRSA and HHS have both violated FOIA by failing to make the required determinations in response to the FOIA requests and by failing to produce records in response to the request.

38. Latham is being harmed by reason of HRSA's and HHS's violations of FOIA and those agencies' unlawful withholding of records to which Latham is entitled. Latham will continue

to be harmed unless HRSA and HHS are compelled to comply with the statute and produce the requested records.

**CLAIM II
(Costs and Fees)**

39. The foregoing paragraphs are incorporated by reference as if set forth in full herein.

40. Pursuant to 5 U.S.C. § 552(a)(4)(E), “[t]he court may assess against the United States reasonable attorney fees and other litigation costs reasonably incurred in any case under this section in which the complainant has substantially prevailed.”

41. Latham is statutorily entitled to recover fees and costs incurred as a result of HRSA and HHS’s failures to make timely determinations with regard to the Latham’s FOIA requests. 5 U.S.C. § 552(a)(4)(E)(i); *Baker & Hostetler LLP v. U.S. Dep’t of Commerce*, 473 F.3d 312, 324 (D.C. Cir. 2006) (complainant law firm is an organizational litigant statutorily eligible for costs and attorney’s fees).

42. Latham asks the court to order HRSA and HHS to pay reasonable attorney fees and other litigation costs incurred in this case.

REQUEST FOR RELIEF

WHEREFORE, Latham respectfully requests that this Court enter judgment in its favor and prays for the following relief:

1. A declaration pursuant to 28 U.S.C. § 2201 that HRSA and HHS have violated the Freedom of Information Act by failing to lawfully satisfy Latham’s FOIA requests.
2. An order enjoining HRSA and HHS to:
 - a. Respond to Latham’s FOIA requests;
 - b. Release immediately all responsive records to Latham’s FOIA requests;

3. An order awarding Latham its costs and attorney's fees; and
4. Such other and further relief as the court deems just and proper.

Dated: July 13, 2021

Respectfully submitted,

/s/ Andrew D. Prins

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