IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SANOFI-AVENTIS U.S. LLC,
55 Corporate Drive
Bridgewater, NJ 08807

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, SW
Washington, DC 20201

HEALTH RESOURCES AND SERVICES ADMINISTRATION,
5600 Fishers Lane
Rockville, MD 20857

Defendants.

Civil Action No. 24-1603

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Sanofi-Aventis U.S. LLC ("Sanofi"), by and through its undersigned attorneys, alleges as follows:

INTRODUCTION

1. Sanofi brings this action under the Freedom of Information Act (FOIA) to enjoin the Health Resources and Services Administration (HRSA), an agency within the Department of Health and Human Services (HHS), from concealing evidence of its ongoing refusal to enforce the 340B statute's prohibition on diverting 340B-priced drugs to persons who are not the covered entity's patient.

2. For years, HRSA has been withholding contracts between 340B covered entities and outside pharmacies that implicate covered entities' compliance with the

340B statute and HHS guidance. On information and belief, nothing in those contracts provides for covered entities to retain title to 340B-priced drugs shipped to contract pharmacies, contrary to the statute. But as the D.C. Circuit recently explained, under HRSA's own guidance, covered entities "must retain title to the drugs" shipped to contract pharmacies. *Novartis Pharms. Corp. v. Johnson*, No. 21-5299, 2024 WL 2279829, at *2 (D.C. Cir. May 21, 2024).

3. Despite knowing all of this, HRSA appears to have turned a blind eye to systemic violations of the 340B statute that have caused the 340B Program to spiral out of control. *Id.* On information and belief, HRSA has never sanctioned a covered entity for not maintaining title over 340B drugs shipped to a contract pharmacy. Nor does HRSA appear to have any interest in investigating covered entities' diversion of 340B drugs to contract pharmacies.

4. Indeed, HRSA *only* invoked FOIA Exemption 4 to withhold the substance of the pharmacy contracts. Its rationale is that those contracts contain confidentiality clauses. On this basis, HRSA withheld the pharmacy contracts in full without attempting to establish that the contracts contain confidential commercial information or even trying to segregate the purportedly exempt information from the nonexempt.

5. But the responsive information in the pharmacy contracts is not confidential commercial information under FOIA Exemption 4. Sanofi is not seeking the financial terms in the pharmacy contracts or, for that matter, even the *identities*

of the contracting parties. It seeks only the portions of those contracts that address compliance with applicable law—including who retains title to 340B-priced drugs.

6. Moreover, HHS's general counsel eliminated any expectation that the pharmacy contracts would remain confidential when he issued his Advisory Opinion on Contract Pharmacies expressly based on the twin premises that covered entities maintain title over 340B-priced drugs shipped to contract pharmacies and that contract pharmacies act as agents of a covered entity. In light of that disclosure, HRSA cannot plausibly argue that the pharmacy contracts—which will either support or refute the general counsel's assertions—are confidential.

7. The Court should order HRSA to disclose the pharmacy contracts it is unlawfully concealing because FOIA Exemption 4 does not apply.

JURISDICTION AND VENUE

8. This Court has jurisdiction over this action under 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. §§ 1331, 2201, and 2202.

9. Venue is proper in this district under 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391(e).

10. This Court has the authority to grant declaratory and injunctive relief under FOIA, the Declaratory Judgment Act, the Administrative Procedure Act, and this Court's inherent equitable powers. 28 U.S.C. §§ 2201, 2202; 5 U.S.C. §§ 702, 706; 5 U.S.C. § 552(a)(4)(B).

11. Sanofi is deemed to have constructively exhausted its administrative remedies under 5 U.S.C. § 552(a)(6)(C)(i) because HRSA has not complied with the

applicable time-limit provisions of FOIA. *See* 5 U.S.C. § 552(a)(6)(A)(ii) (20 days to adjudicate an administrative appeal).

PARTIES

12. Plaintiff Sanofi is a global healthcare leader that produces prescription medicines and other consumer health products.

13. Defendant HHS is an agency of the United States government.

14. Defendant HRSA is an HHS agency.

STATEMENT OF FACTS

A. 340B Program

15. Section 340B of the Public Health Service Act, 42 U.S.C. § 256b, requires drug manufacturers participating in the 340B Program to offer "certain drugs at discounted prices to select healthcare providers." *Novartis*, 2024 WL 2279829, at *1. These providers are known as "covered entities," 42 U.S.C. § 256b(a)(1), and they "benefit through insurance reimbursements that exceed the marked-down cost of the drugs," *Novartis*, 2024 WL 2279829, at *1.

16. To distribute 340B-priced drugs to patients, covered entities often contract with outside pharmacies. In 1996, HRSA issued guidance stating that each covered entity may contract with one outside pharmacy. Then, in 2010, HRSA issued new guidance opining that each covered entity may contract with an unlimited number of such pharmacies.

17. HRSA's 2010 guidance "prompted a significant expansion in the section 340B program." *Id.* at *3. And as the use of contract pharmacies skyrocketed, so too did waste and abuse.

18. One form of abuse is called diversion, which occurs when covered entities "resell or otherwise transfer the drug to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B). The 340B statute prohibits diversion. *Id.*

19. Covered entities violate Section 340B's prohibition on diversion by transferring title over 340B-priced drugs to contract pharmacies. Indeed, HRSA has stated that maintaining title to drugs is an "essential element[]" of covered entities' compliance with the prohibition against diversion. *Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services*, 75 Fed. Reg. 10,272, 10,277 (March 5, 2010).

20. Arrangements for delivery of 340B-priced drugs to contract pharmacies increase the risk of diversion because most pharmacies do not keep separate inventories of 340B drugs, but instead "fill prescriptions from inventories that intermingle discounted and non-discounted drugs." *Novartis*, 2024 WL 2279829, at *3.

21. "Only after dispensing the drugs do these pharmacies attempt to discern whether individual customers were patients of covered entities—in other words, whether individual prescriptions were eligible for the discount." *Id.*

22. And pharmacies often overstate the number of discount-eligible prescriptions. For one, pharmacies generally "outsource this determination to third-

party administrators, who often receive a larger fee for every prescription deemed eligible for the discount." *Id.* For another, pharmacies may "rely on manipulable algorithms to code whether prescriptions warrant the discount." *Id.*

23. After categorizing certain prescriptions as eligible for the discount, "the pharmacy places an order to replenish its section 340B purchases." *Id.* "The covered entity, the pharmacy, and the third-party administrator often divvy up the spread between the discounted price and the higher insurance reimbursement rate." *Id.* For this reason, "[e]ach of these actors … has a financial incentive to catalog as many prescriptions as possible as eligible for the discount." *Id.*

24. This method for distributing prescription drugs—known as the replenishment model—is a main driver of waste and abuse in the 340B Program.

25. Despite its view that covered entities may rely on contract pharmacies for distribution, HRSA has affirmed—and reaffirmed—that covered entities must retain title to the drugs shipped to pharmacies. HRSA's 1996 guidance, for example, "stressed that a covered entity, in directing shipments to its contract pharmacy, must retain title to the drugs." *Novartis*, 2024 WL 2279829, at *2; *Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services*, 61 Fed. Reg. 43,549, 43,553 (August 23, 1996) (observing that the covered entity must "retain title" of drugs shipped to contract pharmacies and thus "retains responsibility for the drug[s]"). And its 2010 guidance "reiterated … that each covered entity must maintain title to and responsibility for the drugs." *Novartis*, 2024 WL 2279829, at

*2; 75 Fed. Reg. at 10,277 (observing that maintaining title is an "essential element[]" of compliance for covered entities).

26. Despite these words on paper, HRSA appears to have done nothing to enforce them or the 340B statute's prohibition on diversion.

27. On information and belief, it is general industry practice that covered entities do *not* maintain title over 340B-priced drugs shipped to contract pharmacies using the replenishment model. Rather, on information and belief, it is general industry practice for contract pharmacies to obtain title to 340B-priced drugs.

28. Moreover, on information and belief, it is general industry practice for contract pharmacies to act as independent contractors when they receive 340B-priced drugs. On information and belief, contract pharmacies do not act as agents of covered entities when they receive 340B-priced drugs.

29. On information and belief, HRSA has never sanctioned a covered entity for not maintaining title to 340B-priced drugs shipped to contract pharmacies.

30. Furthermore, HRSA is not currently investigating any covered entities for not maintaining title to 340B-priced drugs shipped to contract pharmacies.

B. HRSA's Advisory Opinion and Enforcement Letter to Sanofi

31. Sanofi sells medicines subject to 340B-discounted prices.

32. In 2020, Sanofi limited the distribution of 340B-priced drugs to contract pharmacies to address the explosive growth of such pharmacies in the 340B Program and resulting, impermissible duplicate discounts.

33. In response to these restrictions adopted by Sanofi, as well as similar restrictions adopted by other pharmaceutical manufacturers, "HHS issued an advisory opinion stating that section 340B requires manufacturers to deliver covered drugs to any contract pharmacies with which a covered entity chooses to partner." *Novartis*, 2024 WL 2279829, at *4.

34. In HHS's view, covered entities do not violate the 340B statute's prohibition on diversion when they direct pharmaceutical manufacturers to deliver 340B-priced drugs to contract pharmacies, because contract pharmacies act as agents of a covered entity, and because covered entities maintain title over 340B-priced drugs shipped to contract pharmacies. *See* Advisory Opinion 20-06 at 6.

35. HRSA then sent enforcement letters to Sanofi and other manufacturers, including Novartis and United Therapeutics, concluding that the manufacturers had a statutory duty under Section 340B to deliver 340B-priced drugs to contract pharmacies. HRSA ordered the manufacturers to deliver their 340B-priced drugs to all contract pharmacies without any restrictions.

36. Sanofi and other manufacturers challenged HRSA's enforcement letters in separate suits. The Third Circuit vacated HRSA's enforcement letter to Sanofi and ordered injunctive relief prohibiting the government from enforcing its position on contract pharmacies. *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696 (3d Cir. 2023). The D.C. Circuit "agree[d] entirely" with the Third Circuit in awarding similar relief to Novartis and United Therapeutics. *Novartis*, 2024 WL 2279829, at *6.

C. Sanofi's FOIA Request

37. On July 21, 2021, Sanofi submitted a FOIA request to HRSA seeking, among other things, all records "reflecting whether (a) contract pharmacies act as agents of covered entities, and (b) covered entities maintain title to drugs shipped to contract pharmacies." Exhibit A.

38. Sanofi's request sought information only regarding the agency relationships between contract pharmacies and covered entities and which party maintains title over the drugs. The request did not seek the pricing terms in the contracts between covered entities and pharmacies or even the identities of the contracting parties. Sanofi sought this information to support or refute HHS's assertions in the Advisory Opinion and to better understand whether covered entities' arrangements with contract pharmacies comply with the 340B statute.

39. With this information, Sanofi would be able to expose HRSA's failure to enforce the 340B statute's prohibition on diversion, more effectively defend itself against covered entities' claims alleging violations of the 340B statute, and consider bringing diversion claims against covered entities.

40. On July 22, 2021, HRSA acknowledged receiving Sanofi's FOIA request and assigned #21F218 to it.

41. On October 19, 2021, a HRSA representative responded that "there are hundreds of contract pharmacies, and each contract will have to be sent to each respective pharmacy for submitter review. This process will take several months to complete. . . . If you would still like to see contracts, would you be okay with receiving

one or two of them, instead of all? My assumption is that the contracts will look fairly uniform except for the names/identifying information unique to each pharmacy."

42. Sanofi responded the same day that it "does not agree to waive its request for contracts that are responsive to the request; however, we would appreciate receiving your production of contracts on a rolling basis. After reviewing 1-2 contracts, we will reconsider whether to waive production of additional contracts that are responsive to the request."

43. On December 8, 2021, HRSA responded that it had identified "43 pages of pharmacy contracts responsive to" Sanofi's request, but that it was "withholding those pages in full pursuant to Exemption 4." Exhibit B. HRSA acknowledged Sanofi's agreement "to receive two pharmacy contracts as an initial offering, while preserving [its] request to receive the remainder of the contracts at a later date." *Id.*

44. According to HRSA, no portion of the pharmacy contracts can be disclosed because the "withheld information includes product pricing and other commercial or financial information," and "the submitters do not customarily release this information to the public." *Id.*

45. HRSA later clarified via email that withholding these contracts in full was appropriate "because the contracts had clauses that prohibited release of any portions of the contracts except to the parties to the contracts."

46. HRSA invoked only FOIA Exemption 4 to withhold the substantive portions of the pharmacy contracts. Although HRSA invoked Exemption 6 to withhold names, emails addresses, and personal cell phone numbers, HRSA did not

invoke any other exemptions. HRSA would have invoked FOIA Exemption 7 if any of the pharmacy contracts were part of an ongoing investigation into covered entities' compliance with Section 340B.

47. Accordingly, HRSA is not currently investigating any covered entity for not maintaining title over 340B-priced drugs shipped to contract pharmacies, and none of the pharmacy contracts being withheld are part of an ongoing law enforcement investigation.

48. On information and belief, nothing in the 43 pages withheld by HRSA demonstrates that the covered entity maintains title of 340B-priced drugs shipped to contract pharmacies.

49. On information and belief, nothing in the 43 pages withheld by HRSA demonstrates that the contract pharmacy acts as an agent of the covered entity.

50. Sanofi timely administratively appealed HRSA's decision to invoke FOIA Exemption 4 on January 4, 2022. Exhibit C. In the appeal, Sanofi argued that HRSA's decision to withhold the pharmacy contracts in full should be reversed for three reasons. First, the requested portions of the pharmacy contracts do not contain commercial or financial information. Second, the requested portions of the pharmacy contracts do not contain confidential information regardless of any purported contract clause prohibiting the parties from disclosing the contracts. Third, HRSA must segregate and disclose the responsive, non-exempt information in the pharmacy contracts (such as the agency relationship of the parties and which party maintains title over the drugs) from any exempt information (such as the pricing terms and the

identities of the contracting parties). Sanofi did not challenge HRSA's reliance on Exemption 6 to withhold personal information for privacy reasons.

51. HRSA has not decided Sanofi's appeal in nearly two-and-a-half years.

52. Because HRSA did not timely respond to Sanofi's appeal, Sanofi is deemed to have exhausted its administrative remedies. 5 U.S.C. § 552(a)(6)(A)(ii) (setting time for response to an appeal at twenty days), (C)(i) (deeming administrative remedies exhausted).

53. Sanofi has a statutory right to the withheld records and is now entitled to judicial action enjoining HRSA from continuing to improperly withhold records and ordering the production of records improperly withheld.

CLAIM FOR RELIEF

Violation of Freedom of Information Act, 5 U.S.C. § 552 Wrongful Withholding of Non-Exempt Records

54. Sanofi incorporates by reference the allegations contained in the previous paragraphs as though set forth fully herein.

55. FOIA authorizes a court "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).

56. Sanofi properly requested records within the possession and control of HRSA.

57. HRSA is an agency subject to FOIA and must therefore release in response to a FOIA request any non-exempt records and provide a lawful reason for withholding any materials.

58. Sanofi exhausted all of its administrative remedies under FOIA and HHS regulations.

59. HRSA is wrongfully withholding non-exempt agency records because the pharmacy contracts do not contain "trade secrets and commercial or financial information obtained from a person and privileged or confidential," 5 U.S.C. § 552(b)(4), particularly because the identities of the contracting parties and any product pricing information may be redacted.

60. HRSA failed to establish that the pharmacy contracts contain "commercial" information within the meaning of Exemption 4.

61. Information regarding an unidentified covered entity's compliance with applicable law—in particular, whether a covered entity maintains title to 340B-priced drugs shipped to contract pharmacies as required by Section 340B and HRSA guidance—is not "commercial" in and of itself. Nor is the legal nature of the business relationship between two anonymous contracting parties commercial in and of itself.

62. HHS waived any argument that the pharmacy contracts are "commercial or financial information [that is] privileged or confidential" when its general counsel asserted in the Advisory Opinion that contract pharmacies act as agents of covered entities and that covered entities maintain title over 340B-priced drugs shipped to contract pharmacies, particularly because the pharmacy contracts reflect a general industry practice among pharmacies using the replenishment model.

63. HRSA also failed to establish that the pharmacy contracts contain "confidential" information within the meaning of Exemption 4.

64. HRSA failed to demonstrate that it assured covered entities that the pharmacy contracts would remain confidential.

65. On information and belief, HRSA never provided any express or implied assurance that the pharmacy contracts would remain confidential, particularly because the responsive information relates to covered entities' compliance with applicable law.

66. HHS withdrew any prior assurance of confidentiality when its general counsel asserted in the Advisory Opinion that contract pharmacies act as agents of a covered entity and that covered entities maintain title over 340B-priced drugs shipped to contract pharmacies.

67. HRSA's rationale for withholding the pharmacy contracts—confidentiality clauses—is insufficient to establish that the contracts are exempt under Exemption 4.

68. Even assuming Exemption 4 applies to some portions of the pharmacy contracts, HRSA failed to segregate the exempt material and disclose the non-exempt material, as required by both FOIA and HHS's implementing regulations. *See* 5 U.S.C. § 552(a)(8)(A)(ii)(II), (b)(9); 45 C.F.R. §§ 5.2(a), 5.28(c). HRSA's failure to provide all non-exempt responsive records violates FOIA and the agency's own regulations. HRSA also failed to provide a detailed justification for its failure to release all reasonably segregable information.

69. Sanofi is therefore entitled to declaratory and injunctive relief requiring HRSA to segregate and promptly produce the nonexempt portions of all pharmacy contracts and to provide an index identifying all pharmacy contracts being withheld.

PRAYER FOR RELIEF

Wherefore, Sanofi prays for the following relief:

1. A declaration that Sanofi is entitled to disclosure of the pharmacy contracts;

2. A declaration that HRSA lacked a legal basis to withhold the pharmacy contracts under FOIA Exemption 4;

3. An order requiring HRSA to segregate and promptly produce the nonexempt portions of the pharmacy contracts;

4. An injunction prohibiting HRSA from withholding the pharmacy contracts;

5. An order requiring HRSA to promptly produce an index identifying all pharmacy contracts being withheld;

6. That the Court retain jurisdiction of this action to ensure no pharmacy contracts are wrongfully withheld;

7. An award of all costs and attorneys' fees pursuant to any applicable statute or authority, including 5 U.S.C. § 552(a)(4)(E); and

8. Any other relief this Court deems just and proper.

Dated: May 31, 2024

Respectfully submitted,

s/ Brett A. Shumate

Brett A. Shumate (D.C. Bar No. 974673)
Megan Lacy Owen (D.C. Bar No. 1007688)
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Counsel for Plaintiff

CIVIL COVER SHEET

JS-44 (Rev. 11/2020 DC)

I. (a) PLAINTIFFS

Sanofi-Aventis U.S. LLC

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF 08807
(EXCEPT IN U.S. PLAINTIFF CASES)

DEFENDANTS

U.S. Department of Health and Human Services; Health Resources and Services Administration

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT _____
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)

Brett A. Shumate and Megan Lacy Owen
Jones Day
51 Louisiana Ave., N.W.
Washington, D.C. 20001-2113
(202) 879-3939

ATTORNEYS (IF KNOWN)

II. BASIS OF JURISDICTION
(PLACE AN x IN ONE BOX ONLY)

- ○ 1 U.S. Government Plaintiff
- ○ 3 Federal Question (U.S. Government Not a Party)
- ◉ 2 U.S. Government Defendant
- ○ 4 Diversity (Indicate Citizenship of Parties in item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN x IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT) **FOR DIVERSITY CASES ONLY!**

	PTF	DFT		PTF	DFT
Citizen of this State	○ 1	○ 1	Incorporated or Principal Place of Business in This State	○ 4	○ 4
Citizen of Another State	○ 2	○ 2	Incorporated and Principal Place of Business in Another State	○ 5	○ 5
Citizen or Subject of a Foreign Country	○ 3	○ 3	Foreign Nation	○ 6	○ 6

IV. CASE ASSIGNMENT AND NATURE OF SUIT

(Place an X in one category, A-N, that best represents your Cause of Action and one in a corresponding Nature of Suit)

○ A. *Antitrust*

- ☐ 410 Antitrust

○ B. *Personal Injury/ Malpractice*

- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Medical Malpractice
- ☐ 365 Product Liability
- ☐ 367 Health Care/Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Product Liability

○ C. *Administrative Agency Review*

- ☐ 151 Medicare Act

Social Security
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

Other Statutes
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 890 Other Statutory Actions (If Administrative Agency is Involved)

○ D. *Temporary Restraining Order/Preliminary Injunction*

Any nature of suit from any category may be selected for this category of case assignment.

(If Antitrust, then A governs)

○ E. *General Civil (Other)* OR **○ F. *Pro Se General Civil***

Real Property
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent, Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

Personal Property
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

Bankruptcy
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

Prisoner Petitions
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Conditions
- ☐ 560 Civil Detainee – Conditions of Confinement

Property Rights
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent – Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016 (DTSA)

Federal Tax Suits
- ☐ 870 Taxes (US plaintiff or defendant)
- ☐ 871 IRS-Third Party 26 USC 7609

Forfeiture/Penalty
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

Other Statutes
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 430 Banks & Banking
- ☐ 450 Commerce/ICC Rates/etc
- ☐ 460 Deportation
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions
- ☐ 470 Racketeer Influenced & Corrupt Organization
- ☐ 480 Consumer Credit
- ☐ 485 Telephone Consumer Protection Act (TCPA)
- ☐ 490 Cable/Satellite TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes
- ☐ 890 Other Statutory Actions (if not administrative agency review or Privacy Act)

○ **G. *Habeas Corpus/ 2255***	○ **H. *Employment Discrimination***	◉ **I. *FOIA/Privacy Act***	○ **J. *Student Loan***
☐ 530 Habeas Corpus – General ☐ 510 Motion/Vacate Sentence ☐ 463 Habeas Corpus – Alien Detainee	☐ 442 Civil Rights – Employment (criteria: race, gender/sex, national origin, discrimination, disability, age, religion, retaliation) *(If pro se, select this deck)*	☒ 895 Freedom of Information Act ☐ 890 Other Statutory Actions (if Privacy Act) *(If pro se, select this deck)*	☐ 152 Recovery of Defaulted Student Loan (excluding veterans)
○ **K. *Labor/ERISA (non-employment)***	○ **L. *Other Civil Rights (non-employment)***	○ **M. *Contract***	○ **N. *Three-Judge Court***
☐ 710 Fair Labor Standards Act ☐ 720 Labor/Mgmt. Relations ☐ 740 Labor Railway Act ☐ 751 Family and Medical Leave Act ☐ 790 Other Labor Litigation ☐ 791 Empl. Ret. Inc. Security Act	☐ 441 Voting (if not Voting Rights Act) ☐ 443 Housing/Accommodations ☐ 440 Other Civil Rights ☐ 445 Americans w/Disabilities – Employment ☐ 446 Americans w/Disabilities – Other ☐ 448 Education	☐ 110 Insurance ☐ 120 Marine ☐ 130 Miller Act ☐ 140 Negotiable Instrument ☐ 150 Recovery of Overpayment & Enforcement of Judgment ☐ 153 Recovery of Overpayment of Veteran's Benefits ☐ 160 Stockholder's Suits ☐ 190 Other Contracts ☐ 195 Contract Product Liability ☐ 196 Franchise	☐ 441 Civil Rights – Voting (if Voting Rights Act)

V. ORIGIN

◉ 1 Original Proceeding ○ 2 Removed from State Court ○ 3 Remanded from Appellate Court ○ 4 Reinstated or Reopened ○ 5 Transferred from another district (specify) ○ 6 Multi-district Litigation ○ 7 Appeal to District Judge from Mag. Judge ○ 8 Multi-district Litigation – Direct File

VI. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE.)

28 U.S.C. §§ 2201, 2202; 5 U.S.C. §§ 552, 702, 706 - FOIA, Declaratory Judgment, and Administrative Procedure Act case

VII. REQUESTED IN COMPLAINT ☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23 **DEMAND $** **JURY DEMAND:** Check YES only if demanded in complaint YES ☐ NO ☒

VIII. RELATED CASE(S) IF ANY (See instruction) YES ☒ NO ☐ If yes, please complete related case form

DATE: 5/31/2024 **SIGNATURE OF ATTORNEY OF RECORD** /s/ Brett A. Shumate

INSTRUCTIONS FOR COMPLETING CIVIL COVER SHEET JS-44
Authority for Civil Cover Sheet

The JS-44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and services of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. Listed below are tips for completing the civil cover sheet. These tips coincide with the Roman Numerals on the cover sheet.

I. COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF/DEFENDANT (b) County of residence: Use 11001 to indicate plaintiff if resident of Washington, DC, 88888 if plaintiff is resident of United States but not Washington, DC, and 99999 if plaintiff is outside the United States.

III. CITIZENSHIP OF PRINCIPAL PARTIES: This section is completed only if diversity of citizenship was selected as the Basis of Jurisdiction under Section II.

IV. CASE ASSIGNMENT AND NATURE OF SUIT: The assignment of a judge to your case will depend on the category you select that best represents the primary cause of action found in your complaint. You may select only one category. You must also select one corresponding nature of suit found under the category of the case.

VI. CAUSE OF ACTION: Cite the U.S. Civil Statute under which you are filing and write a brief statement of the primary cause.

VIII. RELATED CASE(S), IF ANY: If you indicated that there is a related case, you must complete a related case form, which may be obtained from the Clerk's Office.

Because of the need for accurate and complete information, you should ensure the accuracy of the information provided prior to signing the form.

EXHIBIT A

JONES DAY

51 LOUISIANA AVENUE, N.W. • WASHINGTON, D.C. 20001.2113

TELEPHONE: +1.202.879.3939 • FACSIMILE: +1.202.626.1700

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July 21, 2021

HRSA Freedom of Information Act (FOIA) Office
5600 Fishers Lane, Room 13N112
Rockville, MD 20857

Re: Freedom of Information Act Request

To Whom it May Concern:

Pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552 *et seq.*, Sanofi-Aventis U.S. LLC ("Sanofi") requests copies of the records described below. For purposes of this request, Sanofi directs your attention to the letter dated May 17, 2021 from HRSA to Mr. Gerald Gleeson, VP & Head, Sanofi US Market Access Shared Services, available at https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-sanofi-covered-entities.pdf ("HRSA's May 17 letter to Sanofi"). If Sanofi's request is denied in whole or in part, please justify all denials by reference to specific exemptions under FOIA. Please also release all segregable portions of otherwise exempt material. Sanofi will pay all fees up to $5,000. Specifically, this letter makes the following requests for records:

1. In HRSA's May 17 letter to Sanofi, HRSA referred to "an analysis of the complaints HRSA has received from covered entities" about Sanofi's 340B integrity initiative. Sanofi is seeking copies of (a) all such complaints, and (b) any emails, memoranda, or documents reflecting HRSA's analysis of such complaints.

2. Copies of, or documents memorializing, any other communications from covered entities to HRSA regarding Sanofi's participation in the 340B program that are not covered by request #1.

3. In HRSA's May 17 letter to Sanofi, HRSA stated that "Sanofi's actions have resulted in overcharges." Sanofi is seeking copies of all documents calculating or reflecting any purported overcharges.

4. In HRSA's May 17 letter to Sanofi, HRSA stated that Sanofi's policy "places restrictions on 340B pricing to covered entities that dispense medication through pharmacies, unless the covered entities provide claims data to a third-party platform." Sanofi is seeking documents reflecting, analyzing, or otherwise

assessing the burden imposed on covered entities of complying with Sanofi's policy.

5. All emails, memoranda, or other documents related to the Sanofi policy referred to in HRSA's May 17 letter to Sanofi from July 2020 to the present, including documents that post-date May 17, 2021.

6. All emails, memoranda, or other documents related to the formulation of HRSA's May 17 letter to Sanofi, including documents that post-date May 17, 2021.

7. The guidance promulgated at 75 Fed. Reg. 10,272, 10,278 (Mar. 5, 2010) instructs that when covered entities discover drug diversion or duplicate discounting at contract pharmacies, they must "take immediate remedial action to assure compliance and notify [the agency] about such compliance problems and actions taken to remedy those problems." Sanofi is seeking copies of all emails, memoranda, or other documents reflecting those notifications and actions taken since March of 2010, and any analysis or response from HRSA about such notifications and actions taken.

8. The guidance promulgated at 75 Fed. Reg. 10,272, 10, 278-79 (Mar. 5, 2010) instructs that covered entities using contract pharmacies must certify compliance with various regulatory requirements. Sanofi is seeking copies of all emails, memoranda, or other documents reflecting those certifications (or re-certifications) since March of 2010, and any analysis or response from HRSA about such certifications or re-certifications.

9. In *Advisory Opinion 20-06 on Contract Pharmacies under the 340B Program* (Dec. 30, 2020), the general counsel "conclude[d] that to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." Sanofi is seeking all emails, memoranda, contracts or other documents reflecting whether (a) contract pharmacies act as agents of covered entities, and (b) covered entities maintain title to drugs shipped to contract pharmacies.

I would appreciate communication by email or telephone, rather than postal mail. Please feel free to contact me directly with any questions at 202-879-3835 or BShumate@JonesDay.com. Thank you for your assistance.

Sincerely,

Brett A. Shumate

Counsel for Sanofi-Aventis U.S. LLC

EXHIBIT B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857

To efficiently correspond with the HRSA FOIA Office during the COVID-19 public health emergency, we request that you communicate with us by email at FOIA@hrsa.gov or by telephone at 301-443-2865.

If you do not have access to email or choose not to use it, you can continue to send correspondence to the FOIA Office mailing address provided in this letter. However, this correspondence will be delayed until normal agency operations have resumed.

December 8, 2021

Sent via Email
Brett A. Shumate
Jones Day
51 Louisiana Avenue, N.W.
Washington, D.C. 20001
bshumate@jonesday.com

Re: Health Resources and Services Administration (HRSA) Freedom of Information Act (FOIA) Request Case Number 21F218 - Interim Response

Dear Mr. Shumate:

This is an Interim Response your FOIA request dated July 21, 2021. You submitted a multi-part request for records pertaining the Health Resources and Services Administration's (HRSA) May 17, 2021 letter to Sanofi regarding 340B integrity initiative. You requested the following records:

1. In HRSA's May 17 letter to Sanofi, HRSA referred to "an analysis of the complaints HRSA has received from covered entities" about Sanofi's 340B integrity initiative. Sanofi is seeking copies of (a) all such complaints, and (b) any emails, memoranda, or documents reflecting HRSA's analysis of such complaints.

2. Copies of, or documents memorializing, any other communications from covered entities to HRSA regarding Sanofi's participation in the 340B program that are not covered by item #1, above.

3. In HRSA's May 17 letter to Sanofi, HRSA stated that "Sanofi's actions have resulted in overcharges." Sanofi is seeking copies of all documents calculating or reflecting any purported overcharges.

4. In HRSA's May 17 letter to Sanofi, HRSA stated that Sanofi's policy "places restrictions on 340B pricing to covered entities that dispense medication through pharmacies, unless the covered entities provide claims data to a third-party platform." Sanofi is seeking documents

reflecting, analyzing, or otherwise assessing the burden imposed on covered entities of complying with Sanofi's policy.

5. All emails, memoranda, or other documents related to the Sanofi policy referred to in HRSA's May 17 letter to Sanofi from July 2020 to the present, including documents that post-date May 17, 2021.

6. All emails, memoranda, or other documents related to the formulation of HRSA's May 17 letter to Sanofi, including documents that post-date May 17, 2021.

7. The guidance promulgated at 75 Fed. Reg. 10,272, 10,278 (March 5, 2010) instructs that when covered entities discover drug diversion or duplicate discounting at contract pharmacies, they must "take immediate remedial action to assure compliance and notify [the agency] about such compliance problems and actions taken to remedy those problems." Sanofi is seeking copies of all emails, memoranda, or other documents reflecting those notifications and actions taken since March of 2010, and any analysis or response from HRSA about such notifications and actions taken.

8. The guidance promulgated at 75 Fed. Reg. 10,272, 10, 278-79 (March 5, 2010) instructs that covered entities using contract pharmacies must certify compliance with various regulatory requirements. Sanofi is seeking copies of all emails, memoranda, or other documents reflecting those certifications (or re-certifications) since March of 2010, and any analysis or response from HRSA about such certifications or re-certifications.

9. In Advisory Opinion 20-06 on Contract Pharmacies under the 340B Program (December 30, 2020), the general counsel "conclude[d] that to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." Sanofi is seeking all emails, memoranda, contracts or other documents reflecting whether (a) contract pharmacies act as agents of covered entities, and (b) covered entities maintain title to drugs shipped to contract pharmacies.

On October 19, 2021, you clarified that the date range for item two of your request is July 1, 2020 to July 21, 2021. You also agreed to receive two pharmacy contracts as an initial offering, while preserving your request to receive the remainder of the contracts at a later date.

An intial records search was conducted in HRSA's Office of Pharmacy Affairs (OPA) and located over 8,127 pages of responsive records that were released to United Theraputics in a previous FOIA request, 21F190. Those records fully satisfy items one, two, three, four, five, six, seven, and eight of your request; the records partially satisfy item nine of your request. We are releasing those pages in part. We reasonably foresee that disclosure would harm an interest protected by one or more of the nine exemptions to the FOIA's general rule of disclosure. We determined that FOIA exemptions 5 U.S.C. § 552(b)(4)(Exemption 4) and (b)(6)(Exemption 6) apply to portions of the records. Additionally, OPA located 43 pages of pharmancy contracts responsive to item nine your request. We are withholding those pages in full pursuant to Exemption 4.

Exemption 4 protects "trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential". The withheld information includes product pricing and other commercial or financial information. The entities that supplied this information (the submitters) are considered persons, because the term "person," under the FOIA, includes a wide range of entities including

"corporations". Finally, the submitters do not customarily release this information to the public; therefore, the information is confidential for the purposes of Exemption 4.

Exemption 6 protects information about individuals in "personnel and medical files and similar files" when the disclosure of such information would constitute a clearly unwarranted invasion of privacy. The withheld information includes names, emails addresses and personal cell phone numbers.

While we believe that an adequate search of the appropriate files was conducted for the records you requested, you have the right to appeal this finding. You can appeal and preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision.

Your appeal can be submitted by email or in the HHS FOIA and Appeal Portal within 90 days from the date of this letter to:

Carol Maloney
Deputy Agency Chief FOIA Officer
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs
Email: FOIARequest@hhs.gov
Portal: https://requests.publiclink.hhs.gov/App/Index.aspx

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, you may contact the HRSA FOIA Public Liaison for assistance:

Brian A. May
HRSA FOIA Public Liaison
U.S. Department of Health and Human Services
Health Resources and Services Administration
Freedom of Information Act Office
5600 Fishers Lane, 13N114
Rockville, MD 20857
Telephone: 301-443-2865
Email: FOIA@hrsa.gov

If we are unable to resolve your FOIA dispute, the Office of Government Information Services (OGIS), the federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and federal agencies. The contact information for OGIS is:

Office of Government Information Services
National Archives and Records Administration
8601 Adelphi Road-OGIS
College Park, MD 20740-6001
Telephone: 202-741-5770
Toll-Free: 1-877-684-6448
Fax: 202-741-5769
Email: ogis@nara.gov

We classified you as a "Commercial Use" category requester and you agreed to pay FOIA processing fees. We did not comply with the FOIA's statutory time limits and we cannot assess search/duplication fees associated with your request. See 5 C.F.R. § 5.53(d)(1). We did not assess duplication fees because

we did not organize, convert, or format data in the electronic records. However, we can assess review fees, which total $92.00. This amount was based upon two (2) hours of review time (GS-14) at $46.00 per hour, as noted on the enclosed invoice. The invoice contains detailed payment instructions and we encourage you to use the electronic payment option (https://www.pay.gov).

If upon review of the attached records, you decide that you want the remainder of the pharmacy contracts, please contact me at: achancellor@hrsa.gov within 10 business days of this letter. If we do not hear from you after 10 days, we will administratively close this request.

Sincerely,

Alexis Chancellor
Deputy Freedom of Information Act Officer

Enclosures

Admin Record 1 of 3_Bates
_FINAL.pdf (109 pages)
Admin Record 2 of 3_Bates_FINAL
_for release.pdf (6,697 pages)
Admin Record 3 of 3_Bates_FINAL
_for release.pdf (1,321 pages)

EXHIBIT C

JONES DAY

51 LOUISIANA AVENUE, N.W. • WASHINGTON, D.C. 20001.2113

TELEPHONE: +1.202.879.3939 • FACSIMILE: +1.202.626.1700

Direct Number: (202) 879-3835
bshumate@jonesday.com

January 4, 2022

VIA EMAIL (FOIARequest@hhs.gov)

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

Re: Freedom of Information Act Appeal in Case No. 21F218

Dear Deputy Agency Chief Maloney:

Pursuant to 45 CFR § 5.61, Sanofi hereby appeals the determination made by the Health Resources and Services Administration ("HRSA") regarding Sanofi's July 21, 2021 Freedom of Information Act ("FOIA") request identified above.

In this FOIA request, Sanofi sought, among other things, "all emails, memoranda, contracts or other documents reflecting whether (a) contract pharmacies act as agents of covered entities, and (b) covered entities maintain title to drugs shipped to contract pharmacies." Sanofi only sought information regarding the agency relationships between contract pharmacies and covered entities and which party maintains title over the drugs—not the pricing terms in the contracts between covered entities and pharmacies.

In its December 8, 2021 response, the HRSA identified "43 pages of pharmacy contracts responsive to" Sanofi's request, but HRSA is "withholding those pages in full pursuant to Exemption 4." According to HRSA, no portion of the pharmacy contracts can be disclosed because the "withheld information includes product pricing and other commercial or financial information," and "the submitters do not customarily release this information to the public." HRSA later clarified via email that withholding these contracts in full was appropriate "because the contracts had clauses that prohibited release of any portions of the contracts except to the parties to the contracts."

HRSA's decision to withhold the pharmacy contracts in full should be reversed for three reasons. First, the requested portions of the pharmacy contracts do not contain commercial or

financial information. Second, the requested portions of the pharmacy contracts do not contain confidential information regardless of any purported contract clause prohibiting the parties from disclosing the contracts. Third, HRSA must segregate and disclose the responsive, non-exempt information in the pharmacy contracts (such as the agency relationship of the parties and which party maintains title over the drugs) from any exempt information (such as the pricing terms and the identities of the contracting parties).

I. Sanofi's FOIA request does not seek commercial or financial information.

FOIA establishes a "strong presumption in favor of disclosure" subject only to a few "narrowly construed" statutory exemptions. *Multi Ag Media LLC v. Dep't of Agriculture*, 515 F.3d 1224, 1227 (D.C. Cir. 2008). FOIA Exemption 4 only exempts from disclosure "trade secrets and commercial or financial information obtained from a person" that is "privileged or confidential." 5 U.S.C. § 552(b)(4).

To withhold commercial or financial information under Exemption 4, the agency "must identify specific evidence demonstrating something unique . . . that logically or plausibly renders [the information] commercial in name or function." *Besson v. U.S. Dep't of Com.*, 480 F. Supp. 3d 105, 112 (D.D.C. 2020). The "touchstone" of this inquiry is "whether the disclosure of contested information could materially affect the commercial fortunes of the business." *Citizens for Resp. & Ethics in Washington (CREW) v. U.S. Dep't of Just.*, No. 19-CV-3626 (DLF), 2021 WL 4502039, at *4 (D.D.C. Sept. 30, 2021) (quoting *Baker & Hostetler LLP v. U.S. Dep't of Comm.*, 473 F.3d 312, 319 (D.C. Cir. 2006)).

HRSA has not identified any reason why the limited information that Sanofi seeks regarding the agency relationship of the contracting parties and which party maintains title over the drugs is "commercial in name or function." Nor could it. Such basic information about the relationship between covered entities and contract pharmacies has no obvious commercial value to any individual company. Disclosure of this limited information should not cause negative commercial consequences to any particular company—unlike, for example, the disclosure of pricing information or internal sales data traditionally within the ambit of Exemption 4. *See CREW*, 2021 WL 4502039, at *4-*5 (collecting traditional examples of "commercial information" such as "customer lists, selling prices, inventory balances, purchase activity, freight charges, costs of goods sold, design recommendations, design concepts including methods and procedures, information on key employees, health and safety data, and general information about an industry's commercial concerns, its strengths and weaknesses, and recommendations for international trade negotiations").

The General Counsel's (now withdrawn) Advisory Opinion 20-06 demonstrates that the limited information requested by Sanofi is not commercial or financial within the meaning of

Exemption 4. According to the General Counsel, the relationship between covered entities and pharmacies is one of "principal-agent," and covered entities "take[] title" to the drugs. Advisory Opinion 20-06 on Contract Pharmacies, at 3, 6 (Dec. 31, 2020). This is the same information that Sanofi seeks in its FOIA request. Because the requested information reflects a purported industry-wide practice that the General Counsel has stated is common to all participants in the 340B program, disclosure would not cause commercial consequences to any individual company.

To be clear, Sanofi is not seeking the identity of the parties to these pharmacy contracts. The identity of the contracting parties could properly be redacted as not responsive to Sanofi's FOIA request. Sanofi only seeks the limited information in the contracts regarding the agency relationship of the parties and which party maintains title over the drugs. Because Sanofi seeks information disconnected from the identity of any individual company, Sanofi's request is thus disconnected from any articulable commercial harm within the scope of Exemption 4. *Cf. Nat'l Bus. Aviation Ass'n, Inc. v. FAA*, 686 F. Supp. 2d 80, 86 (D.D.C. 2010) (finding that a list of aircraft registration numbers was not commercial information when it could not be used to "determine the identity of the occupants of any particular flight" or "discover the business purpose of any flight"). When the contracting parties need not even be identified, there is no plausible basis to find that release of this information would cause commercial consequences to any particular company. *See Jud. Watch, Inc. v. U.S. Dep't of Health & Hum. Servs.*, 525 F. Supp. 3d 90, 97 (D.D.C. 2021) (rejecting agency's "generalized observations" about commercial harm caused by disclosure when the agency "asserts no commercial interest on behalf of [a company] *specifically*" (emphasis added)).

II. Sanofi's FOIA request does not seek confidential information.

Nor is the information that Sanofi requested "confidential" within the meaning of Exemption 4. To be deemed confidential for purposes of Exemption 4, information must be (1) "customarily kept private, or at least closely held," by the submitter, and (2) the government must have provided "some assurance" that the information would not be publicly disclosed. *Food Mktg. Inst. v. Argus Leader Media*, 139 S. Ct. 2356, 2360 (2019).

Neither requirement is satisfied here. First, HRSA's suggestion that the pharmacy contracts themselves establish confidentiality is wrong. Private confidentiality agreements are "not sufficient in and of themselves to establish confidentiality under Exemption 4." *Elec. Priv. Info. Ctr. v. United States Dep't of Homeland Sec.*, 117 F. Supp. 3d 46, 64 (D.D.C. 2015). HRSA thus cannot hang its hat solely on the contracts' confidentiality provisions to assert blanket confidentiality over the entirety of the pharmacy contracts. But HRSA pointed to no other evidence that covered entities retain confidentiality over the limited information requested. "Conclusory statements by an agency official about what the agency official may believe about

how a submitter customarily treats the information" will not suffice to justify nondisclosure under Exemption 4. *Ctr. for Investigative Reporting v. U.S. Customs & Border Prot.*, 436 F. Supp. 3d 90, 111 (D.D.C. 2019).

Second, HRSA made no finding that the submitting parties requested—much less that HRSA gave assurances—that the requested information in the pharmacy contracts would not be disclosed. If anything, the opposite appears to be true, because the General Counsel already publicly disclosed the substance of the information contained in the pharmacy contracts when he asserted that contract pharmacies are "agents" of covered entities, which maintain "title" to the drugs. Advisory Opinion 20-06 on Contract Pharmacies, at 3, 6. Releasing the same basic information—again, on an anonymized basis—in response to Sanofi's FOIA request would not harm any particular company's interest in confidentiality.

Accordingly, there is no basis to assert confidentiality over the relationship of the parties and which party maintains title over the drugs—particularly when that information would be divorced from the identities of the contracting parties.

III. The information that Sanofi requested is segregable from any exempt information.

HRSA cannot withhold the contracts in full because it has an obligation to release all other parts of the contracts that can be reasonably segregated as non-exempt. Even if some portions of the pharmacy contracts are exempt from FOIA (as HRSA contends), "non-exempt portions of a document must be disclosed unless they are inextricably intertwined with exempt portions." *Sussman v. U.S. Marshals Serv.*, 494 F.3d 1106, 1116 (D.C. Cir. 2007). In addition, HRSA must provide "a 'detailed justification' and not just 'conclusory statements' to demonstrate that all reasonably segregable information has been released." *Valfells v. CIA*, 717 F. Supp. 2d 110, 120 (D.D.C. 2010). To comply with this obligation, HRSA must release the information regarding the agency relationship of the parties and which party maintains title over the drugs while redacting other exempt information, such as product pricing information and the like.

For all of these reasons, HRSA's decision to withhold 43 pages of pharmacy contracts should be reversed and remanded with instructions to release responsive information that is segregable from any exempt information.

Respectfully submitted,

/s/ Brett A. Shumate

Brett A. Shumate

Counsel for Sanofi-Aventis U.S. LLC

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Sanofi-Aventis U.S. LLC
Plaintiff

v.
U.S. Department of Health and Human Services; Health Resources and Services Administration
Defendant

Civil Action No. 24-1603

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

A lawsuit has been filed against you.

Within 30 days after service of this summons on you (not counting the day you received it) you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Brett Shumate
Jones Day
51 Louisiana Avenue, NW
Washington, DC 20001

If you fail to respond, judgment by default may be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: 5/31/2024

Signature of Clerk or Deputy Clerk

Civil Action No. 24-1603

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

.

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Sanofi-Aventis U.S. LLC
Plaintiff

v.
U.S. Department of Health and Human Services; Health Resources and Services Administration
Defendant

Civil Action No. 24-1603

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857

A lawsuit has been filed against you.

Within 30 days after service of this summons on you (not counting the day you received it) you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Brett Shumate
Jones Day
51 Louisiana Avenue, NW
Washington, DC 20001

If you fail to respond, judgment by default may be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: 5/31/2024

Signature of Clerk or Deputy Clerk

Civil Action No. 24-1603

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

.

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Sanofi-Aventis U.S. LLC
Plaintiff

v.
U.S. Department of Health and Human Services; Health Resources and Services Administration
Defendant

Civil Action No. 24-1603

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

Merrick Garland
Attorney General of the United States
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530

A lawsuit has been filed against you.

Within 30 days after service of this summons on you (not counting the day you received it) you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Brett Shumate
Jones Day
51 Louisiana Avenue, NW
Washington, DC 20001

If you fail to respond, judgment by default may be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: 5/31/2024

Signature of Clerk or Deputy Clerk

Civil Action No. 24-1603

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

.

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Sanofi-Aventis U.S. LLC
Plaintiff

v.
U.S. Department of Health and Human Services; Health Resources and Services Administration
Defendant

Civil Action No. 24-1603

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

Civil Process Clerk
United States Attorney's Office
601 D Street, NW
Washington, DC 20530

A lawsuit has been filed against you.

Within 30 days after service of this summons on you (not counting the day you received it) you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Brett Shumate
Jones Day
51 Louisiana Avenue, NW
Washington, DC 20001

If you fail to respond, judgment by default may be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: 5/31/2024

Signature of Clerk or Deputy Clerk

Civil Action No. 24-1603

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

.

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc: