IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SANOFI-AVENTIS U.S. LLC, *Plaintiff*, v. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., *Defendants*.	Civil Action No. 1:24-cv-1603 (DLF)

BRIEF OF ELI LILLY AND COMPANY AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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CORPORATE DISCLOSURE STATEMENT

I, the undersigned, counsel of record for *amicus curiae*, Eli Lilly and Company, pursuant to Local Civil Rules 7(o)(5) and 26.1, and Federal Rule of Appellate Procedure 26.1(a), certify that Eli Lilly and Company has no parent corporation and no publicly held corporation owns ten percent or more of its stock.

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INTEREST OF *AMICUS CURIAE*

Amicus Curiae Eli Lilly and Company sells its medicines through the 340B Program. In 2023 alone, Lilly and other manufacturers sold $66.3 billion in discounted medicines through the 340B Program to participating providers such as hospitals and clinics. That represented a $12.6 billion increase from 2022—meaning the program grew a shocking 23.4% in just one year. Given this unchecked growth, Lilly has a keen interest in the proper operation of the Program—and in ensuring the Program's integrity and the legality of contract pharmacy arrangements. Lilly submits this brief to underscore that the Freedom of Information Act request here targets contract pharmacy agreements that are imperative to uncovering violations of the 340B statute. Lilly also writes to detail the insufficiencies of the audit procedures under the 340B statute that might otherwise yield such documents and to explain why FOIA requests like this one are, as a result, critical for obtaining information indispensable to maintaining the Program's integrity. Lilly urges the Court to grant the request because it will help prevent the rampant abuse that plagues the 340B Program.

INTRODUCTION

This case shows the lengths to which HRSA will go to hide widespread illegal conduct in the broken 340B Program. Since 1996, HRSA has asserted that the use of contract pharmacies in the 340B Program does not result in unlawful diversion—*i.e.*, the transfer of 340B-priced medicines to non-patients—because for-profit contract pharmacies are merely covered entities' agents and don't take title to 340B-priced medicines. It has taken that position in multiple forums, including nonbinding guidance, a now-withdrawn advisory opinion, and in both declarations sworn under penalty of perjury and filed in court and in statements made in open court. But HRSA has never provided any *proof* to support its assertion. That proof is readily available. HRSA concedes it has contract pharmacy agreements, and does not dispute that they will show whether its assertions on title and agency are true. Yet the agency has fought tooth and nail to prevent their disclosure.

Both title and agency form the foundations of today's 340B Program. To keep the 340B Program within its intended bounds, Congress in the 340B statute prohibited covered entities from transferring 340B-priced medicines to anyone that isn't a covered entity's patient. The statutory prohibition on diversion would plainly bar contract pharmacy relationships. For-profit contract pharmacies are not patients at all, so they cannot lawfully obtain 340B-priced medicines. As a workaround, HRSA opined that for-profit contract pharmacy arrangements do not result in unlawful diversion—because pharmacies act as covered entities' agents and do not take title to 340B-priced medicine. With that rationale, both the use of for-profit pharmacies and 340B transactions predictably exploded. There are now more than 33,000 contract pharmacies nationwide—up from approximately 1,300 in 2010—with over 194,000 unique contractual

relationships with covered entities.[1] In 2023, manufacturers provided $66.3 billion in discounted medicines through the 340B Program.[2] That is $12.6 billion more than in 2022—meaning that the Program grew by a shocking 23.4% in just one year.[3]

Lilly has grave concerns about whether for-profit contract pharmacies are operating consistent with HRSA's public assertions. More than a year ago, Lilly exercised its right under the 340B statute to audit two covered entities. HRSA's own covered entity audits recognize the importance of contract pharmacy agreements to the 340B Program's integrity—they are routinely produced to the agency. Lilly's audit workplans (which HRSA approved) followed the same playbook and specifically requested documents, including contract pharmacy agreements, that bear directly on agency and title. But both covered entities refused to produce their agreements with for-profit pharmacies, citing sweeping confidentiality provisions that the contract pharmacies refused to waive. And HRSA has refused to force their production. The practical result is that for-profit entities—which play no role in the 340B Program that Congress designed—control the statutory rights of program participants like manufacturers, covered entities, and even the federal government itself.

HRSA's refusal to make contract pharmacy agreements available—either via FOIA or manufacturer audits—is an apparent effort to conceal their contents and thereby hide the truth.

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1 Adam J. Fein, *EXCLUSIVE: For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market* (Jul. 11, 2023), *available at* https://www.drugchannels.net/2023/07/exclusive-for-2023-five-for-profit.html.

2 HRSA, 2023 340B Covered Entity Purchases, *available at* https://www.hrsa.gov/opa/updates/2023-340b-covered-entity-purchases.

3 Adam J. Fein, *The 340B Program Reached $66 Billion in 2023—Up 23% vs. 2022: Analyzing the Numbers and HRSA's Curious Actions* (Oct. 22, 2024), *available at* https://www.drugchannels.net/2024/10/the-340b-program-reached-66-billion-in.html.

Publicly available for-profit contract pharmacy agreements contain provisions showing, indisputably, that HRSA's assertions about agency and title are false. The contract pharmacy agreements at issue here likely have similar provisions. HRSA just does not want the public to see them because they would reveal that unlawful diversion is rampant and completely unchecked, contrary to HRSA's many statements asserting the opposite. That is exactly why FOIA exists. The Court should grant Sanofi's motion for summary judgment and require HRSA to produce all contract pharmacy agreements in its possession.

I. Today's 340B Program Is Built On The Fiction That Covered Entities Retain Title To 340B-Priced Medicines And That Contract Pharmacies Act As Their Agents.

The requirements of agency and title are indispensable pillars of the contract pharmacy arrangements that now define the 340B Program. HRSA has repeatedly relied on these two "requirements" to explain the purported lawfulness of contract pharmacy arrangements. HRSA also has invoked them time and time again when defending and permitting the expansion of contract pharmacy participation in the 340B Program.

HRSA first identified the significance of contract pharmacies having an agency relationship with covered entities in its initial contract pharmacy guidance in 1996. In that nonbinding guidance—which contemplated only one contract pharmacy per covered entity—HRSA rationalized that third-party pharmacy relationships with covered entities were permissible because "[t]he *contract pharmacy would act as an agent of the covered entity*, in that it would not resell a prescription drug but rather distribute the drug on behalf of the covered entity. This situation is *akin to a covered entity having its own pharmacy*." 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996) (emphasis added).

In 2010, the agency revisited the subject of contract pharmacies in nonbinding guidance. In contrast to the 1996 guidance, the 2010 guidance contemplated unlimited contract pharmacies

for each covered entity, and HRSA instructed that, for these arrangements to work, the covered entity must "purchase the drug" and "maintain title to the drug." 75 Fed. Reg. 10,272, 10,277 (Mar. 5, 2010). In that same guidance, HRSA declined to limit the number of permissible contract pharmacy arrangements based on its contention that "[e]ach covered entity retains the obligation to ensure its program remains compliant with [this guidance]." *Id.* at 10,276. HRSA emphasized that covered entities and contract pharmacies are "responsible for ensuring that [their] . . . contracting arrangements and operations" remain lawful. *Id.* Elsewhere, HRSA reminded stakeholders that "the covered entity is ultimately responsible for assuring full compliance with 340B." *Id.* That means covered entities must maintain "sufficient information to ensure it is meeting" its compliance obligations, including "[a]uditable records . . . to demonstrate compliance" with the prohibition on diversion. *Id.* at 10,273, 10,278. The purpose of these mandates is obvious: they allow HRSA and manufacturers to audit covered entities for compliance with the 340B statute.

HRSA's parent agency, HHS, continued this theme in an advisory opinion issued by its general counsel. In that opinion, HHS argued that the contract pharmacy system is lawful because ultimately "*the covered entity and contract pharmacy are not distinct, but function as principal-agent*" and "the covered entity remains the purchaser whether it chooses to have discount drugs distributed through an in-house pharmacy or a contract pharmacy." Ex. 1 at 6 (emphasis added). HHS ultimately withdrew this advisory opinion, though HHS and HRSA have stood by its agency and title assertions.

HHS, in fact, doubled down on them in open court when trying to defend its limitless contract pharmacy policy. *See, e.g.*, Ex. 2 at 12:20-25 (government counsel contending that a covered entity "maintains title" to the drugs it purchases through contract pharmacy

arrangements); Ex. 3 at 71:6-8 (government counsel contending that "HHS' consistent guidance has been that covered entities need to take title to the purchased drugs"); Ex. 4 at 53:20-54:8 (government counsel claiming that "covered entities do maintain title to the 340B drugs that they've purchased"). Further, in a 2022 declaration, the then administrator of HRSA described the logistics of placing the replenishment order—the mechanism by which most covered entities and their pharmacy partners purchase 340B-priced drugs. Ex. 5 ¶ 10. When describing the steps in that process, she stated: "sometimes the covered entity places the order, *sometimes the contract pharmacy orders it as a purchasing agent of the covered entity*, sometimes the order is submitted by the [third-party administrator]." *Id.* (emphasis added).[4]

Courts have repeatedly relied on these agency and title requirements in denying relief to manufacturers in disputes about the 340B Program and the use of contract pharmacies in particular. For example, Arkansas recently enacted a law requiring pharmaceutical manufacturers to transfer their medicines to for-profit pharmacies at the 340B price if those pharmacies have a contract arrangement with a covered entity. *See* Arkansas Code § 23-92-604(c). The Eighth Circuit rejected challenges to that law, in part because it assumed that contract pharmacies remain agents of covered entities and that covered entities retain title to the 340B medicines. *See Pharm. Rsch. & Manufacturers of Am. v. McClain*, 95 F.4th 1136 (8th Cir. 2024). Specifically, the Court rejected the argument that the law effectively added for-profit pharmacies as beneficiaries of the 340B Program on the ground that, as the Court put it, covered entity use of contract pharmacies "does not in any way extend this pricing to entities which do not meet program eligibility" because

[4] A third-party administrator (or "TPA") is a for-profit organization typically affiliated with a contract pharmacy that reviews pharmacy sales to purportedly identify 340B claims and subsequently place "replenishment orders" for new 340B medicines ostensibly on behalf of covered entities.

"[c]overed entities maintain legal title to the 340B drugs" and "the pharmacy becomes an agent of the covered entity." *Id.* at 1142; *see also Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs.*, 570 F. Supp. 3d 129, 151-52 (D.N.J. 2021) (similar). For these propositions, the court quoted and relied upon the representations from HHS and HRSA cited above.

Other courts have rejected challenges to similar state laws on these same grounds. *See, e.g.*, *AbbVie Inc. v. Fitch*, 2024 WL 3503965, at *4-5, *15, *19 (S.D. Miss. July 22, 2024). And state government officials and others continue to rely on these assumptions in defending their own similar state laws. *See, e.g.*, Ex. 6 at 8 n.3.

To be clear, nothing in the 340B statute requires or sanctions the use of contract pharmacies, much less in the manner that covered entities seem to prefer. *See, e.g.*, *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 457 (D.C. Cir. 2004); *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 703 (3d Cir. 2023). Thus, to support those relationships, the government has relied on its view of agency and title to legitimize the contract pharmacy model. As HRSA would have it, a contract pharmacy stands in the shoes of the covered entity for legal purposes. That, in turn, implies control, accountability, transparency, and most importantly, ownership. In other words, it implies the characteristics that could render contract-pharmacy arrangements permissible, and not violative of the prohibitions on diversion. *See* 42 U.S.C. § 256b(a)(5)(B).

The documents Sanofi seeks would demonstrate that covered entities and contract pharmacies are engaged in unlawful diversion on a massive scale, and that HRSA knows it but turns a blind eye. Lilly, like Sanofi, has been harmed by the government's continued concealment of contract pharmacy agreements and its disingenuous claims that these relationships are based on

principal-agent relationships. Shedding light on the truth about these relationships goes to the heart of the accountability by covered entities and HRSA itself. That is exactly what FOIA is for.

II. Lilly Has Been Unable To Obtain Information On Contract Pharmacy Arrangements, Including Agency And Title Relationships, Through Means Other Than FOIA.

Lilly's own experiences demonstrate that FOIA provides a critical path to obtaining contract pharmacy agreements and thus exposing the government's falsities concerning agency and title. Lilly has been unable to obtain such agreements through statutorily authorized audits—because covered entities have improperly refused to provide them and HRSA has tacitly licensed those refusals. Without FOIA enforcement, the public will continue to be left in the dark about the nature of contract pharmacy agreements.

In October 2023, Lilly exercised its statutory right to audit two covered entities for compliance with the 340B statute. 42 U.S.C. § 256b(a)(5)(C). Consistent with HRSA's nonbinding audit guidelines, Lilly submitted two audit workplans to HRSA for approval.[5] Those workplans identified evidence, based on extensive internal investigation and analysis, that two covered entities had likely engaged in violations of the 340B statute, including duplicate discounting and diversion.

Lilly's workplans sought the covered entities' contract pharmacy arrangements. HRSA initially resisted that request, but relented only after Lilly reminded the agency that, among other things, it has repeatedly represented that audits provide a vehicle for redressing manufacturers' concerns about contract pharmacy relationships and HRSA's own audits require production of

[5] Lilly was forced to submit these work plans because HRSA has claimed for itself the authority to approve and disapprove manufacturer audits—even though the statute plainly does not give that power to the agency. 42 U.S.C. § 256b(a)(5)(C). Lilly believes these audit guidelines are unlawful and reserves the right to challenge them at the appropriate time.

contract pharmacy agreements.[6] HRSA thus approved Lilly's work plans, including the requests for contract pharmacy agreements.

But what HRSA gave with one hand, it took away with the other. Today, over a year after that approval, Lilly is still attempting to complete those audits—largely because covered entities have refused to cooperate and HRSA has refused to require compliance and enforce the very document requests that it previously approved. And Lilly has not received any contract pharmacy agreements.

One covered entity ("Covered Entity 1") delayed the start of the audit for six months. And even after dragging its feet, it specifically refused to comply with Lilly's request for relevant contract pharmacy agreements—even though HRSA had specifically approved that request. This entity has *hundreds* of contract pharmacy locations listed on HRSA's website, but it provided only a single contract pharmacy agreement related to a pharmacy that has *never actually purchased or distributed a Lilly medicine* on behalf of that covered entity. The entity refuses to produce the relevant agreements allegedly because they include confidentiality provisions that require the contract pharmacies' consent before they are produced. That effectively gives for-profit contract pharmacies a veto right over a covered entity's production—apparently even in a HRSA-approved audit. And the contention that covered entities must seek contract-pharmacy approval in these circumstances itself suggests that covered entities do not maintain the type of control over contract pharmacies that HRSA has long claimed.

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[6] *See, e.g.*, Ex. 7 at 27 ("In any event, HRSA did, in fact, consider Lilly's concerns about contract pharmacy arrangements, including diversion and duplicate discounts. The Violation Letter concluded that the 340B statute 'provides a mechanism by which a manufacturer can address these concerns.' VLTR_4. 'Specifically, the manufacturer must (1) conduct an audit and (2) submit a claim through the Administrative Dispute Resolution process as described in the statute.'")

HRSA has refused to intervene or take any action against Covered Entity 1. But it's even worse than that. After continued pressing, the covered entity ultimately told Lilly that HRSA already had the contract pharmacy agreements, and that Lilly should request those agreements from HRSA itself. So that's what Lilly did. But HRSA refused to provide them, even with Covered Entity 1's consent. Again, these are the very documents that HRSA authorized Lilly to seek from Covered Entity 1 and that could allay Lilly's well-founded concerns about potential violations of the 340B statute. The agency did not deny that it possessed the agreements. Instead, it claimed that because HRSA is not a party to the contracts, it is not at liberty to disclose them without (i) consent from *all* the parties (including the contract pharmacies that are supposed to be acting as mere agents of the covered entity), or (ii) a FOIA request (which this case shows is futile without judicial intervention).

Lilly's attempted audit of another covered entity ("Covered Entity 2") confirms that its experience with Covered Entity 1 was not unique. Once again, HRSA approved Lilly's workplan that required the production of contract pharmacy agreements from Covered Entity 2. The entity, once again, has yet to comply or indicate that it intends to comply. And HRSA has, of course, imposed no consequences on Covered Entity 2. The entity, which again has hundreds of contract pharmacy locations listed on HRSA's website, has provided only a single, unexecuted "template" agreement. It has provided none of its actual, existing contract pharmacy agreements, and no evidence that the template it did provide was ever actually used.

Lilly's audit experiences make plain that a judicially enforceable FOIA request is a crucial path to overcome HRSA's stonewalling—indeed, one the agency even told Lilly to pursue (a position seemingly in conflict with its position in this case). The agency has repeatedly asserted that covered entities retain title to 340B drugs dispensed at contract pharmacies, and that such

pharmacies remain mere agents of the covered entities. But when pushed for actual *proof* of those claims, HRSA points the finger to covered entities for contracts, while covered entities point the finger back at the agency. It's all a part of the compliance shell game. Enforcing FOIA demands such as Sanofi's thus provides a critical means of confirming the lawfulness or unlawfulness of modern contract pharmacy arrangements. And it will provide medicine manufacturers with access to information that is needed to create accountability, to enforce their rights under the 340B Program, and to protect themselves from well-documented and widespread abuse.[7]

III. Publicly Available Evidence Suggests HRSA Is Not Perpetuating The "Agency" And "Title" Myth in Good Faith.

Lilly's concern that contract pharmacy agreements rarely, if ever, involve principal-agent relationships is well-founded and based on publicly available documents. Lilly located a collection of publicly available contract pharmacy agreements, and every single one disclaims any agency relationship. These inconvenient facts—which Lilly presented to HRSA nearly two years ago—cast serious doubt that HRSA is acting in good faith and demonstrates that Sanofi's FOIA request is no fishing expedition. Rather, it targets the core of the federal government's improper rationalization concerning fundamental issues in the 340B Program.

First, Lilly located a contract between the Monterey County Health Department in California and a large retail pharmacy chain. The agreement explicitly disclaims any agency relationship: "**Independent Contractors.** The Parties to this Agreement are independent contractors, and have no other legal relationship under or in connection with this Agreement. The provisions of this Agreement ***do not, and are not intended to***, create a partnership, joint venture, ***agency***, or employment relationship among or between the parties." Ex. 9 at 9, §26

[7] *See, e.g.*, Ex. 8 at 44 (finding that two-thirds of the diversion findings in HRSA's audits involved medicines distributed at contract pharmacies).

(emphasis added). Other publicly available agreements from the same Monterey County entity include substantially similar language. It has an agreement with another large retail pharmacy chain that says: "**Independent Contractor**. None of the provisions of this Agreement are intended to create, nor shall they be deemed or construed to create, any relationship between the parties hereto other than that of independent entities contracting solely for the purposes of effecting the provisions of this Agreement. Neither of the parties shall be construed to be the partner, co-venturer, or employee ***or representative of the other party***." Ex. 10 at 13, §8.10 (emphasis added). This agreement also clarifies that title to the 340B medicines passes to the pharmacy when it takes delivery. *Id.* at 5, §3.3.5.

ReCept, a smaller independent contract pharmacy, has an agreement that states: "**Independent Contractor**. None of the provisions of this Agreement are intended to create, nor shall they be deemed or construed to create, any relationship between the parties hereto other than that of independent entities contracting solely for the purposes of effecting the provisions of this Agreement. Neither of the parties shall be construed to be the partner, co-venturer, or employee, or representative of the other party." Ex. 11 at 15, §8.10. This agreement also describes that the pharmacy takes title to the 340B medicines when it accepts delivery. *Id.* at 6, §3.2. Finally, Lilly also obtained the template agreement for Bon Secours Hospital, which states: "Relationship Between Parties. Pharmacy shall perform all professional and other services under the terms of this Agreement as an independent contractor." Ex. 12 at 12, §14.

In response to an Information Collection Request, Lilly notified HRSA that these form agreements disclaim any agency relationship. Ex. 13 at 5.[8] Still, the agency has done nothing in

[8] Remarkably, HRSA *weakened* one of the few meaningful compliance requirements for covered entities using contract pharmacies, despite the minimal burden that it imposed. 87 Fed. Reg. 65,212 (Oct. 28, 2022). Specifically, it removed the requirement that an "Authorizing

the face of this knowledge, nor has it attempted to explain how contract pharmacy arrangements remain lawful.

Official" from a covered entity must, during the entity's annual recertification, accept responsibility for ensuring that any contract-pharmacy arrangement is performed in accordance with the agency's requirements and guidance for contract pharmacies. *Id.* at 65,213. That means there is no accountability for the conduct of contract pharmacies, despite the fiction that they are purportedly acting as agents of the covered entities. That, in turn, means there is even less transparency and less ability for manufacturers to eliminate abuse.

CONCLUSION

HHS and its subagency HRSA have consistently leaned on the concepts of agency and title when defending the lawfulness of contract pharmacy arrangements in the 340B Program. But neither covered entities nor the agency are willing to produce contract pharmacy agreements, through any means, to prove that contract pharmacies *are* agents of covered entities and that covered entities *do* retain title to the 340B medicines that pharmacies purchase using their accounts. FOIA was enacted for the precise purpose of cutting through this type of subterfuge and providing the public with much needed transparency. This Court should grant Sanofi's motion for summary judgment and order HHS and HRSA to release all records responsive to Sanofi's FOIA request.

Dated: October 31, 2024

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this document complies with the formatting rules pursuant to Local Rules 5.1(d) and 7(o)(4)-(5). This document contains the standard 8 ½ by 11-inch word processing format, the text is 12-point font and double-spaced (except block quotations and footnotes, which are single-spaced), and does not exceed 25 pages.

Dated: October 31, 2024

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RULE 29(A)(4)(E) CERTIFICATION

Pursuant to Local Civil Rule 7(o)(5) and Federal Rule of Appellate Procedure 29(a)(4)(E), I, John C. O'Quinn, undersigned counsel for Eli Lilly and Company, certify that (1) Lilly's *amicus* brief was authored entirely by its counsel and not by counsel for any party, in whole or in part; (2) no party or counsel for any party contributed money to fund preparing or submitting the brief; and (3) apart from *amicus curiae* and its counsel, no other person contributed money to fund preparing or submitting the brief.

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CERTIFICATE OF SERVICE

I hereby certify that on October 31, 2024, I electronically filed the foregoing with the Clerk of the Court for the United States District Court for the District of Columbia by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by using the CM/ECF system.

Dated: October 31, 2024

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