IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SANOFI-AVENTIS U.S. LLC,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al*.,

Defendants.

Case No. 24-CV-3496 (DLF)

UNOPPOSED MOTION OF AMERICAN HOSPITAL ASSOCIATION, NATIONAL ASSOCIATION OF CHILDREN'S HOSPITALS, INC. D/B/A CHILDREN'S HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES AND AMERICA'S ESSENTIAL HOSPITALS TO FILE *AMICI CURIAE* BRIEF IN SUPPORT OF DEFENDANTS

The American Hospital Association, the National Association of Children's Hospitals, Inc. d/b/a Children's Hospital Association, the Association of American Medical Colleges, and America's Essential Hospitals (collectively, the Proposed *Amici*) respectfully move this Court, pursuant to Local Civil Rule 7(o), for leave to file the attached brief in support of Defendants (Exhibit A). Proposed *Amici* also submit a Proposed Order.

Amici are four hospital associations whose members receive 340B discounts. Sanofi-Aventis U.S. LLC's "Integrity Initiative" will grievously harm those hospitals and the patients they care for. *Amici* therefore have a strong interest in preserving the Health Resources and Services Administration's lawful decision to reject that rebate policy, so that *Amici's* members can continue to provide high-quality, affordable medical care to their underserved patients and communities.

"Courts have wide discretion in deciding whether to grant a third party leave to file an amicus brief." *Search of Info. Assoc. with [redacted]@mac.com that is Stored at Premises*

Controlled by Apple, Inc., 13 F. Supp. 3d 157, 167 (D.D.C. 2014). "Generally, a court may grant leave to appear as an *amicus* if the information offered is timely and useful," *Ellsworth Assocs. v. United States*, 917 F. Supp. 841, 846 (D.D.C. 1996) (quotation marks omitted), or when *Amici* have "relevant expertise and a stated concern for the issues at stake in [the] case," *District of Columbia v. Potomac Elec. Power Co*., 826 F. Supp. 2d 227, 237 (D.D.C. 2011); *see Ellsworth,* 917 F. Supp. at 846 (a court should grant a motion to participate as *amicus curiae* when the movant has a "special interest in th[e] litigation as well as a familiarity and knowledge of the issues raised therein that could aid in the resolution of this case"); *N. Mariana Islands v. United States,* No. 08-1572, 2009 WL 596986, at *1 (D.D.C. Mar. 6, 2009) (holding that "the filing of an amicus brief should be permitted if it will assist the judge 'by presenting ideas, arguments, theories, insights, facts or data that are not to be found in the parties' briefs").

Amici easily satisfy this standard. As the attached proposed brief demonstrates, *Amici* provide the Court with specific insights, information, and legal arguments about the operation of the 340B Program and the consequences of the rebate policies. *Amici* further demonstrate that if the Court were to grant Sanofi's summary judgment motion, their member-hospitals would be severely harmed, thereby underscoring their "concern for the issues at stake," *Potomac Elec.*, 826 F. Supp. 2d at 237, and "special interest" in the litigation, *Ellsworth,* 917 F. Supp. at 846.

This Court has recognized Movants' value as *Amici* in the past. Specifically, it granted a similar motion in *Novartis Pharms. Corp. v. Espinosa*, No. 21-cv-1479, 2021 WL 5161783 (D.D.C. Nov. 5, 2021). *See* Minute Order (June 29, 2021). And earlier this week, the Court granted similar motions in cases brought by Novartis, Bristol Myers Squibb, and Eli Lilly.

Proposed *Amici* consulted with counsel for Plaintiffs and Defendants. Sanofi does not oppose the Motion. The government takes no position on *Amici's* Motion.

Accordingly, Proposed *Amici* respectfully ask the Court to grant their motion for leave to file an *amici curiae* brief.

March 6, 2025

Respectfully submitted,

/s/

Chad Golder, Fed. Bar No. 976914
American Hospital Association
2 City Center, Suite 400
800 10th Street, NW
Washington, DC 20001-4956
202-626-4624
cgolder@aha.org
Counsel for *Amici Curiae*

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SANOFI-AVENTIS U.S. LLC,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al*.,

Defendants.

Case No. 24-CV-3496 (DLF)

***AMICI CURIAE* BRIEF OF AMERICAN HOSPITAL ASSOCIATION, NATIONAL ASSOCIATION OF CHILDREN'S HOSPITALS, INC. D/B/A CHILDREN'S HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES AND AMERICA'S ESSENTIAL HOSPITALS IN SUPPORT OF DEFENDANTS**

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Federal Register

Rules

Other Authorities

STATEMENT OF INTEREST[1]

Amici are four hospital associations whose members receive 340B discounts. Sanofi-Aventis U.S. LLC's "Integrity Initiative" will grievously harm those hospitals and the patients they care for. *Amici* therefore have a strong interest in preserving the Health Resources and Services Administration's lawful decision to reject that rebate policy, so that *Amici*'s members can continue to provide high-quality, affordable medical care to their underserved patients and communities.

The **American Hospital Association** represents nearly 5,000 hospitals, healthcare systems, and other healthcare organizations across the country. Its members are committed to improving the health of the communities they serve and to helping ensure that affordable care is available to all Americans.

The **National Association of Children's Hospitals, Inc. d/b/a Children's Hospital Association** is the national voice of more than 220 children's hospitals. It advances child health through innovation in the quality, cost, and delivery of care in children's hospitals.

The **Association of American Medical Colleges** is dedicated to improving the health of people everywhere through medical education, healthcare, medical research, and community collaborations. Its members include all 160 LCME-accredited medical schools; nearly 500 academic health systems and teaching hospitals; and more than seventy academic societies.

America's Essential Hospitals is dedicated to high-quality care for all people, including those who face social and financial barriers. Consistent with this mission, the association's more than 350 members provide a disproportionate share of the nation's uncompensated care, with three-quarters of patients uninsured or covered by Medicare or Medicaid.

---

[1] Pursuant to Local Civil Rule 7(o)(5) and Fed. R. App. P. 29, counsel states that all parties consented to the filing of this brief. No party's counsel authored any part of this brief, and no person other than *Amici* funded its preparation or submission.

INTRODUCTION[2]

This case is about an undisguised power grab. Sanofi makes no secret of its belief—hyperbolic as it is—that there is abuse in the 340B program. It makes no secret of its belief that the Health Resources and Services Administration has not taken sufficient action to address this alleged abuse. And most important, Sanofi makes no secret of its belief that it must now take the law into its own hands to fix all of this with its new policy. Sanofi's motives and intentions do not "come before the Court clad, so to speak, in sheep's clothing." *Morrison v. Olson*, 487 U.S. 654, 699 (1988) (Scalia, J., dissenting). "[T]his wolf comes as a wolf." *Id*.

Amici appreciate that Sanofi does not hide why it wishes to engage in this self-help.[3] And while Sanofi's complaint artificially separates its new policy into two counts, Sanofi is clear that the "two core components" of its new policy are linked together and motivated by a single goal. *See* Mem. of P. & A. in Supp. of Pl.'s Mot. for Summ. J. (Dkt. 27-1) at 1. Announced in the same November 22, 2024 letter, both components demand purchase data from 340B hospitals so that Sanofi can unilaterally enforce the law as part of its self-proclaimed "Integrity Initiative." Compl. Ex. E at 1; *see* Mem. of P. & A. in Supp. of Pl.'s Mot. for Summ. J. (Dkt. 27-1) at 12 (stating that the "key features" of Sanofi's new policy "rest on a data request" so that it can "combat continued

[2] *Amici* have filed similar briefs in other cases pending before this Court. We respectfully wish to bring this Court's particular attention to pages 2-3 (including footnote 3) and pages 9-11 of this brief, which contain arguments related to Sanofi's policy that were not included in our other *amici curiae* briefs.

[3] *E.g.*, Compl. ¶¶ 10, 49, 53; Ex. E at 2 ("Sanofi is implementing the 340B Credit Model to rein in the 340B waste and abuse we see today."); Mem. of P. & A. in Supp. of Pl.'s Mot. for Summ. J. (Dkt. 27-1) at 12 ("To combat continued problems with duplicate discounts and diversion, Sanofi decided to adopt the Credit Model, which is a new model for selling drugs under the 340B program."); *see also* Adam Gluck, *Sanofi Tackles 340B Abuse with Innovative Credit Model* (Dec. 16, 2024), https://www.sanofi.us/en/sanofi-today/your-health/sanofi-tackles-340b-abuse-with-innovative-credit-model ("[T]his program will provide a badly needed checks-and-balances approach to eliminate the fraud and abuse of duplicate discounts and diversion.").

problems with duplicate discounts and diversion"). Sanofi's rebate model component, or what it sometimes calls the "Credit Model," is designed to "identify potential duplicate discounts and prevent instances of illegal diversion." Compl. Ex. E at 2. Its "Patient Definition" component is similarly designed to "stop diversion." Compl. Ex. A at 10. Under that component, Sanofi seeks to "validate" hospital-patient information in order to enforce "HRSA's 1996 guidance" about who qualifies as a patient under the 340B statute. Compl. Ex. E at 4; Compl. Ex. B at 3 (viewing the "Patient Definition" component as "assuming a quasi-enforcement role of the statutory diversion prohibition and HRSA's 1996 patient definition guidance").

Even though Sanofi is candid about why it is pursuing its "Integrity Initiative," it is far less frank about the consequences of it. As Sanofi seeks to boost its own profits, this policy will devastate safety-net hospitals, their vulnerable patients, and the struggling rural and urban communities they serve. In that respect, this case is not just about a power grab—it's also about a money grab.

Whether Sanofi's "Integrity Initiative" is a power-grab, a money-grab, or both, one thing is pellucidly clear: Sanofi's policy is "incompatible" with the 340B statute. *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 113 (2011). The text, structure, history, and purpose of the 340B statute reveal a carefully calibrated legal regime in which "Congress vested authority to oversee compliance with the 340B Program in HHS and assigned *no auxiliary enforcement role* to" program participants. *Id.* at 117 (emphasis added). Congress also did not permit drug companies to demand what are, effectively, prospective audits in exchange for providing discounts that are owed under the 340B statute. And, ultimately, Congress did not permit drug companies to unilaterally condition 340B pricing on their subjective determination of program compliance or the surrender of purchase and patient data.

For good reason. Sanofi's "Integrity Initiative" will be ruinous for 340B hospitals. As much as Sanofi tries to malign 340B hospitals, these hospitals treat America's most vulnerable patients. They care for a significant share of the nation's children, cancer patients, and those living in rural and other underserved communities. For much of this care, 340B hospitals do not get paid at all. As the D.C. Circuit has noted: "A congressionally mandated study of how eligible providers use [their] income from the 340B program found that [340B income] help[s] safety-net providers fund the uncompensated care they supply and expand the services they offer." *Cares Cmty. Health v. HHS*, 944 F.3d 950, 955 (D.C. Cir. 2019) (cleaned up).

But as a bipartisan group of nearly 200 lawmakers wrote after the first rebate policy was announced: "This unapproved and unlawful change would have severe consequences for our nation's safety net providers and the patients they serve.… A rebate model would create significant financial challenges for safety-net hospitals." Congressional Letter to Secretary Becerra 1, 2 (Sept. 27, 2024), at https://d12t4t5x3vyizu.cloudfront.net/spanberger.house.gov/uploads/2024/09/Quill-Letter-L20840-Letter-to-HHS-on-JJ-340B-Rebate-Model-Version-1-09-27-2024-@-03-08-PM.pdf. The letter went on to accurately explain that the rebate model "would reduce resources available for providing comprehensive services to patients and communities, undermining the core purpose of 340B." *Id*. at 1.

In particular, these rebate policies will dramatically erode the 340B discount that Congress intended for them to receive. For starters, hospitals will be forced to advance millions of dollars to the drug companies. "This approach is to the manufacturer's financial benefit because the company retains those sums for a longer time and creates hurdles for covered entities to claim the discount." *Id*. Already "operating under much lower operating margins than non-340B hospitals," *id*. at 2, America's 340B hospitals cannot afford to make zero-interest loans without any guarantee

of when—or whether—they will be paid the discounts they are owed by law. In fact, *hundreds of hospitals* self-reported to *Amici* that these rebate policies could cause them to violate their bond covenants, which would lead to catastrophic financial distress and, for some, permanent closure.

340B hospitals also will have to spend enormous amounts to comply with policies like Sanofi's "Integrity Initiative." These policies have no precedent in the three decades since the start of the 340B Program. Hospitals therefore have no existing infrastructure to comply with them—let alone the many different variations and requirements across the hundreds of drug companies that could adopt them. 340B hospitals will be forced to hire new full-time employees to meet Sanofi's demands, and they will have to purchase new technologies to provide the required purchase data and to track the rebates they are owed. In a world of finite resources, 340B hospitals will have no choice but to divert funds away from patient services and towards burdensome compliance.

Ultimately, as the Court evaluates this case, it should bear in mind what Justice Kavanaugh wrote for a unanimous Supreme Court a few years ago: "340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 738 (2022). Sanofi's policy shrinks that already-limited funding even further, endangering the care that 340B hospitals provide for their patients and communities. But perhaps worse than anything, Sanofi does so in flagrant disregard of the 340B statute. Sanofi may be dissatisfied with that law or how the Executive Branch is enforcing it, but that does not permit it to try to enforce the law itself. Nor does it permit Sanofi to co-opt this Court in its vigilante efforts. If Sanofi is dissatisfied with 340B law or policy, it can seek change in the political branches. But it cannot take the law into its own hands and then seek judicial permission for its extra-legal actions.

ARGUMENT

I. The Structure, History, And Purpose Of The 340B Statute Precludes Sanofi's "Integrity Initiative."

The textual arguments in this case are straightforward. The 340B statute, using the unambiguous phrase "as provided by the Secretary," gives HRSA the authority to approve any "rebate" model. 42 U.S.C. § 256b(a)(1).[4] The Pharmaceutical Pricing Agreements between HRSA and the drug companies "set[] out terms identical to those contained in the statute," and thus confer the same rebate-approval authority. *Astra*, 563 U.S. at 114.

Amici need not repeat those dispositive textual arguments here. Instead, we focus on the structure, history, and purpose of the 340B statute because they, too, prove that Congress never intended for drug companies to take the law into their own hands to pursue their own self-interested plan for program integrity. These traditional tools of statutory construction also demonstrate that whatever comparisons Sanofi tries to make with hospitals' "replenishment system" for inventory management or a previous HRSA-approved rebate model for AIDS Drug Assistance Programs, the sweeping, surveillant nature of *this* rebate model is "incompatible" with "the statute Congress enacted." *Id*. at 113, 121. Put differently, the 340B statute does not bar all rebate models. It does, however, bar the model that Sanofi seeks to impose here.

[4] The legislative history supports this plain text. *E.g.*, H.R. Rep. No. 102-384, pt. 2, at 16 (1992) ("The Committee bill does not specify whether 'covered entities' would receive these favorable prices through a point-of-purchase discount, through a manufacturer rebate, or through some other mechanism. A mechanism that is appropriate to one type of 'covered entity,' such as community health centers, may not be appropriate to another type, such as State AIDS drug purchasing programs. The Committee expects that the Secretary of HHS, in developing these agreements, will use the mechanism that is the most effective and most efficient from the standpoint of each type of 'covered entity.'"). This "legislative history not only speaks to the issue; it confirms the government's interpretation." *Guedes v. ATF*, 356 F. Supp.3d 109, 143 (D.D.C. 2019) (Friedrich, J.).

A. Sanofi's "Integrity Initiative" is incompatible with the 340B statute's structure.

A statute's structure can inform its meaning. So when courts are "called on to resolve a dispute over a statute's meaning," the parties "are entitled … to have independent judges exhaust all the textual *and structural* clues bearing on that meaning." *Niz-Chavez v. Garland*, 593 U.S. 155, 160 (2021) (quotation marks omitted and emphasis added). Here, the structure and design of the 340B statute provide extremely informative "clues." In particular, the statute contains several provisions addressing audits, compliance, and dispute resolution that are inconsistent with Sanofi's "Integrity Initiative."

These provisions send two unmistakable messages about Congress' intent for the 340B Program. *First*, Congress did not intend for participants in the 340B Program to engage in unconstrained self-enforcement. Quite the contrary. The 340B statute contemplates that HHS will always have a role in enforcing program requirements. Consider the following provisions:

- 42 U.S.C. § 256b(a)(5)(C) provides for audits to enforce the statute's prohibitions on diversion and duplicate discounts. This provision gives audit responsibility to the "Secretary and the manufacturer of a covered outpatient drug"—not the manufacturer alone. *Id*. It also gives the Secretary—and not the manufacturer—the authority to develop procedures "relating to the number, duration, and scope of audits." *Id*.
- 42 U.S.C. § 256b(a)(5)(D) relatedly provides for "[a]dditional sanction for noncompliance" with the diversion and duplicate discount provisions, but only *after* an audit is completed and only *after* the covered entity is given an opportunity for "notice and hearing." *Id.* This subsection also specifies that the sanction will be "an amount equal to the reduction in the price of the drug," *i.e*., exactly what Sanofi will refuse to pay up-front (without any audit, notice, or hearing) under its "Integrity Initiative." *Id.*
- 42 U.S.C. § 256b(d)(2) directs the Secretary to "provide for improvements in compliance by covered entities with the requirements of this section in order to prevent diversion and violations of the duplicate discount." *Id.* It also specifies certain compliance improvements, including the "imposition of sanctions, in appropriate cases *as determined by the Secretary*." *Id*. (emphasis added).
- 42 U.S.C. § 256b(d)(3) formalizes a statutory ADR process with HHS playing a central role. Not only does the statute require the Secretary to "promulgate regulations to establish and implement" the ADR process, but it requires that these regulations "designate or establish a decision-making official or decision-making body *within the Department of*

Health and Human Services to be responsible for reviewing and finally resolving claims." *Id*. (emphasis added).

These structural features make clear that Congress did not want drug companies to engage in self-help. Critically, the Supreme Court has recognized this statutory design. As the Court held in *Astra*, Congress "centralized" 340B "enforcement in the "government," creating a "unitary administrative and enforcement scheme." 563 U.S. at 119-120 (quotation marks and citations omitted). Congress did *not* give an "auxiliary enforcement role" to participants in the 340B program. *Id*. at 117. Sanofi knows this. It made this exact point in opposing 340B Health's Motion to Intervene, arguing that "*Astra* forbids[ ] the *private* enforcement of 340B program requirements *in all forms*." Pls.' Joint Opp'n to Mot. to Intervene (Dkt. 22) at 10, *Novartis Pharm. Corp. v. Becerra*, No. 25-cv-117 (D.D.C. filed Jan. 15, 2025) (second emphasis added and quotation marks omitted); *see id*. at 9-10 (quoting *Astra* twice more for same proposition).

It made no difference to the *Astra* Court that there had been various "reports of inadequate HRSA enforcement." 563 U.S. at 121. Sanofi points to similar reports in this case. *See* Compl. ¶¶ 37-38. But in *Astra*, the Court explained that Congress was aware of those kinds of reports when it amended the 340B statute in 2010, and yet it still did not unleash program participants to go out and fend for themselves. Rather, Congress chose to reinforce the ADR process and to "strengthen and formalize HRSA's enforcement authority." 563 U.S. at 121-122.[5] Thus, *Astra* holds that

[5] There is active litigation throughout the country about state legislation addressing drug company limitations on contract pharmacy arrangements. *E.g.*, *Pharm. Rsch. & Mfrs. of Am. v. McClain*, 95 F.4th 1136 (8th Cir. 2024) *cert. denied*, --- S. Ct. ----, No. 24-118, 2024 WL 5011712 (Dec. 9, 2024); *Pharm. Rsch. & Mfrs. of Am. v. Murrill*, No. 23-cv-00997, 2024 WL 4361597, at *9 (W.D. La. Sept. 30, 2024), *appeal docketed*, No. 24-30673 (5th Cir. Oct. 21, 2024). In those cases, drug companies or their trade association, PhRMA, made arguments about *Astra*'s holdings on HRSA's centralized enforcement scheme. The AHA opposed those arguments, explaining that *Astra* did not address preemption of state laws or the subject of contract pharmacies. Should Sanofi attack *Amici* as hypocritical for relying on *Astra* here, it is important to underscore just how different the contract pharmacy context is from this one. In the contract pharmacy context, courts—including this one—have found the statute to be silent on the subject. But in this context, Sanofi is pursuing

participants in the 340B Program—be they covered entities in that case or drug companies in this one—cannot seek to unilaterally enforce the statute themselves.

Second, the 340B statute does not contemplate audits or other enforcement *before* payment at discounted 340B pricing. All of the enforcement processes included in the statute are to be conducted after covered entities have paid discounted 340B prices. Accordingly, the 340B statute contemplates: 1) some awareness of a past violation, which then kicks off; 2) a review of completed transaction records, followed by; 3) a determination and remedy by HHS, either under the ADR process, *see* 42 U.S.C. § 256b(d)(3)(B)(i), or through agency-imposed sanctions and civil monetary penalties, *see id*. §§ 256b(a)(5)(D), 256b(d)(2)(B)(v). *See generally Am. Hosp. Ass'n v. HHS*, No. 4:20-cv-08806, 2021 WL 616323, at *6 (N.D. Cal. Feb. 17, 2021) ("Congress made explicit that alleged 340B Program violations are to be first adjudicated by HHS through an established ADR process. This process provides the agency an initial opportunity to develop rules and regulations applicable to the enforcement of the 340B Program requirements."). Neither the audit process nor the ADR process contemplates a regime where drug companies can conduct their own free-wheeling self-enforcement *before* providing 340B discounts, with the authority to refuse such pricing based on a drug company's unilateral belief that violations of the statute are occurring.

For this reason, Sanofi is especially wrong that Section 340B authorizes the "Patient Definition" component of its "Integrity Initiative." It contends that "[n]othing in Section 340B requires that Sanofi must nonetheless provide 340B pricing for drugs that Sanofi knows have *already been* dispensed to individuals who are not patients of the covered entity." Mem. of P. & A.

---

its unlawful rebate "Integrity Initiative" because it believes that: i) covered entities are violating the 340B statute's prohibitions against diversion and duplicate discounts; and ii) a federal agency is not doing a good enough job enforcing those express statutory prohibitions. There are no silences about those subjects, and *Astra* speaks directly to HRSA's role in superintending the 340B Program through audits and dispute resolution.

in Supp. of Pl.'s Mot. for Summ. J. (Dkt. 27-1) at 30. But when Sanofi demands purchase data from hospitals, it does not *already know* that someone is not a patient. Sanofi may *want* purchase information so that it can figure out who is not a patient. But there is a world of difference between actually "knowing," on the one hand, and demanding purchase data "in order to know," on the other.

As clearly as the 340B statute precludes diversion, it also sets forth a carefully calibrated regime where suspected diversion first must be audited and then addressed in the ADR process. *See* 42 U.S.C. § 256b(a)(5)(C); 42 U.S.C. § 256b(d)(3)(B)(iv). That regime does not permit Sanofi to demand purchase data from 340B hospitals simply because it wants to know, in advance, who may not be a patient under HRSA's 1996 guidance. As Sanofi admits, if it later determines that someone is not a patient, it can "claw back the discount from the diverting covered entity on the back end." Mem. of P. & A. in Supp. of Pl.'s Mot. for Summ. J. (Dkt. 27-1) at 31. But the 340B statute, decades-old agency guidance, and *Astra* all require Sanofi to follow certain procedures to get to that point. They *do not* allow Sanofi to demand purchase data from 340B hospitals as a precondition for discounts, long before an audit or ADR process is completed, so that the company can self-police diversion and self-enforce HRSA's patient definition. HRSA got this exactly right. *See* Compl. Ex. F at 2 n.1; *Garland v. Ming Dai*, 593 U.S. 357, 369 (2021) ("[A] reviewing court must 'uphold' even 'a decision of less than ideal clarity if the agency's path may reasonably be discerned.'" (quoting *Bowman Transp., Inc. v. Ark.-Best Freight Sys., Inc*., 419 U.S. 281, 286 (1974)); *Inv. Co. Inst. v. CFTC*, 720 F.3d 370, 372-373 (D.C. Cir. 2013) ("So long as CFTC provided a reasoned explanation for its regulation, and the reviewing court can reasonably ... discern[ ] the agency's path, we must uphold the regulation, even if the agency's decision has less than ideal clarity.… CFTC's regulation clears this low bar.").

It is important to reemphasize that Congress expressly gave *the Secretary* discretion to establish audit procedures to enforce the prohibitions against diversion. *See* 42 U.S.C. § 256b(a)(5)(C). Pursuant to that discretion, in 1996 the Secretary began requiring manufacturers to demonstrate "reasonable cause" before conducting an audit. Manufacturer Audit Guidelines and Dispute Resolution Processes, 61 Fed. Reg. 65,406, 65,409 (Dec. 12, 1996); *see id*. at 65,406 (explaining that the "reasonable cause" standard "will ensure that the audits are performed where there are valid business concerns *and are conducted with the least possible disruption to the covered entity*" (emphasis added)). The Secretary did not want a free-for-all where dozens of different drug companies had "the right to routinely conduct an audit as a normal business practice without the need for Departmental approval." *Id*.

Sanofi's "Integrity Initiative," by contrast, is not based on individualized suspicion of any covered entity or even "reasonable cause" that a particular violation has occurred. It casts an exceedingly wide net, demanding purchase data as a matter of course, all based on the belief that some abuse surely must be occurring. The 340B statute and decades-old agency guidance bar this kind of fishing expedition. *E.g.,* 42 U.S.C. § 256b(a)(5)(C) (giving Secretary, not drug companies, the authority to determine the "number" of audits). Sanofi cannot, as part of its normal business practices, require covered entities to provide swaths of information in advance, before it pays covered entities at the 340B price.

In fact, the same HHS audit guidelines that set forth the "reasonable cause" standard also responded to public comments insisting that "[m]anufacturers should not be required to continue to sell to a covered entity at the mandated price once an audit has been initiated, particularly since reasonable cause has already been demonstrated." 61 Fed. Reg. at 65,408. HHS, acting in its statutory discretion to establish audit procedures, rejected that proposal:

> Manufacturers must continue to sell at the statutory price during the audit process. Once the audit has been completed and the manufacturer believes that there is sufficient evidence to indicate prohibited entity activity, then the manufacturer may bring the claim to the Department through the informal dispute process. Not until the entity is found guilty of prohibited activity and a decision is made to remove the entity from the covered entity list, will the manufacturers no longer be required to extend the discount.

Id.[6]

Thus, the Secretary, acting within his statutory authority, did not want drug companies to unilaterally deny 340B discounts in advance based on mere suspicion of prohibited activity—precisely what Sanofi is now seeking to do with its "Integrity Initiative." Both Congress and HHS sought to channel disputes through an orderly audit and ADR process, during which covered entities would continue to be paid the discounted 340B pricing. This again proves that any effort by Sanofi to police the 340B statute in its sole discretion—before providing 340B discounts and only in exchange for purchase data—is incompatible with the structure and design of the statute.[7]

---

[6] Congress was presumably aware of this guidance when it amended the 340B statute in 2010 to codify an audit as a prerequisite for the ADR process. *See Lorillard v. Pons*, 434 U.S. 575, 581 (1978) ("[W]here, as here, Congress adopts a new law incorporating sections of a prior law, Congress normally can be presumed to have had knowledge of the interpretation given to the incorporated law, at least insofar as it affects the new statute."); *cf. Astra*, 563 U.S. at 121-122.

[7] HRSA's rationale for rejecting the rebate models—especially as set forth in Footnote 1 of its December 13, 2024 letter to Sanofi, *see* Compl. Ex. F at 2 n.1—flows directly from its 1994 and 1996 guidances (as well as *Astra*). Any counts alleging that HRSA acted arbitrarily and capriciously by failing to address or distinguish certain issues in its rejection letters are therefore meritless. *See Hall v. McLaughlin*, 864 F.2d 868, 872-873 (D.C. Cir. 1989) ("Where the reviewing court can ascertain that the agency has not in fact diverged from past decisions, the need for a comprehensive and explicit statement of its current rationale is less pressing.… [T]he decision of the Secretary in the present case—though of less than ideal clarity—must be upheld. We conclude that the Secretary did not swerve from her prior decisions. Consequently, her explanation need only be sufficient to permit the court to discern the path she has taken." (quotation marks omitted)); *see also Nat'l Weather Serv. Emps. Org. v. FLRA*, 966 F.3d 875, 884 (D.C. Cir. 2020) ("Although not articulated by the Authority, this distinction is sufficiently evident that the court is confident that the Authority has not arbitrarily departed from its established precedent.); *Gilbert v. NLRB*, 56 F.3d 1438, 1445 (D.C. Cir. 1995) ("[W]here the circumstances of the prior cases are sufficiently different from those of the case before the court, an agency is justified in declining to follow them,

Statutory structure matters. *E.g.*, *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 321 (2014) (rejecting an interpretation would be "inconsistent with—in fact, would overthrow—the Act's structure and design"); *Swinomish Indian Tribal Cmty. v. Azar*, 406 F. Supp.3d 18, 25 (D.D.C. 2019) ("'The structure of the statute is also relevant in understanding' its meaning." (quoting *Bullcreek v. Nuclear Regul. Comm'n*, 359 F.3d 536, 541 (D.C. Cir. 2004))); *see generally* Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 167 (2012) ("Perhaps no interpretive fault is more common than the failure to follow the whole-text canon, which calls on the judicial interpreter to consider the entire text, *in view of its structure* and of the physical and logical relation of its many parts." (emphasis added)). Here, the structural features discussed above are incompatible with the conditions that Sanofi would impose with its "Integrity Initiative."

Contrary to that policy, the statute does not permit Sanofi to engage in unbridled self-enforcement. Congress granted *HHS* the authority to "superintend" and "control" the 340B Program. *Astra*, 563 U.S. at 113-14. "That control could not be maintained were" hundreds of drug companies permitted to impose their own individual policies regarding rebates and patient definitions. *Id*. at 114. Nor could it be maintained if *every* drug company were permitted to pre-condition payment on the surrender of *different* data depending on what *any given* company demands at *any given* time. Instead, the 340B statute (and the time-honored HHS guidelines established under its statutory authority) sets forth procedures where subjective manufacturer suspicions about diversion and duplicate discounts do not permit drug companies to withhold 340B discounts until purchase data is turned over or program compliance is verified. Anything else—

---

and the court may accept even a laconic explanation as an ample articulation of its reasoning." (quotation marks omitted)).

including and especially Sanofi's "Integrity Initiative"—"runs contrary to how the [340B] Program is supposed to work." *Ams. for Clean Energy v. EPA*, 864 F.3d 691, 710 (D.C. Cir. 2017).

B. Sanofi's "Integrity Initiative" is incompatible with the 340B statute's history.

In keeping with this statutory structure and design, HHS has long and consistently interpreted the 340B statute to preclude what Sanofi seeks to do here. As the D.C. Circuit has recognized, this "agency guidance" is relevant to the analysis. *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 460 (D.C. Cir. 2024). Here, the guidance squarely supports HRSA's conclusion.

In 1993, HRSA sought public comment to inform its superintendence of the 340B Program, particularly with regard to the statutory bars on diversion and duplicate discounts. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 58 Fed. Reg. 68,922 (Dec. 29, 1993). Five months later, the agency issued a Final Notice stating: "A manufacturer may not condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions." Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110, 25,113 (May 13, 1994).[8] HRSA also specifically stated that drug companies may *not* require hospitals to submit information about "drug acquisition" and "purchase" as a condition for 340B discounts. *Id*. at 25,113-114.[9]

---

[8] The only time in thirty years that HRSA exercised its statutory authority to approve a rebate model, in the narrow and distinguishable context of State AIDS Drug Assistance Programs, it reemphasized this longstanding limitation on drug company behavior. *See Notice Regarding Section 602 of the Veterans Health Care Act of 1992—Rebate Option*, 63 Fed. Reg. 35,239, 35,240 (June 29, 1998) ("In addition, manufacturers and covered entities are referred to 59 FR 25113 for a reminder that 'a manufacturer may not condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions.'").

[9] Although that guidance did allow manufacturers to request "standard information," Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. at 25,113-114, there is nothing "standard" about Sanofi's current demands. Most important, the term "standard information" must be understood in light of the rest of HRSA's guidance. By explicitly barring demands for "drug acquisition" and "purchase" information, the term "standard information" cannot include exactly the kind of data that Sanofi now demands under its "Integrity

HHS's analysis is precisely the type of agency interpretation that can assist this Court in construing the 340B statute. As the Supreme Court explained in *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 394 (2024), "courts may—as they have from the start—seek aid from the interpretations of those responsible for implementing particular statutes." Here, that responsibility is HHS's. What's more, this particular HHS interpretation was "issued contemporaneously with the statute at issue" and has "remained consistent over time." *Id*. It is therefore "especially useful in determining the statute's meaning." *Id*. And last but not least, the 340B statute "empowers" HHS "to prescribe rules to 'fill up the details'" of the 340B statute's oversight scheme. *Id*. at 395 (quoting *Wayman v. Southard*, 10 Wheat. 1, 43 (1825)). Thus, as this Court "exercise[s] independent judgment in determining the meaning of statutory provisions," *id*. at 394, HRSA's well-established position that drug companies cannot condition or withhold 340B discounts on the handover of drug acquisition or purchase data should be given "great weight," *id*. at 388 (internal quotation marks omitted), and "due respect," *id*. at 403; *see id*. at 430 (Gorsuch, J., concurring)

Initiative." Nor can it include the scope and quantity of data at issue here, which is far greater than the contract pharmacy-related data at issue in *Novartis*, 102 F.4th 452. And if all of that were not enough—and it surely is—another portion of the Final Notice seems to equate "standard information" with "routine information necessary to set up and maintain an account." Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. at 25,112. Not only did *Novartis* <u>not</u> consider the full text of HRSA's guidance (including and especially its statements regarding "drug acquisition" and "purchase" information), but unlike the policies at issue in *Novartis*, the burden and administrative cost of these rebate policies are much more than "minimal." *Novartis*, 102 F.4th at 463; *see infra* at Section I.C.

Another especially powerful clue about the meaning of "standard information" is that the purchase and patient data demanded under the "Integrity Initiative" was not required in 1994 when HRSA issued its guidance, nor did Sanofi require it until the fall of 2024. *Amici* recognize that this Court previously considered the role that past practice plays in evaluating manufacturer conditions. *Novartis Pharms. Corp. v. Espinosa*, No. 21-cv-1479, 2021 WL 5161783, at *7 (Nov. 5, 2021). *Amici* agree that the 340B statute may allow some conditions beyond those "previously imposed," *id*., but we respectfully submit that consistent practice for nearly three decades—including at the time when HRSA's guidance was initially provided—should at least count for something in evaluating what is deemed "standard."

("[T]his Court has also long extended great respect to the contemporaneous and consistent views of the coordinate branches about the meaning of a statute's term." (quotation marks omitted).[10]

The D.C. Circuit's decision in *Novartis Pharms. Corp. v. Johnson*, does not undermine HHS's interpretation of the 340B statute. Nor does it authorize Sanofi's "Integrity Initiative." *See Novartis*, 102 F.4th at 464 ("We do not foreclose the possibility that other, more onerous conditions might violate the statute."); *Novartis Pharms. Corp.,* 2021 WL 5161783, at *9 ("The statute's plain language, purpose, and structure do not ... *permit* all conditions." (emphasis in original)). That decision upheld a United Therapeutics policy requiring "covered entities to provide claims data associated with all 340B contract pharmacy orders to a third-party platform, to facilitate efforts to police diversion and duplicate discounts." *Novartis,* 102 F. 4th at 458; *see Novartis*, 2021 WL 5161783, at *4 ("United Therapeutics also requires all covered entities using contract pharmacies to regularly provide claims data to [United Therapeutics] via a third-party platform, among other things, allowing [the manufacturer] to confirm that contract pharmacies are genuinely acting on behalf of a covered entity." (quotation marks omitted)). But United Therapeutics' policy was *meaningfully different* from Sanofi's policy. It dealt *only* with contract pharmacies and drug company limits related to distribution. *See Novartis*, 102 F.4th at 461-462 ("HRSA invokes the statutory audit and dispute-resolution mechanisms.… [T]hey serve to ensure compliance with the

[10] *Accord Nat'l Lead Co. v. United States,* 252 U.S. 140, 145–146 (1920) ("[G]reat weight will be given to the contemporaneous construction by department officials, who were called upon to act under the law and to carry its provisions into effect, especially where such construction has been long continued, as it was in this case for almost 40 years before the petition was filed."); *United States v. Am. Trucking Ass'ns, Inc*., 310 U.S. 534, 549 (1940) ("The Commission and the Wage and Hour Division, as we have said, have both interpreted Section 204(a) as relating solely to safety of operation. In any case such interpretations are entitled to great weight. This is particularly true here where the interpretations involve 'contemporaneous construction of a statute by the men charged with the responsibility of setting its machinery in motion; of making the parts work efficiently and smoothly while they are yet untried and new.'" (quoting *Norwegian Nitrogen Co. v. United States*, 288 U.S. 294, 315 (1933))).

various obligations that section 340B imposes.… HRSA reasons that this enforcement scheme is carefully calibrated, which tends to suggest that it is exclusive. Perhaps so, but that at most shows that section 340B establishes the precise metes and bounds of audits and administrative adjudications. It does not suggest that contractual limits *on distribution* are unlawful." (emphasis added and internal citation omitted)).

The differences between these contexts are determinative. In the contract pharmacy context, *Novartis* found the statute to be silent as to distribution. *Id*. at 460. Here, the statute includes "carefully calibrated" compliance, audit, and dispute resolution procedures that do not permit unilateral drug company enforcement. *Id*. at 462. In the contract pharmacy context, drug companies and HRSA could *not* audit those pharmacies because the 340B statute does not provide for audits of third parties. Here, drug companies *can* audit 340B hospitals, provided they follow the appropriate processes. These distinctions are dispositive, as they directly implicate the textual and structural features discussed above that are incompatible with the rebate model.

More fundamentally, the scope of the policy at issue here, and the consequences to hospitals for violating it, are even more drastic than anything at issue in *Novartis*. United Therapeutics' policy did not deny 340B discounts to hospitals altogether. It refused to sell *only to contract pharmacies* if data was not provided. *See* Pl.'s Compl. (Dkt. 1) Ex. 3 at 6, *United Therapeutics Corp. v. Espinosa*, No. 21-cv-1686, 2021 WL 5161783 (D.D.C. Nov. 5, 2021). A hospital still could obtain 340B pricing if it distributed a drug from its in-house pharmacy. Here, Sanofi's "Integrity Initiative" would *completely deny* hospitals their 340B discounts if those covered entities refuse to surrender important purchase data or assure program compliance.

It is not too much to say that Sanofi's policy, unlike United Therapeutics' policy, strikes at the heart of the 340B Program. Not merely addressing where 340B drugs can be sold, Sanofi's

policy touches on the core function of the Program—whether 340B discounts are provided at all. This runs headlong into HRSA's three-decade-old ban on drug companies conditioning 340B discounts on their own satisfaction about a covered entity's compliance or the handover of purchase data. Because *Novartis* adjudicated a far narrower set of drug company conditions, it has no bearing on the policy at issue here.

C. Sanofi's "Integrity Initiative" is incompatible with the 340B statute's purpose.

Purpose also can be relevant to statutory interpretation—particularly where, as here, it aligns with the statute's text, structure, and history. *See Loving v. IRS*, 742 F.3d 1013, 1016 (D.C. Cir. 2014) (Kavanaugh, J.) ("[I]n ultimately determining whether the agency's interpretation is permissible or instead is foreclosed by the statute, [courts] must employ all the tools of statutory interpretation, including text, structure, *purpose*, and legislative history." (quotation marks omitted and emphasis added)); *see also U.S. Sugar Corp. v. EPA*, 113 F.4th 984, 999 (D.C. Cir. 2024) ("Reading Section 112(d)(3) to require EPA to use the data it 'has' in its possession until the moment a rule is promulgated would frustrate the statutory purposes of the Clean Air Act."); *United States v. Griffin*, 119 F.4th 1001, 1025 (D.C. Cir. 2024) ("We reject Griffin's reading, which is so squarely at odds with that clear purpose."). Of course, "even the most formidable argument concerning the statute's purposes could not overcome the clarity ... in the statute's text," *Kloeckner v. Solis*, 568 U.S. 41, 55 n.4 (2012), and "no legislation pursues it purposes at all costs." *CTS Corp. v. Waldburger*, 573 U.S. 1, 12 (2014). But if purpose is considered at all—and it should be here—it is important to understand what the 340B statute's purpose *actually is* and how Sanofi's policy bulldozes it.

The purpose of the 340B Program is indisputable and well-recognized. Drawing on language from a congressional report, courts have held that the "program was intended to enable certain hospitals and clinics 'to stretch scarce Federal resources as far as possible, reaching more

eligible patients and providing more comprehensive services.'" *Am. Hosp. Ass'n v. Hargan*, 289 F. Supp.3d 45, 47 (D.D.C. 2017) (quoting H.R. Rep. No. 102–384, pt. 2, at 12 (1992)); *see Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 822 (D.C. Cir. 2020), *rev'd sub nom. Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724 (2022) (quoting same language from the House Report). Thus, while the statute's provisions regarding diversion and duplicate discounts indicate that Congress did not want covered entities to obtain 340B discounts fraudulently (*i.e.*, "at all costs"), those provisions and the HHS-superintendence provisions must be considered in light of this purpose—*not* as separate, equally important purposes, as the drug companies occasionally insist in their briefs. In fact, the same congressional report also makes clear that "in developing [audit] procedures, the Secretary will make every effort to *minimize* the administrative and financial burdens that these audits impose on 'covered entities.'" H.R. Rep. No. 102–384, pt. 2, at 17 (1992) (emphasis added). Putting all of this together, these statements make clear that Congress wanted any anti-fraud efforts to interfere *as little as possible* with the statute's true purpose of allowing 340B hospitals to stretch their limited financial resources as far as possible to better serve patients.

Sanofi's policy flouts this statutory purpose. Far from helping 340B hospitals to stretch financial resources, it squeezes them. The key function of the 340B Program is to allow "covered entities (including eligible hospitals) to purchase drugs from manufacturers at heavily discounted rates." *Azar*, 967 F.3d at 822. But Sanofi's policy eats away at those intended discounts in two main ways.

First, Sanofi's policy will require hospitals and other covered entities to float significant sums to drug companies. The American Hospital Association surveyed its membership while preparing this *amicus* brief, and it learned that 340B hospitals anticipate, on average, *multi-million-dollar* annual losses as a result of just the announced policies. *Hundreds* of 340B hospitals have

reported that they, in turn, will have to restrict or close healthcare service lines, thus directly harming the patients that the 340B program is supposed to help.

For example, Baptist Hospital in Pensacola, Florida reports that if forced to comply with just the announced rebate policies, it would have to advance *$33 million* per year to the drug companies. Not only would it be handing the drug companies any interest it could earn on that sum, but Baptist fears that it will not be reimbursed for 100% of the rebates they are rightly owed under the law. What's more, Baptist reports that, due to these upfront costs, it likely would not be able to keep certain drugs in stock. In particular, it would have to pay more than $9 million a year in upfront costs for *just five* oncology medications; Baptist Hospital has explained to *Amici* that it would need to take a hard look whether they could continue to offer these costly medications to its cancer patients. More generally, Baptist Hospital uses its 340B savings to further its charitable mission of delivering health care services to all individuals within the Pensacola and Northwest Florida communities. One service in particular that has benefited from 340B savings is oncology care for underinsured patients. That program would be in real jeopardy. As Baptist Hospital explained, the "rebate program would severely curtail our ability to provide nonessential community services and our ability to remain in certain service lines with high drug expenses."

Similarly, UC San Diego Health in San Diego, California reports an estimated annual financial impact of more than $25 million in connection with just a small subset of drugs from the initial rebate proposals. As additional manufactures release their own versions of a rebate model, the tens-of-millions-of-dollars of impact will multiply. This strain on the health system will directly affect patients. UC San Diego Health uses its 340B savings to offer *free* medication to eligible patients. Manufacturer rebate policies pose an imminent risk to UC San Diego's ability to maintain these financial assistance programs. In addition, the rebates would jeopardize UC San Diego

Health's ability to use its 340B savings to help vulnerable patients with medication treatment management, *i.e.*, services that help patients understand and use their medications safely and effectively, and adhere to the prescribed course of care.

Stories like these abound. But another way to measure the financial impact of Sanofi's policy is to look at hospitals' cash-on-hand. According to an August 7, 2024 report from the independent ratings agency S&P Global, median days cash-on hand have plummeted to a 10-year low for U.S. hospitals. *See* Laura Dyrda, *Hospital average days cash on hand hit 10-year low: S&P*, Becker's Hospital CFO Report (Aug. 9, 2024), at https://www.beckershospitalreview.com /finance/hospital-average-days-cash-on-hand-hit-10-year-low-s-p.html. Indeed, a second independent report confirms that, from February 2022 to February 2024, the number of days cash-on-hand for hospitals and health systems has declined by 25.4%. *See* Jay Asser, *Hospitals' Cash Reserves Diminished in Recent Years*, Health Leaders (Apr. 4, 2024), *at* https://www.healthleadersmedia.com/finance/hospitals-cash-reserves-diminished-recent-years. According to that report, "[t]he steep decrease … highlights continued financial uncertainties for the sector, as having lower cash reserves means hospitals are less prepared for unexpected emergencies or sudden market changes." *Id*. The unilateral imposition of a policy in which hospitals must advance millions of dollars from their cash reserves to Sanofi easily qualifies as a "sudden market change" that many 340B hospitals are not financially prepared for.

To put an even finer point on it, Sanofi's policy puts hospitals at risk of violating their bond covenants. 340B hospitals rely on bond financing to raise money for new projects that enhance patient care. Those bonds typically include covenants requiring hospitals to maintain a certain amount of days cash-on-hand. *See* Steven Shill, *Healthcare providers face a growing risk of violating debt covenants*, Healthcare Financial Management Magazine (Feb. 2022), at

https://www.bdo.com/getmedia/bdd99fa0-6f39-4f70-b28d-accf0ba66ea2/0222_HFM_Debt-Covenants.pdf. Following the announcement of these rebate policies, *more than 200 hospitals* self-reported to the AHA that their cash-on-hand would drop low enough to risk violating their bond covenants. This would have calamitous effects on 340B hospitals, including downgrades in credit ratings, increased borrowing costs, lack of access to state-of-the-art medical equipment, and more. Worst of all, "[v]iolating a debt covenant can have a downward spiral effect on an organization's ability to continue *as a going concern*." *Id*. (emphasis added). That consequence—closing a hospital's doors—is obviously antithetical to the 340B statute's purpose.

Second, the rebate policies will further gobble up the intended 340B discounts by raising administrative costs. Sanofi's "Integrity Initiative" requires a 340B hospital to do two things: provide data to drug companies and then track whether it received the discount. At both ends, hospitals will be required to spend considerable resources, all to obtain a discount that they are entitled to under law. *Amici*'s member hospitals report that, among other things, they will be required to hire new full-time employees, develop or purchase new software, and incur the costs of filing disputes to challenge inevitable unjustified denials of the 340B discounts. As this Court knows, moreover, Sanofi is not the only drug company to impose a rebate policy. Not every drug company will impose the *same* requirements, use the *same* data fields or feeds, accept the *same* electronic or manual formatting, rely on the *same* vendors, have the *same* contractual language, or provide rebates on the *same* timetables. Indeed, the "Patient Definition" component of Sanofi's "Integrity Initiative" is unique to that company. So when thinking about these new costs and burdens, the Court—like *Amici*'s members—must think about them exponentially.

For example, CHRISTUS Children's Hospital is the only free-standing academic pediatric hospital in San Antonio, Texas that is exclusively focused on pediatric and high-risk maternal care.

It serves some of South Texas' most vulnerable women, children, and families. CHRISTUS Children's reports to *Amici* that having to comply with the drug companies' rebate policies will impose significant costs and administrative burdens. As for costs, it predicts $3.5 million in up-front increases in drug expenses annually, creating a considerable cash flow issue for the hospital. As for administrative burdens, CHRISTUS Children's predicts that it will have to hire new staff to manage the drug companies' data demands and to monitor whether the hospital receives the rebates that it is owed. CHRISTUS Children's also expects that it (and its other affiliated CHRISTUS Health 340B hospitals) would need to develop or buy new software to manage and track such rebate issues, which carries further costs. And the hospital expects that it will need to challenge denial decisions when drug companies choose not to provide appropriate 340B discounts, once again resulting in increased administrative and legal expenses.

Unfortunately, this sizable administrative expense means fewer 340B resources will be available for patients and for the San Antonio and South Texas communities. CHRISTUS Children's relies on the 340B Program to purchase critical lifesaving drugs for cancer treatments, chemotherapy, and other expensive medicines necessary to treat numerous pediatric medical conditions. For instance, savings from the 340B Program allow CHRISTUS Children's to provide high-quality treatment and novel therapies for rare diseases, such as pediatric Spinal Muscular Atrophy and Duchenne Muscular Dystrophy; patients from San Antonio and South Texas no longer must travel long distances to receive these curative high-cost gene therapies. Other initiatives CHRISTUS Children's has implemented with its 340B savings include: 1) improved access to high-quality care by opening community-based maternal-fetal and pediatric subspecialty clinics to serve Bexar County patients closer to their homes; 2) comprehensive medical and surgical programs for children with complex conditions (including wraparound services and care

coordination); and 3) partnerships with community-based non-profit organizations for family support services, behavioral health, care coordination, and education to improve the overall health of the communities CHRISTUS Children's serves. Without support from 340B savings, many of these programs—which provide hope, healing, and new beginnings for children, expectant mothers, and families in Texas—will suffer as a direct result of these unlawful rebate policies.

Likewise, Dallas County Medical Center is a small Critical Access Hospital in Fordyce, Arkansas. It uses its 340B savings to provide uncompensated care to the rural population of South-Central Arkansas. Complying with the rebate policies will inflict substantial administrative costs on its 25-bed facility—on top of the costs of having to float its cash reserves to the drug companies while hoping that all of its claims are actually rebated. Already thinly-staffed, it will have to hire expensive outside contractors, along with new full-time employees, to assist with the compliance and operations of the rebate policies. Over time, these contractors, FTEs, and other administrative expenses are likely to cost more than the 340B discounts bring in. If all the discounts are doing is breaking-even (or worse) on compliance and administrative costs and not allowing Dallas County Medical Center to help its patients, it will have to weigh the benefit of participating in the 340B Program at all—something Congress certainly did not intend when enacting the 340B statute.

For all of these reasons, Sanofi's policy is incompatible with Congress' purpose in enacting the 340B statute. *Amici* recognize, of course, that "it frustrates rather than effectuates legislative intent simplistically to assume that *whatever* furthers the statute's primary objective must be the law." *Rodriguez v. United States*, 480 U.S. 522, 526 (1987). But what if Sanofi's policy is doing the "frustrating"—here, by dramatically draining the discount Congress intended to provide? *Amici* also recognize, as this Court did, that the 340B statute's diversion and duplicate discount provisions "suggest[] that Congress did not intend Section 340B's purpose to be pursued at all

costs." *Novartis*, 2021 WL 5161783, at *7. But what if the *literal costs* of Sanofi's policy overwhelms that statutory purpose? At some point, even if Congress did not intend to pursue its purpose at *all* costs, the costs to that purpose will be *great enough* to shed light on a statute's meaning. *See NextEra Energy Res., LLC v. FERC*, 118 F.4th 361, 371 (2024) ("[C]ourts should prefer textually permissible readings that would advance statutory or regulatory goals over ones that would frustrate them. These are bedrock principles of statutory construction." (internal citations omitted)); *see generally* Scalia & Garner at 63 ("A textually permissible interpretation that furthers rather than obstructs a document's purpose should be favored.").

This is one of those cases. When combined with text, structure, and history, the consequences of Sanofi's self-proclaimed "Integrity Initiative" cannot be squared with Congress' intent in enacting the 340B statute.[11]

CONCLUSION

The 340B statute does not permit drug companies to unilaterally withhold discounts from 340B hospitals in exchange for the surrender of purchase data or what are, in essence, pre-payment audits. The Health Resources and Services Administration therefore correctly exercised its statutory authority to reject both components of Sanofi's "Integrity Initiative." Accordingly, this Court should deny Sanofi's Motion for Summary Judgment.

[11] It also is worth underscoring that "[e]very statute purposes, not only to achieve certain ends, but also to achieve them by particular means—and there is often a considerable legislative battle over what those means ought to be." *Dir., OWCP v. Newport News Shipbuilding & Dry Dock Co*., 514 U.S. 122, 136 (1995). As explained above, Congress had a precise intention about what "means" should be used to enforce the statute's prohibitions on diversion and duplicate discounts—namely, the audit and ADR processes. The rebate policies are incompatible with those "means," thereby violating statutory purpose in a second (but equally consequential) way.

March 6, 2025

Respectfully submitted,

/s/

Chad Golder, Fed. Bar No. 976914
American Hospital Association
2 City Center, Suite 400
800 10th Street, NW
Washington, DC 20001-4956
202-626-4624
cgolder@aha.org
Counsel for *Amici Curiae*

CERTIFICATE OF COMPLIANCE

I hereby certify this brief complies with Local Rule 7(o)(4) and Fed. R. App. P. 29(a)(5) and 32(g)(1) because it does not exceed 25 pages. The Brief also complies with the typeface and type-style requirements of the Local Rules because it is double-spaced and has been prepared using Microsoft Word in a proportionally spaced 12-fond (Times New Roman) in the text and the footnotes.

/s/
Chad Golder

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SANOFI-AVENTIS U.S. LLC,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al*.,

Defendants.

Case No. 24-CV-3496 (DLF)

ORDER

Upon consideration of the March 6, 2025 unopposed Motion for Leave to File *Amicus* Brief in Support of Defendants, filed by the American Hospital Association, the National Association of Children's Hospitals, Inc. d/b/a Children's Hospital Association, the Association of American Medical Colleges, and America's Essential Hospitals, and the entire record herein, it is hereby, for good cause shown:

1. **ORDERED** that the March 6, 2025 Motion for Leave to File *Amicus* Brief in Support of Defendants, filed by the American Hospital Association, the National Association of Children's Hospitals, Inc. d/b/a Children's Hospital Association, the Association of American Medical Colleges, and America's Essential Hospitals shall be and hereby is **GRANTED**; and it is further

2. **ORDERED** that the American Hospital Association, the National Association of Children's Hospitals, Inc. d/b/a Children's Hospital Association, the Association of American Medical Colleges, and America's Essential Hospitals shall be and hereby are **GRANTED LEAVE** to file an amicus brief in support of Defendants; and it is further

3. **ORDERED** that the Clerk shall cause the *amici curiae* brief attached to the March 6, 2025 Motion for Leave to File *Amicus* Brief in Support of Defendants, filed by the American Hospital Association, the National Association of Children's Hospitals, Inc. d/b/a Children's Hospital Association, the Association of American Medical Colleges, and America's Essential Hospitals to be filed and entered on the docket in the above-captioned proceeding; and it is further

4. **ORDERED** that the Clerk shall cause copies of this Order to be delivered to all parties of record.

So **ORDERED** this _____ day of _____, 2025

_____
DABNEY L. FRIEDRICH
United States District Judge