UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

FLORIDA HEALTH SCIENCES CENTER, INC. d/b/a TAMPA GENERAL HOSPITAL,

Plaintiff,

v. Case No. 8:26-cv-01918

ELI LILLY AND COMPANY; and LILLY USA, LLC,

Defendants.
_____/

BRIEF OF AMICUS CURIAE WASHINGTON LEGAL FOUNDATION SUPPORTING DEFENDANTS' MOTION TO DISMISS

Dated: September 22, 2026

Cory L. Andrews, Fla. Bar No. 25677
WASHINGTON LEGAL FOUNDATION
2009 Massachusetts Ave., NW
Washington, DC 20036
(202) 588-0302
candrews@wlf.org

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INTEREST OF AMICUS CURIAE*

Washington Legal Foundation is a nonprofit, public-interest law firm and policy center with supporters nationwide, including many in Florida. WLF promotes free enterprise, individual rights, limited government, and the rule of law. It often appears as amicus curiae in cases involving administration of the 340B program, urging courts to adhere to the program's statutory framework under 42 U.S.C. § 256b. *See, e.g., Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452 (D.C. Cir. 2024); *Sanofi Aventis U.S. LLC v. U.S. Dep't of HHS*, 58 F.4th 696 (3d Cir. 2023). WLF believes that business certainty and American prosperity both suffer when state law, including state tort law, imposes upon an industry an additional layer of liability that frustrates the aims of Congress's careful and thorough statutory regimes, including Section 340B of the Public Health Service Act.

INTRODUCTION AND SUMMARY OF ARGUMENT

Tampa General Hospital's complaint should be dismissed because it seeks to do something that Congress never authorized: privately enforce alleged violations of the 340B statute against a drug manufacturer in federal court. Since that dooms its case, TGH tries to dress up its 340B dispute as a

* No party's counsel authored any part of this brief. No one, apart from WLF and its counsel, contributed money intended to fund the brief's preparation or submission. No party opposes the filing of this brief.

collection of state-law claims under Florida's Deceptive and Unfair Trade Practices Act, Fla. Stat. § 501.201, *et seq*. But the Supreme Court's decision in *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011) forbids such a disguise. TGH's suit seeks to expand 340B beyond Congress's boundaries and expectations, "inhibit[ing] the 340B program as a whole." *AbbVie Inc. v. Wrigley*, 832 F. Supp. 3d 920, 928 (D.N.D. 2026), appeal docketed, No. 26-1863 (8th Cir. May 5, 2026). The Court should not allow it.

Congress enacted 340B in 1992 to help safety-net providers serve the prescription-drug needs of low-income patients. To be eligible to participate in Medicaid and Medicare Part B, drug manufacturers must also participate in 340B by offering deep discounts (often between 25% and 50%) on drugs purchased by qualifying healthcare providers known as "covered entities." 42 U.S.C. § 256b(a); 42 U.S.C. § 1396r-8(a)(1). The statute's obligations flow through uniform "Pharmaceutical Pricing Agreements" (PPA) between the manufacturers and the Department of Health and Human Services (the Department). 42 U.S.C. § 256b(a). To prevent program misuse by covered entities, Congress prohibits them from (1) claiming Medicaid reimbursement for 340B prescriptions; and (2) providing 340B drugs to anyone who is not their patient. 42 U.S.C. § 256b(a)(5).

The program has since expanded far beyond its modest origins. The Health Resources and Services Administration (HRSA), the Department's sub-

agency that oversees the program, has issued non-binding guidance allowing covered entities to use an unlimited number of outside pharmacies to dispense 340B drugs. *See* Notice Regarding 340B Rebate Model Pilot Program 91 Fed. Reg. 48,883, 48,886 (Aug. 3, 2026) (summarizing expansion of the program over time). And in 2010, Congress expanded the definition of "covered entities" for providers eligible to participate in the program. *Id*. A program that once involved roughly 1,000 healthcare providers today includes nearly 60,000 covered entity sites. U.S. Gov't Acct. Office, *340B Drug Discount Program*, GAO-26-108784 at 5 (Oct. 23, 2025). By 2025, annual 340B purchases exceeded $100 billion. *See* HRSA, *2025 340B Covered Entity Purchases* (July 2026), https://perma.cc/5HPU-ADYH.

Financial incentives have fueled 340B's growth. Despite Congress's expectation that covered entities would use 340B discounts to help "low-income and uninsured patients," H.R. Rep. No. 102-384, pt. 2, at 10, covered entities regularly buy drugs at the 340B price (which can be as low as a penny), bill insurers or patients at full price, and then pocket the difference. Abuse of this practice has prompted commentators, courts, and lawmakers to lament that 340B has drifted away from Congress's intended goal of helping needy patients. *Wrigley*, 832 F. Supp. 3d at 928–29 (stating that 340B has become a "windfall to hospital[s]" and "pharmacies"); Wall St. J. Editorial Board, *The Great 340B Healthcare Grift*, The Wall Street Journal (May 7, 2026) (referring

to 340B as "a cash cow for hospitals"); S. Comm. on Health, Educ., Labor & Pensions, 119th Cong., *Congress Must Act to Bring Needed Reforms to the 340B Drug Pricing Program* 39 (Comm. Print 2025) (noting the need to ensure "a more transparent link between program savings and patient benefit").

TGH now seeks to reshape the program even further—by circumventing the dispute resolution scheme authorized under 42 U.S.C. § 256b(d)(3) that Congress requires for manufacturers and covered entities. With well-founded concerns that today's 340B model increases risk of duplicate discounts and diversion of 340B drugs, drug manufacturers, including Eli Lilly, have adopted conditions that require covered entities to submit claims data to receive 340B pricing. But TGH refused to provide the data, and so Lilly suspended the hospital's 340B discounts. TGH insists that it is entitled to the discounts anyway, but rather than pursue its claims through the dispute-resolution process that Congress required in § 256b(d)(3), it has sued Lilly for the discounts in federal court under state-law theories. This it may not do.

Congress never allowed private 340B suits, and no amount of state-law dress-up can oust the federal government from its position. U.S. Const. art. VI, cl. 2. Holding otherwise would sacrifice Congress's design of "unitary" agency enforcement for a "multitude of dispersed and uncoordinated lawsuits"—an outcome that *Astra* rejected. *Astra,* 563 U.S. at 120. Under *Astra's* reasoning, private suits are barred "no matter the clothing in which 340B entities dress

their claims." *Id.* at 114 (cleaned up). And if that were not enough, applicable law permits Lilly's claims-data condition as a means to ensure program integrity.

TGH faces an inescapable conundrum: to survive *Astra*, it must show its claims arise independently of section 340B; but to prevail on the merits, it must prove violations of that very statute. TGH cannot avoid the contradiction at the heart of this case. And because it cannot state a valid claim, its case should be dismissed. *See* Fed. R. Civ. P. 12(b)(6).

ARGUMENT

I. TGH'S LAWSUIT IS AN IMPERMISSIBLE ATTEMPT TO PRIVATELY ENFORCE 340B PRICING.

This case begins and ends with *Astra*.

A. *Astra* bars attempts to end-run 340B's lack of a private right to sue.

Nothing in Section 340B authorizes covered entities to sue manufacturers to enforce the statute's pricing requirements. *See Astra*, 563 U.S. at 113 ("Congress [has] authorized no private right of action under § 340B."). Yet that is what TGH seeks to do here. Its complaint asserts that Lilly has "effectively increase[d] the cost of covered outpatient drugs above the 340B ceiling price" and has violated "Section 340B's pricing mandate" by merely requesting "claims level data." Compl. ¶ 9. Each of TGH's counts is a

cause of action, masquerading as a FDUTPA claim, to enforce 340B pricing. *Astra* forbids all such schemes to privately enforce 340B indirectly.

In *Astra*, a covered entity sued a drug manufacturer for allegedly charging prices above 340B's ceiling price. The plaintiff styled its claim as a federal-common-law contract action, asserting third-party-beneficiary rights under the manufacturer's PPA with the government. *Id*. at 118. But the Supreme Court rejected that theory. *Id*. at 118–19. The Court refused to let the plaintiff accomplish through crafty "label[ling]" what Congress had barred it from doing directly: suing in court to enforce the statute. *Id*. at 114. Allowing covered entities to proceed that way, the Court explained, would render "[t]he absence of a private right to enforce the statutory ceiling-price obligations . . . meaningless." *Id*. at 118. This case is no different.

B. TGH's FDUTPA claims are disguised efforts to enforce 340B pricing.

Every one of TGH's claims seeks to enforce 340B pricing indirectly through FDUTPA and is no different from the third-party beneficiary claim rejected in *Astra*.

Start with count II, which alleges that Lilly committed an "unfair trade practice" by misrepresenting to the "market" that it "offers 340B discounts." Compl. ¶ 142. TGH bases this assertion on Lilly's PPA with the Department, *id*. ¶¶ 55–59, and Lilly's later request for claims data, which TGH

characterizes as Lilly "br[eaking] its word" on 340B pricing, *id.* ¶ 146. Because the claim seeks to enforce 340B by alleging that Lilly breached its PPA, it mirrors the third-party beneficiary claim rejected in *Astra*. The count has no content apart from the 340B statute. Counts I and III try similar moves and are similarly unavailing. Count I, which asserts an "unfair method of competition" under FDUTPA, alleges that Lilly has used purported "market power in numerous markets" to deny "TGH from 340B pricing, causing TGH damages." Compl. ¶¶ 132, 137. And count III, TGH's "*per se*" FDUTPA claim, asserts that Lilly has breached the law of *other states*—but not Florida—by "conditioning access to 340B discounts on satisfaction of data requests." *Id.* ¶ 154. All three counts seek damages and injunctive relief on the ground that Lilly has "denied access to 340B discounts." *Id.* ¶ 146, *see also* ¶¶ 137, 155–57.

As in *Astra*, there is no "independent substantive obligation" that TGH seeks to enforce aside from 340B pricing itself. *Astra*, 563 U.S. at 119. As shown by its own pleading, TGH seeks to enforce alleged pricing obligations under the 340B statute and Lilly's PPA. Remove 340B from the complaint, and no claim remains. All that remains is a manufacturer selling drugs at list price to a buyer that suddenly declined its terms. Every alleged duty, every alleged injury, every requested remedy, and every theory of liability hinges on the assertion that Lilly violated 340B pricing obligations. And so this suit, which is "in essence a suit to enforce the [340B] statute" is barred. *Astra*, 563 U.S. at

118; *see also Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001) (rejecting state-law claim seeking to enforce federal statute, where claim "exist[ed] solely by virtue of the [relevant federal statute's] disclosure requirements," which did not include a private right of action).

Simply put, TGH cannot use alternative legal theories to enforce the 340B statutory pricing that Congress chose not to make privately enforceable in court. *Astra*, 563 U.S. at 118.

C. *Astra*'s reasoning applies fully to TGH's FDUTPA claims.

TGH cannot avoid *Astra* by hiding behind state law. Lower courts are bound, not just by *Astra's* result, but by its reasoning. *See, e.g. Miller v. Gammie*, 335 F.3d 889, 900 (9th Cir. 2003) ("[T]he issues decided by the higher court need not be identical in order to be controlling."); Antonin Scalia, *The Rule of Law as a Law of Rules*, 56 U. Chi. L. Rev. 1175, 1177 (1989) (explaining that lower courts are bound by the higher court's "mode of analysis," in addition to its decisions). And *Astra*'s reasoning—which consists of two interrelated principles—applies all the same "no matter the clothing in which 340B entities dress their claims." *Astra*, 563 U.S. at 114 (cleaned up).

First, *Astra* emphasizes that Congress has chosen not to authorize private causes of action to enforce 340B but has instead opted for "centralized enforcement" over the program in the Department. *Astra*, 563 U.S. at 119 (internal citations and quotation marks omitted). As *Astra* explained at the

time, the Department, through HRSA, exclusively "handl[ed] overcharge complaints through informal procedures" and could require manufacturers to "reimburse" covered entities for overcharges. *Id.* at 115–16. The Court explained that this "unitary administrative and enforcement scheme" necessarily barred the imitation 340B claims before it. *Id.* at 120. To hold otherwise would defeat the very enforcement structure that Congress enacted. *Id.* at 118.

Astra's reasoning holds true for TGH's FDUTPA claims—though with even greater force today. Congress has not responded to *Astra* by creating a private right of action. It has continued to stand by its decision to centralize enforcement in the Department. In fact, while *Astra* was pending in the courts, Congress enacted 42 U.S.C. § 256b(d)(3) to further "strengthen and formalize" HRSA's enforcement authority. *Astra*, 563 U.S. at 121–22. That provision directs the Department to establish a robust "administrative process for the resolution of claims by covered entities." 42 U.S.C. § 256b(d)(3). And in the years since *Astra*, the Department has done just that, creating a process that covers alleged overcharge claims, including claims—just like those that TGH presses here—"that a manufacturer has limited the covered entity's ability to purchase . . . drugs at or below the 340B ceiling price." 42 C.F.R. § 10.21.

The Department's exclusive dispute-resolution process is comprehensive. It establishes claim review by a three-member panel, filing

deadlines, procedures for discovery, written decisions by the panel, and a reconsideration process. 42 C.F.R. §§ 10.20–10.24. The statute also authorizes the Department to comprehensively award remedies, including refunds for "overcharges," and to issue penalties. 42 U.S.C. § 256b(d)(1)(B). TGH cannot bypass Congress's and the Department's dispute-resolution framework through artful pleading of state-law claims, just as the plaintiff in *Astra* could not bypass HRSA's less formal procedures in place at the time the case was decided. "[C]areful and thorough remedial scheme[s]" cannot be "circumvented by artful pleading." *Brown v. Gen. Servs. Admin.*, 425 U.S. 820, 833 (1976).

Second, *Astra* emphasized *why* Congress declined to impart a private cause of action. *Astra*, 563 U.S. at 120. Centralized enforcement in the Department was needed, the Court stressed, to avoid "a multitude of dispersed and uncoordinated lawsuits," including the corresponding "risk of conflicting adjudications." *Id.* at 120. These concerns are especially strong in the 340B context since 340B is "interdependent" with the federal Medicaid Drug Rebate Program. *Id.* (internal citations and quotation marks omitted). Because 340B prices are tied to Medicaid pricing—and manufacturers must participate in 340B to participate in Medicaid—enforcement must remain concentrated in a national agency capable of considering both programs together. *Id.* at 113, 115, 120.

The substantial risks posed by a "multitude of dispersed and uncoordinated lawsuits" has only grown since 2011. *Id*. at 120. What was once a program of roughly 1,000 providers now includes nearly 60,000 covered entity sites. *See* GAO-26-108784 at 5. Allowing this mass of providers to pursue different remedies, under different state consumer-protection laws, would accelerate the "risk of conflicting adjudications" that *Astra* feared most. *Astra*. 563 U.S. at 120. And as the United States recently told the Fifth Circuit, if manufacturer costs of participating in 340B continue to rise, "rational manufacturers" may withdraw from 340B, which means withdrawal from Medicaid as well, weakening both programs. *See* Br. of the United States, *AbbVie, Inc. v. Murrill*, No. 24-30651 at 12 (5th Cir. Apr. 1, 2026). State-law causes of action would disrupt the Department's ability to "administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis" at least as much as the third-party-beneficiary claim rejected in *Astra*. 563 U.S. at 120 (cleaned up).

TGH's state-law labels cannot avoid succumbing to *Astra's* logic. Under the Supremacy Clause, a state-law claim is impliedly preempted when it stands as an obstacle to an enforcement scheme that Congress committed exclusively to a federal agency. U.S. Const. art. VI, cl. 2. The Supreme Court in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), applied that principle to state-law claims that sought to police a manufacturer's compliance

with federal duties that Congress had made enforceable only by the agency. *Id.* at 348, 353. The *Buckman* Court explained that permitting such claims would interfere with the agency's ability to police misconduct "consistently with [its] judgment and objectives," *id.* at 350, and would expose regulated entities to the very "unpredictable civil liability" Congress sought to avoid. *Id.* No "presumption against pre-emption" applies where the claims arise from a "relationship between a federal agency and the entity it regulates," rather than from a field the States have traditionally occupied. *Id.* at 347–48. State-law claims that "exist solely by virtue of [federal law]" are therefore preempted where Congress has vested enforcement authority exclusively in the agency. *Id.* at 353.

The Eleventh Circuit applies *Buckman* the same way. In *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319 (11th Cir. 2017), the court held that a Florida negligence claim premised on a device manufacturer's failure to report adverse events to the FDA was impliedly preempted, because that theory of liability was "based on a duty to file a report with the FDA" and was "not one that state tort law has traditionally occupied." *Id.* at 1330. The line *Mink* drew is the one that matters here: traditional state-law claims "survive implied preemption so long as they don't seek to privately enforce a duty owed to the FDA," *id.* at 1327, whereas claims that do seek to enforce such a duty are "private rights of action enforcing the violation of a statute" in all but name. *Id.* at 1329.

TGH's claims fall on the preempted side of that line. Its FDUTPA claims exist only because 340B exists. *See* Section I(B) *supra*. The claims arise from Lilly's participation in 340B, Medicaid and Medicare, and its relationship with the Department, where its Pharmaceutical Pricing Agreement implements the 340B pricing that TGH seeks to enforce. The fatal problem for TGH is that the 340B statute gives that enforcement power only to the Department. TGH may avail itself of Congress's prescribed dispute-resolution process to secure the Department's enforcement, but it cannot bypass that process here.

It's no surprise, then, that courts since *Astra* have repeatedly applied its reasoning to bar claims seeking to enforce 340B pricing through various pleading labels and state-law theories. *See, e.g., Sagebrush Health Servs. v. Amgen Inc.*, No. 2:26-cv-00466, 2026 WL 1030817, at *7 (C.D. Cal. Apr. 15, 2026), appeal docketed, No. 26-3248 (9th Cir. May 20, 2026) (applying *Astra* to bar California tort law claims seeking 340B pricing); *Am. Hosp. Ass'n v. Dep't of Health & Hum. Servs.*, No. 4:20-cv-08806, 2021 WL 616323, at *5 (N.D. Cal. Feb. 17, 2021) (applying *Astra* to bar APA claims seeking to enforce 340B pricing). These cases align with the law more broadly, which holds that a private plaintiff cannot use state law "to circumvent the absence of a private right of action under a federal statute." *Umland v. PLANCO Fin. Servs., Inc.*, 542 F.3d 59, 66 (3d Cir. 2008); *accord Miller v. Chase Home Finance, LLC*, 677 F.3d 1113, 116-17 (11th Cir. 2012) (per curiam).

No case supports TGH's maneuver. TGH can't seek help from *AbbVie, Inc. v. Murrill*, 180 F.4th 747 (5th Cir. 2026). There, the Fifth Circuit rejected a preemption challenge to a Louisiana law governing manufacturers' "delivery" of 340B drugs to pharmacies. *Murrill*, 180 F.4th at 759. But *Murrill* didn't involve a private covered entity's damages suit for 340B pricing; it involved the Louisiana Attorney General's enforcement of the State's own rules governing drug deliveries. *Id.* at 756. The Fifth Circuit further distinguished "Congress's enforcement scheme," where the Department has "exclusive authority" to enforce 340B pricing, from the Louisiana law, which, it said, governs the "delivery logistics" of drugs. *Id.* at 760-61. Because TGH's case seeks damages for what it concedes are 340B overcharges, it falls on the 340B-pricing side of *Murrill's* "Venn Diagram" and is foreclosed by *Astra*, even under the Fifth Circuit's analysis. *Murrill* 180 F.4th at 761.

TGH's complaint is an impermissible effort to morph 340B's enforcement regime into something Congress never authorized. If *Astra* means anything, it means that TGH cannot bring this suit as an end-run around the statutory scheme Congress's designed.

II. IN ANY EVENT, APPLICABLE LAW PERMITS LILLY'S CLAIMS-DATA CONDITION.

Even if *Astra* did not exist, TGH still cannot state a valid claim. The 340B program was enacted for underinsured patients who need prescriptions

but cannot afford list price. To help ensure the program advances this end—and is not used simply to enrich hospitals—the statute imposes two restrictions on covered entities. First, a covered entity cannot claim Medicaid reimbursement for a drug purchased at a 340B discount. Second, it cannot dispense a 340B drug to someone who is not its patient. *See* 42 U.S.C. § 256b(a)(5). A purchase invoice does not capture these facts, but claims data does. That is why the data that Lilly has requested is not merely incidental to program integrity; it is essential to verify that the program is used to help low-income patients.

To survive a motion to dismiss, a complaint's allegations must "plausibly give rise to an entitlement to relief." *Resnick v. AvMed, Inc.* 693 F.3d 1317, 1325 (11th Cir. 2012). But rather than do that, TGH's complaint posits a novel theory that is unsupported by statute and runs contrary to regulatory and appellate authority.

TGH identifies no provision of the 340B statute that prohibits manufacturers from conditioning access to discount drugs on the submission of claims data needed to verify program compliance. On the contrary, its FDUTPA claims fail precisely because they are anchored in federal law that *permits* Lilly's claims-data request. Three sets of authorities show how.

First, appellate authority addressing manufacturer conditions under federal law agrees that reasonable claims-data conditions are permissible. In

Sanofi Aventis U.S. LLC v. U.S. Dep't of HHS, 58 F.4th 696 (3d Cir. 2023) and *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452 (D.C. Cir. 2024) the appeals courts rejected categorical interpretations of 340B that would prohibit manufacturers from imposing conditions on the distribution of discounted drugs. *Novartis*—which addressed similar versions of HRSA's May 17, 2021 letter cited in the complaint (Compl. ¶¶ 60-62)—explicitly held that a manufacturer's requirement that "contract pharmacies provide claims data for contract-pharmacy orders" did *not* violate "section 340B on [its] face." *Novartis*, 102 F.4th at 463–64. In reaching that conclusion, the court explained that HRSA's 1994 guidance permits manufacturers to require "standard information" from covered entities and that the burden of providing claims data would be "minimal." *Id*. at 463.

Second, HRSA's audit framework, far from advancing TGH's argument (Compl. ¶ 48), reinforces why claims-data conditions are permitted. To initiate an audit, HRSA requires a manufacturer to "set forth a clear description of why it has reasonable cause to believe" that a covered entity has violated 340B. *See* Health Res. & Servs. Admin., *Manufacturer Audit Guidelines and Dispute Resolution Process*, 61 Fed. Reg. 65,406, 65,410 (Dec. 12, 1996). But that "reasonable cause" cannot be assembled from purchase invoices alone. Claims data is the only evidence from which such cause is formed.

Another district court has agreed. *See Pharm. Rsch. & Mfrs. of Am. v. Morrisey*, 760 F. Supp. 3d 439, 453 (S.D. W. Va. 2024), aff'd sub nom. *Pharm. Rsch. & Mfrs. of Am. v. McCuskey*, 171 F.4th 675 (4th Cir. 2026), vacated and reh'g en banc granted, 176 F.4th 830 (4th Cir. 2026). There, the court observed that a manufacturer who is denied claims data is left with "no alternatives" and may be unable to "formulate the 'reasonable cause' necessary to conduct an audit in the first place." *Morrisey*, 760 F. Supp. 3d at 453. A regime where a covered entity gets to withhold the data that would reveal its own noncompliance, the court added, is one in which "the fox guards the hen house." *Id*. Under TGH's reading, the manufacturer retains a right to audit but has no means of ever invoking it. The "340B Program certainly did not establish" such a system. *Id*.

Third, recent HRSA's guidance confirms that claims data impose little burden on covered entities but serve the important interests of program integrity. In proposing a 340B rebate-model pilot, HRSA explained that "use of standardized claims-level data" may "improve the identification and prevention of duplicate discounts." *See* 91 Fed. Reg. 48,883, 48,890. It further clarified that "[t]he burden associated with limited claims-level reporting" is "justified by the importance of ensuring program integrity, duplicate discount prevention, and coordination across federal pricing programs." *Id*. at 48,896.

To support its FDUTPA "*per se*" count, TGH invokes the laws of other States that purport to restrict claims-data conditions. Compl. ¶¶ 116-17, 154. But Florida is not among them. The fact that TGH must look beyond federal and Florida law to locate a statutory prohibition underscores a fatal defect in its case: no generally applicable law prohibits Lilly's claims-data condition. TGH alleges that Lilly's request for claims data is "unethical" and "oppressive," *id.* ¶ 120, but it fails to say how this can be so when some 2,350 covered entities have already honored it (Compl. ¶ 84), and when HRSA has agreed that claims-data requests are justified. 91 Fed. Reg. 48,883, 48,890. Whatever else FDUTPA reaches, it does not reach a manufacturer's effort to comply with federal law by confirming that a federal subsidy intended for low-income patients is not being duplicated elsewhere.

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One does not need to look far to see that the 340B program suffers from integrity challenges and that the absence of program transparency has not inured to the benefit of patients, who often have no way of knowing whether 340B discounts are being used to reduce their costs or simply to generate revenue for hospitals. *See* Ellen Gabler, *How a Company Makes Millions Off a Hospital Program Meant to Help the Poor*, N.Y. Times, Jan. 15, 2025, at A1. In 2018, the New England Journal of Medicine found no evidence that the covered entities it studied used 340B savings to expand care for low-income patients or

improved care for low-income groups in ways that reduce mortality. *See* Sunita Desai & J. Michael McWilliams, *Consequences of the 340B Drug Pricing Program*, 378 New Eng. J. Med. 539, 546 (2018).

Whether 340B's promise of helping needy patients is being fulfilled depends on what happens between the manufacturer's discount and the patient's bill. TGH's position is that a manufacturer acts unlawfully when it asks to see the claims data that would show what happens. As shown above, that theory conflicts with both the law and the program's design. Even if *Astra* did not independently bar this suit—and it does—TGH still fails to state a valid claim.

CONCLUSION

Congress never created a private right of action to enforce 340B pricing. Yet TGH asks this Court to recognize one under the banner of state law. *Astra* rejected that maneuver fifteen years ago and forecloses it today. Because TGH seeks to accomplish indirectly what Congress and the Supreme Court have not allowed directly, and because no applicable law prohibits Lilly's claims-data policy, the complaint should be dismissed.

Dated: September 22, 2026

Respectfully submitted,

/s/ Cory L. Andrews

Cory L. Andrews, Bar No. 25677
WASHINGTON LEGAL FOUNDATION
2009 Massachusetts Ave., NW
Washington, DC 20036
(202) 588-0302
candrews@wlf.org