IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, ***Plaintiff*,** **v.** **JONATHAN SKRMETTI, in his official capacity as Attorney General of Tennessee,** ***Defendant*.**	**No. 3:25-cv-00582** **Judge: Hon. Aleta Trauger**

MEMORANDUM IN SUPPORT OF PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTIVE RELIEF

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INTRODUCTION

Tennessee Senate Bill 1414 ("S.B. 1414"), Tenn. Code §§ 47-18-136, 47-18-104(b), regulates and fundamentally changes the operation of the federal 340B Drug Pricing Program, 42 U.S.C. § 256b ("340B"). It is preempted by the Supremacy Clause of the U.S. Constitution. *See Pharm. Rsch. & Mfrs. of Am. v. Morrisey*, 760 F. Supp. 3d 439, 450-64 (S.D. W. Va. 2024) (preliminarily enjoining state 340B statute as likely preempted).

340B is a unique form of a privately-funded federal subsidy. It requires that drug manufacturers make an "offer" to sell certain drugs to 15 statutorily enumerated types of healthcare providers, known as "covered entities," at "strikingly generous" prices, often "penn[ies] per unit." *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 456 (D.C. Cir. 2024). Congress could not have outright mandated these deeply reduced-price drug sales—doing so would raise serious constitutional concerns. Instead, Congress struck a specific bargain with manufacturers: If manufacturers sign a federal contract obligating them to "offer" certain drugs at these severely reduced 340B prices to covered entities, those drugs will also be eligible for reimbursement under Medicare Part B and the federal share of Medicaid. Otherwise, they will not be. *Id.* at 455.

As the U.S. Supreme Court made clear in *Astra USA, Inc. v. Santa Clara County*, 340B is inextricably intertwined with these other federal programs. 563 U.S. 110, 119-22 (2011). Thus, Congress intended that the federal agency running 340B, the U.S. Department of Health and Human Services ("HHS"), would "hold the control rein," to ensure these federal programs would be administered "harmoniously and on a uniform, nationwide basis." *Id.* (holding healthcare provider could not enforce 340B's requirements through other means because Congress entrusted HHS alone with 340B's administration and created a detailed set of federal remedial measures).

What specific terms are appropriate in a drug manufacturer's federal "offer" to sell its drugs

at 340B prices is a question of federal law requiring construction of 42 U.S.C. § 256b(a)(1). Multiple federal courts have already addressed and resolved this question, concluding that Congress intended for manufacturers to be able to attach reasonable conditions to their 340B offers, so long as the offers remain "bona fide." *Novartis*, 102 F.4th at 460-64; *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 703-06 (3d Cir. 2023). Those courts upheld two of the specific conditions that Tennessee seeks to regulate here: (1) manufacturer "one contract pharmacy" policies (*infra* at 9-11, 13); and (2) manufacturer "claims data" policies (*infra* at 9-11, 13). *Novartis*, 102 F.4th at 463-64; *Sanofi*, 58 F.4th at 701, 706. As with any other contractual offer, covered entities remain free to reject a 340B offer with these conditions, but if they do so they are not entitled to the benefit of the bargain—here, purchasing the drugs *at the 340B price*. *Infra* at 13.

Tennessee's S.B. 1414 would materially alter the federal 340B program and is preempted for at least four separate reasons. ***First***, S.B. 1414 attempts to modify the federal requirements for the content of a manufacturer's 340B "offer," which is governed by federal law under 42 U.S.C. § 256b(a)(1). It does so by threatening criminal and civil enforcement against a manufacturer who strictly complies with the "shall offer" requirements of federal law, as repeatedly affirmed by federal appellate courts. Specifically, S.B. 1414 seeks to compel 340B-priced sales in circumstances where the federal 340B statute would not require such sales. This effort to expand the scope of 340B's federal requirements to make an "offer" fundamentally alters the careful balance struck by Congress by increasing dramatically the manufacturer's cost of participation in 340B, Medicare, and Medicaid. Tennessee could have chosen to use its own resources to provide assistance to covered entities, but it instead is attempting to hijack a federal program to force manufacturers to do so.

Second, although it is essential to 340B's functioning that manufacturers have access to information on the specific prescriptions for which 340B price reductions are sought, S.B. 1414 conceals that information. It does so by prohibiting manufacturers from "requiring the submission of any health information, claims or utilization data, purchasing data, payment data, or other data as a condition for allowing the acquisition of a 340B drug . . . or delivery of a 340B drug," Tenn. Code § 47-18-136(a)(1)—i.e., the very "condition" the D.C. Circuit has explicitly held that manufacturers may impose, *Novartis*, 102 F.4th at 463-64—which in turn has the effect of limiting manufacturers' federal audit rights. S.B. 1414 also explicitly limits manufacturers' federal audit rights. Tenn. Code § 47-18-136(a)(4). These bars directly interfere with 340B's specific remedial provisions, and manufacturer compliance with another federal law—the Inflation Reduction Act ("IRA").

Third**,** S.B. 1414 attempts to open the same door for private suits to enforce federal 340B requirements that the Supreme Court explicitly slammed shut in its unanimous 2010 opinion in *Astra*. *See id.* § 47-18-104(b)(68); *id.* § 47-18-109(a)(1). As the Supreme Court explained, Congress "authorized no private right of action under § 340B for covered entities who claim they have been charged prices exceeding the statutory ceiling" and that bar cannot be circumvented by "dress[ing] their claims" in other "clothing." *Astra*, 563 U.S. at 113-14.

Fourth, as the Supreme Court's *Astra* opinion also makes clear, Congress in 2010 chose to address a series of 340B disputes between healthcare providers and drug manufacturers by creating a detailed series of federal remedial provisions, including administrative dispute resolution ("ADR") administered by the federal agency. The agency itself has concluded that those federal remedies address exactly the same issues S.B. 1414 seeks to regulate. 89 Fed. Reg. at 28,643, 28,649 (Apr. 19, 2024); HRSA ADR Panel, *St. Croix Reg'l Med. Ctr. Decision Summary*

(2025) (adjudicating ADR petition premised on these issues and holding that contract pharmacy policies do not constitute a violation), https://tinyurl.com/3pvw43zd. Yet Tennessee believes it can create its own competing enforcement regime. As the U.S. Supreme Court already explained in *Astra*, "[r]ecognizing [covered entities'] right to proceed in court could spawn a multitude of dispersed and uncoordinated lawsuits by 340B entities," wresting control from the federal government and creating "substantial" "risk of conflicting adjudications." 563 U.S. at 120.

Finally, S.B. 1414 poses several other conflicts, all of which endanger the federal government's unitary control. Tenn. Code § 47-18-136(a)(2)-(3), (5)-(6).

Although portions of S.B. 1414 seem to acknowledge that the State cannot contradict federal law, it nevertheless does so repeatedly and explicitly. To date, Tennessee's Attorney General has declined to provide any assurances that the Act will not apply in a way that subjects lawful conduct under federal law to state criminal and civil enforcement. *See* Ex. 5 (Cagle Decl.) ¶¶ 2-3. Thus, PhRMA members are forced to choose between complying with an unconstitutional state law and incurring irreparable harm on the one hand, or subjecting themselves to possible criminal liability and/or crippling civil penalties on the other. Because S.B. 1414 threatens potentially imminent criminal or civil enforcement by the Tennessee Attorney General and private litigants, PhRMA seeks to preliminarily enjoin enforcement of S.B. 1414 pending a final ruling in this case.

BACKGROUND

A. The Federal 340B Drug Pricing Program

1. Congress Established 340B's Structure And Purpose

Generally, drug manufacturers must participate in 340B to have certain of their drugs reimbursed under Medicare Part B and the federal portion of Medicaid. Congress intended 340B's

scope to be small, which kept its incentive structure balanced. H.R. Rep. No. 102-384, pt. 2, at 13 (1992) (anticipating only 90 hospitals, and a range of clinics and health centers would participate).

340B is purely a creature of federal law that sets requirements for when manufacturers must offer their drugs at reduced prices. The statute first defines the federal contractual obligation on drug manufacturers. It provides that manufacturers must "enter into an agreement" with the HHS Secretary, and that such an agreement "shall require that the manufacturer *offer* each covered entity covered outpatient drugs for purchase" at or below a ceiling price. 42 U.S.C. § 256b(a)(1) (emphasis added); *see also Novartis*, 102 F.4th at 462 (discussing the "shall offer" provision); *Sanofi*, 58 F.4th at 703. The "offer" must be "bona fide," by providing reasonable terms for delivery, consistent with the statute. *Novartis*, 102 F.4th at 463-64. The statute next defines which entities are entitled to access 340B pricing: fifteen types of healthcare providers. 42 U.S.C. § 256b(a)(4). Even if it falls within a category, a covered entity can lose its eligibility if it engages in "diversion"—selling or transferring the drugs to anyone other than its patients—or duplicate discounting—seeking a rebate under Medicaid for a 340B-priced drug. *Id.* § 256b(a)(4), (5).

As the Supreme Court has explained, Congress created an entirely federal scheme for enforcement as the "proper remedy" for disputes between drug manufacturers and covered entities regarding 340B-priced drugs. *Astra*, 563 U.S. at 120-22. In 42 U.S.C. § 256b(d)(1)(B)(vi), Congress instructed HHS to create a system of enforcement, including monetary sanctions on a manufacturer who "knowingly and intentionally" charges a covered entity more than the 340B price. Before imposing sanctions, HHS must serve written notice, 42 C.F.R. § 1003.1500(a), and provide advance warnings, *see* 42 U.S.C. § 256b(d)(1)(B)(i)-(ii) (requiring HHS to establish procedures to resolve disputes amicably, including through dialogue). Congress also created a special process known as ADR. *Id.* §256b(d)(3). The United States has described that scheme as

the "exclusive remedy" for disputes between manufacturers and covered entities. *Infra* at 23. And covered entities have repeatedly invoked ADR to resolve the same disputes S.B. 1414 addresses.[1]

2. Contract Pharmacies Barge Into 340B

In 1996, the U.S. Health Resources and Services Administration ("HRSA"), a subcomponent agency of HHS, issued guidance allowing certain covered entities (those without their own in-house pharmacies) to identify one "contract pharmacy" to receive and dispense 340B-priced drugs to patients of the covered entity. *See* 61 Fed. Reg. 43,549, 43,550, 43,555 (Aug. 23, 1996). HRSA's guidance provided criteria for the contractual arrangement between the covered entity and the pharmacy, including verification at the time of dispensing that the patient to whom the prescription was dispensed had been treated at the covered entity. *Id.* at 43,551, 43,553-55.

In 2010, HRSA issued guidance lifting its one-pharmacy limit. 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010). As the Government Accountability Office ("GAO") and the HHS Inspector General ("OIG") explained, the floodgates opened. Many for-profit pharmacies—including the nation's largest chains—recognized that if they could insert themselves into 340B, they could acquire drugs at 340B prices and sell them at or near full price, and pocket a portion as profit for themselves. *Novartis*, 102 F.4th at 456-58; *see also* Minn. Dep't of Health, *340B Covered Entity Report* 9 (Nov. 25, 2024) (finding approximately $1 out of $6 of gross revenue from 340B went to contract pharmacies and third-party administrators), https://tinyurl.com/5v69tbft.[2] Predictably, the number of for-profit pharmacies participating in 340B increased exponentially, with the

[1] *See* Pet. ¶ 1, *Open Door Cmty. Health Ctrs. v. AstraZeneca Pharms., LP* (HHS ADR Bd. Jan. 13, 2021) (Covered entities asking panel "to order [the manufacturer] to resume offering covered outpatient drugs at the 340B ceiling price to Petitioner through its contract pharmacies."), https://tinyurl.com/2twhwhtc; Ex. 5-A (petition by other entities requesting similar).

[2] Both CVS and Walgreens have publicly disclosed that 340B profits are material to their finances. CVS, SEC Form 10-K 23 (2024), https://tinyurl.com/4pbtt9x8; Walgreens, SEC Form 10-K 30 (2024), https://tinyurl.com/zp9vv465.

number of contract pharmacy arrangements rising "more than fifteen-fold, from about 1,300 to approximately 20,000" between 2010 and 2018, and to *33,000* in 2023. GAO, GAO-18-480, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 10 (2018), https://tinyurl.com/mr4xbp2m ("2018 GAO Report"); U.S. S. Comm. on Health, Educ., Lab., & Pensions, *Congress Must Act to Bring Needed Reforms to the 340B Drug Pricing Program* 3 (Apr. 2025), https://tinyurl.com/3rh429c9 ("HELP Report").

This explosion ballooned 340B's size and increased the risk of abuse. Covered entities' in-house pharmacies are almost guaranteed to dispense drugs to the covered entities' patients. Not so with contract pharmacies, which serve both covered entities' patients and other consumers. *Examining Oversight Reports on the 340B Drug Pricing Program*, 115th Cong. 11 (2018) (statement of Ann Maxwell, OIG Assistant Inspector Gen.), https://tinyurl.com/3bx8dk42 ("Maxwell"). In a GAO study, contract pharmacies accounted for nearly two-thirds of unlawful diversion violations. 2018 GAO Report at 44-45 ("The expansion of contract pharmacies . . . increases potential . . . risks related to diversion and duplicate discounts."); GAO, GAO-11-836, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 27-28 (2011), https://tinyurl.com/yc2mhbeu. Overall, "growth in the use of contract pharmacies has amplified the complexity of 340B Program oversight, particularly regarding patient eligibility, drug diversion, and duplicate discounts." HELP Report at 3.

The opportunity for abuse is even more acute given most contract pharmacies' use of the product "replenishment model." *Id.* at 31. Although HRSA has directed, in light of the diversion and duplicate discounting prohibitions, that covered entities should retain title to 340B drugs and require contract pharmacies to operate as their agents, 61 Fed. Reg. at 43,550, 43,553, the product

replenishment model jettisons these limitations.[3] Using this model, contract pharmacies dispense drugs from their general inventories to all customers (covered entity patient or not). Maxwell at 11-12. On the back end, contract pharmacies use undisclosed algorithms to retroactively identify customers that may have some relationship to a covered entity. *Id.* at 11; 2018 GAO Report at 2. Contract pharmacies then restock their general inventories with 340B-priced drugs based on the algorithms' outcome. Decl. of Krista Pedley ¶¶ 5-11, *Sanofi-Aventis U.S., LLC v. HHS*, No. 21-cv-634 (D.N.J. June 24, 2021), ECF No. 93-2. This black-box system—which does not require verification of patient status at dispensing—creates more opportunities for illegal diversion. Maxwell at 11-12. It also results in greater profits, creating an incentive to "catalog as many prescriptions as possible as eligible for the discount." *Novartis*, 102 F.4th at 457-58. Given these dynamics, 340B has ballooned. With the list price value (i.e., based on wholesale acquisition cost) of 340B purchases rising to $124.1 billion in 2023, 340B is now the second largest government pharmaceutical program.[4]

Unfortunately, these price reductions are not passed onto patients. Indeed, because drugs come out of a pharmacy's general inventory and 340B pricing is not applied until after patients depart, most 340B price reductions are not shared with patients. *Morrisey*, 760 F. Supp. 3d at 447; *See* Rory Martin & Kepler Illich, IQVIA, *Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies?* 3, 12, https://tinyurl.com/3d4tk9ae.

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[3] *See, e.g.*, Walgreens Contract §§ 3.3.5, 8.10, *Sanofi-Aventis U.S. LLC v. HHS*, No. 24-cv-1603 (D.D.C. Nov. 29, 2024), ECF No. 24-2 (showing contract pharmacies take title and do not operate as agents); Dallas Cnty. 340B Contract – ReCept Pharmacy 5, https://tinyurl.com/4wm5d9fd; Monterey Cnty. and CVS Pharmacy Contract, Inc. 9, https://tinyurl.com/yr72mhup.

[4] Adam J. Fein, *The 340B Program Reached $66 Billion in 2023—Up 23% vs. 2022: Analyzing the Numbers and HRSA's Curious Actions*, Drug Channels (Oct. 22, 2024), https://tinyurl.com/59ckpy5w.

3. Manufacturers Attempt To Curb Abuse

Faced with the increased risk of abuse, many manufacturers individually adopted policies on contract pharmacy use. The policies differ, but each permits covered entities to purchase an unlimited number of 340B-priced drugs for delivery to the covered entity itself, while placing reasonable conditions on when manufacturers will provide delivery of 340B-priced drugs to contract pharmacies. *Sanofi*, 58 F.4th at 701; *Novartis*, 102 F.4th at 458, 463-64. For example, to detect diversion and duplicate discounting, PhRMA member declarants require claims data where contract pharmacies are involved. Ex. 2 (Costello Decl.) ¶ 13; Ex. 3 (Janco Decl.) ¶ 12.

In subsequent litigation with HHS and HRSA, multiple manufacturers—including several PhRMA members—challenged HRSA's interpretation of 340B as requiring manufacturers to accede to covered entities' demands that they provide, without limitation or condition, 340B-priced drugs to all "contract pharmacies." *See Novartis Pharms. Corp. v. Espinosa*, 2021 WL 5161783, at *5-6 (D.D.C. Nov. 5, 2021). Both the D.C. and Third Circuits agreed with manufacturers. Congress chose specific requirements to impose on 340B-participating manufacturers, including that they make a "bona fide" offer. *Novartis*, 102 F.4th at 460-64. Manufacturers thus remain free to impose "conditions on the distribution of covered drugs to covered entities," so long as those conditions are reasonable and consistent with the federal statute. *Id.* at 464; *see also Sanofi*, 58 F.4th at 703-04 ("Congress's use of the singular 'covered entity' in the [statute's] 'purchased by' language suggests that it had in mind one-to-one transactions between a covered entity and a drug maker *without mixing in a plethora of pharmacies*." (emphasis added)). These opinions define the outer boundary of federal obligations to deliver 340B-priced drugs to contract pharmacies. *Novartis*, 102 F.4th at 459-64.

B. Tennessee Senate Bill 1414

S.B. 1414's regulatory object is the federal 340B program and, without that federal program, S.B. 1414 would have no meaning or effect. *See* Tenn. Code § 47-18-136(g)(1) ("340B drug" means a "drug that is a covered outpatient drug within the meaning of 42 U.S.C. § 256b(a)(1); . . . and is purchased by a 340B entity or would have been purchased by a 340B entity but for a restriction or limitation described in § 56-7-3119(b)"). S.B. 1414's core purpose is to alter the terms of the federally-mandated offer manufacturers must make to covered entities pursuant to 340B.

S.B. 1414 includes several prohibitions that control manufacturers' 340B practices. It instructs that "a drug manufacturer . . . shall not, either directly or indirectly": (1) "Impose additional requirements or limitations on a 340B entity, including requiring the submission of any health information, claims or utilization data, purchasing data, payment data, or other data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity unless such data submission is explicitly required by the United States department of health and human services or applicable state law"; (2) "Require a 340B entity to reverse, resubmit, or clarify a claim after the initial adjudication unless these actions are in the normal course of business and not related to the 340B program"; (3) "Impose any requirements relating to inventory management systems of 340B drugs, unless such requirement is required by the United States department of health and human services or applicable state law"; (4) "Impose any requirement relating to the frequency, duration, or scope of audits that are not imposed on pharmacies or providers that are not 340B entities"; (5) "Impose requirements relating to accreditation, recertification, credentialing, or recredentialing that are not imposed on pharmacies or providers that are not 340B entities"; or (6) "Impose any requirement determined by the attorney general and

reporter to interfere with the ability of a 340B entity to access discounts provided under the 340B program." *Id.* § 47-18-136(a).

S.B. 1414 also provides:

> A drug manufacturer . . . shall not, either directly or indirectly, deny, impose any restrictions or prohibitions on, discriminate against, or otherwise limit the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity or other location that is under contract with, or otherwise authorized by, a 340B entity to receive 340B drugs on behalf of the 340B entity unless such receipt is prohibited by the United States department of health and human services[.]

Id. § 47-18-136(c).

S.B. 1414 is not about drug access or inability of pharmacies to acquire drug products at commercial prices: PhRMA members already sell and ship their drugs to the same pharmacies at commercial prices. Ex. 2 ¶¶ 10-11, 13, 15; Ex. 3 ¶¶ 9-10, 14; Ex. 4 (O'Harra Decl.) ¶¶ 24, 28-29. Instead, S.B. 1414, by defining "340B drug" in reference to the federal pricing obligation, requires manufacturers to extend deeply reduced *prices* on their drugs far beyond 340B's requirements and punishes manufacturers based on the prices charged.

S.B. 1414 subjects manufacturers to potential civil and criminal liability. Tenn. Code §§ 47-18-104(a), (b)(68). It imposes draconian civil penalties of up to $50,000 per violation, with each "package of 340B drugs" constituting a separate violation. *Id.* §§ 47-18-106, 108, 136(d)(2). And, by defining a violation of its provisions as an unfair or deceptive act under the Tennessee Consumer Protection Act, S.B. 1414 effectively creates a private right of action. *Id.* §§ 47-18-104(b)(68), 109(a)(1). S.B. 1414 therefore appears to empower private entities in Tennessee to circumvent the ADR system Congress established as 340B's sole enforcement mechanism.[5]

[5] *See Astra*, 563 U.S. at 118 ("The absence of a private right to enforce the statutory ceiling-price obligations would be rendered meaningless if 340B entities could overcome that obstacle by suing to enforce the contract's ceiling-price obligations instead."); *infra* at 17-18.

ARGUMENT

When a party seeks preliminary injunctive relief, a court considers whether the party is "likely to succeed on the merits," whether it will be "irreparably injured absent a stay," "whether issuance of [injunctive relief] will substantially injure the other parties interested in the proceeding," and "where the public interest lies." *Nken v. Holder*, 556 U.S. 418, 425-26 (2009). Where the government is the opposing party, the last two factors merge. *Id.* at 435. This case easily satisfies the merits and balance-of-the-equities inquiries.

I. PHRMA IS LIKELY TO SUCCEED ON THE MERITS

The "Constitution, and the Laws of the United States," are "the supreme Law of the Land . . . any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." U.S. CONST. art. VI, cl. 2. S.B. 1414 is impliedly preempted under both field and conflict preemption principles. *See Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 872-73 (2000).

A. S.B. 1414 Conflicts With The Federal Regime Created By Congress

Where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000), or "interferes with the methods by which the federal statute was designed to" achieve those purposes and objectives, it is conflict preempted, *Int'l Paper Co. v. Ouellette*, 479 U.S. 481, 492 (1987) (state law preempted because it would "upset[] the balance of public and private interests so carefully addressed by the [federal statute]"). S.B. 1414, which explicitly prohibits manufacturers from undertaking several actions that are fully permissible under federal law and can be lawfully imposed as conditions as part of manufacturers' 340B offers, conflicts with 340B.

First, S.B. 1414 directly "interferes with the methods by which the federal statute was designed to" achieve its purposes, *id.*, and reworks manufacturers' obligations under the federal program in the process. Congress chose to utilize an offer-acceptance framework for 340B.

Specifically, as the D.C. Circuit has explained, Congress set the governing constraints on how manufacturers may operate vis-à-vis "offers" of 340B-priced drugs. *Novartis*, 102 F.4th at 462-64. Each manufacturer offer must be "bona fide," which means that certain "onerous conditions might violate the statute." *Id.* at 464. But that determination is for the federal government, reviewed by federal courts, to make. *Id.* at 462-64. Thus, manufacturers remain free to impose "conditions on the distribution of covered drugs to covered entities." *Id.* at 464. As two courts have addressed, such permissible conditions include a limitation on contract pharmacy use and claims data requirement. *Sanofi*, 58 F.4th at 706; *see also Novartis*, 102 F.4th at 463-64.

Covered entities are thus given a choice when manufacturers include reasonable conditions. Ex. 2 ¶¶ 14-15; Ex. 3 ¶¶ 13-14; Ex. 4 ¶¶ 28-29. Under fundamental principles of contract law, if covered entities accede to those conditions, they accept the terms of the offer and may purchase 340B-priced drugs. Williston on Contracts § 6:11 (4th ed.) ("Thus, if an act is requested [as part of an offer], that very act and no other must be performed."). If covered entities reject the conditions, the offer is rejected and no purchase of the 340B-priced drugs occurs. *Id.* By permitting the inclusion of reasonable terms and requiring acceptance to obtain the 340B price, Congress has tied the scope of obligations to the terms of a permissible 340B offer. Yet, Tennessee directly interferes with Congress's chosen method by seeking to impose—as a matter of state law—a bar on conditions on contract pharmacy use and claims data collection, even though the federal government, the administrator of the federal program, was enjoined from imposing a similar bar. *Sanofi*, 58 F.4th at 706; *see also Novartis*, 102 F.4th at 463-64.

S.B. 1414 explicitly seeks to outlaw conditions permitted by federal law and to force many more transactions at the 340B price than would otherwise be required under 340B. *See* Tenn. Code § 47-18-136(g)(1) (defining "340B drug" to mean a drug that "is eligible for any offer for

reduced prices by a manufacturer [under 340B]" and is purchased by a covered entity, but not requiring purchase through program). Under 340B (as written by Congress), manufacturers include these conditions in their 340B offers. These conditions are then incorporated into the platform used by drug distributors and wholesalers. Ex. 4 ¶¶ 21-24. If covered entities and their contract pharmacies do not accept the conditions, they cannot purchase 340B-priced drugs. *Id.* ¶¶ 26-29. Thus, by outlawing these conditions and applying its law to drugs not actually purchased under the 340B program, Tennessee vastly expands the number of 340B transactions.

By doing so, Tennessee has upended the bargain that was struck between Congress and manufacturers, which was for a limited subsidy. This expansion of obligations under a federal incentive program is preempted. *Forest Park II v. Hadley*, 336 F.3d 724, 732-33 (8th Cir. 2003) (holding states may not impose additional obligations on participants in incentive-based, federal programs, even where the federal statute does not explicitly bar such additional obligations).[6]

Second, S.B. 1414's prohibitions on manufacturers gathering information and explicit limitations on the "frequency, duration, or scope of audits" are preempted. Tenn. Code § 47-18-136(a)(1), (4). If those limits stand, they will essentially break the federal remedial regime. *See Morrisey*, 760 F. Supp. 3d at 450-53 (holding similar state law that barred collection of claims data was preempted because it conflicted with manufacturers' 340B audit rights); *Eli Lilly & Co. v. Kennedy*, 2025 WL 1423630, at *13 (D.D.C. May 15, 2025) (affirming manufacturers' right to

[6] The State may contend that S.B. 1414 is solely about delivery and drug access. But because drugs come out of a pharmacy's general inventory and the price reduction is sought after dispensing, S.B. 1414 is not about drug access but rather price. As the *Morrisey* court explained, "[b]ecause the drug is already in the hands of the contract pharmacy even before the patient arrives at the pharmacy, the question is not about delivery of the drug. The question is only about what price the pharmacy and the covered entity will pay the manufacturer for the replenished drug upon distribution of the 340B Program eligible one. Put another way, the system is about delivery *at a given price*, not delivery *per se*." 760 F. Supp. 3d at 455. And because 340B pricing is not applied until after patients depart, most 340B price reductions are not shared with patients. *Id.* at 447.

"impose data-reporting conditions on covered entities" and explaining why claims data is important to maintaining program integrity).

Under the federal regime, a manufacturer must first audit a covered entity before initiating ADR. *See* 42 U.S.C. § 256b(a)(5)(C), (d)(3)(B)(iv). Audits, in turn, are conducted "in accordance with procedures established by the Secretary relating to the number, duration, and scope." *Id.* § 256b(a)(5)(C). HRSA, which oversees ADR, has specified manufacturers are only permitted to conduct an audit where they "ha[ve] documentation which indicates that there is reasonable cause." 61 Fed. Reg. 65,406, 65,409 (Dec. 12, 1996); *see also Novartis*, 2021 WL 5161783, at *7. "Reasonable cause" is defined to mean "that a reasonable person could believe that a covered entity may have violated" the prohibitions on transfer or sale, or on duplicate discounting. 61 Fed. Reg. at 65,409. Accordingly, to even access the audit process, manufacturers must be able to gather information that will allow them to determine if reasonable cause exists to suspect a covered entity is violating 340B's provisions—access that S.B. 1414 cuts off. *See Novartis*, 2021 WL 5161783, at *8 (explaining manufacturer "convincingly argues that the claims data conditions . . . will enable it to better utilize the anti-fraud audit and ADR procedures that Congress established for manufacturers in Section 340B").

S.B. 1414 would prohibit such reasonable conditions on 340B drug sales and create a significant obstacle to the program's audit and ADR process. This creates a direct conflict with the federal regime. As the *Morrisey* court stated: "By restricting the very method by which data collection is made, [the state statute] frustrates drug manufacturers' ability to take the initial steps necessary to start the very audit required to access" ADR and thus "stands as an obstacle to achieving the federal objective of preventing fraud in" 340B. 760 F. Supp. 3d at 453. S.B. 1414 directly subverts availability of the federal enforcement mechanism.

That conflict is reinforced by S.B. 1414's impact on rooting out duplicate discounting. Under the new Medicare Drug Price Negotiation Program, HHS is to "negotiate" with manufacturers the "maximum fair price[s]" for certain drugs. 42 U.S.C. § 1320f-3(a). Manufacturers must provide access to selected drugs at the so-called maximum fair prices, except when such selected drugs are 340B-eligible and the 340B price is lower. *Id.* § 1320f-2(d). To avoid duplicating price reductions, this scheme necessarily requires identifying when a specific drug is acquired at the 340B price, a burden the Centers for Medicare and Medicaid Services ("CMS") places on manufacturers.[7] As a result, manufacturers require claims data to avoid providing duplicative price reductions. Yet, S.B. 1414 bars its collection. *See* Tenn. Code § 47-18-136(a)(1) (referring to "health information, claims or utilization data, purchasing data, payment data, or other data").

Not only does S.B. 1414 restrict access to the federal enforcement regime by curtailing manufacturers' ability to collect information, it also appears to *explicitly* restrict manufacturers' ability to audit. S.B. 1414 specifies that manufacturers may not "[i]mpose any requirement relating to the frequency, duration, or scope of audits that are not imposed on pharmacies or providers that are not 340B entities." *Id.* § 47-18-136(a)(4). But audits for 340B compliance are a creature of federal 340B law and are meant as a tool to ensure covered entity compliance with 340B rules. 42 U.S.C. § 256b(a)(5)(C) (providing that manufacturers can audit covered entities with regard to "the entity's compliance [with the bars on duplicate discounting and diversion] with respect to drugs of the manufacturer"). And it is the federal government that is explicitly given

[7] CMS, Medicare Drug Pricing Negotiation Final Guidance 57-58, 60 (Oct. 2, 2024) (stating CMS "will not assume responsibility for deduplicating discounts" and that manufacturers bear that burden), https://tinyurl.com/3sx8hmah.

control over the "number, duration, and scope of audits." *Id.* Yet, S.B. 1414 now seeks to impermissibly impose its own limitations on manufacturers' audit rights.

Third, S.B. 1414 impermissibly attempts to permit private suits to enforce 340B, despite the Supreme Court's determination that Congress explicitly chose not to create a private right of action. Tenn. Code §§ 47-18-104(b)(68), 109(a)(1). As the Supreme Court made clear, Congress chose not to authorize private rights of action, which would "undermine the agency's efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis." *Astra*, 563 U.S. at 120. Instead of permitting "340B entities to launch lawsuits in district courts across the country," Congress chose to "create a formal dispute resolution procedure, institute refund and civil penalty systems, and perform audits[.]" *Id.* at 121. Despite that, Tennessee purports to allow private entities to bring their own suits, creating the same "risk of conflicting adjudications" that prompted the Supreme Court to hold that private actions were barred no matter if the claims were "dress[ed]" in other "clothing." *Id.* at 113-14, 120.

Fourth, S.B. 1414 conflicts with Congress's chosen scheme of exclusive federal oversight for 340B. *See Astra*, 563 U.S. at 113; *see also Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349-50 (2001) (where agency had "a variety of enforcement options that allow it to make a measured response," greenlighting state-law tort claims would "inevitably conflict with the [agency's] responsibility to police fraud consistently with [its] judgment and objectives"); *Morrisey*, 760 F. Supp. 3d at 453-60 (holding similar state law was preempted because it conflicted with 340B's enforcement regime). In *Astra*, covered entities operated by Santa Clara County brought suit to enforce 340B pricing against drug manufacturers directly, rather than bringing that issue to HRSA. *See* 563 U.S. at 116-17. Two things happened. First, in response to such disputes, Congress stepped in and amended the 340B statute to add detailed administrative enforcement

mechanisms—all to be overseen by HRSA, subject to federal court review. 42 U.S.C. § 256b(d). Second, the Supreme Court ruled against Santa Clara County, explaining that the new federal agency administrative enforcement mechanisms were the "proper remedy" for disputes about the operation of 340B. *Astra*, 563 U.S. at 119-22. The Court stressed repeatedly that it was essential 340B be administered "harmoniously and on a uniform, nationwide basis." *Id.* at 120.

S.B. 1414 conflicts with that regime in multiple ways. Like the claims considered in *Astra*, S.B. 1414 conflicts with the federal enforcement regime by usurping the federal agency's unitary enforcement authority. Federal ADR regulations issued in 2024 and a recent ADR decision make clear HRSA's view that it has federal statutory authority to address, including through ADR, the very issues S.B. 1414 targets. *See* 89 Fed. Reg. at 28,649 (defining overcharge claim, to be brought via ADR, to encompass "a claim that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price or the manufacturer does not offer the 340B ceiling price"); *St. Croix Decision Summary*; 42 U.S.C. § 256b(d)(1) (covering "overcharges and other violations of the discounted pricing requirements"). Yet Tennessee seeks to address the very same disputes, contra to *Astra*. *Morrisey*, 760 F. Supp. 3d at 453-59.

A preview of potential state enforcement proceedings underscores the impermissible conflict. Tennessee has tied S.B. 1414 to 340B and specified that violations occur *per package* of 340B drugs, meaning each will need to be assessed separately. Accordingly, determining whether a manufacturer violated S.B. 1414 requires determining if there was an underlying 340B obligation in the first place as to each package of drugs dispensed. To make the latter determination, a decisionmaker will need to answer several federal law questions, including: (1) whether the drugs are actually covered outpatient drugs under 340B; (2) whether they are eligible for 340B pricing; (3) whether the manufacturer provided the 340B price; (4) whether a covered entity is a 340B

covered entity under federal law; and (5) whether there has been diversion or duplicate discounting (which includes determining whether a specific drug was distributed to a covered entity's "patient"). *See id.* at 458-59; *Eli Lilly*, 2025 WL 1423630, at *2 (noting 340B patient requirement).

This conflict strikes at the heart of the federal government's ability to uniformly apply and enforce 340B nationwide. *Arizona v. United States*, 567 U.S. 387, 406-07 (2012); *see also Wis. Dep't of Indus., Lab. & Human Rels. v. Gould Inc.*, 475 U.S. 282, 286 (1986). And it ultimately compromises the federal government's ability to balance the interests of 340B, Medicare, and Medicaid, precisely in the way that *Astra* found problematic. 563 U.S. at 120 ("Recognizing the [] right to proceed in court could spawn a multitude of dispersed and uncoordinated lawsuits[.]"). The *Morrisey* court (the first court to seriously contend with *Astra*) concluded as much, recognizing that *Astra*'s "holding … controls." 760 F. Supp. 3d at 458.

S.B. 1414 also conflicts with the federal enforcement regime by unbalancing it. S.B. 1414 gives state decisionmakers the right to impose draconian civil and criminal penalties "withheld from [a federal agency]." *San Diego Bldg. Trades Council, Millmen's Union v. Garmon*, 359 U.S. 236, 247 (1959). While the federal statute caps civil monetary penalties, inflation adjusted, at $7,000 per violation, 42 U.S.C. § 256b(d)(1)(B)(vi), S.B. 1414 authorizes penalties of *$50,000* per violation—again, for conduct that fully complies with federal law. S.B. 1414 also wholly ignores that Congress carefully calibrated HHS's power to levy civil monetary penalties, by requiring it to undertake several other steps first. *Supra* at 5-6. S.B. 1414 thus lacks the nuanced approach adopted by Congress to foster compliance through corrective measures rather than punitive actions.

Finally, S.B. 1414 poses several other conflicts, all of which endanger the federal government's unitary control. To start, S.B. 1414's bar on "impos[ing] any requirements relating

to inventory management systems of 340B drugs" or "requir[ing] a 340B entity to reverse, resubmit, or clarify a claim after the initial adjudication unless the actions are in the normal course of business and not related to the 340B program" directly interferes with the ability of manufacturers to structure their 340B transactions in ways fully compliant with federal law and that increase transparency. Tenn. Code § 47-18-136(a)(2), (3). These provisions appear to be aimed at preventing the use of cash replenishment, cash-rebate, or credit models, by individual manufacturers. Under those models generally, manufacturers will provide cash rebates when covered entities submit a 340B-rebate claim to the manufacturer, rather than sell the 340B-priced drugs at an upfront reduced price. S.B. 1414 attempts to prevent such models' use despite the federal statute providing for the use of rebates. *See* 42 U.S.C. § 256b(a)(1) ("taking into account any *rebate* or discount" (emphasis added)); *see also* 63 Fed. Reg. 35,239, 35,240 (June 29, 1998) (rebate option is "consistent with the section 340B rebate program"); *Eli Lilly*, 2025 WL 1423630, at *9 n.11 (stating 340B statute "explicitly contemplates a rebate mechanism" and holding rebate models are allowed by the federal statute). The permissibility and precise contours of these models under federal law is subject to active litigation, including in the D.C. Circuit, and HRSA is preparing to publish guidance about these models imminently. *Novartis Pharms. Corp. v. Kennedy*, No. 25-5177 (D.C. Cir.); *see also* Office of Mgmt. & Budget ("OMB"), *Regulatory Review* (proposed guidance with OMB for review), https://tinyurl.com/37ahk282.

S.B. 1414's prohibition on manufacturers imposing conditions such as credentialing or "any requirement determined by the attorney general . . . to interfere with the ability of a 340B entity to access discounts provided under the 340B program" also impermissibly turns one state attorney general—rather than Congress—into the arbiter of the scope of an acceptable federal offer and attached conditions. Tenn. Code § 47-18-136(a)(5), (6). As just one example, the statute's

broad bar on credentialing and certification requirements conflicts with the federal statute's certification requirements for covered entity status. *See* 42 U.S.C. § 256b(a)(7).

S.B. 1414 thus directly conflicts, in multiple ways, with Congress's chosen means for effectuating the federal program's purpose and objectives. *See Int'l Paper*, 479 U.S. at 494; *Forest Park*, 336 F.3d at 730, 732-33 (holding that where Congress enacts a benefits program that relies on participation by private parties via incentives and sets the obligations of those private parties under the program, additional state obligations conflict with the federal scheme, whether or not they purportedly serve the same "purpose"); *see also Villas at Parkside Partners v. City of Farmers Branch, Tex.*, 726 F.3d 524, 531 (5th Cir. 2013) (laws that "interfere[] with the careful balance struck by Congress" are conflict preempted); *Teltech Sys., Inc. v. Bryant*, 702 F.3d 232, 238-39 (5th Cir. 2012) (state law that interfered with Congress's careful calibration, as reflected in the federal statute's "measured language," was conflict preempted); *Odebrecht Constr., Inc. v. Sec'y, Fla. Dep't of Transp.*, 715 F.3d 1268, 1281-84 (11th Cir. 2013).

The Supremacy Clause does not permit Tennessee to adopt a regulatory scheme that destroys the uniformity Congress intended and upsets the bargain Congress struck in governing a federal benefits program. *See Buckman*, 531 U.S. at 350. With many states separately enforcing their own visions of 340B, the delicate equilibrium required to administer the program will be destroyed. *See Gould*, 475 U.S. at 286 ("[C]onflict is imminent' whenever 'two separate remedies are brought to bear on the same activity."); *see also City of Burbank v. Lockheed Air Terminal Inc.*, 411 U.S. 624, 639 (1973) (recognizing danger of "fractionalized control").

B. S.B. 1414 Intrudes On The Exclusively Federal Field Of 340B's Operation

Field preemption exists where (1) Congress's "framework of regulation [is] so pervasive that Congress left no room for the States to supplement it," or (2) where there is a "federal interest . . . so dominant that the federal system will be assumed to preclude enforcement of state laws on

the same subject." *Arizona*, 567 U.S. at 399. Field preemption is especially likely where a state law "diminish[es] the [federal government]'s control over enforcement and detract[s] from the integrated scheme of regulation created by Congress." *Id.* at 402.

As the Supreme Court recognized, Congress created a comprehensive federal program in 340B, centralized enforcement of that program exclusively within HHS, and made the provisions of 42 U.S.C. § 256b(d) the "proper remedy" for disputes regarding the 340B program. *See Astra*, 563 U.S. at 110, 119-122; *see also* 89 Fed. Reg. at 28,649.[8] Congress made 340B a closed system. It carefully delineated manufacturers' obligations via the offer provision. And it explicitly enumerated the fifteen categories of intended beneficiaries with a high degree of specificity to limit 340B's bounds. 42 U.S.C. § 256b(a)(1), (4); *see AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 60 (D. Del. 2021). Congress then barred covered entities from even "transfer[ring]" 340B-priced drugs to anyone other than a patient, 42 U.S.C. § 256b(a)(5)(B), reinforcing that Congress intended to limit the manufacturers' subsidy within strict bounds.

To ensure uniformity and keep the system circumscribed to facilitate manufacturer participation, Congress created a multi-faceted administrative enforcement scheme centralized within HHS. HRSA may audit manufacturers and covered entities to ensure compliance and, in specific circumstances, impose sanctions on covered entities and civil monetary penalties on manufacturers. *Id.* §§ 256b(d)(1)(B)(ii)-(iv), (a)(5)(C). The statute also directed HHS to establish ADR. *Id.* § 256b(d)(3)(B), (C). Covered entities have invoked ADR to raise disputes over contract pharmacies' role in 340B. And an ADR Panel recently addressed one manufacturer's contract pharmacy policy and held it complied with 340B. *St. Croix Decision Summary*.

[8] Those considerations mirror what courts consider in the field preemption context. *See NLRB v. Nash-Finch Co*., 404 U.S. 138, 144 (1971); *Arizona*, 567 U.S. at 402; *Buckman*, 531 U.S. at 341.

As the federal government argued and the Supreme Court held, this oversight is "intended to be exclusive." Br. for the United States as *Amicus Curiae* at *10, *Astra*, No. 09-1273, 2010 WL 4717264 (U.S. Nov. 19, 2010). By choosing to centralize these functions in HHS, Congress codified its assessment that HHS "is best positioned to determine manufacturers' obligations in the first instance." *Id.* at *33. Congress thus chose to vest HHS and the federal courts—rather than 50 individual states—with the power to make measured determinations on disputes, enforcement, and penalties. The field of 340B's operation is exclusively federal.

The Act impermissibly intrudes into that exclusive federal field. S.B. 1414 invades the field substantively by purporting to define as a matter of state law the scope of manufacturers' 340B obligations and by limiting manufacturers' rights under 340B. *Novartis*, 102 F.4th 460-64; *Sanofi*, 58 F.4th at 703-04; *see supra* at 10-11. This invasion also directly impacts manufacturers' ability to comply with the IRA, another federal drug pricing program. *See supra* at 16. S.B. 1414 invades the federal field procedurally by creating its own scheme of oversight and enforcement. It grants Tennessee's Attorney General authority to independently investigate 340B drug sales, which will (as the *Astra* Court predicted) create contradictory results. Tennessee would thus usurp HHS's authority to make exclusive discretionary enforcement judgments and compromise HHS's ability to balance the interests of 340B, Medicare, and Medicaid. *See Astra*, 563 U.S. at 120 (noting danger of "HHS [being] unable to hold the control rein"); *Gould*, 475 U.S. at 288 ("Each additional [state] statute incrementally diminishes the [federal government]'s control."). At bottom, the inquiry here is fundamentally the same as in *Astra*: Did Congress intend for states to insert themselves into 340B to resolve disputes about contract pharmacies outside the established remedial scheme? *See Arizona*, 567 U.S. at 399, 402-03. *Astra* provides the answer: *No.*

II. THE REMAINING FACTORS FAVOR AN INJUNCTION

Without injunctive relief, PhRMA's members will suffer irreparable harm in the form of

unrecoverable compliance costs and unrecoverable lost resources, among other things, or face Tennessee's imposition of criminal and civil penalties. *See Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 381 (1992); Ex. 1 ¶¶ 12-15; Ex. 2 ¶¶ 18-23; Ex. 3 ¶¶ 17-22.

S.B. 1414 creates immediate and substantial compliance costs for PhRMA's members. Under S.B. 1414, manufacturers must provide price concessions where they would not otherwise be required under federal law. Once given, there is no clear mechanism to recover them. Even if there were, manufacturers would need to institute many actions against many covered entities, creating an administrative burden that would engulf any recovery. As a result, PhRMA members would have "[d]ifficulty in collecting a damage judgment," which supports a finding of irreparable harm. *Simpson v. Zaveri*, 2009 WL 602332, at *2 (E.D. Ky. Mar. 6, 2009); *Lee v. Bickell*, 292 U.S. 415, 421 (1934). Manufacturers' practical inability to recover 340B price concessions—estimated to be many millions of dollars—constitutes irreparable injury.

Furthermore, PhRMA's members have already spent, and will continue to expend, significant time and financial resources analyzing the effects of the Act and determining how to comply with both the Act and federal law. PhRMA's members have already devoted hundreds of hours and hundreds of thousands of dollars to determine how the requirements of S.B. 1414 will be implemented. Ex. 1 ¶ 14; Ex. 2 ¶ 20; Ex. 3 ¶ 19. Members will be required to continue to devote funds and resources, including employee time, to ensuring compliance with S.B. 1414. Ex. 1 ¶ 14; Ex. 2 ¶ 21; Ex. 3 ¶ 20; *Kentucky v. Biden*, 57 F.4th 545, 556 (6th Cir. 2023) (concluding unrecoverable compliance costs can constitute irreparable harm); *NetChoice, LLC v. Yost*, 711 F. Supp. 3d 844, 855 (S.D. Ohio 2024) (holding company's compliance costs constituted irreparable harm because there was "no cause of action through which they could seek to recover th[em]"); *Monticello Banking Co. v. Consumer Fin. Prot. Bureau*, 2023 WL 5983829, at *3 (E.D. Ky. Sept.

14, 2023) (holding plaintiffs demonstrated irreparable injury where they were "already incurring expenses in preparation for enforcement of the Rule" and could not recoup expenses). Those costs are unrecoverable given sovereign immunity. *See Kentucky*, 57 F.4th at 556.

Significantly, these expenditures of time and funds will also divert manufacturer resources from investment in research and development and other priorities, which will have far-reaching impacts. Ex. 1 ¶ 14; Ex. 2 ¶ 21; Ex. 3 ¶ 20; *Ridge Corp. v. Kirk Nat'l Lease Co.,* 2024 WL 4817434, at *13 (S.D. Ohio Nov. 18, 2024) (loss of revenue and goodwill, resulting in reduction of research and development, supports finding of irreparable harm). Finally, manufacturers face draconian penalties and irreparable reputational harm from having their federally-compliant policies branded "criminal." *See Hall v. Edgewood Partners Ins. Ctr., Inc.*, 878 F.3d 524, 530 (6th Cir. 2017) ("[l]oss of customer goodwill" can be irreparable harm).

The balance of harms and public interest also favor relief. Preliminary injunctive relief is intended to preserve the status quo. *Certified Restoration Dry Cleaning Network, L.L.C., v. Tenke Corp.*, 511 F.3d 535, 542 (6th Cir. 2007). Here, the federal government has long regulated 340B exclusively without state intrusion, and PhRMA's members have operated under that scheme and relied on its exclusively federal nature. This case does not concern reduced pricing for patients, *supra* at 8; it concerns covered entities' use of for-profit pharmacies, which obtain windfall pricing benefits. Tennessee's intrusion upends the status quo and the federal government's control over a federal area, favoring an injunction. *Ass'n of Am. R.R.s v. Hatfield*, 435 F. Supp. 3d 769, 782 (E.D. Ky. 2020) (enjoining preempted state law was in public interest because "[o]stensibly, Congress passed the [federal statute] believing its provisions . . . served the public interest").

CONCLUSION

PhRMA respectfully requests the Court grant its motion for preliminary injunctive relief.

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Respectfully submitted,

LEWIS THOMASON, P.C.
/s/ Charles W. Cagle
Charles W. Cagle (B.P.R. No.: 013738)
Katherine R. Kimmel (B.P.R. No.: 038320)
424 Church Street, Suite 2500
Nashville, TN 37219
(615) 259-1366
ccagle@lewisthomason.com
kkimmel@lewisthomason.com

Attorneys for Plaintiff

CERTIFICATE OF SERVICE

I hereby certify that on June 17, 2025, I electronically filed the foregoing Memorandum in Support of Plaintiff's Motion for Preliminary Injunctive Relief with the Clerk of Court using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

Charles W. Cagle
Charles W. Cagle