**UNITED STATES DISTRICT COURT**
**FOR THE MIDDLE DISTRICT OF TENNESSEE**
**NASHVILLE DIVISION**

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| PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,<br><br>*Plaintiff*,<br><br>*v.*<br><br>JONATHAN SKRMETTI, in his official capacity as ATTORNEY GENERAL OF TENNESSEE,<br><br>*Defendant*. | Case No. 3:25-cv-00582<br><br>Judge Aleta A. Trauger |

# BRIEF OF *AMICI CURIAE* AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, TENNESSEE HOSPITAL ASSOCIATION, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS IN SUPPORT OF DEFENDANT


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## INTEREST OF *AMICI CURIAE*

*Amici* and their members are committed to improving the health of the communities they serve through the delivery of high-quality, efficient, and accessible health care. The discounts provided by the 340B program are essential to achieving this goal. *Amici* therefore have a strong interest in the success of Tennessee's legislative efforts to protect the 340B program.

The **American Hospital Association** (AHA) represents nearly 5,000 hospitals, healthcare systems, and other healthcare organizations nationwide. AHA members are committed to helping ensure that healthcare is available to and affordable for all Americans. AHA promotes the interests of its members by participating as *amicus curiae* in cases with important and far-ranging consequences, including cases related to the 340B program.

**340B Health** is a national, not-for-profit organization founded in 1993 to advocate for 340B hospitals—a vital part of the nation's healthcare safety net. 340B Health represents over 1,600 public and private nonprofit hospitals and health systems participating in the 340B program.

The **Tennessee Hospital Association** (THA) is a not-for-profit membership association that serves as an advocate for hospitals, health systems and other healthcare organizations and the patients they serve. THA also provides education and information for its members and informs the public about hospitals and healthcare issues at the state and national levels.

The **American Society of Health-System Pharmacists** (ASHP) is the largest association of pharmacy professionals in the United States. ASHP advocates and supports the professional practice of pharmacists in hospitals, health systems, ambulatory care clinics, and other settings spanning the full spectrum of medication use. For over 80 years, ASHP has championed innovation in pharmacy practice, advanced education, and professional development, and has served as a steadfast advocate for members and patients.

## INTRODUCTION

Starting in 2020, nearly 40 drug companies, including members of Plaintiff Pharmaceutical Research and Manufacturers of America ("PhRMA"), broke with decades of precedent and began refusing to deliver drugs purchased by 340B hospitals to their contract pharmacies. The federal government believed this was unlawful and sought to require manufacturers to continue delivering drugs to 340B hospitals regardless of whether the hospital's requested place of delivery was its in-house pharmacy or its contract pharmacy.[1]

The drug companies (including PhRMA's members) fought that effort tooth and nail. In lawsuit after lawsuit, they argued that the federal government could not interfere with their contract pharmacy restrictions. The companies began with the premise that their new policies strictly addressed *delivery—i.e.*, where drugs would and would not be shipped. Next, they insisted that the federal 340B statute had absolutely nothing to say about delivery.[2] The drug companies won. *See Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 460 (D.C. Cir. 2024) (Section 340B is "silent about delivery conditions"); *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 703 (3d Cir. 2023) (Section 340B's "text is silent about delivery").

Like many other states, Tennessee has filled the federal statutory gap that drug companies spent years fighting for by requiring drug companies to ship drugs to 340B entities' contract

[1] *See, e.g.*, Letter from Dep't of Health & Hum. Servs., Health Resources & Servs. Admin. Administrator C. Johnson to AbbVie, Inc. Vice Pres., U.S. Market Access C. Compisi (Oct. 17, 2022), https://www.hrsa.gov/sites/default/files/hrsa/opa/programintegrity/hrsa-letter-abbvie-covered-entities.pdf.

[2] *E.g.*, Novartis Opening Brief at 4, *Novartis Pharms. Corp. v. Johnson*, No. 21-5299, Doc. 1949831 (D.C. Cir. June 8, 2022) ("Section 340B . . . is *silent* as to whether manufacturers must deliver those drugs to contract pharmacies."); AstraZeneca Opening Br. at 4, *AstraZeneca Pharms. L.P. v. U.S. Dep't of Health & Hum. Servs.*, No. 22-01676 (3d Cir. July 21, 2022) ("Section 340B is 'silent' on the role of contract pharmacies under the program. That silence means the statute does not impose contract pharmacy obligations on manufacturers.").

pharmacies on the same terms as they ship those drugs to 340B entities' in-house pharmacies. Faced with the drug industry's unprecedented assault on Tennessee's health care safety net and the acknowledged gap in federal law, the Tennessee legislature enacted Senate Bill 1414 ("S.B. 1414"). S.B. 1414's central provision does only what the pharmaceutical industry and the federal courts said the *federal* law did not do: regulate the delivery of 340B drugs. *See* S.B. 1414 § 1(c) (prohibiting drug companies from restricting "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").

Now comes the whiplash: PhRMA claims in its Complaint that S.B. 1414 is a "*pricing* requirement"—*not* "a distribution requirement." Compl., ECF No. 1, ¶ 142 (emphasis added). Even though Tennessee has legislated in precisely the area that drug companies successfully insisted was *not* addressed under federal law—the delivery of 340B drugs—PhRMA has reversed course in this litigation to claim that S.B. 1414 is preempted by federal law. And as part of that about-face, PhRMA now insists that states cannot fill the federal statutory gap that drug companies (including PhRMA's members) spent years fighting for.

This history is important—and not just because it exposes the hypocrisy in PhRMA's legal position. It also serves as a reminder of *why* Tennessee chose to step into the federal statutory void. Put simply, Tennessee acted because drug companies, their trade association, and the federal courts all but invited it to.

The primary issue here is whether Tennessee, exercising its historic police power over health and safety, can fill the gap in the federal 340B statute and regulate the delivery of 340B drugs (purchased by 340B hospitals) to contract pharmacies. It can. Numerous district courts have

said so,[3] as has the Eighth Circuit in the only Court of Appeals decision to date addressing a drug industry challenge to a state contract pharmacy statute. *See PhRMA v. McClain*, 95 F.4th 1136, 1143–45 (8th Cir.), *cert. denied*, 145 S. Ct. 768 (2024).

At bottom, PhRMA's attack on S.B. 1414 is really an attack on federalism itself. PhRMA tries to transform an acknowledged federal statutory silence into a reason to displace "the historic primacy of state regulation of matters of health and safety." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). That is not the law, and each of PhRMA's claims seeking to undermine Tennessee's lawful exercise of traditional state authority should be rejected.

## ARGUMENT

### I. PHRMA'S CLAIMS ARE MERITLESS.

#### A. S.B. 1414 Is Not Preempted.[4]

"The purpose of Congress is the ultimate touchstone of pre-emption analysis." *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (citation omitted). In every preemption case, "and particularly in those in which Congress has 'legislated in a field which the States have traditionally

[3] *See AstraZeneca Pharms. LP v. Bailey*, No. 2:24-cv-4143-MDH, 2025 WL 644285 (W.D. Mo. Feb. 27, 2025); *Novartis Pharms. Corp. v. Bailey*, No. 2:24-cv-04131-MDH, 2025 WL 489881 (W.D. Mo. Feb. 13, 2025); *AstraZeneca Pharms. LP v. Fitch*, No. 1:24-cv-196-LG-BWR, 2024 WL 5345507 (S.D. Miss. Dec. 23, 2024); *PhRMA v. Murrill*, No. 6:23-cv-997, 2024 WL 4361597 (W.D. La. Sept. 30, 2024); *AbbVie Inc. v. Fitch*, No. 1:24-cv-184-HSO-BWR, 2024 WL 3503965 (S.D. Miss. July 22, 2024); *Novartis Pharms. Corp. v. Fitch*, 738 F. Supp. 3d 737 (S.D. Miss. 2024).

[4] General Skrmetti convincingly explains why PhRMA has no valid cause of action under the federal Civil Rights Act or *Ex parte Young*. *See* Def.'s Mot. to Dismiss ("MTD"), ECF No. 16 at 4–7. To the extent that PhRMA is attempting to assert a preemption cause of action directly "under the Supremacy Clause of the U.S. Constitution," Compl. at 41, it cannot do so because, as the Supreme Court has explained, the Supremacy Clause "does not create a cause of action" through which a plaintiff may claim that state law is preempted, *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 325 (2015), and Congress displaced any equitable remedy in the 340B statute by foreclosing any private enforcement role by program participants, *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 113 (2011).

occupied,'" *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996), courts "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress," *City of Columbus v. Ours Garage & Wrecker Serv., Inc.*, 536 U.S. 424, 432 (2002). That is "particularly" true in "matters of health," given "the historic primacy of state regulation" in that area. *Medtronic, Inc.*, 518 U.S. at 485. PhRMA cannot satisfy its "burden of overcoming th[e] presumption" against preemption. *PhRMA v. Walsh*, 538 U.S. 644, 662 (2003). This Court should reject each of PhRMA's myriad preemption theories—just as numerous district courts as well as the Eighth Circuit have done with preemption challenges to substantially similar state contract pharmacy statutes.[5]

*1. Congress did not create or occupy a field in the 340B statute.*

PhRMA's field-preemption theory, *see* Pl.'s Mot. for Prelim. Inj. ("Pl.'s MPI"), ECF No. 14, at 21–23, both misapplies the relevant standard and mischaracterizes the 340B statute. Field preemption occurs only in narrow circumstances, "when federal law occupies a 'field' of regulation 'so comprehensively that it has left no room for supplementary state legislation.'" *Murphy v. NCAA*, 584 U.S. 453, 479 (2018) (citation omitted). Indeed, "[t]he subjects of modern social and regulatory legislation often by their very nature require intricate and complex responses from the Congress, but without Congress necessarily intending its enactment as the exclusive means of meeting the problem." *N.Y. State Dep't of Soc. Servs. v. Dublino*, 413 U.S. 405, 415 (1973). Thus, the Supreme Court has "reject[ed] . . . the contention that pre-emption is to be

[5] *See PhRMA v. McClain*, 95 F.4th at 1143–45; *see also, e.g.*, *Novartis v. Fitch*, 738 F. Supp. 3d at 747; *AstraZeneca v. Fitch*, 2024 WL 5345507, at *4–9; *Novartis v. Bailey*, 2025 WL 489881, at *2–4. The only decision in which a court found a similar state contract pharmacy statute to be preempted is *PhRMA v. Morrissey*, 760 F. Supp. 3d 439 (S.D.W. Va. 2024), and *amici* respectfully submit that *Morrissey* was wrongly decided for the reasons articulated by General Skrmetti. *See* MTD at 14–15.

inferred merely from the comprehensive character" of a federal statute. *Id.* Rather, a statute preempts an entire field only if it "reflect[s] a congressional decision to foreclose any state regulation in the area," and thus "confer[s] a federal right to be free from any other" requirements in the same field. *Murphy*, 584 U.S. at 479 (citation omitted).

PhRMA's field-preemption theory relies entirely on the (supposed) comprehensiveness of the 340B statute and its dispute-resolution system. *See* Pl.'s MPI at 21–23; Compl. ¶ 128 (alleging that, in the 340B statute, "Congress designed a pervasive and integrated scheme of regulation"). But PhRMA is simply wrong to characterize the 340B statute as "comprehensive." Pl.'s MPI at 22. PhRMA should know this: PhRMA and many of its members ferociously argued, and convinced federal courts, that the 340B statute is "silent about delivery conditions." *Novartis v. Johnson*, 102 F.4th at 460. And for precisely that reason, the Eighth Circuit concluded that the 340B statute is *not* comprehensive and rejected a field preemption challenge to a state contract pharmacy statute substantially similar to S.B. 1414. *See PhRMA v. McClain*, 95 F.4th at 1143 ("Congress's decision not to legislate the issue of pharmacy distribution indicates that Section 340B is not intended to preempt the field."). This Court should follow the Eighth Circuit's reasoning and reject PhRMA's field preemption theory here.[6]

*2. S.B. 1414 does not conflict with the 340B statute.*

The Court also should follow the Eighth Circuit in rejecting PhRMA's conflict preemption theories. *See PhRMA v. McClain*, 95 F.4th at 1144–45. A proper conflict preemption analysis requires parties to demonstrate that the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67

[6] In addition, and as discussed in more detail below, *see infra* at 13, HRSA's exclusive authority to resolve certain disputes arising under the 340B statute itself is no reason to doubt Tennessee's authority to impose and enforce *its own* requirements—which, as PhRMA repeatedly emphasizes, are *different* from the requirements of the 340B statute. *See, e.g.*, Pl.'s MPI at 12–14.

(1941). This is a "high threshold," *Chamber of Commerce of U.S. v. Whiting*, 563 U.S. 582, 607 (2011), and PhRMA comes nowhere close to meeting it.

The 340B statute was passed to help covered healthcare providers "reach[] more eligible patients and provid[e] more comprehensive services." HRSA, *Final Rule, 340B Drug Pricing Program; ADR Regulation*, 89 Fed. Reg. 28,643, 28,643 (Apr. 19, 2024) (hereinafter, "ADR Rule"). Tennessee's S.B. 1414, in turn, enables 340B providers to continue to benefit from contract pharmacy arrangements and thereby offer expanded healthcare to their patients. *See* Opp. at 24–25 (discussing the General Assembly's purpose in enacting S.B. 1414). Thus, not only does S.B. 1414 not stand as an obstacle to the purposes of the 340B statute, "it does the opposite: [S.B. 1414] assists in fulfilling the purpose of 340B." *PhRMA v. McClain*, 95 F.4th at 1144–45; *see also CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 83 (1987) (rejecting conflict preemption challenge because, although state statute imposed additional rules in an area heavily regulated by a federal statute, it "further[ed] the federal policy" embodied by the federal statute).

More specifically, PhRMA proffers several ways in which S.B. 1414 purportedly conflicts with the federal 340B statute. Each of PhRMA's arguments fails.

**a. S.B. 1414 does not "expand the scope of 340B's federal requirements."**

The crux of PhRMA's attack on S.B. 1414 is that it "expand[s] the scope of 340B's federal requirements." Pl.'s MPI at 2; *see also id.* at 14 ("This expansion of obligations under a federal incentive program is preempted."). According to PhRMA, S.B. 1414 aims "to force many more transactions at the 340B price than would otherwise be required under 340B." *Id.* at 13.

But S.B. 1414 does not expand *federal* requirements; it sets forth Tennessee's own requirements, with their own consequences. The federal 340B statute dictates what price manufacturers must offer (the "ceiling price") and to whom (340B "covered entities"). S.B. 1414 does not alter either requirement. S.B. 1414's core provision states only that a drug company may

not restrict its provision of "a 340B drug" to "a 340B entity"—including by discriminating against or otherwise limiting "*delivery* of a 340B drug *to[] a . . . location* that is under contract with, or otherwise authorized by, a 340B entity to receive 340B drugs on behalf of the 340B entity." S.B. 1414 § 1(c) (emphasis added). Put another way, S.B. 1414 bars drug companies from discriminating against Tennessee 340B hospitals based on their chosen delivery location. It simply requires drug companies to allow covered entities to be treated like any other purchaser of those drugs, with the same freedom to select where their drugs will be delivered. *See PhRMA v. Fitch*, No. 1:24-cv-160-HSO-BWR, 2024 WL 3277365, at *11 (S.D. Miss. July 1, 2024) ("While federal law comprehensively regulates the determination of ceiling prices on Section 340B drugs . . . , Congress has not precluded Mississippi from enacting its own policy governing delivery of Section 340B drugs."); *id.* at *9 ("House Bill 728 prohibits manufacturers from interfering with covered entities ordering delivery of Section 340B drugs to pharmacies for distribution—something Section 340B may not require, but does not implicitly preclude either.").

Critically, S.B. 1414 does *not* set the price of any drug sales. To borrow from the Eighth Circuit's description of a substantially similar Arkansas statute, "[S.B. 1414] does not set or enforce discount pricing." *PhRMA v. McClain*, 95 F.4th at 1145; *see also PhRMA v. Murrill*, 2024 WL 4361597, at *9 ("[D]iscounts are set by the federal government, not the State of Louisiana or Act 358.").

PhRMA appears to attack the mere fact that S.B. 1414 speaks directly to the federal 340B program and expressly invokes the 340B statute in defining its reach. *See* Compl. ¶ 110 (noting S.B. 1414's definition of "340B drug"); *id.* ("S.B. 1414 is clear that its regulatory object is the federal 340B program."). But there is nothing improper about a state statute defining its reach by reference to federal law (and then imposing its own requirements)—or even a state statute whose

"regulatory object" is a federal program. *See, e.g.*, *Chamber of Commerce*, 563 U.S. at 607–08 (rejecting preemption challenge to a state statute under which employers had to check their employees' *federal* immigration status using a specified *federal* database). Nor is it unusual for a state statute to expressly reference a federal program in defining its reach. *See, e.g.*, Tenn. Code § 39-14-412(a) (setting forth criminal penalties for tampering with a mailbox that "is used for the receipt or deposit *of United States mail*" (emphasis added)); Tenn. Code § 53-10-305(a) (requiring healthcare practitioners who "are required to have *a federal [DEA] registration pursuant to federal law*" to register in Tennessee's controlled substance database (emphasis added)); Tennessee Lawful Employment Act, Tenn. Code §§ 50-1-701–15 (requiring employers to check employees' federal immigration status, like in *Chamber of Commerce*).

Like many other state statutes, S.B. 1414 *references* a federal statute, but it *regulates* drug delivery—a subject on which the 340B statute is silent.[7] By imposing its own complementary

[7] Numerous courts have held that congressional silence cannot give rise to preemption. *E.g.*, *Conway v. United States*, 997 F.3d 1198, 1211 (Fed. Cir. 2021) ("Combined with the presumption against preemption, Congress' silence is powerful evidence that Congress did not intend to preempt state law fixing creditors' rights during insolvency." (quotation marks omitted)); *Chinatown Neighborhood Ass'n v. Harris*, 794 F.3d 1136, 1143 (9th Cir. 2015) ("Silence, without more, does not preempt—'a clear and manifest purpose of pre-emption is always required.'"); *Planned Parenthood of Indiana, Inc. v. Commissioner of Indiana State Dept. Health*, 699 F.3d 962, 985 (7th Cir. 2011) ("As we have noted, congressional and regulatory silence usually *defeats* a claim of preemption, not the other way around."); *Iowa, Chicago & Eastern R.R. Corp. v. Washington County, Iowa*, 384 F.3d 557, 561 (8th Cir. 2004) ("[The statute's] silence cannot reflect the requisite clear and manifest purpose of Congress to preempt traditional state regulation of public roads and bridges that Congress has encouraged in numerous other statutes." (citation omitted)); *Schafer v. American Cyanamid Co.*, 20 F.3d 1, 6 (1st Cir. 1994) ("Pre-emption law, for example, cautions us against finding that a congressional act pre-empts a state law through silence."); *Paul v. Monts*, 906 F.2d 1468, 1475 n.8 (10th Cir. 1990) ("Congressional silence will not be presumed to mandate preemption. On the contrary, it will not be presumed that a federal statute was intended to supersede the exercise of the power of the state unless there is a clear manifestation of intent to do so." (citation omitted)); *see also Camps Newfound/Owatonna, Inc. v. Town of Harrison*, 520 U.S. 564, 616 (1997) (Thomas, J., dissenting) ("Even where Congress has legislated in an area subject to its authority, our pre-emption jurisprudence explicitly rejects the notion that mere congressional silence on a particular issue may be read as preempting state law.").

requirements with their own consequences, S.B. 1414 does not conflict with the pricing provision (or any other provision) of the federal 340B statute.

**b. S.B. 1414 does not impede the federal audit and ADR process.**

PhRMA's complaint that S.B. 1414 "create[s] a significant obstacle to the [340B] program's audit and ADR process," Pl.'s MPI at 15, relies on a misleading description of the process. Under the 340B statute, a manufacturer must audit a covered entity before initiating the statute's administrative dispute resolution ("ADR") process. 42 U.S.C. § 256b(d)(3)(B)(iv). According to PhRMA, S.B. 1414's restriction on demanding certain types of data from covered entities "cuts off" manufacturers' "access [to] the audit process" under the 340B statute because it prevents them from establishing "reasonable cause" to suspect that a covered entity is violating its statutory obligations—which manufacturers must do before conducting an audit. Pl.'s MPI at 15. PhRMA focuses its attack on S.B. 1414's provision that prohibits manufacturers from "[i]mpos[ing] additional requirements or limitations on a 340B entity, including requiring the submission of any . . . claims or utilization data . . . as a condition for allowing the acquisition of a 340B drug." S.B. 1414 § 1(a)(1).

But S.B. 1414's data-demand restriction does not interfere with the 340B statute's audit and ADR process. As HRSA has explicitly stated, the threshold that a drug manufacturer must meet when seeking HRSA's approval to audit a 340B entity is "*not overly burdensome*" and does not "present *any barriers* to a manufacturer's ability to perform an audit of a covered entity." ADR Rule, 89 Fed. Reg. at 28,646 (emphasis added). The standard for audit approval—"reasonable cause"—is satisfied whenever "a reasonable person *could* believe that a covered entity *may have* violated [certain provisions of the 340B statute]." HRSA, *Manufacturer Audit Guidelines and Dispute Resolution Process*, 61 Fed. Reg. 65,406, 65,409 (Dec. 12, 1996). This standard can be met in various ways that do not require claims data. For example, it can be met by pointing to

"[s]ignificant changes in quantities of specific drugs ordered by a covered entity," or by citing "complaints from patients/other manufacturers about activities of a covered entity[.]" *Id.* at 65,406; *see, e.g.*, Ex. A, Decl. of Chantelle V. Britton, HRSA Office of Pharmacy Affairs, at ¶ 9 (Dec. 19, 2024) (noting HRSA's approval of a manufacturer's audit request that was "based on a stark increase in [a provider's] utilization of the 340B program," not any data suggesting issues with specific claims).[8] In 2024, HRSA stated that, "[i]n the last 5 years," it had not denied *a single manufacturer request* to audit a covered entity. ADR Rule, 89 Fed. Reg. at 28,646.

In addition, the 340B statute contemplates that manufacturers will collect specific evidence of covered entities' potential statutory violations *through an audit*—not as a prerequisite to conducting one. The statute expressly addresses a manufacturer's access to "the records of [a 340B] entity that directly pertain to the entity's compliance with [the 340B statute] with respect to the drugs of the manufacturer." 42 U.S.C. § 256b(a)(5)(C). It provides that a manufacturer can access those records *via an* "*audit*." *Id.* (emphasis added). HRSA guidance similarly explains that, in the ADR process, manufacturers can establish covered entity violations because they "have the ability to gather needed information *through the audits*." ADR Rule, 89 Fed. Reg. at 28,652 (emphasis added). In contrast, HRSA's decision to *approve* a manufacturer audit is "preliminary [in] nature," *Or. Health & Sci. Univ. v. Engels*, 2025 WL 1707630, at *5 (D.D.C. June 17, 2025), and does not require that the manufacturer be able to prove any suspected violations using data regarding specific claims. PhRMA's concern that its members need claims data *before* any audit relies on a basic misunderstanding of the statutory scheme.

[8] As the Director of HRSA's Office of Pharmacy Affairs ("OPA"), Ms. Britton "oversee[s] the OPA staff that reviews requests by drugmakers that participate in the 340B Program to audit covered entities." Ex. A at ¶ 2. HRSA submitted Ms. Britton's declaration in connection with *Or. Health & Science Univ. v. Engels*, Case No. 1:24-cv-2998-RC (D.D.C.).

Nor is there any merit to PhRMA's argument concerning S.B. 1414's prohibition on "[i]mpos[ing] any [340B-specific] requirement relating to the frequency, duration or scope of audits." Pl.'s MPI at 16 (quoting S.B. 1414 § 1(a)(4)). This provision plainly does not, as PhRMA suggests, impede the "audits for 340B compliance [that] are a creature of federal 340B law." *Id.* Rather, the challenged provision speaks of manufacturers "*[i]mpos[ing]* any [340B-specific] requirements" *of their own* relating to audits—for example, through a right-to-audit contract clause. S.B. 1414 § 1(a)(4) (emphasis added).

Ultimately, PhRMA's sky-is-falling assertion that S.B. 1414 "will essentially break the federal remedial regime" is misguided. Pl.'s MPI at 14; Compl. ¶ 134. Manufacturers seldom ask to conduct audits, and even when they do, manufacturers frequently fail to follow through with them. *See* Ex. A, Decl. of Chantelle Britton at ¶ 15 (noting that, "over the past decade-plus," HRSA approved 37 manufacturer audit requests, but only 18 audits were conducted).[9] And more fundamentally, *amici* are not aware of a single instance when HRSA has *ever* required, as a condition of authorizing a manufacturer audit, the sort of data that PhRMA now claims its members must be allowed to demand from covered entities.

Put simply, S.B. 1414 is not an obstacle to pursuing the audit and ADR process under the 340B statute, and the Court should reject PhRMA's audit-based preemption theory.

**c. S.B. 1414 does not interfere with 340B's remedial regime.**

PhRMA next contends that S.B. 1414 "impermissibly attempts to permit private suits to enforce 340B" and creates a state-level enforcement regime that "conflicts with Congress's chosen

[9] In contrast, HRSA itself audits approximately 200 covered entities each year for compliance with their 340B obligations. *See* U.S. Gov't Accountability Office, *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance With 340B Requirements* at 11 (Dec. 2020), https://www.gao.gov/assets/gao-21-107.pdf. This includes "targeted" audits of covered entities when HRSA receives "information from stakeholders such as drug manufacturers about potential noncompliance." *Id.* at 11 n.22.

scheme of exclusive federal oversight for 340B." Pl.'s MPI at 17. But S.B. 1414 does not authorize private citizens or General Skrmetti to "enforce *340B*" or engage in "oversight *for 340B*." *Id.* (emphasis added). Instead, S.B. 1414 strictly provides for the enforcement of *its own* requirements—not the requirements of the 340B statute. *See* S.B. 1414 § 1(d) (setting civil penalties for violations of specific subsections of S.B. 1414).

As the Eighth Circuit explained with respect to a similar Arkansas statute:

> Act 1103 ensures that covered entities can utilize contract pharmacies for their distribution needs and authorizes the Arkansas Insurance Division to exact penalties and equitable relief if manufacturers deny 340B drugs to covered entities' contract pharmacies. Ark. Code Ann. § 23-92-604(c). The 340B Program, on the other hand, addresses discount pricing. ***Therefore, HHS has jurisdiction over different disputes***: disputes between covered entities and manufacturers regarding pricing, overcharges, refunds, and diversion of 340B drugs to those who do not qualify for discounted drugs.

*PhRMA v. McClain*, 95 F.4th at 1144 (emphasis added). Because the requirements that can be enforced under S.B. 1414 (like the statute in *PhRMA v. McClain*) are different from the 340B program requirements, it does not conflict with the 340B program's enforcement regime.

**d. S.B. 1414 does not conflict with 340B by preventing manufacturers from imposing additional requirements.**

PhRMA raises a hodgepodge of additional preemption arguments. These contentions are primarily aimed at provisions of S.B. 1414 that prohibit manufacturers from "impos[ing]" certain types of "requirements" on 340B entities. Pl.'s MPI at 19–21 (quoting S.B. 1414 §§ 1(a)(2)–(3), (5)–(6)). But as with S.B. 1414's audit provision, *see supra* at 12, these provisions only prevent manufacturers from "*imposing*" requirements on 340B entities—*i.e.*, requiring 340B entities to do more than what is already required of them by the 340B statute itself (or by the federal government in administering the 340B statute). By preventing manufacturers from going *beyond* the requirements of the 340B statute, Tennessee's law in no way poses any conflict with the 340B statute's actual requirements.

In particular, PhRMA complains that, if manufacturers are not free to "[i]mpose any requirements relating to inventory management systems of 340B drugs," S.B. 1414 § 1(a)(3), then they will not be able to require 340B entities to submit post-sale, prescription-specific data as a condition of obtaining the 340B discount to which they are statutorily entitled. *See* Pl.'s MPI at 19–20. PhRMA notes that "HRSA is preparing to publish guidance" in this area "imminently." *Id.* at 20. But S.B. 1414, of course, will not interfere with any "requirements relating to inventory management systems" that *HRSA* may impose, because any such requirement would not be imposed *by a manufacturer*. A simple reading of the statute's plain text makes clear that Tennessee does not create any conflict with the 340B statute by prohibiting "manufacturers"—not HRSA—from imposing their own, additional requirements on 340B entities.[10]

**B. S.B. 1414 Is Not an Impermissible Extraterritorial Regulation.**

PhRMA also claims that S.B. 1414 violates the dormant Commerce Clause, but PhRMA's claim is foreclosed by the Supreme Court's recent decision in *National Pork Producers Council v. Ross*, 598 U.S. 356 (2023), and has been directly rejected by several district courts evaluating efforts to enjoin state contract-pharmacy statutes. *See PhRMA v. Fitch*, 2024 WL 3277365, at *12–13 (Mississippi); *Novartis v. Bailey*, 2025 WL 595189, at *3–5 (Missouri).

PhRMA offers no coherent argument that S.B. 1414 violates the "antidiscrimination principle" that "lies at the very core" of the Supreme Court's dormant Commerce Clause cases. *Nat'l Pork Producers Council*, 598 U.S. at 369. That principle is implicated only by state laws that

[10] The same would be true of PhRMA's attack on S.B. 1414's bar on imposing credentialing requirements, *see* Pl.'s MPI at 20–21 (discussing S.B. 1414 § 1(a)(5) (6)), even if PhRMA were correct that the 340B statute addresses "certification requirements for covered entity status," *id.* at 21 (citing 42 U.S.C. § 256b(a)(7)). But PhRMA is misreading the cited provision of the 340B statute, which applies only to certain types of covered entities that provide treatment for tuberculosis, HIV, and other sexually transmitted diseases. *See* 42 U.S.C. § 256b(a)(4)(J)–(K).

privilege "in-state economic interests" over "out-of-state *competitors.*" *Id.* (emphasis added). Because discrimination is the focus, "the objects of disparate treatment [must] be *similarly situated* before a law may be deemed to run afoul of the dormant Commerce Clause." *Energy Mich., Inc. v. Mich. Pub. Serv. Comm'n*, 126 F.4th 476, 494 (6th Cir. 2025) (emphasis added).

Although PhRMA passingly alleges that "S.B. 1414 is discriminatory," it gives away the game by complaining of discrimination between "in-state participants in the 340B program" (*i.e.*, covered entities) and "out-of-state *manufacturer[s]*." Compl. ¶ 154 (emphasis added). PhRMA does not purport to argue, nor could it, that healthcare providers and drug manufacturers are "similarly situated" for purposes of the dormant Commerce Clause.

Absent any colorable claim of discrimination, PhRMA is left to repeatedly contend that S.B. 1414 "directly regulate[s] out-of-state transactions by those with no connection to the State." Compl. ¶ 150 (citation omitted). But PhRMA never explains how S.B. 1414 does so. *See generally id.* ¶¶ 147–56. PhRMA notes that the statute's definition provisions lack an express geographic limitation, *id.* ¶ 151, but PhRMA ignores the bedrock legal principle that

> the relevant context for a statute's interpretation usually includes certain assumptions—what the law sometimes calls background principles—that an ordinary reader would bring to her understanding of the statutory text. One such assumption is that *a statute's geographic reach is ordinarily confined within the borders of the government that enacts it.* And so an ordinary reader might well assume, for example, that a Tennessee auctioneering statute does not impose licensing requirements on auctioneers located in Alaska or New Zealand.

*McLemore v. Gumucio*, No. 22-5458, 2023 WL 4080102, at *1 (6th Cir. June 20, 2023) (emphasis added). PhRMA's argument would endanger countless Tennessee statutes that do not recite this background assumption in explicit terms.

The only out-of-state transactions that PhRMA identifies are sales from manufacturers to "distributors and wholesalers," through which PhRMA alleges that manufacturers "predominantly

sell and deliver their drugs." Compl. ¶ 152. According to PhRMA, the price of these transactions will be set "[a]s a result" of S.B. 1414's protections for 340B covered entities. *Id.* ¶ 153. But S.B. 1414 does not directly regulate drug purchases by distributors or wholesalers—it regulates "purchase[s] by a 340B entity." S.B. 1414 § 1(g)(1). Whatever out-of-state effects PhRMA's members may experience are not the result of S.B. 1414 "directly" regulating transactions with "no connection" to Tennessee.

Like "many (maybe most) state laws," S.B. 1414 may indirectly impact "extraterritorial behavior" for drug companies that are headquartered outside of Tennessee. *Nat'l Pork Producers*, 598 U.S. at 374. But the statute does not *target* extraterritorial activity or privilege in-state actors over their out-of-state competitors; its prohibitions apply equally to in- and out-of-state sellers of drugs. This Court should reject PhRMA's attempt to revive the "extraterritoriality doctrine" so shortly after the Supreme Court rejected it. *See id.* at 371.

### C. S.B. 1414 Is Not Void For Vagueness.

PhRMA's vagueness claim mirrors challenges to other states' contract-pharmacy statutes, and the two courts that have thus far addressed such challenges on the merits have rejected them. *See PhRMA v. Murrill*, 2024 WL 4361597, at *10-11; *PhRMA v. Fitch*, 2024 WL 3277365, at *13–15. This Court should follow suit.

A law is void for vagueness only "if it fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits" or "authorizes or even encourages arbitrary and discriminatory enforcement." *Hill v. Colorado*, 530 U.S. 703, 732 (2000). Because courts are loathe to "invalidate [a statute] based on scenarios that may never come to pass," vagueness challenges must fail if they are unripe for review—which is often true of a "preenforcement-facial-vagueness challenge" like the one here. *Carman v. Yellen*, 112 F.4th 386, 402 (6th Cir. 2024).

On the merits, PhRMA's void-for-vagueness challenge plainly fails. PhRMA takes issue with a catchall provision of S.B. 1414 that prohibits "imposing any requirement" that, as determined by the attorney general and reporter, "interfere[s] with the ability of a 340B entity to access discounts provided under [the federal 340B statute]." S.B. 1414 § 1(a)(6); *see* Compl. ¶¶ 163–65. But the word "interfere" appears in countless statutes that impose criminal and civil liability,[11] and people of ordinary intelligence are reasonably able to understand what it means to "interfere." *See Cameron v. Johnson*, 390 U.S. 611, 616 (1968) (rejecting vagueness challenge because "[t]he terms 'obstruct' and 'unreasonably interfere' plainly require no guessing at their meaning"); *cf. United States v. Kassouf*, 144 F.3d 952, 955, 959 (6th Cir. 1998) (rejecting vagueness challenge to criminal statute that applied to whoever "corruptly . . . obstructs *or impedes*" a known IRS investigation (emphasis added)). That is especially true where the *object* of prohibited interference (here, 340B entities receiving federally-required discounts for specific drugs) is concrete and makes reasonably clear what conduct could be viewed as interfering.[12]

[11] *E.g.*, 15 U.S.C. § 77kk(c) ("[I]t shall be unlawful for [specified entity] . . . to do any act directly or indirectly which would interfere with or obstruct or hinder or which might be calculated to obstruct, hinder, or interfere with the policy or policies of the said Department of State or the Government of the United States . . ."); 18 U.S.C. § 245(b); 29 U.S.C. § 158(a); 29 U.S.C. § 2615 (a)(1); 42 U.S.C. § 3617; 47 U.S.C. § 333.

[12] In contrast, all of PhRMA's cases involved statutes where the object of prohibited interference offered little help in understanding what conduct could be viewed as interfering. For example, one case involved a statute that made it a crime "to interfere with or to disturb in any way or in any place *the students or teachers of any school or college* in this State" (as well as "to loiter about such school or college premises" or "to act in an obnoxious manner thereon"). *Caroline Youth Action Project v. Wilson*, 60 F.4th 770, 776 (4th Cir. 2023). As the Fourth Circuit observed, "[i]t is hard to know where to begin with the vagueness problems with th[at] statute." *Id.* at 786.

## II. AN INJUNCTION WOULD NOT SERVE THE PUBLIC INTEREST.

The public interest would not be served by enjoining S.B. 1414 and allowing manufacturers to interfere with Tennessee 340B hospitals' partnerships with contract pharmacies. Contract pharmacy arrangements play a crucial role in 340B hospitals' ability to serve their communities.

PhRMA spends a significant portion of its Complaint maligning hospitals that rely on the 340B program and that partner with contract pharmacies. *See* Compl. ¶¶ 63–87. But this is not how the Supreme Court has viewed 340B hospitals. As Justice Kavanaugh wrote for a unanimous Supreme Court just 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).

Savings from the 340B program are crucial in enabling 340B hospitals to continue serving these communities. For example, East Tennessee Children's Hospital in Knoxville has used savings from the 340B program to help support numerous programs and services, including a program that provides inhalers to children who cannot afford them. Ascension Saint Thomas—a health system with 340B locations in Centerville, Murfreesboro, McMinnville, and Waverly—uses 340B savings to support its charitable clinics as well as a program that provides free and reduced-cost medications to uninsured patients, among other programs and services. Some of Ascension Saint Thomas's 340B locations have negative operating margins, including Ascension Saint Thomas Hickman—a critical-access hospital in Hickman County that serves roughly 10,000 patients each year, with the nearest other hospital being 30 miles away. Savings from the 340B

program help Ascension Saint Thomas to stretch its scarce resources, provide uncompensated care, and serve its community.[13]

Relationships with contract pharmacies play a crucial role in 340B hospitals' ability to serve their communities. Partnerships with contract pharmacies "allow for drug dispensation closer to where low-income patients reside." *PhRMA v. McClain*, 95 F.4th at 1139. As HRSA has noted in issuing guidance for 340B hospitals' use of contract pharmacies:

> It would be a significant benefit to patients to allow the use of more easily accessible, multiple contract pharmacy arrangements by covered entities. This would permit covered entities to more effectively utilize the 340B program and create wider patient access by having more inclusive arrangements in their communities which would benefit covered entities, pharmacies, and patients served.

HRSA, *Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services*, 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010).

Contract pharmacy arrangements are especially important because fewer than half of 340B hospitals operate in-house pharmacies.[14] "This is in large part due to the fact that building or maintaining a pharmacy is cost-prohibitive for many covered entities." *PhRMA v. McClain*, 95 F.4th at 1139. Even fewer—only one in five 340B hospitals—have in-house "specialty" pharmacies, which many insurers require for the dispensing of "specialty" drugs. These drugs are typically used to treat chronic, serious, or life-threatening conditions, and are generally priced much higher than non-specialty drugs.[15] Thus, 340B hospitals typically *must* contract with at least

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[13] *See* Ascension, *Tennessee Covered Entities*, https://about.ascension.org/about-us/community-impact/340b-drug-pricing-program/tennessee.

[14] 340B Health, *Drugmakers Pulling $8 Billion Out of Safety-Net Hospitals: More Expected as Growing Number Impose or Tighten 340B Restrictions* 2, https://www.340bhealth.org/files/Contract_Pharmacy_Financial_Impact_Report_July_2023.pdf.

[15] Adam J. Fein, Drug Channels Institute, *Insurers + PBMs + Specialty Pharmacies + Providers: Will Vertical Consolidation Disrupt Drug Channels in 2020?* (Dec. 12, 2019), https://www.drugchannels.net/2019/12/insurers-pbms-specialty-pharmacies.html.

one specialty pharmacy outside of its in-house pharmacy.[16] Some 340B hospitals—including East Tennessee Children's Hospital—have had to terminate relationships with contract pharmacies that previously served many of their patients in large part because of restrictions imposed by drug manufacturers.

Moreover, a quarter of hospitals' 340B benefit historically came from drugs dispensed at contract pharmacies. The drug industry's efforts to stop 340B hospitals from relying on contract pharmacies has hurt 340B hospitals and adversely impacted their ability to serve at-risk populations. Denied 340B savings associated with contract pharmacies, many 340B hospitals—which typically operate with razor-thin (and often negative) margins—report that they have been forced to curtail critical programs and services or eliminate them entirely.[17]

The General Assembly, with an unbiased interest in protecting Tennessee citizens, hospitals, and pharmacies, has acted to advance the objectives of the 340B program and protect 340B hospitals' ability to serve their communities by partnering with contract pharmacies. Enjoining S.B. 1414 would not serve the public interest.

## CONCLUSION

For the foregoing reasons, PhRMA's Motion for a Preliminary Injunction should be denied and General Skrmetti's Motion to Dismiss should be granted.

Dated: June 27, 2025

Respectfully submitted,

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[16] 340B Health, *supra* note 14, at 7 (citing Adam J. Fein, Drug Channels Institute, *The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers* (Mar. 2022)).

[17] 340B Health, *Restrictions on 340B Increase Drug Company Profits but Lead to Lost Savings, Patient Harm, and Substantial Burden for Safety-Net Hospitals* at 2, 5, 8, https://www.340bhealth.org/files/Contract_Pharmacy_Survey_Report_March_2023.pdf.

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**CERTIFICATE OF SERVICE**

I certify that on June 27, 2025, I caused the foregoing to be served via the Court's ECF filing system on all registered counsel of record.

*/s/ Simon Levitsky*
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