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

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, *Plaintiff*, v. JONATHAN SKRMETTI, *in his official capacity as* TENNESSEE ATTORNEY GENERAL, *Defendant*.	Case No. 3:25-cv-582 District Judge Aleta A. Trauger

GENERAL SKRMETTI'S MOTION TO DISMISS AND SUPPORTING MEMORANDUM OF LAW

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INTRODUCTION*

The Court should put a quick end to this meritless lawsuit. Plaintiff Pharmaceutical Research and Manufacturers of America, or "PhRMA," is the lobbying and litigating arm of the international pharmaceutical industry. *See* Compl., D.1 at 11. PhRMA says its "members," none of which are based in Tennessee, do business with (unidentified) Tennessee hospitals under the federal "340B" drug-pricing program. *Id.* Through this program, drug companies gain the privilege of selling drugs to the federal government by also committing to discount their products for a "narrow categor[y]" of hospitals — called "covered entities" — that "primarily serve low-income patients." *Novartis Pharm. Corp. v. Johnson*, 102 F.4th 452, 456 (D.C. Cir. 2024); *see Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113–16 (2011). Contrary to PhRMA's belief, this commitment does not entitle drug companies to exemption from Tennessee's consumer-protection laws. *See, e.g.*, *PhRMA v. McClain*, 95 F.4th 1136 (8th Cir. 2024); *PhRMA v. Bailey*, No. 2:24-cv-4144, 2025 WL 644281 (W.D. Mo. Feb. 27, 2025); *PhRMA v. Murrill*, Nos. 6:23-cv-997, -1042, -1307, 2024 WL 4361597 (W.D. La. Sept. 30, 2024); *PhRMA v. Fitch*, No. 1:24-cv-160, 2024 WL 3277365 (S.D. Miss. July 1, 2024). The Court should dismiss PhRMA's complaint.

BACKGROUND

PhRMA brings this lawsuit to secure judicial veto of Tennessee's Hospital Protection Act, a new statute that regulates Tennessee's drug-product marketplace. *See* Compl., D.1 at 2 (citing "S.B. 1414"). By its terms, the Hospital Protection Act applies to sales of drugs that have been priced at a discount under the federal 340B program. *See* Hosp. Prot. Act (attached as Ex.A). But importantly, the 340B program only dictates the size of this agreed-to discount. *Novartis*, 102 F.4th at 460. Its implementing statute is "silent about delivery conditions" or the other sales terms

* Pincites to docket entries use the Page ID file-stamp pagination.

that drugmakers might negotiate with 340B Hospitals. *Id.* And in recent years, that silence has led to a problem that the Hospital Protection Act now seeks to solve.

Specifically, drugmakers participating in the 340B program have begun using their outsized bargaining power to force additional, non-price terms on the sale of 340B drugs. *AstraZeneca v. Fitch*, 766 F. Supp. 3d 657, 661 (S.D. Miss. 2024). This practice appears to stem from a perception that federal regulators have failed to prevent program abuses, such as the unlawful "diversion" of discounted drugs to non-program buyers. *Novartis*, 102 F.4th at 456 (quoting 42 U.S.C. § 256b(a)(5)(B)); *see Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 700–03 (3d Cir. 2023); *Eli Lilly & Co. v. Kennedy*, Nos. 21-cv-2608; 24-cv-3220, -3337, -3496; 25-cv-117; 2025 WL 1423630, at *3 (D.D.C. May 15, 2025). And the drugmakers' response addresses two industry practices *not* dictated by federal law: the 340B Hospitals' use of "contract pharmacies" and widespread adoption of the "replenishment model." *See* Compl., D.1 at 4.

To be clear, third-party "contract pharmacies" have always played an important role in the 340B program by working on behalf of 340B Hospitals to distribute the discounted drugs to patients. *See Sanofi*, 58 F.4th at 700; *AstraZeneca*, 766 F. Supp. 3d at 660. And although federal law "prohibits 'diversion'" of the drugs to anyone else, drug manufacturers have long "argued that [contract pharmacy] arrangements lead to" that very result. *Novartis*, 102 F.4th at 456, 458. In particular, they have complained that diversion can occur through the "replenishment model," under which 340B Hospitals claim the 340B discount on purchases made to *replace* drugs already dispensed from a third-party contract pharmacy's inventory. *Eli Lilly*, 2025 WL 1423630, at *2.

If the federal government shared the drugmakers' concerns, it would have more-than-adequate means to investigate and even end the above-mentioned practices. *See McClain*, 95 F.4th at 1142 (citing 42 U.S.C. § 256b(a)(5)). But in the absence of such action, the drugmakers have

begun "imposing" various special and onerous "conditions" on the 340B Hospitals with which they do business. *Novartis*, 102 F.4th at 459; *Sanofi*, 58 F.4th at 701.

Enter the Hospital Protection Act. Attempting to protect 340B Hospital access to the 340B discount, the Act addresses the drugmakers' recent sales tactics through two principal mechanisms. *First*, it prohibits "drug manufacturer[s] or their agent[s] or affiliate[s]" from "[i]mpos[ing]" five enumerated types of "requirements" on 340B Hospitals. Hosp. Prot. Act § 1(a). Specifically, drugmakers may not (1) demand "health information" or related "data" from the Hospitals beyond what is already required by law; (2) "[r]equire" the Hospitals to "reverse, resubmit, or clarify" a drug-reimbursement request outside of "the normal course of business"; (3) impose "inventory management systems" not required by law; (4) impose "audit[]" requirements that are "not imposed" on "pharmacies or providers" operating outside of the 340B program; or (5) "[i]mpose requirements relating to accreditation, recertification, credentialing, or recredentialing that are not imposed on" hospitals and pharmacies in other contexts. *Id.*; *see also id.* § 1(g) (defining terms). *Second*, and relatedly, the Hospital Protection Act prevents drug manufacturers from restricting who can "receive 340B drugs on behalf of" a 340B Hospital beyond what is already prohibited by the federal government or "applicable state law." *Id.* § 1(c).

Eager to relieve its members from these new regulations, PhRMA has sued Tennessee's Attorney General, Jonathan Skrmetti, to prevent their enforcement. PhRMA's fifty-seven-page complaint is full of information about the 340B program. *See* Compl., D.1 at 1–58. Still, it lacks what PhRMA needs to justify this Court's intervention: factual allegations that, if proved, would give PhRMA itself a right to relief from General Skrmetti's future conduct.

ARGUMENT

PhRMA has not stated a claim to such relief; its lawsuit should be dismissed. To state a claim in federal court, a complaint must offer more than "conclusory allegations . . . that the

defendant violated" or might soon violate "the law." *16630 Southfield Ltd. P'ship v. Flagstar Bank, F.S.B.*, 727 F.3d 502, 504 (6th Cir. 2013). Instead, the plaintiff must "plead enough 'factual matter' to raise a 'plausible' inference" that ties the defendant to actionable "wrongdoing." *Id.* (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)); *see Bates v. Green Farms Condo. Ass'n,* 958 F.3d 470, 481 (6th Cir. 2020); *Rondigo, L.L.C. v. Twp. of Richmond*, 641 F.3d 673, 684 (6th Cir. 2011). In this case, PhRMA has (1) failed to connect any actionable personal injuries to General Skrmetti's conduct and (2) failed to allege any violation of any constitutional provision regardless. At best, PhRMA seeks an advisory opinion regarding the Hospital Protection Act's abstract validity. But this Court cannot provide that relief under the Civil Rights Act while staying within the guardrails of Article III — especially not in the face of Tennessee's sovereign immunity. And those threshold issues aside, PhRMA's claims all fail on the merits.

I. PhRMA has failed to establish a cause of action for this Court to remedy.

PhRMA seems to think it can litigate based purely on "associational standing." *Ass'n of Am. Physicians & Surgeons v. FDA*, 13 F.4th 531, 537 (6th Cir. 2021); *see* Compl., D.1 at 11–12. But a plaintiff with standing does not necessarily have a viable right of action. *See Keen v. Helson*, 930 F.3d 799, 802 (6th Cir. 2019). And here, PhRMA must also evade Tennessee's sovereign immunity. *See S & M Brands, Inc. v. Cooper*, 527 F.3d 500, 507 (6th Cir. 2008).

This typically does not pose a problem for organizations litigating under certain statutory regimes, including regimes that waive sovereign immunity and allow any "aggrieved" party to sue the government. 5 U.S.C. § 702; *see Am. Physicians*, 13 F.4th at 535. But PhRMA does not invoke any capacious right of action or waiver of sovereign immunity here. Instead, PhRMA has sued under the Civil Rights Act and invoked the narrow forms of relief provided by the Declaratory Judgment Act and *Ex parte Young*. *See* Compl., D.1 at 12. And that poses several problems for PhRMA, which incurably doom its complaint.

First, the Civil Rights Act affords PhRMA no right of action against General Skrmetti. This law only allows plaintiffs "to vindicate their *own* constitutional right[s]." *Chambers v. Sanders*, 63 F.4th 1092, 1100 (6th Cir. 2023) (citing *LeFever v. Ferguson*, 645 F. App'x 438, 447 (6th Cir. 2016), and *Foos v. City of Delaware*, 492 F. App'x 582, 593 (6th Cir. 2012)). "[B]y virtue of the explicit language" Congress adopted, the statute grants "a personal [right of] action cognizable only by the party whose civil rights [are being] violated." *Jaco v. Bloechle*, 739 F.2d 239, 242 (6th Cir. 1984). Put differently, the right to relief this statute affords is "entirely personal to the direct victim of the alleged constitutional tort," such that "[o]nly the purported victim" of state action "may prosecute" a Civil Rights Act claim. *Chambers*, 63 F.4th at 1100 (quoting *Claybrook v. Birchwell*, 199 F.3d 350, 357 (6th Cir. 2000)). So to state a Civil Right Act claim, PhRMA "must . . . identify a constitutional right, then show that" General Skrmetti is "depriv[ing *PhRMA*] of that right." *Susselman v. Washtenaw Cnty. Sheriff's Off.*, 109 F.4th 864, 870 (6th Cir. 2024).

But in this case, PhRMA has not and cannot allege any personal rights at stake. PhRMA is a "trade association," not a drug manufacturer. Compl., D.1 at 11. PhRMA does not itself participate in the 340B program. *See id.* PhRMA therefore does not "directly or indirectly" negotiate sales terms for "340B drug[s]" with 340B Hospitals. Hosp. Prot. Act § 1(a). This means PhRMA could not possibly violate the Hospital Protection Act or be prosecuted by General Skrmetti. *See id.* And that leaves the Court no right to remedy under the Civil Rights Act. *See Chambers*, 63 F.4th at 1101; *Jaco*, 739 F.2d at 242–43.

Second, and relatedly, PhRMA has failed to play by the rules of *Ex parte Young*, 209 U.S. 123 (1908). Only through *Young* can PhRMA invoke this Court's jurisdiction, because only through *Young* can PhRMA evade Tennessee's sovereign immunity. *See Ernst v. Rising*, 427 F.3d 351, 358–59 (6th Cir. 2005). But *Young* allows just one type of suit: a request for personalized

protection from a state officer's "specified un[constitutional] actions." *Whole Woman's Health v. Jackson*, 595 U.S. 30, 44 (2021). And equitable relief under *Young* can "extend[no] further than necessary to remedy [each successful] plaintiff's injury." *L.W. ex rel. Williams v. Skrmetti* (*L.W. II*), 83 F.4th 460, 490 (6th Cir.), *cert. dismissed in part sub nom. Doe v. Kentucky*, 144 S. Ct. 389 (2023), *and cert. granted sub nom. United States v. Skrmetti*, 144 S. Ct. 2679 (2024) (quoting *Kentucky v. Biden*, 57 F.4th 545, 556 (6th Cir. 2023)); *see Kallstrom v. City of Columbus*, 136 F.3d 1055, 1069 (6th Cir. 1998).

Again, this creates a problem for PhRMA due to PhRMA's purely tangential interest in the Hospital Protection Act. Without a theory as to how General Skrmetti will seek to impose liability on PhRMA itself, PhRMA has failed to construct a pre-enforcement suit that comports with "historical" principles of equity. *Jackson*, 595 U.S. at 44. Those principles may allow for "decree[s]" dictating General Skrmetti's "'behavior . . . towards'" drug manufacturers. *Universal Life Church Monastery Storehouse v. Nabors*, 35 F.4th 1021, 1032 (6th Cir. 2022) (quoting *Hewitt v. Helms*, 482 U.S. 755, 761 (1987)). But they do not allow "court order[s] that go[] beyond" those manufacturers' individualized harm. *L.W. II*, 83 F.4th at 490.

Third and finally, even if PhRMA could somehow skip past the issues above, it still has failed to plead facts indicating that General Skrmetti poses a "'*certainly impending*'" threat to any of PhRMA's members. *Friends of George's, Inc. v. Mulroy*, 108 F.4th 431, 435 (6th Cir. 2024) (quoting *Crawford v. U.S. Dep't of Treasury*, 868 F.3d 438, 454 (6th Cir. 2017)); *see Christian Healthcare Ctrs., Inc. v. Nessel*, 117 F.4th 826, 843 (6th Cir. 2024). PhRMA mistakenly fixates on "criminal penalties" that General Skrmetti lacks the power to pursue. Compl., D.1 at 11; *see Nabors*, 35 F.4th at 1032. And PhRMA's complaint alleges no facts to raise a plausible inference that the circumstances of any *actual*, *discrete* enforcement action are on the horizon.

On the contrary, PhRMA does not allege how any particular member's actual sales "policies" violate the Hospital Protection Act. Compl., D.1 at 5. Instead, it speaks of (often unidentified) members' conduct in only the broadest of strokes. *See id.* at 11–13, 30, 37, 57. And to the extent it discusses General Skrmetti, it only confirms that he has not offered "guidance" on how he expects to enforce this brand-new legislation. *Id.* at 9. PhRMA's *pre*-enforcement challenge thus lacks the "concrete context" ordinarily "afforded by an enforcement action." *Ammex, Inc. v. Cox*, 351 F.3d 697, 706–07 (6th Cir. 2003). And without that "need[ed] . . . factual development," this Court cannot provide appropriate Article III relief. *Id.* at 707; *see L.W. ex rel. Williams v. Skrmetti* (*L.W. I*), 73 F.4th 408, 415 (6th Cir. 2023); *Christian Healthcare*, 117 F.4th at 851.

II. PhRMA's efforts to negate Tennessee law lack merit.

Threshold issues aside, PhRMA has not put forward any viable substantive theory of relief. Federal law does not preempt the Hospital Protection Act. PhRMA's two vagueness theories fall short. And this statute does not impermissibly regulate interstate commerce.

A. Federal law does not preempt the Hospital Protection Act.

According to PhRMA, the Hospital Protection Act "intrudes upon the exclusive field created by [the] 340B" statute and otherwise frustrates the "purposes and objectives" of the 340B program. Compl., D.1 at 42, 44. But neither contention can withstand scrutiny.

To begin, PhRMA takes no heed of the presumption that Congress respects "the constitutional balance" of state and federal power. *Bond v. United States* (*Bond II*), 572 U.S. 844, 862 (2014) (quoting *Bond v. United States* (*Bond I*), 564 U.S. 211, 222 (2011)). On this basis, federal courts construe only "unmistakably clear [statutory] language" to intrude on the traditional spheres of state sovereignty. *Gregory v. Ashcroft*, 501 U.S. 452, 460 (1991) (quoting *Will v. Mich. Dep't of State Police*, 491 U.S. 58, 65 (1989)); *see U.S. Forest Serv. v. Cowpasture River Pres. Ass'n*, 590 U.S. 604, 621–22 (2020). And this "presumption" against preemption applies to the contours

of the 340B program because the program encroaches on the traditional state-law domains of private contract and the sale of medical drugs. *McClain*, 95 F.4th at 1140 (quoting *Hillborough Cnty. v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 715 (1985); *see Dayton Power & Light Co. v. FERC*, 126 F.4th 1107, 1128 n.12 (6th Cir. 2025); *AstraZeneca*, 766 F. Supp. 3d at 663.

Indeed, the States' power to regulate contracts is so much a part of our federal fabric that Congress *relies* on "background principles of state contract law" when it legislates on matters affecting contractual relationships. *Arthur Andersen LLP v. Carlisle*, 556 U.S. 624, 630 (2009). And from its earliest days, our country has kept the "police power" in the hands of the States, leaving them with the prerogative and duty to "regulate the administration, sale, prescription and use of . . . drugs." *Minn. ex rel. Whipple v. Martinson*, 256 U.S. 41, 45 (1921); *see id.* at 43–44; *N. Va. Hemp & Agric., LLC v. Virginia*, 125 F.4th 472, 492 (4th Cir. 2025); *see also Pharm. Soc'y of N.Y., Inc. v. Lefkowitz*, 586 F.2d 953, 958 (2d Cir. 1978) (distinguishing between state power and federal power in this area).

This alone could suffice to foreclose PhRMA's ambitious theories of "implied" preemption, which are based on equating the 340B program with a regulatory "field" and ascribing unspoken "purposes and objectives" to Congress. *See* Compl., D.1 at 42–51; *McClain*, 95 F.4th at 1140, 1143–44. The Supreme Court no longer condones "freewheeling judicial inquiry into whether a statute is in tension with federal objectives." *Kansas v. Garcia*, 589 U.S. 191, 202 (2020) (quoting *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 607 (2011)). And even if considered in more detail, PhRMA's preemption theories fall short just the same.

Field Preemption. "Field preemption" is a "rarely" employed concept whereby "Congress legislate[s] so comprehensively in a particular field that there is no room for 'supplementary state legislation.'" *Virginia Hemp*, 125 F.4th at 493 (quoting *Garcia*, 589 U.S. at 208). It has been

applied to traditional federal domains like immigration, as well as palpable national-security concerns like nuclear safety. *See, e.g.*, *Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n*, 461 U.S. 190, 212 (1983); *City of Burbank v. Lockheed Air Terminal Inc.*, 411 U.S. 624, 638 (1973); *Hines v. Davidowitz*, 312 U.S. 52, 74 (1941). But contrary to PhRMA's assertions, the 340B statute "does not come close to th[e] level of regulation" that gives rise to implicit field preemption. *Virginia Hemp*, 125 F.4th at 495.

In fact, it is not even clear PhRMA has "[]identif[ied]" an appropriate "field" for field-preemption analysis. *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156, 177 (1st Cir. 2009). In the broader field of pharmaceutical regulation, state law dominates while federal law merely complements. *See Wyeth v. Levine*, 555 U.S. 555, 566–68 (2009); *supra* at 8. And the States' regulation of pharmacies and hospitals has carried on, even as the federal government has become an increasingly important purchaser of healthcare. *See, e.g.*, *Downhour v. Somani*, 85 F.3d 261, 268 (6th Cir. 1996). This leaves PhRMA to assert that the niche 340B program *itself* somehow constitutes a "field" of exclusive federal regulation, such that no state law could in any way reach the drug sales affected by this highly specific federal statute. *See* Compl., D.1 at 42–44. But the program's terms and history show that this cannot be right.

From the beginning, the 340B statute has narrowly addressed the price at which drugs are offered. *See Novartis*, 102 F.4th at 460; *Sanofi*, 58 F.4th at 699. It has thus necessarily relied on preexisting "state-law standards" to otherwise govern participants "rights and obligations." *Kamen v. Kemper Fin. Servs., Inc.*, 500 U.S. 90, 98 (1991). And 340B Hospitals' use of third-party "[p]harmacies ha[s] always been an essential part of the" 340B program — a part Congress notably left unaddressed, unlike the role of other "third-part[ies]." *McClain*, 95 F.4th at 1143 (citing 42 U.S.C. § 256b(a)(8)). These features of the statute's text and historical backdrop indicate

congressional intent "*not* to" regulate the "distribution" of 340B drugs beyond forbidding diversion. *Id.* (emphasis added). And that decision "indicates" the 340B statute does not "preempt the field" of drug sales eligible for the statute's discounted pricing. *Id.*

Obstacle Preemption. Perhaps recognizing this, PhRMA provides several scattershot theories of "obstacle" preemption, each more suspect than the last. Obstacle preemption occurs when a state law frustrates a federal statute's apparent "'purpose and intended effects.'" *Id.* at 1144 (quoting *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000)). But "[w]hat qualifies as 'a sufficient obstacle is a matter of judgment,'" which should be based in text — not just speculation. *Id.* (quoting *Crosby*, 530 U.S. at 373); *see Heard v. Strange*, 127 F.4th 630, 636 (6th Cir. 2025); *Virginia Hemp*, 125 F.4th at 495. And PhRMA's theories of obstacle preemption all stem from a gross overestimation of what the 340B statute says.

First, PhRMA claims that the Hospital Protection Act frustrates 340B's "remedial regime" by regulating the way in which "manufacturers gather[] information" about drug distribution. Compl., D.1 at 45. But this argument overreads the Hospital Protection Act while inflating drugmakers' role in federal enforcement. Tennessee law does not keep manufacturers from conducting "audit[s] full stop." *Id.* at 46. It only prevents them from "requir[ing]" 340 Hospitals to assume self-auditing burdens, particularly those "not imposed" on other "pharmacies or providers." Hosp. Prot. Act § 1(a). If the drugmakers want "data" about how their drugs are being distributed, they can still seek that data by other means and through other parties. *Id.* § 1(a)(1). And if they want to "[i]mpose requirements relating to accreditation," "audits," or reimbursements, they can do so for *all* healthcare "providers" and "in the normal course of business." *Id.* § 1(a)(2), (4), (5). Tennessee law thus places only marginal burdens on current fact-gathering practices. And by making it more difficult for drug companies to foist additional costs on 340B Hospitals, Tennessee law

furthers Congress's purposes rather than impeding them. *See Fitch*, 2024 WL 3277365, at *9 (citing *McClain*, 95 F.4th at 1145).

But even if this Court viewed Tennessee law as a meaningful hurdle to the drugmakers' self-help, that would not be enough basis to deem the law an "obstacle" to federal enforcement. *McClain*, 95 F.4th at 1144. PhRMA itself acknowledges that "Congress chose to assign oversight and enforcement responsibilities" for the 340B program "exclusively to" federal regulators. Compl., D.1 at 17. And nothing in the Hospital Protection Act prevents federal regulators from gathering information, conducting audits, or meting out punishment. *See Novartis*, 102 F.4th at 456; *Sanofi*, 58 F.4th at 700–03. On the contrary, Tennessee's law explicitly avoids "conflict with . . . federal law and regulations," including the provisions of the 340B statute allowing federal regulators to police the 340B program. Hosp. Prot. Act § 1(e)(1). So again, PhRMA's grievances spring from displeasure with how the *federal law* actually operates, not how Tennessee law impedes congressional objectives. *Cf. Eli Lilly*, 2025 WL 1423630, at *3 (noting drugmaker concerns that program "is rife with abuse").

Second, PhRMA says the Hospital Protection Act "directly interferes with the ability of manufacturers to structure their 340B program transactions in ways fully compliant with federal law and . . . intended to increase transparency." Compl., D.1 at 47 (citing Hosp. Prot. Act § 1(a)(2), (3)). But even assuming that is true, it does not constitute obstacle preemption.

Of course, drug manufacturers must "compl[y] with federal law." *Id.* But the 340B statute implicitly assumes that they must *also* comply with state law. *See supra* at 8. How else could the drugmakers and 340B Hospitals engage in "the [purchase and] sale . . . of . . . drugs," an activity over which the States have long exercised primary "regulat[ory]" control? *Whipple*, 256 U.S. at 45. Indeed, States set the medical standards of care through which drugs are "prescri[bed]" and

"administ[ered]." *Id.* And States make the laws that allow pharmacies and hospitals to exist. *See* Tenn. Code Ann. §§ 63-10-202, 68-11-202(a)(1). The 340B program, by contrast, regulates only the price that drugmakers must offer in the context of certain sales. *See Novartis*, 102 F.4th at 460; *Sanofi*, 58 F.4th at 699. And the program supplies its own means of ensuring "transparency," which do not require drug companies to assert a sweeping immunity from state law. Compl., D.1 at 47; *see Novartis*, 102 F.4th at 456; *Sanofi*, 58 F.4th at 700–03.

Third, PhRMA asserts that the Hospital Protection Act "turns the [Tennessee] Attorney General . . . into the arbiter of the scope of an acceptable federal offer and attached conditions." Compl., D.1 at 48. But this nub of an argument makes little sense. It seems to assert that a prohibition on *drug manufacturers* imposing "credentialing" requirements on 340B Hospitals somehow impacts the "certification requirements" imposed by *Congress* under federal law. *Id.* (quoting Hosp. Prot. Act § 1(a)(5)) (citing 42 U.S.C. § 256b(a)(7)). PhRMA cannot credibly conflate drugmakers' sales tactics with the 340B statute's actual requirements. *See supra* at 2–3. Nor does it have any basis for its barely related assertion that Congress alone controls all the "conditions" of 340B sales. Compl., D.1 at 48; *see supra* at 8.

Fourth, PhRMA says the Hospital Protection Act "reworks manufacturers' obligations under" federal law by "rewriting the terms of the required federal offer" and thereby "dramatically expand[ing] manufacturers' obligations." Compl., D.1 at 48. This argument misunderstands both the text of the 340B statute and the history of the 340B program. The text says nothing about "the terms of the required federal offer," *other than* that the offer set the price of drugs at the agreed-to discount. *Id.*; *see Novartis*, 102 F.4th at 460. And history shows that Congress assumed other terms would be negotiated — most notably the terms of delivery to contract pharmacies acting "on behalf of" the 340B Hospitals. Hosp. Prot. Act § 1(c); *see McClain*, 95 F.4th at 1144 (citing

Sanofi, 58 F.4th at 700). It is thus the drugmakers who have recently attempted to alter the program by "dramatically expand[ing]" the "obligations" of 340B Hospitals. Compl., D.1 at 48; *see Novartis*, 102 F.4th at 458; *Sanofi*, 58 F.4th at 701. Tennessee has the power to prevent this, and Congress has not clearly prohibited Tennessee from doing so. *See supra* at 8.

Fifth, PhRMA claims the Hospital Protection Act "skews the carefully balanced enforcement scheme enacted by Congress" for the 340B program. Compl., D.1 at 50. But the "penalties" imposed under the Hospital Protection Act cover Tennessee's restrictions, not violations of federal law. *Id.*; *see* Hosp. Prot. Act § 2. And that is true whether enforcement occurs through General Skrmetti or the private right of action. *See id.* "[T]he constitutional balance" of power dictates that States be allowed to enforce their own laws. *Bond II*, 572 U.S. at 862 (quoting *Bond I*, 564 U.S. at 222); *see AstraZeneca*, 766 F. Supp. 3d at 663–64. The notion that Tennessee somehow impedes federal regulation by enforcing complementary state laws has no merit. *See Murrill*, 2024 WL 4361597, at *9.

Finally, PhRMA briefly asserts "various [additional] ways" Tennessee law impedes congressional objectives, such as by "increas[ing] the cost" drugmakers pay to participate in the 340B program and "frustrating the disclosure of claims data" needed to "prevent duplicate discounting with the 'maximum fair prices' established under the Inflation Reduction Act." Compl., D.1 at 50–51 (citing 42 U.S.C. § 1396r-8(a)(5)(C)). But PhRMA fails to develop these additional ideas in any coherent manner. *See id.* And it is neither the Court's nor General Skrmetti's place to develop them on PhRMA's behalf. *See United States v. Sineneng-Smith*, 590 U.S. 371, 375–76 (2020). In any event, these ideas do not tread any ground left uncovered by PhRMA's other preemption arguments. In essence, they do no more than repackage PhRMA's *field* preemption argument. In so doing, they necessarily fail for all the reasons already given. *See supra* at 8–9.

Morrisey. Throughout its complaint, PhRMA resists the conclusions above by invoking *PhRMA v. Morrisey*, 760 F. Supp. 3d 439 (S.D. W.Va. 2024). *See* Compl., D.1 at 2, 7, 45, 49–50. But this Court should disregard *Morrisey* for several important reasons. To begin, the *Morrisey* court did not confront or address any of the serious threshold issues General Skrmetti has raised. *Compare* 760 F. Supp. 3d at 450 n.5, *with supra* Part I. *Morrisey* also ignores the presumption against preemption while conflating federal *law* with "widespread industry practice[s]." 760 F. Supp. 3d at 451. As a result, *Morrisey* presents a free-wheeling assessment of 340B's "purposes and objectives," unmoored from the terms of the statute *or* the litigating parties' real-world conduct. *Id.* 452 (quoting *Crosby*, 530 U.S. at 373). This Court should not follow that path. It exceeds the judicial power. *See supra* Part I. And it leads to errant results.

Indeed, *Morrisey*'s reasoning appears to suggest that *any* state law doing *anything* that "hampers" a drug company's access to information "creates an impermissible obstacle" to the (broadly conceived) "objective" of "preventing fraud" in the 340B program. 760 F. Supp. 3d at 432. And the *Morrisey* court improperly required the defendant state officers to *disprove* that sprawling line of reasoning, rather than requiring the plaintiffs to establish an entitlement to gather information by whatever means they deem most expedient. *See id.* The *Morrisey* court then addressed the West Virginia law's "[e]nforcement [p]rovisions" as an obstacle somehow separate from the law's substantive terms. *Id.*; *see id.* at 453–60. And within that lengthy analysis, the *Morrisey* court made several confusing and errant leaps.

Most notably, the analysis in *Morrisey* slips into nebulous hypotheticals best understood as addressing *impossibility* preemption, which assign fault to West Virginia for not making "federal compliance" a "defense" to hypothetical assertions of state-law liability. *Id.* at 455; *see id.* at 452, 459. Then, for reasons loosely couched in widespread private adoption of "the replenishment

model," *Morrissey* construes West Virginia law as regulating drug "price, not delivery." *Id.* at 455. At no point does the *Morrisey* court ground these concerns in the "part[ies]" or their specific, anticipated "injur[ies]." *L.W. I,* 73 F.4th at 415; *see Friends*, 108 F.4th at 437. And that fundamental flaw — more than anything else — explains the errant result reached in *Morrisey*.

The Eighth Circuit's decision in *PhRMA v. McClain*, 95 F.4th 1136 (8th Cir. 2024), by contrast, provides a crisp rejection of drugmakers' preemption arguments, laying down a holding from which the Sixth Circuit will not readily depart. *See Terry v. Tyson Farms, Inc.*, 604 F.3d 272, 278 (6th Cir. 2010). *McClain* gives proper weight to the presumption against preemption. *See* 95 F.4th at 1140, 1143–44. And it recognizes that federal law *requires* contract pharmacies to operate as "agent[s] of the" 340B Hospitals they serve. *Id.* at 1142; *see supra* at 2, 9–10; *AstraZeneca*, 766 F. Supp. 3d at 666; *AbbVie v. Fitch*, No. 1:24-cv-184, 2024 WL 3503965, at *13–15 (S.D. Miss. July 22, 2024). PhRMA thus errs by attempting to make a factual issue out of whether contract pharmacies take "title to [340B] drugs." Compl., D.1 at 24. This is not the forum to litigate whether the replenishment model violates federal law. Even assuming that were true, it would have nothing to do with the state-law restrictions imposed by the Hospital Protection Act.

B. Tennessee is not impermissibly regulating interstate commerce.

The second constitutional problem, according to PhRMA, is that the Hospital Protection Act violates the "dormant limitation on the States' power to regulate interstate commerce." *Garber v. Menedez*, 888 F.3d 839, 842 (6th Cir. 2018); *see* Compl., D.1 at 51–54. But neither new nor old jurisprudence leaves no room for this mistaken theory.

To begin, "[c]ompanies that choose to sell products in various States must normally comply with the laws of those various States." *Nat'l Pork Prods. Council v. Ross*, 598 U.S. 356, 364 (2023). And "[c]ourts generally reserve dormant Commerce Clause review for laws that protect in-state economic interests at the expense of out-of-state *competitors*." *Garber*, 888 F.3d at 843

(emphasis added). This "antidiscrimination principle lies at the 'very core' of . . . dormant Commerce Clause jurisprudence." *Ross*, 598 U.S. at 369 (quoting *Camps Newfound/Owatonna, Inc. v. Town of Harrison*, 520 U.S. 564, 581 (1997)). And the Supreme Court has never invoked that jurisprudence to "prevent a State from regulating the sale of an ordinary consumer good within its own borders on nondiscriminatory terms." *Id.* at 391.

Although PhRMA does characterize the Hospital Protection Act as "discriminatory," the law does not discriminate within the meaning of the caselaw just mentioned. Compl., D.1 at 54. That is, PhRMA could not and "does not [argue] that [Tennessee's new] law seeks to advantage in-state firms or disadvantage out-of-state *rivals*." *Ross*, 598 U.S. at 370 (emphasis added). And that's because the Hospital Protection Act applies to "drug manufacturer[s]," their "agent[s]," and "affiliate[s]," whether they are within or outside of Tennessee. Hosp. Prot. Act § 1(a); *see Flynt v. Bonta*, 131 F.4th 918, 927 (9th Cir. 2025). It thus does not matter that hospitals may be "[t]he legislative winners here" while drugmakers are "the losers." *N.J. Staffing All. v. Fais*, 110 F.4th 201, 207 (3d Cir. 2024). To run afoul of the dormant Commerce Clause, a law must favor "in-state economic interests" over "out-of-state *competitors*." *Garber*, 888 F.3d at 843 (emphasis added); *see Ross*, 598 U.S. at 369. In other words, there must be "'discrimination between similarly situated entities' within and outside the state." *Flynt*, 131 F.4th at 927 (quoting *Nat'l Ass'n of Optometrists & Opticians v. Brown*, 567 F.3d 521, 525 (9th Cir. 2009)).

Here, in lieu of a cogent theory regarding in-state favoritism, PhRMA claims that the Hospital Protection Act "regulates conduct occurring wholly beyond the borders of Tennessee." Compl., D.1 at 53. Unfortunately for PhRMA, this argument invokes "the very 'extraterritoriality doctrine' that" the Supreme Court has recently "rejected." *N.J. Staffing*, 110 F.4th at 205 n.2; *see Flynt*, 131 F.4th at 924. With that rejection, the Court has reaffirmed that Tennessee law *can*

regulate "out-of-state" sellers engaged in Tennessee-centric "transactions." Compl., D.1 at 53; *see Town of Smyrna v. Mun. Gas Auth. of Ga.*, 723 F.3d 640, 646 & n.3 (6th Cir. 2013). Of course, multinational drug companies would prefer to do business everywhere "on the terms they find most convenient." *Flynt*, 131 F.4th at 927 (quoting *Rocky Mt. Farmers Union v. Corey*, 730 F.3d 1070, 1092 (9th Cir. 2013); *see* Compl., D.1 at 54. But nothing in Commerce Clause jurisprudence comes anywhere close to compelling that result. *See Ross*, 598 U.S. at 364.

C. PhRMA's vagueness theory falls short.

In PhRMA's third try at a constitutional claim, it says the Hospital Protection Act is impermissibly vague. *See* Compl., D.1 at 55–58. But "[e]very reasonable construction must be resorted to, in order to save a statute from" fatal vagueness. *Colum. Nat. Res., Inc. v. Tatum*, 58 F.3d 1101, 1105 (6th Cir. 1995) (quoting *Chapman v. United States*, 500 U.S. 453, 464 (1991)); *accord Willeford v. Klepper*, 597 S.W.3d 454, 465 (Tenn. 2020)). And "[t]he root of [this] doctrine is a rough idea of fairness." *Colten v. Kentucky*, 407 U.S. 104, 110 (1972). Vagueness doctrine is not a license to manufacture "constitutional dilemma[s]" from the ever-present "practical difficulties" of legislative drafting. *Id.* Nonetheless, PhRMA errs by attempting just that.

To begin, the Hospital Protection Act does not "hand[] the Tennessee Attorney General virtually unlimited enforcement discretion." Compl., D.1 at 56. PhRMA aims this criticism at the statute's "'catch-all' provision," which allows the Attorney General to identify and address forms of "interference" that drug companies may yet invent and employ. *Id.*; *see* Hosp. Prot. Act § 1(a)(6). But contrary to PhRMA's contentions, the Tennessee General Assembly need not "define the term 'interfere'" for this provision to provide sufficient clarity. Compl., D.1 at 57.

Rather, "[t]he statute must simply put the [drugmakers] on notice that [they are] entering a potentially forbidden zone." *Tatum*, 58 F.3d at 1109; *N.J. Staffing*, 110 F.4th at 208. And "where the challenged language 'is commonly used in both legal and common parlance,' it often will be

'sufficiently clear so that a reasonable person can understand its meaning.'" *Platt v. Bd. of Comm'rs*, 894 F.3d 235, 247 (6th Cir. 2018) (quoting *Deja Vu of Cincinnati, L.L.C. v. Union Twp. Bd. of Trs.*, 411 F.3d 777, 798 (6th Cir. 2005) (en banc)).

The vagueness doctrine also "appl[ies] less strictly to economic regulations." *Johnson v. Morales*, 946 F.3d 911, 929 (6th Cir. 2020). And it leaves "substantially more room for imprecision" with respect to laws imposing the type of civil liability General Skrmetti can pursue. *Meriwether v. Hartop*, 992 F.3d 492, 518 (6th Cir. 2021) (quoting *Dade v. Baldwin*, 802 F. App'x 878, 885 (6th Cir. 2020)). This is so much the case that "[t]he Supreme Court has [not] held [a] civil statute unconstitutionally vague since [1966]." *Tatum*, 58 F.3d at 1108. So PhRMA must clear a high bar to succeed on its theory of unconstitutional vagueness.

PhRMA cannot hope to do so. The term "interfere" cannot just be "imprecise"; PhRMA "must prove that 'no standard of conduct is specified at all.'" *Id.* (quoting *United States v. Angiulo*, 897 F.2d 1169, 1179 (1st Cir. 1990)); *see N.J. Staffing*, 110 F.4th at 208 (citing *CMR D.N. Corp. v. City of Philadelphia*, 703 F.3d 612, 631–32 (3d Cir. 2013)). But the word "interfere" gives the text a distinct "core" that prevents drug companies from impeding 340B Hospitals' access to the 340B discount. *Tatum*, 58 F.3d at 1108; *see Fitch*, 2024 WL 3277365, at *14–15. "[E]ven if the words leave some wiggle room," PhRMA's members will receive notice from the Attorney General before facing liability. *Platt*, 894 F.3d at 247; *see* Tenn. Code Ann. § 47-18-108(a)(2). So while there may be "some imprecision" in the statute's terms, that does not render its text unconstitutionally vague. *Kutchinski ex rel. H.K. v. Freeland Cmty. Sch. Dist.*, 69 F.4th 350, 361 (6th Cir. 2023) (citing *Fowler v. Bd. of Educ.*, 819 F.2d 657, 665–66 (6th Cir. 1987)); *see N.J. Staffing*, 110 F.4th at 208. Several Courts have already held as much. *See Fitch*, 2024 WL 3277365, at *14–15; *Murrill*, 2024 WL 4361597, at *10. This Court should do the same.

Nor can PhRMA make up for the shortcomings in its vagueness argument by claiming that "First Amendment interests are implicated." Compl., D.1 at 55. Regulating "conduct . . . carried out by means of language" has "never been deemed an abridgement of free[] . . . speech." *United States v. Hansen*, 599 U.S. 762, 783 (2023) (quoting *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 502 (1949)). Instead, a law must "target *expression*" to trigger Free Speech Clause concerns. *Lichtenstein v. Hargett*, 83 F.4th 575, 584 (6th Cir. 2023); *see Rumsfeld v. F. for Acad. & Institutional Rts., Inc.* (*FAIR*), 547 U.S. 47, 61, 65 (2006) (citing *United States v. O'Brien*, 391 U.S. 367, 376 (1968)). And if it merely "bar[s] conduct based on the harm the conduct causes," it does not warrant special First Amendment treatment. *Lichtenstein*, 83 F.4th at 583.

Any other rule would upset our federal system and run the risk of frustrating the democratic process the First Amendment exists to serve. The Court should always use "history and tradition" as a guide when a party invokes First Amendment rights. *Vidal v. Elster*, 602 U.S. 286, 301 (2024). And federal courts have a well-established tradition of rejecting First Amendment arguments attempting to defend unlawful "conduct [that] incidentally involves speech." *Del Castillo v. Secretary*, 26 F.4th 1214, 1222 (11th Cir. 2022) (quoting *Nat'l Inst. of Family & Life Advocs. v. Becerra* (*NIFLA*), 585 U.S. 755, 768 (2018)). In "most instances," a person's "conduct" is "brought about through speaking and writing." *Giboney*, 336 U.S. at 502. But merely "integrat[ing]" language into one's conduct does not implicate core free-speech concerns. *Id.* at 498.

Here, the Hospital Protection Act does no more to implicate the First Amendment than would any other run-of-the-mill "business regulation." *Liberty Coins, LLC v. Goodman*, 748 F.3d 682, 691 (6th Cir. 2014). Nothing in the First Amendment gives drug companies a right to "conduct audits" of Tennessee's 340B Hospitals or otherwise "seek information" in ways prohibited by state law. Compl., D.1 at 55. And nothing in the Hospital Protection Act prevents drug

companies from "fil[ing] complaints" with the federal government. *Id.* at 57. PhRMA's invocation of the right to free speech thus makes sense only with respect to its concern that drug companies remain free to "publicize information about unlawful activity." *Id.* But contrary to PhRMA's belief, nothing in the Hospital Protection Act targets such communication.

Instead, the Hospital Protection Act merely keeps drug manufacturers from doing business with 340B Hospitals in various ways that impede those Hospitals' access to the 340B discount. *See supra* at 3. They can "publicize information" all they want — inside or outside that business relationship. Compl., D.1 at 57. But their attempts to gather such information through negotiating leverage constitute "business conduct," and the Hospital Protection Act "proscribes" only that business conduct, "not speech." *Liberty Coins*, 748 F.3d at 697. Of course, "[s]o long as we use words to govern conduct, there will be gray areas in the law." *Tatum*, 58 F.3d at 1109. But whether PhRMA invokes the First Amendment, the Fifth Amendment, or both, the Court has ample basis to dismiss PhRMA's void-for-vagueness claim.

III. The Court should foreclose PhRMA's pursuit of improper relief.

If the Court decides to go forward with this lawsuit, it should make clear that the stakes align with the "nature of the federal judicial power." *L.W. I*, 73 F.4th at 415. PhRMA cannot pursue a remedy any "broader than [what is] necessary" to cure proven "violation[s]" of PhRMA's constitutional rights. *Kallstrom*, 136 F.3d at 1069. So the Court must reject PhRMA's request for a broad "declar[ation]" of "unconstitutional[ity]." Compl., D.1 at 58. The only relief available is a "provision-by-provision" accounting of what actions General Skrmetti cannot take against PhRMA. *Doe v. Lee*, 102 F.4th 330, 340 (6th Cir. 2024).

CONCLUSION

For the reasons given above, this Court should dismiss PhRMA's lawsuit.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that I filed the above document using the Court's CM/ECF system on June 17, 2025, which electronically served a copy to all counsel of record::

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