

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI**

PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA,

Plaintiff,

v.

LYNN FITCH, in her official capacity as
ATTORNEY GENERAL OF THE STATE OF
MISSISSIPPI,

Defendant.

Case No. 1:24-cv-00160-HSO-BWR

**BRIEF OF *AMICI CURIAE* AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH,
MISSISSIPPI HOSPITAL ASSOCIATION, AND RURAL HOSPITAL ALLIANCE
IN SUPPORT OF DEFENDANT LYNN FITCH'S
OPPOSITION TO PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION**

George H. Ritter
WISE CARTER CHILD & CARAWAY, P.A.
401 East Capitol Street, Suite 600
Jackson, Mississippi 39201
Post Office Box 651
Jackson, Mississippi 39205
(P): 601-968-5500
(F): 601-944-7738
ghr@wisecarter.com
Counsel for Amici Curiae

TABLE OF CONTENTS

| | |
|--|----|
| TABLE OF AUTHORITIES | ii |
| INTERESTS OF <i>AMICI CURIAE</i> | 1 |
| BACKGROUND AND SUMMARY OF ARGUMENT | 2 |
| ARGUMENT | 5 |
| A. H.B. 728 Is Not Preempted By the 340B Statute..... | 5 |
| 1. 340B Does Not Occupy an Exclusively Federal Field. | 6 |
| 2. <i>Arizona v. United States</i> is Inapposite. | 8 |
| B. H.B. 728 Does Not Violate the Dormant Commerce Clause. | 9 |
| C. H.B. 728 is Not Unconstitutionally Vague. | 10 |
| CONCLUSION | 13 |

TABLE OF AUTHORITIES

CASES

| | |
|--|---------|
| <i>Abramski v. United States</i> , 573 U.S. 169 (2014)..... | 12 |
| <i>Altria Grp., Inc. v. Good</i> , 555 U.S. 70 (2008)..... | 7 |
| <i>Arizona v. United States</i> , 567 U.S. 387 (2012)..... | 6, 8, 9 |
| <i>Ass’n of Taxicab Operators USA v. City of Dallas</i> , 720 F.3d 534 (5th Cir. 2013) | 6 |
| <i>Bates v. Dow Agrosiences LLC</i> , 544 U.S. 431 (2005)..... | 7 |
| <i>City of Columbus v. Ours Garage & Wrecker Serv., Inc.</i> , 536 U.S. 424 (2002)..... | 6 |
| <i>Crosby v. Nat’l Foreign Trade Council</i> , 530 U.S. 363 (2000)..... | 6 |
| <i>English v. Gen. Elec. Co.</i> , 496 U.S. 72 (1990)..... | 7, 8 |
| <i>Ford Motor Co. v. Tex. Dep’t Transp.</i> , 264 F.3d 493 (5th Cir. 2001) | 10 |
| <i>Hillsborough Cnty. v. Automated Med. Labs., Inc.</i> , 471 U.S. 707 (1985)..... | 8 |
| <i>Hines v. Davidowitz</i> , 312 U.S. 52 (1941)..... | 6 |
| <i>Hoyt v. Sprague</i> , 103 U. S. 613 (1881)..... | 9 |
| <i>Hurley v. Lederle Labs. Div. of Am. Cyanamid Co.</i> , 863 F.2d 1173 (5th Cir. 1988) | 8 |
| <i>MacDonald v. Monsanto Co.</i> , 27 F.3d 1021 (5th Cir. 1994) | 4 |
| <i>McKinney ex rel. NLRB v. Creative Vision Res. LLC</i> , 783 F.3d 293 (5th Cir. 2015) | 5 |

| | |
|---|-------------|
| <i>Medtronic, Inc. v. Lohr</i> , 518 U.S. 470 (1996)..... | 5, 6 |
| <i>Mock v. Garland</i> , 75 F.4th 563 (5th Cir. 2023) | 4 |
| <i>Murphy v. NCAA</i> , 138 S. Ct. 1461 (2018)..... | 7 |
| <i>N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.</i> , 514 U.S. 645 (1995)..... | 6 |
| <i>N.Y. State Dep’t of Soc. Servs. v. Dublino</i> , 413 U.S. 405 (1973)..... | 7 |
| <i>Nat’l Press Photographers Ass’n v. McCraw</i> , 84 F.4th 632 (5th Cir. 2023) | 6 |
| <i>National Pork Producers Council v. Ross</i> , 598 U.S. 356 (2023)..... | 4, 5, 9, 10 |
| <i>Pharm. Care Mgmt. Ass’n v. Wehbi</i> , 18 F.4th 956 (8th Cir. 2021)..... | 4 |
| <i>PhRMA v. McClain</i> , 95 F.4th 1136 (8th Cir. 2024) | 2, 4, 12 |
| <i>Planned Parenthood of Houston & S.E. Tex v. Sanchez</i> , 403 F.3d 324 (5th Cir. 2005) | 6 |
| <i>Rex Distrib. Co., Inc. v. Anheuser-Busch, LLC</i> , 271 So. 3d 445 (Miss. 2019)..... | 11 |
| <i>State Farm Ins. Company v. Gay</i> , 526 So.2d 534 (Miss. 1988)..... | 12 |
| <i>United Motorcoach Ass’n, Inc. v. City of Austin</i> , 851 F.3d 489 (5th Cir. 2017) | 5, 6 |
| <i>United States v. Clinical Leasing Serv., Inc.</i> , 925 F.2d 120 (5th Cir. 1991) | 10 |
| <i>Winter v. Natural Res. Def. Council, Inc.</i> , 555 U.S. 7 (2008)..... | 5 |
| STATUTES | |
| 15 U.S.C. § 77kk(c) | 11 |

| | |
|---|--------------------|
| 18 U.S.C. § 245(b) | 11 |
| 21 U.S.C. § 355-1 | 3 |
| 29 U.S.C. § 158(a) | 11 |
| 29 U.S.C. § 2615(a)(1)..... | 11 |
| 42 U.S.C. § 256b(a)(1)(4)..... | 2 |
| 42 U.S.C. § 256b(a)(5)(B) | 7 |
| 42 U.S.C. § 3617..... | 11 |
| 47 U.S.C. § 333..... | 11 |
| Miss. Code Ann. § 1-3-65 (Rev. 2005)..... | 11 |
| Miss. Code H.B. 728..... | 3, 4, 6, 9, 10, 12 |

OTHER AUTHORITIES

| | |
|---|----|
| 340B Informed, <i>Drugmakers Cutting 340B Discounts Reported Record Revenues in 2021</i> (updated Jan. 13, 2023)..... | 3 |
| Merriam-Webster Dictionary, (last visited June 22, 2024)..... | 10 |
| Black’s Law Dictionary (10th ed. 2014)..... | 10 |
| Maya Goldman, <i>Hospital Groups Worry As More Drugmakers Limit 340B</i> <i>Discounts</i> , Modern Healthcare (Mar. 25, 2022) | 3 |
| <i>Mississippi 340B Hospitals Serve More Patients With Low Incomes and Provide</i> <i>the Majority of Hospital Care to Medicaid Patients</i> , Dobson DaVanzo Health Economics Consulting | 3 |

RULES

| | |
|-----------------------------------|---|
| Fed. R. App. P. 29(a)(4)(A) | 1 |
|-----------------------------------|---|

INTERESTS OF *AMICI CURIAE*¹

Amici are four hospital associations whose members receive 340B discounts for drugs that they purchase, many of which are dispensed through contract pharmacies. *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 Mississippi'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. The AHA promotes the interests of its members by participating as *amicus curiae* in cases with important and far-ranging consequences for their members, 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 1,500 public and private nonprofit hospitals and health systems participating in the 340B program.

The **Mississippi Hospital Association** (MHA) represents approximately 82 hospital members, many of which participate in the 340B program and are impacted by efforts of drug companies to limit access to 340B-discounted drugs. Among its many services, MHA develops and improves healthcare policy through legislative, regulatory, and judicial processes.

The **Rural Hospital Alliance** (RHA) represents the interests of Mississippi rural hospitals. Its mission includes assisting rural hospitals with their unique and often challenging issues,

¹ Pursuant to Fed. R. App. P. 29(a)(4)(A), *Amici Curiae* state that that they are not-for-profit organizations. None of *Amici* has a parent company, and no publicly traded company holds ten percent or more interest in any of *Amici*.

including through advocacy for federal and state legislation to maintain and improve rural healthcare. Many RHA members participate in the 340B program and are impacted by the efforts of drug companies to reduce distribution of 340B-acquired drugs.

BACKGROUND AND SUMMARY OF ARGUMENT²

Beginning almost four years ago, amid a devastating pandemic, multiple drug companies—many of which are members of Plaintiff Pharmaceutical Research and Manufacturers of America (PhRMA)—started to break with decades of precedent and devised a plan to undermine the 340B drug discount program. Under that program, drug companies that participate in Medicaid and Medicare Part B must provide discounts on drugs sold to patients of certain nonprofit or public hospitals and community health centers. *See* 42 U.S.C. § 256b(a)(1)(4). Before 2020, drug companies had provided drug pricing discounts to eligible hospitals for drugs dispensed *both* through in-house pharmacies and community pharmacies with which the hospitals had contracts. *See PhRMA v. McClain*, 95 F.4th 1136, 1139 (8th Cir. 2024) (“For 25 years, drug manufacturers . . . distributed 340B drugs to covered entities’ contract pharmacies.”). But in July 2020, one drug company suddenly refused to provide these discounts for one of its drugs if dispensed to 340B patients at community pharmacies (or contract pharmacies), later expanding

² *Amici* earlier filed a brief in *Novartis v. Fitch*, No. 1:24-cv-00164-HSO-BWR, ECF No. 13 (AHA *Novartis Amicus* Br.). *Amici* refer the Court to that brief for the background on Mississippi’s 340B hospitals’ use of contract pharmacy arrangements, their significant benefit to Mississippi’s neediest patients, and a more extensive discussion of the appropriate preemption analysis. *Amici* largely focus this brief on new or distinct issues PhRMA raises in its motion for a preliminary injunction.

this new policy to cover essentially all its drugs.³ Recognizing an opportunity to boost their own bottom lines, 35 other major drug companies quickly followed suit.⁴

The contract pharmacy arrangements that drug companies honored for almost 30 years served as a cornerstone of the program—helping to sustain hospitals operating on razor-thin margins and their patients, many of whom are indigent. Now, the restrictions drug companies have imposed on contract pharmacies have substantially cut the savings from the 340B program, which is devastating for the very hospitals in Mississippi that provide 82% of all hospital care that is provided to Medicaid patients.⁵ And, of course, this means that patients lose services.

Faced with the drug industry’s unprecedented assault on Mississippi’s health care safety net, the Mississippi legislature responded. By an overwhelming bipartisan 132/33 vote, it passed a new law, entitled “Defending Affordable Prescription Drug Costs Act.” *See* Miss. Code H.B. 728, Section 4.⁶ This law prohibits 340B manufacturers from directly or indirectly denying, restricting, prohibiting, discriminating against, or otherwise limiting the acquisition or delivery of 340B drugs by/to pharmacies that are authorized by covered entities to receive 340B drugs on their behalf, unless such limitation is required under 21 U.S.C. § 355-1.⁷ Any violation of this provision

³ *See* Maya Goldman, *Hospital Groups Worry As More Drugmakers Limit 340B Discounts*, Modern Healthcare (Mar. 25, 2022), <https://www.modernhealthcare.com/safety-net-hospitals/hospitals-worry-more-drugmakers-limit-340b-discounts>.

⁴ Collectively, 19 of these companies made more than \$660 billion in profits in 2021. *See* 340B Informed, *Drugmakers Cutting 340B Discounts Reported Record Revenues in 2021* (updated Jan. 13, 2023), <https://340binformed.org/2023/01/updated-drugmakers-cutting-340b-discounts-reported-record-revenues-in-2021/>.

⁵ *Mississippi 340B Hospitals Serve More Patients With Low Incomes and Provide the Majority of Hospital Care to Medicaid Patients*, Dobson DaVanzo Health Economics Consulting, <https://www.340bhealth.org/files/MS-340B-Low-Income15022.pdf>.

⁶ The text of the statute can be found at <https://legiscan.com/MS/text/HB728/2024>.

⁷ *Id.* 21 U.S.C. § 355-1 is a provision that permits the U.S. Food and Drug Administration to require a drug to have in place a Risk Evaluation and Management Strategy, pursuant to which, among other things, the distribution of a drug may be limited. 21 U.S.C. § 355-1.

is considered an unfair, abusive, or deceptive trade practice, subject to enforcement and penalties under the Mississippi Consumer Protection Act. H.B. 728, Section 5.

PhRMA now seeks a preliminary injunction that would halt Mississippi's lawful exercise of its police power to protect public health and safety. The motion for preliminary injunction should be denied because PhRMA cannot demonstrate that it is likely to succeed on the merits. "[T]here is authority" in this Circuit that likelihood of success "is the most important of the preliminary injunction factors." *Mock v. Garland*, 75 F.4th 563, 587 n.60 (5th Cir. 2023). And here, PhRMA has no chance of success. *First*, H.B. 728 is not preempted because Congress did not create or occupy any field through its 340B legislation, nor does H.B. 728 conflict with the 340B statute. *See PhRMA v. McClain*, 95 F.4th at 1143–45. *Second*, PhRMA's argument that the Mississippi statute violates the dormant Commerce Clause ignores the Supreme Court's analysis in *National Pork Producers Council v. Ross*, 598 U.S. 356 (2023). That case eviscerates their dormant Commerce Clause claim. *Third*, H.B. 728 is not unconstitutionally vague.

At bottom, PhRMA takes the position that whenever Congress creates a detailed federal program, that comprehensiveness wrests traditional police power from the States. That has never been the rule in our federal system. It is especially untrue in this instance because "[p]harmacy has traditionally been regulated at the state level, and we must assume that absent a strong showing that Congress intended preemption, state statutes that impact health and welfare are not preempted." *PhRMA v. McClain*, 95 F.4th at 1144 (citing *Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956, 972 (8th Cir. 2021); *see MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1023 (5th Cir. 1994). Likewise, PhRMA's sweeping reading of the dormant Commerce Clause, which would essentially bar any state law that has extraterritorial effects, was rejected just a year ago by the Supreme Court. *See Nat'l Pork Producers*, 598 U.S. at 375. Indeed, like the petitioners in that

case, PhRMA’s “‘almost *per se*’ rule against laws that have the ‘practical effect’ of ‘controlling’ extraterritorial commerce would cast a shadow over laws long understood to represent valid exercises of the States’ constitutionally reserved powers.” *Id.* Invalidating Mississippi’s valid exercise of State authority would turn upside down the very “federalism concerns” that underlie preemption questions, *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996), upend “the historic primacy of state regulation of matters of health and safety,” *id.*, and gut the basic constitutional principle that “[c]ompanies that choose to sell products in various States must normally comply with the laws of those various States.” *Nat’l Pork Producers*, 598 U.S. at 364.

ARGUMENT

To meet the requirements for a preliminary injunction, PhRMA must establish (1) that it is likely to succeed on the merits; (2) that it is likely to suffer irreparable harm in the absence of preliminary relief; (3) that the balance of equities tips in its favor; and (4) that an injunction is in the public interest. *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *see also McKinney ex rel. NLRB v. Creative Vision Res. LLC*, 783 F.3d 293, 297 (5th Cir. 2015). PhRMA fails to establish that it has met any of these factors. *Amici* focus primarily on arguments they did not address in their brief in their AHA *Novartis Amicus Br.* and incorporate that brief by reference.

A. H.B. 728 Is Not Preempted By the 340B Statute.

“In determining a federal statute’s preemptive reach, congressional purpose is ‘the ultimate touchstone.’” *United Motorcoach Ass’n, Inc. v. City of Austin*, 851 F.3d 489, 492 (5th Cir. 2017) (quoting *Medtronic*, 518 U.S. at 485). In every preemption case, “and particularly in those in which Congress has ‘legislated in a field which the States have traditionally occupied,’” *Medtronic*, 518 U.S. at 485 (citation omitted), 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,” *United Motorcoach*, 851 F.3d at 492 (quoting *City of Columbus v. Ours*

Garage & Wrecker Serv., Inc., 536 U.S. 424, 432 (2002)). PhRMA has the burden to show that Congress intended to preempt H.B. 728. *See Planned Parenthood of Houston & S.E. Tex v. Sanchez*, 403 F.3d 324, 336 (5th Cir. 2005).

PhRMA does not claim that H.B. 728 is expressly preempted. Nor does it deny that States have police power over public health policy, including the regulation of healthcare. *See, e.g., N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995) (recognizing the regulation of healthcare as a “field[] of traditional state regulation”); *Ass’n of Taxicab Operators USA v. City of Dallas*, 720 F.3d 534, 538 (5th Cir. 2013) (same regarding public safety). Thus, unlike state laws that intrude into uniquely federal areas such as immigration and foreign relations, H.B. 728 is presumptively *not* preempted.⁸ PhRMA therefore must demonstrate Congress’s “clear and manifest purpose” to supersede Mississippi’s historic authority to regulate in the public health arena, *Medtronic*, 518 U.S. at 485 (citation omitted), which it has failed to do. For all of the reasons set forth more fully in the AHA *Novartis Amicus* Br. at 8–15, and for two additional reasons, H.B. 728 is not subject to field or conflict preemption. *First*, PhRMA’s contention that 340B is a “closed system” cannot establish that the program occupies an exclusively federal field. *Second*, PhRMA’s reliance on *Arizona v. United States*, 567 U.S. 387 (2012), a Supreme Court case premised on the federal government’s historic, exclusive power to regulate immigration, is misplaced.

1. 340B Does Not Occupy an Exclusively Federal Field.

“Field preemption of state law is disfavored.” *Nat’l Press Photographers Ass’n v. McCraw*, 84 F.4th 632, 657 (5th Cir. 2023). Indeed, “when the text of a pre-emption clause is susceptible of more than one plausible reading, courts ordinarily ‘accept the reading that disfavors pre-emption.’”

⁸ *See, e.g., Arizona v. United States*, 567 U.S. 387 (2012) (immigration); *Crosby v. Nat’l Foreign Trade Council*, 530 U.S. 363 (2000) (national security); *Hines v. Davidowitz*, 312 U.S. 52 (1941) (immigration).

Altria Grp., Inc. v. Good, 555 U.S. 70, 77 (2008) (quoting *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005)). In rare instances, it “occurs when federal law occupies a ‘field’ of regulation ‘so comprehensively that it has left no room for supplementary state legislation.’” *Murphy v. NCAA*, 138 S. Ct. 1461, 1480 (2018) (citation omitted). Courts acknowledge that “[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 rejected “the contention that pre-emption is to be inferred merely from the comprehensive character” of federal provisions. *Id.*; see also *English v. Gen. Elec. Co.*, 496 U.S. 72, 87 (1990). With the 340B program, “a detailed statutory scheme was both likely and appropriate, completely apart from any questions of pre-emptive intent.” *Dublino*, 413 U.S. at 415.

PhRMA erroneously argues that the “closed nature” of the 340B program supports its contention that Congress intended to occupy the field through the program. See PhRMA Mem. at 15. PhRMA lists components of the federal scheme as proof of Congress’s intent to create an exclusively federal field. Specifically, PhRMA notes that Congress (i) “carefully enumerated the fifteen categories of intended beneficiaries—the covered entities—with a high degree of specificity”; (ii) “carefully delineated the obligation of manufacturers, providing that they must ‘offer’ drugs to ‘covered entities’ with a specific ‘price’ term—the 340B ‘ceiling price’”; (iii) “barred covered entities from ‘reselling or otherwise transferring’ 340B-discounted drugs ‘to a person who is not a patient of the entity,’” *id.* (alterations adopted) (quoting 42 U.S.C. § 256b(a)(5)(B)); and (iv) “created a multi-faceted administrative enforcement scheme centralized within [the U.S. Department of Health and Human Services (HHS)].” PhRMA Mem. at 15–16. These features of the 340B program do not support the conclusion that Congress intended to create an exclusively federal field into which Mississippi may

not tread. The fact that Congress limited which providers can participate in the 340B program, dictated the maximum price at which drug companies can sell 340B drugs, prohibited duplicate discounts and diversion of 340B drugs, and developed federal enforcement mechanisms to enforce those requirements and prohibitions does not show that Congress intended to create (or occupy) a field. If it did, every time Congress created a federal program, it would create an exclusively federal field into which States cannot intrude. But that is not the law. *See English*, 496 U.S. at 89 (“Absent some specific suggestion in the text or legislative history of § 210 [of the Energy Restoration Act of 1974], which we are unable to find, we cannot conclude that Congress intended to pre-empt all state actions that permit the recovery of exemplary damages.”) (emphasis added); *Hillsborough Cnty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 717 (1985) (“To infer pre-emption whenever an agency deals with a problem comprehensively is virtually tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive. Such a rule, of course, would be inconsistent with the federal-state balance embodied in our Supremacy Clause jurisprudence.”); *Hurley v. Lederle Labs. Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1177 (5th Cir. 1988) (“[Appellant] also argues that the Public Health Service Act and its attendant regulations represent a pervasive federal scheme, and as such, preempt state law products liability for vaccine manufacturers. As Justice Marshall explains in *Hillsborough*, this argument is over inclusive.”).

2. *Arizona v. United States* is Inapposite.

PhRMA also tries to sidestep the well-established high bar for field preemption by arguing that “*Arizona*’s logic dictates the outcome here,” *see* PhRMA Mem. at 21, but that contention ignores how the unique context of immigration dictated the Supreme Court’s analysis in that case. In *Arizona*, the Court found that federal law preempted an Arizona statute imposing criminal penalties for violations of federal immigration registration requirements. 567 U.S. at 393–94. The Court did *not* find preemption merely because of the comprehensive nature of the federal law.

Rather, as the Court emphasized, “[t]he federal power to determine immigration policy is well settled,” in part because “[i]t is fundamental that foreign countries concerned about the status, safety, and security of their nationals in the United States must be able to confer and communicate on this subject with one national sovereign, not the 50 separate States.” *Id.* at 395; *see id.* at 394–95 (citations omitted) (“The Government of the United States has broad, undoubted power over the subject of immigration and the status of aliens. This authority rests, in part, on the National Government’s constitutional power to ‘establish a uniform Rule of Naturalization,’ and its inherent power as sovereign to control and conduct relations with foreign nations.”). In stark contrast to immigration regulation, the 340B program and H.B. 728 address matters of public health and safety—matters that are squarely within the historic police powers of the States.

B. H.B. 728 Does Not Violate the Dormant Commerce Clause.

PhRMA argues that H.B. 728 violates the dormant Commerce Clause because it regulates conduct “wholly outside of” Mississippi. *See* PhRMA Mem. at 31. But that contention is directly foreclosed by *National Pork Producers Council v. Ross*, 598 U.S. 356 (2023).

As a factual matter, H.B. 728 applies *only* to 340B drugs dispensed to patients of *Mississippi* 340B hospitals pursuant to contract pharmacy arrangements. Even to the extent H.B. 728, like “many (maybe most) state laws,” may *indirectly* impact “extraterritorial behavior” for drug companies that are headquartered outside of Mississippi, *see Nat’l Pork Producers*, 598 U.S. at 374, H.B. 728 itself in no way targets “the sale and terms of the sale of drugs by manufacturers that occur wholly outside of the state.” PhRMA Mem. at 31. To the contrary, H.B. 728 is focused entirely on drug distribution to patients of Mississippi hospitals. Thus, even if PhRMA had a valid legal theory about extraterritorial effects, it would not apply to H.B. 728 on the facts. *See Nat’l Pork Producers*, 598 U.S. at 375 (quoting *Hoyt v. Sprague*, 103 U. S. 613, 630 (1881)) (“[T]his

Court has recognized the usual “legislative power of a State to act upon persons and property within the limits of its own territory.”).

But, critically, PhRMA has no valid legal theory. *National Pork Producers* flatly rejected the kind of “almost *per se*” extraterritoriality rule that PhRMA seeks here, holding that the dormant Commerce Clause does *not* forbid “enforcement of state laws that have the “practical effect of controlling commerce outside the State.” *Nat’l Pork Producers*, 598 U.S. at 371. Instead, *National Pork Producers* explained that the “very core” of its dormant Commerce Clause jurisprudence is the “antidiscrimination principle,” *i.e.*, prohibiting States from engaging in “economic protectionism” by privileging in-state competitors over out-of-state competitors. *Id.* at 369. Here, PhRMA does not claim that Mississippi’s state law is in some way discriminatory against out-of-state manufacturers. Nor could they. The law treats in-state and out-of-state manufacturers the same. PhRMA should not be permitted to revive this “extraterritoriality doctrine” just one year after the Supreme Court rejected it. *Id.* at 371.

C. H.B. 728 is Not Unconstitutionally Vague.

An economic regulation is invalid “only if it commands compliance in terms ‘so vague and indefinite as really to be no rule or standard at all’ . . . or if it is ‘substantially incomprehensible.’” *Ford Motor Co. v. Tex. Dep’t Transp.*, 264 F.3d 493, 507 (5th Cir. 2001) (citing *United States v. Clinical Leasing Serv., Inc.*, 925 F.2d 120, 122 n. 2 (5th Cir. 1991)). That is not the case here.

That H.B. 728 does not include a definition of “interference” does not render the statute unconstitutionally vague.⁹ “Interfere” as used in H.B. 728 is not unconstitutionally vague because

⁹ Black’s Law Dictionary defines “interference” as “[t]he act of meddling in another’s affairs” or “[a]n obstruction or hindrance.” *Interference*, Black’s Law Dictionary (10th ed. 2014). Merriam-Webster defines “interfere” as “to enter into or take a part in the concerns of others,” “to interpose in a way that hinders or impedes,” or “to act reciprocally so as to augment, diminish, or otherwise affect one another.” *Interfere*, Merriam-Webster Dictionary, <https://www.merriam-webster.com/dictionary/interfering> (last visited June 22, 2024).

drug “manufacturer[s] or distributor[s]”—the only entities subject to the provisions’ prohibitions—can readily assess what conduct is prohibited by its terms. Indeed, countless criminal and civil statutes prohibit “interference” without expressly defining the term. The Supreme Court of Mississippi, for example, has upheld the application of a state law that used the term “interfere” without providing a statutory definition based on the “the oft-cited (and statutorily mandated) rule of statutory interpretation that nontechnical [w]ords contained in statutes are to be interpreted ‘according to their common and ordinary acceptance and meaning.’” *Rex Distrib. Co., Inc. v. Anheuser-Busch, LLC*, 271 So. 3d 445, 455 (Miss. 2019) (cleaned up) (quoting Miss. Code Ann. § 1-3-65 (Rev. 2005)). And there are numerous examples in the U.S. Code. *See, 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) (“Whoever . . . by force or threat of force willfully injures, intimidates or interferes with, or attempts to injure, intimidate or interfere with [specified persons] shall be fined . . . or imprisoned . . .”); 29 U.S.C. § 158(a) (“It shall be an unfair labor practice for an employer [] to interfere with, restrain, or coerce employees in the exercise of the rights . . . [or] to dominate or interfere with the formation or administration of any labor organization . . .”); 29 U.S.C. § 2615(a)(1) (“It shall be unlawful for any employer to interfere with, restrain, or deny the exercise of or the attempt to exercise, any right . . .”); 42 U.S.C. § 3617 (“It shall be unlawful to coerce, intimidate, threaten, or interfere with any person in the exercise or enjoyment of . . .”); 47 U.S.C. § 333 (“No person shall willfully or maliciously interfere with or cause interference to any radio communications . . .”). Thus, finding the term “interfere”

to render H.B. 728 unconstitutionally vague would have vast repercussions throughout the various civil and criminal codes of Mississippi and the nation.

In any event, it is disingenuous for PhRMA to argue that its members do not understand what is meant by “interference.” Mississippi and the six other states that have passed these laws are specifically responding to the drug companies’ efforts, since 2020, to restrict the use of contract pharmacies. The drug companies know exactly what the law is aimed at preventing. Courts must “interpret the relevant words not in a vacuum, but with reference to the statutory context, ‘structure, history, and purpose.’” *Abramski v. United States*, 573 U.S. 169, 179 (2014) (citation omitted). And to the extent there is any doubt, the Mississippi courts recognize the “doctrine of ‘noscitur a sociis,’ the philosophy of which is that the meaning of a doubtful word may be ascertained by reference to words associated with it,” meaning that the term “interference” can be considered in the context of the surrounding words “deny,” “restrict,” and “prohibit.” *State Farm Ins. Company v. Gay*, 526 So.2d 534, 537 (Miss. 1988).

Moreover, H.B. 728 is not, as PhRMA implies, seeking to prevent drug companies from utilizing the federal statute’s audit and ADR mechanisms. In fact, the new law explicitly states that it does not preempt the 340B statute. H.B. 728, section 6. As the Eighth Circuit has recognized in upholding an analogous Arkansas state law, the ADR mechanisms provided by the 340B statute are wholly separate from the enforcement mechanism of H.B. 728. “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*, 95 F.4th at 1144. In contrast, H.B. 728 provides that the Mississippi Attorney General enforce H.B. 728’s state-law requirement that drug manufacturers not deny the 340B discount to covered entities that dispense 340B drugs to their patients at contract pharmacies.

CONCLUSION

For the foregoing reasons, and those outlined in Defendant's response, *Amici* respectfully request that the Court deny PhRMA's motion for a preliminary injunction.

Respectfully submitted,

/s/ George H. Ritter
George H. Ritter
WISE CARTER CHILD & CARAWAY, P.A.
401 East Capitol Street, Suite 600
Jackson, Mississippi 39201
Post Office Box 651
Jackson, Mississippi 39205
(P): 601-968-5500
(F): 601-944-7738
ghr@wisecarter.com

Counsel for Amici Curiae