IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF ARKANSAS
CENTRAL DIVISION

FILED
U.S. DISTRICT COURT
EASTERN DISTRICT ARKANSAS
SEP 29 2021
TAMMY H. DOWNS, CLERK
By: DEP CLERK

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff,

v.

ALAN MCCLAIN, in his official capacity as Commissioner of the Arkansas Insurance Department, and LESLIE RUTLEDGE, in her official capacity as Attorney General of Arkansas,

Defendants.

No. 4:21-cv-864-LPR

This case assigned to District Judge Rudofsky
and to Magistrate Judge Ervin

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Pharmaceutical Research and Manufacturers of America ("PhRMA") represents the nation's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that help patients to live longer and healthier lives. PhRMA brings this complaint for declaratory and injunctive relief against Alan McClain, in his official capacity as Commissioner of the Arkansas Insurance Department, and Leslie Rutledge, in her official capacity as Attorney General of Arkansas.

PRELIMINARY STATEMENT

1. In recent years, a nationwide dispute has arisen regarding the use of so-called "contract pharmacies" under what is known as the federal "340B" drug discount program. The core of the dispute is between drug manufacturers, on the one hand, and for-profit pharmacies (including national pharmacy chains and other private entities) on the other. PhRMA members believe that for-profit pharmacy interests (and others) have found illegal ways to leverage the 340B discounts to their financial benefit, often without assisting the vulnerable patient populations that the 340B program was intended to help. Litigation brought by PhRMA members on these issues is proceeding in federal district courts in Maryland, Indiana, Delaware, New Jersey, and the District of Columbia.

2. This case challenges Ark. Code Ann.§ § 23-92-604(c)(1)–(2), the provisions in Act 1103 that purport to mandate federal 340B program pricing for certain pharmacies in Arkansas (the "340B pricing mandate provisions"). The Arkansas legislature enacted Act 1103 in May 2021. Enforcement of the statute is currently stayed by the Arkansas Insurance Department, the agency charged with its implementation and enforcement. Act 1103's 340B pricing mandate provisions impermissibly wade into the dispute concerning the operations of the federal 340B program by attempting to regulate and alter the operations of that program as a matter of state law. The provisions impose requirements that squarely conflict with a comprehensive federal program

and that impair the program's efficacy, and they purport to regulate commercial transactions occurring entirely outside of Arkansas. Arkansas Code Annotated § 23-92-604(c) is accordingly invalid under the Supremacy and Commerce Clauses of the U.S. Constitution, and its application should be enjoined.

3. Congress enacted the 340B Drug Pricing Program, 42 U.S.C. § 256b ("340B"), in 1992. The 340B program requires that drug manufacturers—as a condition of having their covered outpatient drugs reimbursed under Medicare Part B or the federal share of the Medicaid Drug Rebate Program—also provide substantial discounts on such drugs to fifteen specified types of healthcare providers ("covered entities") that generally treat indigent, uninsured, and other vulnerable patient populations. *See id.* § 256b(a)(4). The principal aim of the 340B program was to assist these covered entities and their patients financially. Congress contemplated that the covered entities would pass the drug discounts they receive under the 340B program on to the vulnerable patient populations that they serve. *See* H.R. Rep. No. 102-384, pt. 2, at 12 (1992).

4. To effectuate the requirements of the 340B program, Congress instructed the Secretary of the U.S. Department of Health and Human Services ("HHS") to "enter into an agreement with each manufacturer of covered outpatient drugs"—known as a pharmaceutical pricing agreement ("PPA")—capping the drug prices those manufacturers may charge covered entities. 42 U.S.C. § 256b(a)(1). These agreements between HHS and manufacturers reflect the statutory requirements of the 340B program and list the responsibilities of drug manufacturers under the program.

5. Act 1103, Arkansas's "340B Drug Pricing Nondiscrimination Act," seeks to regulate manufacturers' participation in this completely *federal* program. In particular, Act 1103 requires manufacturers to provide 340B pricing not just to the fifteen types of "covered entities"

that Congress specified in the statute, but also to any Arkansas ***pharmacies*** with whom the covered entities may choose to enter into a contract arrangement. Moreover, Act 1103 appears to require manufacturers to provide 340B pricing not only for outpatient drugs prescribed for a covered entity's patients, but also in many other circumstances where the federal 340B program does not provide for any discount at all. The requirements imposed on manufacturers by Act 1103 do not appear anywhere in the 340B statute or in PPAs between manufacturers and HHS.

6. Quite the opposite—Act 1103's requirements related to manufacturers directly conflict with explicit requirements in both the federal 340B statute and the PPAs. The 340B statute defines the entities eligible to receive 340B pricing, and those entities do *not* include pharmacies. As one federal court recently explained: "It is hard to believe that Congress enumerated 15 types of covered entities with a high degree of precision and intended to include contract pharmacies as a 16th option by implication." *AstraZeneca Pharms. LP v. Becerra*, No. 1:21-cv-00027-LPS, 2021 WL 2458063, at *10 (D. Del. June 16, 2021). The 340B statute also expressly *prohibits* a *covered entity* from reselling or otherwise transferring a drug purchased at the 340B price to anyone other than its patients: "With respect to any covered outpatient drug that is subject to an agreement under this subsection, a *covered entity* shall not resell or *otherwise transfer* the drug to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B) (emphasis added). This federal statutory prohibition contains no exception allowing the Government to mandate that drug manufacturers provide 340B pricing to for profit "contract pharmacies" outside covered entities. And this prohibition establishes that—as a matter of federal law—the only patients allowed to receive 340B discounted drugs are a *covered entity's* patients.

7. Act 1103, by contrast, purports to require drug manufacturers to transfer drugs at 340B prices to any Arkansas-based pharmacy that maintains a contract arrangement with a covered

entity—regardless of the ultimate recipients of the drugs. Act 1103 does this by barring manufacturers from "[p]rohibit[ing] a pharmacy from contracting or participating with an entity authorized to participate in 340B drug pricing" and from "[d]eny[ing] or prohibit[ing] 340B drug pricing for an Arkansas-based community pharmacy that receives drugs purchased under a 340B drug pricing contract pharmacy arrangement." Ark. Code Ann. § 23-92-604(c)(1)–(2).

8. So Act 1103 allows a covered entity to contract with any pharmacy in Arkansas, allows such pharmacies to access a covered entity's 340B pricing, and requires manufacturers to honor that arrangement—an arrangement that is presently at the center of numerous active federal court cases. In other words, Act 1103 effectively seeks to pencil a sixteenth type of covered entity into the federal 340B statute.

9. Other conflicts abound. For example, Congress prohibits manufacturers from dispensing certain drugs at a 340B price in the manner that Act 1103 contemplates—due to drug safety risk evaluation and mitigation strategy ("REMS") requirements or limited distribution plans. *See, e.g.*, 21 U.S.C. § 355-1. And the federal agency that implements the 340B program, the Health Resources and Services Administration ("HRSA"), has specifically instructed how manufacturers can and should comply with the 340B statute's requirements—instructions that Act 1103 appears to countermand. *See infra* ¶¶ 32–35. These and other requirements of Act 1103 are irreconcilable with the 340B statute and program.

10. Act 1103 also improperly intrudes in a field regulated comprehensively by Congress. Congress has carefully balanced the rights and responsibilities of participants in the 340B program, and has crafted a carefully calibrated scheme by, among other things: (1) enumerating the specific "covered entities" eligible to receive 340B pricing, 42 U.S.C. § 256b(a)(1); (2) placing particular obligations on such covered entities (including prohibiting

duplicate discounts and the diversion of drugs purchased at a 340B price as discussed *infra* ¶¶ 28, 35, 42–43), *e.g.*, *id.* § 256b(a)(5), (d)(2); (3) providing mechanisms for resolution of disputes among manufacturers and covered entities through audit and Administrative Dispute Resolution ("ADR") processes, *e.g.*, *id.* § 256b(d)(1)(B)(v), (d)(3); and (4) addressing enforcement of any violations of the 340B statute or agreement with civil monetary penalties and appropriate procedural safeguards, *e.g.*, *id.* § 256b(d)(1)(B)(vi), (d)(2)(B)(v). There is no room for Arkansas to step into this comprehensive federal regime and impose and enforce its own separate and conflicting requirements.

11. For these and other reasons, Act 1103's 340B pricing mandate provisions are preempted by federal law. *See Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 486 (2013) (holding that when "federal law forbids an action that state law requires" it is preempted); *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000) (where state law stands as an "obstacle to the accomplishment and execution of the full purposes and objectives of Congress," it is preempted (citation omitted)); *McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 316 (1819); *Arizona v. United States*, 567 U.S. 387, 399 (2012) ("[T]he States are precluded from regulating conduct in a field that Congress, acting within its proper authority, has determined must be regulated by its exclusive governance.").

12. Act 1103's 340B pricing mandate provisions also violate the Commerce Clause. The Supreme Court has long held that no state may "project its legislation into [another state] by regulating the price to be paid in that state for [goods] acquired there," even if the goods at issue are destined for resale in the regulating state. *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 521 (1935). Indeed, any "state law that has the 'practical effect' of regulating commerce occurring wholly outside that State's borders" "exceeds the inherent limits of the enacting State's authority"

and "is invalid under the Commerce Clause." *Healy v. Beer Inst.*, 491 U.S. 324, 332, 336 (1989) (citation omitted). Arkansas Code Annotated § 23-92-604(c) is a textbook violation of this extraterritoriality principle. The practical effect of Act 1103's 340B pricing mandate provisions is to directly regulate two types of wholly out-of-state transactions: (1) transactions between manufacturers (including certain of PhRMA's members) and their wholesale-distributor partners, the vast majority of which take place outside of Arkansas; and (2) transactions between manufacturers and out-of-state "covered entities" that are entitled to benefits under the federal 340B program.

13. For these and other reasons, PhRMA brings this lawsuit seeking a declaration that Ark. Code Ann. § 23-92-604(c) is both preempted and unconstitutional, and requests an injunction barring Defendants from enforcing it against PhRMA and its members.

PARTIES

14. Plaintiff PhRMA is a trade association representing the nation's leading innovative biopharmaceutical research companies. PhRMA's members, which manufacture and sell pharmaceutical products, participate in the federal 340B program.

15. Defendant Alan McClain is Commissioner of the Arkansas Insurance Department. In that role, he implements and enforces the challenged legislation. This suit is brought against him in his official capacity only.

16. Defendant Leslie Rutledge is the Attorney General of Arkansas, the chief law enforcement officer of the state. This suit is brought against her in her official capacity only.

JURISDICTION AND VENUE

17. PhRMA`s causes of action arise under 28 U.S.C. § 1331, 42 U.S.C. § 1983, and the United States Constitution. The Court has jurisdiction under 28 U.S.C. §§ 1331 and 1343(a)(3).

18. The Declaratory Judgment Act provides that, in a case of actual controversy within its jurisdiction, a United States court may declare the rights and other legal relations of any interested party seeking such declaration. 28 U.S.C. § 2201(a).

19. This Court has inherent equitable powers to enjoin the actions of state officials if they contradict the federal Constitution or federal law. *Ex parte Young*, 209 U.S. 123, 159–60 (1908); *accord, e.g.*, *Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689 (1949).

20. Venue is proper in this district because this action challenges an Arkansas law, passed in and administered from Little Rock, which is within this district. 28 U.S.C. § 1391(b)(1).

BACKGROUND

A. The Federal 340B Program

21. Congress established the 340B program in 1992 to "provide[] protection from drug price increases to specified Federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans." H.R. Rep. No. 102-384, pt. 2, at 12 (1992). To that end, the federal 340B statute "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health care facilities," known as "covered entities," that provide healthcare to certain underserved populations. *Pharm. Rsch. & Mfs. of Am. v. HHS*, 43 F. Supp. 3d 28, 31 (D.D.C. 2014) (quoting *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 113 (2011)).

22. The federal 340B program now accounts for nearly 10% of all prescription-drug sales in the United States.

23. The 340B program is governed by a federal statutory framework, implemented by HRSA, a federal agency within HHS. Under the federal 340B statute, participating manufacturers must offer to each "covered entity" (as defined by the federal 340B statute) all "covered outpatient drugs" (as defined by the 340B statute) at or below the applicable "ceiling price" (another term defined by the 340B statute) "if such drug[s are] made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1).

24. Federal law defines "covered entity" for purposes of the 340B statute to mean "an entity that meets the requirements described in paragraph (5)," which restricts unlawful transfers and duplicate discounts (*see infra* ¶¶ 28, 35, 42–43), and that "is one of" fifteen types of specifically enumerated categories of nonprofit healthcare providers. 42 U.S.C. § 256b(a)(4). For instance, Federally-Qualified Health Centers, children's hospitals, rural hospitals, and other clinics serving vulnerable populations are all specifically defined as "covered entities" eligible to enroll and participate in the 340B program. *Id.*; *see also Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 820–22 (D.C. Cir. 2020). Retail pharmacies, including "Arkansas-based community pharmacies," are not among the listed covered entities.

25. Federal law defines "covered outpatient drug" for purposes of the 340B program to have "the meaning given such terms in section 1927(k) of the Social Security Act [42 U.S.C. § 1396r-8(k)]," 42 U.S.C. § 256b(b)(1), which in turn generally defines this term (subject to exceptions) to mean drugs and biologics approved by the federal Food and Drug Administration ("FDA") to "be dispensed only upon prescription," *id.* § 1396r-8(k)(2)(A). Covered outpatient drugs do *not* include, *inter alia*, drugs or biological products provided "as part of, or as incident to and in the same setting as" inpatient hospital services, hospice services, dental services, physicians' services, or outpatient hospital services and "for which payment may be made . . . as

part of payment for" these services "and not as direct reimbursement for the drug." *Id.* § 1396r-8(k)(3). In other words, 340B pricing is available for outpatient drugs that are separately payable from medical services, and not for inpatient drugs.

26. Federal law defines the "ceiling price" for purposes of the 340B program to mean "the maximum price that covered entities may permissibly be required to pay for the drug." *Id.* § 256b(a)(1). Federal law also provides that participating manufacturers shall "calculate[]" the ceiling price by determining the difference between the drug's "Average Manufacturer Price" and its Medicaid rebate amount, as both are determined under Section 1927 of the Social Security Act, the Medicaid Drug Rebate Program statute. *Id.* § 256b(a)(1); *see also* 42 C.F.R. § 10.10 ("Ceiling price for a covered outpatient drug"). In plain English, the ceiling price is the highest price a manufacturer may charge to 340B covered entities for a covered outpatient drug on 340B purchases. That ceiling price is deeply discounted compared to the drug's ordinary price.

27. Only "covered entities" may receive these "ceiling price" discounts under the express terms of federal law. *See* 42 U.S.C. § 256b(a)(1). For-profit hospitals and commercial businesses such as retail pharmacies, including community pharmacies, are not entitled to receive 340B pricing. *See id.*

28. To the contrary, the 340B statute forbids covered entities from "resell[ing] or otherwise transfer[ring]" a covered outpatient drug "to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B). In other words, covered entities are prohibited from providing 340B-covered outpatient drugs to anyone but their own patients. As some PhRMA members argue in related litigation against HRSA, the 340B statute provides no exception from this broad prohibition—not for contract pharmacies or anyone else. *See, e.g.*, *Eli Lilly & Co. v. Becerra*, No. 1:21-cv-81 (S.D. Ind. May 10, 2021), ECF 89 at 29 ("But the plain text of the statute of course does not bless such

arrangements; rather, its prohibition against diversion ***explicitly disallows them***." (emphasis added)).

29. Congress has not expressly commanded pharmaceutical manufacturers to participate in the federal 340B program. *See Astra USA*, 563 U.S. at 117–18. As a practical matter, however, manufacturers' participation in the 340B program is far from optional: Manufacturers cannot have any of their products reimbursable under either Medicare Part B or the federal share of Medicaid—programs that provide access to two enormously important patient populations—unless they participate in the 340B program. 42 U.S.C. § 1396r-8(a)(1), (5).

30. Manufacturers "opt into" the 340B program by signing a form contract with HHS "for covered drugs purchased by 340B entities." *Astra*, 563 U.S. at 113. That form contract is known as the Pharmaceutical Pricing Agreement, or PPA. *Id.* at 117. A PPA is no ordinary contract. Rather, PPAs are drafted entirely by HHS, they "have no negotiable terms," and they "simply incorporate statutory obligations and record the manufacturers' agreement to abide by them." *Id.* at 111, 118. "The statutory and contractual obligations, in short, are one and the same." *Id.* at 118. The federal government may terminate a PPA if it determines that a manufacturer has breached its obligations under the 340B statute, including its obligation to offer "covered entities" "covered outpatient drugs" at or below the applicable "ceiling price." *See* 42 U.S.C. § 1396r-8(b)(4)(B)(v); Manufacturer Audit Guidelines and Dispute Resolution Process 0905–ZA–19, 61 Fed. Reg. 65,406, 65,412–13 (Dec. 12, 1996); Dep't of Health & Human Servs., Health Res. & Servs. Admin., *General Instructions for Completing the Pharmaceutical Pricing Agreement* §§ IV(c), VI(c), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/pharmaceutical-pricing-agreement-example.pdf (last reviewed Sept. 27, 2021).

31. The 340B statute assigns oversight and enforcement responsibilities exclusively to HHS, which in turn has delegated the 340B program's oversight and enforcement to HRSA. Neither the 340B statute nor any federal regulations promulgated under it authorize, envision, or create room for state regulation regarding these issues within or on top of the 340B program.

32. Congress has also specified the audit, dispute-resolution, and enforcement mechanisms for the 340B program. For instance, the statute specifies that manufacturers have a right to audit covered entities to ensure that the covered entity is complying with the 340B program's requirements. 42 U.S.C. § 256b(a)(5)(C). Manufacturers, in turn, are also subject to compliance audits. *Id.* § 256b(d)(1)(B)(v).

33. HRSA evaluates manufacturers' compliance with the 340B statute's requirements and may seek to have HHS impose civil monetary penalties on manufacturers that purposefully charge covered entities more than the statutory 340B ceiling price for covered outpatient drugs. Specifically, HRSA may seek to have HHS impose civil monetary penalties of nearly $6,000 "for each instance of overcharging" a covered entity. Annual Civil Monetary Penalties Inflation Adjustment, 85 Fed. Reg. 2,869, 2,873 (Jan. 17, 2020) (final rule); *see also* 42 U.S.C. § 256b(d)(1)(B)(vi); 42 C.F.R. § 10.11(a). "Overcharging" refers to charging a covered entity a price above the applicable 340B "ceiling price." Congress has specified that these civil monetary penalties can attach to manufacturers only where they "knowingly and intentionally" overcharge. 42 U.S.C. § 256b(d)(1)(B)(vi)(III).

34. The 340B statute also provides for resolving 340B program disputes between manufacturers and covered entities via an ADR process to be established through "[r]egulations promulgated by the Secretary [of Health and Human Services]." Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7102(a), 124 Stat. 119, 826–27 (2010) (codified at 42 U.S.C.

§ 256b(d)(3)) (amending the statute to require HHS to promulgate regulations establishing ADR). These regulations must "designate or establish a decision-making official or body within [HHS] to be responsible for reviewing and finally resolving claims by covered entities that they have been charged prices for covered outpatient drugs in excess of the ceiling price . . . and claims by manufacturers that violations of [statutory prohibitions on conduct like unlawful transfer to non-covered entities] have occurred." *Id.* (codified at 42 U.S.C. § 256b(d)(3)(B)(i)). Regulations also must be designed with such safeguards and "procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously"—including required audits and discovery. 42 U.S.C. § 256b(d)(3)(B). To ensure finality and repose, the statute provides that "administrative resolution of a claim or claims . . . shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction." *Id.* § 256b(d)(3)(C).

35. Covered entities must also comply with additional requirements under the 340B statute. For example, covered entities are prohibited from "resell[ing] or otherwise transfer[ring] the drug to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B) (prohibiting unlawful transfers, known as diversion). And covered entities are prohibited from seeking unlawful "duplicate discounts or rebates" from manufacturers. 42 U.S.C. § 256b(a)(5)(A). Such "duplicate discounting" most often occurs when a covered entity obtains a drug at a 340B price and dispenses it to a Medicaid patient, and the manufacturer then also pays a Medicaid rebate to the state Medicaid agency on the same drug.

B. Contract Pharmacy Abuses And Resulting Litigation

36. As noted above, the 340B statute requires that a manufacturer offer discounted prices only to a "covered entity." 42 U.S.C. § 256b(a)(1). Retail pharmacies, including

community-based pharmacies, are not "covered entit[ies]," so they are ineligible to receive 340B discounts.

37. But certain private entities—including commercial pharmacies—have in increasing numbers sought to leverage the 340B program as a tool to enhance their profitability in a way that Congress never intended. This is accomplished through complicated contractual arrangements between a covered entity, a pharmacy, and typically other entities like a third-party administrator. The core feature of these arrangements is that the for-profit pharmacies end up obtaining drugs purchased at the 340B price. These contract pharmacies, however, serve not only patients of 340B covered entities, but the general public as well—despite the fact that 340B-covered outpatient drugs are permitted to be dispensed only to patients of 340B covered entities.

38. Between 2010 and 2018, the number of such contract pharmacy arrangements with covered entities exploded, increasing "more than fifteen-fold, from about 1,300 to approximately 20,000 [as of 2018]." U.S. Gov't Accountability Off., GAO-18-480, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 10 (June 2018) ("2018 GAO Report"), https://www.gao.gov/assets/gao-18-480.pdf. A more recent study put the increase at 4,228%, with now "more than 27,000 individual pharmacies (almost one out of every three pharmacies)" participating in the 340B program as contract pharmacies. Aaron Vandervelde et al., *For-Profit Pharmacy Participation in the 340B Program* at 4, Berkeley Rsch. Grp. (Oct. 2020), https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf. By 2020, each covered entity used an average of 22 contract pharmacies. *Id.* at 7. And the number of actual claims for 340B discounts nationwide *tripled* between 2014 and 2019. *See* Adam J. Fein, *New HRSA Data: 340B Program Reached*

$29.9 billion in 2019; Now Over 8% of Drug Sales, Drug Channels, (June 9, 2020), https://www.drugchannels.net/2020/06/new-hrsa-data-340b-program-reached-299.html.

39. Several federal watchdogs, including the U.S. Government Accountability Office ("GAO") and HHS's own Office of the Inspector General ("OIG"), have warned that the growth of these arrangements exacerbates concerns about fraud and unlawful 340B discounting. *See* 2018 GAO Report at 44 ("The identified noncompliance at contract pharmacies raises questions about the effectiveness of covered entities' current oversight practices."); *id.* at 45 ("The expansion of contract pharmacies . . . increases potential risks to the 340B Program, such as risks related to diversion and duplicate discounts.").

40. Here is how the system has evolved over recent years: Often with the assistance of specialized consultants, thousands of retail pharmacies (including the nation's largest pharmacy chains) conduct undisclosed data analyses to "find" new opportunities to retroactively claim 340B discounts on drugs already sold to patients at a non-340B price. Then contract pharmacies and others obtain additional drugs purchased at the 340B prices (with the help of a covered entity) to "replenish" their general inventories, with no intention of selling (dispensing) those new drugs solely to patients of the covered entities. So the contract pharmacy replenishes non-340B drugs at a commercial price, and then comingles all replenished units when it adds them to its inventory.

41. This "replenishment" practice, when employed, does not pass 340B program discounts on to patients (*i.e.*, the people that Congress intended to benefit from the 340B program)—but it can enhance the profitability of the pharmacies and covered entities involved. *See Examining Oversight Reports on the 340B Drug Pricing Program: Hearing Before the S. Comm. on Health, Educ., Labor, & Pensions*, 115th Cong. 11 (2018) (testimony of Ann Maxwell, Assistant Inspector Gen. for Evaluation & Inspections, OIG) ("[M]any contract pharmacies

dispense drugs to all of their customers—340B-eligible *or otherwise*—from their *regular* inventory." (emphasis added)); U.S. Gov't Accountability Off., GAO-20-108, *340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements* 5 (Dec. 2019), https://www.gao.gov/assets/gao-20-108.pdf (explaining that covered entities "purchase [340B program] drugs at the 340B Program price for all eligible patients regardless of the patients' income or insurance status" and "receiv[e] reimbursement from patients' insurance that may exceed the 340B prices paid for the drugs"); Decl. of Krista M. Pedley, *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Human Servs.*, No. 21-cv-634 (D.N.J. June 24, 2021), ECF No. 93-2 (HRSA Director of Office of Pharmacy Affairs stating that under the replenishment system, contract pharmacies use stock replenished at 340B prices as "neutral inventory" that "may be dispensed to any subsequent patient").

42. The use of contract pharmacies can also exacerbate unlawful "duplicate discounting." 42 U.S.C. § 256b(a)(5)(A)(i). As described *supra* ¶ 35, unlawful duplicate discounting forces the manufacturer to provide a discount on its drug twice-over—once on the front end to the covered entity, and again on the back end in the form of a rebate to the state Medicaid agency. Under the 340B statute, Congress placed responsibility for preventing such unlawful duplicate discounts on covered entities. GAO has found that duplicate discounting happens with outsized frequency when covered entities use contract pharmacies. *See, e.g.*, 2018 GAO Report at 45; *see generally* U.S. Gov't Accountability Off., GAO-20-212, *340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement* (Jan. 2020), https://www.gao.gov/assets/gao-20-212.pdf.

43. Besides diverting discounts intended for vulnerable populations, the explosion in contract pharmacy arrangements has also led to an increase in unlawful transfers of drugs

purchased at a 340B price (so-called "diversion"). *See, e.g.*, 42 U.S.C. § 256b(a)(5)(B) (prohibiting transfer or sale to anyone "who is not a patient of the [covered] entity"); U.S. Gov't Accountability Off., GAO-11-836, *Drug Pricing, Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 28 (Sept. 2011), https://www.gao.gov/assets/gao-11-836.pdf ("Operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies."). Indeed, approximately two-thirds of violations for diversion uncovered by HRSA audits "involved drugs distributed at contract pharmacies." 2018 GAO Report at 44.

44. The explosion in contract pharmacy arrangements, and the replenishment model specifically, led in part to certain PhRMA members independently adopting new policies directed at addressing the 340B program abuses reported by federal watchdogs. *See, e.g.*, *AstraZeneca Pharms. LP v. Becerra*, No. 1:21-cv-00027-LPS (D. Del. Feb. 12, 2021), ECF 13 at 17–19.

45. In response, the General Counsel of HHS issued a legal opinion on December 30, 2020, purporting to interpret the 340B statute and declaring that "*to the extent* contract pharmacies are acting as *agents* of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." HHS, Off. of the Sec'y, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program at 1 (Dec. 30, 2020) ("Advisory Opinion"), https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf (last reviewed Sept. 27, 2021) (emphasis added); *AstraZeneca*, 2021 WL 2458063, at *6 ("[T]he [Advisory] Opinion is the first document in which HHS explicitly concluded that *drug manufacturers* are required *by statute* to provide 340B drugs to *multiple* contract pharmacies."). In May 2021, HRSA issued letter decisions to the manufacturers who

were implementing policies to address the 340B program's abuses. HRSA asserted that the manufacturers were in violation of the 340B statute and threatened them with penalties. *See* HRSA, 340B Drug Pricing Program, *HRSA Determines Six Pharmaceutical Manufacturers Are In Violation of the 340B Statute*, https://www.hrsa.gov/opa/index.html (last reviewed Sept. 27, 2021).

46. Litigation ensued. Multiple pharmaceutical manufacturers—including several PhRMA members—sued HHS, HRSA, and relevant government officials, in their official capacities, in federal courts across the country. Among other things, these suits challenge the Advisory Opinion, HRSA's current view that pharmaceutical manufacturers are required to honor an unlimited number of contract pharmacy arrangements, as well as certain 340B ADR regulations. *See Eli Lilly & Co. v. Becerra*, No. 1:21-cv-81 (S.D. Ind.) (complaint filed Jan. 12, 2021); *AstraZeneca Pharms. LP v. Becerra*, No. 1:21-cv-00027-LPS (D. Del.) (complaint filed Jan. 12, 2021); *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Human Servs.*, No. 3:21-cv-00634-FLW-LHG (D.N.J.) (complaint filed Jan. 12, 2021); *Novo Nordisk Inc. v. U.S. Dep't of Health & Human Servs.*, No. 3:21-cv-00806-FLW-LHG (D.N.J.) (complaint filed Jan. 15, 2021); *Novartis Pharms. Corp. v. Becerra*, No. 1:21-cv-01479 (D.D.C.) (complaint filed May 31, 2021); *United Therapeutics Corp. v. Espinosa*, No. 1:21-cv-1686-DLF (D.D.C.) (complaint filed June 23, 2021); *cf. Pharm. Rsch. & Mfrs. Ass'n of Am. v. Becerra*, No. 21-cv-00198-PWG (D. Md.) (complaint filed Jan. 22, 2021). These cases thus implicate the very federal policy that Arkansas's Act 1103 purports to regulate.

47. On March 16, 2021, Judge Barker, presiding over the *Lilly* case in the United States District Court for the Southern District of Indiana, granted Lilly's motion for a preliminary injunction. Judge Barker enjoined (as to Lilly) the enforcement of HHS and HRSA's new ADR regulation, which would have governed the process for resolving particular disputes under the

340B program. *See* Order Granting Plaintiffs' Motion for Preliminary Injunction at 1, *Lilly*, No. 1:21-cv-81 (S.D. Ind. Mar. 16, 2021), ECF No. 81 (enjoining application of 42 C.F.R. §§ 10.20-24).

48. On June 16, 2021, Chief Judge Stark, presiding over the *AstraZeneca* case in the United States District Court for the District of Delaware, issued a decision holding that the 340B statute does not unambiguously require manufacturers to provide 340B pricing to contract pharmacies and concluding that the Advisory Opinion was unlawful. *AstraZeneca*, 2021 WL 2458063, at *8–9, 11. On June 17, 2021, one day after Chief Judge Stark's opinion, HHS withdrew the Advisory Opinion. Chief Judge Stark subsequently entered an order vacating the Advisory Opinion. *See* Order at 3, *AstraZeneca*, No. 1:21-cv-00027-LPS (D. Del. June 30, 2021), ECF No. 83.

49. Other courts will soon issue more decisions addressing the use of contract pharmacies. For example, Judge Friedrich in the United States District Court for the District of Columbia scheduled an expedited summary-judgment hearing for October in the *Novartis* and *United Therapeutics* cases. And cross-motions for summary judgment have been fully briefed since the end of July in *Novo Nordisk* and *Sanofi-Aventis* pending in the United States District Court for the District of New Jersey, so rulings in those matters are likely to issue soon as well.

50. Notably, the federal government has changed its position as these cases have progressed. For example, HHS and HRSA no longer purport to rely on the notion that contract pharmacies operate in a *principal-agent* relationship with covered entities (as the Advisory Opinion asserted)—likely because there is no evidence to support that notion. *See, e.g.*, *United Therapeutics Corp. v. Espinosa*, No. 1:21-cv-1686-DLF (D.D.C. Aug. 10, 2021), ECF No. 17 at 24 n.4 (defendant conceding that HRSA no longer relies on any "so-called 'principal-agency

rationalization'" and thus "does not rest on the assumption that a covered entity and its contract pharmacies are 'legally one and the same'").

C. Arkansas Enacts Act 1103 To Impose State-Law Conditions On The Federal 340B Program

51. On May 3, 2021, as these lawsuits about the use of contract pharmacies in the 340B program were well underway, Arkansas enacted Act 1103, the "340B Drug Pricing Nondiscrimination Act" (formerly known as Arkansas House Bill 1881).

52. Act 1103 expressly provides that its regulatory object is the federal 340B program. *See* Ark. Code Ann. § 23-92-601 (title); § 23-92-602(5) ("'340B drug pricing' means the program established under section 602 of the Veterans Health Care Act of 1992, Pub. L. No. 102-585.").

53. Act 1103 does not specify any source for the state's purported authority to add requirements to a comprehensive federal healthcare program.

54. Act 1103 applies to all 340B-eligible drugs, including FDA approved drugs subject to a REMS under 21 U.S.C. § 355-1.

55. Act 1103 enacts Ark. Code Ann. § 23-92-604(c)(1), which instructs that "[a] pharmaceutical manufacturer shall not . . . [p]rohibit a pharmacy from contracting or participating with an entity authorized to participate in 340B drug pricing by denying access to drugs that are manufactured by the pharmaceutical manufacturer."

56. This provision contains no geographical limit.

57. Act 1103 also enacts Ark. Code Ann. § 23-92-604(c)(2), which mandates that "[a] pharmaceutical manufacturer shall not . . . [d]eny or prohibit 340B drug pricing for an Arkansas-based community pharmacy that receives drugs purchased under a 340B drug pricing contract pharmacy arrangement with an entity authorized to participate in 340B drug pricing."

58. Section 23-92-604(c)(2)'s phrase "an Arkansas-based community pharmacy" is the sole geographical limit on this provision's reach. But Act 1103 does not define "Arkansas-based" (or "community pharmacy"), so it is unclear whether this refers to the physical location of the pharmacy, the corporate headquarters of it or its parent company, or something else.

59. Act 1103 lacks any geographical limitation for the "entity authorized to participate in 340B drug pricing," *i.e.*, the covered entity. Ark. Code Ann. § 23-92-604(c)(1).

60. Act 1103's text nowhere requires that drugs purchased at a 340B price that are provided to a pharmacy be dispensed only to patients of a covered entity.

61. Act 1103 also does not account for HRSA's enforcement authority or the Congressionally mandated safeguards for administrative dispute resolution under the 340B program.

62. Arkansas Code Annotated § 23-92-606 provides that "[t]he Insurance Commissioner shall promulgate rules to implement this subchapter." To date, no such rules have been promulgated.

63. Act 1103 was to take effect on July 28, 2021, by operation of law.

64. On July 28, 2021, PhRMA petitioned Defendant Alan McClain, Commissioner of the Arkansas Insurance Department, for declaratory relief about enforcement of Sections 23-92-604(c)(1) and (c)(2), enacted by Act 1103. PhRMA asked that the Commissioner stay enforcement of these provisions (1) pending decisions in the ongoing federal suits against HHS and HRSA about the use of contract pharmacies in the 340B program, or (2) for at least 120 days. PhRMA further reserved the right to ask a federal court to decide whether Sections 23-61-604(c)(1) and (c)(2) are preempted or otherwise invalid under federal law—noting that under Arkansas law the Insurance Department "is not empowered or authorized" to decide "constitutional objections." Ex.

1, PhRMA Petition for Declaratory Relief ¶ 21, *In Re Act 1103*, AID No. 2021-37 (citing Declaratory Order ¶ 11, *In re Rate and Form Review Time Periods Under Ark. Code Ann. § 23-79-109*, AID No. 2016-091); *see also, e.g.*, *AT&T Commc'ns. of the Sw., Inc. v. Ark. Pub. Serv. Comm'n*, 344 Ark. 188, 196, 40 S.W.3d 273, 279 (2001) (agencies cannot decide constitutional challenges because "to allow the [agency] to declare unconstitutional a statute that it was required to enforce would violate the separation of powers doctrine" (citing *Lincoln v. Ark. Pub. Serv. Comm'n*, 313 Ark. 295, 854 S.W.2d 330 (1993))).

65. That same day, the Commissioner granted PhRMA's petition in part and suspended enforcement of Sections 23-61-604(c)(1) and (c)(2) for 90 days, until October 26, 2021. The provisions of Act 1103 challenged in this Complaint have thus not yet taken effect.

CLAIMS FOR RELIEF

CLAIM I
(Declaratory/Injunctive Relief—Preemption Under The Federal 340B Statute)

66. PhRMA re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

67. Federal law is "the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2.

68. Act 1103's 340B pricing mandate provisions (and certain related provisions) are preempted because they conflict with the federal 340B program. Conflict preemption "occurs where either 'compliance with both state and federal law is impossible' or 'the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Soo Line R.R. Co. v. Werner Enters.*, 825 F.3d 413, 420 (8th Cir. 2016) (quoting *Oneok, Inc. v. Learjet, Inc.*, 575 U.S. 373, 377 (2015)). A conflict exists between the 340B statute and federal

PPAs, on the one hand, and Act 1103's 340B pricing mandate provisions, on the other, for several reasons.

69. *First*, Congress placed strict limits on the types of entities entitled to 340B pricing and the types of patients that may receive drugs sold at a 340B price. Specifically, Congress provided that only "covered entities" are eligible to receive 340B discounts, and it expressly defined that term to include only fifteen enumerated types of medical facilities. Neither contract pharmacies nor "community pharmacies" are among the fifteen enumerated covered entities. Congress, therefore, did not intend for retail pharmacies to receive discounted 340B pricing. *See Meese v. Keene*, 481 U.S. 465, 484 (1987) ("It is axiomatic that the statutory definition of [a] term excludes unstated meanings of that term."); *Colautti v. Franklin*, 439 U.S. 379, 392 n.10 (1979) ("[A] definition which declares what a term 'means' . . . excludes any meaning that is not stated.").

70. Congress also expressly prohibited any covered entity from reselling or otherwise transferring a drug bought at the 340B price to anyone other than its patients: "With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or *otherwise transfer* the drug to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B) (emphasis added). Several PhRMA members have taken the position in pending litigation that because a retail pharmacy is not a "patient of [a covered] entity," it is prohibited by federal statute from receiving 340B-program drugs. *See, e.g.*, *Eli Lilly & Co.*, No. 1:21-cv-81 (S.D. Ind. May 10, 2021), ECF No. 89 at 29. At a minimum, it is clear that the 340B statute does not expressly allow *covered entities* to transfer drugs to retail pharmacies or require manufacturers to engage in such transfers on behalf of covered entities. Moreover, the federal transfer prohibition also makes clear that the only individuals eligible to receive 340B-covered outpatient drugs are patients of a covered entity.

71. Act 1103's 340B pricing mandate provisions, by contrast, purport to *require* drug manufacturers to transfer drugs at 340B prices to any "Arkansas-based community pharmacy" that maintains a contract with a covered entity—a requirement that can be found nowhere in federal law. It also appears to require manufacturers to do so without regard to whether those drugs will ultimately be dispensed to any patient of a covered entity—without regard to the requirements of federal law.

72. Act 1103 does these things by barring pharmaceutical manufacturers from "[p]rohibit[ing] a pharmacy from contracting or participating with an entity authorized to participate in 340B drug pricing" and from "[d]eny[ing] or prohibit[ing] 340B drug pricing for an Arkansas-based community pharmacy that receives drugs purchased under a 340B drug pricing contract pharmacy arrangement." Ark. Code Ann. § 23-92-604(c)(1)–(2). Act 1103 does not define or otherwise provide any limits on what constitutes a valid "340B drug pricing contract pharmacy arrangement"; apparently, manufacturers are obligated to honor any such arrangement that might be agreed upon between a covered entity and a pharmacy, regardless of the ultimate disposition of the drugs under the arrangement. *Id.* § 23-92-604(c)(2). These requirements are irreconcilable with the federal 340B statute.

73. *Second*, Congress established a process for policing 340B compliance and resolving disputes between manufacturers and covered entities through audit procedures and ADR—including claims that a manufacturer's prices exceed the applicable price ceiling—and delegated authority to the HHS Secretary to develop the specifics of such procedures under federal law. *See* 42 U.S.C. § 256b(d)(1)(B)(v), (d)(3). In doing so, Congress specifically required that these procedures "ensure that claims shall be resolved fairly, efficiently, and expeditiously," and conferred in some instances the right to an audit or discovery. 42 U.S.C. § 256b(d)(3)(B)(ii). And

Congress required that such dispute-resolution outcomes would be final, thus ensuring repose. *See supra* ¶ 34.

74. Other provisions of Act 1103 address how that statute's 340B pricing mandate provisions must be implemented and disputes regarding the pricing mandate resolved—and those too are in conflict with federal law, imposing additional and conflicting requirements related to 340B-program dispute resolution. To the extent that these additional and conflicting provisions impact the 340B pricing mandate provisions challenged here, they are at odds with the federal program. *See* Ark. Code Ann. § 23-92-604(a)(4), § 23-92-605. Such requirements, which are fundamentally intertwined with the central contract pharmacy provisions challenged here, purport to limit the extent to which manufacturers and 340B covered entities may contest whether certain contract pharmacy claims are or are not subject to 340B pricing—and in this context they conflict with the procedures established by the 340B statute and HHS.

75. A parallel, state-imposed dispute resolution system "is hardly what Congress contemplated when it centralized [340B] enforcement in the [federal] government." *Astra USA*, 563 U.S. at 119. As the Supreme Court held in *Astra USA*, no third party—including covered entities—can interfere with the contractual PPA relationship between HHS and drug manufacturers that participate in the federal 340B program. *See id.* at 119–20. That principle applies with full force here. Just as covered entities cannot disrupt the federal government's contractual relationship with manufacturers through litigation seeking to enforce the covered entities' view of the 340B program, states cannot themselves interfere with the federal 340B program by setting up alternate, conflicting means of enforcing the pricing provisions of the same federal program. *See id.* at 120 ("With HHS unable to hold the control rein, the risk of conflicting adjudications would be substantial.").

76. *Third*, in certain circumstances, federal law prohibits dispensing certain drugs purchased at the 340B price in the manner Act 1103 requires. Federal law imposes limitations on certain drugs that give rise to safety concerns, that require special education and training, or that are subject to other limitations imposed by FDA, and some PhRMA members manufacture these types of drugs. For example, HRSA has recognized that "[c]ertain covered [340B-priced] outpatient drugs may be required to be dispensed by specialty pharmacies (*e.g.*, drugs approved with a risk evaluation and mitigation strategy (REMS) pursuant to section 505-1 of the Federal Food, Drug, and Cosmetic Act [FDCA])." 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52,300, 52,312 (Aug. 28, 2015) (proposed rule). That is, in certain circumstances it may be unlawful to permit a standard community pharmacy to dispense particular drugs, because such drugs must be handled only by specialty pharmacies. "As a result, certain manufacturers may use a restricted network of certified specialty pharmacies, which do not fall under the terms of a contract pharmacy agreement or wholesaler contract for the distribution of drugs to a covered entity." *Id.* Yet Act 1103's 340B pricing mandate provisions apparently require drug manufacturers to sell *all* drugs purchased at the 340B price to *any* Arkansas-based community pharmacy that maintains a "340B drug pricing contract pharmacy arrangement" with a covered entity, irrespective of other requirements of federal law that restrict distribution of 340B-priced drugs.

77. Act 1103 thus purports to impose requirements related to dispensing such drugs that directly conflict with federal requirements applicable to those drugs, such as REMS restrictions imposed under the FDCA, or limited distribution plans established by a manufacturer under the 340B program.

78. *Fourth*, Act 1103 frustrates the "accomplishment and execution of the full purposes and objectives of Congress," *Soo Line R.R. Co.*, 825 F.3d at 420 (quoting *Oneok*, 575 U.S. at 377), in various ways in addition to those described above. For example, by imposing additional, onerous terms on the federal 340B program, Act 1103 increases the cost of participation in the federal Medicare and Medicaid programs, without providing corresponding additional benefits. That serves to discourage manufacturers from participating in Medicare and Medicaid in the first place by raising the price for participating above the level Congress intended.

79. Arkansas Code Annotated § 23-92-604(c)(1)–(2)'s interference with the federal 340B scheme is particularly inappropriate because that scheme is comprehensive and carefully designed. *See, e.g.*, *Arizona*, 567 U.S. at 399 (holding that when Congress creates "a framework of regulation 'so pervasive . . . that Congress left no room for the States to supplement it,'" any state law that "supplement[s] it" is preempted (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947))).

80. Unlike some federal programs, *Congress provided no room for states to add onto or have any involvement in 340B drug pricing.* Instead, as described *supra* ¶¶ 21–35, the 340B statute establishes a detailed scheme to induce and regulate the nationwide provision of steeply discounted pharmaceutical products to statutorily specified providers and patients. This comprehensive federal regime creates a marketplace that would not otherwise exist and that hinges on federal spending as an inducement to persuade manufacturers to participate.

81. Everything about the 340B program that is relevant here is federally defined and federally dictated. Congress exhaustively defined "covered entity" (the types of providers eligible for 340B pricing) by referencing many other federal statutes. *See* 42 U.S.C. § 256b(a)(4). Congress defined "covered outpatient drug" (*i.e.*, the products whose prices are set by the 340B

statute) to have "the meaning given such terms in section 1927(k) of the Social Security Act," *id.* § 256b(b), another federal statute that carefully defines this term for the purpose of manufacturer participation in the separate Medicaid Drug Rebate Program. *Id.* § 1396r-8(k). Congress defined "ceiling price" for purposes of the 340B statute to mean "the maximum price that covered entities may permissibly be required to pay for the drug." *Id.* § 256b(a)(1). And Congress provided that the Secretary of HHS shall "calculate[]" "the ceiling prices" by determining the difference between a manufacturer's "Average Manufacturer Price" (another term defined in section 1927(k) of the Social Security Act) and its Medicaid rebate amount (as determined pursuant to section 1927(c) of the Social Security Act). *Id.* § 256b(a)(1)–(2) & (b), (d)(1)(B)(i)(II). Such connections between the 340B statute and the separate Medicaid Drug Rebate Program, including the shared term "covered outpatient drug" and determining 340B ceiling prices based on Medicaid rebate calculations, reflect a careful balance that Congress struck between the federal government and manufacturers when establishing the 340B program two years after the Medicaid Drug Rebate Program. Indeed, participation in the federal 340B program is necessary for manufacturers to have their drugs reimbursable under Medicare Part B or the federal share of Medicaid . *See* 42 U.S.C. § 1396r-8(a)(1), (a)(5). Moreover, a manufacturer's participation in the 340B program is governed by a contract with a federal agency. *See Astra*, 563 U.S. at 113, 117.

82. Neither the 340B statute nor any regulations promulgated under it authorize state regulation concerning 340B pricing.

83. Yet Act 1103 directly invokes the federal 340B program, *see* Ark. Code Ann. § 23-92-601 (title); § 23-92-602(5) ("'340B drug pricing' means the program established under section 602 of the Veterans Health Care Act of 1992, Pub. L. No. 102-585."), and its operative terms not only depend on the federal 340B program, but add pricing requirements to it. For these reasons

and more, Congress's occupation of the field in relation to 340B pricing preempts the requirements of Act 1103 challenged here.

84. Act 1103's contemplation of rules promulgated by the Arkansas Insurance Commissioner to guide the Act's enforcement vividly demonstrates exactly why Congress has occupied the field. Congress provided a detailed scheme for enforcing the 340B statute by providing for civil monetary penalties and other remedies for their violation, but accompanied these provisions with important safeguards. *See* 42 U.S.C. § 256b(d)(1)(B)(vi), (d)(2)(B)(v). For instance, Congress specified that a manufacturer may be held liable only when it "*knowingly and intentionally*" overcharges a covered entity. *Id.* § 256b(d)(1)(B)(vi)(III) (emphasis added). Yet Ark. Code Ann. § 23-92-606 contemplates state enforcement and instructs that "[t]he Insurance Commissioner *shall* promulgate rules to implement this subchapter," (emphasis added); *see also Ferguson v. State*, 2016 Ark. 319, *7, 498 S.W.3d 733, 737 (2016) ("[T]he word 'shall' is mandatory rather than discretionary."). To begin enforcement of the Act without providing clear notice of what consequences manufacturers would face under Act 1103, and to allow imposition of state-law penalties without the safeguards that Congress designed, is exactly what Congress sought to avoid when it enacted the 340B statute.

85. For all of the foregoing reasons, Act 1103's 340B pricing mandate provisions are preempted and their enforcement should be enjoined. *See Melikian Enter., LLLP v. McCormick*, 863 F.3d 802, 806 (8th Cir. 2017) ("Preemption may be implied, for example, when federal and state laws directly conflict, when state law stands as an obstacle to accomplishing the purposes of federal law, or when federal law is so pervasive that it reflects an intent to occupy a regulatory field." (internal quotation marks and citation omitted)); *Qwest Corp. v. Minn. Pub. Utils. Comm'n*, 684 F.3d 721, 727–28 (8th Cir. 2012).

CLAIM II
(Declaratory/Injunctive Relief—Dormant Commerce Clause—Extraterritoriality)

86. PhRMA re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

87. The Commerce Clause provides that "Congress shall have power . . . [t]o regulate commerce . . . among the several states." U.S. Const. art. I, § 8, cl. 3.

88. Although framed in terms of an affirmative grant to Congress, the Commerce Clause has long been understood also to limit "the power of the States to interfere with or impose burdens on interstate commerce." *Ark. Elec. Coop. Corp. v. Ark. Pub. Serv. Comm'n*, 461 U.S. 375, 389 (1983) (citation omitted). This limitation on state power, often called the "negative" or "dormant" component of the Commerce Clause, means that the Constitution itself sometimes precludes state laws, even without preemptive Congressional legislation.

89. In particular, "the Commerce Clause protects against . . . the projection of one state regulatory regime into the jurisdiction of another State." *Healy*, 491 U.S. at 336–37 (footnote omitted). Under this extraterritoriality doctrine, "a state law that has the 'practical effect' of regulating commerce occurring wholly outside that State's borders" "exceeds the inherent limits of the enacting State's authority," "is invalid under the Commerce Clause," and will be struck down "whether or not the [regulated out-of-state] commerce has effects within the [regulating] State," and even if the "extraterritorial reach was [not] intended by the legislature." *Id.* at 332–33, 336 (citation omitted); *see Cotto Waxo Co. v. Williams*, 46 F.3d 790, 793 (8th Cir. 1995) ("Extraterritorial reach invalidates a state statute when the statute requires people or businesses to conduct their out-of-state commerce in a certain way."). Put another way, "a state regulation is per se invalid . . . when the statute has the practical effect of controlling conduct beyond the boundaries of the state." *Cotto Waxo*, 46 F.3d at 793.

90. Applications of this anti-extraterritoriality rule take many forms, but the most fundamental is that no state may "project its legislation into [another state] by regulating the price to be paid in that state for [goods] acquired there," even if the goods at issue are destined for resale in the regulating state. *Baldwin*, 294 U.S. at 521.

91. *Baldwin* is the foundational case in this area. The dispute in *Baldwin* arose after a Vermont "creamery" (manufacturer) sold milk wholesale to a New York "milk dealer" (wholesale distributor) at a price that New York's Milk Control Act considered too low. *Id.* at 518. It was undisputed that the transaction occurred in Vermont, and the milk sold in that transaction was intended for resale to New York retailers (and then to New York consumers). *Id.* The statute "applied only to milk that would eventually be sold to New York consumers," and it said nothing on its face about out-of-state transactions. *Carolina Trucks & Equip., Inc. v. Volvo Trucks of N. Am., Inc.*, 492 F.3d 484, 490–91 (4th Cir. 2007) (discussing *Baldwin*). But that did not matter, let alone drive the Supreme Court's constitutional analysis. What mattered instead was that the state statute had the practical effect of regulating out-of-state wholesale transactions: Even though the Milk Control Act only reached transactions upstream of in-state consumer transactions in New York, the Court still determined that it was unconstitutional vis-à-vis transactions that took place outside New York. As the Supreme Court explained, under the Commerce Clause, "New York has no power to project its legislation into Vermont by regulating the price to be paid in that state for milk acquired there," even if the out-of-state transactions regulated are wholesale transactions, and even if the milk sold there may later be resold in a downstream sale in New York. *Baldwin*, 294 U.S. at 521; *see also Cotto Waxo*, 46 F.3d at 793 ("Extraterritorial reach invalidates a state statute when the statute requires people or businesses to conduct their out-of-state commerce in a certain way.").

92. So too here. Arkansas "has no power to project its legislation into" another state "by regulating the price to be paid in that [other] state for [drugs] acquired there." *Baldwin*, 294 U.S. at 521. And that remains true *even if* the drugs sold in those upstream, out-of-state wholesale transactions may later be resold in downstream retail-pharmacy sales in Arkansas.

93. Act 1103's 340B pricing mandate provisions violate this fundamental limitation on state power, as evidenced by the fact that they would apply completely extraterritorially to the majority of PhRMA's members, who have no direct sales, manufacturing, or distribution operations of 340B-covered outpatient drugs in the State of Arkansas. Just as in *Baldwin*, the challenged provisions of Act 1103 "effectively . . . instruct[] manufacturers and wholesale distributors as to the prices they are permitted to charge in transactions that do not take place in [Arkansas]." *Ass'n for Accessible Meds. v. Frosh*, 887 F.3d 664, 672 (4th Cir. 2018) (striking down a Maryland drug-pricing law on extraterritoriality grounds); *see also Pharm. Rsch. & Mfrs. of Am. v. District of Columbia*, 406 F. Supp. 2d 56, 68–70 (D.D.C. 2005) (striking down a D.C. law vis-à-vis "transactions between manufacturers and wholesalers that occur wholly out of state" as "a *per se* invalid extraterritorial reach in violation of the Commerce Clause"), *aff'd sub nom. Biotech. Indus. Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007).

94. To understand how Act 1103's 340B pricing mandate provisions will inevitably regulate commerce wholly outside Arkansas's borders, it is necessary to understand how "an Arkansas-based community pharmacy that receives drugs purchased under a 340B drug pricing contract pharmacy arrangement" actually "receive[s] drugs." Ark. Code Ann. § 23-92-604(c)(2).

95. Most PhRMA members do not make ***any*** covered outpatient drug sales directly to retail pharmacies in Arkansas. (Some of PhRMA's members do make a smaller number of sales to national retail pharmacy chains that warehouse the products themselves. These transactions,

however, generally take place entirely outside Arkansas.) And none of PhRMA's members is based in Arkansas, none manufacture any final products there, and most have no sales or distribution operations in the state involving 340B-covered outpatient drugs.

96. Following nationwide industry practice, retail pharmacies typically purchase drugs from wholesale distributors rather than manufacturers. In particular, nearly all of PhRMA's members sell the bulk of their products at the wholesale level to one of the "Big Three" distributors: AmerisourceBergen, McKesson, and Cardinal Health. None of the Big Three is headquartered in Arkansas. (AmerisourceBergen is based in Pennsylvania; McKesson in California; and Cardinal Health in Ohio.) As a general matter, pharmacies then purchase their drugs from these wholesale distributors.

97. Yet because Sections 23-92-604(c)(1) and (c)(2) apply to "pharmaceutical manufacturer[s]" like PhRMA's members, as opposed to distributors, they effectively regulate transactions that are (1) out-of-state transactions between manufacturers and their nationwide distributors and (2) out-of-state transactions between manufacturers and covered entities.

98. In the typical case, PhRMA members sell their products to the "Big Three" wholesale distributors. *See supra* ¶¶ 96. By requiring manufacturers to grant 340B prices to Arkansas contract pharmacies, the statute effectively regulates manufacturers' out-of-state sales to these out-of-state wholesale distributors by setting the price that a manufacturer ultimately receives from its distributors for drugs destined for Arkansas community pharmacies.

99. In relatively rare instances, PhRMA members do sell to covered entities directly. But these sales too generally take place between out-of-state manufacturers and out-of-state covered entities.

100. Even though these transactions take place outside of Arkansas, Act 1103's 340B pricing mandate provisions purport to regulate them. As noted, Ark. Code Ann. § 23-92-604(c)(1) provides: "A pharmaceutical manufacturer shall not . . . [p]rohibit a pharmacy from contracting or participating with an entity authorized to participate in 340B drug pricing by denying access to drugs that are manufactured by the pharmaceutical manufacturer." And Section 23-92-604(c)(2) explicitly prohibits pharmaceutical manufacturers participating in the 340B program from "[d]eny[ing] or prohibit[ing] 340B drug pricing for an Arkansas-based community pharmacy that receives drugs purchased under a 340B drug pricing contract pharmacy arrangement with an entity authorized to participate in 340B drug pricing." Indeed, *only* by interfering with out-of-state transactions could these provisions of Act 1103 have any real effect *at all*: As explained, PhRMA's members generally do not sell 340B-covered outpatient drugs directly to Arkansas pharmacies themselves, and thus Act 1103's requirement that manufacturers not "[d]eny" "340B drug pricing for an Arkansas-based community pharmacy" could be enforced only at the level of manufacturers' out-of-state sales to wholesalers. *See supra* ¶¶ 95–96.

101. Such interference with out-of-state sales runs afoul of the Commerce Clause. Arkansas has no power to regulate entirely out-of-state transactions. *See Healy*, 491 U.S. at 335–36; *see, e.g.*, *North Dakota v. Heydinger*, 825 F.3d 912, 921–22 (8th Cir. 2016) (invalidating Minnesota laws that "seek to reduce emissions that occur outside Minnesota by prohibiting transactions that originate outside Minnesota," because "their practical effect is to control activities taking place wholly outside Minnesota"). And this remains true even if the out-of-state transactions have effects (*e.g.*, lead to higher prices) in Arkansas, and even if the complaining pharmacy or covered entity is in Arkansas. *See, e.g.*, *Baldwin*, 294 U.S. at 518–21; *Healy*, 491 U.S. at 332–36; *Ass'n for Accessible Meds.*, 887 F.3d at 669–72.

102. Thus, under "*Baldwin* and *Healy*," a state law that requires "manufacturers [to] sell their drugs to a wholesaler for a certain price," "either by its express terms or by its inevitable effect," is per se invalid as a violation of the Commerce Clause. *Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 669 (2003). To the extent that this is exactly what Act 1103's 340B pricing mandate provisions appear to effectively require, they cannot survive constitutional scrutiny.

103. Section 23-92-604(c)(2) would also be unconstitutional to the extent that its prohibition on "[d]eny[ing] or prohibit[ing] 340B drug pricing for an Arkansas-based community pharmacy" means that manufacturers that do not already do business with an Arkansas-based community pharmacy now must do so. The statute could potentially be read to require manufacturers to provide 340B-discounted product to Arkansas pharmacies merely because the manufacturer sells drugs to an out-of-state covered entity that has a contractual relationship with an Arkansas pharmacy. But, as noted, most of PhRMA's members do not sell any 340B-covered outpatient drugs directly to retail pharmacies in Arkansas. And as the Supreme Court has long made clear, neither Arkansas nor any other state can require an out-of-state enterprise to do business in the state. "While a State may seek lower prices for its consumers, it may not insist that producers or consumers in other States surrender whatever competitive advantages they may possess." *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 580 (1986).

104. For these reasons, Act 1103's 340B pricing mandate provisions are per se invalid under the dormant Commerce Clause.

PRAYER FOR RELIEF

PhRMA respectfully prays that this Court:

a. issue an order and judgment declaring that Ark. Code Ann. § 23-92-604(c) is unconstitutional and violates federal law;

b. issue an order and judgment declaring that Act 1103 does not require PhRMA's members to offer price discounts under the 340B program to contract pharmacies in Arkansas;

c. enjoin the implementation and enforcement of Act 1103 against PhRMA's members;

d. award PhRMA costs and reasonable attorneys' fees, as appropriate; and

e. grant any other relief the Court finds just and appropriate.

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Counsel for Plaintiff

BEFORE THE ARKANSAS INSURANCE DEPARTMENT

In re Act 1103 **PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA,** *Petitioner.*	**AID No.** _____

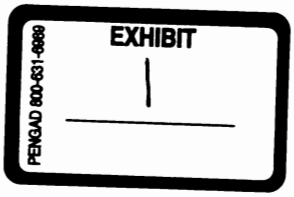
PETITION FOR DECLARATORY RELIEF

Comes now the above-named Petitioner, the Pharmaceutical Research and Manufacturers of America ("PhRMA"), and for its Petition for Declaratory Relief under Ark. Code Ann. § 25-15-206 and this Department's Rule 121 states as follows:

PRELIMINARY STATEMENT

1. This petition concerns Act 1103, the "340B Drug Pricing Nondiscrimination Act." Act 1103 was enacted on May 3, 2021. Specifically, this declaratory order is sought under Section 23-92-604(c)(1) and Section 23-92-604(c)(2) of Act 1103.

2. Act 1103 regulates and imposes additional requirements on the operations of a comprehensive federal program. That federal program, enacted as the 340B Drug Pricing Program, *see* 42 U.S.C. § 256b, and known as 340B, requires drug manufacturers to offer covered outpatient drugs at large discounts to specified non-profit "covered entities" that serve indigent, uninsured, and certain other specific vulnerable patient populations. *See PhRMA v. HHS* (*Orphan Drug I*), 43 F. Supp. 3d 28, 31 (D.D.C. 2014) (explaining that 340B "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health care facilities," known as



covered entities) (quoting *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 113 (2011)); *see also* Ark. Code Ann. § 23-92-601 (title); *id.* § 223-92-602(5) ("'340B drug pricing' means the program established under section 602 of the Veterans Health Care Act of 1992, Pub. L. No. 102-585.").

3. Federal law defines the term "covered entity" for purposes of 340B to mean an entity that "is" "one of" 15 types of specifically enumerated categories of nonprofit healthcare providers. 42 U.S.C. § 256b(a)(4). For instance, Federally Qualified Health Centers, children's hospitals, rural hospitals, and other clinics serving vulnerable populations are all specifically defined as "covered entities" eligible to participate in 340B. *Id.*; *see also Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 820 (D.C. Cir. 2020).

4. Congress has made drug manufacturers' compliance with this federal program a condition of coverage for their drugs under Medicaid and Medicare Part B. To effectuate that requirement, 340B obligates manufacturers to enter into contracts with the U.S. Department of Health and Human Services ("HHS") that promise to offer the discounts required by the statute to the federally defined "covered entities."

5. PhRMA, a trade association representing the nation's leading innovative biopharmaceutical research companies, represents the interests of many of the manufacturers that operate under the federal 340B program. PhRMA's members manufacture and sell patented pharmaceutical products.

6. Act 1103 seeks to regulate the manner in which manufacturers participate in the federal 340B program. In particular, Act 1103 requires manufacturers to provide their drugs at 340B prices not just to the 15 types of "covered entities" Congress specified in the federal statute, but also to or through all "community pharmacies" based in Arkansas with whom those covered entities may choose to have business dealings. Act 1103, § 23-92-604(c)(2). As a federal district

court recently concluded, it "is hard to believe that Congress enumerated 15 types of covered entities with a high degree of precision and intended to include contract pharmacies as a 16th option by implication." *AstraZeneca Pharms. LP v. Becerra*, No. CV 21-27-LPS, 2021 WL 2458063, at *10 (D. Del. June 16, 2021).

7. In Section 23-92-604(c)(1), Act 1103 states: "A pharmaceutical manufacturer shall not … [p]rohibit a pharmacy from contracting or participating with an entity authorized to participate in 340B drug pricing by denying access to drugs that are manufactured by the pharmaceutical manufacturer."

8. In Section 23-92-604(c)(2), Act 1103 states: "A pharmaceutical manufacturer shall not … [d]eny or prohibit 340B drug pricing for an Arkansas-based community pharmacy that receives drugs purchased under a 340B drug pricing contract pharmacy arrangement with an entity authorized to participate in 340B drug pricing."

9. PhRMA's members are "pharmaceutical manufacturers" under Section 23-92-604 of Act 1103. They do not appear to otherwise be regulated by Act 1103 or subject to the jurisdiction of the Insurance Department.

10. Act 1103 implicates a key issue of federal law that is currently pending before multiple federal courts across the nation: Whether, under federal law, the 340B statute requires manufacturers to transfer their drugs at 340B prices to "contract pharmacies" at the request of covered entities.

11. On December 30, 2020, HHS issued an "Advisory Opinion" ("AO") which stated "that drug manufacturers must provide 340B discounts when a contract pharmacy is acting as an agent of a covered entity, providing services on behalf of the covered entity." HHS, Press Release, *HHS Releases Advisory Opinion Clarifying that 340B Discounts Apply to Contract Pharmacies*

(Dec. 30, 2020); *see also* HHS Office of the General Counsel, *Advisory Opinion 20-06 on Contract Pharmacies under the 340B Program*, at 1 (Dec. 30, 2020) ("We conclude" that "a drug manufacturer in the 340B program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs" whenever a contract pharmacy acts as a covered entity's "agent."), https://bit.ly/357nqfk.

12. Many pharmaceutical manufacturers (including some of PhRMA's members) filed suit against HHS, the federal Health Resources and Services Administration ("HRSA"), and their respective leaders in federal district courts across the country, challenging the conclusions and reasoning contained in the AO (and further challenging certain 340B administrative dispute resolution regulations (known collectively as the ADR Rule)). *See Eli Lilly & Co. v. Becerra*, No. 1:21-cv-81 (S.D. Ind.) (complaint filed Jan. 12, 2021); *AstraZeneca Pharms. LP v. Becerra*, No. 1:21-cv-00027-LPS (D. Del.) (complaint filed Jan. 12, 2021); *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Human Servs.*, No. 3:21-cv-00634-FLW-LHG (D.N.J.) (complaint filed Jan. 12, 2021); *Novo Nordisk Inc. v. U.S. Dep't of Health & Human Servs.*, No. 3:21-cv-00806-FLW-LHG (D.N.J.) (complaint filed Jan. 15, 2021); *Novartis Pharms. Corp. v. Becerra*, No. 1:21-cv-01479 (D.D.C.) (complaint filed May 31, 2021); *United Therapeutics v. Espinosa*, No. 1:21-cv-01686 (D.D.C.) (complaint filed June 23, 2021); *cf. Pharm. Research & Mfrs. Ass'n of Am. v. Becerra*, No. 8:21-cv-99198-PWG (D. Md.) (complaint filed Jan. 22, 2021). Collectively, these suits will be referred to as the "Pending Cases."

13. The position of the manufacturers in the Pending Cases includes that the text of 340B enumerates the 15 types of "covered entit[ies]" eligible to receive the 340B price and expressly *prohibits* a covered entity from transferring a drug purchased at the 340B price to anyone other than its patients: "With respect to any covered outpatient drug that is subject to an agreement

under this subsection, a covered entity shall not resell or *otherwise transfer* the drug to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B) (emphasis added). The manufacturers assert that neither contract pharmacies nor "community pharmacies" (the term used in § 21-61-604(c)(2)) are among the 15 enumerated covered entities. And because a pharmacy is obviously not a "patient of [a covered] entity," covered entities are prohibited from "resell[ing] or otherwise transfer[ring]" 340B drugs to them. *See AstraZeneca*, 2021 WL 2458063, at *10 (recognizing that it is "hard to believe" that Congress "intended to include contract pharmacies as a [covered entity] by implication").

14. By contrast, the federal government in the Pending Cases maintains that federal law *requires* manufacturers to transfer their drugs at the 340B discounted price to contract pharmacies. *See, e.g.*, *id.* at *8. Thus, these suits squarely present the issue whether manufacturers, such as PhRMA's members, must under federal law provide 340B drugs to contract pharmacies.

15. Several of these Pending Cases have already progressed significantly. On June 16, 2021, Chief Judge Stark, presiding over the *AstraZeneca* case in the United States District Court for the District of Delaware, issued a decision holding that the federal 340B statute does not unambiguously obligate manufacturers to give 340B discounts on drugs dispensed by contract pharmacies. *AstraZeneca*, 2021 WL 2458063, at *8-12. Thereafter, Chief Judge Stark entered an order vacating the AO. Order 3, *AstraZeneca*, No. 1:21-cv-00027-LPS (D. Del. June 30, 2021). Meanwhile, multiple other challenges remain pending in courts across the country, including in the U.S. District Court for the District of Columbia ("D.D.C."). *See supra* ¶ 12. D.D.C. is proceeding quickly to resolve these matters, including setting a schedule for expedited consideration of summary judgment motions with a hearing scheduled for early October. *See* Minute Order, *United Therapeutics v. Espinosa*, No. 1:21-cv-01686 (D.D.C.) (July 15, 2021)

(consolidating and expediting D.D.C. cases and setting joint hearing in October). And both the *Sanofi-Aventis* and *Novo Nordisk* cases are fully briefed.

16. Accordingly, multiple federal courts will likely soon rule on whether federal law requires the use of contract pharmacies. Because Act 1103 requires manufacturers to provide 340B drugs to Arkansas-based community pharmacies, *see* Ark. Code Ann. § 23-92-604, the constitutionality and lawfulness of Act 1103 is intimately tied to the outcome of these federal Pending Cases.

17. Act 1103 directly and substantially affects PhRMA's members. Absent a declaratory order staying enforcement of Sections 23-92-604(c)(1) and 23-92-604(c)(2) against PhRMA's members at this time, PhRMA's members will be required to provide contract pharmacies access to manufacturers' drugs at 340B prices—at great financial cost—or risk the threat of enforcement by the Insurance Department, which would almost certainly lead to further litigation. *See, e.g.*, Decl. of Odalys Caprisecca, *AstraZeneca Pharms. LP v. Becerra*, No. 1:21-cv-00027-LPS (D. Del.) (ECF No. 16) (filed Jan. 12, 2021) (averring to irreparable harm).

18. PhRMA thus respectfully requests that the Insurance Department stay enforcement of Sections 23-61-604(c)(1) & (2) of Act 1103 as to its members while the Pending Cases are resolved, or for a minimum of 120 days (subject to renewal).

19. Act 1103 will take effect on July 28, 2021, by operation of law. *See* Op. Ark. Att'y Gen. No. 29 (2021). A stay of enforcement is thus urgently needed.

20. To be clear, PhRMA believes that the provisions of Act 1103 applicable to pharmaceutical manufacturers are preempted by the Supremacy Clause of the U.S. Constitution because they conflict with the requirements, purposes, and objectives of the federal 340B statute and program—and that this is true no matter the outcome of the pending federal-court litigation.

Whereas federal law forbids the forced transfer of manufacturers' drugs to non-patients such as pharmacies, Act 1103 requires it. And Act 1103's interference with the federal 340B scheme is particularly inappropriate because that scheme is comprehensive and carefully crafted, leaving no room for state interference. *See, e.g.*, *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 486 (2013); *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000); *Arizona v. United States*, 567 U.S. 387, 399 (2012). Act 1103 also appears to violate the Commerce Clause, because its practical effect will be to directly regulate two types of transactions: (1) transactions between manufacturers such as PhRMA's members and their wholesale-distributor partners, nearly all of which take place entirely outside of Arkansas; and (2) transactions between manufacturers and out-of-state "covered entities" that are actually entitled to benefits under the federal 340B program. *See Healy v. Beer Inst., Inc.*, 491 U.S. 324, 333, 336 (1989).

21. All that said, PhRMA does *not* hereby seek a ruling by the Insurance Department on whether Sections 23-61-604(c)(1) and (2) of Act 1103 are preempted or are otherwise invalid under federal law. Indeed, the Insurance Department "is not empowered or authorized" to decide "constitutional objections," Declaratory Order, *In re Rate and Form Review Time Periods Under Ark. Code Ann. § 23-79-109*, AID No. 2016-091, ¶ 11, and PhRMA expressly reserves the right to have a federal court decide those issues should the need arise.

22. Instead, PhRMA, through this petition, seeks a ruling staying enforcement of Act 1103 as to PhRMA's members by the Insurance Department pending the outcome of the Pending Cases that are directly relevant to the federal program Act 1103 purports to address, or for a minimum of 120 days (subject to renewal). These cases will bear directly on the legality of Act 1103.

23. PhRMA does not request a hearing on this petition.

PRAYER FOR RELIEF

PhRMA respectfully prays that the Insurance Department:

a. issue a declaratory order staying enforcement of Sections 23-92-604(c)(1) and 23-92-604(c)(2) of Act 1103 as to PhRMA and its members, pending resolution of the federal Pending Cases or for at least 120 days (subject to renewal); and

b. issue an interim order staying enforcement of Sections 23-92-604(c)(1) and 23-92-604(c)(2) of Act 1103 as to PhRMA and its members, while the Insurance Department considers this petition.

Dated: July 28, 2021

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CERTIFICATE OF SERVICE

The undersigned certifies that a true and correct copy of the above styled document has been served via e-mail on July 28, 2021, and will be served via hand delivery on July 29, 2021, upon:

Jim Brader
jim.brader@arkansas.gov

Booth Rand
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Crystal Phelps
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I am also mailing a copy of this document via certified mail on July 29, 2021 to:

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Joshua C. Ashley