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

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Plaintiff, v. ALAN MCCLAIN, *et al.*, Defendants.	Case No. 4:21-cv-864-BRW

INTERVENOR-DEFENDANTS' SUMMARY JUDGMENT REPLY BRIEF ON CLAIM I (PREEMPTION)

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INTRODUCTION

Act 1103, which regulates drug distribution, is not preempted by the federal 340B statute, which regulates drug pricing. To understand why, it is important to distinguish between two manufacturer activities involved in 340B contract pharmacy arrangements. The first involves a manufacturer calculating the 340B ceiling price for its drugs and sending a 340B price file to covered entities either directly or, more often, through a wholesaler. Receipt of the price file by a covered entity allows it to purchase the manufacturer's drugs at 340B prices. The second activity involves the physical delivery of 340B drugs to contract pharmacies. Except for a few manufacturers that ship directly to customers, manufacturers contractually require wholesalers to transport 340B drugs from their facilities to locations requested by the covered entity which, in this case, are contract pharmacy locations.

The two actions are governed under different laws. The first is governed by the 340B statute and is how a manufacturer satisfies its obligation to "offer" 340B pricing on drugs. The second—distribution of 340B drugs—is territory where states have a legitimate right to legislate and regulate. It is the second area that is the exclusive focus of Act 1103. It is an area in which Arkansas has already ventured. In 1975, it passed legislation forbidding most Arkansas non-profit hospitals from operating retail pharmacies, forcing them to rely on contract pharmacies instead. Ark. Code Ann. § 17-92-607. Act 1103 builds on this tradition of supporting contract pharmacy arrangements by prohibiting manufacturers from blocking or interfering with delivery to contract pharmacies of drugs offered and purchased at the 340B ceiling price. Ark. Code Ann. § 23-92-604(c)(2). Through regulations implementing Act 1103, Arkansas has declared such

interference to be an unfair method of competition or unfair or deceptive trade practice. AID Rule 123: 340B Drug Program Nondiscrimination Requirements I-VII.[1]

All of the available evidence shows that Act 1103 governs drug distribution, not drug pricing. The Arkansas legislature intended Act 1103 to control distribution and not drug pricing, as demonstrated by a plain reading of Act 1103 and by contemporaneous statements from an Arkansas legislator about the manufacturer activity that Act 1103 is intended to prohibit. Also, the Arkansas Insurance Department ("AID"), which is charged with implementing Act 1103, adopted regulations that interpret Act 1103 to address drug distribution only.

PhRMA argues that the 340B statute preempts Act 1103 but relies on case law interpreting federal statutes that *expressly* preempt state law, rather than *implied* preemption cases involving federal statutes, like 340B, that do not include an express preemption provision. The applicable case law shows that the 340B statute, which does not include an express preemption provision, does not impliedly preempt Act 1103. PhRMA also argues that the 340B statute is a comprehensive statutory scheme—a contention that Intervenor-Defendants ("Intervenors") strongly reject. But even if it were comprehensive, Congress left a decided gap in the statute regarding drug distribution, an area traditionally regulated by the states.

PhRMA has also not successfully countered several other arguments of Intervenors, including that Congress acquiesced to state regulation of drug distribution by declining to add federal drug distribution requirements when it amended the 340B statute through the Patient Protection and Affordable Care Act ("Act"). The cases that PhRMA relies on, including Supreme Court holdings, support Intervenors' position and not PhRMA's.

[1]https://insurance.arkansas.gov/uploads/pages/rule_123_340b_drug_program_nondiscrimination_requirements.pdf.

Furthermore, Act 1103 does not conflict with the federal Food, Drug and Cosmetic Act ("FDCA"), as contended by PhRMA, because any conflict would lead to absurd results that the Arkansas legislature could not have intended, and AID has disclaimed PhRMA's interpretation. Lastly, the presumption against federal preemption of state law applies to this case.

For all of the above reasons, and as explained in Intervenors' opening brief, the Court should deny PhRMA's motion for summary judgment and grant Intervenors' motion for summary judgment on the issue of preemption.

ARGUMENT

I. Act 1103 Regulates Distribution and Is Not Preempted by the 340B Statute, Which Regulates Pricing

Act 1103 governs drug distribution, not the "pricing mechanisms prescribed by the federal statute," as PhRMA claims. PhRMA Reply Br. at 7 (ECF No. 41). Act 1103 references the federal 340B statute merely to describe the drugs subject to the Act's distribution requirements, drugs that are already discounted in accordance with the 340B statute. Act 1103's focus on drug distribution is clear from its legislative history. PhRMA's preemption arguments are also directly contrary to AID's authoritative interpretation that Act 1103 regulates drug distribution, not pricing. PhRMA relies on inapplicable express preemption case law, but implied preemption cases recognize that a state law may parallel a federal law, particularly, as here, when both the state and federal governments disclaim any preemptive effect. PhRMA's alternative arguments fare no better. The Health Resources and Services Administration ("HRSA"), the Government Accountability Office ("GAO") and federal courts have never viewed shipments of drugs to contract pharmacies as violating the 340B diversion prohibition because covered entities retain title to those drugs, notwithstanding PhRMA's mischaracterization of a few publicly available contracts. Likewise, PhRMA misreads Act 1103

as requiring manufacturers to sell drugs to contract pharmacies. Finally, PhRMA's repeated insistence that title shifts from the covered entity to the contract pharmacy remains a disputed issue of material fact that defeats PhRMA's motion for summary judgment.

A. Act 1103 Is Not Preempted Because It Addresses Manufacturer's Interference with Distribution of 340B Drugs, Not Manufacturers' Compliance with 340B Pricing Requirements

The 340B statute governs drug pricing by requiring manufacturers to "offer" 340B prices to covered entities. 42 U.S.C. § 256b(a)(1). Act 1103 prohibits a manufacturer from restricting the delivery of drugs *already subject to* the manufacturer's 340B price. Act 1103 only becomes applicable *after* the manufacturer has rendered an "offer" of 340B-prices for covered entity purchases. AID, which is statutorily authorized to implement Act 1103, has properly interpreted Act 1103's reference to "340B drug pricing" as the "acquisition and delivery" of drugs already purchased at a 340B price. AID Rule 123: 340B Drug Program Nondiscrimination Requirements II(7) (defining "340B drug pricing"). AID's interpretation is consistent with the express intent of the Arkansas General Assembly, which an Arkansas legislator described as a law regulating drug shipping, not drug pricing. Prior courts have held in implied preemption cases that statutes like Act 1103 that operate parallel to federal law are not preempted.

PhRMA argues that Act 1103 conflicts with the 340B statute by conflating the 340B prohibition on *covered entities* transferring 340B drugs to individuals who are not patients of the covered entity (commonly referred to as the diversion prohibition) with Act 1103's distribution requirements *for manufacturers.* PhRMA Reply Br. at 10-14. Despite PhRMA's selective quotations from a few form contracts, contract pharmacies do not purchase 340B drugs, and PhRMA's repeated insistence that they do purchase 340B drugs is a disputed material fact.

1. From Its Inception, Act 1103 Was Intended to Regulate Distribution

Act 1103 governs drug distribution, not pricing, contrary to PhRMA's claim that Act 1103 somehow expands the list of covered entities that are eligible for 340B pricing. PhRMA's characterization of Act 1103 must be rejected because it conflicts with the statute's plain meaning, the legislative history of Act 1103, and the interpretation of Act 1103 by AID in Rule 123.

a. PhRMA Misconstrues the Plain Meaning of Act 1103

PhRMA's analogy to a car sale is off base because Arkansas is not forcing manufacturers to sell drugs at a particular price (a car for $1 in PhRMA's analogy). PhRMA Reply Br. at 9. The price is set by the 340B program. A more apt analogy describes manufacturer conduct that Act 1103 seeks to remedy: "I am required to sell you a discounted car, but I will only deliver it where you can't drive it." The 340B program sets the statutory price for drugs, but manufacturers have established onerous distribution restrictions that prevent Arkansas covered entities from actually obtaining and dispensing those drugs. Act 1103 appropriately regulates distribution, ensuring that 340B priced drugs are delivered where they can be dispensed to patients (*cf.*, a car delivered to a paved road).

Section 23-92-604(c) of Act 1103 has two subparagraphs, neither of which intrude on the 340B program. The first subparagraph forbids a manufacturer from prohibiting pharmacies from "contracting or participating" with a covered entity. Ark. Code Ann. § 23-92-604(c)(1). That provision focuses on the relationship between a pharmacy and a covered entity and the covered entity's access to a manufacturer's drugs, which is governed under state contract law. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996) (contract pharmacy distribution arrangements "simply recogniz[e] an existing right that covered entities enjoy under State law") ("1996 Guidance").

Arkansas law has traditionally governed access to a manufacturer's drugs by addressing a party's ability to order and receive drugs and other aspects of the drug delivery system. *See, e.g.*, Ark. Code Ann. § 20-64-505 (wholesale distribution of prescription drugs); Ark. Code Ann. § 20-64-506 (drug shipment).

Likewise, the second subparagraph of Act 1103 does not intrude on the 340B program. That paragraph prohibits a manufacturer from "deny[ing] or prohibit[ing] 340B drug pricing for an Arkansas-based community pharmacy," which PhRMA contends is an attempt by Arkansas to qualify contract pharmacies as covered entities under the 340B statute. PhRMA Reply Br. at 8-9. PhRMA ignores the remainder of that subparagraph, which clarifies that the contract pharmacy "receives" the drugs at issue, which have already been "purchased" through the 340B program by "an entity authorized to participate in 340B drug pricing." Ark. Code Ann. § 23-92-604(c)(2). The term "purchased" is used in the past tense, demonstrating that Act 1103 regulates distribution of drugs that are already subject to a 340B price. *Id.* The Arkansas contract pharmacy "receives," not purchases, the 340B drugs, meaning the contract pharmacy receives *possession* of drugs already subject to federal 340B-prices. *Id.* Thus, Act 1103 does not transform contract pharmacies into covered entities because the statute plainly applies to drugs already purchased by covered entities.

PhRMA asks this Court to read the phrase "340B drug pricing for an Arkansas-based community pharmacy" in Ark. Code Ann. § 23-92-604 to "extend the pricing provided by Congress for statutorily enumerated covered entities under the 340B Program to Arkansas-based contract pharmacies." PhRMA Reply Br. at 9. PhRMA's reading is precisely the type of "semantics" and "creative statutory interpretation or description at odds with [Act 1103's] intended operation and effect." PhRMA Reply Br. at 7-8 (quoting *Wos v. E.M.A.*, 568 U.S. 627, 636 (2013)). Act 1103 does not permit contract pharmacies to purchase 340B drugs, and

therefore cannot "expand the list of entities entitled to reap the 340B pricing benefit." PhRMA Reply Br. at 8. Under a plain reading of Act 1103, the manufacturer already offered 340B prices to a covered "entity authorized" to receive those prices before Act 1103 becomes applicable to a manufacturer. Ark. Code Ann. § 23-92-604(c)(2).

b. Arkansas Enacted Act 1103 to Protect Distribution of 340B Drugs, Not to Regulate Their Price or Sale

In enacting Act 1103, the Arkansas General Assembly recognized that numerous drug companies have expressly restricted *distribution* of 340B-priced drugs, which damages Arkansas' health care safety net. *See, e.g.*, Lilly Notice (entitled "*Limited Distribution Plan* Notice for Eli Lilly and Company Products," stating "Lilly is *limiting distribution* of all 340B ceiling priced product directly to covered entities and their child sites only") (emphasis added) (undated).[2] To protect the health and safety of individuals within its borders, the Arkansas

[2] Lilly is a member of PhRMA, and other PhRMA members similarly stress that they are restricting distribution. Novo Nordisk, "Notice Regarding Limitation on Hospital Contract Pharmacy Distribution," (Novo Nordisk will no longer *facilitate 'bill-to/ship-to' distribution* of 340B drugs and distinguishing distribution from the "offer" of 340B prices: "[a]t no time will Novo Nordisk *fail to offer* 340B prices to 340B covered entity.") (emphasis added) (Dec. 1, 2020), https://www.novonordisk-us.com/partnering-and-innovation/hospital-contract-pharmacy-distribution.html; Johnson & Johnson, Notice to 340B and Non-340B End Customers Regarding Bill To/Ship To Orders (Mar. 21, 2022) (stating that "no end customer will be permitted *to direct shipment or delivery of product to a Ship To location* that is not part of the Bill To purchaser" and that Johnson and Johnson "will[, nevertheless,] *continue to offer* 340B covered outpatient drugs to all Covered Entities") (emphasis added), https://www.jom.com/sites/default/files/JJHCS%20Notice%20to%20End%20Customers%20Regarding%20Bill%20To%20Ship%20To%20Orders.pdf; Bausch Health US, LLC (stating that it "is altering its approach to *distributing* products purchased at the 340B price," that it will only "*ship* products purchased at the 340B price exclusively to" covered entity locations, and "contract pharmacies will no longer be eligible *recipients*" of bill-to/ship-to drugs) (emphasis added), https://340breport.com/wp-content/uploads/2022/07/BHC-340B-Policy_CE.pdf; Bristol Myers Squibb (stating that "BMS has developed a coordinated, enterprise-wide approach to the company's *distribution practices*" and that it will restrict distribution of drugs purchased at 340B prices to only "two designated 340B contract pharmacy locations") (emphasis added), https://www.bms.com/assets/bms/us/en-us/pdf/340B-distribution-practice-factsheet.pdf; GlaxoSmithKline, (stating that "GSK will *ship* products purchased at the 340B price exclusively

General Assembly passed Act 1103 to require manufacturers to "actually ship[] medications" subject to 340B-prices to legally authorized Arkansas contract pharmacies. *To Establish the 340B Drug Pricing Nondiscrimination Act*, *Hearing on H.B. 1881 Before the Ark. House of Representatives*, 93d Gen. Assemb., Reg. Sess. (Ark. 2021) (statement of Rep. Michelle Gray) (also stating that the [Arkansas] 340B Drug Pricing Nondiscrimination Act "is not price setting").[3] Representative Gray stated to the Arkansas House of Representatives immediately prior to its vote on Act 1103 that, beginning in the preceding year, "manufacturers decided that they would no longer ship … medications to the contract pharmacy" and that Act 1103 was passed to curb these predatory distribution limitations. *Id.* Representative Gray emphasized that "nowhere [in Act 1103] are we setting a price." *Id.* The Arkansas House of Representatives immediately passed Act 1103. *To Establish the 340B Drug Pricing Nondiscrimination Act*, *Hearing on H.B. 1881 Before the Ark. House of Representatives*, 93d Gen. Assemb., Reg. Sess. (Ark. 2021).

Even Leo Hauser, testifying on behalf of PhRMA to the Arkansas Senate Insurance and Commerce Committee, acknowledged that "the real sense of [Act 1103] is, the bill would require manufacturers to ship" 340B drugs. Leo Hauser, Representative for PhRMA, *Hearing on House Bill 1881 Before the Ark. Sen. Ins. And Commerce Comm.* (Apr. 26, 2021).[4] Mr. Hauser never alleged that Act 1103 would regulate drug pricing. *Id.*

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to" the covered entity's location and that "contract pharmacies will no longer be eligible *recipients*" for drugs purchased at 340B prices) (emphasis added), https://340breport.com/wp-content/uploads/2022/02/GSK-letter-to-340B-covered-entities-02.12.2022.pdf.

[3] https://sg001-harmony.sliq.net/00284/Harmony/en/PowerBrowser/PowerBrowserV2/20221024/-1/21626# (Representative Gray's testimony regarding Act 1103 begins at 1:46 PM, and her statement that Act 1103 does not set prices and requires drugs to be shipped to Arkansas begins at 1:50:40 PM).

[4] https://sg001-harmony.sliq.net/00284/Harmony/en/PowerBrowser/PowerBrowserV2/20210426/-

Thus, the Arkansas legislature intended Act 1103 to address drug distribution. The distribution focus of the Act is not "creative statutory interpretation or description at odds with the statute's intended operation and effect" as PhRMA contends. PhRMA Reply Br. 7-8 (quoting *Wos*, 568 U.S. at 636). Act 1103 only applies to those drugs that are already subject to 340B pricing, and it neither modifies 340B pricing nor permits contract pharmacies to purchase 340B drugs. Act 1103 regulates drug distribution, which is precisely consistent with the express intent of the Arkansas General Assembly. *Wos*, 568 U.S. at 636.

c. PhRMA Ignores AID's Authoritative Interpretation of Act 1103 As Reflected in Rule 123

In Final Rule 123, AID clarifies that Act 1103 regulates the "delivery and acquisition" of drugs already subject to a manufacturer's 340B-price. AID Rule 123: 340B Drug Program Nondiscrimination Requirements II(7) (defining "340B-drug pricing").[5] PhRMA addresses Rule 123 only in a footnote, dismissing it as a "linguistic sleight of hand." PhRMA Reply Br. at 8. AID's interpretation of Act 1103 is entitled to deference. *Arkansas Pub. Emps. Ret. Sys. v. Taylor*, 425 S.W.3d 738, 741 (Ark. 2013); *Yamaha Motor Corp., U.S.A. v. Richard's Honda Yamaha*, 38 S.W.3d 356, 360 (Ark. 2001). Act 1103 specifically mandates AID to "promulgate rules to implement" its provisions. Ark. Code Ann. § 23-92-606.

AID promulgated Final Rule 123 under the Arkansas Administrative Code, and it carries the force and effect of Arkansas law. Ark. Code Ann. §§ 25-15-202 (defining "rule"), 25-15-204 (requiring notice and comment rulemaking procedure by Arkansas agencies to promulgate regulations). AID's well-informed definition of "340B drug pricing" is entitled to deference.

1/21667?viewMode=1#info. (Mr. Hauser's testimony begins at 9:31 AM and the referenced statement is made at 9:34 AM).

[5] https://insurance.arkansas.gov/uploads/pages/rule_123_340b_drug_program_nondiscrimination_requirements.pdf.

See Nucor Steel-Arkansas v. Arkansas Pollution & Ecology Comm'n, 478 S.W.3d 232, 240 (Ark. Ct. App. 2015). Arkansas courts overturn an agency's interpretation of a statute that the agency is charged with administering only when the agency is clearly wrong, such as an agency interpretation that conflicts with the plain meaning of the statute, is not supported by "substantial evidence," or is "arbitrary and capricious." *Douglass v. Dynamic Enters., Inc.*, 869 S.W.2d 14, 16 (Ark. 1994); *Brimer v. Arkansas Contractors Licensing Bd.*, 849 S.W.2d 948, 951 (Ark. 1993). An agency interpretation is arbitrary only if it is not "supportable on any rational basis." *Ramsey v. Dep't of Hum. Servs.*, 783 S.W.2d 361, 364 (Ark. 1990).

Thus, when analyzing the meaning of a statute, Arkansas courts defer to the expertise of the state agency that is responsible for administering that statute because the agency is far-better equipped by specialization, insight, and experience to analyze legal issues affecting statutory programs that they administer. *See Lamar Outdoor Advert. v. Ark. Hwy. & Transp. Dep't*, 184 S.W.3d 461, 467 (Ark. Ct. App. 2004); *Pine Bluff for Safe Disposal v. Ark. Pollution Control & Ecology Comm'n,* 127 S.W.3d 509 (Ark. 2003). Likewise, this Court should defer to AID's interpretation of "340B drug pricing" as meaning the "acquisition and delivery" of drugs. AID's interpretation, which was properly promulgated under Rule 123, is that Act 1103 encompasses only the distribution of drugs that have already been discounted and purchased by covered entities under the 340B program.

d. PhRMA Ignores Implied Preemption Cases and Instead Relies on Inapplicable Express Preemption Cases

PhRMA relies on cases interpreting the preemptive effect of statutes with *express* preemption clauses, which are inapplicable here because the 340B statute contains no express preemption clause. *See* PhRMA Reply Br. at 9-10 (citing *Nat'l Meat Ass'n v. Harris,* 565 U.S. 452 (2012); *Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246 (2004)). The

issue before the Court requires an *implied* preemption analysis, which does not justify a "freewheeling judicial inquiry into whether a state statute is in tension with federal objectives," and "would undercut the principle that it is Congress rather than the courts that preempts state law." *Chamber of Com. of the U.S. v. Whiting*, 563 U.S. 582, 607 (2011).

For example, the Supreme Court held that a state statute prohibiting uranium mining in Virginia was not preempted by the federal Atomic Energy Act ("AEA"). *Virginia Uranium, Inc. v. Warren*, 139 S. Ct. 1884 (2019). The AEA, which "contain[ed] no provision expressly preempting state law," granted the federal Nuclear Regulatory Commission "extensive and sometime exclusive authority to regulate nearly every aspect of the nuclear fuel life cycle *except* mining." *Virginia Uranium, Inc.*, 139 S. Ct. at 1896. Like the AEA, the 340B statute addresses every aspect of drug pricing but does not address drug distribution. This court should reject PhRMA's request for this Court to "ascribe unenacted purposes and objectives to a federal statute" by conflating a federal pricing requirement that is merely a precondition to a state-law distribution requirement. *Id.*

PhRMA ignores the implied preemption cases cited by Intervenors.[6] Intervenors' Br. at 12, 24, 33, 36, 40, 41 (ECF No. 36). In each of those cases, courts upheld state laws that operated in parallel to federal laws. *See Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 240-41,

[6] AID correctly explained in its brief that the Eighth Circuit has delineated four factors that guide a court's implied preemption analysis. AID Br. at 6, ECF No. 30 (discussing *Northern States Power Co. v. Minnesota*, 447 F.2d 1143 (8th Cir. 1971)). PhRMA asserts that *Northern States* is not controlling "because the Eighth Circuit in that case was just summarizing factors that can be relevant to various forms of implied preemption—not establishing a mandatory multi-factor test." PhRMA Reply Br. at 21. In reality, the Eighth Circuit describes these factors as "key" to a preemption analysis and cites Supreme Court precedent for each of these factors. *Northern States*, 447 F.2d at 1146. AID analyzed each of the factors from the *Northern States* case and explained why each demonstrates that Act 1103 is not preempted by federal law. AID Br. at 9-10.

258 (state penalties for radiation hazards not preempted by federal regulation of nuclear energy); *Exxon Shipping Co. v. Baker*, 554 U.S. 471, 475-76, 489 (2008) (state damages against polluters not preempted by federal statute protecting navigable waters); *Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n*, 461 U.S. 190, 205 (1983) (state economic regulation of nuclear power construction not preempted by federal law governing nuclear power safety); *Fla. Lime & Avocado Growers v. Paul*, 373 U.S. 132, 141 (1963) (state law regulating maturity of avocados not preempted by federal avocado regulations); *Hillsborough Cnty. v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 719 (1985) (local regulation of blood donations not preempted by federal regulation of blood plasma).

The *Pacific Gas & Electric* case is particularly instructive. In that case, the Court held that a state law imposing requirements on nuclear reactors was not preempted by the federal AEA because "California's avowed economic rather than safety purpose" was "the rationale for enacting" the state law. 461 U.S. at 216. The Supreme Court, therefore, looks to a state's declared purpose for enacting a statute to determine whether that statute preempts federal law. The Arkansas General Assembly has expressly avowed that the purpose of Act 1103 is to regulate shipment, or distribution, of drugs already subject to federal 340B-price offers. *To Establish the 340B Drug Pricing Nondiscrimination Act*, *Hearing on H.B. 1881 Before the Ark. House of Representatives*, 93d Gen. Assemb., Reg. Sess. (Ark. 2021) (statement of Rep. Michelle Gray). Likewise, AID has promulgated regulations clarifying that Act 1103 regulates the "acquisition and delivery" of drugs already subject to 340B prices. AID Rule 123: 340B Drug Program Nondiscrimination Requirements II. Accordingly, both the Arkansas legislature and AID have avowed that distribution, rather than pricing, is the rationale for Act 1103. This Court should be guided by these statements of the purpose of Act 1103 and hold that Act 1103 is not preempted by the federal 340B statute.

Moreover, federal laws do not preempt state laws when a federal agency charged with administering the federal statute disclaims preemptive effect, which HRSA has done here. In *Hillsborough Cnty. v. Automated Med. Lab'ys, Inc*., the Supreme Court held that federal regulations issued by the federal Food and Drug Administration ("FDA") addressing blood plasma donations did not preempt local regulations that imposed requirements on donators when the FDA expressly disavowed any intent to preempt state law. 471 U.S. 707, 719 (1985). Similarly, HRSA acknowledged that its 340B contract pharmacy guidance was "simply recognizing an existing right that covered entities enjoy *under State law*." 1996 Guidance, 61 Fed. Reg. at 43,550 (emphasis added). HRSA emphasized that "the covered entity will adhere to all Federal, *State and local laws and requirements*" relating to contract pharmacy distribution arrangements. *Id.* at 43,555. HRSA also explained that "if State X permits a covered entity to use contract pharmacy services to purchase drugs on its behalf, the entity could presumably use this mechanism." 1996 Guidance, 61 Fed. Reg. at 43,551. Accordingly, HRSA provided an express "disavowal … of any intent to pre-empt state and local regulation." *See Hillsborough*, 471 U.S. at 716-17.

e. Even if Act 1103 Regulates a Manufacturer's Requirement to Offer 340B Pricing, It is Not Preempted

Even if this Court deems that Act 1103 regulates a manufacturer's 340B sales (it does not), Act 1103 would not be preempted because, as PhRMA has admitted, the 340B statute is silent "on how manufacturers sell 340B-discounted drugs." PhRMA Reply Br. at 15. As discussed *supra* section I.A.1.d, implied preemption caselaw instructs that even for allegedly comprehensive federal regulatory schemes (section 340B is not), states may still impose "a higher standard demanded … for its consumers." *Fla. Lime & Avocado Growers,* 373 U.S. at 145; *see also Hillsborough*, 471 U.S. at 719.

Rather than addressing *Florida Lime* and *Hillsborough County*, PhRMA relies almost exclusively on *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011), but *Astra* only addresses matters expressly governed by the 340B statute: overcharge complaints by covered entities. *Astra* does not address a state's regulation of drug distribution within its borders. Moreover, unlike the covered entities in *Astra*, Intervenors do not seek a compensatory remedy as a "third-party beneficiary" to a manufacturer's contracts with HHS. *See Astra*, 563 U.S. at 112 ("Asserting that the 340B entities … are the intended beneficiaries of the PPAs and that the [covered entity] sought *compensatory damages* for … breach of contact." (emphasis added)).

Rather, Act 1103 dictates standards for manufacturers distributing 340B drugs within the state of Arkansas. PhRMA admits that the 340B statute is silent regarding how manufacturers deliver their sales of 340B drugs, and this admission is fatal to its preemption claim on that same conduct. PhRMA Reply Br. at 15. The Court should not presume that the 340B statute "was intended to eliminate *sub silentio* [drug manufacturers'] duties to refrain from" obstructing safety-net healthcare providers and their vulnerable underprivileged patients from obtaining discounted medications, which are often life saving. *Exxon Shipping Co.*, 554 U.S. at 489. Moreover, PhRMA's preemption claims fail because no evidence exists that Congress intended to forbid states from sanctioning manufacturers that violate drug distribution requirements, even if Congress gave HRSA exclusive authority to regulate overcharge disputes between manufacturers and covered entities. Significantly, AID would not need to determine whether a manufacturer overcharged a covered entity when determining whether the manufacturer failed to distribute discounted drugs to contract pharmacies.

2. PhRMA's Arguments That Act 1103 Is Preempted Even if Viewed as a Distribution Law Are Meritless

PhRMA next asserts that, even if the Court agrees with Intervenors that Act 1103 governs distribution, the statute is preempted because "it impermissibly wades into, and conflicts with, the comprehensive 340B scheme." PhRMA Reply Br. at 10. In support of this conclusion, PhRMA offers a novel interpretation of the 340B provision prohibiting diversion of 340B drugs by covered entities, an interpretation contrary to HRSA's. PhRMA argues that this covered entity requirement somehow shows Congress's intent to regulate the distribution of 340B drugs and, in particular, to prohibit the transfer of drugs to contract pharmacies. According to PhRMA, covered entities retaining title to the 340B-priced drugs delivered to contract pharmacies does not avoid the transfer violation, and, even if it did, there is "ample publicly available evidence" that covered entities do not retain title. PhRMA Reply Br. at 14. PhRMA's attempt to stretch the scope of the 340B statute to include drug distribution is meritless. Its attacks on the well-accepted contract pharmacy model, which requires that drugs are billed to the covered entity, the covered entity retains title to the drugs, and the drugs are shipped to the contract pharmacy, are also unpersuasive. None of its arguments, either individually or in combination, support a conclusion that Act 1103 conflicts with the 340B statute.

a. PhRMA Is Alone in Believing the 340B Statute Governs Distribution

PhRMA asserts that the 340B diversion prohibition "covers and governs" drug distribution. PhRMA Reply Br. at 10-11 (citing 42 U.S.C. § 256b(a)(5)(B)) [hereinafter "diversion prohibition"]. The 340B diversion provision states that 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). Deliveries to contract pharmacies are not diversion. HRSA enforces the diversion prohibition, and for more than twenty-six-years, HRSA has never interpreted contract

pharmacy distribution as diversion. 1996 Guidance, 61 Fed. Reg. at 43,549-51; Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,274 (Mar. 5, 2010). PhRMA is hinging its federal preemption argument on an interpretation of the 340B statute that has been rejected by the federal agency charged with administering the statute. HRSA has explained that the contract pharmacy "mechanism does not in any way extend [340B] pricing to entities which do not meet [covered entity] eligibility" requirements. *Id.* HRSA "found no indication that the [contract pharmacy] guidelines contravene Federal or State law," and contract pharmacy distribution arrangements are "akin to a covered entity having its own pharmacy." *Id.* HRSA's longstanding interpretation is entitled to deference. *Skidmore v. Swift & Co*., 323 U.S. 134, 140 (1944) (deferring to agency's consistent interpretation).

PhRMA's novel theory that contract pharmacy shipments are diversion, if accepted by the Court, would undo twenty-six years of both covered entities and manufacturers participating in contract pharmacy arrangements and would exclude from the 340B program those covered entities, especially in Arkansas, that cannot own or operate in-house pharmacies due to legal or operational constraints.

PhRMA asserts that "several federal courts will soon be addressing these issues." PhRMA Reply Br. at 11. But Intervenors have already provided this Court with several federal district court decisions that *have* considered this issue and determined that contract pharmacy distribution arrangements do not constitute diversion. *See, e.g*., *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs*., 570 F. Supp. 3d 129, 193 n.50 (D.N.J. Nov. 5, 2021) (Sanofi's contract pharmacy diversion assertion is "not a reasonable construction of the statute," "HHS has never interpreted § 256b(a)(5)(B) in this manner," and "[t]he 340B Program's non-transfer/resale provision refers to situations where 340B drugs are given to individuals who are not receiving health care services from covered entities or are receiving services inconsistent with the type of

services for which the covered entity qualified for 340B status."); *Eli Lilly & Co. v. U.S. Dep't of Health & Hum. Servs*., No. 1:21-cv-00081, 2021 WL 5039566, at *20 (S.D. Ind. Oct. 29, 2021) (rejecting Lilly's assertions that "sales of 340B drugs to covered entities utilizing contract pharmacy arrangements [are not] 'purchases by' covered entities," that contract pharmacies purchase drugs, and that use of a "replenishment model" at contract pharmacies constitutes diversion).

Even the Government Accountability Office's report recommending increased federal oversight of contract pharmacies (cited in PhRMA Reply Br. at 5), treats contract pharmacy arrangements as a legally permissible distribution system under the 340B statute and does not characterize them as diversion. U.S. Gov't Accountability Off., GAO-18-480, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement 2 (2018), ECF No. 24-1, Ex. 1-C ("A covered entity typically purchases and dispenses 340B drugs through … the use of a contract pharmacy arrangement, in which the entity contracts with an outside pharmacy and pays it to dispense drugs on its behalf," and "they are prohibited from diverting 340B drugs—that is, transferring 340B drugs to individuals who are not eligible patients of the covered entities.").[7]

Finally, the "resale" is inapplicable to contract pharmacy arrangements because contract pharmacies do not purchase 340B drugs. 42 U.S.C. § 256b(a)(1); *id.* § 256b(a)(5)(B); Decl. of Krista M. Pedley, ¶¶ 7, 8, 9, ECF No. 24-1, Ex. 1-E (former OPA Director, Rear Admiral Krista Pedley stating that contract pharmacies do not purchase 340B drugs and that covered entities purchase 340B drugs) ("Pedley Decl."). The prevailing understanding of the term "purchase" in

[7] https://www.gao.gov/assets/gao-18-480.pdf.

1992, when Congress enacted the 340B statute, was to obtain title *by paying a price*, rather than obtain possession.[8]

b. PhRMA's Argument That Covered Entities Relinquish Title to 340B Drugs in Replenishment-Based Contract Pharmacy Arrangements Is Neither Accurate Nor Evidence of Preemption

PhRMA claims that covered entities do not retain title to drugs shipped to contract pharmacies and it does so by mischaracterizing certain drug inventory systems. PhRMA Reply Br. at 13-14. When a manufacturer sells drugs through a wholesaler, the drugs shipped by the manufacturer to the wholesaler are not intended to fill a particular order placed by a pharmacy; instead, they are to supply inventory to the wholesaler that the wholesaler then sells to a pharmacy. *See, e.g.*, Robert Handfield, Biopharmaceutical Supply Chains 11-13 (2012) (ebook) (explaining "forward buying" and fee-for-service buying by wholesalers where the next distribution-chain purchaser may not yet have been determined). And even if the drugs shipped by the manufacturer to the wholesaler filled a pharmacy order, the drugs shipped to the wholesaler would not necessarily be the same drugs delivered by the wholesaler to the pharmacy because particular prescription drugs are manufactured in a precise and reproducible manner such that manufacturers and wholesalers treat them as fungible. *See* 21 U.S.C. § 360(e); 21 C.F.R. § 207.33 (the FDA assigns NDC numbers specific to the drug's label and manufacturer, chemical composition, route of administration, and package size); 21 U.S.C. § 360eee-1 (requiring manufacturers, wholesale distributors, repackagers, and dispensers to exchange certain data, including NDC numbers and drug pedigree information, upon each transaction regarding

[8] *Purchase*, Webster's Third New International Dictionary Unabridged (1992); *see also Purchase*, Black's Law Dictionary (11th ed. 2019) (the "act or instance of buying" or the "acquisition of an interest . . . by sale, discount, negotiation, mortgage, pledge, lien, issue, reissue, gift, or any other voluntary transaction."); U.C.C. § 2-106(1).

FDA approved drugs); *see also* 21 C.F.R. § 207.35 (describing "[w]hat changes [in a prescription drug product] require a new NDC?"); *National Drug Code Database Background Information*, FDA (Mar. 20, 2017) (listing all FDA-approved NDCs).[9] They share the same labeling, chemical composition and route of administration but are otherwise different products. *See* 21 U.S.C. § 360(e); 21 C.F.R. § 207.33.

The fungibility of prescription drugs enables wholesalers and manufacturers to use a replenishment-based system for distributing drugs. Rather than acquiring a particular drug from a manufacturer and ensuring that specific drug is delivered to a pharmacy, the wholesaler is free to ship a drug to a pharmacy that has the same labeling, chemical composition, route of administration and package size as the drug ordered from the manufacturer by the wholesaler. The FDA assigns National Drug Codes ("NDCs") to drugs to facilitate this drug replacement process. 21 U.S.C. § 360(e); 21 C.F.R. § 207.33. The eleven-digit NDC code identifies the drug's manufacturer, label, chemical composition, route of administration and package size. *Id.* The NDC system allows the wholesaler to purchase a large stock of drugs with the same NDC and to replenish that stock with additional NDC-specific purchases from the manufacturer as inventory levels decline due to the wholesaler's day-to-day sales to pharmacies or other customers. *See* Handfield, *supra*, at 11-13, 24-31. If prescription drugs were not fungible and identifiable through NDCs, wholesalers would have to ensure that a drug ordered from, and shipped by, the manufacturer was the same drug shipped to the pharmacy.

Covered entities and contract pharmacies rely on the same replenishment-based inventory management process used by wholesalers and manufacturers to manage their inventory of prescription drugs. The only difference is that, for 340B drugs, a drug is ordered only if the drug

[9] https://www.fda.gov/drugs/development-approval-process-drugs/national-drug-code-database-background-information.

it is intended to replace a drug that was already dispensed to a 340B-eligible patient of the covered entity. Pedley Decl. ¶¶ 7, 8, 9. In contrast to wholesalers, covered entities and contract pharmacies do not stock up on 340B drugs when using a replenishment-based inventory management system. And to ensure that the replenishment process is implemented accurately, they rely on software systems that track drugs dispensed to patients that are eligible to receive those drugs, and place replenishment orders. *Id.* This replenishment process is preferred by most covered entities and pharmacies because it not only spares the pharmacy from having to maintain multiple separate inventories, but also because it enables more accurate inventory record keeping than would a physical inventory system. *See, e.g.*, 1996 Guidance, 61 Fed. Reg. at 43,554 (HRSA stating that "the requirement for a separate inventory of 340B drugs is unnecessary, because the covered entity is required to monitor dispensing and inventory records" and that those "records will accurately indicate use of 340B drugs"); Pedley Decl. ¶¶ 5-9, 12 (stating that software is used to analyze and ensure that only the covered entity's patients receive 340B drugs, that "[w]hen utilizing a replenishment model, covered entities … ensure that the covered entity is replenishing inventory with 340B drugs only in instances where drugs have been provided to qualified 340B patients," and that replenishment models track drugs dispensed to covered entity patients using an 11-digit National Drug Code product identifier).[10]

By ensuring that 340B replenishment drugs are only ordered and purchased if they replace drugs that have been dispensed, covered entities always retain title to 340B drugs that are dispensed to their patients. *See, e.g., United States v. Gen. Elec. Co.*, 272 U.S. 476, 484 (1926) (holding that a distribution and sales partner of General Electric did not take title to the fungible

[10] *See* PhRMA's Exhibit 1-E, ECF No. 24-1, Declaration of Rear Admiral Krista Pedley, at paragraphs 5-12.

goods, but rather, "title passes directly from [General Electric] to [General Electric's end] purchasers").

If PhRMA is concerned that replenishment-based inventory management systems cause diversion, then the federal administrative dispute resolution ("ADR") process is available to its members to investigate and remedy such concerns. 42 C.F.R. § 10.20-24. Manufacturers could and should use the federal ADR process to adjudicate their claim that replenishment-based contract pharmacy arrangements lead to diversion. By electing to use self-help instead, the eighteen manufacturers that unilaterally imposed restrictions on contract pharmacies stepped outside the bounds of the 340B program into a state regulated area.

PhRMA makes a conclusory assertion that there is "ample publicly available evidence that confirms covered entities do not retain title to 340B-discounted drugs in contract-pharmacy arrangements." PhRMA Reply Br. at 14. This "ample" evidence that PhRMA cites includes only two contracts, neither of which involve Arkansas covered entities or pharmacies. *Id.* at 14-15. PhRMA misinterprets the language in its examples to support its claim that covered entities do not retain title under contract pharmacy arrangements. In reality, the contract agreements in PhRMA's brief describe the mechanics of how a replenishment-based inventory system operates and ensures that, because 340B drugs are only ordered to replenish the contract pharmacy's drugs dispensed to 340B eligible patients, covered entities always retain title to the 340B drugs. Furthermore, attached to this brief is an affidavit from a 340B hospital located in Arkansas attesting to its use of a contract pharmacy agreement and clearly stating that the "Covered Entity . . . maintain[s] ownership of the 340B Drugs." when 340B drugs pass through the contract pharmacy's physical possession. Maggie Williams, Pharm.D Aff., Ex. 1, at ¶¶ 8-9.

PhRMA's selective reliance on a few publicly available contracts fails to address how title is maintained by a covered entity under inventory replenishment systems. The key is that at

the beginning of the contract pharmacy arrangement, the pharmacy essentially loans the initial inventory to the covered entity as 340B-priced drugs, and the covered entity then replaces drugs *already dispensed* from that starting inventory to the covered entity's patients as repayment for the starting inventory. *See* Cnty. of Monterey & Walgreen Co. 340B Contract Pharmacy Services Agreement at 11 (stating that "[u]pon termination of this Agreement, Walgreens will provide Covered Entity with an invoice detailing those drugs dispensed under the 340B Drug Program which have not been replenished" and "Covered Entity will . . . reimburse Walgreens for those pharmaceutical products at" Walgreens' acquisition cost for the drug). Accordingly, the covered entity has essentially purchased the starting inventory of drugs upon termination of the arrangement. This inventory system has been endorsed by HRSA as compliant with the 340B program. 1996 Guidance, 61 Fed. Reg. at 43,554; Pedley Decl. ¶¶ 5-9, 12.

c. Act 1103 Does Not Require Non-Covered Entities, Including Contract Pharmacies, to Take Title to 340B Drugs

Central to the 340B contract pharmacy model is the covered entity's retention of title to the 340B drugs possessed by the contract pharmacy. It is how the contract pharmacy bill to/ship to arrangement has worked during the 340B program's thirty year history and how it worked before there was a 340B program. *Id.* Yet PhRMA finds "many problems" with the model. PhRMA Reply Br. at 11-12. "Most glaringly," according to PhRMA, "Act 1103's contract pharmacy mandate provisions are not limited to situations where covered entities might nominally retain title." *Id.* PhRMA misreads Act 1103 as forcing manufacturers to honor contract pharmacy arrangements when covered entities do not take title, presumably if contract pharmacies take title instead.

PhRMA misreads Act 1103. The relevant provision in Act 1103 plainly applies only to drugs "purchased under a 340B drug pricing contract pharmacy arrangement with an entity

authorized to participate" in the 340B program. Ark. Code Ann. § 23-92-604. If the drugs in question have already been purchased, then the only way an illegal transfer can occur is if the covered entity transfers title to the contract pharmacy. Act 1103 does not compel covered entities to transfer ownership of 340B drugs to contract pharmacies.

PhRMA goes a step farther and asserts that the anti-diversion requirement outlaws transfers even if the covered entity does not "convey formal 'title.'" PhRMA Reply Br. at 12. Again, HRSA has never interpreted contract pharmacy shipments as diversions. 1996 Guidance, 61 Fed. Reg at 43,549, 43,554. To the contrary, HRSA has consistently interpreted the provision as allowing covered entities to transfer possession of 340B drugs to pharmacies while retaining title to the drugs. *Id. Compare* 42 U.S.C. § 256b(a)(1) (requiring a covered entity to "purchase") *with* 38 U.S.C. § 8126 (requiring federal agencies to "procure[]," meaning possess, FCP drugs). PhRMA cites no authority that would allow its unprecedented interpretation to prevail over HRSA's. And contrary to common sense, a prohibition against physical transfer of 340B drugs to non-patients would bar covered entities from allowing family members of a 340B-eligible patient to pick-up drugs for the patient or using couriers or the U.S. postal service to deliver drugs. No such prohibition exists.

d. Whether Covered Entities Retain Title to Drugs Shipped to Contract Pharmacies Is a Disputed Issue of Material Fact

Notwithstanding this textual and contextual evidence, PhRMA asserted in its opening brief that contract "pharmacies … purchase drugs at the 340B price" to replenish the drugs dispensed to covered entity patients, and, according to PhRMA, this creates conflict with the 340B statute's resale prohibition. PhRMA MSJ Br. at 9 (ECF No. 26); *see also* PhRMA Statement of Material Facts ¶¶ 27, 28, 29 (ECF No. 25). PhRMA asserted that statement, while simultaneously offering an exhibit stating the exact opposite – that contract pharmacies do not

purchase 340B drugs. PhRMA MSJ Br. at 9 (citing Declaration of former OPA Director, Rear Admiral Krista Pedley ¶¶ 7, 8, 9, stating that contract pharmacies do not purchase 340B drugs and that covered entities purchase 340B drugs). And Intervenors offered an affidavit consistent with Rear Admiral Pedley's declaration to defeat PhRMA's assertion that contract pharmacies purchase 340B drugs and thereby violate the diversion prohibition. Decl. of Dr. Lanita S. White, Chief Executive Officer of Community Health Centers of Arkansas ¶ 8, ECF No. 17, Ex. 3 (CHCA's "community health centers purchase and take title to the 340B medications, but the drugs are shipped to and dispensed by the contract pharmacies.").

Now, PhRMA asserts that "there is [no] genuine issue of material fact precluding summary judgment" because whether a "covered entity retains title to 340B-discounted drugs is unquestionably immaterial to PhRMA's argument regarding Act 1103's intrusion into, and conflict with, the unitary federal administrative and enforcement scheme." PhRMA Reply Br. at 12 n.6. This conclusory statement does not eliminate the material factual dispute central to PhRMA's conflict preemption claim. Contract pharmacies do not purchase 340B drugs. They receive possession of the drugs from drug manufacturers and wholesalers to be dispensed to a covered entity's patients.

PhRMA asks this Court to "declar[e] that Act 1103 does not require PhRMA's members to *offer price discounts under the 340B program to contract pharmacies in Arkansas*." PhRMA Compl. at 35, ¶ b (emphasis added). Without any substantiation that contract pharmacies actually purchase 340B drugs – meaning pay a price to acquire title in them – PhRMA's request for relief should be denied and PhRMA's motion for summary judgment must fail because the

issue is material and Intervenors have offered contrary evidence.[11] *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 248 (1986) ("[T]he substantive law will identify which facts are material" and "[d]isputes over facts that might affect the outcome of the suit under the governing law [should] properly preclude the entry of summary judgment.").

B. PhRMA Fails to Refute Intervenors' Other Arguments Supporting Act 1103

In addition to the distribution-related issues discussed in Section I.A, Intervenors advanced several other arguments in support of its position that Act 1103 is not preempted by the 340B statute. PhRMA's attempts to refute those arguments are unsuccessful.

1. Intervenors' Observation That the 340B Statute Regulates Neither Contract Pharmacies nor Wholesaler Arrangements Does Not Create a False Equivalency as PhRMA Contends

The 340B statute is silent on drug distribution, which permits manufacturers to sell 340B drugs through wholesalers and covered entities to order and receive drugs through contract pharmacies. And just as the 340B statute does not address the role of contract pharmacies in the distribution of 340B drugs, neither does it address the role of wholesalers. Accordingly, PhRMA's assertion that the statute is silent regarding the role of wholesalers in manufacturer sales supports the use of contract pharmacy distribution arrangements, for which the statute is also silent. PhRMA Reply Br. at 15.

References in the 340B statute to "distribution" and "wholesalers" do not authorize, limit, or otherwise regulate manufacturer use of wholesalers to distribute 340B drugs. 42 U.S.C. § 256b(d)(1)(B)(v) (permitting auditing of wholesalers); *id.* § 256b(a)(1)(8) (establishing an *optional* prime vendor program for covered entities); PhRMA Reply Br. at 15-16. The two

[11] PhRMA's assertion that Intervenors "explicitly disclaimed that this case involves any question of fact" when moving for intervention should not be taken seriously. PhRMA Reply Br. at 12 n.6. This factual dispute arose from PhRMA's opening brief and statement of material facts, which were filed well after Intervenors moved to intervene.

references in the 340B statute to "distribution" are in the context of a voluntary prime vendor program that Congress directed HRSA to establish to enable covered entities to acquire drugs more efficiently. 42 U.S.C. § 256b(a)(1)(8) ("[T]he Secretary shall establish a prime vendor program under which covered entities *may* enter into contracts with prime vendors for the distribution of covered outpatient drugs.") (emphasis added). The single reference to "wholesalers" was not part of the original statute and was only added by Congress under the Patient Protection and Affordable Care Act ("ACA") to clarify HRSA's authority to audit wholesalers which, prior to enactment of the ACA, was unclear. *Id.* § 256b(d)(1)(B)(v); Pub. L. No. 111-148, § 7102, 124 Stat. 824 (2010). The mere appearance of these two words in the 340B statute does not mean that the statute regulates 340B drug distribution. Nor does it preempt Act 1103.

PhRMA provides no support for its assertion that "Congress's differential treatment [regarding the 340B transfer prohibition] makes obvious sense" because "Congress understood that the extraordinary discounts" under the 340B program "would present an enticing opportunity for profit-minded interlopers to benefit." PhRMA Reply Br. at 16. This assertion also asks this Court to step into a policy debate about how PhRMA believes covered entities should *use reimbursement* they obtain on 340B drugs. The Court should heed the Supreme Court's admonition that "[i]n all events, this Court is not the forum to resolve that policy debate" about 340B reimbursement. *Am. Hosp. Ass'n v. Becerra*, 142 S. Ct. 1896, 1906 (2022).

2. PhRMA's Attack on the Federal Trade Commission's Recognition of Contract Pharmacy Arrangements Misses the Mark

PhRMA next takes aim at Intervenors' discussion of how contract pharmacy arrangements are used outside the 340B program, as shown by a Federal Trade Commission ("FTC") advisory opinion. PhRMA Reply Br. at 16-18. PhRMA tries to obfuscate Intervenors'

argument by highlighting the differences between the 340B statute, the Robinson-Patman Act, and the Non-Profit Institutions Act ("NPIA"), which is the focus of the FTC opinion. *Id.* at 17-18; *see* Fed. Trade Comm'n, Univ. of Mich. Advisory Opinion Letter to Dykema Gossett (Apr. 9, 2010) ("FTC Advisory Opinion").[12] Any differences between the statutes do not erase the fundamental point that contract pharmacies are commonly used outside the 340B program, preceded enactment of the 340B statute, and led Congress not to impose distribution limitations. Regular use of contract pharmacies outside the program is another reason why Act 1103 is not preempted.

It is beside the point that the NPIA and the Robinson-Patman Act are antitrust laws focused on price discrimination and that neither law expressly addresses prescription drug discounts. 15 U.S.C. §§ 13, 13a, 13c, 14, 15c. It is well accepted that the purpose of the NPIA is to give non-profit institutions access to deeply discounted supplies, including drugs. *See Abbott Lab'ys v. Portland Retail Druggists Ass'n, Inc.*, 425 U.S. 1, 4 (1976) (acknowledging the purpose of the NPIA is to permit non-profit organizations to obtain "favored prices" lower than those charged in the regular commercial marketplace for supplies, including drugs purchased by non-profit hospitals). The Eighth Circuit agrees. *United States v. Ferro*, 252 F.3d 964, 966 (8th Cir. 2001) ("Pharmaceutical sellers grant deep discounts to non-profit customers."). Therefore, the voluntary nature of discounting under the NPIA does not diminish the analogy to 340B.

PhRMA's other attacks on the analogy also fail. It argues that, contrary to the 340B statute, the antitrust laws do not bar the resale or transfer of discounted drugs. PhRMA Reply Br. at 17. This is inaccurate because the NPIA clearly states that non-profit purchasers may only use NPI-discounted supplies "for their own use," and the Robinson-Patman act bars resales. 15

[12] https://www.ftc.gov/sites/default/files/documents/advisory-opinions/university-michigan/100409univmichiganopinion.pdf.

U.S.C. § 13(a) (barring price discrimination for "commodities . . . sold for . . . resale"); *id*. § 13c (exempting "own use" purchases from the § 13 resale prohibition). The NPIA "own use" limitation is strikingly similar to the 340B prohibition against resale to non-patients because they both are intended to prevent diversion to individuals who fall outside the scope of the relevant laws.[13]

PhRMA also argues that, whereas for-profit entities may not benefit directly or indirectly from contract pharmacy arrangements according to the FTC Advisory Opinion, 340B contract pharmacy arrangements are intended to generate revenue, some of which is paid to for-profit pharmacies for their services. PhRMA Reply Br. at 17-18. But this distinction does not diminish Intervenors' broader point that the FTC Advisory Opinion is evidence of how the contract pharmacy model exists outside the 340B program and is a perfectly appropriate way of distributing drugs.

3. Congress Was Aware That Many Covered Entities Lacked In-House Pharmacies

Intervenors cited legislative history describing Congress's decision not to impose restrictions in the 340B statute to allow covered entities to participate in the program through contract pharmacy arrangements. Intervenors' Br. at 20–22. The only evidence PhRMA offers to refute this history is a single statement in a Federal Register notice suggesting that HRSA did

[13] For example, PhRMA's own board member, Johnson & Johnson, recognized the commonplace nature and similarity between aspects of NPIA and 340B contract pharmacy distribution arrangements in its contract pharmacy distribution policy. Johnson & Johnson, Notice to 340B and Non-340B End Customers Regarding Bill To/Ship To Orders at 1 (Mar. 21, 2022) ("[b]oth in the non-340B and 340B context, [Johnson & Johnson] has long attempted to control diversion and inappropriate claims for discounts and rebates by requiring end customers to only buy product for their '*own use*' and seeking to prohibit the transfer of purchased drugs *outside of the applicable class of trade*."). Use "[o]utside of the applicable class of trade" for 340B covered entities is dispensing or administering to individuals that are not patients of the covered entities. *Id.*

not become aware of the small number of covered entities operating an in-house pharmacy until "the early period of program implementation." PhRMA Reply Br. at 18 (quoting 61 Fed. Reg. at 43,550). HRSA's statement has no bearing on the statute's legislative history or congressional intent.

PhRMA then sidesteps the program's legislative history and attempts to redefine the program's basic purpose. *Id.* at 18–19. PhRMA claims, without any supporting legislative history, that Congress only established the 340B program "to restore discounts previously voluntarily given to direct-care providers." *Id.* at 18. The legislative record of 340B reflects otherwise. The statute's true purpose—to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services"—has been endorsed not only by HHS and HRSA, but by the GAO and the federal courts. *See, e.g.,* GAO Report at 25–27; *see also Sanofi-Aventis U.S., LLC*, 570 F. Supp. 3d at 198 ("It is unrealistic to assume that 'Congress enacted a comprehensive legislative scheme to aid safety-net providers and vulnerable patients – but intentionally and implicitly structured it in such a way that only 5% of providers statutorily eligible to participate would be able to access the program in practice.'" (citation omitted)). PhRMA has also failed to acknowledge that the Senate precursor language to the 340B statute (referenced at page 20 of Intervenors' Brief) contained the same covered entity diversion prohibition found in the 340B statute while simultaneously *permitting covered entities to use contract pharmacies*. S. Rep. No. 102-259, at 2 (1992) (considering S. 1729, 102d Cong. (1992)) (permitting covered entities to use contracted "on-site pharmacy services" while simultaneously prohibiting a covered entity from "resell[ing] or otherwise transfer[ing]" 340B drugs "to a person other than a patient of the covered entity.").

PhRMA similarly distorts the legislative history of pharmacy licensure in Arkansas. Intervenors explained in their Opening Brief that Arkansas Code §§ 17-92-605(d) and 17-92-607

prevent most 340B hospitals in Arkansas from participating in the 340B program except through contract pharmacies. Ark. Code Ann. §§ 17-92-605(d), 17-92-607. PhRMA essentially blames the victim by inaccurately claiming that it was "Arkansas' decision to indirectly limit some covered entities' participation in the 340B program . . . ." PhRMA Reply Br. at 19. But these statutes were passed in 1975, seventeen years *before* enactment of the 340B statute. The real purpose of these statutory provisions is to protect retail pharmacies from anticompetitive sales of drugs purchased by non-profit hospitals at discounts under the NPIA, not to limit hospitals' participation in the 340B program. *See Homecare Pharmacy, Inc. v. Douglas*, No. CA 00-196, 2000 WL 1702008, at *1 (Ark. Ct. App. Nov. 8, 2000) ("The legislature's goal with this statutory language is to prevent a non-profit hospital from purchasing drugs at a discount *for its own use*, and then diverting those drugs to its retail pharmacy for sale." (emphasis added)). PhRMA's misrepresentation of the Arkansas law's legislative intent does not counter Intervenors' very real concern that, if Act 1103 is preempted, most 340B hospitals in Arkansas will continue to be deprived of the only way they can participate in the 340B program for retail drugs, namely, through contract pharmacy arrangements.

4. Congress Has Acquiesced to State Regulation of Drug Distribution

PhRMA argues that Intervenors have not shown that Congress acquiesced to states' authority to oversee drug distribution arrangements.[14] PhRMA Reply Br. at 20. PhRMA is incorrect. Intervenors have demonstrated that Congress considered the contract pharmacy arrangements and state regulation of drug distribution.

[14] PhRMA also alleges that "Intervenors argue precisely the *opposite*—that Congress declined to consider distribution mechanisms and instead left that issue to the States." PhRMA Reply Br. at 21. This argument holds no merit. Congress has recognized that states have traditionally regulated contract pharmacy arrangements, and Congress declined to interfere with those state schemes after considering bills, traditional industry practices, and agency guidance regarding those arrangements.

Congress acknowledged the existence of, and therefore acquiesced to, contract pharmacy arrangements in multiple proposed bills. For example, the Healthy America Act of 2005 and the 340B Program Improvement and Integrity Act of 2007 contained "use of multiple contract pharmacies" sections stating that "[n]othing in this section shall be construed as prohibiting a covered entity from entering into contracts with more than one pharmacy for the provision of covered drugs." Healthy America Act of 2005, S. 4, 109th Cong. § 332(b) (2005); 340B Program Improvement and Integrity Act of 2007, S. 1376, 110th Cong. § 5(a) (2007). Congress, therefore, was well aware of the existence of contract pharmacy distribution arrangements and chose not to enact legislation that would govern such arrangements.

In 2010, Congress comprehensively modified the 340B statute in the ACA, which added additional categories of covered entities, additional program integrity measures that included the authority to impose civil monetary penalties against manufacturers, and a dispute resolution program. ACA, Pub. L. No. 111–148, § 7101, 124 Stat. 821. Significantly, Congress chose not to make any additions to the 340B statute to address drug distribution through the ACA.

PhRMA characterizes the ACA changes as "isolated amendments" and argues that the Court should not consider Congress' silence on drug distribution in these amendments as acquiescence. PhRMA Reply Br. at 21. PhRMA's characterization completely ignores that the ACA affected every aspect of the 340B program, and Congress refrained from any infringement on states' authority to oversee drug distribution.[15] Congress is presumed to be "knowledgeable about existing law pertinent to the legislation it enacts." *Goodyear Atomic Corp. v. Miller*, 486

[15] PhRMA's argument that the ACA amendments were "isolated" is also at odds with its argument that the ADR process is evidence of a "comprehensive" or "unitary" federal scheme favoring preemption. PhRMA Reply Br. at 3, 21, 26.

U.S. 174, 176 (1988). Therefore, it must be assumed that Congress knew about contract pharmacy arrangements when it adopted the ACA.

It is also telling that Congress had multiple opportunities to codify, or upend, the contract pharmacy guidance that HRSA issued in 1996 and 2007 but chose not to do so. 1996 Guidance, 61 Fed. Reg. at 43,551; Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,278 (Mar. 5, 2010). Thus, Congress revisited the 340B statute in its amendments to the ACA, and chose not to revise or repeal HRSA's policies on contract pharmacies, which is "persuasive evidence" that Congress chose not to disrupt existing contract pharmacy arrangements. *Commodity Futures Trading Comm'n v. Schor,* 478 U.S. 833, 846 (1986) ("[W]hen Congress revisits a statute giving rise to a longstanding administrative interpretation without pertinent change, the congressional failure to revise or repeal the agency's interpretation is persuasive evidence that the interpretation is the one intended by Congress." (citation omitted)).

Courts have long recognized that Congress is aware of the existence of state law schemes that are traditionally within the state's power and that the decision not to override those state schemes demonstrates acquiescence to them. *See In re Pharm. Industry Average Wholesale Price Litig.*, 582 F.3d 156, 175 (1st Cir. 2009). ("Congress relied on the existence of state consumer protection and fraud statutes to combat severely manipulative pricing schemes resulting in overpayments by Medicare and its beneficiaries"); *see also Silkwood*, 464 U.S. 238; *Penn. Med. Soc'y v. Marconis,* 942 F.2d 842, 850 (3d Cir. 1991). Accordingly, Congress is presumed to be aware that states traditionally regulate drug distribution. Therefore, considering the multiple bills and the comprehensive modification of the 340B statute in 2010, Congress's decision not to address contract pharmacy distribution arrangements in legislation demonstrates

that Congress was aware that such arrangements were governed by state law and acquiesced to those state laws.

5. PhRMA Relies on Caselaw That Supports Intervenors' Position

PhRMA continues to rely on inapplicable case law to support its preemption argument. PhRMA again tries to tie the holding in *Astra* to this lawsuit by alleging that the Supreme Court's "inquiry largely overlapped with a preemption inquiry." PhRMA Reply Br. at 26. *Astra* addressed congressional intent regarding 340B *pricing* disputes: "Congress thus opted to strengthen and formalize HRSA's enforcement authority, to make the new adjudicative framework the proper remedy for covered entities complaining of 'overcharges and other violations of the discounted pricing requirements.'" *Astra*, 563 U.S. at 121–22 (citation omitted). *Astra* did not address drug distribution and does not apply to Act 1103. Intervenors' Br. at 46.

Similarly, PhRMA's continued reliance on *Buckman* is misplaced. In *Buckman*, the Supreme Court noted that the presumption against preemption did not apply to state fraud-on-the-FDA tort claims because "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied." *Buckman Co. v. Plaintiffs' Legal Comm.,* 531 U.S. 341, 347 (2001) (citation omitted). PhRMA quotes *Buckman* to argue that Act 1103 is skewing the "delicate balance of [federal] statutory objectives." PhRMA Reply Br. at 27 (quoting *Buckman*, 531 U.S. at 348). Once again, PhRMA obfuscates the scope of the 340B statute and Act 1103. While the 340B statute addresses drug pricing offered by manufacturers to covered entities, Act 1103 addresses protections for covered entities that need pharmacies to dispense 340B-priced drugs to vulnerable Arkansas patients. Unlike the fraud-on-the FDA claims in *Buckman*, Act 1103 addresses an issue related to public health and safety, which is a field that "States have traditionally occupied." *Wyeth v. Levine,* 555 U.S. 555, 565 (2009) (citation omitted).

Also, unlike *Buckman*, Congress has not provided clear evidence that it intended federal authorities to have exclusive authority to oversee all aspects related to the federal program at issue. *See Buckman Co*., 531 U.S. at 352. In fact, Congress has traditionally left the regulation of drug distribution to the states, Intervenors' Br. at 26-27, and Congress gave no indication in the 340B statute that it intended to confer authority to the federal government to regulate drug distribution. Thus, the conduct that Act 1103 seeks to regulate does not arise from, nor is it dictated by, the 340B statute.

PhRMA also cites to *San Diego Building Trades Council v. Garmon* to support its argument that the enforcement authority granted to AID under Act 1103 conflicts with the enforcement authority granted to HRSA under the 340B statute. PhRMA Reply Br. at 26-27. *Garmon*, however, involved the question of whether a state court could properly award damages to an employer that alleged financial harm due to picketing by a labor union, which is an activity specifically addressed in the National Labor Relations Act ("NLRA"). *See San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 244–45 (1959). Unlike *Garmon,* the drug distribution activities that Act 1103 regulates are not addressed in the 340B statute.

6. The Remedies Authorized Under 340B ADR and CMPs Do Not Extend to Conduct Regulated by Act 1103

PhRMA asserts that if "contract pharmacy purchases are actually 'covered entity' purchases, as AID and Intervenors contend, then it would seem to follow that a manufacturer 'overcharges' a covered entity by 'deny[ing] . . . 340B drug pricing' for contract pharmacy purchases and instead selling the drugs at a normal commercial rate." PhRMA Reply Br. at 22. A violation of Act 1103, according to PhRMA, can only occur if an overcharge has occurred, creating an overlap of the enforcement provisions of Act 1103 and the 340B statute and

providing further basis for granting PhRMA's preemption claim. PhRMA's argument should be rejected for the reasons explained in Section I.A.1.

PhRMA fails to recognize the required sequence of actions for Act 1103 to apply to a manufacturer: the manufacturer must have *first offered* the drug at 340B prices before Act 1103's drug delivery requirements become effective, as explained *supra* section I.A.1. The legality of the first action (the offer and payment) does not control the legality of the second action (delivery of drugs *after* that offer has been rendered).[16]

Accordingly, manufacturers will have violated Act 1103 if they block or otherwise interfere with the delivery of 340B drugs to Arkansas contract pharmacies that were offered to, and purchased by, covered entities at 340B prices. It is between the manufacturer and HRSA whether the offer was too high or too low, but as long as a 340B offer *has been* rendered, Act 1103 addresses any manufacturer interference with distribution to contract pharmacies. This distinction is fatal to PhRMA's assertion that "Act 1103's imposition of additional penalties (above and beyond those countenanced by Congress) and attempt to regulate *the same conduct* … necessarily creates a conflict." *Id.* at 23 (emphasis added). In addition, Act 1103's regulation of the second step, the delivery of a 340B-purchased drug, is consistent with HRSA's interpretation that state laws govern contract pharmacy distribution arrangements because the 340B statute "is silent as to permissible drug distribution systems." 1996 Guidance, 61 Fed. Reg. at 43, 549; Intervenors' Br. at 24–25.

[16] Examples of how manufacturers might violate Act 1103 without overcharging covered entities in violation of 340B include: directing wholesalers to charge an exorbitant distribution fee to covered entities that purchase drugs for delivery to their contract pharmacies or requiring covered entities to enter into onerous contracts as a condition of 340B shipments to the covered entities' contract pharmacies.

PhRMA again relies on caselaw that is inapplicable. PhRMA cites *Wisconsin Department of Industry, Labor, & Human Relations v. Gould* for the proposition that "'[c]onflict is imminent' whenever 'two separate remedies are brought to bear on the same activity.'" 475 U.S. 282, 286 (1986) (quoting *Garner v. Teamsters,* 346 U.S. 485, 498–499 (1953)). In *Gould,* the state law imposed sanctions on conduct that was also penalized under the NLRA. In contrast, Act 1103 does not penalize violations of the 340B statute. Indeed, a manufacturer may be found in violation of Act 1103 for conduct that *may or may not* constitute an overcharge of covered entities. And, as recognized in *Gould* and ignored by PhRMA, "Congressional purpose is of course the ultimate touchstone of preemption analysis." *Id.* at 290 (citations omitted).

PhRMA also relies on *Arizona v. United States* for the proposition that "'[c]onflict in technique' – such as a conflict in the method of enforcement – "'can be fully as disruptive to the system Congress erected as conflict in overt policy.'" PhRMA Reply Br. at 23. But like *Gould*, this case dealt with state penalties for the exact conduct regulated under federal law. *See Arizona v. United States*, 567 U.S. 387, 401 (2012). Again, the 340B statute and Act 1103 regulate different conduct.

Next, PhRMA contends that Act 1103 should be preempted because Congress conferred HHS with authority to issue "civil monetary penalties that are not purely compensatory." PhRMA Reply Br. at 24. Both CMPs and ADR are irrelevant because they pertain only to overcharges to covered entities and do not address remedies for blocking or interfering with the distribution of drugs to contract pharmacies. Intervenors' Br. at 39-42.

PhRMA also alleges that "AID fails to explain how it would reach an enforcement decision under Act 1103 without first determining a manufacturer's obligations to a covered

entity under the 340B statute."[17] PhRMA Reply Br. at 24. Act 1103 contemplates that manufacturers *are complying* with the 340B statute by offering drugs at 340B discounts. PhRMA also invents a purported "collision course" with the 340B program that does not exist. *Id.* at 25. PhRMA claims that in any enforcement action, AID will be required to determine whether a health care provider qualifies as a covered entity. AID can simply refer to HRSA's Office of Pharmacy Affairs Information System to determine the covered entity's status.[18] If a manufacturer believes that a covered entity is ineligible for 340B discounts, the manufacturer should address that concern to HRSA.

II. Act 1103 Does Not Conflict With the Federal Food, Drug, and Cosmetic Act

Act 1103, Section 23-92-604(c)(2), does not conflict with the Risk Evaluation and Mitigation Strategy ("REMS") provisions of the FDCA because Act 1103 does not require manufacturers to distribute 340B-priced REMS drugs to all pharmacies. 21 U.S.C. § 355-1(a). PhRMA argues that Act 1103 would require manufacturers to ship REMS drugs to Arkansas contract pharmacies because Act 1103 does not specifically exempt manufacturers from doing so. PhRMA Reply Br. at 27-29. PhRMA's interpretation of the statute, however, is overly broad and would result in absurd consequences not intended by AID or the General Assembly.

AID, which is charged with administering Act 1103, stated in its brief that the department "does not interpret Ark. Code Ann. § 23-92-604(c) as a means to circumvent, or avoid, any separate or additional state or federal laws governing the health and safety of the drugs, civil or criminal in nature, or separate FDCA laws limiting the transfer of the drugs themselves." AID

[17] PhRMA appears to be shifting its burden to meet its summary judgment standard on to AID. Fed. R. Civ. P. 54(a) ("The court shall grant summary judgment if the *movant* shows that there is no genuine dispute as to any material fact) (emphasis added).
[18] *340B Office of Pharmacy Affairs Information System*, HRSA (Nov. 2021), https://www.hrsa.gov/opa/340b-opais.

Br. at 11. AID's interpretation of Act 1103 should be given deference. *Nucor Steel-Arkansas*, 478 S.W.3d at 240. Therefore, as a practical matter, the boogeyman that PhRMA invents—requiring manufacturers to ship REMS drugs to pharmacies that are not approved to accept the REMS drugs—is non-existent.

Furthermore, PhRMA's statutory argument that Section 23-92-604(c)(2) of Act 1103 obligates manufacturers to provide 340B-discounted drugs to contract pharmacies even if the drug is subject to REMS restrictions, PhRMA Reply Br. at 28, should be rejected because it leads to absurd consequences. *See Friedman v. United States*, 374 F.2d 363, 367 (8th Cir. 1967); *First State Bank v. City of Elkins*, 546 S.W.3d 477, 481 (Ark. 2018). Instead, Arkansas courts "seek[] to reconcile statutory provisions to make them consistent, harmonious, and sensible." *First State Bank*, 546 S.W.3d at 481.

With the vast number of federal and state laws and regulations that govern the safe handling, storage and dispensing of drugs, the General Assembly could not expressly include an exception for every federal requirement that could potentially overlap with Act 1103. *See Hurd v. Arkansas Oil & Gas Comm'n*, 601 S.W.3d 100, 105 (Ark. 2020) ("[I]t would be impracticable for statutes to cover every possible situation that an agency may encounter when carrying out its statutory duties."). Act 1103's silence on REMS does not suggest that it forces manufacturers to violate REMS.

III. The Presumption Against Preemption Applies to Act 1103

The long-standing presumption against federal preemption of state law is fully applicable to the present case, despite PhRMA's assertions. PhRMA Reply Br. at 29.[19] Under the

[19] In a footnote, PhRMA questions the presumption against preemption's "vitality," but recent Supreme Court and Eighth Circuit cases have not reversed this long-standing precedent. *See, e.g.*, *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 505, 518 (1992) (detailing one of the Supreme

presumption against preemption, courts assume that the historic police powers of states are not superseded by federal law unless Congress expresses a "'clear and manifest'" purpose to do so. *Hillsborough Cnty.*, 471 U.S. at 719 (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)); *see also Wyeth*, 555 U.S. at 565.

PhRMA argues that Act 1103 does not address areas that are traditionally regulated by state law and instead "is expressly directed at the 340B Program." PhRMA Reply Br. at 29–30. As a primary matter, Act 1103 addresses drug distribution, which directly impacts the health and safety of a state's citizens. As stated above, courts have long recognized a state's interest in regulating in areas of public health and safety. *See Hillsborough Cnty.*, 471 U.S. at 719 ("[R]egulation of health and safety matters is primarily, and historically, a matter of local concern."); *see also Buckman Co.*, 531 U.S. at 347; *Wyeth* 555 U.S. at 565 ("[T]he historic police powers of the States [are] not to be superseded … unless that was the clear and manifest purpose of Congress."). In fact, Ark. Code Ann. § 17-92-607 is evidence that the State of Arkansas has traditionally policed the drug distribution within the state.

This Court should not, therefore, "conclude that Congress legislated the ouster of [a] [State] statute . . . in the absence of an unambiguous congressional mandate to that effect." *Fla. Lime & Avocado Growers, Inc.*, 373 U.S. at 146–47. Courts also look to federal regulations and their history to determine if a federal program was intended to preempt state law claims. *See Weubker v. Wilbur-Ellis Co.*, 418 F.3d 883, 888 (8th Cir. 2005). Not only is there no evidence of

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Court's older considerations of the "presumption against the pre-emption of state police power regulations"); *Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956, 967 (8th Cir. 2021) (addressing the presumption against preemption as applied to federal statutes that expressly preempt state law and not questioning the validity of the presumption against preemption where the federal statute is silent); *Wisconsin Educ. Ass'n Ins. Tr. v. Iowa State Bd. of Pub. Instruction*, 804 F.2d 1059, 1064 (8th Cir. 1986) (detailing one of the Eighth Circuit's earliest considerations of the presumption). The presumption against preemption should "apply full strength" to this case. *Gobeille v. Liberty Mut. Ins. Co.*, 577 U.S. 312, 338 (2016).

a "clear and manifest" intent to preempt state law, but the evidence points to the opposite conclusion. Intervenors have explained in detail that Congress considered but rejected federal statutory provisions that would have addressed drug distribution and acquiesced to the use of contract pharmacies. Intervenors' Br. at 28-31 (also above).

PhRMA claims that the cases cited by Intervenors are inapplicable (with the exception of *Wehbi*) because those cases relate to the question of whether federal law (including federal product labeling requirements) preempts state tort-law claims. PhRMA Reply Br. at 32-33. Those cases are applicable, and Intervenors have also discussed other, non-tort cases on the presumption against preemption, including a case upholding a state prescription drug rebate program against a preemption challenge. Intervenors' Br. at 28-31.

PhRMA states that Intervenors did not provide any case where "state law operate[s] to alter and expand a federal-benefits program (like the 340B Program), much less specifically target the federal-benefits program by name." PhRMA Reply Br. at 32-33. First, Act 1103 does not alter and expand the 340B program, as discussed in detail above. *See also* Intervenors' Br. at 34-39. Moreover, PhRMA ignores *New York State Dept. of Social Services v. Dublino*, cited by Intervenors. Intervenors' Br. at 29. In *Dublino*, the Supreme Court held that a state statute that imposed employment requirements as conditions for continued eligibility for Aid to Family with Dependent Children ("AFDC") was not preempted even though the state requirements were more onerous than the federal AFDC work requirements. 413 U.S. 405 (1973). In the *Dublino* case, therefore, an individual's eligibility for federal AFDC program benefits was directly impacted by the state law.

PhRMA claims that "Act 1103 came into existence nearly thirty years after the 340B Program was created, and regulates relationships that 'originate from, [are] governed by, and terminate[] according to federal law,' and thus are not afforded the benefit of the presumption

against preemption." PhRMA Reply Br. at 32 (quoting *Buckman*, 532 U.S. at 347–48). The presumption against preemption is not impacted by whether the state law was in effect before or after the federal law. Instead, the presumption against preemption recognizes the important role that the states have in regulating activity that impacts the state's citizens:

> We rely on the presumption [against preemption] because respect for the States as "independent sovereigns in our federal system" leads us to assume that "Congress does not cavalierly pre-empt state-law causes of action." The presumption thus accounts for the historic presence of state law but does not rely on the absence of federal regulation.

Wyeth, 555 U.S. at 565 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)) (internal citations omitted).

Lastly, PhRMA claims that *Buckman* is controlling precedent in this case. Intervenors point the Court to their memorandum in support of their motion for summary judgment for an explanation as to why *Buckman* is "starkly dissimilar to this case." Intervenors' Br. at 44-45.

CONCLUSION

For the foregoing reasons, and for the reasons stated in Intervenors' opening brief, Act 1103 is not preempted by federal law, and the Court should grant Intervenors' motion for summary judgment and deny PhRMA's motion for summary judgment.

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Respectfully submitted,

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