No. 22-3675

IN THE

United States Court of Appeals

for the Eighth Circuit

Pharmaceutical Research and Manufacturers of America,

Plaintiff-Appellant,

VS.

Alan McClain, in his official capacity as Commissioner of the Arkansas Insurance Department

Defendant-Appellee,

Community Health Centers of Arkansas; and Piggott Community Hospital

Intervenors-Appellees.

On Appeal from the United States District Court for the Eastern District of Arkansas

---

DEFENDANT-APPELLEE'S BRIEF

Booth Rand
General Counsel
Arkansas Insurance Department
One Commerce Way, Suite 102
Little Rock, AR 72202
(501) 371-2820

Allison P. Hatfield
General Counsel
Arkansas Department of Commerce
One Commerce Way
Little Rock, AR 72202
(501) 647-7443

Attorneys for Defendant-Appellee, Alan McClain

SUMMARY OF THE CASE

Appellant is a trade organization representing drug manufacturers that participate in the 340B program with health providers through pharmaceutical pricing agreements ("PPAs") entered into with the Federal Secretary of Health and Human Services ("HHS"). Under the 340B program, these manufacturers provide steeply, discounted drug prices to participating hospitals and clinics defined as "covered entities," in exchange for having their drugs covered by Medicaid and Medicare. Over the last several years, Appellant members have imposed limitations and exclusions on covered entities that use contract pharmacies to administer their 340B drugs to patients.

Arkansas enacted Act 1103 in 2021. A section of this Act, now codified in Ark. Code Ann. § 23-92-604(c), requires drug manufacturers to honor covered entities using contract pharmacies in the State of Arkansas in the delivery and acquisition of 340B drugs. Shortly after the Act went into effect on July 28, 2021, Appellant filed suit in the District Court seeking to invalidate Ark. Code Ann. § 23-92-604(c) under the Federal Supremacy Clause (Article VI, Cl. 2, U.S. Constitution) and Federal Commerce Clause. The District Court denied Appellant's federal preemption claim and granted summary judgment for Intervenors-Appellees. This Court should affirm. This Court would benefit from oral argument which should be set at fifteen (15) minutes per side.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Rules

STATEMENT OF THE ISSUES PRESENTED

I. Should the District Court be reversed on a *de novo* basis for granting summary judgment to Defendant-Intervenors holding that 42 U.S.C. § 256b (the 340B Program) does not by implication preempt Act 1103 in Ark. Code Ann. § 23-92-604(c)? (No)

Most Apposite Cases:

Sanofi Aventis U.S. LLC., v. U.S. of Health and Human Servis., 58 F.4th 696 (3rd Cir. 2023)

In re Aurora Dairy Corp. Organic Milk Marketing and Sales Practices Litig., 621 F.3d 781 (8th Cir. 2010)

Pharm. Care Mgmt. Ass'n v. Wehbi, 18 F.4th 956 (8th Cir. 2010)

Most Apposite Statutes:

42 U.S.C. § 256b

Ark. Code § 23-92-604(c) (Arkansas Act 1103 of 2021)

Most Apposite Administrative Regulations:

42 C.F.R. § 10 - 340B Drug Pricing Program

Arkansas Insurance Department Rule 123, "340B Drug Program Nondiscrimination Requirements"

II. Should the District Court be reversed on a *de novo* basis for granting summary judgment to Defendant-Intervenors finding that the Federal Food, Drug and Cosmetic Act (FDCA) does not preempt Ark. Code Ann. § 23-92-604(c) (Arkansas Act 1103 of 2021)? (No)

Most Apposite Cases:

Wyeth v. Levine, 555 U.S. 555 (2009)

Lefaivre v. KV Pharm. Co., 636 F.3d 935 (8th Cir. 2011)

Most Apposite Statutes:

21 U.S.C. § 355-1

INTRODUCTION

As the Supreme Court recently held, "340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." *Am. Hosp. Ass'n v. Becerra*, 142 S.Ct. 1896, 1905-06 (2022). The use of contract pharmacies is a vital tool that enables 340B hospitals to perform these essential services for America's—and Arkansas'—most vulnerable communities. "Outside pharmacies" or "contract pharmacies" are pharmacies not actually located in a hospital or clinic itself, but which allow patients to pick up prescriptions for 340B drugs where they usually shop and closer to where they live. Contract pharmacies are especially important in Arkansas because state law precludes most nonprofit and

governmentally-funded hospitals from operating an in-house pharmacy. Thus, for many Arkansas hospitals, contract pharmacies are the only game in town--and they are thus vital for the distribution of life-saving 340B drugs to low-income and rural patients.

Despite their importance to the citizens of Arkansas, a number of drug companies, many of which are members of Appellant, have recently refused to sell 340B medications to covered entities in Arkansas that use contract pharmacies to dispense the drugs. In response to this growing trend, the Arkansas Legislature passed a law in 2021, Act 1103, that requires drug manufacturers to permit the distribution of 340B drugs via contract pharmacies throughout the state. Appellant challenges a subsection of this law as preempted by federal law.[1] The district court correctly rejected Appellant's challenge and upheld the constitutionality of Act 1103.

BACKGROUND

"Section 340B of the Public Health Services Act, 42 U.S.C. § 256b (2006 ed. and Supp. IV), imposes ceilings on prices drug manufacturers may charge for medications sold to specified health-care facilities . . . . Those facilities, here called

[1] Specifically, Appellant challenges Ark. Code Ann. § 23-92-604(c)(1) and (c)(2). For purposes of this brief, the term, "Act 1103" means the subsection and subdivisions being challenged by the Appellant in this action and not the entire Act. The Appellee is a party to this proceeding because it is statutorily required to implement and enforce this state law under Ark. Code Ann. § 23-92-606.

'340B' or 'covered' entities, include public hospitals and community health centers, many of them providers of safety-net services to the poor." *Astra USA, Inc. v. Santa Clara Cnty*, 563 U.S. 110, 113 (2011). In particular, fifteen (15) enumerated types of hospitals and medical clinics qualify for participation in the federal program by registering with HRSA. These health providers include federally-qualified health centers, disproportionate care hospitals, children's hospitals, critical access hospitals, freestanding cancer hospitals, rural referral centers, sole community hospitals, and other federal grantees.[2]

Covered entities are entitled to discounted drug pricing in their outpatient drug purchases from drug manufacturers. Pursuant to agreements with Department of Health and Human Services (HHS), participating drug manufacturers in the 340B program must provide discounted pricing to covered entities, if these manufacturers want to participate in Medicaid or Medicare drug programs. 42 U.S.C. § 1396r-8(b)(4)(B)(v). The pricing amounts are calculated under a federal, statutory formula based off an average manufacturer's price of the drug minus a rebate percentage. 42 U.S.C. § 256b(a)(1). The formula ultimately results in what are defined as "ceiling prices" for the drugs.

"The § 340B *ceiling-price program* (340B Program) is superintended by the Health Resources and Services Administration (HRSA), a unit of the Department of Health

[2] For a complete list, see 42 U.S.C. § 256b(a)(4).

and Human Services." *Astra*, 563 U.S. at 113. Drug manufacturers report their 340B ceiling prices to HRSA on a quarterly basis, and HRSA in turn makes those prices available to covered entities via its 340B Office of Pharmacy Affairs Information System ("340B OPAIS"), an online database that allows covered entities to access ceiling prices for covered outpatient drugs. 42 U.S.C. § 256b(d)(1)(B)(i)(II); *Mosaic Health Inc. v. Sanofi-Aventis U.S., LLC*, No. 6:21-CV-06507 EAW, 2022 WL 4017895, at *1 (W.D. N.Y. Sept. 2, 2022).

A vast majority of 340B hospitals rely upon pharmacies with whom they contract to dispense their 340B medications to patients. U.S. Gov't Accountability Off., GAO-18-480, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, at 2 (June 2018) ("2018 GAO Report"), https://www.gao.gov/assets/gao-18-480.pdf. In most situations, the covered entities dispense and fill their outpatient prescriptions through pharmacies under a replenishment cycle, in which covered entities purchase the 340B drugs from wholesalers, then the drugs are shipped to pharmacies where they are kept in inventory until there is a need to re-fill or replenish the drugs again.[3] Contract pharmacies must register through HRSA for the 340B Program and be listed as active

[3] *Contract Pharmacy Arrangements in the 340B Program, Memorandum Report, Office of Inspector General, Department of Health and Human Services*, OEI-05-13-00431, February 4, 2014, at 5, https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf

in the 340B OPAIS prior to dispensing 340B drugs on a covered entity's behalf.[4] Contract pharmacies participating in this process charge the covered entity a fee for these services. 2018 GAO Report, at 13 and 26-30.

Today, the 340B program is over thirty (30) years old. It has its critics and supporters. Health providers engaged in this program benefit tremendously from the drug pricing discounts, which in turn allows them to provide greater care and services to their communities. In the processing of 340B drug claims, a participating hospital or clinic may retain the difference between the price of the drug with a 340B discount at its ceiling price and what it secondarily bills a private insurer for the same drug. *Sanofi Aventis U.S. LLC., v. U.S. Dep't of Health and Human Servs.*, 58 F.4th 696, 699 (3rd Cir. 2023). These discounts or savings are intended to enable covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. H.R. Rep. No. 102-34, pt. 2 at 12 (1992) (conf. report).

For at least ten (10) years, Appellant members complied with covered entities using outside pharmacies to dispense 340B discounted drugs, especially in cases where the covered entity had no in-house pharmacy in place. Beginning in 2010, federal authorities permitted the unlimited use of outside pharmacies for covered entities. 75 Fed. Reg. 10272, 10277 (Mar. 5, 2010). Since that time, drug manufacturers began to

[4] HRSA Guideline: https://www.hrsa.gov/opa/implementation-contract

gradually tap the brakes on these arrangements, imposing numerical and geographic restrictions to a covered entity's use of an outside pharmacy. Further, drug manufacturers have begun to require audits asking for a covered entity's claims data to see where or to whom the discounts from the money are actually going. *Sanofi*, 58 F.4th at 701.

Covered entities in the 340B program now rely upon outside contract pharmacies to administer the program at an extraordinary rate. 2018 GAO Report at 10. As a result, an aggressive vanguard of approximately eighteen (18) drug manufacturers instituted policies to exclude outside, contract pharmacies from playing any part in the 340B reimbursement program. App. 586, R.Doc.48 at 7. In targeting and applying its exclusions to outside pharmacies with this strategy, the Appellant members are crippling the 340B program for covered entities that are dependent upon outside pharmacies. Because of Appellant's restrictions, it is estimated that thousands of adversely affected patients are no longer receiving their medications, and covered entities are experiencing significant financial losses. *See* American Hospital Association: Survey Brief: Drug Companies Reduce Patients' Access to Care by Limiting 340B Community Pharmacies (November 2022), https://www.aha.org/system/files/media/file/2022/11/survey-brief-drug-companies-reduce-patients-access-to-care-by-limiting-340b-community-pharmacies.pdf. *See also* 340B Health Survey, "Contract Pharmacy Restrictions Represent Growing Threat to 340B Hospitals and Patients (May 2022),

https://www.340bhealth.org/files/Contract_Pharmacy_Survey_Report_FINAL_05-05-2022.pdf.

The harms caused by these pharmacy exclusions are likely greater in magnitude in Arkansas than in other states. In Arkansas, nonprofit, tax exempt, or governmentally-funded hospitals formed after 1975 may not obtain a pharmacy permit under Ark. Code Ann. § 17-92-607 to operate an in-house pharmacy.[5] Thus, for many Arkansas participating hospitals without in-house pharmacies, contract pharmacies are absolutely critical for distribution of their outpatient drugs to patients.

To alleviate these harms, in 2021, the State of Arkansas enacted Act 1103 which forbids drug manufacturers from denying access to 340B drugs to covered entities in Arkansas using contract pharmacies. This Act went into effect on July 28, 2021.[6] The subsection challenged by the Appellant in this action, now codified in Ark. Code Ann. § 23-92-604(c), in its entirety provides as follows:

> (c) A pharmaceutical manufacturer shall not:
>
> (1) Prohibit 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; or
>
> (2) Deny 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.

[5] Proposed Arkansas House of Representatives Bill 1300, which is pending in the 2023 Arkansas regular legislative session, would remove this restriction.

[6] App. 481, R.Doc.25 at 9. The Act was passed on May 3, 2021 but went into effect by *sine die* ninety days following adjournment, July 28, 2021.

On or about September 2021, the Appellant sought declaratory and injunctive relief in the district court, contending that Act 1103 is invalid under the Supremacy Clause and the Commerce Clause of the U.S. Constitution. App. 8, R.Doc. at 1. The court first considered the preemption claim and reserved review of the Commerce Clause claim. The parties submitted cross-summary judgment motions on preemption.

While the parties were briefing arguments in Phase I of the district court proceeding, the Appellee issued Rule 123, "340B Drug Program Nondiscrimination Requirements," (hereafter, "Rule 123"), http://170.94.37.152/REGS/003.22.22-005F-23027.pdf. This Rule went into effect on September 30, 2022. In Section 2 (7), the Rule defined the term, "340B drug pricing," as the acquisition and delivery of 340B-priced drugs as established under Section 602 of the Veterans Health Care Act of 1992, Pub. L. No. 102-585."

The district court denied Appellant's motion for summary judgment and granted the Defendant-Intervenor's cross-motion for summary judgment. App. 580, R.Doc.48. The district court found that that Act 1103 was a delivery and acquisition statute governing 340B drugs that did not conflict, interfere or impede with any exclusive federal administration or jurisdiction of the 340B program. App. 583, R.Doc.48 at 4. The district court found there was no express or implied preemption in

the 340B program. App. 587-594, R.Doc.48, 8-15. After the parties agreed to certify the district court order as a final ruling for an interlocutory appeal under Fed.R.Civ.P. 54(b), the appellant filed its notice of appeal. App. 597, R.Doc.52, at 1. [7] App. 600, R.Doc.57.

SUMMARY OF THE ARGUMENT

Appellant agrees that there is no "express preemption" provision in the federal legislation governing the 340B program, in 42 U.S.C. § 256b, or any implementing rules. Given the absence of such language, the main issue for this Court is whether the 340B statute by implication preempts Act 1103 under the field or conflict preemption doctrines. App. 589, R.Doc.48 at 10. Act 1103 is not preempted for several reasons:

- The 340B program is silent as to how 340B drugs are to be distributed, acquired or delivered to covered entities, which is what Act 1103 regulates.
- The 340B program does not address the role contract pharmacies play in the acquisition and delivery of 340B drugs.
- The 340B program is essentially a system of pricing controls, and Act 1103 does not address or interfere with the price federal law establishes for 340B drugs.

[7] The district court stayed proceedings pending the Supreme Court's issuance of a decision in *National Pork Producers Council v. Ross*, No. 21-468.

- Act 1103 is presumptively not preempted because it addresses a traditional area of state regulation.

The district court correctly held that the FDCA does not preempt Act 1103. As the district court concluded and the Appellees have argued, Act 1103 does not override any federal laws relating to the public health and safety of the 340B drugs being distributed in the program. App. 595, R.Doc.48, at 16. Accordingly, this Court should affirm the district court's judgment.

ARGUMENT

I. The 340B Program Does Not By Implication Preempt Act 1103

The key issue for this Court is whether the 340B statute impliedly preempts Act 1103. It manifestly does not.

A. Appellant Has Burden Of Proof

Before turning to the many reasons why Act 1103 is not preempted, it is important to bear in mind that Appellant has the burden to prove that Act 1103 is preempted by the 340B program. App. 589, R.Doc.48 at 10. The Appellant refuses to acknowledge this obligation, but blackletter law in this Circuit and others makes this burden clear. *See Williams v. Nat'l Football League*, 582 F.3d 863, 880 (8th Cir. 2009*); In re Aurora Dairy Corp. Organic Milk Mktg. & Sales Practices Litig.*, 621 F.3d 781, 792 (8th Cir. 2010) (citing *Williams*, 582 at 880); *see also Capron v. Off. of Att'y Gen. of Mass.*, 944

F.3d 9, 21 (1st Cir. 2019); *In re Methyl Tertiary Butyl Ether ("MTBE") Prods. Liability Litig.*, 725 F.3d 65, 96 (2d Cir. 2013) (citing *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 255 (1984)); *Elam v. Kan. City S. Ry. Co.*, 635 F.3d 796, 802 (5th Cir. 2011). Further, with regard to preemption, the law is clear. In determining a federal statute's preemptive reach, congressional purpose is "the ultimate touchstone." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). "'Evidence of pre-emptive purpose is sought in the text and structure of the statute at issue,' and 'in the first instance [we] focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.'" *United Motorcoach Ass'n, Inc. v. City of Austin*, 851 F.3d 489, 492 (5th Cir. 2017) (*quoting CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993)). Additionally, courts "when considering pre-emption, 'we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.' "*City of Columbus v. Ours Garage & Wrecker Serv., Inc.*, 536 U.S. 424, 432–33 (2002).

B. Act 1103 Is Not Invalid Under The "Field" Preemption Doctrine

Act 1103 does not offend or violate the field preemption doctrine. Field preemption exists where a federal statutory scheme is so pervasive in scope that it occupies the field, leaving no room for state action. *In re Aurora Dairy Corp. Organic Milk Mktg.& Sales Pracs. Litig.* , 621 F.3d 781 (8th Cir. 2010); *Gade v. National Solid Wastes Mgmt Ass'n.*, 505 U.S. 88, 98 (1992); *Cipollone v. Ligget Grp, Inc.*, 505 U.S. 504,

516 , (1992*); Abdullah v. Am. Airlines, Inc.*, 181 F.3d 363, 367 (3rd Cir. 1999); *NE Hub Partners, L.P. v. CNG Transmission Corp.*, 239 F.3d 333, 348 (3rd Cir. 2001). Similarly, field preemption occurs where Congress intended to foreclose any state regulation in the area, irrespective of whether state law is consistent or inconsistent with federal standards. *Soo Line R.R. Co. v. Werner Enters.* , 825 F.3d 413, 420 (8th Cir. 2016).

Under the above analysis, where the federal legislation or law instead does not occupy an area or facet of a program, *or is silent about it*, it is not foreclosed upon for a state to regulate it. This is the case here.

The Appellant offers an extensive parade of federal functions and national, uniform objectives in the 340B program in support of its argument that the 340B federal administration is so pervasive, so absolutely and unequivocally federal in nature, that it "leaves no room for state action." Appellant Br. 28-34. These arguments were rejected by the district court, which correctly concluded that the 340B program provides ample "room" for state participation. The program is definitely not a "closed [federal] system," as the Appellant now repeats as its theme throughout its brief. Appellant Br. 29 and 35.

1. Federal Legislation Does Not Occupy Delivery and Acquisition Standards

A review of the 340B federal legislation exposes a federal gap or space in its jurisdiction. App. 591, R.Doc.48 at 12. The federal government has not occupied the

activity related to the manner of delivery or acquisition of the 340B drugs to covered entities. There exists no provision or language in the 340B legislation or rules of HRSA or HHS addressing the manner in which the 340B drugs are to be acquired or delivered to covered entities. In all of the mandated governmental standards in 340B, none of these address the manner of a covered entity's acquisition or delivery of the 340B drugs. The federal 340B enacted standards instead pertain to: (1) ceiling price restrictions (42 U.S.C. § 256b(a)(1)) and methodologies for calculating it (42 U.S.C. § 256b(a)(2)); (2) overcharging restrictions (42 U.S.C. § 256b(d)); (3) prohibitions against duplicate discounts and diversions of the discounted pricing(42 U.S.C. § 256b(a)(5)); (4) arbitration remedies for overcharging, diversions, and duplicate discounts (42 U.S.C. § 256b(d)(3)); (5) audits by HRSA (42 U.S.C. § 256b(a)(5)(C)); (6) penalties and enforcement (42 U.S.C. § 256b(d)(1)(vi)) and licensing or registration (42 U.S.C. § 256b(a)(7)). Wholly absent from these categories is any reference or restrictions relative to a participating health provider's acquisition or delivery of the drugs.

2. Federal Legislation Does Not Occupy Contract Pharmacy Standards

Since the federal law does not address the activity of distribution or delivery of the 340B drugs to covered entities, neither does it specifically reference the role third

parties play, such as contract pharmacies, in the delivery or acquisition of the drugs for covered entities. As the district court correctly observed in its order:

> Pharmacies are not mentioned anywhere in it—neither in 42 U.S.C. § 256b(a)(1), which contains the sum total of the statute's language regarding manufacturers' obligations, nor in § 256b(a)(4), which defines covered entity.

App. 590, R.Doc.48 at 11.

3. Current Case Law Confirms Congress Does Not Occupy Delivery or Pharmacy Standards

The conclusion that the 340B program has left open the aspects of delivery and contract pharmacies was recently echoed by the Third Circuit Court of Appeals and before that by various federal district courts recently reviewing drug manufacturers' challenges to HHS and HRSA publications on this issue under the Federal Administrative Procedures Act ("APA").

The Third Circuit Court of Appeals just recently concluded: "the text [in the 340B legislation] is silent about delivery," "… nowhere does Section 340B mention contract pharmacies." *Sanofi*, 58 F.th 696, 703.

Other federal district courts have reached the same conclusion. *Novartis Pharms. v. Espinosa*, No. 21-cv-1479, 2021 WL 5161783 *4 (D.D.C. Nov. 5, 2021)(concluding that "the statute is silent as to permissible drug distribution systems…the statute's silence on these questions suggests that the statute does not compel any particular outcome with respect to covered entities use of pharmacies."); *AstraZeneca Pharms. LP v. Becerra*, 543 F.Supp.3d 47, at 59 (D.Del. 2021) (explaining that "when a statute does

not include even a single reference to the pertinent word, 'pharmacy,' it is highly unlikely, if not impossible, that the statute conveys a single, clear, and unambiguous directive with respect to that word. Here the absence of any reference to 'pharmacies' is a strong indication that the statute does not compel any particular outcome with respect to covered entities' use of pharmacies."); *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Human Servs.* , 570 F.Supp.3d 129, 193 (D.NJ. 2021) (noting that "HHS has recognized as much, stating in its 1996 Guidance that § 340B 'is silent as to permissible drug distribution systems' and contains 'many gaps.' 61 Fed. Reg. at 43,549.") *Eli Lilly & Co. v. U.S. Dep't of Health & Human Servs.*, No. 1:21-CV-00081-SEB-MJD, 2021 WL 5039566 at *17 (D.Ind. October 29, 2021) ("The 340B statute is silent as to contract pharmacy arrangements and drug manufacturers' delivery obligations.").

4. State Law Does Not Intrude Upon Any 340B Federal Standards

Further, a separate review of the state legislation itself in Act 1103 reveals it is solely aimed at regulating the delivery and acquisition of the 340B drugs to covered entities using contract pharmacies. Under Ark. Code Ann. § 23-92-604(c), a drug manufacturer is forbidden from prohibiting a pharmacy from contracting or participating with a covered entity by denying *access* to drugs under the 340B program, or by denying or prohibiting an Arkansas-based community pharmacy for *340B drug pricing*. In other words, the first subdivision applies its restriction to denials of

"access" (to the drugs) to pharmacies, by the drug manufacturer, and the second subdivision refers to denials or prohibitions as to "340B drug pricing." First, how a drug is "accessed" is about how it is obtained, acquired, or received, and *not* about how it is priced, or how its price is calculated. Secondly and more importantly, the term or phrase, "340B drug pricing," which is referenced three (3) times in Ark. Code Ann. § 23-92-604(c), is a precisely defined, rule-based term that restrains the Act to the acquisition and delivery of the 340B-priced drugs.

As previously noted in its summary, the Appellee issued Rule 123, "340B Drug Program Nondiscrimination Requirements," effective on September 30, 2022. Under Act 1103, in Ark. Code Ann. § 23-92-606, the Insurance Commissioner is authorized to issue a rule to implement Act 1103. He did so, defining the term "340B drug pricing" in Section 2(7) of Rule 123 in the following manner:

> (7) "340B drug pricing" means the acquisition and delivery of 340B-priced drugs as established under section 602 of the Veterans Health Care Act of 1992, Pub. L. No. 102-585.

The Arkansas Legislative Council, and Subcommittee on Rules and Regulations, reviewed and approved this exact language on September 16, 2022.[8] Accordingly, the regulation definitively defines the term "340B drug pricing," to mean the *acquisition and delivery* of the 340B drugs.

[8]https://www.arkleg.state.ar.us/Calendars/Attachment?committee=000&agenda=25041&file=Exhibit+F.01+-+ALC-Admin+Rules+Report+-+September+2022+.pdf

Just as it unsuccessfully raised below, the Appellant again reminds us here that an earlier draft version of Rule 123 was proposed that provided for a HRSA-arbitration exhaustion requirement before enforcement of the Rule could occur. Appellant Br. 19-21. The Appellant now misleadingly characterizes the final Rule 123 as "The Modified Rule." *Id.* However, this earlier draft version was never promulgated. Therefore, it was never adopted as a Rule for there to be a subsequent "modification" or amendment of it—as if it was actually a previously issued Rule. There has only been one administrative rule issued to implement Act 1103, and it is the current Rule 123 cited in this brief.

The Appellant makes numerous references in its brief to the Appellee's earlier removal of a federal exhaustion requirement in a draft Rule to enforce Act 1103, as tantamount to an admission by the Appellee that there were recognized fatal federal preemption concerns over the Rule and Act. The Appellee did earlier require in a draft rule that covered entities first exhaust their HRSA ADR procedures before seeking enforcement by the Department. The Appellee later removed this requirement, but this was in response to a significant number of public comments during the rule-making phase, lodged by over twenty (20) or more state-based community hospitals and the fact that the proposed language did not assuage the Appellant's preemption concerns anyway. In its April 13, 2022 public comment, the Appellant even objected to that exhaustion requirement as also being preempted. The Appellant in fact stated that the "Enforcement Policy," violated the holding in *Astra*,

improperly tied the imposition of state law unfair practices liability to federal ADR proceedings which are not suited for that person, and tied state law penalties without the "federal process and safeguards for imposition of penalties." The Appellant simply wants to object to *any* enforcement position by the State on preemption, whether the jurisdiction is direct or even contingent.

The Appellant fails to acknowledge that the final rule, as ultimately promulgated, resulted in limiting the application of the Act to the acquisition and delivery of 340B drugs. The Appellant is still confounded to counter this limitation in the final promulgated Rule. The Appellant finally addresses it at the end of its brief. Appellant Br. 49-51. Its answer is the repeating of the same mantra it repetitively utters throughout its brief: Act 1103 "directly conflicts with the closed system that Congress crafted." Appellant Br. 51. But, as the Appellee has pointed out, this is no closed federal system because Congress has not "crafted" standards on the delivery of 340B drugs.

Validly promulgated agency rules have the full force and effect of law, especially those issued through the notice-and-comment process. *Azar v. Allina Health Services*, 139 S.Ct. at 1804 (2019); *Perez v. Mortgage Bankers Ass'n.*, 575 U.S. 92, at 96 (2015); *Chrysler Corp. v. Brown*, 441 U.S 281, 302-303 (1979); *Clonlara, Inc., v. State Bd. of Educ.*, 442 Mich. 230, at 240 (1993). Further, under Arkansas law, state agency rules are entitled to deference by the Courts. *Nucor Steel-Ark, v. Ark. Pollution & Ecology Comm'n*. 2015 Ark. App. 703, 478 S.W.3d 232, 240 (Ark. App. 2015).

In light of both the language in the statute and its implementation in Rule 123, Act 1103 is indubitably an acquisition and delivery statute and not a mandated system of pricing controls. Thus, in spite of statutory phrasing referring to "pricing," in its title and sections, the more accurate understanding of this statute is one that addresses how 340B drugs are distributed--not how they are priced. The Appellant now recoils from the Act even referencing the term "340B drug pricing." Appellant Br. 18. As indicated in its arguments below in district court, the Arkansas General Assembly is simply trying to caption and accurately identify the federal program at issue in a brief phrase throughout the Act, and not declare in the modifier, "pricing," that it was engaged in imposing price controls over 340B drugs. The federal legislation establishing the 340B-drug pricing program, after all, is entitled, "Limitation on Drug *Pricing* By Covered Entities," and the word, "*pricing*," in the phrase, 340B *drug pricing* is referenced in the Federal program legislation, and in various HRSA publications, as *the 340B drug pricing program*. The Arkansas Legislature is simply captioning an embedded phrase to quickly label the federal program at issue throughout the Act.

To confuse matters, the Appellant has broadly misstated that pharmacies "receive" the 340B pricing.[9] However, a contract pharmacy for a covered entity does not itself actually "receive" the 340B financial discount. It instead "receives" the

[9] The Appellant in its Complaint below states "only covered entities may receive the ceiling prices, and retail pharmacies, including community pharmacies are not entitled to receive 340B pricing." App. 11, R.Doc.1, at 3. App. 16, R.Doc.1, at 8.

discounted drug for and on behalf of its covered entity. The covered entity ultimately "receives" the discount, and its pharmacy processes the discount for its client covered entity, and the pharmacy charges a "fee" for providing its services in connections with dispensing 340B drugs, as it does any time it dispenses a drug.

For its contention that Act 1103 is a pricing law, the Appellant's argument is that the discounted price follows delivery. Appellant Br. 49-50. According to Appellant, because Act 1103 requires delivery to contract pharmacies, the Act, in result or in effect, compels discounted pricing for all covered entities using contract pharmacies in Arkansas, thus mandating that a discount be provided by drug manufacturers who previously would not deliver to contract pharmacies there. Under this contention, the Act's delivery requirements allegedly involve pricing, in result, because it is impacting *who* receives the pricing discount—if the discounted price follows delivery. However, accepting Appellant's premise, the culprit creating this circumstance is actually from the Act's underlying operation on the manufacturer's own, private delivery policies or standards and not because the Act is directly operating on the activity of pricing itself, the federal standards on pricing, or what the pricing amount is, or how it is specifically calculated, all before delivery. The Act simply prohibits contract pharmacy delivery exclusions. Even if this prohibition impacts who is provided the discount, or affects the destination of the discount, the field preemption issue here is missed. The issue is whether Arkansas is pre-occupying

a federal pricing standard itself and not whether it is preempted because it is changing a drug manufacturer's internal, delivery standards.

Importantly, as stated above, it is irrefutable that Act 1103 does not involve Arkansas in setting what the actual amount of the discounted price *is*, or *how* it is calculated, or involved in the *methodology* behind its calculated amount before delivery. These pricing actions are instead driven from federal terms and requirements and not state law, applied *before* the delivery of the 340B drugs.

In conclusion, a review of both the state and federal legislation demonstrates that the only activity being occupied by Arkansas in Act 1103 is the delivery and acquisition of the 340B drugs to contract pharmacies. Congress could occupy these fields but has not yet done so, or, that HRSA and HHS have shown an interest in this area as evidenced by its previously issued guidances, opinions or letters of enforcement to drug manufacturers commanding them to honor outside pharmacy contracts but have been legally unable to enforce such requirements. Such circumstances are not the issue in this case—the question is whether Congress, in the 340B federal legislation itself, intended to occupy any standards related to the delivery of the 340B drugs. The answer is no. Despite Appellant's play on verbiage, the crux of this case is preemption, and here preemption is not implicated.

5. No Congressional Purpose To Occupy Delivery or Pharmacy Standards

The purpose of Congress is the ultimate touchstone in every preemption case. *Medtronic, Inc. v. Lohr*, 578 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996).

Thus, preemption analysis first requires an assessment of the congressional purpose. *Id.*, at 486. Congress' intent is discerned from the language of the preemption statute and the statutory framework surrounding it. *Id.* Also relevant is the structure and purpose of the statute as a whole as revealed not only in the text, but also in the way Congress intended the statute and its surrounding regulatory scheme to be implemented. *Id.*

In this matter, no congressional intent or purpose can be inferred from the language in the 340B program related to the acquisition or delivery of the 340B drugs to covered entities. The most relevant language in 42 U.S.C. 256b(a)(1) lies in its introductory mandate which addresses the PPA agreements and provides:

> Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the "ceiling price"), and shall require that the manufacturer *offer* each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.

Thus, the manufacturer must only *offer* each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price, and the issue of how the outpatient drugs are either delivered to or received by the covered entity is left open

by Congress, without any expressed or inferred congressional purpose. Therefore, here the field remains open for state regulation.

C. Act 1103 Is Not Invalid Under The "Conflicts" Or "Impossibility" Preemption Doctrines

The Appellant urges that Act 1103 and its prospective state enforcement collide and interfere with the uniform, federal administration of the program, and its national, jurisdictional objectives, but this argument is without merit. Appellant Br. 24-25. This argument is simply a rehashing of Appellant's field preemption argument. Even if there were a difference between the two, it is clear that Act 1103 does not offend or violate conflicts or impossibility preemption doctrines.

Implied preemption can occur where state law has not been completely displaced but is superseded to the extent that it conflicts with federal law—this is known as conflict preemption. *In re Aurora Dairy Corp. Organic Milk Marketing and Sales Practices Litig.*, at 792. (citing *Pet Quarters, Inc. v. Depository Trust & Clearing Corp.*, 559 F.3d 772, 780 (8th Cir. 2009). Conflict preemption exists where a party's compliance with both federal and state law would be impossible or where state law would pose an obstacle to the accomplishment of congressional objectives. *Id.* State law that poses an obstacle to the establishment of a national standard should therefore be preempted. *Id.* Impossibility preemption is a type of conflict preemption, and it arises when compliance with both federal and state regulations is a physical impossibility. *Lefaivre v. KV Pharm. Co.*, 636 F.3d 935, 939 (8th Cir. 2011) (citing *Wis. Pub. Intervenor v.*

Mortier, 501 U.S. 597, 605, 111 S.Ct. 2476 (1991)). There is no such impossibility or conflict here.

1. Act 1103 Does Not Conflict with Federal Compliance Functions

As previously outlined in this brief, these major functions are: (1) adherence to the PPA agreements with HHS; (2) providing restrictions against overcharging, duplicative discounts, and diversions; (3) establishing sanctions or penalties for noncompliance; (4) auditing; (5) certification or licensing of the covered entities; and (6) alternate dispute resolution actions ("ADR"). However, here no major function is impaired or blocked by Act 1103 sufficient to act as an obstacle to the federal administration of a national, uniform program.

First, Arkansas does not review and approve the PPA agreements under Act 1103 to insure or confirm that drug manufacturers honor covered entity outside pharmacy arrangements, at the initial contract level, in compliance with Act 1103. Neither the Act nor rule of the Appellee authorizes any state regulatory review of such agreements, or provide oversight over drug manufacturers contracts with wholesalers, concerning the recognition of covered entity outside pharmacy arrangements. Neither the Act or the rule establishes any comprehensive bulwark of regulatory requirements in terms of outside contract review, besides simply mandating the delivery of the 340B drugs to contract pharmacies.

Second, neither the Act nor the rule addresses or enforces 340B restrictions against overcharging, diversion, or duplicate discounts. Act 1103 is entirely silent about such matters, and such reticence, instead of colliding into federal enforcement actions for such violations, actually implicitly recognizes that is the federal government's responsibility, or HRSAs, to enforce such restrictions, not the State of Arkansas. Covered entities may still file complaints for overcharging at HRSA without any interference from Act 1103. By the same token, drug manufacturers may still file complaints for diversions and duplicate discounts at HRSA without any obstacle from Act 1103.

Third, the 340B program provides equitable and monetary penalties for its violations in 42 U.S.C. § 256b(d)(6). Although Act 1103 does not itself set out statutory-based penalties, the implementation rule does so in Rule 123. Section VI of Rule 123 applies insurance code trade practice penalties for violations of the Act under Ark. Code Ann. §§ 23-66-209 and 23-66-210. The penalties in the state and federal schemes however differ in function and purpose. The state administrative rule applies punitive penalties for a drug manufacturer's failure to honor the delivery or acquisition of the drugs to contract pharmacies. It provides no penalties beyond that, or compensatory relief, for violations separately falling under the previously listed 340B categories such as for overcharging or diversions. The 340B federal penalties on the other hand largely relate to charged pricing violations, improper discounts or

diversions but also provide for refunds for overcharges, as well as an ADR process for such pricing violations.

Fourth, Act 1103 does not interfere with a drug manufacturer's or covered entity's right to participate in the ADR process permitted in the 340B program or HRSA ADR rule. Act 1103 does not supply either contract pharmacies or covered entities with ADR remedies for violations of its acquisition and delivery provisions. The ADR relief is largely compensatory in nature, and nothing in Act 1103 limits or impairs the federally offered dispute resolution process.

Finally, Act 1103 does not conflict with any auditing or registration functions of HRSA in the administration of the 340B program. HRSA is free to audit and register covered entities participating in the program without any limitation from Act 1103. The Appellee is in fact not given any statutory authority under Act 1103 to even audit or examine participating entities or license them for compliance with Act 1103. This differs significantly from more comprehensive regulations over insurers the Appellee is more accustomed to regulating. Act 1103 provides no grand scheme of contract review, licensing requirements, financial or market conduct restrictions, or examination provisions which might duplicate or interfere with those of HRSA.

In sum, based on the discussion above, Act 1103 is not preempted by federal law and the district court should be affirmed.

2. Appellant's Argued Conflicts Are Misplaced

The Appellant raises several objections to expose conflicts between Act 1103 and the 340B program, all of which are either exaggerated or misplaced. The main thrust of Appellant's objections is that Act 1103 authorizes "illegal" diversions to pharmacies and to non-patients of covered entities in the transfers of 340B drugs. Appellant Br. 30 and 35. In response to Appellant's observations, the Appellee maintains exactly what it explained already below, state law in Act 1103 governs the action of physical delivery, federal 340B standards apply both before and after delivery.

a. Transfers of 340B Drugs to Pharmacies Are Not Diversions

First, the Appellant protests that Act 1103 requires distributions of 340B discounted drugs to contract pharmacies which may constitute illegal diversions under a strict reading of federal law, because pharmacies are not one of the authorized types of covered entities or patients of them.

The district court however found Appellant's interpretation, "not a reasonable construction of the statute [Act 1103]." App. 592, R.Doc.48, 13-14. The district court reasoned that it "was beyond its purview to determine whether purchases made using the replenishment model constitute diversion as Congress explicitly required manufacturers to address diversion and duplicate-discounting concerns in the ADR process and to audit covered entities before availing themselves of the ADR process."

Congress wanted concerns regarding diversions to be addressed first through ADR procedures, not in federal court. *Id.*

The Appellee agrees and again defers to HHS and HRSA as to whether there exists a "diversion," or "overcharging" under HRSA's purview for a drug manufacturer's providing of a discounted drug to unauthorized persons, or pricing 340B drugs above their ceiling prices to pharmacies. Arkansas is only governing the physical delivery of the drugs to contract pharmacies, and whether there is diversion, overcharging or duplicate discounts is a matter for those federal agencies enforcing the law.

Finally, the Appellant's claim that transfers of 340B drugs to contract pharmacies are diversions flies in the face of HRSA and HHS pronouncements to the contrary dating back to 1996. HRSA and HHS have issued guidances and opinions commanding drug manufacturers to honor pharmacy arrangements in 1996, 2010, 2020 and recently maintained this position in 2022, in letters of enforcement. See *AstraZeneca Pharmaceuticals LP v. Becerra*, 543 F.Supp.3d 47, at 51-56 (D.Del. 2021) for a detailed chronology of HRSA or HHS statements on this issue. Had pharmacies been viewed as receiving improper diversions, those bodies would have said so, instead of recognizing and directing, just the opposite, that they be allowed to participate in the program, within the last twenty-seven (27) years. The Appellee again defers to HRSA and HHS about the current legality of whether contract pharmacies are or are not receiving diversions. However, currently and historically, the receipt of 340B drugs by

covered entity pharmacies have not been interpreted by those bodies as diversions in terms of enforcement policies. The Appellee is aware that several federal courts have recently ruled that such administrative pronouncements on contract pharmacies were improperly promulgated under APA standards, but neither have these rulings held that transfers of 340B drugs to contract pharmacies are diversions. However, in spite of such rulings, the history is also clear that in terms of historic enforcement policies by those bodies, these have recognized contract pharmacies in the deliveries of the drugs.

b. Act 1103 Does Not Regulate 340B Drug Transfers To Non-Patients

Second, and again related to diversion(s), the Appellant alleges that Act 1103's text nowhere requires the drugs purchased at a 340B price that are provided to a pharmacy be dispensed only to patients of a covered entity. Appellant Br. 30. However, neither does Act 1103, in its strict text, affirmatively compel pharmacies to dispense the 340B medications to non-patients of the covered entity for whom they are providing services. Instead, it is only compelling physical delivery of those drugs to the pharmacies. The challenged Act is simply not governing what happens after delivery. If, after receipt of the drugs, a pharmacy illegally diverts those drugs to non-patients of the covered entity, then it may risk 340B sanctions or HRSA-related enforcement. The state Act is however not compelling federal violations to occur after the pharmacy receives the 340B drugs, and therefore, there is no conflict.

c. Act 1103 Does Not Conflict With Any Unitary National Standards

Third, the Appellant's next point on conflicts is that if Act 1103 is deemed valid, other states may follow suit and fragment 340B drug distribution laws into a myriad of different state laws, making any federal, unitary, nationally uniform standard unachievable. However, this argument is weak. The ultimate arbiter of whether that is a national objective or strategy in the 340B program lies with Congress, and Congress has certainly not maintained that states may not play a role in 340B drug deliveries, in either expressed or inferred language in the 340B legislation. Congress has had abundant opportunities to restrict state regulation of this program, or aspects of this program, since the inception of this program, but has chosen not to do so. Appellant's remedy is to change the federal legislation and not have a judicial body essentially legislate a restriction on the states, which is not in the federal legislation itself, related to the delivery of 340B drugs, or forbid state laws requiring access to those drugs for contract pharmacies serving hospitals.

d. Act 1103 Penalties Do Not Conflict With 340B Penalties

Fourth, the Appellant complains that the State's penalties and enforcement of Act 1103 would necessarily be duplicative or conflict with federal enforcement under the purview of HRSA. Appellant Br. 35-37. The Appellee poses the situation of a drug manufacturer not honoring the delivery of 340B drugs to an Arkansas-based pharmacy and instead of charging its discounted 340B rates, charges its normal,

commercial rates. Here, the manufacturer is now exposed both to federal and state penalties; one, federally for overcharging, and then another, under Arkansas law for not delivering the drugs to the pharmacy—in one transaction. However, this scenario does not expose a fatal conflict between the state and federal systems. The underlying misconduct for each violation is different even though its one transaction. The manufacturer has liability at the federal level for the charged *pricing* violation, and the manufacturer has separate and independent administrative penalty liability at the state-level for the *delivery* of the drugs to the pharmacy. The transaction has two separate and independent areas of jurisdiction or components: one is pricing, the other is delivery. The manufacturer may have two penalties associated with the transaction, but this does not necessarily mean that the two penalties *conflict* with each other. The Appellant is once again exaggerating a conflict.

The Appellant also complains about the monetary difference between the state-based fine under the Trade Practices Act in Ark. Code Ann. § 23-66-210(a)(1) and HRSA penalties ($10,000.00 vs. $5,000.00 per unintentional violation). Appellant Br. 35. The Appellee is actually applying the same penalty scales here that it imposes on pharmacy benefit managers ("PBMs") under AID Rule 118, Section 11(3). The Appellee is clearly not regulating meagerly resourced insurance agents or brokers here. Many Appellant member organizations have assets and capital surplus far exceeding millions of dollars or more, the ranges set here are entirely appropriate for effective deterrence.

e. Federal Law Limits What Constitutes A Valid 340B Drug Pricing Contract Pharmacy Arrangement Not Act 1103

Fifth, the Appellant contends that because Act 1103 does not provide any limit on what constitutes a valid 340B "drug pricing contract pharmacy arrangement," manufacturers would be obligated to honor any such arrangements regardless of the ultimate disposition of the drugs. Appellant Br. 43-44. The Appellant argues this lack of limitation is "irreconcilable with the federal 340B statute." The Appellant's rather alarming inference here is that Arkansas, in Act 1103, because it does not define what a "valid" pharmacy arrangement is, is granting permission to permit illegal actions of pharmacies or covered entities to contravene 340B standards in their 340 pharmacy arrangements related to the "ultimate disposition of the drugs." However, the Appellee responds that federal 340B standards would still govern the "validity" of such arrangements, and the underlying 340B legality of such arrangements, and these standards would still apply to any actions from such arrangements, including illegal diversions, as to whether the arrangements violate 340B standards. This is not an irreconcilable conflict. Arkansas is not trying to subvert the HRSA or HHS jurisdiction on this issue but is simply mandating that the 340B drugs be physically delivered to contract pharmacies for covered entities.

Thus, a review of the major 340B functions, comparing them to the limited nature of Act 1103's delivery requirements, reveals that nothing in either the state Act or implementing rule acts as a barrier, obstacle or impossibility to the federal, uniform

administration of this program. The schemes may co-exist in their own respective spheres.

3. Appellant's Case Law Is Inapplicable

For its conflict preemption arguments, the Appellant relies heavily upon *Astra USA, Inc. v. Santa Clara County, Cal.*, 563 U.S. 110 (2011) and *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001) and claims that Act 1103 is at odds with Congress' unitary administrative and enforcement scheme in the 340B program.

In *Astra*, a number of county-operated 340B covered entities in California sued six (6) drug manufacturers for overcharging (charging pricing above ceiling prices) in their purchases of 340B drugs, in violation of the PPA agreements. The case presented the question whether 340B entities, though accorded no right to sue for overcharges under the 340B program itself, may nonetheless sue drug manufacturers for overcharging as third-party beneficiaries under the PPAs. *Astra*, at 113. The United States Supreme Court held that suits by 340B entities to enforce ceiling-price contracts running between drug manufacturers and the Secretary of HHS were incompatible with the statutory scheme. *Id.*

Astra is however not on point to the matter before this Court. The plaintiffs in the *Astra* proceeding were privately suing drug manufacturers, outside the 340B scheme, for compensatory relief for overcharging, for pricing claims above the federally required ceiling prices. Under 340B, however, pricing or overcharging is

under the purview of the federal government and is inside the 340B scheme. The ruling in *Astra* that in terms of pricing related claims, the 340B administrative remedies should be exclusive over private causes of action for that relief, therefore is not inconsistent with the Arkansas statute at issue here. As already argued in this brief, Act 1103 is not engaged in the field of pricing. *Astra* is addressing preemption in the field of 340B drug pricing claims and not in the delivery of the drugs—a field not occupied by the federal government. Act 1103 pertains only to the manner of delivery of the 340B drugs. The federal government has expressed no uniform, national objectives related to either the delivery of the 340B drugs, or the role contract pharmacies play in that system, for there to be any objective to be frustrated. Additionally, Act 1103 does not grant any person a private right of action to sue for violations of that Act and vests exclusive regulatory control over its enforcement with the Appellee. Therefore, unlike in *Astra*, there is no issue of private causes of action populating under state law to diffusely frustrate either state or federal uniform standards.

The Appellant's reliance on *Buckman* is also misplaced. In *Buckman*, the United States Supreme Court invalidated a state law claim of fraud against the Food and Drug Administration, brought against a representative of device manufacturers which marketed defective orthopedic screws. The Court held that such actions were impliedly preempted by the Food, Drug, and Cosmetic Act ("FDCA"), as amended by the Medical Devices Amendments of 1976 ("MDA"). *Buckman*, at 345. The Court

concluded that the state fraud claims, which were based exclusively in the MDA, inevitably conflict with the Food and Drug Administration's ("FDA's") responsibility to police fraud consistently with its objectives. *Id.* at 342. The Court noted that if it were to permit such claims, this would conflict with the FDA's detailed regulatory regime and dramatically increase the burdens facing potential applicants, burdens not contemplated by Congress in enacting the FDCA and the MDA. *Id.* at 350. The Court believed that the potential litigation "would exert an extraneous pull on the scheme established by Congress, and it is therefore preempted by that scheme." *Id.* at 353.

Again, in the 340B program, the federal government is not "policing" any delivery requirements related to the distribution of 340B drugs, and Act 1103 thus does not increase any existing federal regulatory burdens or objectives. The 340B statute expresses no objectives as to how 340B drugs are to be distributed to covered entities for there to arise a conflict between Act 1103 and what the federal government is "policing." Secondly, Act 1103 does not supply any rights for private causes of action for its violations to cause a proliferation of tort litigation at issue in *Buckman* that would act to frustrate either state or federal policies.

Both *Astra* and *Buckman* fail to address implied preemption of state laws which do not conflict, interfere or frustrate *federally unoccupied fields*.

In conclusion, a review of the major functions in the 340B program along with a review of the Appellant's case law, confirms there is no conflict or impossibility preemption. The district court's finding on this issue is correct.

D. Act 1103 Is Presumed Valid As A Public Health And Safety Law

Not only does the Appellant have the burden of showing preemption, Act 1103 is also presumed valid against preemption claims if it is viewed by this Court as a public health and safety law or area traditionally regulated by the states. In all pre-emption cases, and particularly in those in which Congress has legislated in a field which the states have traditionally occupied, we start with the assumption that the historic police powers of the states were not to be superseded by the federal Act unless that was the clear and manifest purpose of Congress. *Wyeth v. Levine*, 555 U.S. 555, at 565, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009); *Medtronic,* at 470*; Cipollone,* at 518.

This Court should construe Act 1103 as a public health and safety law, or traditional state regulated area, for four (4) reasons. In addition, counter-veiling United States Supreme Court rulings refusing to apply the presumption in several implied preemption cases are not applicable here, as the Appellee later discusses.

1. Act 1103 Regulates Traditional State Functions

First, Act 1103 governs the manner in which 340B outpatient medications or drugs are distributed or received to patients of participating hospitals or clinics. A vast majority of these patients receive such medications through outside pharmacies used by covered entity hospitals and clinics. Thus, the Act pertains to the distribution of medications to citizens of the State of Arkansas and is therefore a state public health law. States traditionally have had great latitude under their police powers to legislate as

to the protection of the lives, limbs, health, comfort and quiet of all persons. *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756, 105 S.Ct. 2380, 85 L.Ed.2d 728 (1985); *Medtronic*, at 475.

Second, because the Act permits or authorizes pharmacies to acquire or deliver the 340B drugs, it addresses a function in the practice or profession of pharmacy, which is a state-regulated profession under a traditional state police power. The Appellee submits that the aspects of how drugs are acquired, delivered or accessed by pharmacies relate to core pharmacy functions.

Third, Act 1103 seeks to prohibit or limit pharmaceutical manufacturer exclusions for covered entity hospitals using outside pharmacies in this State; as such, the Act is clearly regulating the space of state-based commercial contracts or arrangements traditionally left to state regulation or police powers. These commercial contracts actually do impact the practices of pharmacies, as they interfere with their administrative relationships with hospitals and clinics in this State.

Last, although the Appellant dismisses language in *Wehbi*, as a mere one line comment by this Court, in reviewing Medicare and ERISA preemption claims by pharmacy benefit managers, this Court has held that the practice of pharmacy "is an area traditionally left to state regulation." *Pharmaceutical Care Management Association v. Wehbi*, 18 F.4th 956, at 972 (8th Cir. 2021). The "practice" of pharmacy should include how pharmacies actually "practice" in their professions in business contracts

or relationships with medical providers, in terms of how they receive and distribute medications for them, including 340B drugs.

2. Act 1103 Does Not Interfere With "Uniquely Federal" Standards

Our law embodies a presumption against preemption for traditional areas of state regulation. Appellee agrees that this is not automatically given. The Third Circuit Court of Appeals discusses the application of this presumption in implied preemption cases in *Fellner v. Tri-Union Seafoods, L.L.C.*, 539 F.3d 237, 248 (3rd Cir. 2008). In *Fellner*, a consumer who was diagnosed with mercury poisoning sued a tuna manufacturer under a New Jersey Products Liability Act, for, inter alia, failing to warn about mercury levels in the product. The manufacturer raised a preemption defense to the state action alleging that regulatory actions taken by the FDA impliedly preempted the consumer's state causes of action. The Court ultimately applied the presumption against preemption, finding that state-tort like actions fall squarely within traditional state regulation; however, the Court recognized that the United States Supreme Court in *Buckman* and in *United States v. Locke*, 529 U.S. 89, 108 (2000), declined to apply the presumption in those implied preemption cases because the interests at stake were "uniquely federal in nature." *Id.*

In *Buckman*, the Court explained that policing fraud against federal agencies is hardly a field which the states have traditionally occupied, to the contrary, the relationship between a federal agency and the entity it regulates is inherently federal in

nature. *Id.* In *Locke*, the Court explained the presumption was declined because national and international maritime commerce was not a traditionally regulated state field. *Id.* However, both *Buckman* and *Locke* are inapposite here on the issue of presumption for two (2) reasons. One, the state activities reviewed in those cases are a far cry from the previously enumerated multitude of traditional state areas impacted by Act 1103. Two, the federal fields in those cases were fully occupied, enforced and policed by the federal government, unlike here.

The regulation of drug deliveries to state-based hospitals, the regulation of what drugs state-based pharmacies may administer in their practice, and the regulation of state-based commercial contracts between hospitals and pharmacies are hardly uniquely or inherently "federal in nature." They are instead inherently traditional areas of state regulation. Act 1103 is not interfering with a federal agency's (HRSA's) own inherent enforcement for violations it self-regulates, as in *Buckman*. Nor is Act 1103 even remotely extending its regulation as far out as was at issue in *Locke*. These cases are distinguishable to the actions of Arkansas in Act 1103.

In conclusion, for all the reasons discussed above, this Court should affirm the district court and hold that Act 1103 is safe from preemption challenges as a traditional area of state regulation, or public health and safety measure.

II. The FDCA Does Not Preempt Act 1103

The Appellant's remaining argument is that Act 1103 supersedes drug safety restrictions in the FDCA. However, as the district court correctly concluded below, Act 1103 does not circumvent or conflict with any FDCA drug control restrictions. App. 595, R.Doc.48, at 16.

The Appellant contends that Act 1103 compels or forces pharmaceutical manufacturers to deliver FDCA restricted drugs to covered entities, in defiance of risk evaluation and mitigation provisions ("REMS"). While Act 1103 does not specifically and expressly carve out any FDCA controlled drug safety provisions, neither does it provide an exception for any drugs subject to a multitude of civil or criminal drug restrictions, administered by state or federal agencies. However, as pointed out below, it does not logically follow or infer that the Act is therefore authorizing the distribution of illegal drugs.

As the district court found, the FDCA does not include any statement preempting state laws governing the distribution of drugs. (relying on *Wyeth v. Levine*, 555 U.S. 555, 567 (2009); *Lefaivre v. KV Pharm. Co.*, 636 F.3d 935, 941 (8th Cir. 2021)). As the district court explained, Act 1103 does not regulate drug safety: Act 1103 and the FDCA regulate completely different subject matter and activities. *Id.*

The Appellant relies upon language by the Arkansas Supreme Court in *Myers v. Yamato Kogyo Company, Ltd.*, 597 S.W3d 613 (Ark. 2020). In *Myers*, the Arkansas Supreme Court is construing a workers compensation law to determine if immunity applied to parent owners of companies under the state workers compensation system.

The Court stated that "in considering the meaning and effect of a statute, we [the Court] construe it just as it reads, giving the words their ordinary and usually accepted meaning in common language." *Myers*, at 617. The Court however also stated that it applies "strict construction," and "strict construction is narrow construction and requires that nothing be taken as intended that is not clearly expressed." *Id.*, at 167. See also *Lawhon Farm Servs. v. Brown*, 335 Ark. 272, 279, 984 S.W.2d 1, 4 (1998). Putting both statements together, the Court is to construe a statute according to its actual language, but to do so narrowly and not infer intent unless it is clearly expressed. In this vein, absolutely nothing in Act 1103 expressly refers to the Act mandating or intending to mandate the delivery of federally prohibited drugs. Act 1103 is not intending to nullify or supplant FDCA controls, and the Act may be read or interpreted to be in harmony with such restrictions. Under Act 1103, a drug manufacturer must deliver 340B drugs to contract pharmacies for covered entities, but there may exist other federal or state laws, such as FDA restrictions, which may impinge upon such distributions. Again, just as is the case of the previously argued preemption analysis on the 340B legislation, the challenged state legislation may exist in harmony with FDCA restrictions.

III. Conclusion

This preemption case ultimately exposes the sometimes difficult constitutional tension in play in our federal system between the Federal Supremacy clause (federal

law) and the 10th Amendment (state law). Although the Appellant's preemption claim against Act 1103 is rooted in the Federal Supremacy Clause, the Appellee's defense to that claim has an equally offsetting constitutional counterbalance too, in the 10th Amendment: "the powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." The balance here is however greatly tipped in favor of state regulation.

In *Northern States Power Co. v. State of Minn.*, 447 F.2d 1143, at 1146 (8th Cir. 1971), this court noted these same tensions in play in that preemption case and concluded that "once it is ascertained that the federal government possesses the power to regulate in a given area, we must ask the question whether Congress has exercised its power of legislation in such a manner as to exclude the states from asserting concurrent jurisdiction over the same subject matter." *Id.* This is one of the core questions before this Court.

Congress has the power to regulate the manner of delivery of 340B drug distributions in the 340B program, Congress has simply not exercised its powers in doing so. This, therefore, is a classic case in which state law, in Act 1103, should prevail against Appellant's preemption or Supremacy Clause claim(s) under the 10th Amendment.

This Court should follow the recent admonition regarding the silence of Congress to regulate the delivery of 340B drugs in *Sanofi Aventis U.S. LLC., v. United States Department of Health and Human Services*, 58 F.4th 699 (3rd Cir. 2023):

> "Statutory silences, like awkward silences, tempt speech. But courts must resist the urge to fill in words that Congress left out. "

The Appellee's argument prevails under constitutional underpinnings but also under case law doctrines. Act 1103 is not impliedly preempted under a field preemption analysis because the federal government does not occupy the entire field but leaves open for state regulation the areas of delivery and contract pharmacies in the 340B program. Nor does it conflict with any federally regulated standards pertaining to the delivery of the drugs, as none exist with which to conflict. The Appellant has neither carried its burden nor overcome the presumption, as the Act is a traditional area of state regulation and is presumed valid. Last, the Act does not conflict with the FDCA. The district court's ruling confirming these matters is sound and correct and should be affirmed by this Court.

DATED: April 7, 2023

Respectfully Submitted,

/s/ Booth Rand

Booth Rand
Allison Hatfield

Arkansas Insurance Department
One Commerce Way, Suite 102
Little Rock, Arkansas 72202
(501) 371-2820

Attorneys for Defendant-Appellee, Alan McClain

CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(g)(1) of the Federal Rules of Appellate Procedure, I hereby certify that this brief is in compliance with the type form and volume requirements. Specifically, the Brief of Appellee is proportionately spaced; uses a Roman-style, serif typeface (Garamond) of 14-point; and contains 11,782 words, exclusive of the material not counted under Rule 32(f) of the Federal Rules of Appellate Procedure.

Pursuant to Rule 28A(h) of the Eighth Circuit's Local Rules, I further certify that the electronic version of this brief was scanned for viruses, and the file is virus free.

/s/ Booth Rand

Booth Rand
Attorney for Defendant-Appellee, Alan McClain

CERTIFICATE OF SERVICE

I hereby certify that I had the foregoing Brief of Appellee electronically filed by tendering it to the Office of the Clerk of the United States Court of Appeals for the Eighth Circuit on April 7, 2023.

I further certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ Booth Rand

Booth Rand
Attorney for Defendant-Appellee, Alan McClain