IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF ARKANSAS

CENTRAL DIVISION

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA — PLAINTIFF

v. — No. 4:21-CV-864-LPR

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

BRIEF IN SUPPORT OF DEFENDANT'S RESPONSE TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

The Defendant, Alan McClain, in his official capacity as Commissioner of the Arkansas Insurance Department, submits the following Brief in Support of his Response to the Plaintiff's Motion for Summary Judgment, and states as follows:

I. INTRODUCTION

In this action, the Plaintiff challenges a subsection from Arkansas Act 1103 of 2021, "An Act to Establish the 340b Drug Pricing Nondiscrimination Act," now codified in Ark. Code Ann. §23-92-604(c) (hereafter, "Act 1103"), on the ground that it violates the Federal Supremacy Clause under Article VI, Cl 2, U. S. Constitution. The Plaintiff specifically alleges that the provision is pre-empted by the Veteran's Health Care Act in 42 U.S.C. 256b (the "340b Program") and the Federal Food, Drug, and Cosmetic Act ("FDCA"). The Plaintiff's primary preemption argument however is aimed at the 340b program.

The State provision or subsection at issue addresses a pharmaceutical manufacturer's limitation or prohibition against third party contracts of hospitals with "outside" pharmacies with respect to 340b drugs. The Arkansas provision at issue states in its entirety the following:

"(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."

This subsection went into effect, by operation of state law and *sine die*, August 28, 2021. Act 1103 requires in Ark. Code Ann. §23-92-606 that the Insurance Commissioner ("Commissioner") issue rules to implement the Act. Shortly after Act 1103 went into effect, the Arkansas Insurance Department ("Department") did in fact begin rulemaking procedures to implement a rule to effectuate Act 1103. The Department is now publishing a final rule, "Rule 123, 340b Drug Program Nondiscrimination Requirements" ("Rule 123"). Both the statute and this final rule make it clear that the statute at issue and implementing rule only apply State restrictions pertaining to the **acquisition and delivery** of the drugs at issue, and not pricing, or resale transfers of the discount, duplicate discounts, or other pricing compensatory remedies regulated by HRSA in 42 U.S.C. § 256b (the "340b Program"), or 42 CFR Part 10, the "340b Drug Pricing Program; Administrative Dispute Resolution Regulation ("ADR Rule") (Emphasis Added).

In fact, Rule 123 states in Section II, Seven (7):

"(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." (Emphasis Added)

Neither Act 1103 or Rule 123 directly or strictly conflict with the reimbursement pricing calculations, methodologies, rebate calculations, covered entity definitions, duplicate discount restrictions, rebate calculations, improper resale of drugs, auditing, certifications or recertifications of covered entities, or alternative dispute resolution processes, as specified in the 340B program and ADR Rule. The Defendant interprets, and asks this Court to interpret, Act 1103 and Rule 123 very narrowly. Act 1103 is simply prohibiting or limiting the manner at the state level in which outpatient drugs in the 340b program are *distributed, delivered, or acquired* with respect to covered entity contracts with third party, outside pharmacies. (Emphasis Added). As later explained, neither the 340b program or the FDCA pre-empt this state legislation either expressly, or, by implication.

II. PLAINTIFF HAS BURDEN OF PROOF IN THIS PROCEEDING

Not referenced or admitted in the Plaintiff's brief or Motion is the fact that the Plaintiff bears a dual burden in proving a federal law pre-empts state law. The Plaintiff first has the general burden of establishing federal preemption. The party asserting federal preemption of state law bears the burden of persuasion. Williams v. National Football League, 582 F.3d 863, at 880 (8th Cir.2009). Secondly, there is an additional, specific presumption against preemption where Congress has legislated in a field in which the States have traditionally occupied. Lefaivre v. KV Pharmaceutical Co., 636 F.3d 935, at 938 (8th Cir.2011). The Court entertains two presumptions when interpreting the presence and scope of preemption:

> First, Congress does not cavalierly pre-empt state-law causes of action. 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, Second, congressional purpose is the ultimate touchstone in every preemption case.

Lefaivre, at 938. These exceptions to federal preemption are rooted in the 10th Amendment to the U.S. Constitution which provides that "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." Northern States Power Co. v. State of Minn., 447 F.2d 1143, at 1146. The state law at issue here pertains to a state regulation limiting or prohibiting contracts between covered entity hospitals and pharmacies in Arkansas. The Eighth Circuit Court of Appeals has already ruled that the regulation of pharmacy contracts by a State insurance department is a role traditionally left to the state, "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). In all preemption cases, where Congress has legislated in a field in which the States have traditionally occupied, we start with the assumption that the historic police powers of the State were not to be superseded by the federal act unless that was the clear and manifest purpose of Congress. In Re Aurora Dairy Corp. Organic Milk Marketing and Sales Practices Litigation., 621 F.3d 781 at 792 (8th Cir. 2010).

The Plaintiff here simply fails to overcome its burdens for preemption under any preemption analysis, whether by express preemption, or due to implied preemption, under case law established by the Eighth Circuit Court of Appeals or U.S. Constitutional cases.

II. THERE IS NO EXPRESS PREEMPTION IN THIS CASE UNDER THE 340B PROGRAM

The first analysis is whether the 340b program expressly preempts Ark. Code Ann. §23-92-604(c). This is easily refuted here. Express preemption exists where Congress uses "explicit" pre-emptive language to express its purpose. In Re Aurora Dairy Corp. Organic Milk Marketing and Sales Practices Litigation., at 792. We first examine the Act as a whole. Gade v. National Solid Wastes Management Ass'n., 112 S.Ct. 2374, at 2383. Here, it is abundantly clear when we review the entirety of 42 U.S.C. §

256b, there exists no express language, in any section or provision, specifically either expressly exempting or limiting the application of state law to regulation of state contracts between covered entities with pharmacies, pertaining to the 340b program. This is also the case with respect to any implementing rules, or guidances issued by the Health Resources and Services Administration ("HRSA") or the Department of Health and Human Services ("HHS") which refer to exclusive jurisdiction of federal law or federal agencies, over state law(s), pertaining to the regulation of the 340b program. Additionally, the Plaintiff does not cite any legislative history, committee report, preamble, or congressional anecdotes, whatsoever, in its brief or Motion identifying any express language, or "expressed" intent by Congress to exempt, limit, or supersede the application of state laws. This is significantly the case with respect to expressed provisions either enacted or promulgated as to how the 340b drugs are to be distributed by covered entities. 42 U.S.C. § 256b and the HRSA ADR Rule are entirely silent, and simply do not address covered entity contracts with outside pharmacies. The fact that HRSA or HHS have issued letters to various pharmaceutical manufacturers warning them to honor covered entity contracts with outside pharmacies, does not itself expose any underlying legal, exclusive jurisdiction imparted to these agencies, on that issue, in the expressed verbiage in the very federal statute establishing this program.

III. THERE IS NO IMPLIED PREEMPTION IN THIS CASE UNDER THE 340B PROGRAM

In the absence of express preemption, the core issue remaining here in the preemption analysis is whether the 340b program, by implication, pre-empts state law or specifically Ark. Code Ann. §23-92-604(c).

The Eighth Circuit Court of Appeals has provided the required analysis for implied preemption in several cases. Implied preemption exists where a federal statutory or regulatory scheme is so pervasive in scope that it occupies the field, leaving no room for state action. This is termed field preemption. Field preemption exists where the scheme of federal regulation is so pervasive as to make reasonable the inference that Congress has left no room for the States to supplement it. In Re Aurora Dairy Corp. Organic Milk Marketing and Sales Practices Litigation., at 792. Secondly, or separately, implied

preemption exists where a state law has not been completely displaced but is superseded to the extent it conflicts with the federal law. This is known as conflict preemption. Conflict preemption exists where a party's compliance with both federal and state laws would be impossible or where the state law would pose an obstacle to the accomplishment of congressional objectives. In Re Aurora Dairy Corp. Organic Milk Marketing and Sales Practices Litigation., at 794. The Court has additionally delineated key factors in this analysis: (1) the aim and intent of Congress as revealed by the Statute itself or legislative history, (2) the pervasiveness of the federal regulation scheme as authorized and directed by legislation and as carried into effect by the federal administrative agency, (3) the nature of the subject matter regulated and whether this is one which demands exclusive federal regulation in order to achieve uniformity vital to national interests, and (4) whether the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. Northern States Power Co., at 1146.

The explicit structure of the 340b program legislation and ADR Rule reveal there is no "field preemption" here. The structure of 42 U.S.C. § 256b reveals the federal legislation is primarily governing "pricing" of the drugs (set by pharmaceutical manufacturers), and prohibition of duplicate discounts, rebates and resale of the discounted drugs, in the 340b program, and not the mere *acquisition or delivery* of the drugs by third parties, including pharmacies of the covered entity. (Emphasis Added). The title to the legislation revealingly declares, "Limitation on Prices of Drugs Purchased by Covered Entities." Section (a)(1) then requires that "each 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." See 42 U.S.C. § 256 (a)(1). The primary restriction is absolutely silent as to manner in which the drugs are to be acquired or distributed by third parties, including pharmacies. The clear legislative purpose therefore is primarily declared to be and set out to govern the "pricing" required of pharmaceutical manufacturers to pay covered entity hospitals. The legislation thereafter provides limiting definitions of "rebate percentage, covered entities, auditing and certifications of covered entities, covered drugs, and duplicate discounts," and other terms, and then addresses audits, and alternate dispute

resolution ("ADR") processes, but the Congressional purpose is clear, and that is to regulate the pricing and discounts offered by pharmaceutic manufacturers of the outpatient drugs to covered entities and not the actions of, or delegation of, the acquisition or delivery of the drugs themselves by the covered entities.

This is also true with respect to the ADR Rule implementing the program at 42 CFR 20. The jurisdiction of this proposed proceeding is over procedures to protest pricing overcharges, duplicate discounts, or improper resale of drugs to a person not a patient of the covered entity, and, apparently, not overtly limiting a covered entity's 3rd party contracts with pharmacies as to acquisition and delivery of the drugs themselves. Indeed, there appears to be no provision or pathway explicitly available in the ADR process for a covered entity to file a claim to challenge a pharmaceutical manufacturer's restriction on a covered entity's outside contracts with pharmacies, as to its mere acquisition or delivery of the drugs themselves. In fact, the ADR Rule states:

> (c) Claims permitted. The ADR process is limited to the following:
> (1) Claims by a covered entity that it has been overcharged by a manufacturer for a covered outpatient drug, including claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price; and
> (2) Claims by a manufacturer, after it has conducted an audit of a covered Entity pursuant to section 340B(a)(5)(C) of the PHSA, that the covered entity has violated section 340B(a)(5)(A) of the PHSA regarding the duplicate discount prohibition, or section 340B(a)(5)(B) of the PHSA regarding the diversion prohibition, including claims that an individual does not qualify as a patient for 340B program purposes and claims that a covered entity is not eligible for the 340B program.

42 CFR 10.21(c). At the very least, the pharmacies themselves under contract with covered entities do not appear to have standing to file claims over pharmaceutical manufacturer cancellations or limitations, of covered entity contracts using outside pharmacies. In conclusion, the impetus of these provisions in both the Act and ADR Rule are such that the pricing and discount transfers are the only fields regulated by the federal government and not the acquisition or delivery of the 340 drugs to third party pharmacies.

The next issue under the analysis is whether the 340b program, by implication, pre-empts state law or specifically Ark. Code Ann. §23-92-604(c), under "conflict" preemption. The explicit structure of the 340b program legislation and ADR Rule reveal there is no "conflict preemption" here either. The key issue is whether state enforcement of Ark. Code Ann. §23-92-604(c) and Rule 123 operate as an obstacle such that a party's compliance with both federal and state laws would be impossible or where the state law would pose an obstacle to the accomplishment of congressional objectives. In Re Aurora Dairy Corp. Organic Milk Marketing and Sales Practices Litigation., at 794. There is no obstacle here. Consistent with this Defendant's already expressed arguments in the previous section, the remedies offered to manufacturers and covered entities in the ADR Rule are largely "compensatory" with the provision for "equitable relief" (equal to $25,000.00) pertaining to overcharging with respect to "pricing" offered by manufacturers for the 340B drugs, or involve improper duplicate discounts, or diversion. See 42 CFR 10.21(b). The relief given is largely monetary in nature or in limitation. The Arkansas legislation at issue here, however, is not remedial at all, but aimed at prohibiting manufacturer cancellation of contracts with covered entities using outside pharmacies for the *acquisition and delivery* of the drugs themselves in the 340B program. (Emphasis Added) The Arkansas legislation does not invade the space of HRSA or its ADR Rule, or operate as obstacle, or frustrate compensatory or equitable remedies for overcharging in violation of ceiling prices, or address or regulate duplicate discounts, or diversion. It is not an obstacle to Congressional purposes. This Defendant is permitted to pursue enforcement under its Trade Practices Act to prohibit manufacturer cancellation or limitation of covered entity contracts with outside pharmacies for outpatient drugs, with respect to how the drugs are *acquired* by the covered entity, or how they are

distributed. (Emphasis Added) The pharmaceutical manufacturers and covered entities are still free to pursue whatever federal remedies they have separately under the ADR Rule.

Nor does the 340B program satisfy the key factors in Northern States Power Co., at 1146, in analyzing implied preemption. What is (1) the aim and intent of Congress as revealed by the Statute itself or legislative history? As previously stated before, the 340B statute itself reveals no state law limitations, expressly, at all. Secondly, there is no legislative history evincing a congressional purpose for the 340B program to prohibit state laws prohibiting or limiting pharmaceutical manufacturers from cancelling or limiting contracts by covered entities with outside pharmacies as to the *acquisition or delivery* of the drugs themselves. (Emphasis Added) What is the (2) the pervasiveness of the federal regulation scheme as authorized and directed by legislation and as carried into effect by the federal administrative agency? It's not all encompassing and not being enforced. As previously indicated, the federal "scheme" is aimed at pricing and diversionary discounts, not delivery and acquisition of the drugs to third party pharmacies. As to the "carrying the federal regulation into effect," the Defendant was unable to find or discover one single case in which the requisite federal agencies (either HRSA or HHS) actually culminated in an ADR ruling or final enforcement infraction Order against a pharmaceutical manufacturer for cancelling or limiting a covered entities contracts with outside pharmacies. Thirdly, what is the nature of the subject matter regulated and whether this is one which demands exclusive federal regulation in order to achieve uniformity vital to national interests? As stated previously, the nature of the subject matter regulated is over 340B drug "pricing" and diversionary or duplicate discounts and not the third party acquisition of drugs in this program from covered entities. There is no expressed national uniformity expressed in any areas outside those two (2) goals, leaving abundant room for state regulation as to the delivery and acquisition of the drugs covered by this program. There is no obstacle which Ark. Code Ann. §23-92-604(c) would pose to either 42 U.S.C. § 256b or the ADR Rule. The pharmaceutical manufacturers and covered entities are still free to pursue whatever federal remedies they have separately under the ADR Rule.

Lastly, the Plaintiff relies heavily on the United States Supreme Court ruling in Astra USA, Inc. v. Santa Clara Cty., Cal., 563 U.S. 110 (2011) as controlling in this matter on preemption. The United States Supreme Court held in Astra that third party beneficiaries for covered entities under the 340B program could not maintain private causes of action for "overcharging" against pharmaceutical manufacturers outside the required, formal procedures for filing such claims, as already established by HRSA. The Court reasoned that suits by 340B entities would undermine the agency's efforts to administer both Medicaid and §340B harmoniously and on a uniform, nationwide basis. Astra USA, Inc., at 1349. Astra is addressing suits for private causes of action by 340B entities related to "overcharging," for which there already is a "compensatory," federal administrative remedy. Here, as stated previously, the state law restriction at issue does not seek to impose compensatory or monetary relief, but applies state penalties over contract limitations or prohibitions of covered entity contracts with third party pharmacies. Unlike in Astra, there appears to be no distinct and expressed manner or pathway in the federal program procedures for covered entities or pharmacies, to make these challenges for the acquisition, distribution, or delivery of the drugs themselves.

IV. INSURANCE DEPARTMENT RULE 123 REMOVAL OF ARBITRATTION REQUIREMENT

The Plaintiff makes numerous references in its brief to this Defendant's earlier removal of a federal exhaustion requirement in a draft Rule to enforce Act 1103, as tantamount to an admission by the Defendant that there were recognized fatal federal preemption concerns over the Rule and Act. The Defendant earlier required in a draft rule that covered entities first exhaust their HRSA ADR procedures before seeking enforcement by the Department, the Defendant's "Enforcement Policy." The Defendant 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 or more state-based community hospitals. The Defendant is not a judicial body, but is an executory agency required to address and respond to legislative and public concerns. Somewhat misleadingly, the Plaintiff gives the impression in its brief, that had the Defendant kept the "Enforcement Policy," in its final Rule, the Plaintiff's preemption claims would be

less of an objection. This is simply not what the Plaintiff earlier argued in its public comments, presented to the Insurance Department. In its April 13, 2022 public comment, the Plaintiff even objected to that exhaustion requirement as also being preempted. The Plaintiff 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 Plaintiff simply wants to object to any enforcement position by the State, whether direct or even contingent.

V. THE FDCA DOES NOT CONFLICT WITH ACT 1103

The Plaintiff's last argument is that the FDCA supersedes Ark. Code Ann. §23-92-604(c). As noted by the Plaintiff in its Motion, in 2007, Congress amended the FDCA to allow the U.S. Food and Drug Administration ("FDA") to require risk evaluation and mitigation strategies ("REMS") for drugs which have a high potential for abuse or high risk of side effects. The Plaintiff does not provide much express or implied preemption analysis here, the Plaintiff states: Act 1103 does not mention REMS or the FDCA, and Act 1103 does not limit its requirements that manufacturers deliver to certain contract pharmacies in light of either REMS or the FDCA. However, Act 1103 does not conflict with the FDCA or REMS. The Act can easily be read in harmony with any FDCA provisions or REMS protocols. The Defendant 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. Both in its structure and definitions, Act 1103 is on its face limited to pharmacy participation *in the 340B program* using outside contracts with covered entity hospitals, and how the drugs are distributed. (Emphasis Added). Separate federal or even state laws governing the health, safety, and monitoring of the drugs themselves, or even licensing of the participants themselves, continue to apply without conflicting with the FDCA.

WHEREFORE, Defendant prays that the Plaintiff's Motion For Summary Judgment be denied, and for all other just and proper relief to which Defendant may be entitled.

Respectfully submitted,

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9-8-2022

DATE

CERTIFICATE OF SERVICE

I, Booth Rand, do hereby certify that a copy of the foregoing has been mailed to the following person(s) on this 8th day of September, 2022:

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