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

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff,

–v–

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

Defendants.

Case No. 4:21-cv-864-BRW

MEMORANDUM IN SUPPORT OF MOTION TO INTERVENE BY PIGGOTT COMMUNITY HOSPITAL AND COMMUNITY HEALTH CENTERS OF ARKANSAS

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INTRODUCTION

In May 2021, the Governor of Arkansas signed into law Act 1103 of 2021 ("Act 1103") (codified at Ark. Code Ann. §§ 23-92-601–606) which includes two provisions—subsections (c)(1) and (c)(2) of Ark. Code Ann. § 23-92-604—requiring pharmaceutical manufacturers to ship drugs discounted under the federal 340B drug pricing program ("340B Program") to pharmacies under contract with Arkansas safety-net providers. Plaintiff in this lawsuit seeks an order declaring both provisions of Act 1103 invalid. Act 1103 was enacted to protect Arkansas safety-net providers, yet no health care provider is a party to this action. Piggott Community Hospital ("PCH") and Community Health Centers of Arkansas, Inc. ("CHCA") (collectively, "Proposed Intervenors") represent the interests of the law's intended beneficiaries. PCH and members of CHCA participate in the 340B Program and rely on contract pharmacy arrangements to meet the pharmacy needs of their patients. Proposed Intervenors are, therefore, entitled to intervene under Rule 24(a) because they have a significant interest in the subject matter of this action that could be impaired by the disposition of the litigation, and no party completely and adequately represents their interests. Alternatively, the Court should grant permissive intervention under Rule 24(b) because Proposed Intervenors have claims and defenses that share commons questions of law and fact with the action, and their intervention will not cause undue delay or prejudice to the parties. This action is in its infancy and the trial is scheduled for next year, January 3, 2023.

BACKGROUND

I. Legal Background

A. Intervention

1. Mandatory Intervention

Under Rule 24(a), a party may intervene as a matter of right if it "claims an interest

relating to the property or transaction that is the subject of the action, and is so situated that disposing of the action may as a practical matter impair or impede the movant's ability to protect its interest, unless existing parties adequately represent that interest." Fed. R. Civ. P. 24(a)(2). To satisfy the requirements under Rule 24(a), a proposed party seeking intervention must file a timely motion that satisfies a tripartite test: 1) the party must have a recognized interest in the subject matter of the litigation; 2) that interest must be one that might be impaired by the disposition of the litigation; and 3) the interest must not be adequately protected by the existing parties. *Mille Lacs Band of Chippewa Indians v. Minnesota*, 989 F.2d 994, 997 (8th Cir. 1993); *see also Nat'l Parks Conservation Ass'n v. EPA*, 759 F.3d 969, 975 (8th Cir. 2014). In the Eighth Circuit, Rule 24 is construed liberally and courts should "resolve all doubts in favor of the proposed intervenors." *United Sates v. Union Elec. Co.*, 64 F.3d 1152, 1158 (8th Cir. 1995).

The requirement for a recognized interest in the litigation is construed broadly, and all parties affected by the litigation should be included if practicable. *Union Elec. Co.,* 64 F.3d at 1162 (quoting *SEC v. Flight Transp. Corp.,* 699 F.2d 943, 949 (8th Cir. 1983) (The court should be mindful "that [t]he interest test is primarily a practical guide to disposing of lawsuits by involving as many apparently concerned persons as is compatible with efficiency and due process.") (internal quotation marks omitted)); *see also Sierra Club v. Robertson,* 960 F.2d 83, 86 (8th Cir. 1992) ("[Intervention] serves the judicial system's interest in resolving all related controversies in a single action.").

"Rule 24(a)(2) requires only that disposition of the action may as a practical matter impair or impede the applicant's ability to protect [its] interest." *Kan. Pub. Emps. Ret. Sys. v. Reimer & Koger Assocs., Inc.*, 60 F.3d 1304, 1307-08 (8th Cir. 1995). A person claiming an interest in the litigation does not have to wait until he or she has suffered irreparable harm before

the requirements for intervention under Rule 24(a) have been met. *Union Elec. Co.*, 64 F.3d at 1162. If the effect of an adverse ruling would have a negative stare decisis effect on a proposed intervenor's interests, that impact would provide the requisite type of impairment to warrant intervention of right. *See Corby Recreation, Inc. v. General Elec. Co.*, 581 F.2d 175, 176-77 (8th Cir. 1978).

A proposed intervenor typically has a "minimal burden" of showing that its interests are not adequately represented by the parties. *Mille Lacs*, 989 F.2d at 1000. A proposed intervenor can rebut the general presumption that the government is adequately representing its interests by showing that its interests actually differ from, or conflict with, the government's interests. *Union Elec. Co.,* 64 F.3d at 1169; *Mille Lacs*, 989 F.2d at 1001.

2. Permissive Intervention

Permissive intervention under Rule 24(b) provides that "[o]n timely motion, the court may permit anyone to intervene who . . . has a claim or defense that shares with the main action a common question of law or fact." Fed. R. Civ. P. 24(b)(1), (b)(1)(B). The decision to grant or deny a motion for permissive intervention is wholly discretionary, but courts construe motions to intervene "liberally . . . in favor of the proposed intervenors." *Smith v. SEECO, Inc.*, 922 F.3d 398, 405–06 (8th Cir. 2019) (internal quotations omitted); *South Dakota ex rel. Barnett v. U.S. Dep't of Interior*, 317 F.3d 783, 787 (8th Cir. 2003).

The principal factor that courts consider in ruling on a Rule 24(b) permissive intervention motion is "whether the proposed intervention would unduly delay or prejudice the adjudication of the parties' rights." *Shelton v. Kennedy Funding, Inc.*, No. 4:02CV00632WRW, 2009 WL 1890579, at *2 (E.D. Ark. June 30, 2009) (quoting *South Dakota ex rel. Barnett v. U.S. Dep't of Interior*, 317 F.3d 783, 787 (8th Cir. 2003)); *Coffey v. Comm'r*, 663 F.3d 947, 951 (8th Cir. 2011) (intervention is improper "only when it causes undue delay or prejudice"). Courts may

consider whether the "prospective intervenors have pledged to meet the Court's existing deadlines" and the "benefit of [having] intervenors' important views." *Little Rock Sch. Dist. v. N. Little Rock Sch. Dist.*, No. 4:82-CV-866-DPM, 2011 WL 6842642, at *6 (E.D. Ark. Dec. 29, 2011).

3. Timeliness

Rule 24 requires that a motion to intervene be "timely." Fed. R. Civ. P. 24(a), (b)(1). Deciding the timeliness of intervention requires the court to "consider[ ] all the circumstances of the case." *United States v. Ritchie Special Credit Invs., Ltd.*, 620 F.3d 824, 832 (8th Cir. 2010) (quoting *Mille Lacs*, 989 F.2d at 998). When considering timeliness, the Eighth Circuit applies the following factors: "(1) the extent the litigation has progressed at the time of the motion to intervene; (2) the prospective intervenor's knowledge of the litigation; (3) the reason for the delay in seeking intervention; and (4) whether the delay in seeking intervention may prejudice the existing parties." *SEECO, Inc.*, 922 F.3d at 405. "The question for determining the timeliness of the motion to intervene is whether existing parties may be prejudiced by the delay in moving to intervene, not whether the intervention itself will cause the nature, duration, or disposition of the lawsuit to change." *Union Elec. Co.*, 64 F.3d at 1159 (citations omitted).

4. Standing

The Eighth Circuit has held that an intervenor must establish Article III standing to litigate. *Liddell v. Special Admin. Bd. of the Transitional Sch. Dist. of the City of St. Louis,* 894 F.3d 959, 964 (8th Cir. 2018). Article III standing requires (1) injury-in-fact; (2) causation, and (3) redressability. *See Lujan v. Defenders of Wildlife,* 504 U.S. 555, 560-61 (1992). To satisfy the injury-in-fact element, an injury must be "concrete, particularized, and actual or imminent." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 408 (2013).

An association has standing to litigate on behalf of its members when: (1) its members

would otherwise have standing in their own right; (2) the interests it seeks to protect are germane to the organization's purpose; and (3) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit. *Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000).

B. The 340B Program and 340B Drug Distribution

Established in 1992, the 340B Program requires drug manufacturers to offer discounts on covered outpatient drugs to statutorily defined safety-net providers, referred to as "covered entities," as a condition of the manufacturers' drugs being reimbursed by Medicaid and Medicare Part B. 42 U.S.C. § 256b(a)(1); 42 U.S.C. § 1396r-8(a)(1). The Health Resources and Services Administration ("HRSA") within the federal Department of Health and Human Services, is responsible for administering the 340B Program. The 340B Program makes drugs more affordable for covered entities because those entities provide significant levels of uncompensated care, and the discounts available through the 340B Program help relieve that burden. Covered entities essentially lose less money on prescription drugs under the 340B Program for their uninsured and underinsured patients. And by avoiding these losses, they can be more generous with reducing or waiving patient co-payments at the pharmacy counter. The 340B Program also generates revenue for covered entities so that they are less dependent on taxpayer support. To the extent a covered entity patient has prescription drug coverage, the difference between the insurer's payment and the discounted price is income to the covered entity to supplement federal funds, thus allowing the covered entity to stretch scarce federal resources as far as possible and enabling it to reach more eligible patients and provide more comprehensive services. H.R. Rep. No. 102-384, pt. 2, at 12 (1992) (Conf. Rep.).

Most illnesses and injuries cannot be adequately treated or managed without the patient

taking one or more medications. That means providers of health care—such as the Proposed Intervenors—must ensure that their patients have access to a pharmacy to fill their prescriptions. For this reason, many providers own and operate their own pharmacies, often referred to as in-house pharmacies. However, because the construction and management of a pharmacy is expensive and requires special expertise, many providers contract with independently owned pharmacies to meet the pharmacy needs of their patients.[1] In most cases, these contract pharmacies are located in the provider's service area in locations that are convenient and accessible to the provider's patients.[2] Typically, drugs dispensed by contract pharmacies are purchased under what is referred to as a "bill to/ship to" arrangement—the drugs are billed to the hospital or clinic but shipped to the contract pharmacy. The provider purchaser takes title to the drugs but not physical possession of them. A wholesaler ships the drugs to the contract pharmacy, which then takes physical custody of the drugs and dispenses them on the provider's behalf.

It became abundantly clear after passage of the 340B statute in 1992 that, if covered entities did not possess the right to acquire drugs through bill to/ship to arrangements, many of them—specifically those lacking in-house pharmacies—would never have been able to

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[1] *See, e.g.,* McKesson Ed. Staff, *Starting a Pharmacy*, McKesson (Oct. 8, 2018), https://www.mckesson.com/Blog/Pharmacy-Ownership/ (estimating that the cost of establishing a pharmacy is between $350,000 to $450,000); Sarah Shoemaker-Hunt et al., Cost of Dispensing Study (Jan. 2020), https://www.nacds.org/pdfs/pharmacy/2020/NACDS-NASP-NCPA-COD-Report-01-31-2020-Final.pdf (stating that the cost of dispensing non-specialty drugs at retail pharmacies ranges from $692,400, for a volume of 40,000 prescriptions a year, to $1,427,988.10, for a volume of 119,999 prescriptions a year, and that the cost of dispensing specialty drugs ranges from $294,320, for a volume of 40,000 prescriptions a year, to $882,952 for a volume of 119,999 prescriptions a year); *see also* Ark. Admin. Code §§ 007.39.4-04-00-0001 to 007.39.4-04-07-0006 (stating nuanced structural, inventory, and personnel requirements of Arkansas pharmacies).

[2] But some medications require special storage and handling and can only be dispensed by a specialty pharmacy through a mail order program. These specialty pharmacies are generally located outside the provider's service area. *See, e.g.,* Am. Soc'y of Health-System Pharmacists, *ASHP Accreditation Standard for Specialty Pharmacy Practice* (July 2020), https://www.ashp.org/-/media/assets/products-services/ASHP-Accreditation-Programs/docs/Accreditation-Standard-Specialty-Pharmacy-Practice.pdf (noting that specialty pharmacy practice involves high cost drugs; complex treatment regimens requiring ongoing clinical monitoring and patient education infrastructure; specialty drug handling, storage, and delivery infrastructure; and other services required for complex high-touch disease states and treatments).

participate in the 340B Program, even though they clearly met the eligibility criteria established by Congress. HRSA felt compelled to remind covered entities that they could still participate so, in 1996, it issued guidance explicitly recognizing covered entities' existing right to use bill to/ship to arrangements for meeting the pharmacy needs of their patients. For nearly three decades, every drug company participating in the 340B Program, including Plaintiff's members, honored bill to/ship to arrangements and treated contract pharmacies the same as in-house pharmacies. That changed abruptly, however, in July 2020 when one manufacturer after another either fully eliminated or significantly restricted distribution of 340B drugs ordered through bill to/ship to arrangements. *See, e.g.,* Sanofi, *Sanofi policy* (Feb. 1, 2021), https://340besp.com/sanofi-policy-2021-02-02-09_18_19.pdf. As of today, sixteen manufacturers have unilaterally imposed these restrictions on contract pharmacy arrangements.[3] These restrictions have deprived covered entities of receiving the revenue and savings intended by Congress which, in turn, reduces the resources available to covered entities to meet the needs of their vulnerable patients, including the need for affordable and accessible prescription drugs.

Several drug manufacturers have sued HHS seeking to halt its enforcement against them regarding their obligations under the 340B statute to ensure that covered entities *purchase* 340B drugs at prices no higher than the statutory ceiling price. These drug companies are AstraZeneca, Lilly USA, LLC ("Lilly"), Novartis Pharmaceuticals ("Novartis"), Novo Nordisk, Sanofi, and United Therapeutics. The district courts have issued decisions in each case, and the parties have appealed those decisions except for the decision in *AstraZeneca Pharmaceuticals*

[3] The following drug companies have restricted 340B drug distribution and are members of Plaintiff: AbbVie, Amgen Inc. ("Amgen"), AstraZeneca Pharmaceuticals LP ("AstraZeneca"), Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer"), Bristol Myer Squibb ("BMS"), Eli Lilly and Company ("Lilly"), Gilead Sciences, Inc. ("Gilead"), GlaxoSmithKline ("GKS"), Merck and Company ("Merck"), Novartis Pharmaceuticals Corporation ("Novartis"), Novo Nordisk, Inc. ("Novo Nordisk"), Pfizer Inc. ("Pfizer"), Sanofi-Aventis US LLC ("Sanofi"), United Therapeutics Corporation ("United Therapeutics"), UCB, and Johnson & Johnson ("J&J").

LP v. Becerra.[4]

C. Arkansas Act 1103

Act 1103 (codified at Ark. Code Ann. §§ 23-92-601–606 and referred to as the 340B Drug Pricing Nondiscrimination Act) includes subsections (c)(1) and (c)(2) of Ark. Code Ann. § 23-92-604, which protect 340B bill to/ship to arrangements for covered entities and contract pharmacies located and doing business in Arkansas. Consistent with the state's authority to regulate drug distribution to pharmacies within its borders, the statute regulates 340B drug distribution through two provisions. The first provision, Ark. Code Ann. § 23-92-604(c)(1), prohibits a drug manufacturer from denying a covered entity access to 340B drugs if the covered entity uses contract pharmacy arrangements to participate in the 340B Program. The second provision, Ark. Code Ann. § 23-92-604(c)(2), prohibits a manufacturer from blocking an Arkansas-based contract pharmacy from receiving 340B drugs on behalf of a covered entity by denying 340B pricing on such drugs.

II. Factual Background

A. Entities Seeking Intervention

PCH is located in Piggott, Arkansas and operates within the Medicare program as a critical access hospital ("CAH"). PCH is owned and operated by the City of Piggott and participates in the 340B Program based on its governmental ownership and CAH status. 42 U.S.C. §§ 256b(a)(4)(N), 1395i–4(c)(2); 42 C.F.R. §§ 485.601–485.647. As a requirement of its CAH designation, PCH is located in an area that serves residents who would otherwise be required to travel long distances to receive inpatient medical care. *See* 42 U.S.C. § 1395i–

[4] No. 21-27-LPS, 2022 WL 484587 (D. Del. Feb. 16, 2022); *Novartis Pharms. Corp. v. Espinosa*, No. 21-CV-1479, 2021 WL 5161783 (D.D.C. Nov. 5, 2021), *appeal docketed*, No. 21-5299 (D.C. Cir. Dec. 30, 2021); *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health and Hum. Servs.*, No. 21-00634, 2021 WL 5150464 (D.N.J. Nov. 5, 2021), *appeal docketed*, No. 21-3168 (3d Cir. Nov. 26, 2021); *Eli Lilly & Co. v. U.S. Dep't of Health & Hum. Servs.*, No. 1:21-CV-00081, 2021 WL 5039566 (S.D. Ind. Oct. 29, 2021), *appeal docketed*, No. 21-3128 (7th Cir. Nov. 15, 2021).

4(c)(2)(B)(i)(I); 42 C.F.R. § 485.610(c). As an Arkansas governmentally funded hospital, PCH is prohibited from owning an on-site retail pharmacy. *See* Ark. Code Ann. § 17-92-607 (making it unlawful for any nonprofit, tax exempt, or governmentally funded hospital to acquire direct or indirect interest in, or otherwise hold directly or indirectly a pharmacy license for the retail sale of drugs). Therefore, PCH relies exclusively on independently-owned contract pharmacies to fill prescriptions for its patients, many of whom are uninsured and low income.

CHCA is a non-profit organization comprised of eleven Arkansas-based community health centers that provide primary health services in over one hundred and twenty service locations across the state. They treat large numbers of uninsured and underinsured low-income Arkansans because they are dedicated and legally obligated to care for anyone regardless of the patient's ability to pay. Each of CHCA's member health centers participates in the 340B Program by virtue of their receipt of federal funding under Section 330 of the PHSA. 42 U.S.C. §§ 254b, 256b(a)(4)(A); 42 U.S.C. § 1396d(l). These entities are referred to as Federally Qualified Health Centers ("FQHCs"). Importantly, Section 330 contains several requirements, including a requirement that health centers provide "pharmaceutical services as may be appropriate." 42 U.S.C. § 254b(b)(1)(A)(i)(I). The majority of CHCA's eleven health centers do not own their own pharmacies. Instead, they rely on outside community-based retail pharmacies to order, receive, and dispense self-administered medications for their patients.

B. Administrative Proceedings Challenging Act 1103 and Regulations

Act 1103 became effective on July 28, 2021, but Plaintiff filed a petition that day requesting that the Arkansas Insurance Department ("AID") "issue a declaratory order staying enforcement of Section 23-92-604(c) of Act 1103 as to Plaintiff and its members, pending resolution of [ongoing federal cases involving Plaintiff's members] or for at least 120 days (subject to renewal)." Petition for Declaratory Relief at 8, ¶ a, *In re Act 1103,* AID No. 2021-37

(July 28, 2021), ECF No. 1, Ex. 1 [hereinafter "Plaintiff's Petition"]. Plaintiff's Petition also requested that the Arkansas Insurance Commissioner (the "Commissioner") issue an interim order staying enforcement of Section 23-92-604(c) as to Plaintiff and its members, while AID considered the matter. Plaintiff's Petition, ¶¶ a-b.

On July 29, 2021, the Commissioner issued an order granting Plaintiff's request to temporarily suspend enforcement of Ark. Code Ann. § 23-92-604(c)(1)-(2) "pending completion of Declaratory review whether such provisions are preempted or inconsistent with federal law." Ex. 1, Order Granting Petition for Declaratory Ruling at 1, ¶ 2, *In re Act 1103 of 2021,* AID No. 2021-37 (July 29, 2021) [hereinafter "AID Suspension Order"]. That suspension was effective for 90 days from the date of Plaintiff's Petition, or October 26, 2021. *Id.* The AID Suspension Order also ordered a public hearing in the matter. *Id.* That same day, the Commissioner issued Bulletin No. 12-2021 permitting "persons affected by the Order . . . to intervene in the proceeding." AID Suspension Order, ¶ 9. On August 25, 2021, CHCA submitted a letter requesting to intervene in that administrative proceeding. Letter from Lisa Weaver, Interim Chief Exec. Officer, Cmty. Health Ctrs. of Ark., to Alan McClain, Comm'r, Ark. Ins. Dep't (Aug. 25, 2021). The AID held a hearing on September 10, 2021 and granted CHCA's request to intervene. Ex. 2, Order Granting Interventions and Setting Schedule for Briefing, *In re Act 1103*, AID No. 2021-46 (Sept. 24, 2021).

On September 16, 2021, Plaintiff submitted a request for further stay of enforcement of Section 23-92-604(c) beyond the initial 90-day period. PhRMA Request to the Commissioner for a Further Stay of Enforcement at 1, *In re Act 1103,* AID No. 2021-37 (Sept. 16, 2021) [hereinafter "Plaintiff's Additional Stay Request"]. Proposed Intervenor CHCA joined three other Arkansas stakeholders—including the Arkansas Hospital Association which represents

Proposed Intervenor PCH—in opposing Plaintiff's Additional Stay Request. Shortly thereafter, Plaintiff filed the instant lawsuit. Complaint for Declaratory and Injunctive Relief, ECF No. 1. It also notified the Commissioner that it would not seek an additional stay beyond the initial 90-days based upon its "reflection on the issues raised in [the] proceedings, as well as" its filing of the instant lawsuit. PhRMA Notice Regarding Need for Hearing on September 29, 2021 Brief and Further Stay ¶ 2, *In re Act 1103* (Oct. 4, 2021).

The parties to the administrative proceeding participated in a hearing on October 5, 2021. AID Order on Declaratory Proceeding in re Act 1103 of 2021 ¶ 3, *In re Act 1103 of 2021,* AID No. 2021-50. At that hearing, CHCA stressed the vital importance of contract pharmacy arrangements to Arkansas safety-net providers and their patients. CHCA also noted the growing number of Plaintiff's members that were restricting distribution of 340B drugs to covered entities through contract pharmacy arrangements. CHCA requested that the suspension of Section 23-92-604(c) be lifted immediately, rather than forcing Arkansas safety-net providers to wait for the 90-day stay to expire. AID denied this request, explaining that a continued stay for the full initial 90-day period was warranted for "equitable" reasons.

On February 22, 2022, AID published a proposed rule to implement Act 1103 including Section 23-92-604(c) ("Proposed Rule"). Ark. Ins. Dep't, *Rule 123 340B Drug Program Nondiscrimination Requirements* (Feb. 22, 2022), https://insurance.arkansas.gov/uploads/pages/proposed_rule_123_markup.pdf [hereinafter Proposed Rule]. The proposed rule essentially repeats the (c)(1) and (c)(2) provisions of Section 23-92-604 of Act 1103 under subsection IV(c). It also states that that those provisions "shall only apply to direct drug pricing contract pharmacy arrangements between a pharmaceutical manufacturer and a covered entity located and conducting business in Arkansas" and "only apply

to 340B drug pricing contract pharmacy arrangement transactions pertaining to a patient" of a covered entity. *Id.* Furthermore, the Proposed Rule adds a provision that is not part of Act 1103. That provision requires complainants, as a condition for relief under Act 1103, to "first exhaust all available federal arbitration and federal administrative rights . . . under the 340B administrative dispute resolution ["ADR"] process described in 42 U.S.C. § 256b(d)(3) and 42 C.F.R. §§ 10.20-24 . . . ." *Id.*

ARGUMENT

Proposed Intervenors satisfy the requirements on intervention as of right and permissive intervention. Proposed Intervenors are entitled to mandatory intervention because they have standing, have timely moved for intervention, and have a significant, legally-protectable interest in the outcome of this litigation, and that interest is not adequately represented by Defendants. In the alternative, Proposed Intervenors should be granted permissive intervention because intervention will not unduly delay or prejudice an existing party, and Proposed Intervenors' motion is timely and presents common questions of law and fact with the current litigation.

I. Proposed Intervenors Have Standing to Intervene in This Litigation

PCH has standing to litigate in its own right, and CHCA has standing to litigate on behalf of its members. Both Proposed Intervenors satisfy the requirements for Article III standing and have interests in this litigation that are "arguably within the zone of interests to be protected or regulated by the statute or constitutional guarantee in question." *See Ass'n of Data Processing Serv. Orgs. v. Camp*, 397 U.S. 150, 153 (1970). Plaintiff's members have obstructed use of bill to/ship to arrangements by Proposed Intervenors and their Arkansas contract pharmacies. Those actions deprive Proposed Intervenors of access to 340B drugs and, as a result, the savings and revenue they rely on to carry out their safety-net missions. Section 23-92-604(c) of Act 1103 protects the contractual rights of Arkansas covered entities and independent pharmacies to

distribute 340B drugs through bill to/ship to arrangements. A ruling in favor of Plaintiff would exacerbate the harms that Plaintiff's members are inflicting on Proposed Intervenors.

A. PCH and CHCA Have Suffered Injuries in Fact

PCH has standing to intervene because it is harmed by the steps taken by Plaintiff's members to limit distribution of 340B drugs to in-house pharmacies rather than contract pharmacies except in a few narrow circumstances. The harm is increasing every day, so if this Court ruled in favor of Plaintiff, PCH's ability to sustain its operations, let alone continue to provide uncompensated care to indigent patients, would be severely compromised. This is due in large part to a unique Arkansas law prohibiting governmentally funded hospitals such as PCH to hold a license as a "retail" pharmacy to dispense drugs. Ark. Code Ann. §§ 17-92-605(d), 607. Accordingly, PCH can only obtain 340B discounts on self-administered drugs through a contract pharmacy arrangement. Without access to 340B drugs through such arrangements, the savings and revenue PCH relies on to support uncompensated care will continue to erode.

PCH's mission is to "provide high-quality, compassionate healing to the community through education, treatment and health services." *Mission Statement*, Piggott Health Sys., https://piggotthealthsystem.com/ (last visited Mar. 2, 2022). PCH's 340B Program savings and income have decreased as a result of Plaintiff's members blocking shipment of 340B drugs to contract pharmacies in Arkansas. PCH is experiencing direct financial harm that establishes injury-in-fact. *See Eckles v. City of Corydon,* 341 F.3d 762, 768 (8th Cir. 2003); *see also Nat'l Parks Conservation Ass'n v. EPA*, 759 F.3d 969, 975 (8th Cir. 2014). If the Court grants the relief that Plaintiff requests in this case, PCH would "unavoidably be harmed economically." *United States v. Metro. St. Louis Sewer Dist.,* 569 F.3d 829, 836 (8th Cir. 2009). Additionally, PCH's primary mission of providing services to a vulnerable patient population would be threatened if this Court invalidates Section 23-92-604(c) of Act 1103. *See Granville House, Inc.*

v. Dep't of Health & Hum. Servs., 715 F.2d 1292, 1297 (8th Cir. 1983) (in addition to economic injury, the plaintiff was injured by having "to withdraw from its primary mission of treating the poor"). If Section 23-92-604(c) of Act 1103 is not enforced, PCH's fiscal health will continue to decline leading to dire consequences.

CHCA's members are eleven Arkansas-based community health centers, each of which participates in the 340B Program. CHCA has standing to intervene because its members, like PCH, have been, and continue to be, significantly harmed by drug manufacturers' obstruction of 340B bill to/ship to arrangements in the State of Arkansas. These restrictions severely compromise the ability of CHCA's members to provide important safety-net services, including offering discounted prescription drugs at contract pharmacies. *See* CHCA Decl., Ex. 3 ¶¶ 5, 12. CHCA seeks to protect interests that are germane to its purpose. *Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000). Participation of individual CHCA members in the litigation is not necessary because this suit presents pure questions of law. Accordingly, CHCA has associational standing. *Id.*

CHCA's interest in upholding Act 1103 goes to the heart of CHCA's mission to advocate for, and facilitate the success of, Arkansas community health centers and to promote access to health care for Arkansas residents. *About*, Cmty. Health Ctrs. Ark., http://www.chc-ar.org/about (last visited Mar. 2, 2022). The majority of CHCA's eleven health centers do not own in-house pharmacies and rely on community-based contract pharmacies to dispense drugs to their patients. CHCA Decl., Ex. 3 ¶ 8. As a result of Plaintiff's members restricting or completely blocking distribution of 340B drugs to contract pharmacies in Arkansas, CHCA's members have less access to 340B drugs and hence cannot provide those discounted drugs to their patients. CHCA Decl., Ex. 3 ¶ 15. These actions have also resulted in an overall decrease in 340B revenue

which, if allowed to continue, will force CHCA members to cut important safety-net services and to reduce activities designed to further the health centers' missions to improve lives and build healthier Arkansas communities. CHCA Decl., Ex. 3 ¶¶ 10, 14. Accordingly, CHCA's members will be adversely affected by an unfavorable decision in this case.

This litigation involves a pure question of law and does not hinge upon facts that pertain to any individual member of CHCA. Plaintiff challenges Act 1103 on purely constitutional grounds. Participation by CHCA's individual members is not necessary for this Court to determine whether Act 1103 is constitutional.

B. The Proposed Intervenors' Harms Have Been Caused by Plaintiff's Actions

The harms that Proposed Intervenors, and their members, continue to suffer are caused by Plaintiff because these harms are "fairly traceable" to the actions of Plaintiff's members to restrict distribution of 340B drugs to Arkansas pharmacies. *Lujan*, 504 U.S. at 560-61. Sixteen drug manufacturers—most of whom are members of Plaintiff's association—have implemented policies that restrict distribution of 340B drugs to Arkansas-based contract pharmacies. *See, e.g.*, Sanofi, *Sanofi policy* (Feb. 1, 2021), https://340besp.com/sanofi-policy-2021-02-02-09_18_19.pdf. These distribution restrictions by manufacturers include, but are not limited to, directly prohibiting, or causing wholesalers to restrict, 340B drugs from being ordered by and shipped to Arkansas contract pharmacies. *See* AmerisourceBergen, *340B Manufacturer updates*, https://www.amerisourcebergen.com/provider-solutions/340b-advisory-services/340b-manufacturer-updates (last visited Mar. 24, 2022) (wholesaler listing all manufacturers that have imposed 340B drug distribution restrictions impacting the wholesaler's operations).

These manufacturers' actions and policies are traceable to the harms suffered by Proposed Intervenors, including lost revenues generated through contract pharmacy arrangements, suffered by CHCA, its members, and PCH. *See, e.g.*, CHCA Decl., Ex. 3 ¶¶ 10,

14, 15. Proposed Intervenors did not begin to lose these revenues until Plaintiff's members began to restrict, or cause wholesalers to restrict, distribution of 340B drugs to contract pharmacies. *See id.* ¶¶ 10, 15.

C. The Proposed Intervenors Harms Are Redressable by This Court

The harms imposed by Plaintiff's members are redressable by this Court because a favorable decision would prohibit drug manufacturers from continuing to restrict distribution of 340B drugs to contract pharmacies, and Proposed Intervenors would be able to order, receive, and dispense self-administered medications for their patients. *Liddell v. Special Admin. Bd. of the Transitional Sch. Dist. of the City of St. Louis*, 894 F.3d 959, 966 (8th Cir. 2018) (charter school parents would be redressed by a favorable decision); *Mausolf v. Babbitt*, 85 F.3d 1295, 1301-02 (8th Cir. 1996) (snowmobiling restrictions at issue were sufficiently definite and imminent enough to confer standing).

II. Proposed Intervenors Satisfy the Standards to Intervene as of Right Under Rule 24(a)

The Proposed Intervenors satisfy the three-prong test for intervention as of right, which is construed liberally. *Union Elec. Co.*, 64 F.3d at 1162; *Kan. Pub. Emps. Ret. Sys.*, 60 F.3d at 1307 ("[W]e construe Rule 24 liberally, and resolve any doubts in favor of the proposed intervenors.") (internal citations omitted). Proposed Intervenors have an interest in this litigation because they rely on 340B contract pharmacies to receive and dispense needed medications for their patients, many of whom are uninsured, underinsured or otherwise medically vulnerable. Proposed Intervenors' interests will be impacted by the litigation because Section 23-92-604(c) protects Proposed Intervenors' right to use contract pharmacy arrangements for purposes of ordering, receiving and dispensing 340B drugs. In addition, Defendants do not adequately represent Proposed Intervenors' interests, which differ from, and in some respects directly

conflict with, the Defendants' interests.

A. The Proposed Intervenors Have a Significant Interest in the Subject Matter of This Action

Proposed Intervenors have a direct and substantial interest in the outcome of this litigation because Section 23-92-604(c) protects their right to enter into contract pharmacy arrangements to order and receive 340B drugs. *Planned Parenthood of Minn., Inc. v. Citizens for Cmty. Action,* 558 F.2d 861, 869 (8th Cir. 1977) (finding a neighborhood association had a "significantly protectable interest" in enforcing a city ordinance). Proposed Intervenors have a significant, legally protectable interest in this lawsuit because their primary mission of providing services to Arkansas' most vulnerable patients would be threatened if this Court invalidated Section 23-92-604(c). *Granville House, Inc.*, 715 F.2d at 1297 (finding injury when an organization's primary mission was impeded). Proposed Intervenors rely heavily on contract pharmacies to provide 340B medications to uninsured and underinsured Arkansas patients at little or no cost. Thus, Proposed Intervenors have an interest in the Court upholding a law that addresses actions by the drug manufacturers that have restricted distribution of drugs to contract pharmacies. Moreover, both Plaintiff and Defendants recognized CHCA's and other 340B stakeholders' interests in this subject matter by consenting to CHCA's intervention in the administrative proceedings Plaintiff brought against AID. AID Intervention Order, at 1.

Proposed Intervenors' interests are not so remote that they are "contingent upon the occurrence of a sequence of events." *Standard Heating & Air Conditioning Co. v. City of Minneapolis*, 137 F.3d 567, 571 (8th Cir. 1998). Until July 2020, every drug manufacturer participating in the 340B Program recognized a 340B covered entity's right to dispense its 340B drugs through contract pharmacies. Now, sixteen drug manufacturers—most of whom are members of Plaintiff's association—have taken actions or implemented policies that restrict

distribution of 340B drugs to contract pharmacies. *See, e.g., Program Integrity*, HRSA (Oct. 2021), https://www.hrsa.gov/opa/program-integrity/index.html. These manufacturer policies can differ, often including complicated exceptions or conditions that may or may not apply to the covered entities in question. Thus, Proposed Intervenors already face significant financial harms that are directly traceable to actions taken by Plaintiff's members and that Section 23-92-604(c) was intended to prohibit. Plaintiff's challenge to this law, if successful, would allow its members to *continue* to prevent distribution of 340B drugs purchased by Proposed Intervenors for dispensation at contract pharmacies. *Standard Heating*, 137 F.3d at 571 ("[I]ntervention may be based on an interest that is contingent upon the outcome of the litigation."). Thus, Proposed Intervenors have a substantial and protectable interest in safeguarding the well-being of their patients and fulfilling their missions to provide health care to vulnerable Arkansas patients.

B. Proposed Intervenors' Interests will be Impaired by the Disposition of the Litigation

Plaintiffs ask this Court to extinguish the Proposed Intervenors' rights to have 340B drugs distributed to contract pharmacies which, if granted, will harm Proposed Intervenors and their patients. Without intervention, disposition of the current action will, therefore, "as a practical matter impair their interests." *Little Rock Sch. Dist. v. Pulaski Cnty. Special Sch. Dist. No. 1*, 738 F.2d 82, 84 (8th Cir. 1984) (internal quotations omitted).

Nearly all Proposed Intervenors do not operate in-house pharmacies and rely exclusively on outside community-based retail pharmacies to order, receive, and dispense 340B drugs. This is because the requirements to obtain a pharmacy license are complex and operating an in-house pharmacy is expensive. And for nonprofit hospitals like PCH, the contract pharmacy model is indispensable because Arkansas law prohibits nonprofit, tax exempt, or governmentally funded hospitals from owning and operating their own in-house retail pharmacies. Ark. Code Ann. §

17-92-607. Without the ability to order, receive, and dispense self-administered drugs at 340B discounts through contract pharmacies, PCH cannot meet the pharmacy needs of its patients.

If the lawsuit is decided in favor of Plaintiff, Proposed Intervenors, and all other 340B covered entities in Arkansas, will be at the mercy of drug manufacturers that prohibit or severely restrict covered entities' ability to order and receive 340B drugs at contract pharmacies. Plaintiff's members may, in effect, eliminate any benefit of Arkansas nonprofit hospitals participating in the 340B Program after more than 25 years of depending on those benefits. *Kan. Pub. Emps. Ret. Sys.*, 60 F.3d at 1307-08 (applicant only needs to show that interest "may be" impaired by litigation).

Proposed Intervenors use 340B savings and revenue from drugs shipped to contract pharmacies to provide vital safety-net services to impoverished patients and communities. Contract pharmacies are, therefore, a vital component of Arkansas' public health care system. The refusal of Plaintiff's members to distribute 340B drugs to contract pharmacies will result in financially needy patients no longer having access to discounted drugs which, in turn, will likely cause them to forgo prescribed medications or request less costly medications that may not be as efficacious. Moreover, Proposed Intervenors will be forced to reduce or eliminate the services that they provide to patients, resulting in harm to their patients and the need for more expensive health care services. Striking down Section 23-92-604(c) would cause a serious hardship to Proposed Intervenors and their vulnerable patients as well as other 340B providers and their patients. *Kan. Pub. Emps. Ret. Sys.*, 60 F.3d at 1308 (applicant successfully showed that its interests may be impaired by the operation of res judicata, collateral estoppel, or stare decisis effect of the result of the litigation); *Corby Recreation, Inc.*, 581 F.2d 167-77.

C. Proposed Intervenors' Interests Are Not Adequately Protected by the Parties

Plaintiff, which seeks to invalidate Section 23-92-604(c) of Act 1103, plainly does not

represent the interests of Proposed Intervenors. Although the Proposed Intervenors' interest in enforcing Section 23-92-604(c) and defending its constitutionality may appear to align with the interests of the Defendants, the Defendants also do not adequately represent the interests of Proposed Intervenors. Proposed Intervenors' interests differ from and, in some cases, directly conflict with the Defendants' interests. *See Union Elec. Co.,* 64 F.3d at 1169.

Plaintiff previously filed a petition with AID to stay enforcement of Section 23-92-604(c) for 90 days, which AID granted while it investigated the merits of the petition. Plaintiff's Petition, ¶¶ a-b; AID Suspension Order, at 1. Plaintiff filed a request for an additional stay that was opposed by CHCA and other covered entity and pharmacy groups. Plaintiff's Additional Stay Request, at 1. Despite requests from CHCA that the stay be lifted before the expiration of 90 days, and statements regarding the significant harms that Arkansas covered entities have continued to face due to Plaintiff's members' restrictive 340B drug distribution practices, the Commissioner issued an order that allowed the stay on enforcement of Section 23-92-604(c) to remain in effect for the full 90-day period for "equitable" reasons. AID Termination of Proceeding, ¶¶ 3-4. Given that Defendants have already granted a stay on enforcement of the law and allowed the stay to continue against the pleas of Proposed Intervenor CHCA, Proposed Intervenors' interests in enforcement of Section 23-92-604(c) is obviously not aligned with Defendants' interests. *Union Elec. Co.*, 64 F.3d at 1169 (the presumption of adequate representation "may be rebutted by a showing that the applicant's interest cannot be subsumed within the shared interest of the citizens of the state").

Furthermore, Defendants' Proposed Rule demonstrates that their interests diverge from the Proposed Intervenors' interests. *Mausolf*, 85 F.3d at 1303-04 (finding government's interests were "adverse" to the intervenors' interests). Specifically, the Proposed Rule appears to

substantially narrow the protective scope of Section 23-62-604(c), which further demonstrates that Defendants will not adequately protect the interests of Proposed Intervenors. Note that Proposed Intervenors are *only* addressing the Proposed Rule as evidence that AID will not adequately represent Proposed Intervenors' interest and not to interject any collateral issues related to the validity of the regulations.

The Proposed Rule requires covered entities to proceed first through the federal 340B Program's administrative dispute resolution ("ADR") process before bringing a state law claim to the AID against a manufacturer. Proposed Rule, at 4 (citing the 340B ADR statute and regulations at 42 U.S.C. § 256b(d)(3) and 42 C.F.R. §§ 10.20-24). That process would require HRSA to first determine "under the [federal 340B] administrative dispute resolution process . . . that a drug manufacturer has improperly denied 340B drug pricing" before a claim could be asserted under Section 23-92-604(c). Proposed Rule, at 4. The requirement for a federal 340B ADR as a prerequisite is inapposite to the text of Section 23-92-604(c) and would impose an undue burden on Proposed Intervenors if finalized.

Section 23-92-604(c) seeks to protect the distribution of 340B drugs to Arkansas-based contract pharmacies. Act 1103 does not, and was not intended to, affect the 340B *price* at which a covered entity purchases 340B drugs or the covered entity's *ability to purchase* 340B drugs. By contrast, the federal 340B ADR process resolves disputes asserted by covered entities that they have been *overcharged* for drugs *that they have purchased*. *See* 42 U.S.C. § 256b(d)(3) (authorizing HRSA to "promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under [the 340B statute]"). Neither the 340B statute nor the 340B ADR process resolves, or entitles HRSA to resolve, a claim that a manufacturer has restricted the contractual

rights of covered entities and independent pharmacies to enter into bill to/ship to arrangements for 340B medications. By requiring 340B ADR as a condition to AID's enforcement responsibility under Act 1103, Defendants' Proposed Rule strays from Act 1103's text and imposes federal requirements that are inconsistent with Proposed Intervenors' interests.

Moreover, Defendants' proposed requirement for federal 340B ADR would substantially delay Proposed Intervenors' relief under Section 23-92-604(c). Securing a 340B ADR decision requires significant time and critical resources before covered entities may obtain relief. *See, e.g.*, 42 C.F.R. § 10.21(b) (stating that the Federal Rules of Civil Procedure govern ADR proceedings unless a federal ADR panel permits otherwise in a proceeding). Defendants' Proposed Rule would drastically hinder the Proposed Intervenors' ability to obtain important relief under Section 23-92-604(c) because, similar to federal litigation, ADR proceedings may take years to adjudicate.

The Proposed Rule states that the law is only applicable to "*direct* drug pricing contract pharmacy arrangements." Proposed Rule, at 3 (emphasis added). However, Section 23-62-604(c) contains no such limitation to its applicability, the Proposed Rule provides no explanation regarding the meaning or purpose of the term "direct," and the rule's proposed limitation to "direct" arrangements could substantially diminish protections for covered entities under the law.

The Proposed Rule also reflects AID's misunderstanding of contract pharmacy bill to/ship to arrangements. The Proposed Rule states that Section 23-62-604(c) applies to "drug pricing *contract pharmacy arrangements between a pharmaceutical manufacturer and covered entity* located and conducting business in Arkansas." Proposed Rule, at 3 (emphasis added). However, contract pharmacy arrangements typically only include health care providers and independent pharmacies, not manufacturers. Proposed Intervenors are unaware of contract

pharmacy arrangements in which drug manufacturers are a party. AID's apparent misunderstanding of contract pharmacy arrangements is yet another reason why Defendants will not adequately represent the interests of Proposed Intervenors.[5]

Finally, Proposed Intervenors can provide the Court with the unique perspective of community-based 340B covered entities, the entities that Act 1103 was enacted to protect. Proposed Intervenors can explain how access to 340B drugs through bill to/ship to arrangements impacts the patients they serve. The Proposed Intervenors can, therefore, provide the Court with the perspective of Arkansas-based 340B covered entities that depend on contract pharmacies, a perspective which neither Plaintiff nor Defendants can offer because they are not health care providers.

III. Proposed Intervenors Satisfy the Standards of Permissive Intervention Under Rule 24(b)(2)

In addition to meeting the requirements for intervention as a matter of right under Rule 24(a), Proposed Intervenors meet the requirements for permissive intervention under Rule 24(b). Proposed Intervenors "share[] with the main action a common question of law or fact" regarding the legality of Section 23-92-604(c) of Act 1103. Fed. R. Civ. P. 24(b)(1)(B). Proposed Intervenors' request is timely and will not unduly prejudice or delay the adjudication of the parties' rights.

A. Intervention Will Not Cause Undue Delay or Prejudice

Allowing Proposed Intervenors to intervene will not result in undue delay or prejudice to the other parties in the lawsuit. *Shelton*, 2009 WL 1890579, at *2; *South Dakota ex rel. Barnett,* 317 F.3d at 787 ("The principal consideration in ruling on a Rule 24(b) motion is whether the proposed intervention would unduly delay or prejudice the adjudication of the parties' rights.").

[5] Again, Proposed Intervenors offer the above references to the Proposed Rule only as evidence that AID will not adequately represent their interests.

Proposed Intervenors' motion is timely, and dispositive motions have not yet been filed by either party. *Coffey*, 663 F.3d at 951; *Union Elec. Co.*, 64 F.3d at 1159. Proposed Intervenors are ready to participate fully and actively in this case and will comply with all the Court's deadlines. *Little Rock Sch. Dist.*, 2011 WL 6842642, at *6 (proposed intervenors participation in the litigation "will not unduly delay the litigation or prejudice the original parties' rights" because it was the beginning of the case and the prospective intervenors pledged to meet the court's existing deadlines).

B. Proposed Intervenors Share a Common Question of Law or Fact

Proposed Intervenors should be permitted to intervene because they "share[] with the main action a common question of law or fact." Fed. R. Civ. P. 24(b)(1)(B). An intervenor can meet the commonality requirement when a "claim is sufficiently intertwined" with the underlying claims already before the Court. *Ratchford v. Evans*, No. 5:11-CV-00180-DPM, 2012 WL 177855, at *1 (E.D. Ark. Jan. 23, 2012). Proposed Intervenors' defenses are sufficiently intertwined and based on the same set of facts pled in Plaintiff's complaint concerning the legality and constitutionality of Section 23-92-604(c). Proposed Intervenors share a common question of law, whether Section 23-92-604(c) is lawful and will not interject collateral issues. *Steel-Arkansas v. EPA*, No. 3:15CV00333 JLH, 2016 WL 4045425, at *2 (E.D. Ark. Apr. 13, 2016) (finding common questions of law and fact between proposed intervenor's defense and the defendant's defense); *Curry v. Regents of Univ. of Minn.*, 167 F.3d 420, 423 (8th Cir. 1999) (denying permissive intervention because "[m]ovants' presence in the case would interject collateral issues").

IV. Proposed Intervenors' Motion is Timely

Proposed Intervenors' request is timely. First, litigation has not progressed substantially since the Complaint was filed on September 29, 2021. *Union Elec. Co.*, 64 F.3d at 1159 (finding

a motion to intervene timely when intervenor "filed slightly more than four months after the suit itself was filed" and because "litigation had progressed little" between filing the complaint and motion to intervene). Plaintiff filed its initial complaint on September 29, 2021. The Court set a final briefing schedule on January 18, 2022, which sets a bench trial on January 3, 2023, more than nine months from now. In addition, AID only issued its proposed rule implementing Act 1103 on February 22, 2022. Granting intervention will cause no disruption or delay in the proceedings and will not prejudice existing parties. The Court's scheduling order sets the trial for January 3, 2023, and the deadline for dispositive motions on October 20, 2022, and as of the date of this motion, neither party has filed such a motion. Final Scheduling Order at 1, ECF No. 14. The parties' Rule 26(f) report proposes a deadline for joining parties thirty days before the close of discovery, and the Court's final scheduling order closes discovery on October 5. *Id.*; Joint Rule 26(F) Report and Discovery Plan at 4, ECF No. 13. Proposed Intervenors are moving to intervene well before the October 5 discovery deadline. *See ACLU of Minn. v. Tarek ibn Ziyad Acad.*, 643 F.3d 1088, 1094 (8th Cir. 2011) (finding untimeliness when "more than a month after the deadline to add parties" passed). Therefore, the motion to intervene is timely under Rule 24(a).

CONCLUSION

For the foregoing reasons, Proposed Intervenors respectfully request that the Court grant their motion to intervene of right under Rule 24(a) or, in the alternative, to allow them to intervene under Rule 24(b).

Dated: March 25, 2022

Respectfully submitted,

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Dated: March 25, 2022

CERTIFICATE OF SERVICE

I, Nate Steel, hereby certify that a copy of the foregoing document was this date served upon all counsel of record by electronically filing it with the Clerk of the District Court for the Eastern District of Arkansas, using its ECF system, which automatically provides electronic notification to the following:

Booth Rand
Arkansas Insurance Department

Amanda Land
Asher Steinberg
Arkansas Attorney General's Office

Joshua Ashley
Philip Perry
Andrew Prins
Pharmaceutical Research and Manufacturers of America

/s/ Nate Steel
Nate Steel