**BEFORE THE ARKANSAS INSURANCE DEPARTMENT**

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

## PETITION FOR DECLARATORY RELIEF

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

## PRELIMINARY STATEMENT

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## PRAYER FOR RELIEF

PhRMA respectfully prays that the Insurance Department:

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

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

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Respectfully submitted,


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