

**THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

ASTRAZENECA PHARMACEUTICALS LP,

Plaintiff,

v.

XAVIER BECERRA, Secretary of Health &  
Human Services, et al.,

Defendants.

C.A. No. 21-27-LPS

ADMINISTRATIVE PROCEDURE ACT  
REVIEW OF AGENCY DECISION

**UNOPPOSED MOTION TO FILE *AMICUS CURIAE* BRIEF IN OPPOSITION TO  
PLAINTIFF’S MOTION FOR SUMMARY JUDGEMENT**

The National Association of Community Health Centers (“NACHC”), Ryan White Clinics for 340B Access (“RWC-340B”), Little Rivers Health Care, Inc. (“Little Rivers”), and WomenCare, Inc., dba FamilyCare Health Center (“FamilyCare”) (collectively the “Amici”), by and through undersigned counsel, respectfully request leave to file a brief as amici curiae in the above captioned case in opposition to the Plaintiff’s Motion for Summary Judgment. D.I. 42; D.I. 43. Amici have conferred with counsel to the Parties regarding this motion. The Defendants consent to Amici’s participation and Plaintiff takes no position on Amici’s participation.

Neither the Federal Rules of Civil Procedure nor the Local Rules of this Court address amicus briefs. Therefore, this Court has inherent power to permit an amicus brief, particularly where it provides “additional views [that] . . . may aid the Court’s review.” *Getty Oil Co. v. Dept. of Energy*, 117 F.R.D. 540, 550 (D. Del. 1987); *see also General Motors Corp. v. Volpe*, 321 F. Supp. 1112 (D. Del. 1970), *aff’d*, 457 F.2d 922 (3d Cir. 1972); *Neonatology Assocs., P.A.*

*v. Comm'r*, 293 F.3d 128, 133 (3d Cir. 2002) (discussing amicus filing standards of Rule 29 of the Federal Rules of Appellate Procedure and observing that it is “preferable to err on the side of granting leave” to file an amicus brief because “if a good brief is rejected, the merits panel will be deprived of a resource that might have been of assistance”). The Third Circuit has allowed amicus briefing “unless it is obvious that the proposed briefs do not” establish the movant’s interest in the case and if the amicus explains why the proposed brief is desirable and relevant to the disposition of the case. *Neonatology Assocs., P.A. v. Comm’r*, 293 F.3d 128, 130, 133 (3d Cir. 2002). This standard may guide the Court here.

Amici’s motion should be granted for several reasons. Amici have an interest in the 340B contract pharmacy program, which enables them to treat their vulnerable patients. The 340B Drug Discount Program (“340B Program”) is vital to Amici who have participated in lawsuits related to this one, and several have filed petitions against Plaintiff under the 340B administrative dispute resolution (“ADR”) process to enforce their contract pharmacy rights.<sup>1</sup> Further, Amici can provide the Court with the unique perspective of small, community-based, federal grantees that participate in the 340B Program, as well as the perspective of their vulnerable patients. No party or other amici represents the unique interests of 340B federal grantees that participate in the 340B Program.

Amici have a critical interest in this case, which concerns the 340B Program, administered for their benefit by Defendant, the Department of Health and Human Services (“HHS”). The 340B Program allows certain healthcare providers (known as “covered entities”) serving medically vulnerable, uninsured, and under-insured patients to purchase outpatient drugs at significant discounts. 42 U.S.C. § 256b. Amici submit the attached brief to apprise the Court

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<sup>1</sup> NACHC filed ADR claims on behalf of 225 FQHCs on January 13, 2021; Little Rivers filed its petition on February 4, 2021; and FamilyCare filed its petition on February 12, 2021.

of the broad-based and far-reaching legal, social, and economic implications inherent in any change to the 340B Program, as well as the substantial harms that will befall covered entities, their patients, and underserved communities if Plaintiff AstraZeneca Pharmaceuticals LP (“AstraZeneca”) is permitted to deny 340B discounts for drugs purchased by covered entities and shipped to contract pharmacies for dispensing. No covered entity is a party to this action, but all covered entities will be negatively impacted if the Court invalidates the HHS General Counsel Advisory Opinion, which confirms the agency’s longstanding position that the 340B statute requires manufacturers to offer 340B discounted drugs to covered entities who use contract pharmacies to store and dispense those drugs to the covered entities’ patients. HHS Gen. Counsel Advisory Op. 20-06 on Contract Pharmacies Under the 340B Program, D.I. 40-3 at 1-8 (“Advisory Opinion”). The Amici have a significant interest in the continued viability of their 340B contract pharmacy arrangements, which for more than twenty years allowed them to obtain and dispense discounted drugs manufactured by Plaintiff.

Amici are plaintiffs in lawsuits against several of the Defendants that seek to redress their rights under the 340B statute to obtain 340B discounted pricing through contract pharmacies. *See* Amended Compl., *RWC-340B v Azar*, No. 1:20-cv- 02906 (D.D.C. Nov. 23, 2020), ECF No. 21 (stayed Jan. 13, 2021), D.I. 40-7 at 1715-1757; Compl., *NACHC v. Azar*, No. 1:20-cv-03032 (D.D.C. Oct. 21, 2020), ECF No. 1 (stayed Jan 7, 2021). Moreover, three of the Amici (Little Rivers, Family Care, and NACHC) have filed petitions under the ADR process to obtain a remedy for Plaintiff’s unilateral decision to stop offering 340B pricing on drugs dispensed by contract pharmacies. D.I. 13-1 at 35-56, 58-92, 94-116. The Amici’s interest in the contract pharmacy program, as demonstrated by these pending lawsuits and ADR petitions, will be materially affected by the Court’s decision on the legality of the Advisory Opinion. To

the best of the Amici's knowledge, other amici in this case have not filed ADR petitions against Plaintiff.

The Amici's covered entity members rely heavily on the 340B contract pharmacy program to serve their vulnerable patients. NACHC, founded in 1971, is a nonprofit organization with a national membership of federally-funded health centers, known as Federally-qualified health centers ("FQHCs"). FQHCs provide crucial primary health care and related services in all fifty states and the District of Columbia and in Puerto Rico and other U.S. territories, regardless of patient insurance status or ability to pay for such services; approximately one in twelve Americans receive care at an FQHC. NACHC is dedicated to furthering the safety-net mission and purpose of FQHCs, and does so through extensive education, training, and advocacy, including legal representation through its associational standing and as amicus curiae. *See, e.g., Cal. Ass'n of Rural Health Clinics v. Douglas*, 738 F.3d 1007 (9th Cir. 2013) (concerning scope of mandatory FQHC services and associated reimbursement rights in Medicaid).

FQHCs receive, or are eligible to receive, federal grant funding under Section 330 of the Public Health Service ("PHS") Act to serve four general patient populations: residents of federally-designated medically underserved areas; homeless populations; migrant and seasonal farmworkers; and residents of public housing. 42 U.S.C. § 254b(a)(1). FQHCs provide comprehensive primary care to approximately one in twelve Americans who fall into one or more of these categories and serve on the front lines in preventing, treating, and containing serious, nationwide public health threats such as the HIV epidemic, the opioid addiction crisis, and the ongoing COVID-19 pandemic. Eighty-two percent of FQHC patients are either publicly insured (e.g., Medicare and Medicaid beneficiaries) or lack health insurance entirely. *See*

NACHC, *Community Health Center Chartbook 2020* (Jan. 2020), Figs. 1-5.<sup>2</sup> For decades, FQHCs have relied on 340B Program savings and revenue to meet the needs of their vulnerable patient populations, which in 2020 included approximately one in three people living in poverty, one in five residents of rural areas, one in nine children, one in eight people of a racial or ethnic minority, and one in six Medicaid beneficiaries. *See Id.*, Figs. 1-1.

RWC-340B is a national, not-for-profit association of clinics that receive funding under the Ryan White Comprehensive AIDS Resources Emergency Act (“Ryan White CARE Act”), Pub. L. No. 101-381, 104 Stat. 576 (codified at 42 U.S.C. §§ 300ff–300ff-140), to provide health care and related support services to individuals living with human immunodeficiency virus/acquired immunodeficiency syndrome (“HIV/AIDS”). Receipt of this funding qualifies the members of RWC-340B to participate in the 340B Program as covered entities and thereby purchase outpatient drugs at discounted prices. Clinics funded under the Ryan White CARE Act provide primary medical care, medications, and support services to over half a million underserved and uninsured individuals living with HIV/AIDS. RWC-340B, *Value of Ryan White Providers and Impacts Associated with Resource Reduction*, 2–3 (Oct. 2020).<sup>3</sup> Ryan White clinic patients are “more likely to have less than a high school education, live in poverty, and be homeless” than people living with HIV/AIDS who are not treated in Ryan White clinics. *Id.* at 6. Nevertheless, Ryan White clinic patients are more likely to achieve HIV viral suppression than patients seen elsewhere. *Id.* at 4.

RWC-340B has members in all regions of the United States. RWC-340B’s members are typically small, nonprofit organizations that do not have the financial resources to operate in-

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<sup>2</sup> <https://www.nachc.org/research-and-data/research-fact-sheets-and-infographics/chartbook-2020-final/> (hereinafter “NACHC Chartbook”) (last visited May 4, 2021).

<sup>3</sup> <https://www.rwc340b.org/wp-content/uploads/2020/10/20200921-RWC340B-White-Paper-FINAL.pdf> (last visited May 4, 2021).

house pharmacies and instead participate in the 340B Program by ordering drugs for shipment to contract pharmacies, which dispense the drugs to the members' patients. For many Ryan White clinics, contract pharmacy arrangements are the primary, or even sole, path to 340B discounts and revenue, a funding source on which these clinics have long relied. Seventy-five percent of Ryan White clinics have contract pharmacy arrangements. *See* HRSA, *Welcome to 340B OPAIS*, <https://340bopais.hrsa.gov/> (last visited May 4, 2021).

Little Rivers is a not-for-profit FQHC with facilities located in Wells River, Bradford, and East Corinth, Vermont. Little Rivers provides respectful, comprehensive primary health care for all residents in its region, regardless of patient ability to pay. Little Rivers has been registered as a covered entity in the 340B Program since 2006. Statistics from the Health Resources and Services Administration ("HRSA"), the division of HHS that administers FQHC grants, show that Little Rivers served more than 5,500 patients in 2019 and that, of those patients with known incomes, 61.2% had income at or below 200% of the Federal Poverty Level ("FPL"), including 19.48% with income at or below 100% of the FPL. HRSA, *Health Center Program Data for Little Rivers, Patient Characteristics*.<sup>4</sup> In 2019, approximately 50% of Little Rivers' patients were either Medicaid or Medicare recipients and approximately 5% of its patients were uninsured. *Id.* Little Rivers does not operate an in-house pharmacy and instead participates in the 340B Program by using contract pharmacy relationships. Little Rivers filed an ADR petition on February 4, 2021, against AstraZeneca to contest its refusal to ship 340B drugs to Little Rivers' contract pharmacies.

FamilyCare is a not-for-profit FQHC with several facilities in West Virginia, including three mobile units and clinics at local schools. FamilyCare's mission is to make high-quality,

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<sup>4</sup> <https://data.hrsa.gov/tools/data-reporting/program-data?grantNum=H80CS06658> (last visited May 4, 2021)

whole-person care available to every member of the family and every member of the community. FamilyCare is an FQHC and is eligible to participate as a covered entity in the 340B Program by virtue of that designation. FamilyCare has been registered as a covered entity in the 340B Program since 2000. According to HRSA statistics, FamilyCare served 32,353 patients in 2019, and of those patients with known incomes, 99.53% have annual incomes at or below 200% of the FPL, including 50.43% with annual incomes at or below 100% of the FPL. HRSA, *Health Center Program Data for WomenCare, Patient Statistics*.<sup>5</sup> In 2019, approximately 63% of FamilyCare’s patients were either Medicaid or Medicare recipients and 7.46% of its patients were uninsured. *Id.* FamilyCare does not operate an in-house pharmacy and instead participates in the 340B Program by using contract pharmacy relationships. FamilyCare filed an ADR petition on February 12, 2021, to contest AstraZeneca’s refusal to ship 340B drugs to FamilyCare’s contract pharmacies.

The Amici can provide the Court with the unique perspective of federal grantees with limited resources that rely on 340B contract pharmacy arrangements to serve their patients, a viewpoint that is not represented by the Parties or other amici in this case. Congress intended the 340B Program to allow covered entities to “stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” H.R. Rep. No. 102-384(II), at 12 (1992); *see also Cares Cmty Health v. U.S. Dep’t of Health & Human Servs.*, 944 F.3d 950, 955 (D.C. Cir. 2019) (340B savings “help safety-net providers fund the uncompensated care they supply and expand the services they offer”). Notably, as federal grantees, Amici are required to provide services to underserved, and often impoverished, communities many of which have been disproportionately affected by the COVID-19 public

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<sup>5</sup> <https://data.hrsa.gov/tools/data-reporting/program-data?grantNum=H80CS00827> (last visited May 4, 2021).

health emergency. Many federal grantees cannot afford to operate in-house pharmacies and are dependent on the contract pharmacy arrangements that are the subject of the Advisory Opinion the Court will review. The Amici can provide the Court with the perspective of the entities that use contract pharmacies for exactly the purpose for which the 340B program was intended, a perspective that neither Plaintiff nor Defendants can provide. Moreover, other amici, which are largely hospital associations, do not typically operate on the shoestring budgets that make the use of contract pharmacy arrangements so critically important to federal grantees.

The Amici's interest in the 340B contract pharmacy program stems from their missions to provide critical safety-net services to vulnerable communities. The future of the contract pharmacy program will affect the Amici's ability to continue to provide services to these communities, to provide discounted drugs to indigent patients, and to offer pharmacy services throughout their service areas for patients who cannot travel vast distances to obtain vital, life-sustaining medications.

This motion and the attached amicus brief are also timely. The Court has permitted the American Hospital Association ("AHA"), *et al.* amici to file a brief on May 4, 2021. D.I. 53. The Amici have filed this motion and accompanying brief on the same date as permitted for the AHA amici.

Therefore, the Amici respectfully move the Court for leave to file the attached amici curiae brief and accompanying exhibits.

Dated: May 4, 2021

Respectfully submitted,

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*\* Pro hac vice applications pending*

**CERTIFICATE OF SERVICE**

I hereby certify that on this 4<sup>th</sup> day of May 2021, a true and correct copy of Unopposed Motion To File Amicus Curiae Brief In Opposition To Plaintiff's Motion For Summary Judgment and was electronically filed with this Court, and thereby simultaneously served via CM/ECF upon all counsel of record.

By: /s/ Leslie Spoltore  
Leslie B. Spoltore, Esquire (#3605)