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SANOFI-AVENTIS U.S., LLC,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al*.,

Defendants.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Civil Action No. 3:21-cv-634-FLW-LHG

BRIEF OF AMICI CURIAE RYAN WHITE CLINICS FOR 340B ACCESS, LITTLE RIVERS HEALTH CARE, INC., AND FAMILYCARE HEALTH CENTER IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

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INTERESTS OF AMICI CURIAE

Amici Curiae are two "covered entities" that participate in the 340B program and a trade association representing certain covered entities (collectively, the "Amici"). Amici Little Rivers Health Care, Inc. ("Little Rivers") and FamilyCare Health Center ("FamilyCare") have filed petitions for 340B Administrative Dispute Resolution ("ADR"), which are currently pending. All three Amici have sued several of the federal Defendants in this case for failing to promulgate 340B ADR regulations. *RWC-340B v. Azar*, No. 1:20-cv-02906 (D.D.C. Oct. 9, 2020) (stayed Jan. 13, 2021). After the Amici filed their lawsuit, the Department of Health and Human Services ("HHS") issued ADR regulations that enabled Little Rivers and FamilyCare to pursue their ADR claims. 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632 (Dec. 14, 2020) ("ADR Rule"). Plaintiff Sanofi-Aventis U.S., LLC, ("Sanofi") now asks this Court to enjoin those same regulations. The Amici therefore have a significant interest in the outcome of this case, and the Amici can provide the Court with a unique perspective because neither party in the instant case is a "covered entity," which is the category of health care provider that Congress intended to benefit through the 340B program. The Amici will therefore focus on the harms that a preliminary injunction will cause to 340B covered entities and their vulnerable patients, which Sanofi has wholly ignored in its motion, and which far outweigh any harms that Sanofi has alleged it will incur.

I. Little Rivers

Little Rivers is a not-for-profit health care provider with facilities located in Wells River, Bradford, and East Corinth, Vermont. Little Rivers is certified by HHS as a federally-qualified health center ("FQHC") and is eligible to participate as a covered entity in the 340B program by

virtue of that designation.[1] Little Rivers provides family medicine, pediatrics, obstetrics, behavioral health, and oral health care. Little Rivers' mission is to provide respectful, comprehensive primary health care for all residents in its region, regardless of their ability to pay. Little Rivers Health Care, *About*, https://www.littlerivers.org/about (last visited Feb. 25, 2021). Statistics from the Health Resources and Services Administration ("HRSA") Health Center Program, 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*, https://data.hrsa.gov/tools/data-reporting/program-data?grantNum=H80CS06658 (last visited Feb. 25, 2021). In 2019, more than 25% of Little Rivers' patients were Medicaid recipients, and approximately 5% of its patients were uninsured. *Id.* Approximately 15.46% of Little Rivers' patients were under the age of 18 and 25.68% were 65 years of age or older. *Id.*

Little Rivers has been registered as a covered entity in the 340B program since 2006. Little Rivers does not operate an in-house pharmacy. Auclair Aff. ¶ 19.[2] Little Rivers relies

[1] An FQHC is a community-based health care provider that receives federal grant funding and "provide[s] primary care services in underserved areas." HRSA, *Federally Qualified Health Centers*, https://www.hrsa.gov/opa/eligibility-and-registration/health-centers/fqhc/index.html (last reviewed May 2018).

[2] The following declarations, which are attached to this brief, were originally submitted as exhibits in the Amici's lawsuit against HHS, Mot. for TRO and Prelim. Inj., *RWC-340B v. Azar*, No. 1:20-cv-02906 (D.D.C. Nov. 23, 2020), ECF No. 24, (stayed Jan. 13, 2021): Declaration of Gail Auclair, M.S.M.-H.S.A., B.S.N., R.N, CEO of Little Rivers Inc. (Ex. A, "Auclair Aff."); Declaration of Craig Glover, MBA, MA, FACHE, CMPE, President and CEO of FamilyCare (Ex. B, "Glover Aff."); Declaration of Terri S. Dickerson, CFO of WomenCare, Inc., dba FamilyCare Health Center (Ex. G, "Dickerson Aff."); Declaration of James D. Duck, Owner of The Corner Drug Store, (Ex. H, "Duck Aff.").

exclusively on contract pharmacy arrangements to dispense 340B retail drugs to its patients. *Id.* Little Rivers filed an ADR petition on February 4, 2021, to contest a manufacturer's action to cease shipping 340B drugs to Little Rivers' contract pharmacies.

II. FamilyCare

FamilyCare is a not-for-profit health care provider with several facilities in West Virginia, including three mobile units and facilities at local schools. FamilyCare is certified by HHS as an FQHC and is eligible to participate as a covered entity in the 340B program by virtue of that designation. FamilyCare's service area is very large, and some patients drive for an hour to reach one of its locations. Most of FamilyCare's facilities provide comprehensive primary care services, but three offer specialized care: a birthing center, a pediatric medicine clinic, and an addiction treatment center. FamilyCare's mission is to "make high-quality, whole-person care available to every member of the family and every member of the community." FamilyCare Health Centers, *About*, https://familycarewv.org/about/ (last visited Feb. 25, 2021). FamilyCare provides patient care services covering a wide variety of specialties, which include adult health care, pediatric health care, a prescription savings program, behavioral health, psychiatry, substance use disorder treatment, urgent care, dental care, women's health care, prenatal health care, birth services, school-based health programs, chronic care management, diabetes education, medical nutrition education, and social services. According to HRSA statistics, FamilyCare served 32,353 patients in 2019, and of those patients with known incomes, 99.53% had 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*, https://data.hrsa.gov/tools/data-reporting/program-data?type=AWARDEE#titleId (last visited Feb. 25, 2021).

FamilyCare has been registered as a covered entity in the 340B program since 2000. FamilyCare does not operate an in-house pharmacy. Glover Aff. ¶ 4. FamilyCare relies exclusively on contract pharmacy arrangements to dispense 340B retail drugs to its patients. *Id.* FamilyCare filed an ADR petition on February 12, 2021, to contest a manufacturer's action to cease shipping 340B drugs to FamilyCare's contract pharmacies.

III. RWC-340B

RWC-340B is a national association of human immunodeficiency virus ("HIV")/acquired immunodeficiency syndrome ("AIDS") health care clinics and service providers that receive funding under the federal Ryan White Comprehensive AIDS Resources Emergency Act ("Ryan White CARE Act"), 42 U.S.C. § 300ff-11, et seq., either through a primary grant or subgrant, and participate as covered entities in the 340B program by virtue of receiving this funding. Entities that receive grants or subgrants under the Ryan White CARE Act are commonly referred to as "Ryan White clinics." RWC-340B, *Ryan White Clinics For 340B Access*, https://www.rwc340b.org/ (last visited Feb. 25, 2021); 42 U.S.C. § 256b(a)(4)(D). Three of RWC-340B's members operate nine clinics in Hackensack, Jersey City, Newark, New Brunswick, Paterson, Plainfield, and Trenton, New Jersey.

Approximately 1.2 million people are currently living with HIV/AIDS in the United States. HIV.gov, *HIV Basics: Overview: Data & Trends: U.S. Statistics*.[3] Ryan White clinics provide critical support to this vulnerable population, serving over half a million individuals by furnishing "HIV primary medical care, medications, and support services for underserved and

[3] https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics (last visited Feb. 25, 2021).

uninsured" people living with HIV/AIDS. RWC-340B, *Value of Ryan White Providers and Impacts Associated with Resource Reduction*, 2-3 (Oct. 2020).[4]

Patients of Ryan White clinics are particularly vulnerable. They 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. Patients at Ryan White clinics, however, achieve better overall outcomes than patients in other settings of care. Patients at Ryan White clinics are more likely to achieve HIV viral suppression than patients seen elsewhere. *Id*. at 4. Viral load suppression can result in an undetectable level of HIV in a patient's blood, reducing the risk of transmission. *Id*. Ryan White clinics increased the rate of viral suppression from 69.5% in 2010 to 87.1% in 2018, which is far higher than the 62.7% suppression in all people living with HIV/AIDS. *Id*. at 4-5. The success of Ryan White clinics is due, in part, to the higher rates of mental health, substance abuse, and case management services that Ryan White clinics provide. *Id*. at 6-7.

Although Sanofi recently modified its policy to permit Ryan White grantees to order discounted drugs for shipment to contract pharmacies, other manufacturers, including Eli Lilly & Co., have not. The coordinated attack by Sanofi and other drug companies on the 340B contract pharmacy program constitutes an existential threat to the 340B program and RWC-340B's members. The Defendants' database of 340B providers shows that 75% of Ryan White clinics have contract pharmacy arrangements. *See* HRSA, *Welcome to 340B OPAIS*, https://340bopais.hrsa.gov/ (last visited Feb. 25, 2021). For many Ryan White clinics, contract pharmacy arrangements are the primary, or even sole, path to 340B discounts and revenue. Loss

[4] https://www.rwc340b.org/wp-content/uploads/2020/10/20200921-RWC340B-White-Paper-FINAL.pdf.

of these discounts or revenue would jeopardize services provided by Ryan White clinics and irreparably harm the very vulnerable patients they serve.

SUMMARY OF ARGUMENT

Covered entities have only one way to take direct action against drug companies that violate 340B requirements: ADR. Covered entities cannot sue drug companies for these violations. *Astra USA, Inc. v. Santa Clara Cty., Cal.*, 563 U.S. 110 (2011) ("*Astra*"). They can only take their disputes to a congressionally mandated ADR panel established through regulations issued by HHS. Congress directed HHS to promulgate regulations to establish ADR ten years ago, but HHS finalized the regulations only recently. The lack of ADR became critically important last summer when Sanofi and other drug companies started a campaign to undermine the 340B program by cutting off discounts on drugs shipped to contract pharmacies, which for many covered entities is the only way to access 340B discounted drugs. Enjoining ADR will irreparably harm covered entities by leaving them at the mercy of Sanofi and other manufacturers that have adopted similar policies. Covered entities will inevitably have to cut services that are supported by 340B discounts. Patients will lose access to low-cost medications, and some may have to forgo their prescriptions altogether. The Amici therefore support the Defendants' opposition to Sanofi's motion for preliminary injunction and urge the Court to deny Sanofi's motion. Mot. for Prelim. Inj., *Sanofi-Aventis U.S., LLC v. U.S. Dept. of Health & Hum. Servs.*, No. 3:21-cv-634 (D.N.J. Feb. 2, 2021), ECF No. 19-1 ("Motion for PI").

STATEMENT OF THE CASE

I. The 340B Drug Discount Program

The 340B program provides significant discounts on drugs to safety-net healthcare providers *at no cost to the federal government* because the discounts are provided by drug manufacturers. Many covered entities do not have the resources to operate their own pharmacies

and can only participate in the program by purchasing the drugs for shipment to contract pharmacies, where they are dispensed to the covered entities' patients.

The 340B statute (along with provisions of the Medicaid statute) requires the Secretary of Health and Human Services ("Secretary") to execute Pharmaceutical Pricing Agreements ("PPAs") with manufacturers as a condition of their participation in the Medicaid and Medicare Part B insurance programs. 42 U.S.C. §§ 256b(a)(1), 1396r–8(a)(1). The PPAs "shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id.* § 256b(a)(1). The "ceiling price" is set by a statutory formula. *Id.* § 256b(a)(1)-(2). The Secretary has delegated authority to administer the 340B program to HRSA.

Health care providers that participate in the 340B program serve as the nation's healthcare "safety net," providing health care to the neediest individuals, regardless of ability to pay. The 340B statute limits participation in the program to certain defined health care providers, referred to as "covered entities." 42 U.S.C. § 256b(a)(4). Each category of covered entity receives some form of federal assistance to treat the nation's most vulnerable patients. 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). Stated differently, by spending less on medications, covered entities can devote more of their precious resources to patient care. The program is a vital and indispensable tool to help offset the costs to healthcare providers of providing uncompensated and under-compensated care. Without the 340B program, taxpayers would have to absorb the costs of uncompensated care or covered entities would be forced to restrict access to services or even cease operations.

The 340B program is designed to permit covered entities to determine how best to use the discounts. Many covered entities choose to pass the discounts on to their most needy patients, particularly the uninsured. For patients with health insurance, covered entities are typically paid for the drugs by the health insurer at a rate set by the insurer. The difference between the insurer's rate and the discounted price is income to the covered entity to supplement federal funds, thus stretching scarce federal resources as far as possible and enabling the covered entity to reach more eligible patients and provide more comprehensive services. *Id.* This is exactly how Congress intended the program to function.

II. Contract Pharmacies Have Been a Critical Component of the 340B Program Since 1996

Sanofi mischaracterizes the 340B contract pharmacy program as a massive giveaway to large, for-profit contract pharmacies. Motion for PI at 5-7. Nothing could be further from the truth. A contract pharmacy is simply a dispensing agent for the 340B covered entity, which is the purchaser of the 340B drugs. The contract pharmacy dispenses the drugs to the covered entity's patients and relinquishes any third-party payments and/or patient co-payments that the contract pharmacy receives for the drugs. These payments are used by the covered entity to support its safety-net missions, including providing necessary health care services for disadvantaged patients. Contract pharmacies are paid a dispensing fee by the covered entity, which is typical in all contract pharmacy arrangements, including those arrangements that do not involve the 340B program. Payment of dispensing fees is also common in agreements between health care insurers and pharmacies. HHS, through HRSA, has recognized contract pharmacy arrangements since 1996 and has consistently interpreted the 340B statute to require drug companies to sell discounted drugs to covered entities for shipment to contract pharmacies that receive and dispense the drugs to the covered entities' patients. Notice Regarding Section 602 of

the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549 (Aug. 23, 1996) ("Contract Pharmacy Notice").

In 1996, after considering comments submitted in response to a November 1, 1995, notice, HRSA published "final guidelines" in the Federal Register regarding contract pharmacy services under the 340B statute. *Id*. "Contract pharmacy services," as HRSA's 1996 guidance described it, means 340B covered entities' ability to contract with pharmacies as the covered entities' agents to dispense 340B drugs to the covered entities' patients. *Id*. at 43,550. Under such arrangements, a covered entity purchases 340B drugs from a manufacturer and directs the manufacturer to ship the 340B drugs to the contract pharmacy.

In its 1996 guidance, HRSA explained why contract pharmacies are essential for the "many covered entities" that "do not operate their own licensed pharmacies":

> Because these covered entities provide medical care for many individuals and families with incomes well below 200% of the Federal poverty level and subsidize prescription drugs for many of their patients, it was essential for them to access 340B pricing. Covered entities could then use savings realized from participation in the program to help subsidize prescriptions for their lower income patients, increase the number of patients whom they can subsidize and expand services and formularies.

Id. at 43,549. The agency's guidance "encouraged" covered entities that did not operate their own licensed pharmacies to use contract pharmacy services. *Id*. at 43,555.

HRSA's 1996 guidance was clear that the 340B statute requires pharmaceutical manufacturers to sell 340B discounted drugs to covered entities through contract pharmacy arrangements:

> The statute is silent as to permissible drug distribution systems. There is no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself. It is clear that Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities.

> It has been the Department's position that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price. If the entity directs the drug shipment to its contract pharmacy, we see no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance.

Id. at 43,549-50. HRSA was clear that it was interpreting the statute and that its contract pharmacy "guidelines create no new law and create no new rights or duties." *Id*. at 43,550; *see also* Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010) (HRSA's contract pharmacy guidance "neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law. . . . Contract pharmacy service guidelines have been considered by HRSA to be 'interpretative rules and statements of policy' exempt from notice and comment rulemaking under the APA.").

Many 340B covered entities do not operate in-house pharmacies. Because the requirements to obtain a pharmacy license are complex and operating a pharmacy can be expensive, many covered entities choose not "to expend precious resources to develop their own in-house pharmacies." Contract Pharmacy Notice, 61 Fed. Reg. at 43,550. Thus, for over twenty-four years, HHS has recognized that the program can only function effectively if certain covered entities purchase 340B discounted drugs to be dispensed by contracted third-party pharmacies. *Id.*

Contract pharmacy arrangements are not unique to the 340B program. These arrangements are a well-settled aspect of the drug distribution system of non-profit healthcare entities. In 2010, the Federal Trade Commission ("FTC") formally recognized the right of certain non-profit organizations to contract with for-profit retail pharmacies for purposes of dispensing drugs subject to discounts negotiated and used within the parameters of the Robinson-Patman Antidiscrimination Act ("Robinson-Patman Act") and the Non-Profit Institutions Act

("NPIA").[5] Federal Trade Commission, University of Michigan Advisory Op., Letter to Dykema Gossett (Apr. 9, 2010).[6] Absent an exemption like the NPIA, the resale of discounted drugs purchased by a non-profit hospital to its patients would be subject to challenge as a violation of the antitrust law. In the favorable opinion, the FTC examined the exact same contract pharmacy model at issue here, with only one difference—the drugs dispensed by the contract pharmacies were subject to discounts obtained under the NPIA, not the 340B statute. *Id.* Importantly, both the 340B statute and the NPIA provide for the purchase and restrict the resale of discounted drugs by non-profit healthcare entities. 15 U.S.C. §§ 13-13c; 42 U.S.C. § 256b(a)(5)(B).

Despite honoring contract pharmacy arrangements for over 24 years, in the summer of 2020, four of 700 manufacturers participating in the 340B program announced that they would either refuse to honor contract pharmacy arrangements or impose onerous conditions on contract pharmacy arrangements. Eli Lilly and Co. ("Lilly") was the first manufacturer to publicize its new, restrictive contract pharmacy policy. HRSA, *Manufacturer Notices to Covered Entities*

[5] In 1936, Congress enacted the Robinson-Patman Antidiscrimination Act to protect small businesses from larger businesses using their size advantages to obtain more favorable prices and terms from suppliers. 15 U.S.C. §§ 13–13b. The Act is primarily designed to prohibit, among other things, discrimination in the sale of fungible products, including drugs, to different buyers. *See id.* Congress then passed the NPIA, which added an additional exception to the Robinson-Patman Act's price discrimination rules. 15 U.S.C. § 13c. The NPIA created an avenue for manufacturers to sell discounted medical supplies, including pharmaceuticals, to non-profit entities that met certain criteria. Specifically, the NPIA exempts "purchases of their supplies for their own use by schools, colleges, universities, public libraries, churches, hospitals, and charitable institutions not operated for profit" from the Robinson-Patman Act. *Id.* As a result, eligible non-profit entities may purchase—and vendors may sell to them—pharmaceutical products and other supplies at reduced prices for the non-profit entity's "own use," without violating the Robinson-Patman Act's prohibitions against price discrimination. *Id.*

[6] https://www.ftc.gov/sites/default/files/documents/advisory-opinions/university-michigan/100409univmichiganopinion.pdf.

(July 2020)[7]; *see also* Eli Lilly & Co., *Limited Distribution Plan Notice for Eli Lilly and Company Products* (Sept. 1, 2020).[8]

Less than one-month later, Sanofi issued letters to 340B covered entities announcing that it would no longer honor contract pharmacy arrangements for covered entities that refuse to provide all of their claims data for 340B drugs purchased through contract pharmacies to a system called the 340B ESP program. Letter from Gerald Gleeson, Vice President & Head, Sanofi US Market Access Shared Services, SanofiAventis U.S. LLC (July 2020).[9] Sanofi has since partially retreated and recently announced that it will provide 340B drugs through contract pharmacy arrangements for all grantees other than FQHCs (and other Consolidated Health Centers Programs covered entities), and for Children's and Cancer hospitals. Letter from Gerald Gleeson, Vice President & Head, Sanofi US Market Access Shared Services, SanofiAventis U.S. LLC (Feb. 2021). Because the Amici Little Rivers and FamilyCare are FQHCs, they do not benefit from Sanofi's partial concession.

AstraZeneca LP ("AstraZeneca") and Novartis Pharmaceuticals Corp. ("Novartis") quickly followed suit in announcing their own policies limiting contract pharmacies. Letter from Odalys Caprisecca, Exec. Dir., Strategic Pricing & Operations, AstraZeneca LP (Aug. 17, 2020)[10]; Letter from Daniel Lopuch, Vice President Novartis Managed Mkts. Fin., Novartis Pharmaceuticals Corp. (Aug. 17, 2020).[11] More recently, Novo Nordisk, Inc. ("Novo Nordisk")

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[7] https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/limited-distribution-plan-notice-cialis.pdf.
[8] https://www.rwc340b.org/wp-content/uploads/2020/12/Eli-Lilly-and-Company_Limited-Distribution-Plan_Public-Notice_Sept-1-2020.pdf.
[9] http://www.avitapharmacy.com/blog/wp-content/uploads/2020/09/Sanofi-Letter.pdf.
[10] http://www.avitapharmacy.com/blog/wp-content/uploads/2020/09/AstraZeneca-Retail-Communication-340B-Final.pdf.
[11] Novartis has since retreated, in part. By letter dated October 30, 2020, Novartis informed covered entities that "all federal grantees, including Ryan White Clinics and Community Health

and United Therapeutics Corporation have announced limitations on providing 340B drugs through contract pharmacies. Letter from Novo Nordisk Inc. to Covered Entities (Dec. 1, 2020)[12]; Letter from Kevin Gray, Senior Vice President, Strategic Operations, United Therapeutics Corporation (Nov. 18, 2020).[13] Hundreds of other drug companies that participate in the 340B program continue to ship to contract pharmacies. Sanofi, Lilly, AstraZeneca, Novartis, United Therapeutics Corporation, and Novo Nordisk are outliers, but their actions nonetheless significantly impact the Amici.

III. 340B Administrative Dispute Resolution

The Patient Protection and Affordable Care Act ("ACA") was signed into law on March 23, 2010, and mandated 340B ADR regulations within 180 days:

> Not later than 180 days after the date of enactment of the Patient Protection and Affordable Care Act, the Secretary shall 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 this section, and claims by manufacturers, after the conduct of audits as authorized by subsection (a)(5)(D), of violations of subsections (a)(5)(A) or (a)(5)(B), including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions.

ACA, Pub. L. No. 111-148, § 7102(a), 124 Stat. 823 (2010) (codified at 42 U.S.C. § 256b(d)(3)). The Secretary's 180-day deadline to promulgate regulations for an ADR process fell on September 19, 2010.

Centers, will continue to receive 340B discounts" at contract pharmacies. Letter from Daniel Lopuch, Vice President Novartis Managed Mkts. Fin., Novartis Pharmaceuticals Corp. (Oct. 30, 2020). The letter also stated that, effective November 16, 2020, Novartis will honor contract pharmacy arrangements with 340B hospitals if the contract pharmacy is located within a 40-mile radius of the main hospital facility. *Id*.

[12] https://bit.ly/2NQlzpc.

[13] https://bit.ly/3pNrfgZ.

On September 20, 2010, the Secretary published an "advance notice of proposed rulemaking and request for comments" in the Federal Register "to obtain information and public comment on how to efficiently and effectively implement the requirements to create an administrative dispute resolution process for the 340B Program authorized by Section 7102 of the Affordable Care Act." 340B Drug Pricing Program Administrative Dispute Resolution Process, 75 Fed. Reg. 57,233, 57,234 (Sept. 20, 2010). The September 20, 2010, Federal Register notice did not propose ADR regulations.

Shortly after the ACA was enacted, the Supreme Court held that 340B covered entities cannot sue drug companies for violating 340B requirements. *Astra USA v. County of Santa Clara*, 563 U.S. 110 (2011) ("*Astra*"). The Court's holding in *Astra* leaves covered entities with no means to bring a dispute directly against a pharmaceutical manufacturer other than ADR.

More than six years after the expiration of the 180-day deadline to promulgate ADR regulations, the Secretary finally proposed regulations. 340B Drug Pricing Program; Administrative Dispute Resolution, 81 Fed. Reg. 53,381 (Aug. 12, 2016). More than four years later, the Secretary had not finalized those ADR regulations. Faced with the refusal by Sanofi and other drug companies to provide 340B discounted drugs through contract pharmacies, the Amici filed suit in the U.S. District Court for the District of Columbia to compel the Secretary to issue final ADR regulations. Amended Compl., *RWC-340B v. Azar*, No. 1:20-cv-02906 (D.D.C. Nov. 23, 2020), ECF No. 21 (stayed Jan. 13, 2021). Other covered entities and associations filed similar actions. *Nat'l Ass'n of Cmt. Health Cts. v. Azar*, No. 1:20-cv-03032 (D.D.C. Oct. 21, 2020) (stayed Jan. 7, 2021); *Am. Hosp. Ass'n v. Azar,* 4:20-cv-08806-YGR, (N.D. Cal. dismissed Feb. 17, 2021).

Shortly after the Amici filed their lawsuit, HRSA issued final regulations to implement the ADR process. 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632 (Dec. 14, 2020) ("ADR Rule"). As a result, the Amici's lawsuit is stayed so they may pursue ADR claims against manufacturers for refusing to sell drugs at 340B discounts for delivery to contract pharmacies. Joint Mot.'s for Stay, *RWC-340B v. Azar*, No. 1:20-cv-02906, ECF No. 58 (D.D.C. Jan. 13, 2021); Status Report, *RWC-340B v. Azar*, No. 1:20-cv-02906, ECF No. 59 (D.D.C. Feb. 16, 2021).

The ADR Rule allows covered entities to file petitions against drug companies to challenge overcharges for drugs purchased under the 340B Program. ADR Rule, 85 Fed. Reg. at 80,637. The ADR Rule also permits manufacturers to file petitions against covered entities for alleged violations of certain 340B prohibitions after the manufacturer has conducted a formal audit of the covered entity. *Id.* at 80,638. The ADR Rule creates an ADR Board, from which an ADR Panel is selected to review the petitions and issue final decisions. *Id.* at 80,634. The ADR Rule became effective on January 13, 2021. *Id.* at 80,632.

The ADR process consists of the following procedures: (1) initiation of an action; (2) request for additional information; (3) proceedings or hearings; and a (4) final agency decision, which is subject to judicial review. A covered entity or manufacturer initiates an action by filing a petition with HRSA along with sufficient documentation to support the claim within three years of the alleged violation, and the petition must allege damages that exceed $25,000. 42 C.F.R. § 10.21(a)-(b). Next, the ADR Panel may allow a covered entity to request additional information from a manufacturer. *Id.* § 10.22(b). The ADR Panel may also request additional information from either party. *Id.* Federal rules applicable to court proceedings and evidentiary matters apply to ADR proceedings unless the parties agree, or the ADR Panel dictates otherwise.

Id. § 10.23(a)-(c). Once the ADR Panel issues a decision, the outcome of the 340B ADR process is binding and precedential and subject to judicial review. *Id*. § 10.24(d).

THE BALANCE OF HARMS WEIGHS IN FAVOR OF DENYING THE PRELIMINARY INJUNCTION BECAUSE AN INJUNCTION WILL DEPRIVE COVERED ENTITES AND THEIR VULNERABLE PATIENTS OF REDRESS AGAINST SANOFI AND OTHER MANUFACTURERS

Sanofi contends that "enforcing the ADR Rule will serve no public interest." Motion for PI at 32. Sanofi's only reasoning for its assertion is that "the public interest is not served by the enforcement of an unconstitutional law" and devotes no time to addressing the harm that a preliminary injunction will cause 340B covered entities and their patients. Motion for PI at 32. In this case, the public interest includes the Amici, other covered entities, and the vulnerable patients that they serve. Currently, many covered entities do not have access to 340B discounts via their contract pharmacies due to Sanofi's policy and similar policies of other manufacturers. Covered entities have waited ten years for the ADR Rule, which has now become vital so that covered entities may challenge the unilateral policy of Sanofi and other manufacturers to limit or deny the provision of 340B discounted drugs at contract pharmacies. The harms that the Amici and their patients will suffer if the ADR Rule is enjoined far outweigh any harm that allowing the process to continue would cause Sanofi. This Court should, therefore, deny Sanofi's motion for preliminary injunction.

A party seeking a preliminary injunction must hurdle a high bar: "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. Natural Res. Def. Council, Inc*., 555 U.S. 7, 20 (2008). The Third Circuit has recognized that a preliminary injunction is an "extraordinary remedy, which should be granted only in limited circumstances." *Frank's GMC*

Truck Ctr., Inc. v. General Motors Corp., 847 F.2d 100, 102 (3d Cir.1988). The party requesting a preliminary injunction must show that the following:

> (1) the party seeking a preliminary injunction has shown a reasonable probability of success on the merits; (2) the party will be irreparably injured by the denial of the relief; (3) granting preliminary relief will result in even greater harm to the nonmoving party; and (4) granting the preliminary relief will be in the public interest.

LCN Enterprises, Inc. v. City of Asbury Park, 197 F. Supp. 2d 141, 145 (D.N.J. 2002), as amended (Apr. 5, 2002). A preliminary injunction should only be granted if there is "evidence sufficient to convince the district court that all four factors favor preliminary relief." *Id*. (quoting *AT&T Co. v. Winback & Conserve Program, Inc*., 42 F.3d 1421, 1427 (3d Cir. 1994)). In considering the effect on the public interest, this Court must consider "possible harm to interested third parties." *LCN Enterprises, Inc.*, 197 F. Supp. 2d at 145.

I. The Balance of Harms Weighs in Favor of Denying the Preliminary Injunction Because the ADR Regulations Were Ten Years in the Making and Are Critical for Amici and Other Covered Entities to Vindicate Their Rights to Obtain 340B Discounted Drugs Through Contract Pharmacies

Covered entities cannot sue drug companies in federal court for violating 340B program requirements. *Astra*, 563 U.S. at 113-14. Instead, Congress provided for an ADR process to allow covered entities to resolve disputes with drug companies. Covered entities waited ten years for the final ADR Rule, even though Congress set a September 19, 2010, deadline for those regulations. 42 U.S.C. § 256b(d)(3)(A). As the Amici explained in their lawsuit in the United States District Court for the District of Columbia, this delay raises very serious due process concerns. Amended Compl., *RWC-340B v. Azar*, No. 1:20-cv-02906 (D.D.C. Nov. 23, 2020), ECF No. 21, (stayed Jan. 13, 2021); *see Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 428 (1982). Enjoining the ADR Rule will further delay the ADR process by months or even years.

Significantly, the United States District Court for the Northern District of California recently ruled that the 340B statute requires that disputes between covered entities and manufacturers must first be adjudicated through the ADR process. Order Granting Mot. to Dismiss, *Am. Hosp. Ass'n v. Dep't of Health & Human Servs.,* No. 4:20-CV-08806-YGR, 2021 WL 616323 (N.D. Cal. Feb. 17, 2021), ECF No. 91.

Sanofi asserts that its constitutional rights will be violated through the ADR process. Motion for PI at 28-31. Defendants have already provided the Court with arguments as to why Sanofi's assertions are groundless. Defs.' Opp'n to Pl's. Mot. for Prelim. Inj., *Sanofi-Aventis U.S., LLC v. U.S. Dept. of Health & Hum. Servs*., No. 3:21-cv-634, 30-32 (D.N.J. Feb. 25, 2021), ECF No. 29. The Court should also weigh any constitutional claim by Sanofi against the Amici's loss of due process rights if they are denied the ability to bring a claim against drug manufacturers to assert their rights to 340B discounted drugs. The balance of harms weighs in favor of denying Sanofi's motion for preliminary injunction so that Amici and other covered entities may assert their due process rights through the ADR process.

II. The Balance of Harms Weighs in Favor of Denying the Preliminary Injunction Because Covered Entities and Their Patients Will Suffer Irreparable Harms

The balance of harms between the parties and the effect of granting a preliminary injunction on the "public interest," *LCN Enterprises, Inc.*, 197 F. Supp. 2d at 145, weighs against enjoining the ADR regulations because the Amici and other 340B covered entities will suffer significant, irreparable harms. Congress authorized the ADR Rule so that covered entities could bring actions against drug manufacturers for violating the 340B statute. Access to the ADR process is vitally importantly currently because Sanofi's unlawful contract pharmacy policy deprives discounts to disadvantaged patients and prevents covered entities from funding necessary health care services. Enjoining the ADR Rule will give Sanofi, and possibly other

drug companies, a free pass to continue flouting 340B program requirements, depriving covered entities of statutory discounts to support health care services during a pandemic. The Amici are on the front lines of caring for our nation's low-income and most vulnerable patients and support the broad goals of increasing access to care and improving health outcomes. The public interest cuts strongly against a preliminary injunction enjoining the ADR Rule because if the Amici are not able to access savings generated from the 340B program, the health of our nation's most vulnerable patients will be harmed. Patients will continue to lose access to inexpensive medications that they need to address chronic conditions and even survive. The Amici are losing discounts that support many of their key health care programs. Some covered entities may even become insolvent. These financial losses will not be recoverable in the ordinary course of litigation. These outcomes would be tragic at any time, but in the midst of the COVID-19 pandemic, they are unconscionable.

A. 340B Covered Entities Use 340B Savings on Drugs Dispensed Through Contract Pharmacies to Provide Deep Discounts on High-Cost Medications to Eligible Patients

The Amici offer discounts on drugs to financially needy patients through contract pharmacy arrangements, and these programs are premised on the Amici being able to purchase the drugs at 340B discounted prices. For example, FamilyCare operates a drug discount program for financially disadvantaged patients in which FamilyCare charges only the amount that it pays for the drug. Glover Aff. ¶ 17. Because the 340B discounted prices, however, are significantly lower than non-340B prices, patients that relied on obtaining medications at the 340B cost now have to pay much higher costs. Glover Aff. ¶ 30.

Similarly, Little Rivers operates a drug discount program that subsidizes the costs of drugs for their financially needy patients. Under this program, the patient does not incur any cost

for the drugs, or pays a percentage of the cost of the drug, depending on the patient's income level. Auclair Aff. ¶ 18. Little Rivers, and other covered entities that offer similar programs, are now bearing the increased cost of drugs produced by Sanofi and filled at contract pharmacies. Auclair Aff. ¶¶ 21, 30. Little Rivers, however, will struggle financially if it is forced to continue to incur these increased costs. Auclair Aff. ¶¶ 31-34. The increased costs to Little Rivers to pay for the drugs under its drug discount program will severely worsen its already precarious financial position.

Through contract pharmacy arrangements, patients of 340B covered entities who do not have insurance or are underinsured are able to fill their prescriptions at convenient locations, often at no cost or a greatly discounted cost. Without the availability of contract pharmacies, many patients of the covered entities would have no access to lifesaving medications, either because the covered entity does not have a pharmacy or because the covered entity is located too far away. Contract pharmacies provide 340B covered entities' patients with access to no-cost or low-cost medications that have been purchased by the covered entity through the 340B program and ensure that patients throughout the covered entity's service area are able to access those discounted drugs. This access to pharmaceutical care provided through 340B contract pharmacy arrangements is consistent with the congressional intent of the 340B statute.

Sanofi has made a tiny concession to allow certain covered entities to designate one pharmacy as a contract pharmacy if they do not operate their own retail, in-house pharmacies, but Sanofi's policy still means that many financially needy patients are left without 340B drugs. Designating only one contract pharmacy is not practical for FamilyCare because it serves a very large area in rural West Virginia and has made contract pharmacy arrangements across its service area. Glover Aff. ¶ 19. Multiple contract pharmacy arrangements enable FamilyCare to provide

covered outpatient drugs to patients that qualify for its Prescription Savings Program at the patient's local pharmacy. Glover Aff. ¶ 19. For covered entities in remote or rural parts of a state, it is important that patients are able to access affordable medications at a pharmacy that is convenient for them. *See* Simila Aff. ¶ 27 ("[t]he travel distance between our northern most and southern most clinical delivery sites is 200 miles.")[14]; Francis Aff. ¶ 19 ("Erie's ability to offer our patients—who are dispersed across more than 185 zip codes—access to affordable life-saving and life-sustaining medications is entirely dependent on our contract pharmacy partnerships."); Chen Aff. ¶ 21 ("NCHC's service area spans approximately 576 miles across all of Northern Arizona. Without contract pharmacies, patients would have to travel [35-180 miles] (one-way trip), to reach the closest of NCHC's in-house pharmacies").

The owner of The Corner Drug Store submitted an affidavit in Amici's lawsuit against Defendants. Duck Aff. The Corner Drug Store is a contract pharmacy for Amici's co-plaintiff, Springhill Medical Center ("Springhill"). In the affidavit, The Corner Drug Store explains how it assists with implementation of Springhill's "Cash Savings Program," which helps uninsured individuals or individuals who must meet a high deductible with paying for their prescription

[14] Sanofi has submitted with its motion for preliminary injunction an ADR petition that was filed against it. Motion for PI, Ex. 6, ECF No. 19-7; Motion for PI, Ex. 7, ECF No. 19-8; *Nat'l Ass'n of Cmty. Health Ctr.s v. Eli Lilly and Co*., *et al.*, ADR Pet. No. 210112-2 (Jan. 13, 2021). Sanofi, however, omitted declarations from covered entities that were submitted as exhibits to that ADR petition, which demonstrate how Sanofi is harming covered entities. The following declarations were submitted as exhibits to ADR petition No. 210112-2: Declaration of Donald A. Simila, CEO of Upper Great Lakes Health Center, Inc. (Ex. C, "Simila Aff."); Declaration of Lee Francis, President and CEO of Erie Family Health Center (Ex. D, "Francis Aff."); Declaration of Kimberly Christine Chen, Director of Pharmacy at North County HealthCare, Inc. ("NCHC") (Ex. E, "Chen Aff."); Declaration of Ludwig M. Spinelli, CEO of Optimus Health Care Inc., (Ex. F, "Spinelli Aff."); Declaration of J.R. Richards, CEO at Neighborhood Improvement Project, Inc., d/b/a Medical Associates Plus (Ex. I, "Richards Aff."); David Steven Taylor, Director of Pharmacy Operations for Appalachian Mountain Community Health Centers (Ex. J, "Taylor Aff."). Amici have attached these declarations to this brief for the Court's reference.

drugs. Duck Aff. ¶ 3. Springhill only charges the 340B price and a dispensing fee to patients who qualify for Springhill's Cash Savings Program. Duck Aff. ¶ 3. The Corner Drug Store stated that several patients were no longer able to afford Sanofi's insulin product, Lantus, because Sanofi no longer allowed the drug to be purchased with 340B discounts. Duck Aff. ¶¶ 4-12. At least two patients who had been paying a 340B price of $17.30 for Lantus were charged $1,360.57 because Sanofi had cut off Springhill's access to 340B pricing for drugs shipped to The Corner Drug Store. Duck Aff. ¶¶ 8, 11. Because of the significant price increase, these patients left the pharmacy without purchasing Lantus.[15] Duck Aff. ¶¶ 4-12.

The CEO of Optimus Health Care Inc. ("Optimus") submitted an affidavit in an ADR petition separate from the Amici's. Spinelli Aff. Optimus describes how Sanofi and other drug manufacturer actions will cause its uninsured patients to lose access to approximately 773 affordable prescriptions. Spinelli Aff. ¶ 21. This includes access to insulins, asthma controllers, and other essential medications, all of which are vital to the patient population that is at the highest risk during the COVID-19 pandemic. Spinelli Aff. ¶ 21. As a result of Sanofi and other drug manufacturers' actions, Optimus estimates that patients who were previously "paying about $12 to $15 for three months' supply of these medications will now have to pay about $300 to $600 per month to continue their treatment." Spinelli Aff. ¶ 21.

These are just a few examples that highlight the plight of thousands of patients nationwide who can no longer afford medications due to Sanofi's restrictive policy. Without the ADR process, covered entities have limited recourse to fight for their right to access 340B prices

[15] The Corner Drug Store also notes that "[d]iabetic patients often must try several insulin products in order to find one that is effective at stabilizing their blood sugar levels" and that "[a] diabetic cannot simply switch from one product to another without working closely with a physician to find the right dosage of insulin," which "often requires numerous visits to a physician and blood sugar tests." Duck Aff. ¶ 5.

at contract pharmacies, which allows them to pass savings on to the patients who rely on the 340B program to afford their medications.

B. Covered Entities Rely on Revenue from Payments for 340B Drugs to Pay for Necessary Health and Related Services

340B covered entities use the revenues from payments for 340B drugs to subsidize the cost of important and life-saving health care and support programs for their patients. For patients with prescription insurance, covered entities benefit from the difference between the 340B price and the reimbursement received from the insurance company. Covered entities may use these funds to supplement their federal grants and other revenues, thereby "reaching more eligible patients and providing more comprehensive services" as Congress intended. H.R. Rep. No. 102-384(II), at 12 (1992).

For covered entities that are federal grantees, examples of these services include case management services to assist patients with transportation, insurance enrollment, linkage to affordable housing, food access, patient care advocacy, in-home support, education for chronic health care conditions, and food pantries. Auclair Aff. ¶¶ 12-16, 22; Glover Aff. ¶¶ 11, 14-15. Without care coordinators, many patients will not be able to access the health care that they need or obtain affordable housing or food. These services are critical for preventing patients' health from deteriorating. Care coordination is particularly important for homeless and indigent individuals, who require additional support services to ensure that they continue to receive necessary health care services. Auclair Aff. ¶ 17; Glover Aff. ¶ 26. Education and in-home assistance for patients with chronic health conditions is also vitally important to manage the patients' diseases and prevent the need for more costly care. Glover Aff. ¶¶ 15, 27. 340B revenues also enable the Amici to provide health, behavioral, and dental services to local school children. Auclair Aff. ¶¶ 10-11; Glover Aff. ¶¶ 11, 25. Covered entities operate medication

assisted treatment programs and offer additional treatment services for opioid use disorder to financially needy individuals. Auclair Aff. ¶ 15; Glover ¶ 14; Simila Aff. ¶ 15-16; Francis Aff. ¶ 9-10.

Little Rivers provides the following services that are not funded, or are only partially funded, through grants and private insurance:

- a chronic care management program to assist patients with chronic diseases;
- working with Willing Hands, a non-profit, charitable organization, to distribute fresh produce and dairy to Little Rivers' clinics for care coordinators to deliver to patients in need;
- behavioral health services at local public schools that include counseling for students and families; and
- a Medication Assisted Treatment ("MAT") program that provides services to individuals who are on a drug regimen to treat addiction.

Auclair Aff. ¶¶ 12-15.

Most of the above services are not paid by insurance or through grant funds. Auclair Aff. ¶ 22; Glover Aff. ¶ 15; Richards ¶ 24; Simila Aff. ¶ 19. Covered entities use the revenue from their 340B contract pharmacy arrangements to pay for these services, and this revenue is significant for covered entities. Little Rivers realizes approximately $200,000 annually by purchasing products through contract pharmacy arrangements from Sanofi and the other drug companies that have refused to honor such arrangements. Auclair Aff. ¶ 23.

Based on data from January 1, 2020, through June 30, 2020, and extrapolated to twelve months, FamilyCare estimates that purchases shipped to contract pharmacies result in approximately $449,178 annually in savings from 340B drugs that are filled through contract

pharmacies, including drugs that are manufactured by Sanofi and the other drug companies that have cut off contract pharmacy arrangements. Glover Aff. ¶ 22; Dickerson Aff. ¶ 6. FamilyCare would have to scale back dramatically the services that it provides to its patients if FamilyCare loses over $449,178 annually as the result of the actions of these drug companies. Glover Aff. ¶ 24; Dickerson Aff. ¶ 8.

Loss of 340B discounts will force the Amici and other covered entities to curtail or even terminate the additional services that they provide. Auclair Aff. ¶ 25; Glover Aff. ¶ 24; Dickerson Aff. ¶ 8; Simila Aff. ¶ 29. If the Amici's patients do not have access to the additional services described above, which focus on preventive care and ensuring that the patient obtains needed health care and related support services, the patients' health will undoubtedly decline. As a result, they will require additional, more extensive and expensive health care visits at the Amici's locations, as well as more expensive care from hospitals and specialists. Auclair Aff. ¶¶ 26-27; Glover Aff. ¶¶ 26-27. The cost of providing additional health care visits will cause an additional strain on the resources of covered entities.

The Amici will also have to divert staff to seek out and apply for additional federal grants or other sources of funding to make up for the lost 340B savings. Auclair Aff. ¶ 28; Glover Aff. ¶ 28; Dickerson Aff. ¶ 9. Expending already scarce financial and human resources will further burden budgets that are already severely strained and cause irreparable harm in the form of additional operational expense. Of course, the Amici have no assurances that they will be able to obtain additional funding. Auclair Aff. ¶ 28; Glover Aff. ¶ 28; Dickerson Aff. ¶ 9.

In 2018 and 2019, Little Rivers operated at a loss. Based on 340B savings that it has historically achieved, Little Rivers calculates that it will lose approximately $200,000 in annual 340B savings and revenue as a result of the actions of Sanofi and other drug companies that now

condition or refuse to offer 340B pricing on drugs that are purchased by Little Rivers and shipped to its contract pharmacies. Auclair Aff. ¶¶ 23, 25. Little Rivers will have to cut or eliminate some of those services if it loses $200,000 annually as the result of the drug companies' actions. Auclair Aff. ¶ 25. Cutting or eliminating services to Little Rivers' patients will be detrimental to their health and well-being.

In response to Sanofi's actions, covered entities have been working to switch patients' medications. Richards Aff. ¶¶ 22-23; Francis Aff. ¶ 26; Chen Aff. ¶ 35; Taylor Aff. ¶ 18. Many patients may wish to stay on the medications they are familiar with or may be fearful of the negative health impact of switching to new medications. Richards Aff. ¶¶ 22-23; Francis Aff. ¶ 26; Chen Aff. ¶ 35. Additionally, before a patient can change medications, a medical provider must "review the patient chart, consider comorbidities, and assess the appropriate dosing for the substitute medication." Francis Aff. ¶ 26. If the new drug treatment has different dosing, this could require significant patient education and "provider troubleshooting." Francis Aff. ¶ 26.

The Director of Pharmacy of North Country HealthCare, Inc. ("NCHC") describes how an uninsured patient with Type 1 diabetes and stable on Lantus (produced by Sanofi) could no longer access the drug through NCHC's contract pharmacy. Chen Aff. ¶ 35. When an individual has Type 1 diabetes, the body cannot produce its own insulin and is therefore reliant on manufactured insulin to survive. Chef. Aff. ¶ 36. Once Sanofi's restrictive policy went into place, Lantus was no longer available at 340B pricing through NCHC's contract pharmacy and the patient was located "approximately 280 miles from [NCHC's] closest in-house pharmacy". Chen Aff. ¶ 35. The patient had adverse side-effects to another insulin so switching medications was not an option. Chen Aff. ¶ 35-36. The Director of Pharmacy Operations for Appalachian Mountain Community Health Centers ("Appalachian Mountain") describes how, when Sanofi's

policy went into place, diabetic patients who were taking Lantus were "having to be switched to the only remaining affordable, long-acting insulin, which is an inferior molecule and requires 2 shots a day versus just one with Lantus." Taylor Aff. ¶ 18. Not only are these patients now forced to bear the burden of twice as many shots per day, but they are also required to purchase twice as many of the lancets used to test their blood sugar. Taylor Aff. ¶ 18.

C. 340B Covered Entities Rely on Revenue From the 340B Program to Continue to Operate

The Amici rely entirely on contract pharmacies to dispense self-administered drugs purchased with 340B discounts to their patients. Auclair Aff. ¶ 19; Glover Aff. ¶ 18. For some covered entities, the revenue from the 340B program has meant the difference between remaining in operation and closing their doors. For FamilyCare, revenue from its contract pharmacy arrangements is comparatively almost half of the income that it receives from its grants. Glover Aff. ¶ 21; Dickerson Aff. ¶¶ 4-5. The loss of all 340B savings to the Amici would be even more "devastating" to the Amici's operations and the patients they serve. Auclair Aff. ¶ 31; Glover Aff. ¶ 31; Dickerson Aff. ¶ 11.

Little Rivers currently operates at a loss and FamilyCare's operating expenses barely exceeds its revenue. Auclair Aff. ¶ 24; Dickerson Aff. ¶ 7. Data from the HRSA webpage shows that, in 2019, Little Rivers' average cost per patient was $1,270.64 and FamilyCare's average cost per patient was $764.39. HRSA, *Health Center Program Data*, https://data.hrsa.gov/tools/data-reporting/program-data?grantNum=H80CS06658 (last visited Feb. 25, 2021). The cost per patient will increase dramatically if these providers are burdened with the obligation of covering the full price of drugs manufactured by Sanofi. The Amici do not have the financial resources necessary to bear the additional costs of drugs for financially needy patients. Auclair Aff. ¶ 34.

D. Amici's Financial Harms Are Not Recoverable in the Ordinary Course of Litigation

Enjoining the ADR regulations will result in economic losses to the Amici that will not be recoverable. A final decision on the merits of Sanofi's ADR claims will not provide relief to the Amici and other covered entities and, therefore, are not recoverable through "'compensatory or other corrective relief . . . at a later date, in the ordinary course of litigation.'" *Bakery Drivers & Salesmen Local 194, IBT v. Harrison Baking Grp., Inc*., 869 F. Supp. 1168, 1177 (D.N.J. 1994) (quoting *Sampson v. Murray*, 415 U.S. 61, 90 (1974)); *see also Instant Air Freight Co. v. C.F. Air Freight, Inc.,* 882 F.2d 797, 801 (3d Cir. 1989).

Furthermore, Amici's losses would not be recoverable in any other forum because covered entities cannot bring a suit against Sanofi for violating 340B requirements. *Astra*, 563 U.S. 110, 113-14. The economic losses to the Amici from Sanofi's contract pharmacy policy will be "devastating" and could cause Amici to have to cease operations. Auclair Aff. ¶¶ 32, 34; Glover Aff. ¶ 31; Dickerson Aff. ¶ 11; *see Doran v. Salem Inn*, 422 U.S. 922, 932 (1975) (finding irreparable harm where movant's business "would suffer a substantial loss of business and perhaps even bankruptcy" absent injunctive relief). Thus, the Amici cannot recover lost 340B savings through "the ordinary course of litigation" and must therefore rely on the ADR regulations to remedy the harm suffered from Sanofi's and other manufacturers' actions. *Bakery Drivers & Salesmen Local 194*, 869 F. Supp. at 1177.

III. The Losses to Amici and 340B Covered Entities Far Outweigh Any Losses to Sanofi

Sanofi contends that it "cannot recover a dime from the government" as a result of the damages that it would incur in defending itself before the ADR panel. Motion for PI at 31. However, any losses that Sanofi would suffer in defending itself against the government pale in comparison to the current and ongoing harms to the Amici and other covered entities. Sanofi's

financial status in 2020 was quite robust. On February 5, 2021, Sanofi reported that its fourth-quarter sales in the United States increased 5.3% from its third-quarter sales. Sanofi-Aventis U.S. LLC, *Press Release* (Feb. 5, 2021).[16] Moreover, Sanofi reported that its U.S. annual sales increased from approximately $14.159 billion in 2019 to approximately $16.023 billion in 2020 at the current exchange rate for those periods. Sanofi-Aventis U.S. LLC, *Press Release* (Feb. 6, 2020)[17]

Sanofi's increased sales are in sharp contrast to the financial plight of Amici and other covered entities, particularly in the midst of the COVID-19 pandemic. An HHS official recently noted that halting contract pharmacy shipments is "at the very least, insensitive to the recent state of the economy." Letter from Robert P. Charrow, General Counsel, U.S. Department of Health and Human Services, to Anat Hakim, Senior VP and General Counsel, Eli Lilly Company (Sept. 21, 2020).[18] HHS also noted that "most health care providers, many of which are covered entities under section 340B, were struggling financially and requiring federal assistance from the Provider Relief Fund established by the CARES Act. Many continue to struggle and depend on emergency taxpayer assistance." *Id*.; Francis Aff. ¶ 29 ("During the COVID-19 pandemic especially, 340B savings have been critical to our ability to continue serving patients and to maintain capacity to provide future services.").

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[16] https://www.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/Sanofi-COM/Home/en/investors/docs/2021_02_05_Results_PR_EN.pdf?la=en&hash=DF27EDA00E7444D1973BF599FBE765E5.

[17] https://www.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/Sanofi-COM/Home/en/investors/docs/2019_Q4_Press_Release_v2_EN.pdf?la=en&hash=85C666D993F5B4ECC1A9CF7C27A2EDD0; *see also* Sanofi-Aventis U.S. LLC, *Press Release* (Feb. 5, 2021), https://www.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/Sanofi-COM/Home/en/investors/docs/2021_02_05_Results_PR_EN.pdf?la=en&hash=DF27EDA00E7444D1973BF599FBE765E5.

[18] Available at https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hhs-eli-lilly-letter.pdf.

The financial harms befalling Amici and other covered entities due to Sanofi's policy are devastating to Amici and covered entities and far outweigh any expense that Sanofi may incur in defending itself before the ADR Panel. The balance of harms weighs in favor of denying Sanofi's motion for preliminary injunction.

CONCLUSION

The public interest cuts strongly against a preliminary injunction enjoining the ADR Rule because if the Amici are not able to access savings generated from the 340B program, our nation's most vulnerable patients will be harmed. HHS has long recognized the importance of the 340B contract pharmacy program and the vital role that it plays for covered entities and their vulnerable patients. Many 340B program participants rely on these contract pharmacy arrangements because they are the only way of serving patients. The ADR Rule provides covered entities with the administrative proceeding they need to remedy the harms from the statutory violations of Sanofi and other drug companies. Amici therefore respectfully request that the Court deny Sanofi's motion for preliminary injunction and permit the ADR regulations to remain in effect.

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