Third Circuit Finds That Plain Language of Section 340B Does Not Require Drug Makers to Provide Discounted Drugs to Unlimited Contract Pharmacies

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The 340B Drug Price Program (340B Program) is a drug-pricing discount regime established by Congress in 1992 within the Public Health Service Act, which is administered by the Secretary of Health and Human Services (HHS).[1] In order to have their drugs covered through Medicaid and Medicare Part B, drug manufacturers are required to participate in the 340B Program.[2] More specifically, pharmaceutical manufacturers must sell their "covered outpatient drugs"[3] at a heavily discounted price to "covered entities," which are defined by statute to include fifteen enumerated types of public and not-for-profit hospitals, community centers and other federally funded clinics serving low-income patients.[4] Notably, all pharmaceutical manufacturers participating in the 340B Program must "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,"[5] thereby requiring drug makers to sell their drugs at or below a price cap. The resulting 340B "ceiling prices," which are calculated according to a prescribed statutory formula,[6] are significantly lower than the amount(s) other purchasers would pay. Covered entities can opt to pass the savings along to uninsured and underinsured patients to subsidize what would otherwise be cost prohibitive rates for medications. As such, the discounted drugs benefit both patients, by helping them to afford costly medications, and covered entities, which use the discounts to take full advantage of federal resources and serve a greater number of uninsured and under-insured patients.[7]

Between 1996 and 2010, covered entities could only use one contract pharmacy to order and pay for 340B drugs. In 2010, HHS issued new guidance that allowed covered entities to use an unlimited number of contract pharmacies. As a result, the use of contract pharmacies increased dramatically, causing drug makers to grow concerned about contract pharmacies increasing duplicative discounting and diversion.[8] To combat these fears, several pharmaceutical manufacturers modified their policies to limit the use of contract pharmacies by covered entities. In response, HHS took three actions: (1) it issued an Advisory Opinion in December 2020 (the Advisory Opinion) requiring drug makers to deliver 340B drugs to an unlimited number of contract pharmacies;[9] (2) it issued Violation Letters to certain drug makers for issuing unlawful policies that limited the number of contract pharmacies, requiring those drug makers to rescind their policies and reimburse covered entities for any overcharges; and (3) following an initial proposed rule-making in 2016, it issued a final Administrative Dispute Resolution (ADR) Rule in 2020 to establish a process through which drug

makers and covered entities could resolve Section 340B-related disputes.

Against this backdrop, three drug manufacturers, namely Sanofi Aventis U.S. LLC, Novo Nordisk Inc./Novo Nordisk Pharma, Inc. and AstraZeneca Pharmaceuticals LP, sued the United States Department of Health and Human Services, among others, to invalidate the Advisory Opinion as arbitrary and capricious and challenge HHS's Violation Letters.[10] In Delaware, the Court held that the Advisory Opinion was arbitrary and capricious because it erroneously found that 340B was unambiguous,[11] and vacated the Violation Letter issued to AstraZeneca on the same basis.[12] HHS appealed.

Meanwhile, in New Jersey, in *Sanofi-Aventis U.S., LLC v. HHS*,[13] the Court held that Sanofi's and Novo Nordisk's challenges to the Advisory Opinion were moot, largely upheld the Violation Letters on the basis that the statute's purpose and legislative history required delivery to at least one contract pharmacy (but remanded to HHS to consider whether 340B required delivery to an unlimited number of contract pharmacies), and upheld the ADR rule. Sanofi and Novo Nordisk appealed.

On January 30, 2023, the Third Circuit resolved the district court split between the Delaware and New Jersey courts in favor of the drug makers. Finding that the plain language of the 340B statute omits any reference to the delivery of drugs to an unlimited number of contract pharmacies, the Third Circuit held that the statute's requirement that drug makers "offer" drugs to "covered entities" did not require the drug makers to deliver goods "wherever and to whomever the buyer demands," observing that all of the drug makers' policies at issue had allowed for the use of at least one contract pharmacy, and in some instances, more than one contract pharmacy.[14] Nor did the "purchased by" provision of the 340B statute require anything more than a price term for drug sales to covered entities. The Third Circuit found that the statute's legislative purpose did not require a different result.[15] The Third Circuit invalidated the Violation Letters for the same reasons it found that the Advisory Opinion was unlawful.[16]

Finally, the Third Circuit addressed Sanofi's challenge to the ADR Rule, rejecting its argument that the Government's 2017 withdrawal of the rule proposed in 2016 required the agency to recommence the notice and comment period under the Administrative Procedure Act (APA). Judge Bibas found that nothing in the APA required such a reading, and that HHS had complied with the notice and comment period before publishing the final rule in 2020.

Undoubtedly, drug makers will use this victory in the Third Circuit to challenge any effort by HHS to expand the number of contract pharmacies utilized by covered entities now that there is precedent that drug makers "need not help [covered entities] maximize their 340B profits."[17] Will other circuits reach the same conclusion? Only time will tell, but for now, unless or until another Circuit Court decides the issue differently from the Third Circuit, thereby creating a split in the circuit courts, it is unlikely that the United States Supreme Court will weigh in on the issue. Accordingly, the Third Circuit Court of Appeals decision will remain the leading authority for other courts to follow.

What will the impact be on 340B entities, which are already facing hardships due to the pandemic and severe financial cuts to reimbursement rates by the Centers for Medicaid and Medicare Services between 2018 and 2022?[18] At least in New Jersey, Pennsylvania, Delaware and the Virgin Islands, the provision of care to vulnerable, low-income populations may be impacted.

About the Author

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Endnotes

[1] *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71 (codified as amended at 42 U.S.C. § 256b). The Health Resources and Services Administration ("HRSA"), a sub-department of HHS, is responsible for administering the 340B Program.

[2] *See* 42 U.S.C. § 1396r-8(a)(1); 42 U.S.C. § 256b(a).

[3] Covered outpatient drugs are those drugs defined under section 1927(k) of the Social Security Act, 42 U.S.C. § 1396r–8(k) (1994). See 42 U.S.C. § 256b(a)(3).

[4] *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967–71 (1992), codified at § 340B Public Health Service Act, 42 U.S.C. § 256b (1992).

[5] 42 U.S.C. § 256b(a)(1).

[6] *See* 42 U.S.C. § 256b(a)(1), (a)(4), (b)(1),

[7] *See* H.R. Rep. No. 102-384, pt. 2 at 12 (1992) (conf. report) (These significant drug pricing discounts are intended to "enable [covered entities] to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.").

[8] *See Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs.,* 570 F. Supp. 3d 129, 152 (D.N.J. 2021), *aff'd in part, rev'd in part sub nom. Sanofi Aventis U.S. LLC v. United States Dep't of Health & Hum. Servs.,* 58 F.4th 696 (3d Cir. 2023), judgment entered, No. 21-3167, 2023 WL 1325507 (3d Cir. Jan. 30, 2023).

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[9]*See* HHS Off. Gen. Couns., *Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program* (Dec. 30, 2020).

[10]Only Sanofi challenged the ADR Rule on the basis that the ADR rule was unconstitutional and violation the APA. *See Sanofi-Aventis U.S., LLC*, 570 F. Supp. 3d at 159.

[11]*See AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 58-62 (D. Del. 2021).

[12]*See AstraZeneca Pharms. LP v. Becerra*, 2022 WL 484587, at *3 (D. Del. Feb. 16, 2022).

[13]*See Sanofi-Aventis U.S., LLC*, 570 F. Supp. 3d at 159 n.3.

[14]*See Sanofi Aventis U.S. LLC v. United States Dep't of Health & Hum. Servs.*, 58 F.4th 696, 701, 703-04 (3d Cir. 2023), *judgment entered*, No. 21-3167, 2023 WL 1325507 (3d Cir. Jan. 30, 2023)).

[15]*See id.* at 705-06.

[16]*See id.* at 706.

[17]*See id.* at 704.

[18]*See* F. Muhammad and M. Kass, "The Relief of Some Financial Burden: CMS to Pay Back 340B Hospitals in 2023," Garden State FOCUS (Winter 2022).

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