Nos. 21-3167, 21-3379, 21-3168, 21-3380

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

SANOFI-AVENTIS U.S. LLC,

Plaintiff-Appellant/Cross-Appellee,

v.

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

Defendants-Appellees/Cross-Appellants.

NOVO NORDISK INC., *et al.*,

Plaintiffs-Appellants/Cross-Appellees,

v.

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

Defendants-Appellees/Cross-Appellants.

On Appeal from the United States District Court
for the District of New Jersey

BRIEF OF AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, AMERICA'S ESSENTIAL HOSPITALS, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, AND CHILDREN'S HOSPITAL ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF APPELLEES/CROSS-APPELLANTS

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Local Rules 26.1 and 28(a) of this Court and Rules 26.1 and 29(a)(4)(A) of the Federal Rules of Appellate Procedure: *Amici Curiae* American Hospital Association, 340B Health, America's Essential Hospitals, Association of American Medical Colleges, and National Association of Children's Hospitals d/b/a Children's Hospital Association are not-for-profit organizations. None of the *Amici* has a parent company, and no publicly held company holds more than a ten percent interest in any of the *Amici*.

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INTEREST OF *AMICI CURIAE*[1]

Amici are five hospital/health system associations whose members use 340B discounts for 340B drugs dispensed through contract pharmacies to support health care programs and services offered by their hospitals. The discounts, for example, allow these members to (1) provide and maintain more patient care services; (2) provide and maintain more uncompensated and unreimbursed care; (3) provide and maintain more services in underserved areas; (4) develop and maintain targeted programs to serve vulnerable patients; and (5) keep their doors open.

INTRODUCTION

The continued viability of the 340B drug discount program—and the care it allows hospitals to provide to America's most vulnerable patients—is at stake in these cases. Congress created the 340B program to make discounts available to nonprofit hospitals and community health centers so that they could offer additional, affordable health care services to the underserved. In Congress's words, the program was designed to enable providers "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive

[1] Appellees and Appellants do not object to the filing of this brief. Undersigned counsel for *Amici Curiae* certify that this brief was not authored in whole or in part by counsel for any of the parties; no party or party's counsel contributed money for the brief; and no one other than *Amici* and their counsel has contributed money for this brief.

services."[2] The 340B program is meeting Congress's goals, and while the discounts required by the 340B statute are a drop in the bucket for tremendously profitable drug companies, they provide an indispensable lifeline for 340B hospitals.

The program now is under attack by the highly profitable pharmaceutical industry. But neither the statute's text nor the drug companies' mischaracterizations of how 340B hospitals use these savings provide a basis to decimate the program. *Amici* urge this Court to hold that drug companies must go back to providing 340B discounted drugs to 340B providers, regardless of whether these vital medicines are being dispensed in-house or through outside pharmacies.

BACKGROUND

A. The 340B Statute and Program

The 340B program, established by section 340B of the Public Health Service Act, 42 U.S.C. § 256b, requires as a condition of participating in Medicaid and Medicare Part B that pharmaceutical manufacturers sell outpatient drugs at a discounted price to certain public and not-for-profit hospitals, community health centers, and other providers that serve low-income patients (340B providers or covered entities). 340B providers play a critical role in the safety net,[3] which is

[2] H.R. Rep. No. 102-384(II), at 12 (1992).

[3] *See, e.g.*, Allen Dobson et al., *The Role of 340B Hospitals in Serving Medicaid and Low-income Medicare Patients* 3 (July 10, 2020), https://www.340bhealth.org/files/340B_and_Medicaid_and_Low_Income_Medicare_Patients_Report_7.10.2020_FINAL_.pdf.

accompanied by substantially lower operating margins than those of non-340B providers—and in fact, often *negative* operating margins.[4] 340B providers provide a disproportionate amount of uncompensated care[5] and community health and other specialized services at a proportionally higher rate than non-340B hospitals.[6] Accordingly, unreimbursed and uncompensated care costs are 27.4 percent higher, on average, for 340B hospitals than for non-340B hospitals.[7]

The purpose of the 340B program is to stretch the funding 340B providers have available to meet the needs of their most vulnerable patients. A 2011 report from the U.S. Government Accountability Office (GAO) found that the 340B program has had its intended effect.[8]

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[4] *See id.* at 3–4 (July 10, 2020); Am. Hosp. Ass'n, *Setting the Record Straight on 340B: Fact vs. Fiction* 2 (Mar. 2021), https://www.aha.org/system/files/2018-02/340BFactvsFiction.pdf.

[5] L & M Policy Research, *Analysis of 340B Disproportionate Share Hospital Services to Low-Income Patients* 1 (Mar. 12, 2018), https://www.340bhealth.org/files/340B_Report_03132018_FY2015_final.pdf.

[6] Dobson et al., *supra* note 3, at 3–4.

[7] L & M Policy Research, *supra* note 5, at 1.

[8] *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836, Report to Congressional Committees 17–18 (Sept. 2011, https://www.gao.gov/assets/gao-11-836.pdf; *see also* 340B Health, *2021 340B Health Annual Survey: 340B Continues to Support Essential Programs and Services in the Face of Significant Financial Stress on Hospitals*, https://www.340bhealth.org/files/340B_Health_Survey_Report_2021_FINAL.pdf; Ryan P. Knox et al., *Risks to the 340B Drug Pricing Program Related to Manufacturer Restrictions on Drug Availability*, JAMA (Apr. 15, 2022), https://jamanetwork.com/journals/jama/article-abstract/2791334.

Drug manufacturers may charge 340B providers no more than the statutorily defined "ceiling price" for 340B covered drugs, which is calculated by subtracting the unit rebate amount from the "average manufacturer price."[9] Congress also provided for a larger rebate when drug companies increase drug prices faster than the inflation rate.[10] This inflation-based penalty could have resulted in *negative* prices for 340B covered drugs, but the Health Resources and Services Administration (HRSA) adopted a policy that when the calculated 340B ceiling price for a drug is zero or less, drug companies may charge one penny for the drug.

Since the beginning of the 340B program, Appellants and all other major pharmaceutical companies provided 340B discounts for drugs dispensed through both in-house and contract pharmacies to covered entities' patients, and since 2010 sold drugs at 340B prices to covered entities that used multiple contract pharmacies. As far as *Amici* can ascertain, between 1996 and 2020, there is no record that Appellants ever contested HHS's interpretation of section 340B as allowing 340B drugs to be dispensed by contract pharmacies. Today, a quarter of 340B hospitals' 340B benefit comes from 340B drugs contract pharmacies dispense. Critical access

[9] *See* 42 U.S.C. § 256b(a); 42 C.F.R. § 10.10.

[10] 42 U.S.C. § 1396r-8(c)(2)(A).

hospitals (small hospitals in rural areas) report an average of 52 percent of their benefit comes from drugs distributed through contract pharmacies.[11]

B. Appellants' and Other Drug Manufacturers' Unlawful Contract Pharmacy Policies

For decades drug manufacturers provided 340B discounts no matter how the drugs were dispensed, but starting in 2020, in the midst of a devastating pandemic, Appellants and fourteen other major drug companies[12] substantially cut the 340B benefit to certain public and not-for-profit hospitals.[13]

The contract pharmacy arrangements Appellants and others now refuse to honor have existed since the beginning. When a 340B provider uses a contract pharmacy outside its premises, it orders and pays for the drugs, which are shipped

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[11] 340B Health, *Contract Pharmacy Restrictions Represent Growing Threat to 340B Hospitals and Patients* (340B Health Survey) 4, https://www.340bhealth.org/files/Contract_Pharmacy_Survey_Report_FINAL_05-05-2022.pdf; *see also* Principal & Resp. Br. Fed. Defs. (HHS Br.) 19 (noting 340B providers "would lose over $3.2 billion over the course of a full year.").

[12] When Appellants initially filed these actions in 2021, just six companies had contract pharmacy policies. As *Amici* predicted, that number only continues to grow. Mem. Law Supp. Mot. Intervene Am. Hosp. Ass'n, 340B Health, Am.'s Essential Hosps., Ass'n Am. Med. Colleges, Children's Hosp. Ass'n, & Am. Soc. Health-System Pharmacists, No. 3:21-cv-00806-FLW-LHG, ECF No. 20-1 at 3.

[13] *See, e.g.*, Maya Goldman, *Hospital groups worry as more drugmakers limit 340B discounts*, Modern Healthcare (Mar. 25, 2022), https://www.modernhealthcare.com/safety-net-hospitals/hospitals-worry-more-drugmakers-limit-340b-discounts.

directly to the pharmacy to be dispensed (or to replenish drugs that have been dispensed) to the provider's patients. The pharmacy receives a fee for this service.[14]

Some providers use a "separate inventory" model, but most use a "replenishment inventory" model. For the separate inventory model, 340B drugs are kept in stock, separate from non-340B drugs. The pharmacy dispenses those drugs to the provider's patients. For the replenishment model, no 340B drugs are kept in stock. When filling prescriptions for the provider's patients, the pharmacy uses its own stock, and the provider purchases replacement drugs at the discounted 340B price to replenish the pharmacy's stock. The pharmacy then remits to the 340B provider the payments the pharmacy received, less a dispensing fee, thus ensuring that the provider receives the benefit of the 340B discount as Congress intended. These arrangements are typically done using a computerized tracking system following rules designed to ensure that only eligible patients of 340B providers are receiving drugs for which the provider receives the 340B discount.[15] Under either arrangement, it is the 340B provider that purchases the 340B discounted drug—not

[14] The fee generally ranges between $6 and $15 per prescription, though it can be as low as $0, and can occasionally be higher for more expensive drugs. *See Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480, Report to Congressional Requesters 26 (June 2018), https://www.gao.gov/assets/gao-18-480.pdf.

[15] *See, e.g.*, Apexus, *340B Split-Billing Software Key Attributes* (July 3, 2019), https://www.340bpvp.com/Documents/Public/340B%20Tools/340b-split-billing-software-key-attributes.docx.

the contract pharmacy. Appellants have ceased or placed conditions on providing 340B discounts to 340B providers for drugs distributed under either model.

On May 17, 2021, HHS sent letters to Appellants and four other pharmaceutical companies, finding after careful deliberation that the companies' refusals to provide 340B discounts for drugs dispensed through contract pharmacies, without restrictions, is unlawful.[16]

Appellants challenge the letters.[17] The district court found "that (1) contract pharmacy arrangements are consistent with the 340B statute, (2) there is no statutory support for [Appellants'] policies, which HHS properly deemed impermissible, and (3) [Appellants'] policies overcharge covered entities in the sense of § 340B."[18] The district court, however, further concluded "that it is not appropriate for this Court to decide in the first instance, based on the complex 340B landscape, whether the

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[16] *See* Letter from Diana Espinosa, Acting Administrator, HRSA, to Farruq Jafery, VP, Pricing, Contract Operations & Reimbursement, Novo Nordisk, Inc. (May 17, 2021, https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-novo-nordisk-covered-entities.pdf; Letter from Diana Espinosa, Acting Administrator, HRSA, to Gerald Gleeson, VP & Head, Sanofi US Market Access Shared Services, Sanofi (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-sanofi-covered-entities.pdf.

[17] Sanofi also challenges HHS's Administrative Dispute Resolution regulation and Appellants challenge an advisory opinion which HHS issued in December 2020 but later withdrew. The district court rejected both. *See Sanofi-Aventis U.S., LLC v. HHS*, Nos. 21-00634 (FLW), 21-00806 (FLW), 2021 WL 5150464, at *1, *10 n.31, *32 (D.N.J. Nov. 5, 2021).

[18] *Id.* at *33.

statute permits multiple or unlimited contract pharmacies," and, in turn, "partially vacate[d] and remand[ed] the Violation Letters."[19]

DISCUSSION

Appellants understate the impact of their unlawful policies on 340B providers and their patients and overstate how reasonable it is to limit access to 340B discounts and to impose conditions found nowhere in the statute. But the central issue for this Court to decide concerns what the 340B statute says. Moreover, Appellants' policies are intended to—and do—increase the companies' profits at the expense of 340B providers and in violation of the 340B statute.

A. The 340B Statute Requires Drug Manufacturers to Provide Discounts on 340B Drugs Purchased by Covered Entities and Dispensed by Contract Pharmacies.

Amici agree with HHS's arguments regarding the 340B statute's meaning, the agency's authority to enforce it, and the propriety of HHS's Violation Letters,[20] and elaborate on certain issues.

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[19] *Id.*

[20] *See* HHS Br. 33–50. *Amici* do not address Appellants' arguments regarding HHS's Administrative Dispute Resolution regulations or withdrawal of the Advisory Opinion.

1. *Critical Statutory Text Requires Drug Manufacturers to Charge Covered Entities No More than the Ceiling Price for 340B Drugs Regardless of Where the Drugs Are Dispensed.*

That the 340B statute is silent with respect to contract pharmacies does not resolve this appeal. The statute is silent regarding essentially all questions of how, administratively, covered entities may operate under the program. It does not dictate how they must order drugs, how they must dispense drugs, or what they must do with the benefit obtained from the 340B discount.

Rather, the statute speaks directly to what drug manufacturers must do and what they may not do. That drug manufacturers cannot deny 340B discounts to covered entities that use contract pharmacies, nor unilaterally impose conditions on the provision of 340B discounts, derives from those requirements and prohibitions.

Appellants emphasize that the 340B statute requires them to "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."[21] But Appellants mention just once—and then completely ignore—the central statutory text, which requires that "the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . *purchased by a covered*

[21] Novo Br. 27 (quoting 42 U.S.C. § 256b(a)(1)); Sanofi Br. 52 (same).

entity . . . does not exceed" the ceiling price.[22] Congress used the "purchased by" language *twice* in the 340B statute,[23] and in its title: "Limitation on prices of drugs *purchased by covered entities*."[24]

It was only in 2010 that Congress added the "shall offer" provision that Appellants exclusively address, further underscoring the central importance of the "purchased by" language.[25] Appellants offer no basis for concluding that by adding the "shall offer" language Congress intended to fundamentally change or displace drug manufacturers' obligation to charge no more than the ceiling price for 340B drugs purchased by 340B providers. Rather, the "shall offer" provision "mostly reiterates that manufacturers cannot prioritize full-priced commercial purchases over § 340B sales."[26]

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[22] 42 U.S.C. § 256b(a)(1) (emphasis added); *see also* Sanofi Br. 7–8 (only reference); Novo Br. 27 (only reference).

[23] 42 U.S.C. § 256b(a)(1); 42 U.S.C. § 256b(a)(3).

[24] 42 U.S.C. § 256b (emphasis added).

[25] *See* Pub. L. No. 111-148, § 7102(b), 124 Stat. 119, 827 (2010) (codified at 42 U.S.C. § 256b(a)(1)).

[26] *Sanofi-Aventis*, 2021 WL 5150464, at *42 (citing 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210, 1225 (Jan. 5, 2017); *see also* 82 Fed. Reg. at 1225; HRSA, *Clarification of Non-Discrimination Policy* (May 23, 2012), https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/nondiscrimination05232012.pdf.

Moreover, the statute does not state that drug companies must provide 340B discounts only when drugs are "purchased *and dispensed* by" a covered entity, and the fundamental rule of statutory construction is that the unambiguous plain language of the statute controls.[27]

Moreover, the 340B statute's legislative history directly supports this conclusion. Congress rejected a version of the bill that would have required 340B discounts *only* for on-site pharmacy services (either operated by the 340B provider or under a contractual arrangement), since the drugs would have had to be "purchased and dispensed by, or under a contract entered into *for on-site pharmacy services*."[28] Appellants twist the import of Congress's omission of "on-site pharmacy services"[29] and ignore that Congress also eliminated the "dispensed by" language, which changed the provision to render where the 340B drug is dispensed legally irrelevant.

Had Congress intended that drug manufacturers need not provide 340B discounts unless the 340B drugs are dispensed directly by the covered entity, excluding the use of even in-house contract pharmacies, it would have said so

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[27] *See United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 240–41 (1989 ("[A]s long as the statutory scheme is coherent and consistent, there generally is no need for a court to inquire beyond the plain language of the statute.").

[28] S. Rep. No. 102-259, at 2 (1992) (emphasis added).

[29] *See* Sanofi Br. 45; Novo Br. 50.

explicitly, and it would not have *rejected* language doing just that. And it is not surprising that Congress decided to permit dispensing by contract pharmacies because, at the time the bill was passed, less than five percent of 340B providers had on-site dispensing services.[30]

Therefore, that drug manufacturers may not charge more than the ceiling price for 340B drugs purchased by covered entities is the core requirement of the statute and program, and the central question in this appeal is whether the drugs subject to Appellants' policies are "purchased by" covered entities. They are.

2. *Appellants' Policies Result in 340B Providers Being Charged More than the Ceiling Price for Covered Drugs, in Violation of the 340B Statute.*

Regardless of the distribution model employed—"replenishment" or "separate inventory"—contract pharmacies never purchase 340B drugs. Rather, covered entities purchase the drugs and direct them to be *shipped* to contract pharmacies. Thus, Appellants' policies unlawfully result in charges above the 340B ceiling price for drugs purchased by certain 340B providers.[31]

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[30] *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996).

[31] That HRSA issued guidance in 1996 that stated that covered entities may use just one contract pharmacy is irrelevant to the issues before this Court. *See id.* at 43,549. Moreover, in that guidance, HRSA likely acted outside of its delegated authority, as nothing in the 340B statute limits how covered entities may dispense 340B drugs. *See also* HHS Br. 48 ("HHS has no statutory authority to restrict covered entities' use of contract pharmacies.").

B. Appellants Misrepresent the Purpose and Impact of Their Contract Pharmacy Policies.

Appellants present their policies as harmless initiatives developed only to "t[ake] steps to address abuses"[32] but (1) Appellants overstate the basis for their apparent concerns about fraud; (2) even if their concerns were valid, Congress directly outlined in the 340B statute how to address such concerns; (3) Appellants designed their policies to maximize profits by decreasing the amount of available 340B discounts and/or to undermine the 340B program by imposing conditions that increase the cost and burden of participating in the 340B program; and (4) Appellants' policies are having major, adverse impacts on 340B hospitals and their patients, undermining the structure of the 340B program and Congress's intent.

1. *Appellants Overstate Their Concerns of Fraud, Which Congress Addressed in the 340B Statute.*

Although not relevant to whether the statute allows Appellants to attempt to unilaterally address duplicate discounting concerns—it does not—Appellants claim that duplicate discounting is a rampant problem that no one is addressing.[33] Not only

[32] Novo Br. 15.

[33] Contrary to Appellants' assertions, hospitals' use of contract pharmacies has not been accompanied by widespread diversion in the 340B program. In fiscal years 2019, 2020, and 2021, HRSA conducted nearly 500 audits of 340B hospitals, and 95 percent of those audits did not identify any instances of diversion related to contract pharmacies. *See* HRSA, *Program Integrity: FY19 Audit Results*, https://www.hrsa.gov/opa/program-integrity/audit-results/fy-19-results; HRSA, *Program Integrity: FY20 Audit Results*, https://www.hrsa.gov/opa/program-integrity/audit-results/fy-20-results; HRSA, *Program Integrity: FY21 Audit Results*,

do Appellants cite only to reports of *potential* duplicate discounts,[34] in fact per the most recent GAO report, between 2012 and 2019, *only 23* of the 429 duplicate discount audit findings related to contract pharmacies.[35] Moreover, there are extensive state and federal laws that effectively limit the use of 340B for Medicaid for most hospitals,[36] and 82 percent of 340B hospitals with contract pharmacies report that they do not use contract pharmacies to dispense 340B drugs to Medicaid managed care patients; only 80 of the 31,000 contract pharmacies used by covered entities involve use of 340B drugs for Medicaid fee-for-service patients.[37]

Regardless, if Appellants have concerns about fraud, Congress provided authority for manufacturers to audit covered entities—"at [HHS's] or the manufacturer's expense," *not* the covered entity's—"in accordance with procedures

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https://www.hrsa.gov/opa/program-integrity/audit-results/fy-21-results. This small number of audit findings hardly supports Appellants' claims that pervasive diversion of 340B drugs necessitates their placing restrictions on contract pharmacy arrangements, and in any event, any concerns Appellants have regarding diversion must also be addressed as Congress outlined in the statute.

[34] *See* Sanofi Br. 14; Novo Br. 43.

[35] *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, GAO-21-107, Report to Congressional Committees 14 (Table 1) (Dec. 2020), https://www.gao.gov/assets/gao-21-107.pdf.

[36] *See, e.g.*, Kathleen Gifford et al., *How State Medicaid Programs are Managing Prescription Drug Costs: Results from a State Medicaid Pharmacy Survey for State Fiscal Years 2019 and 2020*, Kaiser Family Found. (Apr. 29, 2020), https://www.kff.org/report-section/how-state-medicaid-programs-are-managing-prescription-drug-costs-state-strategies-to-manage-340b-programs/.

[37] 340B Health Survey, *supra* note 11, at 8.

established by [HHS]."[38] Congress clearly recognized that abuse in the 340B program could be a problem and specifically addressed the issue. Congress's regulatory scheme must inform any interpretation of the statutory provisions at issue here.[39] If Appellants believe Congress's regulatory structure is insufficient to address their concerns, they must address the issue with Congress, not by instituting policies that result in the violation of basic textual requirements.

2. *Appellants' Policies Maximize Profits at the Expense of 340B Providers and Patients, and Increase the Burden on 340B Providers of Participating in the 340B Program.*

Appellants (and the other drug companies with similar contract pharmacy policies) are among the largest companies in an industry that between 2000 and 2018 generated $8.6 trillion dollars in profits.[40] These companies participate in the 340B program only because they *must* do so to participate in Medicaid and Medicare Part B. The larger the 340B program, the lower their profits. Simply put, having been unable to convince Congress to limit the program, drug companies began taking

[38] 42 U.S.C. § 256b(a)(5)(C); *see also id.* § 256b(d)(2) (addressing how *HHS*, not drug manufacturers, "shall provide for improvements in compliance by covered entities with the requirements of this section in order to prevent diversion and violations of the duplicate discount provision").

[39] *See Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000).

[40] Fred D. Ledley et al., *Profitability of Large Pharmaceutical Companies Compared with Other Large Public Companies*, 323(9) J. Am. Med. Ass'n 834–43 (Mar. 3, 2020), https://jamanetwork.com/journals/jama/fullarticle/2762308.

action to severely curb it. Two specific data points further demonstrate the profit motive driving Appellants' policies.

(a) *Drug Manufacturers Are Using Their Policies to Skirt Congress's Inflationary Penalty.*

First, drug manufacturers, including Appellants, are using these policies to avoid having to pay congressionally imposed penalties they otherwise would face. As explained above, Congress sought to minimize skyrocketing drug prices by creating a scheme in which drug companies pay a penalty when they increase prices on drugs covered by 340B or Medicaid above the rate of inflation.[41] Indeed, Appellants emphasize that "many drugs are available under the 340B program at a penny per pill,"[42] but such drastic discounts come into play only because the drug company opted to increase its drug prices faster than the inflation rate.[43] Research has demonstrated that this penalty against price increases slows price increases for drugs sold to all purchasers, not just 340B providers.

Appellants and other drug manufacturers should not be permitted to avoid this inflationary penalty simply by developing policies that allow them to deny 340B discounts to covered entities altogether. Yet the companies' policies allow them to

[41] *See* Background, sec. A, above; 42 U.S.C. § 1396r-8(c)(2)(A).

[42] Novo Br. 9 (citing 42 U.S.C. § 1396r-8(c); 42 U.S.C. § 256b(a)(1)); *see also* Sanofi Br. 8.

[43] *See* 42 U.S.C. § 1396r-8(c)(2)(A).

do just that.[44] For eight of the companies with such policies, including Appellants, the estimated discount on drugs that are nominally priced because of the inflationary penalty accounts for the majority of the discounts for hospitals associated with those companies' restricted drugs.[45] For Novo, 86 percent of hospitals' 340B discounts come from nominally priced drugs.[46] Reducing the share of these drugs subject to inflationary penalties greatly reduces the effectiveness of Congress's scheme by undermining the 340B statute's use of the inflationary penalty to exert pressure on drug companies to limit drug price increases.

(b) *Drug Manufacturers Are Using Unlawful Contract Pharmacy Policies to Avoid Providing Discounts on Specialty Drugs.*

Second, Appellants are using their policies to avoid having to provide 340B discounts on particularly expensive "specialty" drugs. 340B providers' increased use of contract pharmacies reflects, in part, a shift in the market toward specialty drugs[47]

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[44] Data based on 340B Health analysis of the difference in cost for hospitals under 340B accounts and non-340B accounts (*i.e.*, hospital group purchasing accounts) based on 2020 340B sales volume for restricted drugs. The volume estimates include drugs dispensed at contract pharmacy and non-contract pharmacy hospital settings. *See also* 340B Health Survey, *supra* note 11, at 3.

[45] *See supra* note 44.

[46] *See supra* note 44. For Sanofi, the percent of 340B savings represented by drugs sold at nominal prices in 2020 compared to non-nominally priced restricted drugs was 68 percent.

[47] *See* IQVIA, *The Use of Medicines in the U.S., Spending and Usage Trends and Outlook to 2025* (May 27, 2021), https://www.iqvia.com/insights/the-iqvia-

for which many payers require the use of specific specialty pharmacies.[48] Specialty drugs are typically used to treat chronic, serious, or life-threatening conditions and are generally priced much higher than traditional drugs.[49] Patients cannot obtain most specialty drugs at retail pharmacies, and specialty pharmacies generally are mail-order pharmacies distributed throughout the country.[50] An analysis across the 16 drug manufacturers with contract pharmacy policies found that nearly *three-quarters* of the total 340B discount associated with their drugs came from drugs that appear on at least one list of specialty drugs across the four largest specialty pharmacy companies.[51]

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institute/reports/the-use-of-medicines-in-the-us (finding that specialty medicines accounted for 53 percent of drug spending in 2020, up from 27 percent in 2010).

[48] For example, major insurers and their associated Pharmacy Benefit Managers (PBMs) require that many patients obtain specialty medicines through their vertically integrated specialty pharmacies. Adam J. Fein, *Insurers + PBMs + Specialty Pharmacies + Providers: Will Vertical Consolidation Disrupt Drug Channels in 2020?*, Drug Channels (Dec. 12, 2019), https://www.drugchannels.net/2019/12/insurers-pbms-specialty-pharmacies.html.

[49] "There is no standard definition for specialty drugs. They may be expensive; be difficult to handle, monitor or administer; or treat rare, complex or chronic conditions." *Specialty Drug Coverage and Reimbursement in Medicaid*, HHS OIG, https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000255.asp.

[50] Ronilee Shye, *Specialty Pharmacy and Specialty Medications: What You Should Know* (Jan. 7, 2014), https://www.goodrx.com/healthcare-access/pharmacies/specialty-pharmacy-and-specialty-medications-what-you-should-know.

[51] 340B Health Survey, *supra* note 11, at 6.

The vast majority of 340B hospitals do not operate specialty pharmacies, and even when they do, those pharmacies are not able to serve all patients. Pharmacy Benefit Managers (PBMs) and payers restrict how specialty drugs may be purchased, often requiring patients to use their own specialty pharmacy networks that often exclude hospital specialty pharmacies.[52] To have access to specialty drugs at the 340B price, 340B hospitals must enter into contracts with pharmacies in each of the networks. Additionally, nearly three-quarters of 340B providers recently surveyed reported that limited distribution networks prevented their hospital from using their hospital- or system-owned specialty pharmacy for all drugs, and 90 percent of 340B hospitals with specialty contract pharmacies reported that the drug manufacturers' policies limit their ability to purchase drugs at the 340B price from specialty contract pharmacies.[53] Thus, to have access to specialty drugs at 340B prices for certain patients, 340B hospitals *must* contract with one or more specialty contract pharmacies, and by limiting 340B providers' ability to use such specialty pharmacies, Appellants' policies directly undermine the 340B program and Congress's intent.

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[52] For example, one benefit guide states, "For specialty medicines . . . you must use Accredo, the Express Scripts specialty pharmacy." Express Scripts, *Your Pharmacy Benefits Handbook* 5, https://www.express-scripts.com/art/open_enrollment/FCPS_MemberHandbook.pdf; *see also* Adam J. Fein, *supra* note 78.

[53] 340B Health Survey, *supra* note 11, at 7.

(c) *Policies Conditioning 340B Discounts on the Provision of Extensive Claims Data Are Also Unlawful.*

Policies like Sanofi's further undermine the 340B program by requiring certain 340B providers to limit the use of contract pharmacies or expend limited resources submitting sensitive claims data before receiving the 340B discounts to which they are entitled. Sanofi portrays its data demands as a benevolent "integrity initiative," by which it can "compar[e] the requested claims data to Medicaid payor data [and] can identify impermissible duplicate discounts."[54] But the data Sanofi requires go far beyond what could potentially address Medicaid duplicate discounts. Sanofi is demanding from providers *all* contract pharmacy claims data for Sanofi's products, including Medicare Part D and commercial claims, which Sanofi apparently intends to use to resolve "ineligible rebates on Medicare Part D and commercial utilization" under its agreements with commercial payers and PBMs.[55]

For the 340B program to operate, *Amici* recognize and agree with HRSA's longstanding position that manufacturers are allowed to "request standard information."[56] But nothing about what Sanofi is demanding of (only selected) 340B

[54] Sanofi Br. 20.

[55] 3:21-cv-00634-FLW-LHG, ECF No. 68-3; *see also id.* ("Data uploaded by 340B covered entities will be used to identify and resolve duplicate Medicaid *and commercial* rebates.") (emphasis added).

[56] Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110, 25,114 (May 13, 1994).

providers is standard,[57] and there is a significant distinction between conditions that help make the 340B program possible and conditions that make it *harder* to participate in the program.

Covered entities have not in the past 30 years ever been required to provide this sensitive information to drug companies, and non-covered entities, non-hospital covered entities, and covered entities using their own in-house pharmacy are *not* being asked to provide the data.[58] And HHS has consistently advised drug companies that they may not demand the information Sanofi demands. In 1994, HHS notified pharmaceutical manufacturers that they "may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective"[59] and that "[m]anufacturers must not place limitations on the transactions (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount program."[60] The conditions Sanofi's policy imposes on certain 340B providers, including *Amici's* members, are thus plainly disallowed.

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[57] *See also* HHS Br. 42–43.

[58] *See Sanofi*, 3:21-cv-00634-FLW-LHG, ECF No. 68-10.

[59] 59 Fed. Reg. at 25,111–12.

[60] *Id.* at 25,1113; *see also* HHS Br. 42–43.

3. *Appellants Drastically Understate the Impact of Their Policies on Covered Entities.*

Appellants further significantly understate the benefit of contract pharmacies to—while also significantly understating the burden of their restrictive contract pharmacy policies on—340B providers and their patients.

(a) *Appellants Understate the Benefit of Contract Pharmacies to 340B Providers and Patients.*

Despite Appellants' assertions otherwise, contract pharmacies have greatly benefitted covered entities and their patients. While the increased use of contract pharmacies has not expanded the number of patients eligible for discounted drugs, it has expanded patients' access to those drugs. 340B providers' patients, who may live very far from their provider,[61] benefit when their local Walgreens or CVS can dispense their 340B drugs. For example, the patients are more likely to fill their prescriptions and take their medications, and pharmacists can more easily manage drug interactions.

Contract pharmacies recoup a modest fee for dispensing 340B drugs, but (1) no matter the fee,[62] the *covered entity* is the one *purchasing* the drug; (2) the covered entity's patients benefit from increased access to 340B drugs; and (3) the covered entity is still getting the 340B benefit by receiving a discount from the manufacturer

[61] *See, e.g.*, HHS Br. 16–17.

[62] *See supra* note 14.

and reimbursement from the patient or third-party payer, which the contract pharmacy remits to the covered entity. Thus, the covered entity still benefits from the 340B program, as Congress intended.

To support their assertion that the use of contract pharmacies does not benefit 340B providers and their patients, Appellants contort the data. Novo, for example, states that "while the use of contract pharmacies has grown exponentially, the overall level of charitable care provided by hospitals has not." [63] But "340B hospitals provide substantial community benefit, and charity care tells just one piece of the story. It is more accurate to look at a hospital's total uncompensated care and their total community benefits rather than just its charity care numbers, as charity care alone does not account for the myriad programs and services that hospitals provide to their communities."[64] When looking at the full picture, "[h]ospitals provided nearly $42 billion in uncompensated care in 2019, of which 340B hospitals roughly made up 68% of that number."[65] In 2017, 340B hospitals participating in 340B provided $64.3 billion in total benefits to their communities, including

[63] Novo Br. 14–15 (citations omitted).

[64] Am. Hosp. Ass'n, *supra* note 4, at 2.

[65] *Id.*

uncompensated care.[66] Those benefits increased to $68 billion in 2018, accounting for almost 14 percent of the hospitals' total expenses.[67] Examples of community benefits include financial assistance to patients in need and programs and services designed to meet specific health needs.

More than half of 340B hospitals do not operate in-house retail pharmacies, and only one in five have their own specialty pharmacy.[68] Contract pharmacies are a necessary and beneficial component of the 340B program, allowing 340B providers to provide and expand services to underserved populations.

(b) *Appellants Understate the Impact of Their Policies on 340B Providers and Patients.*

340B providers are increasingly feeling the harmful impact of drug manufacturers' policies.[69] Between December 2021 and March 2022, during which

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[66] Am. Hosp. Ass'n, *340B Hospital Community Benefit Analysis* 2 (Sept. 2020), https://www.aha.org/system/files/media/file/2020/09/340b-community-benefits-analysis-report.pdf.

[67] Am. Hosp. Ass'n, *340B Hospital Community Benefit Analysis* 2 (Sept. 2021), https://www.aha.org/system/files/media/file/2021/09/340b-community-benefits-analysis-0921.pdf.

[68] 340B Health Survey, *supra* note 11, at 4. Thirty-eight percent of DSH, rural referral centers, and sole community hospitals, as well as 85 percent of critical access hospitals, do not operate their own retail pharmacies where their patients can pick up their prescriptions. *Id.*

[69] *E.g.*, Knox et al., *supra* note 8 s("[D]isproportionate share hospitals, rural referral centers, and sole community hospitals had lost on average 23% of their contract pharmacy revenue because of manufacturers' restrictions, while critical access hospitals had lost on average 39% [by late 2021]."); Gina Shaw, *Manufacturers' 340B Restrictions On*

time the number of manufacturers imposing restrictions increased from eight to 14, the financial impact on 340B hospitals more than doubled.[70] The median annualized impact on disproportionate share hospitals, rural referral centers, and sole community hospitals went from $1 million to $2.2 million, and 10 percent of those hospitals expect annual losses of $21 million or more.[71]

More than three quarters of 340B hospitals reported that they will need to cut or adjust programs if the drug manufacturers' restrictions become permanent. These include cuts to patient care services (80 percent), services in underserved areas (74 percent), and targeted programs to serve low-income patients that live in rural areas or are otherwise vulnerable (72 percent). A third of critical access hospitals report that the restrictions put their hospitals at risk of closure.[72]

Sanofi's policy imposes additional onerous burdens on 340B providers. On top of logistical (including staffing and financial) burdens in compiling the data, complying with Sanofi's policy does not necessarily result in 340B discounts. 340B hospitals must submit claims data to Second Sight Solution's 340B ESP data

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Contract Pharmacies Draw Ire, Pharmacy Practice News (May 10, 2021), https://www.pharmacypracticenews.com/Article/PrintArticle?articleID=63395 (outlining impacts on patients).

[70] 340B Health Survey, *supra* note 11, at 3.

[71] *Id.*

[72] *Id.* at 5.

platform for Sanofi's 340B drugs.[73] The data platform, however, currently has more than 800 national drug codes (NDCs) that are subject to restrictions requiring submission of data[74]—Sanofi is just one of at least 10 companies with such a policy. The specific claim elements that 340B ESP requires hospitals to provide include the prescription number, the prescribed date, the fill date, the NDC, the quantity, the pharmacy ID, and 340B covered entity ID.[75]

To submit these data, hospitals must obtain the data elements relating to all their contract pharmacy claims that include these 800 NDCs. Prior to launching contract pharmacy arrangements, hospitals also contract with a third-party administrator (TPA) to assist with managing the arrangement. To get the data they need, then, hospitals must go to each TPA's portal and download claims information for all contract pharmacies covered by each TPA. TPAs all have different systems, and all generate reports with vastly more information than is needed for submission to 340B ESP. Hospitals download the information into a spreadsheet, then manually review it to remove unrequested information. This can involve manually reviewing and editing information related to thousands of claims.

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[73] *E.g.*, 3:21-cv-00634-FLW-LHG, ECF No. 68-6.

[74] 340B ESP, *What NDCs do we look for?*, https://help.340besp.com/en/articles/4455011-what-ndcs-do-we-look-for.

[75] *See* Submitting your 340B claims through 340B ESP, https://help.340besp.com/en/articles/4323537-submitting-your-340b-claims-through-340b-esp.

This process needs to be completed biweekly, but it can take days to obtain the data from the TPA(s) and to edit and submit the data to 340B ESP. As a result, hospitals using the replenishment model do not always receive the 340B price on those drugs, even when they attempt to report the requested data.[76] Not only do 340B hospitals not receive the 340B discount to which they are entitled, they also incur *more* cost than just the higher drug price because of the administrative expenses associated with complying with Sanofi's policy and the fees owed to the contract pharmacies to dispense the drugs. 340B hospitals spend a significant amount of time identifying why purchases were not processed at the 340B price and seeking refunds via the credit/rebill process. Even then, the refunds are not always granted, and many hospitals have reported having to hire additional staff just to handle issues associated with collecting and submitting data, as well as correcting improperly withheld discounts.

[76] 340B hospitals are finding several reasons why this is happening, including an inability to obtain information about specific requirements from the drug manufacturers; the time limits imposed on submitting the data for drugs replenished in the previous two weeks; manufacturers' errors in the instructions provided to wholesalers, and wholesalers' errors in failing to update hospitals' accounts consistent with manufacturers' instructions. *See* Letter from Maureen Testoni, President & CEO, 340B Health, to Xavier Becerra, Secretary of Health and Human Services, HHS, & Carole Johnson, Administrator, HRSA (May 10, 2022), https://www.340bhealth.org/files/340B-Health-Letter-to-HHS-on-Burdens-of-Manufacturer-Claims-Data-Conditions-5.10.22.pdf.

Sanofi states that "hundreds of covered entities have participated in Sanofi's integrity initiative,"[77] but that is not surprising, as these policies have forced 340B hospitals into a Hobson's choice: comply with the policies or be denied the 340B benefit.[78] The burden of complying with these increasingly numerous policies demonstrates why *Congress's* solution for addressing concerns of fraud in the 340B program—allowing manufacturers to audit covered entities "in accordance with procedures established by [HHS]"[79]—is the proper one.

As a final note, a recent survey shows that Appellants' policies of allowing 340B providers to use "a single, designated contract pharmacy, if the covered entity has no in-house pharmacy,"[80] also impose an impermissible burden on 340B hospitals and their patients, undermining the purpose of the 340B program. For example, 90 percent of hospitals surveyed reported that choosing one pharmacy location would limit the hospital's access to 340B discounts for eligible patients, and

[77] Sanofi Br. 2.

[78] Ninety-one percent of 340B hospitals surveyed reported they would not consent to submitting the requested data if they were not facing significant financial harm from the loss of 340B discounts. 340B Health Survey, *supra* note 11, at 8.

[79] 42 U.S.C. § 256b(a)(5)(C); *see also id.* § 256b(d)(2) (addressing how *HHS*, not drug manufacturers, "shall provide for improvements in compliance by covered entities with the requirements of this section in order to prevent diversion and violations of the duplicate discount provision").

[80] Sanofi Br. 19; *see also* Novo Br. 16.

54 percent reported concern that patients would be forced to switch pharmacies, limiting the ability to flag drug interactions.[81]

CONCLUSION

For the foregoing reasons and those outlined in HHS's brief, the district court's judgment should be reversed insofar as it vacated the May 17, 2021 enforcement letters and remanded to HHS and should otherwise be affirmed.

Dated: May 16, 2022

Respectfully submitted,

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[81] 340B Survey, *supra* note 11, at 7–8.

COMBINED CERTIFICATIONS

1. Pursuant to Local Rule 28.3(d), I, William B. Schultz, certify that I am a member in good standing of the bar of this Court.

2. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 29(a)(5) because this brief contains 6,398 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

3. This brief complies with the typeface requirements of Federal Rule Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word with 14-point Times New Roman font.

4. Pursuant to Local Rule 31.1(c), the text of the electronic version of this brief is identical to the text in the paper copies.

5. Pursuant to Local Rule 31.1(c), the electronic version of this brief was scanned using virus-detection software—namely with Cylance Smart Antivirus—and no virus was detected.

/s/ William B. Schultz
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CERTIFICATE OF SERVICE

I certify that on May 16, 2022, I caused a copy of this Brief of American Hospital Association, 340B Health, America's Essential Hospitals, Association of American Medical Colleges, and Children's Hospital Association as *Amici Curiae* in Support of Appellees/Cross-Appellants to be served electronically via the Court's CM/ECF system on all counsel registered to receive electronic notices.

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