No. 22-1676

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

ASTRAZENECA PHARMACEUTICALS LP,

Plaintiff-Appellee,

v.

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

Defendants-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 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*.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

OTHER AUTHORITIES

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

As outlined by *Amici* in the *amicus* brief filed in *Sanofi-Aventis U.S., LLC v. United States Department of Health and Human Services*, Nos. 21-3167, 21-3168, and *Novo Nordisk Inc. v. United States Department of Health and Human Services*, Nos. 21-3379, 21-3380, 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.[2] AstraZeneca Pharmaceuticals' (AstraZeneca's) unlawful

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[1] Appellees and Appellants consent 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 contributed money for this brief.

[2] *See generally* Corrected Br. Am. Hosp. Ass'n, 340B Health, Am.'s Essential Hosps., Ass'n Am. Med. Colls., & Children's Hops. Ass'n as *Amici Curiae* Supp. Appellees/Cross-Appellants (*Amicus* Brief), No. 21-3379, Doc. No 35. Pursuant to this Court's Order of April 28, 2022, *see* Doc. No. 28, and Federal Rule of Appellate

contract pharmacy policy is another effort by a highly profitable pharmaceutical company to undermine Congress's 340B program, to the detriment of 340B providers[3] and their patients.

Neither the statute's text nor AstraZeneca's mischaracterizations regarding how contract pharmacy arrangements work provide a basis to undercut the program. Indeed, the Supreme Court's recent pronouncements on the 340B program conclusively demonstrate the weakness of AstraZeneca's position. Just two weeks ago, the Court noted that Congress has been aware of how the 340B program is operating.[4] But the Court explained that Congress did *nothing* to change the statute to address certain alleged concerns, and so the only answer would be to "ask Congress to change the law."[5]

So too here. Even if AstraZeneca were correct in its mischaracterizations about the use of contract pharmacies—and it is not—Congress has done *nothing* to amend the statute in all the years covered entities have been using contract

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Procedure 28(i), *Amici* incorporate by reference the *amicus* brief they filed in the four other consolidated cases. To avoid redundant briefing, this *amicus* brief contains only arguments and information not otherwise contained in the earlier filed brief.

[3] Defined terms herein have the same meanings as set forth in the *amicus* brief *Amici* filed in the consolidated cases. *See Amicus* Brief.

[4] *See Am. Hosp. Ass'n v. Becerra*, 596 U.S. ____ (2022) (slip op., at 12–13).

[5] *Id*. at 13.

pharmacies (*i.e.*, since the beginning of the program, and even after 2010 as contract pharmacy use increased). And even if Congress did consider the issue, it "would presumably have to confront the other side of the policy story here: 340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support."[6] One thing is clear, however: absent any statutory change, AstraZeneca cannot take matters into its own hands with its unlawful unilateral decision to deny 340B discounted drugs to 340B providers.

Amici therefore urge this Court to hold that AstraZeneca must offer 340B discounted drugs to 340B providers, regardless of whether these vital medicines are being dispensed in-house or through outside pharmacies, as it previously did for 24 years.

BACKGROUND[7]

Since the beginning of the 340B program, AstraZeneca—just like Novo Nordisk, Sanofi, and other major pharmaceutical companies—provided 340B discounts to covered entities for drugs dispensed through both in-house and contract pharmacies to covered entities' patients, and since at least 2010 sold drugs at 340B prices to covered entities that used multiple contract pharmacies. As far as *Amici* can

[6] *Id.*

[7] *See also Amicus* Brief 2–8 (providing more fulsome background, incorporated by reference here).

ascertain, between 1996 and 2020, there is no record that AstraZeneca ever contested HHS's interpretation of section 340B as allowing 340B drugs to be dispensed by contract pharmacies. But starting in 2020, AstraZeneca, along with 16 other major drug companies,[8] substantially cut the 340B benefit to certain public and not-for-profit hospitals. AstraZeneca's policy restricts the 340B discount to drugs dispensed in-house, unless a covered entity has no in-house pharmacy, at which point the covered entity may receive the 340B discount for drugs dispensed from a single contract pharmacy.[9] The contract pharmacy arrangements AstraZeneca and others now refuse to honor have existed since the beginning of the 340B program, including the "separate inventory" and "replenishment" models.[10] AstraZeneca has 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 AstraZeneca and five other pharmaceutical companies, including Novo Nordisk and Sanofi, finding after careful

[8] After *Amici* filed their *amicus* brief in the Novo Nordisk and Sanofi appeals, another drug company announced a restrictive contract pharmacy policy. *See Notice to 340B Covered Entities of Exelixis' 340B Program Integrity Initiative*, Exelixis (June 7, 2022), https://340besp.com/Exelixis%20340B%20Integrity%20Initiative.pdf.

[9] JA245.

[10] *See Amicus* Brief 5–7 (describing separate inventory and replenishment models).

deliberation that the companies' refusals to provide 340B discounts for drugs dispensed through contract pharmacies, without restrictions, are unlawful.[11]

AstraZeneca challenges the letter.[12] The district court found that "the 340B statute is 'silent as to the role that contract pharmacies may play in connection with covered entities' purchases of 340B drugs'" and that both HHS's and AstraZeneca's textual "interpretations are permissible readings of the 340B statute but that neither interpretation is compelled by the plain text of the statute."[13] The court vacated the letter because (1) it "evinces an understanding that its conclusion is driven by a clear statutory command with respect to drug manufacturers' obligations";[14] and (2) it "fail[ed] to acknowledge that the agency's position has shifted over time" with respect to how to interpret the 340B statute.[15]

DISCUSSION

Along with Novo Nordisk and Sanofi, AstraZeneca understates the impact of its unlawful policy on 340B providers and their patients and overstates how reasonable it is to limit access to 340B discounts and to impose conditions found

[11] *See* JA157–58.

[12] AstraZeneca also challenges an advisory opinion that HHS issued in December 2020 but later withdrew. The district court set aside and vacated the advisory opinion. *See* JA53.

[13] JA35 (citation omitted).

[14] JA43.

[15] JA49.

nowhere in the statute.[16] AstraZeneca's contract pharmacy policy is unlawful under the terms of the 340B statute, and the district court's decision should be reversed.

As in the Novo Nordisk and Sanofi appeals, *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,[17] and elaborate on certain issues not already addressed in *Amici's* earlier brief.[18]

A. The 340B Statute Requires Drug Manufacturers to Provide Discounts on 340B Drugs Purchased by Covered Entities and Dispensed by Contract Pharmacies.[19]

As *Amici* outlined before, 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. On the other hand, 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.

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[16] *See, e.g.*, Br. AstraZeneca Pharms. LP as Amicus Curiae Supp. Appellants (AstraZeneca Am. Br.), No. 21-3379, Doc. No. 18.

[17] *See* Opening Br. Fed. Defs. 9–12.

[18] *See Amicus* Brief 8–29.

[19] *See also id.* at 8–12.

While *Amici* incorporate by reference the analysis outlined in their earlier *amicus* brief, AstraZeneca raises additional arguments in the *amicus* brief it filed in the Novo Nordisk and Sanofi appeals. *Amici* address those here.

First, AstraZeneca quotes the district court for the proposition that "it is hard to believe that Congress enumerated 15 types of covered entities with such a high degree of precision and intended to include contract pharmacies as a 16th option by implication."[20] But contract pharmacies are *not* covered entities and do not act as such. Only covered entities—and not contract pharmacies—are authorized to purchase drugs from manufacturers at the 340B discount, and only covered entities do so; covered entities then direct the drugs to be *shipped* to a contract pharmacy. Put another way, all 15 of the covered entities listed in the statute—whether a "Federally-qualified health center," a "black lung clinic," a "State-operated AIDS drug purchasing assistance program," or another[21]—can have drugs shipped to contract pharmacies, but doing so does not transform the contract pharmacies into anything akin to a covered entity. As such, Congress need not have included contract pharmacies in the text of the statute for drug manufacturers to still be required in that scenario—per the statute's text—to charge no more than the ceiling price for drugs purchased by covered entities.

[20] AstraZeneca Am. Br. 9 (alterations omitted) (quoting JA22).

[21] 42 U.S.C. § 256b(a)(4).

Second, AstraZeneca points out that Congress elsewhere in the Veterans Health Care Act of 1992 "prescribed special treatment for discounted drugs purchased by a federal agency but 'delivered through a commercial entity operating under contract with such agency.'"[22] However, contrary to AstraZeneca's argument, there was no need for Congress to include language in the 340B statute referring to contract pharmacies the way it referenced contracts in section 603 of the Veteran's Health Care Act, an unrelated statute involving contracts between commercial entities and certain federal agencies, in which the agency contracts with the commercial entity to procure covered drugs.[23] Unlike the commercial entities covered by that provision, contract pharmacies are not purchasing covered outpatient drugs at 340B discounts on behalf of the federal government (or 340B providers)—they are not purchasing 340B drugs at all.

Third, AstraZeneca appears to argue that despite Congress's explanation that the 340B program was designed to enable providers "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services,"[24] Congress intended for covered entities *always* to pass

[22] AstraZeneca Am. Br. 10 (ellipsis omitted) (quoting 38 U.S.C. § 8126(h)(3)(A)(ii)).
[23] *See* 38 U.S.C. §§ 8126(a)(2), (h)(3)(A)(ii).
[24] H.R. Rep. No. 102-384(II), at 12 (1992).

the 340B discount onto their patients.[25] But Congress said no such thing in the 340B statute. Indeed, the statute is silent with respect to how covered entities must order drugs, how they must dispense drugs, and what they must do with the additional resources obtained from the 340B discount.[26] Had Congress intended to require covered entities to pass the 340B discount onto patients in every instance, it could and would have said so.[27] And it certainly would have said so when it expanded the program in 2010 following 18 years of covered entities passing on the 340B discounts to patients only when the covered entity elected to do so—but Congress did not. Congress left it to the discretion of covered entities to determine how to use the 340B benefit to serve their patients.

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[25] *See* AstraZeneca Am. Br. 17–19.

[26] Still, although not required by statute to do so, more than half of 340B hospitals recently surveyed reported that they offer free or low-cost drugs to low-income and/or uninsured patients through contract pharmacies. 340B Health, *Contract Pharmacy Restrictions Represent Growing Threat to 340B Hospitals and Patients* 4–5, https://www.340bhealth.org/files/Contract_Pharmacy_Survey_Report_FINAL_05-05-2022.pdf. By restricting the use of contract pharmacies, AstraZeneca and the other manufacturers have cut off patients' access to these discounts.

[27] AstraZeneca's expanded quotation from the Committee Report only further underscores that Congress intended *covered entities* to receive the 340B discount, with no requirement to pass on the discount directly to patients, so long as the covered entities seek to "reach[] more eligible patients and provid[e] more comprehensive services." *See* AstraZeneca Am. Br. 19 ("*In giving these 'covered entities' access to price reductions* the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.") (emphasis AstraZeneca's) (quoting H.R. Rep. No. 102-384, pt. 2, at 12).

To the extent AstraZeneca is making a different argument—that Congress never intended for covered entities to benefit from the sale of 340B drugs to individuals who are *not* the covered entities' patients—then that is correct, but AstraZeneca distorts the point. Clearly, Congress intended to prohibit covered entities from reselling 340B drugs to non-patients; it said so expressly in the statute.[28] But AstraZeneca states without support that "the resale of 340B drugs to pharmacy customers with insurance—who in many cases are *not* covered entity patients—is precisely how the current contract pharmacy system generates most of its revenue."[29] In fact, a covered entity receives the 340B discount *only* for drugs dispensed to the covered entity's patients, under either the separate inventory or replenishment model. As noted in *Amici's* earlier brief, the replenishment model typically involves 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.[30] Both the United States Supreme Court and the Federal Trade Commission have endorsed accounting systems like these as an appropriate way to distinguish drugs that qualify for a discount from those that

[28] *See* 42 U.S.C. § 256b(a)(5)(B) ("[A] covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.").

[29] AstraZeneca Am. Br. 19.

[30] *Amicus* Brief 6 & n.15.

do not.[31] The 340B program thus operates as Congress intended—with covered entities receiving the 340B discount *only* for drugs dispensed to their patients—when covered entities use contract pharmacies, notwithstanding AstraZeneca's assertions otherwise.

Finally, AstraZeneca tries to diminish the importance of the key statutory text—the "purchased by" provision[32]—by arguing that "the language imposes obligations on the HHS Secretary ('The Secretary shall …'), requiring him to ensure that covered entities make appropriate reimbursement payments 'to the manufacturer.'"[33] This effort fails.

First, it was not until 2010 that Congress added the "shall offer" provision to the 340B statute.[34] AstraZeneca can hardly support an argument that Congress required *nothing* of drug manufacturers from 1992 until 2010, and AstraZeneca offers no basis for concluding that by adding the "shall offer" language Congress intended to fundamentally change or displace drug manufacturers' obligation to

[31] *See Abbott Labs. v. Portland Retail Druggist Ass'n, Inc.*, 425 U.S. 1, 20 n.11 (1976); Federal Trade Commission, University of Michigan Advisory Opinion 1 (Apr. 9, 2010), https://www.ftc.gov/sites/default/files/documents/advisory-opinions/university-michigan/100409univmichiganopinion.pdf.

[32] *See* 42 U.S.C. § 256b(a)(1); *Amicus* Brief 9–12.

[33] AstraZeneca Am. Br. 22.

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

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."[35]

Second, AstraZeneca ignores the actual language of the "purchased by" provision, which does not require the HHS Secretary "to ensure that covered entities make appropriate reimbursement payments" to drug companies as AstraZeneca asserts.[36] Rather, the provision requires the Secretary to "enter into an agreement with each [drug] manufacturer . . . under which the amount *required to be paid*" by covered entities to the drug manufacturer "*does not exceed*" the ceiling price for the 340B drug.[37] And as the United States Supreme Court has explained, those agreements between the Secretary *and the drug manufacturers* "simply incorporate statutory obligations and record the manufacturers' *agreement to abide by them*."[38] Thus, the 340B statute requires that, if a covered entity purchases AstraZeneca's

[35] *Sanofi-Aventis U.S., LLC v. HHS*, Nos. 21-00634 (FLW), 21-00806 (FLW), 2021 WL 5150464, at *42 (D.N.J. Nov. 5, 2021) (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.

[36] AstraZeneca Am. Br. 22.

[37] 42 U.S.C. § 256b(a)(1) (emphasis added).

[38] *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 118 (2011) (emphasis added).

340B drugs—which it is uncontested they do when using contract pharmacies—AstraZeneca may not require the covered entity to pay more than the ceiling price.

B. AstraZeneca Misrepresents the Purpose and Impact of Its Contract Pharmacy Policy.[39]

AstraZeneca presents its policy as a harmless initiative developed only to "remedy program abuses,"[40] but (1) AstraZeneca overstates the basis for its apparent concerns about diversion;[41] (2) even if its concerns were valid, Congress directly outlined in the 340B statute how to address such concerns;[42] (3) AstraZeneca and the other drug companies designed their policies to maximize profits by decreasing the amount of available 340B discounts;[43] and (4) AstraZeneca's and the other drug companies' policies are having major, adverse impacts on 340B hospitals and their patients, undermining the structure of the 340B program and Congress's intent.[44] *Amici* addressed these points in their earlier brief but provide additional analysis concerning points (1) and (3) here.

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[39] *See also Amicus* Brief 13–29.

[40] Pl.'s Opening Br. Supp. Mot. Summ. J., No. 21-cv-27-LPS, ECF No. 43 at 5 (capitalization altered).

[41] AstraZeneca makes no reference in its *amicus* brief to concerns about duplicate discounts, but in any event, *Amici* addressed any such unfounded concerns in its earlier brief. *See Amicus* Brief 13–15.

[42] *See id.* at 14–15.

[43] *See id.* at 15–19.

[44] *See id.* at 22–29.

1. *AstraZeneca Overstates Its Concerns of Diversion.*

Although not relevant to whether the statute allows AstraZeneca to attempt to unilaterally address diversion concerns—it does not—AstraZeneca claims that the use of contract pharmacies "inherent[ly]" results in prohibited diversion.[45] This argument misrepresents what qualifies as diversion and how contract pharmacy arrangements work, and is belied by AstraZeneca's own policy, which allows the use of contract pharmacies if a covered entity does not have an in-house pharmacy and which denies 340B discounts regardless of whether the covered entity uses the separate inventory or replenishment model.

Covered entities have used contract pharmacies since the beginning of the 340B program, and certainly well before Congress expanded the program in 2010 without noting even a concern that the use of contract pharmacies constituted diversion. And it makes perfect sense that Congress would not have had such a concern: the statutory prohibition on diversion provides that "a covered entity shall not resell or otherwise transfer [a 340B] drug to a person who is not a patient of the

[45] AstraZeneca Am. Br. 11; *see also id.* at 13 ("[T]he contract pharmacy process entails precisely the sort of diversion that the 340B Statute forbids. The drug is 'transfer[red]' to 'a person who is not a patient of the [covered] entity,'—in fact, it happens twice. The first transfer is to the contract pharmacy, which acquires title and control of the drug and puts the drug into 'the contract pharmacy's own inventory.' The second transfer is to the pharmacy's customer, who may or may not be a patient of the covered entity ('any subsequent patient').") (alterations AstraZeneca's) (citation omitted).

entity."[46] When a covered entity contracts with a pharmacy to dispense its 340B drugs, the contract pharmacy is, on behalf of the covered entity, dispensing the 340B drug to a person who is a patient of the covered entity (or replenishing with a 340B drug the non-340B drug that was initially dispensed to that patient), and thus is acting in a manner consistent with the statute.[47] There is no diversion.[48]

2. *AstraZeneca's Policy Seeks to Maximize Profits at the Expense of 340B Providers and Patients.*

As with Novo Nordisk and Sanofi, AstraZeneca is a highly profitable company whose profits continue to grow.[49] And as with Novo Nordisk and Sanofi,

[46] 42 U.S.C. § 256b(a)(5)(B).

[47] That HHS previously issued prophylactic guidance "insist[ing] that a covered entity must 'maintain title to the drug'" is irrelevant. AstraZeneca Am. Br. 15 (quoting Notice Regarding Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,272–73 (Mar. 5, 2010)). The statute nowhere states that a covered entity must maintain title to the 340B drug, and as noted above, the Supreme Court and Federal Trade Commission have endorsed the use of accounting systems like those used with the replenishment model to ensure that discounts are applied appropriately. *See supra* note 31.

[48] *See also Amicus* Brief 13 n.33 (explaining how "hospitals' use of contract pharmacies has not been accompanied by widespread diversion in the 340B program").

[49] *See* Fred D. Ledley et al., *Profitability of Large Pharmaceutical Companies Compared With Other Large Public Companies*, JAMA (Mar. 3, 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7054843/ (finding that between 2010 and 2018, "the median net income (earnings) expressed as a fraction of revenue was significantly greater for pharmaceutical companies compared with nonpharmaceutical companies (13.8% vs 7.7%)").

AstraZeneca is using its contract pharmacy policy to skirt Congress's policies and increase its profits at the expense of 340B providers and their patients.

Significantly, AstraZeneca is using its policy to evade Congress's inflationary penalty. As explained in *Amici's* earlier *amicus* brief, Congress sought to minimize skyrocketing drug prices by requiring drug companies to pay a penalty when they increase prices on drugs covered by 340B or Medicaid above the rate of inflation.[50] But AstraZeneca's contract pharmacy policy allows it to skirt Congress's scheme. For example, Farxiga—one of AstraZeneca's nominally priced drugs—is one of the company's top selling drugs and is among a handful of drugs primarily responsible for the company's 39 percent increase in U.S. sales in 2021 (up to $12 billion in sales).[51] Indeed, Farxiga has seen a 67 percent revenue growth year-over-year, reaching $1 billion in quarterly sales for the first quarter of 2022.[52] And AstraZeneca's effort to skirt congressional intent is not limited to just one drug: 79

[50] *Amicus* Brief 4; *see also id.* at 16–17.

[51] *What science can do*, AstraZeneca Annual Report and Form 20-F Information 2021, at 36, https://www.astrazeneca.com/content/dam/az/Investor_Relations/annual-report-2021/pdf/AstraZeneca_AR_2021.pdf.

[52] Angus Liu, *AstraZeneca's Farxiga hits $1B quarterly mark, but flagship oncology and China units lag*, Fierce Pharma (Apr. 29, 2022), https://www.fiercepharma.com/pharma/astrazenecas-farxiga-hits-1b-quarterly-mark-flagship-oncology-china-businesses-pull-back.

percent of the total 340B discount for hospitals associated with AstraZeneca's restricted drugs comes from nominally priced drugs.[53]

Importantly, AstraZeneca is not alone: the drug industry's own estimates of program size suggest that more than half of the 340B discount is attributable to manufacturer decisions to increase prices in excess of inflation.[54] By developing a policy that allows it to deny 340B discounts to covered entities, AstraZeneca—and the other drug companies with similar policies—is improperly avoiding that penalty.

[53] Data based on 340B Health analysis of the difference in cost for hospitals under 340B accounts versus 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 settings.

[54] *See* Adam J. Fein, *New HRSA Data: 340B Program Reached $29.9 Billion in 2019; Now Over 8% of Drug Sales*, Drug Channels (June 9, 2020), https://www.drugchannels.net/2020/06/new-hrsa-data-340b-program-reached-299.html (calculations based on industry data on the total discount compared to the statutory discount percentage).

CONCLUSION

For the foregoing reasons, those outlined in the *amicus* brief *Amici* filed in the consolidated cases, and those outlined in HHS's brief, the district court's judgment should be reversed.

Dated: June 28, 2022

Respectfully submitted,

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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 3,910 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
William B. Schultz

CERTIFICATE OF SERVICE

I certify that on June 28, 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 Appellants to be served electronically via the Court's CM/ECF system on all counsel registered to receive electronic notices.

/s/ William B. Schultz
William B. Schultz