Nos. 21-3128, 21-3405

IN THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

ELI LILLY AND COMPANY and LILLY USA, LLC,

Plaintiffs-appellants–cross-appellees,

v.

XAVIER BECERRA, et al.,

Defendants-appellees–cross-appellants.

On Appeal from the United States District Court
for the Southern District of Indiana,
No. 21-81 (Barker, J.).

REPLY BRIEF FOR THE FEDERAL DEFENDANTS

SARAH E. HARRINGTON
Deputy Assistant Attorney General

ZACHARY A. MYERS
United States Attorney

ALISA B. KLEIN
DANIEL AGUILAR
(202) 514-5432
Attorneys, Appellate Staff
Civil Division
U.S. Department of Justice
950 Pennsylvania Ave., NW
Washington, DC 20530

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ARGUMENT

Pursuant to Federal Rule of Appellate Procedure 28.1(c)(4), we limit this reply to the issue presented by our cross appeal.

The district court correctly analyzed the 340B statute "with reference to the statutory context, structure, history, and purpose." SA42 (quotation marks omitted). Based on that well-reasoned analysis, SA37-50, the court concluded that drug manufacturers may not "unilaterally condition or control the availability of their 340B pricing to a particular delivery location of their choosing." SA46-47. That conclusion is consistent with the decades-long understanding that 42 U.S.C. § 256b does not permit drug manufacturers to deny or restrict access to the statutory discounted price for covered entities. And it is consistent with precedent that statutes are not construed to permit regulated entities to evade their obligations through gamesmanship and sharp practices. *See, e.g.*, *County of Maui v. Hawaii Wildlife Fund*, 140 S. Ct. 1462, 1473 (2020) (rejecting an interpretation that would "create such a large and obvious loophole in one of the key" statutory provisions); *Czyzewski v. Jevic Holding Corp.*, 137 S. Ct. 973, 984 (2017) (rejecting an interpretation that would create "a backdoor means to achieve the exact kind of" activity that the statute forbade); *The Emily*, 22 U.S. 381, 390 (1824) (rejecting an interpretation

that would facilitate "evasion of the law"). Accordingly, the district court held that Section 340B "does not permit drug manufacturers, such as Plaintiffs, to impose unilateral extra-statutory restrictions on their offer to sell 340B drugs to covered entities." SA71.

Despite that conclusion, the district court determined that it was appropriate to vacate and remand the enforcement letter for HHS to explain a "change in position regarding its authority to enforce potential violations of the 340B statute connected to contract pharmacy arrangements." SA52. As explained in our principal brief (at 44-46), that conclusion was error: HHS has consistently taken the position that the statute prohibits drug manufacturers from imposing extra-textual restrictions on a covered entities' ability to receive drugs at the 340B price. From the Program's inception, HHS has explained that "manufacturer[s] may not condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions," because the statute's enforcement "is a Federal responsibility." 58 Fed. Reg. 68922, 68925 (Dec. 29, 1993).

To the extent that the district court's vacatur was based on its belief that HHS changed its position on whether it can enforce guidance concerning the 340B program, that too was mistaken. As Eli Lilly

recognizes, HHS does not have general rulemaking authority under the 340B statute. Eli Lilly Response & Reply Br. 16. Thus, HHS has consistently stated that its guidance on covered entity use of contract pharmacies is nonbinding. *See, e.g.*, 61 Fed. Reg. 43549, 43550 (Aug. 23, 1996) (explaining that "these guidelines create no new law and create no new rights or duties"). HHS explained that nonbinding nature when it advised covered entities to use a single contract pharmacy to dispense medications, *id.* at 43550, 43555, and when HHS later advised that covered entities could use multiple contract pharmacies to do so, 75 Fed. Reg. 10272, 10273 (Mar. 5, 2010) (explaining that "[t]his guidance neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities"). But even while nonbinding, this guidance has never given manufacturers carte blanche to impose restrictions on whether and how covered entities can purchase drugs at the statutory discount.

Accordingly, as the enforcement letter correctly explained, the 340B statute prohibits Eli Lilly's unilateral and restrictive policy.

CONCLUSION

The district court's judgment should be reversed insofar as it vacated the enforcement letters and remanded to HHS. The judgment should otherwise be affirmed.

Respectfully submitted,

SARAH E. HARRINGTON
Deputy Assistant Attorney General

ZACHARY A. MYERS
United States Attorney

ALISA B. KLEIN
/s/ Daniel Aguilar
DANIEL AGUILAR
(202) 514-5432
Attorneys, Appellate Staff
Civil Division
U.S. Department of Justice
950 Pennsylvania Ave., NW
Washington, DC 20530

August 2022

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Fed. R. App. P. 32(a) (5) and (6) because it has been prepared in 14-point Georgia, a proportionally spaced font.

I further certify that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 604 words, excluding the parts of the brief exempted under Rule 32(a)(7)(B)(iii), according to the count of Microsoft Word 2016.

/s/ Daniel Aguilar
Daniel Aguilar

CERTIFICATE OF SERVICE

I certify that on August 15, 2022, I filed a copy of this brief with the Clerk of Court for the Seventh Circuit Court of Appeals through the Court's CM/ECF system, which will serve counsel for all parties.

/s/ Daniel Aguilar
Daniel Aguilar