McCarter & English

Daniel M. Silver
Partner
T. 302-984-6331
F. 302-691-1260
dsilver@mccarter.com

McCarter & English, LLP
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, DE 19801-3717
www.mccarter.com

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VIA CM/ECF
The Honorable Leonard P. Stark
United States District Court for the District of Delaware
J. Caleb Boggs Federal Building
844 N. King Street
Unit 26, Room 6124
Wilmington, DE 19801-3555

Re: *AstraZeneca Pharmaceuticals LP v. Becerra, et al.*, C.A. No. 21-27-LPS

Dear Judge Stark:

Plaintiff AstraZeneca Pharmaceuticals LP writes in response to Defendants' notice of supplemental authority, D.I. 106, which addresses the decision of the U.S. District Court for the Southern District of Indiana in *Eli Lilly & Co. v. U.S. Department of Health & Human Services*, No. 21-cv-81 (S.D. Ind. Oct. 29, 2021) (ECF No. 144). AstraZeneca respectfully submits that the *Eli Lilly* decision is inconsistent with this Court's prior ruling and should not affect the Court's resolution of this case.

The *Eli Lilly* decision comprises three holdings.

First, the decision endorses this Court's view that the 340B statute is "silen[t] both as to covered entities' entitlement to utilize unlimited contract pharmacy arrangements and as to any delivery obligations imposed on drug manufacturers." Ex. A to D.I. 106 (*Lilly* Slip Op.) at 34. The *Eli Lilly* decision accordingly vacates the Advisory Opinion because it was "'legally flawed' in its 'unjustified assumption that Congress imposed [the HHS General Counsel's] interpretation as a statutory requirement.'" *Id.* (quoting *AstraZeneca Pharms. LP v. Becerra*, 2021 WL 2458063, at *11 (D. Del. June 16, 2021)).

Second—and contrary to the first holding—the *Eli Lilly* decision holds that the 340B statute precludes manufacturers from imposing restrictions on the delivery of drugs to contract pharmacies. The decision correctly notes that "[t]he 340B statute is silent as to contract pharmacy arrangements and drug manufacturers' delivery obligations." *Id.* at 41 (emphasis omitted). But it then mistakenly proceeds to find, notwithstanding this statutory silence, that a manufacturer's failure to provide discounts for contract pharmacy sales "directly conflicts with the statutory requirement otherwise." *Id.* at 46. The decision concludes: "Construing the 340B statute not to permit drug manufacturers to impose extra-statutory conditions on covered entities' access to discounted medications is . . . the construction that best aligns with congressional intent." *Id.* at 49.

The *Eli Lilly* decision does not explain how the statute's "silence . . . as to any delivery obligations imposed on manufacturers," *id.* at 34, can be reconciled with the view that drug manufacturers who fail to deliver 340B-discounted drugs to contract pharmacies are "impos[ing] extra-statutory conditions," *id.* at 49. The decision also does not acknowledge that drug manufacturers, as private parties, are free to sell their products at the market price unless some statutory provision (or binding regulation) compels them to do otherwise, whereas Defendants may "impose" requirements only when authorized by statute to do so. Nor does the decision reconcile its view that the statute is silent on the contract pharmacy issue with the agency's lack of authority to fill statutory gaps. *See PhRMA v. HHS*, 138 F. Supp. 3d 31, 48 (D.D.C. 2015) (HRSA "was not delegated authority to make binding rules that carry the force of law related to section 340B[(a)(1)].").

More fundamentally, the *Eli Lilly* decision does not identify the text that creates the "statutory requirement" that manufacturers are supposedly violating. Although the decision refers to the 340B statute's "must offer" and "purchased by" language, it does not locate a contract pharmacy requirement in either provision, or in any other statutory text. Indeed, there is no analysis of the meaning of the statute's words at all. Unlike this Court's ruling, the *Eli Lilly* decision does not consider that:

- "Neither the operative provision in § 256b(a)(1) nor the definition of 'covered entity' in § 256b(a)(4) speaks about covered entities' agents although other provisions in the 340B statute do speak about covered entities' affiliates." D.I. 78 at 20.

- "Congress enumerated 15 types of covered entities with a high degree of precision," yet nowhere mentioned contract pharmacies. *Id.*

- Unlike the 340B statute, "another part" the Veterans Health Care Act "refers specifically" to drugs received, stored, and delivered by "'a commercial entity ***operating under a contract*** with [the purchasing] agency.'" *Id.* at 20-21 (quoting 38 U.S.C. § 8126(h)(3)).

- Unlike the 340B statute, another healthcare statute "explicitly covers 'a person authorized to act as a purchasing ***agent*** for a group of individuals or entities who are furnishing services reimbursed under a Federal health care program.'" *Id.* at 21 (quoting 42 U.S.C. § 1320a-7b(b)(3)(C)).

The *Eli Lilly* decision reaches other conclusions that are similarly inconsistent with this Court's ruling. The decision opines that "the agency has consistently espoused the view" that drug manufacturers "must accommodate all contract pharmacy arrangements that the government permits." *Lilly* Slip Op. at 53. That contradicts this Court's view that "the government's position on drug manufacturers' obligations with respect to participation in the 340B Program has ***not*** remained constant but has, instead, materially shifted." D.I. 78 at 12. The *Eli Lilly* decision also disagrees with this Court's view that "[t]he legislative history is of no greater assistance to the

government." *Id.* at 21. In a footnote, the *Eli Lilly* decision refers to an unenacted provision, considered by Congress in connection with the Veterans Health Care Act, that "would have restricted 340B-discounted sales to drugs 'purchased and dispensed by, or under a contract entered into for on-site pharmaceutical services with' a covered entity." *Lilly* Slip Op. at 49 n.15 (quoting S. Rep. No. 102-259 at 1-2 (1992)). But the *Eli Lilly* decision does not acknowledge (as this Court did) that "Congress chose not to include pharmacy services in the version of the bill that it ultimately passed," an "omission suggest[ing] that Congress did not clearly intend to require manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies." D.I. 78 at 21.

Third—and contrary to its second holding—the *Eli Lilly* decision determines that the May 17 letter is arbitrary and capricious because the agency failed to explain its change of position on whether manufacturers may face liability for failing to provide discounts for contract pharmacy sales. *Lilly* Slip Op. at 53-58. Whereas the agency had previously taken the position that "'the 340B statute does not address contract pharmacy use,'" *id.* at 57 (quoting GAO Report), the May 17 letter expresses the view that the agency may "take enforcement action related to drug manufacturers' dealings with covered entities through contract pharmacy arrangements," *id.* at 57-58. The decision accordingly holds that the May 17 letter is "arbitrary and capricious and must be set aside and vacated and the issues remanded to the agency as actions violative of the APA." *Id.* at 58. (The decision does not address that the May 17 letter is arbitrary and capricious for additional reasons identified in AstraZeneca's briefing, including that the letter violates the *Chenery* principle. *See* D.I. 95 at 8-14.)

Finally, AstraZeneca respectfully submits that Defendants' notice of supplemental authority itself underscores why this Court should articulate the best reading of the 340B statute in its ruling on the parties' cross-motions for summary judgment, and should enjoin Defendants from taking further action against AstraZeneca if the Court agrees that the statute does not forbid AstraZeneca's contract pharmacy policy. Defendants assert that, notwithstanding the *Eli Lilly* decision's holding that the May 17 letter is unlawful and must be set aside, if Eli Lilly fails to acquiesce to Defendants' view of the statute, it "will continue to [face] liability," including "the potential imposition of civil monetary penalties already being considered by the Office of the Inspector General and potential termination of its PPA (and a corresponding expulsion from Medicaid and Medicare Part B coverage)." D.I. 106 at 4. Taking Defendants at their word, only a ruling that interprets the statute's meaning, and that orders Defendants not to take further action based on a contrary interpretation, would have any effect on Defendants' conduct, which AstraZeneca contends is not authorized under the law.

Respectfully submitted,

/s/ Daniel M. Silver

Daniel M. Silver (#4758)

cc: All Counsel of Record (via CM/ECF and E-Mail)