UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S., LLC,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Civil Action No. 3:21-cv-634

PLAINTIFF'S RESPONSE TO DEFENDANTS' NOTICE OF SUPPLEMENTAL AUTHORITY

Sanofi-Aventis U.S., LLC ("Sanofi") respectfully submits this response to the government's notice of supplemental authority (ECF 108) regarding the October 29, 2021 decision in *Eli Lilly & Co. v. HHS*, No. 21-cv-81 (S.D. Ind.).[1] The *Lilly* decision supports Sanofi because the court vacated both Advisory Opinion 20-06, which Sanofi challenges in this action, and HRSA's May 17 letter to Eli Lilly & Co. ("Lilly"), which is similar to HRSA's May 17 letter to Sanofi (the "May 17 Letter") also at issue in this action. ECF 108-1 ("*Lilly* Op.") at 3, 61. While the *Lilly* court also ruled that HRSA did not act contrary to law in concluding that Lilly had violated Section 340B, that conclusion was limited to Lilly's specific program and, respectfully, was poorly

[1] On November 2, 2021, Sanofi asked the Court by letter for leave to file a supplemental brief regarding the *Lilly* decision. ECF 107. The government declined to join Sanofi's request, explaining that it did "not think it is necessary to provide supplemental briefing on the *Lilly* decision," *id.* at 1, but then promptly filed a four-page brief (entitled a "notice") with arguments about the import of *Lilly*. Sanofi is now submitting this response so that the Court has the benefit of both parties' views on the matter.

reasoned. This Court should not follow that ruling here, particularly given the unique features of Sanofi's integrity initiative—which is meaningfully different from Lilly's program and is permissible even under the *Lilly* court's interpretation of Section 340B. Given the repeated enforcement threats that HHS has made toward Sanofi, it is imperative that the Court clarify Sanofi's rights and obligations under Section 340B and enter injunctive relief—without which Sanofi will continue to face enforcement actions from HHS, as evidenced by the threats in the government's notice. ECF 108, at 4.

I. The *Lilly* Decision Supports Sanofi's Claims That the Advisory Opinion and May 17 Letter Are Arbitrary and Capricious.

Like the court in *AstraZeneca Pharmaceuticals LP v. Becerra*, No. 21-cv-27-LPS, 2021 WL 2458063 (D. Del. June 16, 2021), the *Lilly* court concluded that Section 340B does not "unambiguously requir[e] drug manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies, if acting as 'agents' of the covered entity." *Lilly* Op. at 34. That is because Section 340B is "silen[t] both as to covered entities' entitlement to utilize unlimited contract pharmacy arrangements and as to any delivery obligation imposed on drug manufacturers." *Id.* The Advisory Opinion is thus arbitrary and capricious because it rests on an "'unjustified assumption' that Congress imposed [the government's] interpretation as a statutory requirement." *Id.* HRSA made the same mistake in its May 17 Letter to Sanofi. ECF 94, at 20–22.

The *Lilly* decision also supports Sanofi's claim that HHS erroneously failed to

account for the agency's previous, inconsistent interpretations of Section 340B. *See id.* at 22–25. As the *Lilly* court held, agreeing with the *AstraZeneca* court, "[t]he agency's view regarding the non-binding nature of its position that drug manufacturers should sell 340B drugs through contract pharmacy arrangements dramatically changed" in the Advisory Opinion, "which for the first time provided that participating manufacturers are obligated by statute to provide 340B discounts to covered entities." *Lilly* Op. at 55. Then, in its May 17 letter to Lilly, HRSA "fail[ed] to acknowledge, never mind explain[,] HRSA's change in position regarding its authority to enforce potential violations of the 340B statute connected to contract pharmacy arrangements." *Id.* at 52; *see also id.* at 56–57. Here as well, Sanofi has challenged both the Advisory Opinion and the May 17 Letter on the basis that the agency ignored its previous, differing interpretations of Section 340B.[2]

II. The *Lilly* Court's Conclusion That HRSA's May 17 Letter Is Not Contrary to Law Is Wrong and Inapplicable to Sanofi.

The *Lilly* court nevertheless concluded that HRSA's letter to Lilly is not contrary to law. This aspect of the *Lilly* court's decision was, respectfully, poorly reasoned, and the Court should not follow it for several reasons.

[2] The government's suggestion (at 4 n.2) that Sanofi did not assert such a challenge to the May 17 Letter is nonsense. *See* ECF 94, at 22–25; *see also* ECF 68-1, at 39–40 (challenging the agency's failure to acknowledge its shifting position on contract pharmacies as arbitrary and capricious); *id.* at 46–47 & n.18 (highlighting HRSA's concession "that it could not enforce any requirement that manufacturers deliver 340B-priced drugs to contract pharmacies" (citing Tom Mirga, HRSA Says Its 340B Contract Pharmacy Guidance Is Not Legally Enforceable, 340B Report (July 9, 2020) (ADVOP_001592–93), and GAO, HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements, at 15–16, GAO-21-107 (Dec. 2020), https://www.gao.gov/assets/gao-21-107.pdf)).

First, the *Lilly* court expressly "limited" its decision to "Lilly's unilaterally adopted policy" and "this specific agency finding in the May 17 Letter." *Lilly* Op. at 35; *see also id.* at 49. Contrary to the government's suggestion, the *Lilly* court did not purport to identify "a general, overarching requirement on behalf of manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies." *Id.* at 35. Indeed, the *Lilly* court emphasized that such a rule does "*not* accurately reflect[]" Section 340B. *Id.* at 45 (emphasis added). Accordingly, the *Lilly* court did not purport to decide that a program like Sanofi's integrity initiative might also violate Section 340B.

Second, there are good reasons to think that the *Lilly* court would find that Sanofi's integrity initiative is consistent with that court's understanding of Section 340B, because Sanofi's program does not "frustrate" the "purposes" of Section 340B. *See id.* at 47. Unlike Lilly's program, which the court emphasized allows delivery of 340B-priced drugs to "only one" contract pharmacy per covered entity, *id.* at 44, 46, 49, 59, Sanofi's program *does not limit* the use of contract pharmacies so long as the covered entity provides minimal claims data—which is used to eliminate duplicate discounts, an express aim of Section 340B. *See* ECF 68-1, at 32–33; ECF 94, at 15–17. There is no evidence that this condition is burdensome, let alone that it "render[s] 340B drugs inaccessible to many covered entities." *Lilly* Op. at 45. The concerns that animated the *Lilly* decision are thus absent with Sanofi's program.

Third, the *Lilly* court's interpretation of Section 340B departs from the statutory text—which, as the *AstraZeneca* decision strongly indicated, does *not* require manufacturers to deliver 340B-priced drugs to contract pharmacies. *See AstraZeneca*, 2021 WL 2458063, at *9–10; ECF 94, at 10–12. The *Lilly* court did not explain how a statute that the court held is "clearly" "silent" (and certainly "not unambiguous[]") about contract pharmacies nonetheless includes a "statutory requirement" that discounted drugs must be provided to contract pharmacies. *Lilly* Op. at 41, 45–46, 59. Nor did the *Lilly* court identify the text that supposedly creates this statutory requirement, or grapple with HHS's lack of authority to fill statutory gaps. *See PhRMA v. HHS*, 138 F. Supp. 3d 31, 36, 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)]").

Instead, based on its assessment of what might "best align[] with congressional intent," *Lilly* Op. at 49, the *Lilly* court added requirements to Section 340B that ignore Congress's careful delineation of the 15 types of entities entitled to receive 340B-priced drugs. The *Lilly* court was candid about its approach, asserting that Lilly's program was impermissible because it would "frustrate" what the court saw as Congress's "purpose," and "would assuredly render 340B drugs inaccessible to many covered entities." *Id.* at 45, 47. Respectfully, this Court should adhere to the statutory text, which does not support the *Lilly* decision.

Dated: November 3, 2021

Respectfully submitted,

s/ Jennifer L. Del Medico

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CERTIFICATE OF SERVICE

I hereby certify that on November 3, 2021, a copy of Plaintiff's Response to Defendants' Notice of Supplemental Authority was filed with the Clerk of the Court by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

Dated: November 3, 2021

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