IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, and LILLY USA, LLC Plaintiffs, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	No. 1:21-cv-81-SEB-MJD

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER

Plaintiffs Eli Lilly and Company and Lilly USA, LLC ("Lilly") have filed a purported emergency motion asking this Court to enjoin a new agency action not challenged in Lilly's complaint, not briefed by the parties, and thus not capable of resolution through the ongoing summary-judgment briefing. That new action consists of a recent violation letter Lilly received from the agency charged with enforcement of the 340B statute. Despite its claims of exigency, Lilly thus far has refused to amend its complaint to vest this Court with jurisdiction over the letter. Lilly's motion should be denied and it should be ordered to amend its complaint so the parties can brief the merits of the new action.

BACKGROUND

The 340B Program, 42 U.S.C. § 256(b), provides discounted medications to safety-net healthcare providers and their uninsured and underinsured patients; its statutory and regulatory background is detailed in Defendants' (collectively, "HHS" or "the Secretary") Motion to Dismiss or for Summary Judgment ("HHS Mot."), ECF No. 88, at 3-9. In that program Congress struck a bargain with drug companies: Manufacturers gain access to coverage for their products under Medicaid and Medicare Part B in exchange for providing discounted drugs (at or below a ceiling price) to certain statutorily defined safety-net providers (called "covered entities"). Congress charged the Secretary of HHS with administration and enforcement of 340B, which the Secretary delegated to the Health Resources and Services Administration ("HRSA"). A manufacturer's failure to comply with its obligation to sell discounted drugs to eligible providers can result in the imposition of civil monetary penalties (CMPs) and/or termination of Medicaid/Medicare coverage for the manufacturer's drugs. Since 1996 HHS has interpreted the statute to *require* manufacturers to honor purchases by covered entities regardless of how they dispense drugs to patients. 61 Fed. Reg. 43,549; HHS Mot. 3-5. This requirement is critical because the majority of safety-net providers do not operate their own, in-house pharmacy, and thus for decades have relied on outside, neighborhood "contract pharmacies" to fill prescriptions for their patients. In 2010 HHS interpreted the statute to allow covered entities to purchase 340B drugs for dispensing through multiple contract pharmacies, while confirming manufacturers' obligation: "if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, *the statute directs the manufacturer to sell the*

drug at a price not to exceed the statutory 340B discount price," regardless whether the covered entity "directs the drug shipment to its contract pharmacy." 75 Fed. Reg. 10,278 (emphasis added); HHS Mot. 5-6.

The present dispute arose in mid-2020 when Lilly led a cohort of six large, global drug makers in an abrupt campaign to upend the twenty-five year operation of the program by restricting access to discounted drugs by covered entities that rely on outside pharmacies. Lilly's policy is more extreme than that of its peers and results in *the denial of* "purchases by" safety-net providers unless they meet restrictive conditions, with no basis in statute, unilaterally imposed by Lilly. HHS Mot. 9. This policy has increased profits for Lilly while dramatically curtailing much-needed funding for safety-net providers and forcing patients to pay more for medications or adjust their medication regimen. *See* Br. Amici Curiae, Nat'l Ass'n of Comm. Health Ctrs. *et al.,* ECF No. 75 at 14-22 (presenting evidence, supported with numerous declarations, of severe consequences to providers and patients accruing from the manufacturers' actions).

Shortly after Lilly announced its restrictions, HRSA explicitly put it on notice that the agency "is considering whether your new proposed policy constitutes a violation of section 340B and whether sanctions apply," "includ[ing], but [] not limited to, civil monetary penalties pursuant to 42 U.S.C. § 256b(d)(1)(B)(vi)." ECF No. 17-9, Adm. Pedley Letter, Aug. 26, 2020. That letter expressly disavowed Lilly's assertion that its plan "did not give rise to any enforceable violation of the 340B statute," and warned Lilly that "the plan would undermine the entire 340B Program and the Congressional intent behind enactment of the 340B statute," while "restrict[ing] access" for "underserved and vulnerable populations" during the global pandemic. *Id.* HRSA confirmed it "continued to examine whether Lilly's actions amount to attempts to circumvent" its statutory obligation "by inappropriately restricting access." *Id.* Unfazed, Lilly proceeded to implement its policy.

While HRSA's review of Lilly's policy proceeded, in response to growing public outcry, HHS's General Counsel (who provides general legal advice to the agency but does not determine 340B enforcement), issued an Advisory Opinion ("AO") confirming his agreement with HRSA's longstanding interpretation that the 340B statute requires manufacturers to *offer* discounted drugs for *purchase by* covered entities, with no qualifications or restrictions on the distribution or dispensing

arrangements selected by the provider. HHS Mot. 22-24. Although the AO did not analyze or determine the legality of any manufacturers' contract-pharmacy policy, Lilly nonetheless attempted to preempt any later enforcement action by HRSA by bringing this suit to challenge the General Counsel's legal advice.

Meanwhile, HRSA's review of Lilly's policy culminated in a new agency action in the form of a 340B-violation letter issued May 17, 2021, directly by HRSA. Letter from D. Espinosa to D. Asay, ECF No. 95-2 ("Violation Letter"). That letter informed Lilly that HRSA "has determined that Lilly's actions have resulted in overcharges and are in direct violation of the 340B statute." *Id.* 1. It relies on statutory text to determine that the requirement that Lilly honor covered entities' purchases "is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs" to its patients, and that "[n]othing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities." *Id.* HRSA directs Lilly to "immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy," and confirms that CMPs may be imposed. *Id.* 2. Although it requests Lilly "provide an update on its plan to restart selling, without restriction," 340B-discounted drugs by June 1, that date is *not* tied to the potential imposition of CMPs. *Id.* On the contrary, although "[c]ontinued failure to provide the 340B price to covered entities utilizing contract pharmacies … may result in CMPs," HHS "will determine whether CMPs are warranted based on Lilly's willingness to comply with its obligations under section 340B(a)(1)." *Id.* HHS thus has not made any determination as to whether sanctions are warranted at all but, should Lilly continue to flout its 340B obligations, any such sanctions will not necessarily be limited to violations that occur after June 1. Importantly, the violation letter does not rest upon—or even reference—the General Counsel's December 2020 legal advice; instead, it culminates the evaluative process Lilly was apprised of in August 2020, months before the AO was issued.

ARGUMENT

HRSA's 340B-violation letter is a new agency action that must be challenged and considered

independently from previous decisions. Lilly's operative complaint challenges legal advice from HHS's General Counsel agreeing generally with prior HRSA guidances on what the 340B statute requires, advice which did not determine the legality of Lilly's restrictions (indeed, it did not impose any new obligations and thus is both time-barred and not reviewable final agency action). HHS Mot. 14-21. By contrast, the violation letter embodies a determination by a different entity altogether—HRSA, the component charged with enforcing Congress's mandate—that Lilly's specific policy is unlawful and may result in sanctions. In its emergency motion Lilly contends that it need not amend its complaint to separately challenge the violation letter. ECF No. 95 ("TRO/PI"), at 11 n. 1. Not so. The APA empowers this Court to review only *agency actions*, not general questions of agency interpretation. Lilly cannot obtain relief (including a TRO) as to an agency action it has not even challenged—*especially* when it seeks to forestall enforcement of a statute Congress charged HHS with administering. *John Doe #1 v. Veneman*, 380 F.3d 807, 819 (5th Cir. 2004) (holding that enjoining agency decision not challenged in complaint "exceed[s] the legal basis for judicial review under the APA" and "constitutes an impermissible advisory opinion"); *Trishan Air, Inc. v. Fed, Ins. Co.*, 635 F.3d 422, 435 (9th Cir. 2011) (claim not challenged in complaint is "not properly before the district court"). Indeed, two of Lilly's peers litigating their own challenges to the AO already have been ordered to amend their complaints to challenge HRSA's violation letter, and HRSA has agreed to promptly produce the administrative record for its decision. *Sanofi-Aventis v. HHS*, No. 3:21-cv-634 (D. N.J.), ECF No. 77 (order to amend complaint); *Novo Nordisk v. HHS*, No. 3:21-cv-806 (D. N.J.), ECF No. 39 (same). This is unsurprising, as it is axiomatic that no jurisdiction exists to issue an injunction based on a motion that "raises issues different from those presented in the complaint." *Sai v. Transp. Sec. Admin.*, 54 F. Supp. 3d 5, 9 (D.D.C. 2014); *see also Clay v. Okla. Dep't of Corr.*, No. CIV-12-1106-C, 2013 WL 3058122, at *2 (W.D. Okla. June 17, 2013). Lilly must amend its complaint before the Court can review HRSA's violation letter.

Relatedly, even were this Court to agree with Lilly that the AO is reviewable *and* that it should be set aside, that would not resolve the merits of HRSA's determination that Lilly is overcharging covered entities. Lilly claims that "the relief Lilly has sought … would preclude Defendants from carrying out their May 17 threats," TRO/PI 11 n. 1, when in truth the relief Lilly seeks would have no

bearing on HRSA's enforcement. Lilly asked the Court to "declar[e] that it would be entirely lawful for Lilly not to offer 340B price discounts to contract pharmacies," Am. Compl., Prayer for Relief b. But as HHS has explained, HHS Mot. 13-14, neither the General Counsel nor HRSA have *ever* interpreted the statute to allow contract pharmacies to receive 340B discounts or otherwise to participate in the program (as opposed to covered entities); Lilly's requested declaration is thus meaningless. In its violation letter HRSA made the specific determination that Lilly overcharges covered entities by denying discounted purchases made through outside-dispensing channels—a determination not encompassed in the AO. HRSA's determination does not rest on the AO, and HRSA's enforcement of the 340B statute would not be impeded by vacatur of the legal advice. The actual dispute between the parties—the legality of Lilly's specific policy—is squarely presented in the 340B violation letter, and must be decided on the basis of new claims challenging HRSA's letter and argumentation on its merits.

This Court should not enjoin HRSA's violation letter even if Lilly amends its complaint.

1. *Lilly will not succeed on the merits of its challenge.*

Even if Lilly amends its complaint to vest this Court with jurisdiction to review HRSA's violation letter, those claims will not succeed on the merits. The letter was issued only after HRSA—the entity that has administered the program for decades—"completed its review of [Lilly's] policy" including "an analysis of the complaints HRSA has received from covered entities." Violation Letter 1. The determination "that Lilly's actions have resulted in overcharges and are in direct violation of the statute," *id.*, is not only consistent with HRSA's interpretation since 1996, *see* HHS Mot. 3-6, 26, but also relies directly on statutory text requiring that Lilly "shall … 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." Violation Letter 1. That straightforward obligation "is not qualified, restricted, or dependent on how the covered entity chooses to distribute" the drugs it purchases to its patients, and no statutory provision authorizes a drug maker to place conditions on its fulfillment of that mandate. *Id.* HRSA also reminded Lilly that it is bound by the terms of the Pharmaceutical Pricing Agreement it signed (*i.e.*, the agreement that enables Lilly's drugs to be covered by Medicare/Medicaid)

and Lilly thus "must ensure that the 340B ceiling price is available to all covered entities." *Id.* HRSA further explained that Lilly's restrictions run afoul of its obligation "to provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered drugs" because Lilly's restrictions prevent covered entities from accessing discounted drugs through the same wholesale channels where drugs are made available for full-price purchase. *Id.* HRSA also relied on existing regulations confirming that "a manufacturer's failure to provide 340B ceiling prices through" existing wholesale distribution agreements will result in CMPs. *Id.* (citing 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017)). Existing regulations also define an "[i]nstance of overcharging" as "any order for a covered outpatient drug … which results in a covered entity paying more than the ceiling price … for that covered outpatient drug." *Id.* (citing 42 C.F.R. § 10.11(b)(2)).

Lilly's claim that, "before the [AO], there was no basis for the government's now-articulated view that it could require manufacturers to provide discounts to an unlimited number of for-profit retail pharmacies," TRO/PI 12, fails for multiple reasons. The violation letter does not require Lilly to provide discounts to *any* pharmacies whatsoever. Equally important is that HRSA's letter *in no way* "bas[e]s" its conclusion on the AO, *contra* TRO/PI 12, and instead relies wholly on the statute itself and the fact that "HRSA has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires manufacturers to honor such purchases regardless of the dispensing mechanism." *Id.* HRSA could not have begun a review of whether Lilly's actions violated *the statute* back in August 2020, ECF 17-9, were there "no basis" for such a determination before the General Counsel opined in December. HRSA (the entity charged with enforcing 340B requirements) has determined that Lilly is overcharging covered entities; its decision was not predicated on the AO and did not even derive from the same administrative process.

And HRSA plainly is correct in its statutory interpretation. In urging this Court to find that it can somehow fulfill its duty to honor "purchases by" covered entities while denying those purchases in many instances, Lilly once again distorts the agency's interpretation as requiring it to *sell discounted drugs to for-profit pharmacies*. Not so. Read "as a whole," *Atlantic Research Corporation*, 551 U.S. at 135, 42 U.S.C. § 256b(a)(1) plainly requires manufacturers to ensure that "the amount required to be paid …

to the manufacturer for covered outpatient drugs … purchased by a covered entity" does not exceed the ceiling price. That language has remained unchanged since the statute's enactment—which, not coincidentally, explains why the 1996 Guidance interpreted the statute just as HRSA does now. AR 371. The "offer" language, added in 2010, codified an *additional* requirement that manufacturers cannot discriminate by prioritizing full-priced purchases over 340B purchases. *See* AR 394. That amendment in no way changed the substance of Lilly's preexisting obligation.

Legislative history forecloses Lilly's argument, too: In 1992 Congress actually considered, but *removed from the statute*, a provision that would have mirrored Lilly's reading. *See* S. Rep. No. 102-259 at 1-2 (proposing to limit 340B-discounted sales to drugs "purchased *and dispensed by*, or under a contract entered into *for on-site* pharmacy services with" a covered entity) (emphasis added). Rather than codify that plain requirement that a covered entity *itself* dispense the drugs—indeed, precisely the restriction Lilly urges this Court to read into the statute—Congress omitted it from the final bill and instead enacted a statute containing no requirement that 340B drugs be dispensed in-house or on-site. Lilly's interpretation is equally incompatible with the Supreme Court's depiction of the pharmaceutical pricing agreements manufacturers sign as "uniform agreements that recite the responsibilities § 340B imposes," including "impos[ing] ceilings on prices drug manufacturers *may charge for medications sold to specified health-care facilities*." *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 113 (2011) (emphasis added); *id.* at 115 ("manufacturers agree to charge covered entities no more than predetermined ceiling prices"). The Court's straightforward pronouncements mirror the agency's interpretation and foreclose Lilly's policy—under which a covered entity is denied 340B discounts (thus paying full price) when the covered entity directs discounted drugs be *shipped to* an outside dispenser. It also defies reason to suggest that, when Congress passed the statute in 1992, it intended discounted drugs to be available solely to the 5% of covered entities that already operated an in-house pharmacy.

Nor did HRSA suggest that it lacked authority to enforce 340B requirements, *contra* TRO/PI 12-14. Lilly selectively edits and rips from context statements in which HRSA acknowledged that it can prosecute only *knowing and intentional* violations by manufacturers; that in no way suggests HRSA is relying on the AO to determine that Lilly's conduct constitutes such a violation.

HRSA agrees with Lilly that "[t]here is no reasonable interpretation of the statute under which manufacturers such as Lilly can be obligated to sell to contract pharmacies." TRO/PI 18. Lilly has no obligation to sell drugs to pharmacies ever, at any price. But continued denial of sales *to covered entities* when those providers dispense drugs through neighborhood pharmacies may result in sanctions.

2. *Lilly has not established any of the equitable factors necessary to obtain injunctive relief.*

Lilly contends it will suffer irreparable harm in the absence of an injunction through "the cost of every discount that Lilly is forced to give to contract pharmacies going forward" "in order to avoid the threat of severe civil monetary penalties." TRO/PI 25. Once again, HRSA has not ordered Lilly to give *any* discounts to contract pharmacies. Regardless how this Court decides Lilly's TRO motion, however, the threat of CMPs will not dissipate. Far from preventing irreparable harm, an injunction *will have no practical impact* on the threat Lilly faces. HHS fully expects to prevail on the statutory-interpretation question, *i.e.*, whether manufacturer-imposed restrictions on covered entities' access to 340B discounts violate the statute. And should the government prevail on the merits, an injunction pending resolution of the dispute *would not prevent the imposition of CMPs once the litigation concludes*, including for the period an injunction was in place. Conversely, in the unlikely event Lilly prevails, no CMPs would be imposed with or without an injunction. Enjoining the agency's enforcement efforts now would be meaningless in practice because the "threat of severe civil monetary penalties," *id.*, will remain so long as Lilly continues to deny purchases by covered entities.[1] Relatedly, Lilly's suggestion that it would suffer irreparable harm should it proceed prudently and suspend its contract-pharmacy restrictions while this litigation proceeds (as it should) is baseless, given that Lilly had complied with the agency's interpretation for decades before it abruptly changed course mid-2020 (and it could always re-impose its restrictions should it prevail). Irreparable harm would not result from Lilly temporarily suspending its non-statutory restrictions and thus *actually* removing the threat of CMPs.

[1] Lilly's June 1 deadline is the date by which it should *communicate to HRSA* its plan to resume honoring all purchases by covered entities. Even if Lilly refuses, any determination regarding sanctions will not be made on June 1. Lilly would receive process before sanctions were imposed, 42 C.F.R. § 10.11(a) (citing 42 C.F.R. Part 1003), and any sanctions imposed would be reviewable by a court. Lilly's claims of exigency in avoiding further agency action defy this reality.

Lilly's contention that HRSA's letter "is political overreach," *id.* 26, ignores the proper functioning of administrative law. HRSA is tasked with enforcing 340B, and the violation letter is the first step in an enforcement action; there is nothing improper in HRSA having concluded that Lilly is violating the statute. It is the role of this Court to review that determination (when properly challenged)—not to decide, in the first instance and before the regulator, what conduct constitutes a violation. In other words, far from a "mid-litigation effort to hijack these proceedings," *id.* 30, as Lilly portrays, the filing of this suit did not place HRSA under any obligation to have the Court pre-approve its enforcement actions. This is particularly true here, where the AO did not determine the merits of Lilly's policy and is not final agency action, so Lilly's complaint itself presented an improper attempt to preempt agency enforcement.[2] Moreover, the determination Lilly still seeks—that, in its words, "manufacturers are *not* required to extend 340B pricing to contract pharmacies," *id.*, would in no way prevent HRSA from imposing CMPs for Lilly's denial of purchases *to covered entities*.

Lilly is equally unable to evidence irreparable harm based on its takings- or procedural-APA claims. Stunningly, Lilly asserts that Congress required it to sell discounted drugs "not for any public purpose" but "for the private gain of third parties." *Id.* 26. Even aside from demonstrating that Lilly's ultimate goal is to blow apart the system that for nearly three decades has provided disadvantaged populations access to costly medications, the suggestion that such a system is intended only for the "private gain" of nonprofits serving the uninsured is farcical. Nor does Lilly's notice-and-comment challenge to the AO, TRO/PI 27, have any relevance; agency enforcement actions certainly are not required to undergo public comment.

Lilly's complaints of "serious reputational injury from the government's unilateral and extrajudicial pronouncement," TRO/PI 28, do not support injunctive relief. Not only is it entirely proper for HRSA, as regulator, to determine unilaterally (in the first instance) what violates the statute it administers, that determination *has been made* and would not be retracted or nullified by an injunction.

[2] Lilly suggests HRSA needed to offer "justification … to make Lilly pay *now*," TRO/PI 26. Again, the filing of a complaint in no way obligates HRSA to pre-clear agency actions with the Court; more importantly, Lilly is not required to "pay," but to sell discounted drugs as required by Congress, and that obligation is urgent given the severe consequences engendered by Lilly's actions.

The "cloud over [Lilly's] hard-earned reputation," TRO/PI 28, will remain so long as Lilly continues to deny purchases by covered entities, and an injunction from this Court would not change HRSA's position that Lilly is non-compliant. And Lilly's insistence that an injunction is warranted to preserve "the status quo," *id.* 30, strains credulity, since the status quo was topped less than a year ago when Lilly and its peers upended the program's twenty-five year settled operation, forcing patients to scramble to afford drugs or find alternates.

Lilly presents a warped view of the balance of harms and the public interest, TRO/PI 28-30. It matters not whether anything "bad will happen to the government if it is forced to wait … before penalizing manufacturers," *id.*, because—contrary to Lilly's insistence—*covered entities and their patients are harmed every day Lilly denies access to discounted drugs*, ECF No. 75 at 14-22, and Lilly has known since last August that HRSA was "considering whether [its] new proposed policy constitutes a violation of section 340B and whether sanctions apply." Lilly's attempt to preempt HRSA's administrative process by challenging the AO does not entitle it to forestall HRSA's performance of its statutory function. And it firmly serves the public interest for this Court to permit the administrative process to play out: HRSA, as regulator, has issued a violation letter, with which Lilly can comply or ignore (thus risking additional sanctions) and this Court can review if Lilly amends its complaint. No authority Lilly provides (and no authority of which undersigned counsel is aware) supports Lilly's attempt to have this Court preemptively enjoin the agency's enforcement process *in totem*. The APA permits this Court only to review agency action—not to forestall enforcement in its infancy.

Finally, Lilly's request that the agency be enjoined from "taking any adverse action against Lilly related to the 340B program based on Defendants' interpretation of the statute," TRO/PI 3, would violate the specificity requirements of Federal Rule of Civil Procedure 65(d). Not only are "adverse action" and "related to" impermissibly vague, it would be impossible for HRSA to determine what such an order prohibited. For example, would internal assessment and consideration of potential CMPs qualify? Or memoranda analyzing the basis for a "knowing" violation? This demonstrates why injunctions of *enforcement proceedings*, as opposed to *agency actions*, are impermissible. This Court should deny Lilly's request for emergency relief.

Dated: May 26, 2021

Respectfully submitted,

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