

**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' UNOPPOSED MOTION FOR AN EXTENSION OF TIME TO FILE
AND TO COMBINE BRIEFING**

Defendants respectfully request that the Court extend the deadline, currently set for June 1, 2021,¹ for Defendants to file their combined reply in support of their motion to dismiss or, in the alternative, for summary judgment and opposition to Plaintiffs' cross-motion for summary judgment to June 4, 2021, and to allow Defendants to combine that brief with their opposition to Plaintiffs' motion for a preliminary injunction. Plaintiffs take no position on Defendants' request. The grounds for this motion are set forth below. A proposed order is attached.

On March 29, 2021, the Court granted the parties' stipulated schedule for briefing dispositive motions on the merits of Plaintiffs' Amended Complaint, ECF No. 85, which challenges (i) the Department of Health and Human Service's Office of General Counsel's Advisory Opinion 20-06 on Contract Pharmacies under the 340B Program (Dec. 30, 2020); and (ii) the Final Administrative

¹ In accordance with the parties' stipulated briefing schedule, the Court ordered Defendants to file their combined reply in support of their motion to dismiss or, in the alternative, for summary judgment and opposition to Plaintiffs' cross-motion for summary judgment on May 31, 2021. Because May 31, 2021, is a legal holiday observed by this Court, Defendants understand the current deadline to fall on June 1, 2021.

Dispute Resolution Rule (Dec. 14, 2020), *see* ECF No. 17. Defendants filed their motion to dismiss or, in the alternative, for summary judgment on April 19, 2021, ECF No. 87, and Plaintiffs filed their combined cross-motion for summary judgment and opposition to Defendants' motion on May 10, 2021, ECF No. 89. Pursuant to the Court's scheduling order, Defendants' combined reply in support of their motion and opposition to Plaintiffs' cross-motion is due by June 1, 2021, *see supra* n.1, after which Plaintiffs' reply in support of their cross-motion will be due by June 14, 2021.

On May 20, 2021, Plaintiffs filed a motion for a preliminary injunction and a temporary restraining order, seeking to enjoin Defendants from taking any action against Plaintiffs "based on Defendants' interpretation of the [340B] statute." ECF No. 94. Plaintiffs' motion specifically requests that the Court "bar[]" Defendants from implementing a new agency action not challenged in Plaintiffs' operative complaint, *id.*—a letter issued by the Health Resources and Services Administration on May 17, 2021, informing Plaintiffs of the agency's determination that their recently imposed restrictions on drug sales to covered entities relying on contract pharmacies violate the 340B statute and may result in the imposition of civil monetary penalties, ECF No. 95-2. On May 21, 2021, the Court ordered Defendants to file any brief in opposition to Plaintiffs' preliminary-injunction motion by June 4, 2021, and that Plaintiffs may file a reply in support of that motion by June 9, 2021. ECF No. 98. The Court further ordered both parties, in advance of the May 27, 2021 hearing on Plaintiffs' motion for a temporary restraining order, to file briefs in support of their respective positions on that motion. ECF No. 97.

Defendants respectfully submit that, due to several recent developments affecting the circumstances contemplated in the present schedule, an extension of the June 1, 2021 deadline to file Defendants' forthcoming brief on the parties' dispositive motions is necessary to adequately address the complex issues of constitutional and administrative law presented in those motions. In addition to Plaintiffs' request for injunctive relief, several other drug manufactures that recently received similar

340B violation letters from HRSA have filed motions for emergency relief in related litigation in other federal courts. *See AstraZeneca Pharmaceuticals LP v. Becerra*, No. 1:21-cv-0027 (D. Del.), ECF No. 66; *Sanofi-Aventis U.S., LLC v. HHS*, No. 3:21-cv-0634 (D.N.J.), ECF No. 72; *Novo Nordisk Inc. v. HHS*, No. 3:21-cv-0806 (D.N.J.), ECF No. 38. Therefore, Defendants' counsel have been under multiple, unexpected deadlines to respond to a raft of emergency motions and prepare for hearings, while also briefing dispositive motions in each of those related cases.

Furthermore, Defendants respectfully suggest that combining their forthcoming brief on the parties' dispositive motions with their opposition to Plaintiffs' preliminary-injunction motion will enable Defendants to present argument for the Court in the most efficient, non-duplicative manner possible. Plaintiffs' preliminary-injunction motion seeks relief from a new agency action that squarely presents the question Plaintiffs have sought to resolve through their challenge to the Advisory Opinion: Whether Plaintiffs' contract-pharmacy restrictions violate the 340B statute's prohibition on overcharging covered entities. Plaintiffs' request for preliminary relief thus presents overlapping contentions on this question of statutory interpretation resting on the arguments they have asserted as grounds for relief from the Advisory Opinion. Moreover, Plaintiffs' preliminary-injunction motion devotes considerable space directly addressing those threshold and merits arguments made in Defendants' motion to dismiss or, in the alternative, for summary judgment. *See* ECF No. 95 at 12–25. Accordingly, the arguments Defendants will present in defense of HRSA's new agency action will overlap and intertwine with the arguments asserted in Defendants' briefing on the parties' dispositive motions. Defendants thus believe combined briefing will avoid this unnecessary duplication and most efficiently present the matters to the Court.

Defendants appreciate the Court's consideration and respectfully request entry of the attached proposed order. In the alternative, if the Court denies Defendants' request to combine the remaining briefing, Defendants respectfully request that the Court extend Defendants' reply deadline to coincide

with the deadline to oppose Plaintiffs' preliminary injunction on June 4, 2021.

Dated: May 26, 2021

Respectfully submitted,

BRIAN D. NETTER
Deputy Assistant Attorney General

MICHELLE R. BENNETT
Assistant Branch Director

/s/ Kate Talmor
KATE TALMOR
RACHAEL WESTMORELAND
JODY D. LOWENSTEIN
Trial Attorneys
U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, N.W.
Washington, D.C. 20005
(202) 305-5267
kate.talmor@usdoj.gov
Attorneys for Defendants

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PROPOSED ORDER

Upon consideration of Defendants' Motion for an Extension of Time to File and to Combine Briefing, the Court hereby GRANTS Defendants' motion. Defendants shall file their combined reply in support of their motion to dismiss or, in the alternative, for summary judgment and opposition to Plaintiffs' cross-motion for summary judgment on or by June 4, 2021, which may be combined in a single brief with Defendants' opposition to Plaintiffs' motion for a preliminary injunction.

SO ORDERED.

Dated: _____

Signed: _____
The Honorable Sarah Evans Barker

Order served on all counsel of record via ECF