IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Plaintiff, vs. XAVIER BECERRA, et al. Defendants.	Civil Action No. 8:21-cv-198-DLB

JOINT STATUS REPORT AND JOINT MOTION TO STAY PROCEEDINGS

In light of the Court's Letter Order dated February 15, 2023, counsel for Plaintiff Pharmaceutical Research and Manufacturers of America (PhRMA) and counsel for Defendants Xavier Becerra, *et al*., have met and conferred.

In addition to providing the below joint status report, the parties jointly request that this Court stay further proceedings in this matter pending the conclusion of an ongoing rulemaking proceeding that the Department of Health and Human Services (HHS) and its Health Resources and Services Administration (HRSA) have initiated. *See* 87 Fed. Reg. 73,516 (Nov. 30, 2022). The notice of proposed rulemaking "proposes to revise the current 340B administrative dispute resolution (ADR) final rule." *Id.* at 73, 516. The parties anticipate that, when the rulemaking proceeding concludes, they will be able to advise the Court regarding appropriate next steps.

I. In Light Of The Ongoing 340B ADR Rulemaking Proceeding, The Parties Jointly Request A Temporary Stay.

As the Court is aware, HHS and HRSA initiated a new rulemaking proceeding by issuing a Notice of Proposed Rulemaking late last year that proposes changes to the current ADR rule. *See* 87 Fed. Reg. 73,517 (Nov. 30, 2022). The deadline to submit comments on the proposed rule was January 30, 2023; the agency received 112 comments, including from PhRMA and many of its members. Counsel for Defendants have stated to counsel for PhRMA, and represent to this Court, that the agency is diligently reviewing those comments and working to issue a final rule; however, it is currently unclear how long that process will take.

In light of the representation that the agency is working diligently to issue a final rule, the parties respectfully submit that considerations of judicial economy warrant a temporary stay at this time, without prejudice to either side. "A district court has broad discretion to stay proceedings as part of its inherent power to control its own docket." *Hunt Valley Baptist Church, Inc. v. Baltimore Co., Md.*, No. 1:17-cv-804, 2018 WL 1570256, at *2 (D. Md. Mar. 29, 2018). "[C]ourts consider the length of the requested stay and whether proceedings in another matter involve similar issues." *Buas Sands Hotel, LLC v. Liberty mut. ins. Co.*, No. 21-cv-1214, 2021 WL 4310956, at *5 (D. Md. Sept. 22, 2021). Here, a stay would preserve judicial and party resources because the agency has proposed to change the rule that PhRMA challenges in this litigation, and, once the agency issues a final rule, the parties can evaluate and present to the Court any remaining disputes.

Accordingly, the parties jointly request that the Court stay proceedings in this case pending conclusion of the agency's currently ongoing rulemaking proceeding. The parties further propose to submit joint status reports every 90 days, updating the Court on the status of the rulemaking proceeding, or on an interim basis as events may warrant. If the Court issues the proposed stay, each party reserves the right to ask the Court to lift the stay if the party believes such relief to be warranted. Each party also reserves the right to oppose any such request.

II. The Parties Do Not Believe Supplemental Briefing Is Needed At This Time.

PhRMA states: As the Court is also aware, the parties completed briefing on their cross-motions for summary judgment in this case in October 2021. In May 2022, the parties submitted supplemental briefing on *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs.*, 570 F. Supp. 3d 129 (D.N.J. 2021), which the Third Circuit recently affirmed in part and reversed in part. *See* 58 F.4th 696 (3d Cir. 2023). PhRMA's position is that the Third Circuit's decision does not directly impact the challenge to the current ADR rule before this Court.

The *Sanofi-Aventis* appeal addressed two primary merits issues. First, the Third Circuit considered the validity of certain contract pharmacy policies adopted by the pharmaceutical manufacturers who were parties to that case. On that issue, the Third Circuit held that the "restrictions on delivery to contract pharmacies do not violate Section 340B." 58 F.4th at 706. The Third Circuit "enjoin[ed] HHS from enforcing against [the plaintiffs] its reading of Section 340B as requiring delivery of discounted drugs to an

unlimited number of contract pharmacies." *Id.* While the contract pharmacies issue is part of the context of the case before this Court (as addressed in the parties' summary-judgment briefing), the Third Circuit's ruling on that issue does not affect PhRMA's specific challenges to the current ADR rule. Second, the Third Circuit considered but rejected Sanofi's argument that the current ADR rule violates the Administrative Procedure Act's notice-and-comment requirements because it was improperly finalized after first having been "withdrawn." *See id.* at 706–07. That ruling does not affect this case: PhRMA's challenges to the current ADR rule in this case do not raise the notice-and-comment argument addressed in *Sanofi*, and, instead, rest on other grounds.

This Court's Letter Order also observed that related litigation was filed in the Southern District of Indiana. In that litigation, plaintiff Eli Lilly challenged (1) Defendants' advisory opinion and violation letter sent to Eli Lilly regarding Eli Lilly's policy on contract pharmacy transactions, and (2) the current ADR rule. *Eli Lilly & Co. v. Cochran*, 526 F. Supp. 3d 393, 404 (S.D. Ind. 2021). The district court has issued a partial final judgment vacating the violation letter. Appeals from that ruling are currently pending before the Seventh Circuit, No. 21-3405, which heard oral argument on October 31, 2022. With respect to Eli Lilly's challenge to the ADR rule, the district court has not yet issued a final judgment on the merits. On a motion for preliminary injunction, however, the court addressed Eli Lilly's notice-and-comment argument that parallels the argument rejected by the Third Circuit in *Sanofi*. *Eli Lilly*, 526 F. Supp. 3d at 405–08. The district court held that Eli Lilly was likely to succeed on the merits of this argument and

granted a preliminary injunction. *Id.* at 410. The district court did not reach Eli Lilly's other grounds for challenging the ADR rule, including an Appointments Clause argument. *See* 526 F. Supp. 3d at 407–08. The rulings in the Eli Lilly litigation to date thus likewise do not affect PhRMA's specific challenges to the current ADR rule.

Finally, there are cases raising similar contract pharmacy issues in the D.C. Circuit and District Court for the District of Columbia. In *Novartis Pharms. Corp. v. Espinos*a, No. 21-cv-1479, 2021 WL 5161783, at *9 (D.D.C. Nov. 5, 2021), the district court vacated violation letters issued by HRSA to drug manufacturers Novartis and United Therapeutics, reasoning that the manufacturers' contract pharmacy "policies do not violate Section 340B under the positions advanced in the Violation Letters and developed" during litigation. An appeal from that decision is currently pending before the D.C. Circuit, Nos. 21-5304 and 21-5299, which heard oral argument on the appeal on October 24, 2022. Other cases raising similar contract pharmacy issues in the D.C. District Court are stayed pending that appeal. As with the other cases, the rulings in the Novartis and United Therapeutics litigation do not affect PhRMA's specific challenges to the current ADR rule. For the foregoing reasons, PhRMA's position is that further supplemental briefing is not needed at this time.

Defendants state: Defendants agree with PhRMA that the opinions cited above do not directly impact the issues raised in this suit and agree with PhRMA that, in light of the parties' request that further proceedings be stayed pending issuance of a final rule, supplemental briefing is not needed at this time.

Date: February 24, 2023

Respectfully submitted,

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