

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**

In light of the Court's Letter Order dated February 27, 2023, counsel for Plaintiff Pharmaceutical Research and Manufacturers of America (PhRMA) and counsel for Defendants Xavier Becerra, *et al.*, submit this Joint Status Report.

The Court's February 27, 2023 Letter Order granted the parties' request to stay this case "pending completion of the defendants' ongoing rulemaking proceeding relating to the 340B administrative dispute resolution rule." ECF No. 51. In the August 24, 2023 Joint Status Report, the Department of Health and Human Services (HHS) and the Health Resources and Services Administration (HRSA) stated that they were aiming to finalize the ADR rule by the end of 2023, as reflected in the Unified Agenda.<sup>1</sup> In the November 22, 2023 Joint Status Report, Defendants stated that the ADR rule was received by the

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<sup>1</sup> See Office of Information & Regulatory Affairs, 340B Drug Pricing Program: Administrative Dispute Resolution, RIN 0906-AB28 (Spring 2023), <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202304&RIN=0906-AB28>.

Office of Management and Budget on October 16, 2023, and that the ADR rule was pending regulatory review pursuant to Executive Order 12866.<sup>2</sup>

At this time, Defendants state that the ADR rule remains pending regulatory review and that the rulemaking process is ongoing. The parties anticipate that, when the rulemaking proceeding concludes, they will be able to advise the Court regarding appropriate next steps.

The parties will submit another Joint Status Report on May 20, 2024, unless the Court orders otherwise.

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<sup>2</sup> See Office of Information & Regulatory Affairs, Office of Management & Budget, 340B Drug Pricing Program: Administrative Dispute Resolution, RIN 0906-AB28 (Oct. 16, 2023), <https://www.reginfo.gov/public/do/eoDetails?rrid=341562>.

Date: February 20, 2024

/s/ Jody D. Lowenstein

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Respectfully submitted,

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