U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, NW
Washington, DC 20005

May 25, 2021

VIA ECF

The Honorable Paul W. Grimm
United States District Judge
District of Maryland
6500 Cherrywood Lane
Greenbelt, MD 20770

Re: *Pharmaceutical Research and Manufacturers of America v. Becerra, et al.*, No. 8:21-cv-00198-PWG (D. Md.)

Dear Judge Grimm:

Pursuant to the Court's Order of May 17, 2021, ECF No. 21, as well as the Court's Letter Order Regarding the Filing of Motions, ECF No. 5, the parties write jointly to propose a revised briefing schedule addressing dispositive motions and a potential motion to supplement or correct the administrative record, as well as the parties' proposal regarding the submission of exhibits.

Plaintiff Pharmaceutical Research and Manufacturers of America ("PhRMA") filed this suit on January 22, 2021 challenging the U.S. Department of Health and Human Services' ("HHS") final rule, 340B Drug Pricing Program; Administrative Dispute Resolution Regulation ("ADR Rule"), 85 Fed. Reg. 80632 (Dec. 14, 2020), as arbitrary and capricious, contrary to law, and unconstitutional. Following a status conference, by order dated May 17, 2021, the Court directed the parties to submit a joint proposal regarding dispositive motions briefing by May 26, 2021.

The parties agree this action can be decided most efficiently through cross-motions presenting pure questions of law. The parties also agree that there is no need for Defendants to file an answer in this matter. The parties may have a disagreement regarding the scope and contents of the administrative record, although after meeting and conferring regarding the issues, the parties believe they may be able to resolve those issues without the need for briefing.

Accordingly, pursuant to the Court's May 17 Order, the parties respectfully request that the Court adopt the following schedule for proceedings in this case:

- Defendants will produce the materials that they believe constitute the administrative record and file an opening brief of no more than 35 pages moving to dismiss or, in the alternative, for summary judgment on June 11, 2021.

- If, following review of the record and brief that Defendants submit, Plaintiff believes it is necessary to file a motion to correct or supplement the administrative record, it will file such a motion, not to exceed 10 pages, on or before June 25, 2021; Defendants will file an opposition, not to exceed 10 pages, on or before July 9, 2021; and Plaintiff will file a reply, not to exceed 5 pages, on or before July 23, 2021. The filing of such a motion by Plaintiff will suspend the schedule for briefing dispositive motions until this Court resolves the dispute. That schedule will resume as follows:

- Within 45 days after the motion to correct or supplement the administrative record is resolved, Plaintiff will file a combined Opposition to Defendants' Motion/Cross-Motion for Summary Judgment of no more than 45 pages;

- 45 days thereafter, Defendants will file a brief a combined Reply in Support of their Motion/Opposition to Plaintiff's Cross-Motion of no more than 30 pages;

- 30 days thereafter, Plaintiffs will file a Reply of no more than 20 pages in support of its motion for summary judgment.

If Plaintiff does not file a motion to correct or supplement the administrative record, then the following schedule applies to the foregoing briefs:

- Plaintiff's combined Opposition/Cross Motion due July 26, 2021

- Defendants' combined Reply/Opposition due September 9, 2021

- Plaintiff's Reply due October 12, 2021.

- On the same day that Plaintiff submits a reply in support of its motion for summary judgment, the parties will jointly submit a tabbed appendix containing the excerpts of the administrative record that are most pertinent to their dispositive motions, including highlighting the most relevant passages of each excerpt, in order to facilitate efficient review by the Court.

- Oral argument on the motions will be set at the Court's discretion following the close of briefing.

In this proposal, the parties are mindful of the Court's remarks regarding the importance of presenting issues as concisely and efficiently as possible. In order to avoid any repetition of arguments or unnecessary length, the proposed page limits are roughly 30% lower than the limits provided by local rule. At the same time, the parties believe that the jointly proposed limits will enable them to fully develop and present argument for the Court on the complex administrative law and constitutional issues raised by Plaintiff's Complaint.

Because this case presents claims that should be decided as questions of law, the parties request that they be excused from providing a statement of material facts not in dispute. The parties also request that the Court vacate Defendants' obligation to answer Plaintiff's Complaint.

The parties appreciate the Court's consideration.

Sincerely,

/s/ Joseph R. Guerra
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APPROVED BY THE COURT
May 27, 2021
_____/s/_____
Paul W. Grimm
U.S. District Judge