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By Electronic Filing

Hon. Zahid N. Quraishi
United States District Judge
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street Room 2020
Trenton, NJ 08608

Re: Argument in Nos. 23-cv-3335, 23-cv-3818, 23-cv-14221, and 23-cv-20814

Dear Judge Quraishi:

Pursuant to this Court's February 7, 2024 minute order, Plaintiffs and Defendants (together, the "Parties") in Nos. 23-cv-3335 (*Bristol Myers Squibb Co. v. Becerra et al.*), 23-cv-3818 (*Janssen Pharmaceuticals, Inc. v. Becerra et al.*), 23-cv-14221 (*Novartis Pharmaceuticals Corp. v. Becerra et al.*), and 23-cv-20814 (*Novo Nordisk Inc. et al. v. Becerra et al.*) submit this letter regarding oral argument in the above-captioned cases.

The Parties met and conferred (by e-mail and by video conference on February 12, 2024) and determined that they have differing positions regarding how and when the argument should proceed. Accordingly, this letter contains two sections—one setting out Plaintiffs' proposal and another setting out Defendants' proposal.

PLAINTIFFS' PROPOSAL

1. Dates for the Argument. Plaintiffs are available on March 7 and March 8, and propose that the Court hear argument in all four cases on one of those dates. Although Plaintiffs raise various claims, hearing all of the cases together on the same day would maximize the efficiency of the oral argument, given the overlapping nature of the claims asserted and certain common defenses to those claims.

Plaintiffs oppose Defendants' proposed format, under which *Bristol Myers* and *Janssen* would be argued in March, while *Novartis* and *Novo Nordisk* would be argued at a later date. According to Defendants, bifurcation is appropriate because Defendants' *Novartis* and *Novo Nordisk* reply briefs are not due until March 27 and March 22, respectively. That rationale has three shortcomings:

- *First*, it is difficult to square Defendants' approach with the Court's order, which directs the parties to propose argument dates and a schedule for all four cases, not just two of them.

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- *Second*, there is no need to postpone the argument for Defendants' reply briefs. Although the Parties' briefing schedules contemplate that Defendants may file a reply, Defendants have not cross-moved for summary judgment on independent claims, but instead have generally asserted *defenses* to the claims raised by *Plaintiffs*. Defendants fully addressed those defenses in their answering briefs, filed in January. If Defendants believe there are any new arguments raised by Plaintiffs in their reply briefs, they can address those issues during the oral argument or in post-argument briefing if the Court so desires. Alternatively, Defendants could file their reply briefs before the oral argument. The final Plaintiff-side briefs in *Novartis* and *Novo Nordisk* will be filed by February 23, roughly two weeks before the proposed hearing dates, leaving sufficient time for Defendants to file their replies before the hearing on any issues that have not already been fully briefed.
- *Third*, Defendants' bifurcated approach would be inefficient and would needlessly burden the Court and prejudice Plaintiffs. Hearing the cases on separate dates would result in duplication of the arguments on overlapping issues. (Although *Novartis* and *Novo Nordisk* involve some issues not presented in the other cases, Defendants have asserted largely the same defenses in all four cases and the Court would benefit from considering all of the claims at the same time.) Splitting up the arguments would also prejudice the Plaintiffs because each argument would address common issues without the participation of two of the Plaintiffs. Hearing all the cases together on a single date would avoid these problems.

2. Schedule for the Argument. Plaintiffs propose that the Court hold argument from 10:00 am to 2:00 pm on a single day. In Plaintiffs' view, four hours of argument is warranted because the argument will involve four separate cases that together assert at least seven constitutional and statutory challenges to the Inflation Reduction Act's Drug Price Negotiation Program and its implementing regulations. The issues presented in these cases are complex and present novel questions arising under a recently enacted federal statute.

To avoid repetition and maximize efficiency, Plaintiffs propose to divide the argument among the different issues. One attorney on each side (i.e., one attorney for all plaintiffs and one attorney for all defendants) would present argument on each issue, and the time allocated to each issue would be divided equally between Plaintiffs and Defendants. Plaintiffs further propose to group these issues into morning and afternoon sessions, separated by a short break, as follows:

MORNING SESSION

(10:00 am – 12:00 pm)

- This session would cover the takings claims, voluntariness defenses, and the unconstitutional conditions doctrine – 120 minutes (60 per side).
- Plaintiffs would begin with a brief introduction and then divide their joint presentation into three segments, each argued by a separate attorney: (1) Plaintiffs' affirmative argument that the Program constitutes a physical taking under the Fifth Amendment; (2) Plaintiffs' argument that the voluntariness doctrine invoked by Defendants does not apply to takings claims; and (3) Plaintiffs' alternative arguments that the Program is not voluntary, and in any event violates the unconstitutional conditions doctrine.
- At the end of Plaintiffs' presentation, Defendants would argue the issues described above.
- Plaintiffs would have 10 minutes of rebuttal, covering all of the issues in this session.

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- This framework would track the briefing, avoid repetition, and ensure that each of the Plaintiffs that has asserted a takings claim (Bristol Myers, Janssen, and Novartis) has an opportunity to address one aspect of the takings issue and the defenses Defendants have raised on that issue. Although the voluntariness and unconstitutional conditions points are also relevant to some of the other claims and have been raised by Defendants in all four cases, it makes sense to address them together with the takings claims given their cross-cutting application.

AFTERNOON SESSION

(12:10 pm – 2:00 pm)

- This session would cover the remaining constitutional claims and also the separate statutory arguments challenging CMS's actions. Each issue would be argued by a separate attorney and Plaintiffs would have the option to reserve a portion of their time for rebuttal.
- First Amendment claims in all four cases – 30 minutes (15 per side).
- Eighth Amendment claim in *Novartis* – 20 minutes (10 per side).
- Separation of Powers and Due Process claims in *Novo Nordisk* – 20 minutes (10 per side).
- Statutory challenges to CMS's actions in *Novo Nordisk* – 40 minutes (20 per side).

DEFENDANTS' PROPOSAL

Defendants are available to present argument in *Bristol Myers* and *Janssen* any day between March 5, 2024 and March 8, 2024—the dates the Court has indicated it is available. These matters have been fully briefed by the parties and Defendants believe these matters can now be set for argument at the Court's convenience.

The parties have not, however, completed summary-judgment briefing in the other two cases—*Novartis* and *Novo Nordisk*. Pursuant to the scheduling order that the Court entered, Plaintiffs in *Novartis* will submit their summary-judgment response brief on February 23, 2024 and Defendants have until March 27, 2024 to submit their reply. *Novartis Pharmaceuticals Corp. v. Becerra*, No. 23-cv-14221-ZNQ-JBD, ECF No. 20 (Dec. 21, 2023). Similarly, Plaintiffs in *Novo Nordisk* will submit their summary-judgment response brief on February 23, 2024, and Defendants' reply is due on March 22, 2024. *Novo Nordisk, Inc. v. Becerra*, No. 23-cv-20814-ZNQ-JBD, ECF No. 24 (Nov. 28, 2023).

Defendants do not believe it is necessary, efficient, or appropriate for the parties to conduct argument in these two other matters before the parties have an opportunity to finish briefing their respective dispositive motions. Indeed, given the significance of these cases and the nature of Plaintiffs' claims, Defendants believe they would be prejudiced by being deprived of an opportunity to submit replies in support of their cross-motions for summary judgment before the Court hears argument. Further, depriving Defendants of an opportunity to finish briefing their dispositive motions before argument would be highly unusual in a summary-judgment posture—and is especially unnecessary given that Plaintiffs have not requested emergency relief nor moved to modify the briefing schedule to which the parties had previously agreed. Accordingly, Defendants respectfully request that the Court defer argument in *Novartis* and *Novo Nordisk* until briefing has been completed.

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Defendants note that proceeding with oral argument in *Bristol Myers* and *Janssen* while briefing is completed in the other two matters will offer appreciable benefits. As the Court is aware, the issues in *Bristol Myers* and *Janssen* overlap completely—so much so that Defendants submitted consolidated briefs in those cases. By contrast, *Novartis* and *Novo Nordisk* introduce a number of new issues and claims—including threshold questions of constitutional and statutory jurisdiction, as well as distinct statutory and constitutional claims—that are not present in *Bristol Myers* and *Janssen*. Accordingly, Defendants believe it would be easier for the parties and the Court to separate the two sets of lawsuits into separate arguments, presented on separate days.

Defendants understand that Plaintiffs oppose this approach and believe that the Court's order directs the parties to make themselves available for argument in all four cases at the beginning of March notwithstanding the fact that briefing will not yet be completed in *Novartis* and *Novo Nordisk*. Defendants do not share that interpretation and, respectfully, do not believe that the Court intended to schedule oral argument in the middle of summary-judgment briefing, or otherwise abrogate the briefing schedules set by the Court without an explicit order so stating.

Defendants will, of course, make themselves available to present argument consistent with whatever order the Court issues. For the reasons set forth above, however, Defendants believe that the Court should defer argument in *Novartis* and *Novo Nordisk* until after March 27, 2024, when briefing is completed in those matters. Defendants do not otherwise object to the format for the argument that Plaintiffs articulate in subsection 2 of their proposal if the Court decides to hold argument in all four cases together after all summary judgment briefing is complete.

Respectfully submitted,

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