

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

NATIONAL INFUSION CENTER
ASSOCIATION *et al.*,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., in his official
capacity as Secretary of Health and Human
Services, *et al.*,

Defendants.¹

Case No. 1:23-cv-00707-DAE

**DEFENDANTS' MOTION FOR TEMPORARY STAY OF SUMMARY-JUDGMENT
BRIEFING PENDING CONSIDERATION OF MOTION TO EXCLUDE**

Defendants in the above-captioned matter respectfully request that the Court temporarily stay briefing on the parties' cross-motions for summary judgment pending consideration of Defendants' motion to exclude the Garthwaite Declaration, ECF No. 61, which Defendants filed earlier today. As good cause for this request, which Plaintiffs oppose, Defendants offer the following:

BACKGROUND

1. Plaintiffs filed this lawsuit on June 21, 2023. ECF No. 1. Plaintiffs bring a facial constitutional challenge to certain provisions of the Inflation Reduction Act, which was signed into law on August 16, 2022.

2. On August 28, 2023, sixty days after service on the U.S. Attorney, *see* Fed. R. Civ. P. 12(a)(2), Defendants moved to dismiss, ECF No. 39. Defendants simultaneously moved to vacate the then-existing scheduling order. ECF No. 40. Judge Pitman granted the motion to vacate on

¹ Pursuant to Federal Rule of Civil Procedure 25(d), Robert F. Kennedy, Jr., Secretary of Health and Human Services, is automatically substituted as a defendant in his official capacity for his predecessor, Xavier Becerra. Stephanie Carlton, Acting Administrator of the Centers for Medicare & Medicaid Services, is likewise automatically substituted as a defendant in her official capacity for her predecessor, Chiquita Brooks-Lasure.

September 11, 2023, among other reasons because doing so “will promote judicial efficiency” and “the prejudice to Plaintiffs is comparatively small.” ECF No. 45.

3. On February 12, 2024, this Court granted Defendants’ motion to dismiss Plaintiff National Infusion Center Association (NICA)—the only Plaintiff that resides in Texas—for lack of subject-matter jurisdiction under Rule 12(b)(1), and then dismissed the entire case (without prejudice) for lack of venue under Rule 12(b)(3). ECF No. 53. Rather than immediately refile in another venue or amending their complaint in this Court, Plaintiffs appealed.

4. On September 20, 2024, a divided panel of the Fifth Circuit reversed and remanded for further proceedings in this Court. *See Nat’l Infusion Ctr. Ass’n v. Becerra*, 116 F.4th 488 (5th Cir. 2024). The mandate issued on November 12, 2024. *See Mandate, Nat’l Infusion Ctr. Ass’n v. Becerra*, No. 24-50180, Dkt. No. 82-2 (5th Cir. Nov. 12, 2024).

5. On December 18, 2024, the parties filed a joint scheduling motion. ECF No. 58. That motion presented the parties’ agreed-upon dates for summary-judgment briefing. It also included the following statement from Defendants, explicitly reserving their rights with respect to the schedule and its relationship to Plaintiffs’ apparent desire to rely on an expert declaration:

Defendants also note that the parties have conferred regarding Plaintiffs’ intent to attach an expert declaration to their forthcoming motion for summary judgment. Defendants do not seek any relief on that issue at this time. Nevertheless, Defendants will review Plaintiffs’ filing when it comes in, and reserve their rights to object or otherwise request any appropriate relief from the Court—including, specifically, relief that may disrupt this otherwise agreed-upon briefing schedule (*e.g.*, by requesting a pause in briefing to allow for expert discovery, submission of expert testimony from the government, a motion to strike or preclude consideration of the declaration, or some combination thereof).

Id. ¶ 8.

6. On January 6, 2025, Magistrate Judge Hightower entered an order (1) granting (in substantial part) the parties’ joint scheduling motion and (2) “return[ing] it to the docket of the Honorable David A. Ezra.” ECF No. 59.

7. Plaintiffs filed their summary-judgment motion on January 10, 2025. ECF No. 60. That motion included, as Exhibit 1, the Expert Declaration of Professor Craig Garthwaite. ECF No. 60-1. Plaintiffs' summary-judgment brief cites or quotes from the Garthwaite Declaration several dozen times.

8. Under the current schedule, Defendants' combined opposition and cross-motion for summary judgment is due on March 7, 2025. ECF No. 59.

ARGUMENT

9. Plaintiffs rely heavily on a purported expert declaration that is inadmissible, for the reasons explained in detail in Defendants' motion to exclude. In short, the Garthwaite Declaration fails to satisfy the Federal Rules of Evidence: (1) it is not "help[ful]" to the Court, and (2) it does not reliably apply any "reliable principle[] [or] method[]." Fed. R. Evid. 702. Those failings are presumably why, in the ten cases challenging the Medicare Drug Price Negotiation Program pending throughout the United States, this is the only one in which any party seeks to rely on any expert testimony. Accordingly, Defendants have moved to exclude the Garthwaite Declaration, in a motion filed earlier today. ECF No. 61.

10. Simultaneously, Defendants have also started preparing portions of their forthcoming summary-judgment brief, which is currently due on March 7, 2025. But that important project is hampered significantly by the fact that the brief to which Defendants are responding may be a moving target. If the Court grants Defendants' pending motion to exclude, then Defendants need not respond to the Garthwaite Declaration at all. On the other hand, if the Court denies Defendants' motion to exclude, then Defendants will have little choice but to respond to the Garthwaite Declaration—which is 78 pages long (not counting the appendices) and is heavily featured in Plaintiffs' brief. Indeed, Plaintiffs cite to that declaration several dozen times, and in every section of their brief.

11. In fact, if the Court concludes that the Garthwaite Declaration is admissible, Defendants may find it necessary to protect their rights by retaining their own expert (if they are able to do so in time), to make a full record on these issues, including for a possible appeal. Hiring an expert for litigation on behalf the federal government is a complicated and administratively intensive

process, in the best of times—and it is even more challenging given the realities of the current budget environment at the Department of Justice and the Department of Health and Human Services. Given the quickly approaching deadline for Defendants’ summary-judgment brief—now just a few weeks away—Defendants should not be forced to scramble to retain an expert while the circumstances surrounding the possible admissibility of (and necessity for) that testimony remains an open question. And the Court should likewise not face needless time pressure in deciding Defendants’ motion to exclude.

12. In response to Defendants’ reservation of rights in the parties’ joint scheduling motion, Plaintiffs previously stated as follows:

Plaintiffs note in response that their expert report was first disclosed to the government in August 2023, and any changes would simply be to update the report (without changing any of the opinions). The government has therefore had notice of those opinions since August 2023, and any delay to take expert discovery at this late date should therefore take that fact into account.

Joint Scheduling Motion ¶ 8, ECF No. 58. That is no basis to deny this motion, for several reasons.

13. First, Defendants are not seeking to “take expert discovery,” at least at this time. *Id.* So this argument is non-responsive.

14. Second, it is incorrect that the Garthwaite Declaration at issue here “was first disclosed to the government in August 2023.” *Id.* Although Plaintiffs’ prior declaration—attached to a brief to which Defendants never had to file a response, ECF No. 35-1—does overlap with the current Garthwaite Declaration in many respects, the prior version did not address the realities of the actual negotiation process. That is necessarily so, because Plaintiffs’ prior declaration was filed *before* the negotiation process even took place. The Garthwaite Declaration at issue here, by contrast, purports to discuss the actual events of the first round of actual drug price negotiations, which took place well after August of 2023. *See, e.g.*, Garthwaite Decl. ¶ 95 (asserting that “the outcomes of this first round of price setting,” which deviated sharply from Dr. Garthwaite’s predictions and assumptions, “are not necessarily reflective or predictive of future outcomes”). Responding to Dr. Garthwaite’s discussion of those issues—and his telling omissions of critical context—may be the most important part of

Defendants' response to that declaration, if the Court concludes that it is admissible. None of that work could possibly have started until Plaintiffs' recent filing.

15. Third, even if it were possible, to the extent Plaintiffs are implying that Defendants should have been preparing to respond to (a prior version of) the Garthwaite Declaration earlier, that argument fails. Defendants *never* had to respond to that prior declaration, because Defendants instead obtained a final judgment dismissing Plaintiffs' complaint in its entirety. ECF No. 53. During Plaintiffs' appeal to the Fifth Circuit, it would not have been reasonable for Defendants to be preparing responses (let alone hiring their own expert) to address an attachment to a summary-judgment brief long overtaken by events, just in case Defendants lost on appeal and Plaintiffs later refiled a similar declaration. That would not have been a responsible use of government resources, and Defendants had no obligation to prepare in advance to respond to a declaration that did not yet exist (and might never have existed, depending on the outcome of the appeal).

16. Finally, Plaintiffs' own litigation choices confirm that they are unlikely to be prejudiced by a temporary pause of the summary-judgment briefing deadlines to allow this Court time to deliberate without undue time pressure. The IRA became law on August 16, 2022; Plaintiffs waited more than ten months, until June 21, 2023, to file this facial challenge to the statute. In the ensuing years, they have never sought any time-sensitive injunctive relief, nor alleged that they face any immediate harm absent a favorable ruling.

17. To the contrary, after this Court granted Defendants' motion to dismiss *without prejudice*—thus giving Plaintiffs the opportunity to immediately refile their complaint in any forum in which venue would have been undisputed—Plaintiffs instead spent 21 months on an appeal to the Fifth Circuit, in a vigorous effort to maintain their suit here, in one of the busiest federal districts in the country. Of course, that appeal was successful, and Plaintiffs had every right to pursue it—but Plaintiffs' own litigation tactics belie the suggestion that they face any sort of imminent or irreparable harm that should prevent this Court from allowing the briefing to play out in an orderly fashion and on a reasonable timeline, after first settling the question of whether Defendants are obligated to respond to Plaintiffs' expert declaration.

18. Defendants acknowledge that, if the Court rules quickly on Defendants' pending motion to exclude, then granting this separate motion for a temporary stay may be unnecessary.² Defendants are nonetheless filing this motion based on their expectation that Plaintiffs intend to file a fulsome response to the motion to exclude, and that this Court may need some time to familiarize itself with the relevant issues. The goal of this motion is to take unnecessary time pressure off both the parties and the Court, to allow these important issues in this important case to be resolved without unnecessary haste.

CONCLUSION

For these reasons, the Court should temporarily stay the current schedule for summary-judgment briefing until the Court resolves Defendants' motion to exclude.

² Depending on the timing of the Court's ruling, Defendants may need to seek a brief extension of time regardless, among other reasons to allow sufficient time for new leadership at the Department of Justice and the Department of Health and Human Services to get up to speed on this significant matter.

Date: February 13, 2025

Respectfully submitted,

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