IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS

NATIONAL INFUSION CENTER ASSOCIATION, on behalf of itself and its members; GLOBAL COLON CANCER ASSOCIATION, on behalf of itself and its members; and PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, on behalf of itself and its members, Plaintiffs, vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the U.S. Department of Health and Human Services; the U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; STEPHANIE CARLTON, in her official capacity as Acting Administrator of the Centers for Medicare and Medicaid Services; and the CENTERS FOR MEDICARE AND MEDICAID SERVICES, Defendants.	Civil Action No. 1:23-cv-00707

PLAINTIFFS' OPPOSITION TO THE GOVERNMENT'S MOTION TO STAY

For the second time in this litigation, the Government comes to this Court with a last-minute motion to derail the parties' agreed-upon expedited summary judgment schedule to allow the Government to separately brief an issue *it knew about when it agreed to that schedule*.

The Government's cited bases for its *Daubert* motion have been known to the Government for well over a year; certainly they were known to the Government at the time it negotiated the current briefing schedule. And even after Plaintiffs filed their motion for summary judgment (citing the Garthwaite expert declaration), the Government still waited *more than a month* before filing its motion to insist that the *Daubert* issue must be resolved first. The Government identifies no valid reason for belatedly attempting to upend the parties' agreed-upon schedule. Because the parties can brief the Government's *Daubert* motion within the existing summary judgment briefing schedule, no good cause supports the Government's stay motion.[1]

Meanwhile, there is ample cause to maintain the current schedule. From the outset, Plaintiffs have repeatedly and unequivocally informed this Court, the Fifth Circuit, and the Government that deadlines under the price-setting provisions of the Inflation Reduction Act (IRA) are causing its members severe prejudice. Indeed, the Government itself has elsewhere acknowledged the need for expedition. Key dates in the implementation of the Drug Pricing Program continue to pass, and the January 1, 2026 effective date for IPAY 2026 is fast approaching, meaning that further delay will severely prejudice Plaintiffs. For the same reasons that the Fifth Circuit ordered expedited briefing in this case, and decided standing issues to speed the case's resolution on remand, this Court should deny the Government's motion for a stay.

[1] Plaintiffs' forthcoming opposition to the Government's motion to exclude the Garthwaite declaration—due next Thursday, February 27—will further support denying the Government's motion to stay. Plaintiffs therefore respectfully submit that, insofar as the Court does not summarily deny the Government's motion to stay, the Court should defer ruling on the motion to stay until after it considers Plaintiffs' opposition to the Government's motion to exclude.

BACKGROUND

Plaintiffs filed their Complaint on June 21, 2023. ECF No. 1. From the outset, and throughout this litigation, Plaintiffs have emphasized the need for expedited resolution of their claims given the impending deadlines under the Inflation Reduction Act. "Plaintiffs proposed that, to avoid the need for Plaintiffs to seek a preliminary injunction or other extraordinary relief, the parties could move directly to cross-motions for summary judgment." ECF No. 41-1 ¶ 4 (Handwerker Decl.). The Government agreed to an expedited schedule, which would have seen briefing completed by November 2023—well before the IRA's key deadlines—and the Court approved it. ECF No. 34.

But after Plaintiffs filed their motion for summary judgment, together with the initial Garthwaite declaration, the Government reneged on the parties' agreement. It successfully moved to vacate the joint scheduling order over Plaintiffs' opposition, and moved to dismiss on a basis that the Government was (or should have been) aware of when it negotiated the briefing schedule: namely, that the lead plaintiff, as an association of providers (NICA), was arguably subject to a statutory exhaustion requirement. *See* ECF Nos. 39–40, 45, 53. This Court dismissed the case for lack of subject-matter jurisdiction and improper venue, concluding that the Medicare statute required NICA to channel its claims through HHS. ECF No. 53.

Because proceeding in another venue would have required Plaintiffs to proceed without NICA, Plaintiffs immediately appealed, ECF No. 54, and moved to expedite resolution of the appeal, *see* Motion to Expedite Briefing and Argument, *Nat'l Infusion Center Ass'n v. Becerra*, No. 24-50180 (5th Cir. Mar. 22, 2024), ECF No. 23. The Fifth Circuit, recognizing that Plaintiffs' claims are time-sensitive, granted the motion to expedite, required all briefing to be completed just *34 days* from when Plaintiffs filed their motion, and set argument for the next sitting. *See id.* ECF Nos. 32, 36. At oral argument, Plaintiffs' counsel again stressed that they needed resolution of their claims on the merits by the end of 2024. Oral Argument at 41:46–42:06, *Nat'l Infusion Center Ass'n v. Becerra*, No. 24-50180

(5th Cir. May 1, 2024). The Fifth Circuit reversed the dismissal of Plaintiffs' suit; addressed standing to speed review on remand, concluding that Plaintiffs had standing to challenge the IRA; and remanded to this Court for further proceedings. *See Nat'l Infusion Ctr. Ass'n v. Becerra*, 116 F.4th 488 (5th Cir. 2024).[2]

On remand, the Government refused to negotiate a briefing schedule until most of the 90-day period for petitioning the Supreme Court for review had passed—though the Government *did not seek* Supreme Court review. Then, the parties again agreed to move directly to cross-motions for summary judgment and jointly proposed a schedule under which briefing will be completed by May 2025. ECF No. 58. While negotiating the current briefing schedule, Plaintiffs again reaffirmed that time was of the essence.. This Court entered the parties' agreed-upon schedule, ECF No. 59, and, in accordance with that schedule, Plaintiffs filed their motion for summary judgment on January 10, 2025, ECF No. 60. More than a month later, the Government moved to exclude Plaintiffs' expert declaration and to stay briefing pending resolution of its *Daubert* motion. ECF Nos. 61, 62.

ARGUMENT

A court may modify a scheduling order "only for good cause." Fed. R. Civ. P. 16(b)(4); *see S&W Enters., L.L.C. v. SouthTrust Bank of Alabama, NA*, 315 F.3d 533, 535 (5th Cir. 2003). The good-cause standard "requires the party seeking relief to show that the deadlines cannot reasonably be met" despite the party's diligence. *Ogden v. Cozumel, Inc.*, 2019 WL 5080370, at *1 (W.D. Tex. Oct. 10, 2019) (quotation marks omitted) (rejecting plaintiffs' request to modify scheduling order to file new motion). This standard applies "any time a party seeks to modify a court-imposed schedule." *United States v. 89.9270303 Bitcoins*, 2021 WL 9870370, at *1 (W.D. Tex. Oct. 7, 2021).

[2] The Government asserts (at 5) that Plaintiffs "spent 21 months on an appeal to the Fifth Circuit." Plaintiffs do not follow the Government's math. Plaintiffs appealed this Court's dismissal on March 6, 2024. ECF No. 54. The Fifth Circuit published its decision September 20, 2024, meaning that Plaintiffs' expedited appeal took just six months (or at most eight months, counting the additional two months for the Court's mandate to issue).

No good cause exists to stay the summary judgment briefing schedule. The Government has known since August 2023 that Plaintiffs would be supporting their summary judgment motion with an expert declaration from Dr. Craig Garthwaite. Indeed, the Government adverted to the fact that it might move to exclude in the motion to set a scheduling order. *See* ECF No. 58 at 3. But rather than promptly moving to exclude the report, or briefing a *Daubert* motion alongside its summary judgment motions (which the generous two-month deadline afforded to the Government would facilitate), it waited more than a month to seek this stay. Granting the Government's motion would, *for a second time*, unnecessarily delay resolution of this important dispute and severely prejudice Plaintiffs; it may force Plaintiffs to seek emergency relief. The Court should deny the Government's motion.

1. No good cause exists for a stay here. The parties can brief the Government's *Daubert* motion without disturbing the current summary judgment schedule. Plaintiffs will file their opposition to the *Daubert* motion next Thursday, February 27; any reply would be due seven days later. Parties regularly brief *Daubert* motions alongside motions for summary judgment, and can do so here. The Government argues (at 3) that a stay is warranted because the Court's ruling on its *Daubert* motion may affect how it responds to Plaintiffs' summary judgment motion, including, if its *Daubert* motion is denied, possibly "retaining [its] own experts." None of the Government's rationales warrants a stay.

As an initial matter, the Government's purported predicament is no different than any party that opposes a summary judgment motion and simultaneously moves to exclude an opposing party's expert. In opposing summary judgment, a party is often required to assume that its adversary's expert will *not* be excluded and to argue accordingly. If the party's *Daubert* motion is ultimately granted, it has suffered no prejudice from simply being required to address the expert's testimony as part of its opposition.

Here, the Government has *two months* under the schedule to file its summary judgment motion. If the Government is correct that the Garthwaite declaration "is irrelevant to the Court's review in

this case" and "is not helpful to the Court," ECF No. 61 at 9, 7 (cleaned up), then the Government will easily be able to make its summary judgment arguments notwithstanding the declaration. And the Government can oppose Plaintiffs' summary judgment motion without having to submit a competing declaration from its own expert.

Moreover, even if the Court *denies* the Government's *Daubert* motion—because the Court determines that the Garthwaite declaration is reliable and useful or because the Court is capable of determining the appropriate weight to give the declaration without excluding it—the Government still would not be entitled to any additional time to submit its own expert declaration. If the Government had wanted to support its arguments with an expert declaration, then it should have retained an expert to draft such a declaration (a) when Plaintiffs filed the initial version of the Garthwaite declaration in August 2023; or (b) when the Fifth Circuit issued its decision on an expedited basis in September 2024; or (c) during the months while the Government ran out the clock for Supreme Court review; or (d) when the parties met and conferred about the remand proceedings in November 2024. At this late date, after repeated notices that its adversary needs to resolve its claims promptly, the Government cannot credibly argue that it needs more time.[3]

2. The Government insists (at 5) that Plaintiffs' filing of the initial version of the Garthwaite declaration in August 2023 did not provide the Government with sufficient notice to consider whether to retain its own expert, because the Government "*never* had to respond to that prior declaration." But the Government was undoubtedly aware of both the substance of the declaration and the possibility that its jurisdictional arguments would fail. Thus, regardless whether the Government is right that it "had no obligation to prepare in advance to respond to [the] declaration,"

[3] Notably, the Government does not even commit to retaining its own expert in the event that the Court denies its *Daubert* motion. Rather, the Government says only (at 3) that "Defendants *may* find it necessary to protect their rights by retaining their own expert." (Emphasis added.)

ECF No. 62 at 5, the Government chose to ignore the very real possibility that it would lose on appeal—a choice all the more inexplicable after the Fifth Circuit ruled in Plaintiffs' favor and the Government deliberated for three months regarding whether to seek Supreme Court review.

Nor can the Government credibly claim (at 4) that its knowledge of the initial version of the Garthwaite declaration is irrelevant because "the prior version," while it "overlap[s] with the current Garthwaite Declaration in many respects, . . . did not address the realities of the actual negotiation process." In fact, the prior version *did* address the negotiation process, albeit with fewer details. *See* ECF No. 35-1 ¶¶ 81-90. And in any event, the Government's *Daubert* arguments against the current version are largely aimed at features of the declaration that did not change: its conclusion that the IRA "provide[s] CMS with substantial and unchecked power to define critical elements of the statute," ECF No. 61 at 8 (quoting Garthwaite Decl. ¶ 49); its supposed "characterizing and opining on the statute," *id.* at 9; its presentation of "nonmaterial facts" that "would be more appropriately presented by a fact witness," *id.*; its "predicting [of] future effects of the Negotiation Program on 'innovative behavior,'" *id.*; and its failure to discuss the Government's "best alternatives option to a negotiated agreement," *id.* at 10. Indeed, the Government actually accuses Dr. Garthwaite of "largely ignor[ing] . . . the results of the first negotiation cycle," *id.* at 11, thus belying the Government's argument that his analysis changed materially.

3. Granting the Government's request for further delay would significantly prejudice Plaintiffs. On January 1, 2026, pricing limits imposed for the first 10 selected drugs under the Drug Pricing Program will go into effect. Continued delay will only make it more difficult for this Court (and the Fifth Circuit, given the inevitability of appeal) to weigh in on the merits of the program's constitutionality before that deadline, thereby raising the chances that Plaintiffs will be required to seek emergency relief—something they have tried to avoid throughout this litigation. The Government argues (at 5) that "Plaintiffs' own litigation choices confirm that they are unlikely to be

prejudiced by a temporary pause of the summary-judgment briefing deadlines" and that "Plaintiffs have never sought any time-sensitive injunctive relief, nor alleged that they face any immediate harm absent a favorable ruling." But as Plaintiffs told the Government in July 2023, Plaintiffs negotiated for expedited briefing explicitly "to avoid the need for Plaintiffs to seek a preliminary injunction or other extraordinary relief." No. 41-1 ¶ 4 (Handwerker Decl.). Plaintiffs also emphasized the need for quick resolution while negotiating the current briefing schedule. But for the Government's repeated reneging on agreed-upon briefing schedules, those schedules would have resulted in a quick decision on Plaintiffs' claims.

Indeed, Plaintiffs' "litigation choices" show precisely the opposite of the Government's claim: that time is in fact of the essence. They have sought expedited briefing, an expedited appeal, and expedited resolution of this case. The Government cynically faults Plaintiffs (at 5) for "wait[ing] more than ten months" to file suit. But as the Government well knows, Plaintiffs were required to wait until enough was known about the IRA that Plaintiffs could prove they would be injured by the selection of drugs for the price-control program. Indeed, during briefing of the last motion to dismiss, the Government strenuously argued that Plaintiffs *had sued too early*, telling this Court that "hypothesizing about . . . possible future events *at this early stage in the Program's implementation* would be 'too speculative to satisfy the well-established requirements that threatened injury must be certainly impending.'" ECF No. 39 at 11 (emphasis added; citation omitted); *id.* at 15 ("If NICA's speculation turns out to be correct and its members face lower reimbursement payments from Medicare at some point in 2028 or later . . . *then* its members can [seek relief].").

The Government's further contention (at 5) that Plaintiffs' appeal to the Fifth Circuit "belie[s] the suggestion that they face any sort of imminent or irreparable harm" is also wrong. Plaintiffs were forced to appeal because *the Government* sought and obtained dismissal of the complaint on grounds that the Fifth Circuit later determined to be incorrect. The Government claims that, rather than appeal,

Plaintiffs could simply have packed up and refiled their Complaint in another venue. But the Government ignores that failing to appeal, and instead refiling in another venue, would have forced Plaintiffs to abandon NICA, the lead Plaintiff in this action. Moreover, the Fifth Circuit, recognizing that further delay irreparably harms Plaintiffs, expedited briefing and promptly issued an opinion that addressed standing—an issue this Court did not discuss in its initial ruling—to clear the way for prompt resolution of the merits on remand. To needlessly delay this action further would be contrary to the clear expectations of the Fifth Circuit.

CONCLUSION

For the foregoing reasons, the Court should summarily deny the Government's motion to stay. Alternatively, Plaintiffs respectfully request that the Court defer ruling on the motion to stay until after it has received Plaintiffs' forthcoming opposition to the Government's motion to exclude, which Plaintiffs will submit next Thursday, February 27, 2025.

DATED: February 20, 2025 Respectfully submitted,

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