

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF TEXAS  
AUSTIN DIVISION**

**NATIONAL INFUSION CENTER  
ASSOCIATION, et al.,  
*Plaintiffs***

v.

**XAVIER BECERRA, in his official  
capacity as Secretary of the  
Department of Health and Human  
Services, et al.,  
*Defendants***

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**CASE NO. 1:23-CV-00707-DAE**

**Order Denying Motion to Exclude and Amending Briefing Schedule**

Now before the Court are Defendants’ Motion to Exclude Expert Declaration, filed February 13, 2025 (Dkt. 61), and Plaintiffs’ Opposition to Defendants’ Motion to Exclude Expert Declaration, filed February 24, 2025 (Dkt. 66).<sup>1</sup> By Text Order entered February 18, 2025, the District Court referred the motion to this Magistrate Judge for disposition, pursuant to 28 U.S.C. § 636(b)(1)(A), Federal Rule of Civil Procedure 72, and Rule 1(c) of the Local Rules of the United States District Court for the Western District of Texas (“Local Rules”).

Plaintiffs bring a facial constitutional challenge to the Inflation Reduction Act of 2022 (“IRA”) authorizing the Secretary of Health and Human Services to negotiate Medicare drug pricing. Plaintiffs assert that provisions of the IRA creating the Drug Price Negotiation Program violate the (1) nondelegation doctrine, (2) Excessive Fines Clause of the Eighth Amendment, and (3) Due Process Clause of the Fifth Amendment.

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<sup>1</sup> Pursuant to Local Rule CV-7(e)(2), the Court need not wait for a reply before ruling on Defendants’ motion.

The parties “agree that this case presents legal questions that can properly be resolved through dispositive motions, without the need for discovery,” and will file cross-motions for summary judgment under Rule 56. Dkt. 33 ¶ 2. Neither side demands a jury.

Plaintiffs filed their summary judgment motion on January 10, 2025, attaching the expert declaration of Dr. Craig Garthwaite. Dkt. 60-1. Defendants ask the Court to exclude the declaration or, in the alternative, extend the briefing schedule. Plaintiffs oppose both requests.

### **I. Legal Standard**

Federal Rule of Evidence 702, which governs the admissibility of expert testimony, provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that:

- (a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert’s opinion reflects a reliable application of the principles and methods to the facts of the case.

The Supreme Court’s landmark case *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), provides the analytical framework for determining whether expert testimony is admissible under Rule 702. *Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 243 (5th Cir. 2002). *Daubert* requires district courts to act as “gatekeepers” to ensure that expert testimony meets the standards of Rule 702. *Wilson v. Woods*, 163 F.3d 935, 937 (5th Cir. 1999). Under *Daubert*, a district court must first “be assured that the proffered witness is qualified to testify by virtue of his ‘knowledge, skill, experience, training, or education.’” *United States v. Cooks*, 589 F.3d 173, 179 (5th Cir. 2009) (quoting FED. R. EVID. 702). Once the court determines that an expert is qualified, it must ensure that the expert’s testimony “both rests on a reliable foundation and is relevant to the task at

hand.” *Daubert*, 509 U.S. at 597; *see also Puga v. RCX Sols., Inc.*, 922 F.3d 285, 293 (5th Cir. 2019) (“When evaluating expert testimony, the overarching concern is generally whether the testimony is relevant and reliable.”).

To be reliable, expert testimony must be grounded in the methods and procedures of science and be more than unsupported speculation or subjective belief. To be relevant, the expert’s reasoning or methodology must be properly applied to the facts in issue.

When performing this analysis, the court’s main focus should be on determining whether the expert’s opinion will assist the trier of fact. Assisting the trier of fact means the trial judge ought to insist that a proffered expert bring to the jury more than the lawyers can offer in argument. As this court has noted, however, the helpfulness threshold is low: it is principally a matter of relevance.

As a general rule, questions relating to the bases and sources of an expert’s opinion affect the weight to be assigned that opinion rather than its admissibility. . . . While the district court must act as a gatekeeper to exclude all irrelevant and unreliable expert testimony, the rejection of expert testimony is the exception rather than the rule.

*Puga*, 922 F.3d at 293-94 (cleaned up). A trial court has broad discretion in ruling on admissibility under Rule 702. *Wellogix, Inc. v. Accenture, L.L.P.*, 716 F.3d 867, 881 (5th Cir. 2013).

## II. Analysis

Because this case will be tried to the District Court, not a jury, “most of the safeguards provided for in *Daubert* are not as essential.” *Gibbs v. Gibbs*, 210 F.3d 491, 500 (5th Cir. 2000); *see also Whitehouse Hotel Ltd. P’ship v. Comm’r*, 615 F.3d 321, 330 (5th Cir. 2010) (“[T]he importance of the trial court’s gatekeeper role is significantly diminished in bench trials, as in this instance, because, there being no jury, there is no risk of tainting the trial by exposing a jury to unreliable evidence.”). As Plaintiffs argue: “The Court does not need to parse the Declaration as part of a gatekeeping exercise now, just to determine whether it may safely consider the Declaration where relevant to its own merits analysis later.” Dkt. 66 at 12-13.

Defendants argue that the Garthwaite Declaration “does not help the Court ‘to understand the evidence or to determine a fact in issue’ in this case. Rule 702(a). Indeed, there are no disputed material facts at issue in this case at all.” Dkt. 61 at 8. For that reason, they contend, it is “unsurprising that among the 10 lawsuits across the nation challenging the constitutionality of the Drug Price Negotiation Program, this is the *only* one in which any party has proffered expert testimony.” *Id.* at 9. Defendants argue that the Garthwaite Declaration usurps the Court’s function by evaluating the statutory provisions at issue, “a legal conclusion well within this Court’s ability to determine.” *Id.* at 10. To the extent the declaration presents facts, Defendants contend, those facts should be presented by a fact witness.

Plaintiffs respond that the declaration is relevant to numerous issues, including their excessive fines claim and whether the IRA’s excise tax would inflict irreparable injury, an exception to application of the Anti-Injunction Act. In response to Defendants’ argument that other plaintiffs challenging the Drug Price Negotiation Program have not submitted expert testimony, Plaintiffs assert that they “can hardly be faulted for providing the factual support that the Government has claimed was lacking in other cases.” Dkt. 66 at 11.

In addition to arguing that the Garthwaite Declaration is not relevant, Defendants contend that Garthwaite “has not ‘reliably applied’ any purported ‘reliable principles and methods’ to the facts.” Dkt. 61 at 11 (quoting FED. R. EVID. 702(c), (d)). Instead, they argue, Garthwaite “offers little more than criticism of the Negotiation Program based on his apparent policy preferences and thinly supported predictions, which are neither relevant nor helpful to the Court.” Dkt. 61 at 13.

Considering the diminished gatekeeping role for evidence to be considered by the District Court at summary judgment, the Court finds that the Garthwaite Declaration is sufficiently relevant to meet the low helpfulness threshold. *Puga*, 922 F.3d at 294. The Court also finds that Defendants’

arguments about the reliability of the Garthwaite Declaration go to the weight properly afforded his testimony, not its admissibility. *Id.* (“As a general rule, questions relating to the bases and sources of an expert’s opinion affect the weight to be assigned that opinion rather than its admissibility.”).

For these reasons, the Court denies Defendants’ motion to exclude.

### **III. Defendants’ Request to Extend the Briefing Schedule**

If the Court denies the motion to exclude, Defendants “request 60 additional days to assess their evidentiary response (and, if necessary, to retain their own expert)” before filing their opposition to Plaintiffs’ motion and cross-motion for summary judgment, now due March 7, 2025. Dkt. 61 at 13. Plaintiffs respond that the “Government is not entitled to extra time for summary judgment simply because it has asked the Court to exclude some of Plaintiffs’ summary judgment evidence.” Dkt. 66 at 16.

Because the Court has denied Defendants’ motion to exclude, the Court also finds that Defendants have shown good cause for a short extension of the briefing schedule to permit time to retain their own expert if needed. And Plaintiffs identify no prejudice from an extension.

Accordingly, the Court **GRANTS IN PART and DENIES IN PART** Defendants’ request to extend the briefing schedule (Dkt. 59). **IT IS ORDERED** that the schedule is extended by **45 days**, as follows:

Defendants’ Combined Cross-Motion for Summary Judgment and Opposition to Plaintiffs’ Motion for Summary Judgment (limited to 40 pages or less) is due by **April 21, 2025**;

Plaintiff’s Combined Reply and Opposition to Defendants’ Cross-Motion (limited to 30 pages or less) is due by **May 27, 2025**; and

Defendants’ Reply (limited to 20 pages or less) is due by **June 27, 2025**.

**IV. Conclusion**

Defendants' Motion to Exclude Expert Declaration (Dkt. 61) is **DENIED** and the briefing schedule (Dkt. 59) is **AMENDED** as detailed above.

It is **ORDERED** that the Clerk remove this case from this Magistrate Judge's docket and return it to the docket of the Honorable David A. Ezra.

**SIGNED** on February 26, 2025.



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SUSAN HIGHTOWER  
UNITED STATES MAGISTRATE JUDGE