UNITED STATES DISTRICT COURT
FOR THE 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-707

DEFENDANTS' MOTION TO EXCLUDE EXPERT DECLARATION

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[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.

INTRODUCTION

Plaintiffs, three membership associations, ask this Court to nullify key provisions of the Inflation Reduction Act (IRA), in which Congress authorized the Secretary of Health and Human Services to try and negotiate a better deal for Medicare beneficiaries and the American taxpayer on some of the pharmaceutical industry's most lucrative drugs. Plaintiffs claim that the challenged statutory provisions violate the constitutional separation of powers, due process rights under the Fifth Amendment, and the Eighth Amendment bar on excessive fines. But it is no secret that Plaintiffs have long opposed the statutory provisions creating the Medicare Drug Price Negotiation Program on policy grounds, and they now channel those policy disagreements through a proffered expert declaration appended to their motion for summary judgment.

The Federal Rules of Evidence require the Court to "ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993). The declaration that Plaintiffs have submitted here fails to satisfy these requirements. The proffered declaration from Dr. Craig Garthwaite—an economist, and not a lawyer—consists largely of his own characterizations of the statutory provisions at issue and his speculative predictions for the effect of the Negotiation Program on drug innovation and, ultimately, American patients. An examination of the declaration reveals that Dr. Garthwaite is serving less as an expert than as an "advocate of policy." *In re Air Crash Disaster at New Orleans*, 795 F.2d 1230, 1233 (5th Cir. 1986). And indeed, his declaration advocates his policy preference for the status quo. That is not a permissible purpose for an expert declaration, and the Court should therefore exclude it as inadmissible under the Federal Rules of Evidence. In the alternative, Defendants request additional time to consider whether to retain their own expert and, if so, for any such expert to produce a report that Defendants may submit with their cross-motion for summary judgment and opposition to Plaintiffs' motion for summary judgment.[2]

[2] Counsel for Defendants met and conferred with counsel for Plaintiffs, who advised that Plaintiffs oppose both the principal and alternative relief requested in this motion.

BACKGROUND

I. Statutory Background

Medicare is a federal program that pays for covered healthcare services provided to program beneficiaries as well as for prescription drugs. *See generally* 42 U.S.C. §§ 1395 *et seq.* The Medicare statute is divided into five "Parts," which set forth the terms by which Medicare will pay for benefits. *See Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011). "Traditional Medicare comprises Part A, which covers medical services furnished by hospitals and other institutional care providers, and Part B, which covers outpatient care like physician and laboratory services," as well as drugs administered (commonly in providers' offices) as part of that care. *Cares Cmty. Health v. HHS*, 944 F.3d 950, 953 (D.C. Cir. 2019) (internal quotation marks omitted); *see* 42 U.S.C. §§ 1395k(a)(1), 1395x(s)(2)(A). In 2003, Congress added Medicare Part D, which provides "a voluntary prescription drug benefit program that subsidizes the cost of prescription drugs and prescription drug insurance premiums for Medicare enrollees." *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 749 (3d Cir. 2017); *see* 42 U.S.C. §§ 1395w-101 *et seq.*

Prior to the IRA, Congress barred the Secretary from negotiating with drug manufacturers for the costs of covered medications under Part D. *See* 42 U.S.C. § 1395w-111(i). This model contributed to rapidly rising costs to Medicare in recent years. Medicare Part D spending doubled over the last decade, and it "is projected to increase faster than any other category of health spending." S. Rep. No. 116-120, at 4 (2019); *see also* Cong. Budget Office (CBO), *Prescription Drugs: Spending, Use, and Prices* 16 (2022), https://perma.cc/9WPC-VLFC. Much of that increase is attributable to a "relatively small number of drugs [that] are responsible for a disproportionately large share of Medicare costs." H.R. Rep. No. 116-324, pt. II, at 37 (2019). Congressional reports have found that generic competitors face many legal and practical obstacles to market entry, sometimes leaving only a single manufacturer of a particular drug on the market for extended periods of time. *See* Staff of H. Comm on Oversight and Reform, 117th Cong., *Drug Pricing Investigation: AbbVie—Humira and Imbruvica* 36 (2021). And the payment formula for drugs covered under Part B permits a manufacturer of a drug without generic

competition to "effectively set[] its own Medicare payment rate." Medicare Payment Advisory Comm'n, *Report to the Congress: Medicare and the Health Care Delivery System* 84 (2022), https://perma.cc/5X4R-KCHC. The result has been a shift of financial burden to the Medicare program, which undermines the program's premise of leveraging market competition to reduce prices for beneficiaries and taxpayers. *Id.* at 120.

This status quo is unsustainable; the IRA seeks to correct course. Inflation Reduction Act of 2022, Pub. L. No. 117-169, §§ 11001–11003 (codifying 42 U.S.C. §§ 1320f–1320f-7 and 26 U.S.C. § 5000D). As relevant here, the IRA requires the Secretary, acting through the Centers for Medicare & Medicaid Services (CMS), to establish the Drug Price Negotiation Program, through which he will negotiate the prices Medicare pays for certain covered drugs: those that have the highest Medicare expenditures and have long enjoyed little market competition. *See* 42 U.S.C. §§ 1320f *et. seq.*

By statute, only certain drugs are eligible for selection in the Negotiation Program: those that account for the highest Medicare expenditures, that have no generic or biosimilar competitors, and that have been on the market for at least seven years (for drugs) or 11 years (for biologics). *See id.* § 1320f-1(d), (e). For the first negotiation cycle, CMS selected 10 of these drugs with the highest Medicare expenditures for participation in negotiations. *Id.* § 1320f-1(a). CMS selected 15 additional drugs for the second negotiation cycle, and additional drugs are to be selected for future cycles.

After selecting the drugs, CMS is directed to negotiate with the manufacturer of each selected drug, in an effort to reach agreement on a "maximum fair price" for that drug, taking into account statutorily prescribed categories of information. *Id.* § 1320f-3(e). Congress both imposed a "ceiling for [the] maximum fair price," based on pricing data for the subject drugs, *id.* § 1320f-3(c), and directed CMS to "aim[] to achieve the lowest maximum fair price" that manufacturers will accept, *id.* § 1320f-3(b)(1). CMS will sign agreements with willing manufacturers to negotiate prices for selected drugs and then to provide Medicare beneficiaries access to the drugs at those prices. *Id.* § 1320f-2.

A manufacturer that does not wish to sign such an agreement—or to otherwise participate in the Negotiation Program—has several options. It can continue selling its drugs to Medicare beneficiaries at non-negotiated prices and pay an excise tax (which is calculated as a percentage of the

sales of designated drugs dispensed, furnished, or administered to individuals under the terms of Medicare). 26 U.S.C. § 5000D(a)–(d); IRS Notice No. 2023-52 (Aug. 4, 2023), https://perma.cc/B9JZ-ZG7P. It can continue selling its other drugs to Medicare and Medicaid but transfer its interest in the selected drug to another entity, which can then make its own choices about participation in negotiations. *See* CMS, *Medicare Drug Price Negotiation Program: Revised Guidance* 131–32 (June 30, 2023), https://perma.cc/K6QB-C3MM. Or it can withdraw from the Medicare and Medicaid programs—in which case it will incur no excise tax and no other liability. *See id.* at 33–34, 120–21, 129–31; 26 U.S.C. § 5000D(c)(1).

In August 2023, CMS published the list of drugs selected for the first negotiation cycle. *See* HHS, *HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023), https://perma.cc/A36P-Z88Z. The 10 drugs selected accounted for more than $50 billion of gross Medicare Part D spending between June 2022 and May 2023, and Medicare beneficiaries paid a total of $3.4 billion in out-of-pocket costs for those drugs in 2022 alone. *See id.*; CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (Aug. 2023), https://perma.cc/X37F-RC94.

In accordance with the schedule established by Congress, CMS presented the manufacturers of selected drugs with initial offers. *See Fact Sheet: Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026*, CMS (Aug. 15, 2024), https://perma.cc/6MVG-BZP8. The manufacturers responded to the initial offers with counteroffers. *Id.* CMS subsequently held three negotiation meetings with each company to discuss the offers and relevant evidence. *Id.* Many companies proposed revised counteroffers during these meetings, and CMS accepted four of these revised counteroffers outright, and reached agreement with a fifth manufacturer on a negotiated price. *Id.* CMS then sent final written offers to manufacturers of the five remaining drugs. By August 1, 2024, CMS and the participating manufacturers had agreed to a negotiated price for each of the 10 selected drugs. *Id.* Assuming that none of the 10 manufacturers withdraw from Medicare and Medicaid by December 2025, these prices will take effect on January 1, 2026. 42 U.S.C. §§ 1320f(b), (d), 1320f-2(a), 1320f-3(b).

In January 2025, CMS published a list of drugs covered by the Negotiation Program for the second cycle of negotiations. *See* CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2027* (Jan. 17, 2025), https://perma.cc/SNY6-3KRL.

II. Litigation Background

Plaintiffs bring a facial constitutional challenge to the provisions of the IRA that create the Negotiation Program, asserting that these provisions violate (1) the nondelegation doctrine, Compl. ¶¶ 130–34; (2) the Excessive Fines Clause of the Eighth Amendment, *id.* ¶¶ 136–41; and (3) the Due Process Clause of the Fifth Amendment, *id.* ¶¶ 143–48. From nearly the beginning of this case, the parties "agree[d] that this case presents legal questions that can properly be resolved through dispositive motions, without the need for discovery." Joint Mot. to Set Briefing Schedule ¶ 2, ECF No. 33 (Aug. 1, 2023). The parties agreed that the merits could appropriately be resolved on "cross-motions for summary judgment pursuant to Federal Rule of Civil Procedure 56." *Id.*

This is one of 10 lawsuits challenging the Negotiation Program in federal courts nationwide. The parties in all of those cases have agreed to resolve the merits in cross-motions for summary judgment, and not a single party in another such case has attempted to introduce expert testimony for any purpose. And the district courts in six of those cases have ruled on the merits (in the government's favor) without the need for any expert testimony. *AstraZeneca Pharm. LP v. Becerra*, 719 F. Supp. 3d. 377 (D. Del. 2024), *appeal pending*, No. 24-1819 (3d Cir.); *Bristol Myers Squibb Co. v. Becerra*, Nos. 23-cv-3335, 23-cv-3818, 2024 WL 1855054 (D.N.J. Apr. 29, 2024) (consolidated opinion resolving challenges by Bristol Myers Squibb Co. and Janssen Pharmaceuticals, Inc.), *appeals pending*, Nos. 24-1810, 24-1821; *Boehringer Ingelheim Pharms., Inc. v. HHS*, No. 23-cv-1103, 2024 WL 3292657 (D. Conn. July 3, 2024); *Novo Nordisk Inc. v. Becerra*, No. 23-20814, 2024 WL 3594413 (D.N.J. July 31, 2024), *appeal pending*, No. 24-2510 (3d Cir.); *Novartis Pharms. Corp. v. Becerra*, No. 23-cv-14221, 2024 WL 4524357 (D.N.J. Oct. 18, 2024), *appeal pending*, No. 24-2968 (3d. Cir.).

Although Plaintiffs originally filed this lawsuit on June 21, 2023, Defendants successfully moved this Court to dismiss the complaint for improper venue. *Nat'l Infusion Ctr. Ass'n v. Becerra*, 716

F. Supp. 3d 478 (W.D. Tex.). Plaintiffs appealed from that decision, and a divided Fifth Circuit panel reversed and remanded back to this Court. *Nat'l Infusion Ctr. Ass'n v. Becerra*, 116 F.4th 488 (5th Cir. 2024). On remand, the parties jointly moved the Court to set a summary-judgment briefing schedule, but Defendants expressly "reserve[d] their rights to object or otherwise request any appropriate relief from the Court" with respect to any forthcoming expert declaration, "including, specifically, relief that may disrupt th[e] otherwise agreed-upon briefing schedule." Joint Mot. to Set Briefing Schedule ¶ 8, ECF No. 58.

On January 10, 2025, Plaintiffs filed a motion for summary judgment, to which they appended the expert declaration at issue. Pls.' Mot. for Summ. J., ECF No. 60. The Declaration of Craig Garthwaite offers the opinion of one individual on the provisions of the IRA governing the Negotiation Program and on what he believes will be its effects on pharmaceutical innovation. *See, e.g.*, Garthwaite Decl. ¶ 7, ECF No. 60-1. After describing his qualification as an economist and professor of economics and healthcare strategy, the declaration, first, "evaluate[s]" the provisions of the IRA governing the Negotiation Program—as well as related agency guidance—and, second, speculates on the potential future effects of the program on the research and development of drugs and patient access to new drug therapies. *Id.*

ARGUMENT

I. The Court Should Exclude the Garthwaite Declaration under Rule 702

Federal Rule of Evidence 702 "assign[s] to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert*, 509 U.S. at 597. Under this rule, a qualified expert may testify if the court is satisfied 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 has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702. The court thus fulfills its "gatekeeping" role by "making a 'preliminary assessment of whether the reasoning or methodology

underlying the testimony is . . . valid and of whether that reasoning or methodology properly can be applied to the facts in issue.'" *Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 244 (5th Cir. 2002) (quoting *Daubert*, 509 U.S. at 592–93). This assessment must be made with respect to not just scientific testimony but all expert testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999).

The Fifth Circuit is especially scrutinizing of expert testimony that is "significantly intertwined with the underlying substantive law." *In re Air Crash*, 795 F.2d at 1233. It has admonished that "trial courts must be wary lest the expert become nothing more than an advocate of policy." *Id.* For this reason, this Circuit does not allow an expert witness to "offer his or her opinion on purely legal matters." *Deaf Interpreter Servs., Inc. v. Webbco Enterprises, LLC*, No. 13-cv-867-RCL, 2015 WL 11565191, at *4 (W.D. Tex. Feb. 11, 2015) (citing *Askanase v. Fatjo*, 130 F.3d 657, 672–73 (5th Cir. 1997)). "There being only one applicable legal rule for each dispute or issue," the resolution of a legal issue "requires only one spokesman of the law, who of course is the judge." *Askanase*, 130 F.3d at 673 (internal quotation marks omitted).

The Court should exclude the Garthwaite Declaration because it fails to satisfy Rule 702's admissibility requirements: (1) it is not "help[ful]" to the Court, and (2) it does not reliably apply any purported "reliable principle[] [or] method[]." Fed. R. Evid. 702; *see generally id.*, advisory comm. note (2000 amends.) ("While the terms 'principles' and 'methods' may convey a certain impression when applied to scientific knowledge, they remain relevant when applied to testimony based on technical or other specialized knowledge.").

A. The declaration does not help the Court to understand the evidence or determine a material fact in issue

First, and most glaringly, 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. The parties have long agreed that this matter "presents legal questions that can properly be resolved through dispositive motions, without the need for discovery." Joint Mot. to Set Briefing Schedule ¶ 2, ECF No. 33. With no material facts in issue for the Court to determine, there is no basis for Plaintiffs to claim that an expert declaration is helpful to the Court, as

required under Rule 702. It is thus 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. And those courts that have reached a decision on the merits have ably evaluated the statutory provisions and determined the constitutional questions at issue without the aid of any purported experts. *See supra* at 5.

Rather than help the Court to understand specific facts in evidence or to determine a (nonexistent) material fact in issue, the Garthwaite Declaration offers his own characterization of the Negotiation Program and makes predictions about future effects of the program on entities and people who are not party to this litigation. Dr. Garthwaite's own description of his task is illuminating: he states that he was "asked [1] to evaluate the 'negotiation' process" set out in the text of the IRA and "[2] to consider the impact of setting prices for certain selected drugs on innovative behavior by manufacturers and the corresponding potential impacts on current and future patients." Garthwaite Decl. ¶ 7.

As to the first, an evaluation of the statutory provisions at issue improperly "usurps the function of the court" by performing a task "well within the capacity and knowledge of the Court." *Caballero v. Archer*, No. 04-cv-561-OG, 2007 WL 9702868, at *2 (W.D. Tex. Feb. 1, 2007); *see Owen v. Kerr-McGee Corp.*, 698 F.2d 236, 240 (5th Cir. 1983) ("[A]llowing an expert to give his opinion on the legal conclusions to be drawn from the evidence both invades the court's province and is irrelevant."). Indeed, that is the Court's principal task in this case: to evaluate the constitutionality of the Negotiation Program created by the IRA. And yet much of the declaration "reads like a lawyer's brief, marshaling the evidence and the legal standards to make a persuasive case" as to the legal questions at issue. *Deaf Interpreter Servs.*, 2015 WL 11565191, at *4; *see, e.g.*, Garthwaite Decl. ¶ 49 (arguing that "provisions in the law provide CMS with substantial and unchecked power to define critical elements of the statute"). This is inappropriate: an expert must provide the Court with something "more than the lawyers can offer in argument." *Salas v. Carpenter*, 980 F.2d 299, 305 (5th Cir. 1992) (internal quotation marks omitted); *see also Popal v. Reliable Cargo Delivery, Inc.*, No. 20-cv-39-DC-DF, 2021 WL 1100095, at *4

(W.D. Tex. Jan. 20, 2021) (holding that proffered expert declaration "seek[ing] to inform the Court of a legal conclusion" was "irrelevant and therefore inadmissible").

True, an expert's "opinion is not objectionable just because it embraces a final issue." *Michelle Hedgecock, DDS, PLLC v. Trang Nguyen DDS PLLC*, No. 20-cv-643-JRN, 2021 WL 2232011, at *2 (W.D. Tex. May 3, 2021); *see* Fed. R. Evid. 704(a). But the opinion must "help the trier of fact." Fed. R. Evid. 702(a). The meaning of the statutory provisions is a legal conclusion well within this Court's ability to determine, and a purported expert's opinion on the meaning and wisdom of Congress's policy decisions is irrelevant to the Court's review in this case presenting structural, Fifth Amendment, and Eighth Amendment constitutional claims. *Cf., e.g.*, *State of Cal. By & Through Brown v. Watt*, 712 F.2d 584, 606 (D.C. Cir. 1983) ("It is not [the court's] function to resolve disagreements among the experts or to judge the merits of competing expert views.").[3] To the extent that the Garthwaite Declaration—in addition to characterizing and opining on the statute—presents nonmaterial *facts* that may be relevant and helpful, those facts would be more appropriately presented by a fact witness, rather than an expert witness. *See, e.g.*, Pls.' Mot. at 3–4 (relying on the Garthwaite Declaration for background factual information), 27 (citing the Garthwaite Declaration together with Plaintiffs' submitted factual declarations in support of factual assertions); *cf.* Nyquist Decl., ECF No. 60-2 (factual declaration); Spiegel Decl., ECF No. 60-3 (same); Bernie Decl., ECF No. 60-4 (same).

Dr. Garthwaite's second task—predicting possible future effects of the Negotiation Program on "innovative behavior"—has little or no relevance to the legal questions at issue. *See* Garthwaite Decl. ¶¶ 96–133. Even if his ominous predictions were correct, they again speak to the wisdom of Congress's decisions in the IRA as a *policy* matter. They have no bearing on whether the statutory provisions run afoul of the separation of powers, the Fifth Amendment Due Process Clause, or the Eighth Amendment Excessive Fines Clause.

[3] The declaration also characterizes guidance issued by CMS and by the Internal Revenue Service, *see, e.g.*, Garthwaite Decl. ¶¶ 48–49, 70–71, but that has no relevance here. Plaintiffs do not challenge any agency action in this lawsuit.

At bottom, in Dr. Garthwaite's characterization of the statutory provisions at issue and his skewed predictions on the effects of the Negotiation Program, Dr. Garthwaite serves as "nothing more than an advocate of policy." *In re Air Crash*, 795 F.2d at 1233. If Dr. Garthwaite believes that an alternative policy would be preferable, it would be appropriate for him to provide that testimony to Congress—and indeed, he has testified before Congress on healthcare-related topics several times before. Garthwaite Decl. ¶ 5. But this is not a proper use for expert testimony in federal court. The "helpfulness" standard under Rule 702 "requires a valid . . . connection to the pertinent inquiry as a precondition to admissibility." *Kumho Tire*, 526 U.S. at 149 (quoting *Daubert*, 509 U.S. at 592). The Garthwaite Declaration fails to satisfy this precondition.

B. The declaration does not reliably apply reliable principles or methods

Even if an expert declaration could be helpful to the Court in this case, the Garthwaite Declaration would still not satisfy the requirements of Rule 702 because Dr. Garthwaite has not "reliably applied" any purported "reliable principles and methods" to the facts. Fed. R. Evid. 702(c), (d); *see Kumho Tire*, 526 U.S. at 147 ("Rule [702] applies its reliability standard to all 'scientific,' 'technical,' or 'other specialized' matters within its scope."). In his characterization of the law and CMS guidance, Dr. Garthwaite does not even profess to base his opinion on any reliable legal principles or methods—unsurprisingly, as he is not a lawyer.

To the extent that the Garthwaite Declaration alludes to some principles or methods, it does not apply them "reliably." Fed. R. Evid. 702(d). For example, Dr. Garthwaite states that he "examine[s] what the BATNAs [i.e., best alternatives option to a negotiated agreement] look like for manufacturers and CMS under the IRA." Garthwaite Decl. ¶ 84. But that promise goes unfulfilled, and his examination is ultimately one-sided: the declaration is entirely devoid of any examination of the government's BATNA. In light of the significant potential consequences of failing to reach an agreement with any of the manufacturers of selected drugs, the government has a powerful incentive to avoid a result that leads to Medicare beneficiaries losing access to these drugs. The Garthwaite Declaration fails even to acknowledge this. And much of the declaration's discussion of selected drug

manufacturers' options consists of inaccurate or disputed characterizations of the law. *See, e.g.*, Garthwaite Decl. ¶ 86 (incorrectly describing the excise tax as escalating to as much as 1,900% of a drug's total U.S. revenues, when the maximum ratio of the tax to the total amount the manufacturer charges for a drug is 95%, *see* 26 U.S.C. § 5000D(a), (d)).

Moreover, Dr. Garthwaite further ignores the government as a party to the negotiation—and its own interest in reaching agreement on a fair price—in emphasizing that "nothing in the IRA prevents" the maximum fair price (MFP) from being equal to zero dollars. Garthwaite Decl. ¶ 15 n.6. It does not take an expert to know that the same market realities would prevent CMS from setting a MFP at zero dollars that would prevent any buyer from offering that price: the seller would walk away. Dr. Garthwaite asserts that "[f]rom an economic perspective, manufacturers . . . would be better off accepting an offer close to a zero price" than taking the alternatives to agreeing to that price. *Id.* ¶ 78(b). But he applies no apparent principle or method—indeed, provides no data whatsoever—in reaching this conclusion.

Indeed, Dr. Garthwaite largely ignores the most relevant facts available for his assignment to make predictions—namely, the results of the first negotiation cycle under the program. The declaration only briefly acknowledges the results of those negotiations, *see id.* ¶¶ 92–95 & tbl.1, and nowhere is that information incorporated into Dr. Garthwaite's analyses or predictions. He quibbles briefly with CMS's treatment of a couple of highly specific issues, *id.* ¶ 94, but otherwise does not substantively engage with the relevant facts—namely, that CMS "engaged in good-faith negotiations," *id.* ¶ 92, including agreeing to several of the manufacturers' counteroffers, and reached an agreement on a MFP with all 10 drug manufacturers. Apparently unable to use this (highly relevant) information in support of his dire prognostications, he merely asserts that those "outcomes . . . are not necessarily reflective or predictive of future outcomes" from future rounds of negotiations. *Id.* ¶ 95.

* * *

The Garthwaite Declaration 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. *See In re Air Crash*, 795 F.2d at 1233; *cf., e.g.*, *Graham v. Dallas Area Rapid Transit*,

288 F. Supp. 3d 711, 729–31 (N.D. Tex. 2017) (rejecting proffered expert declaration that was "riddled with legal conclusions" and did "not address whether [the expert] had sufficient facts to reach his conclusions or discuss procedures or methodologies in the area of" purported expertise). The declaration is therefore inadmissible under the Federal Rules of Evidence.

II. Defendants Alternatively Request Additional Time to Assess Their Evidentiary Response

In the alternative, if the Court deems the Garthwaite Declaration admissible and thus denies the primary relief requested in this motion, Defendants respectfully request 60 additional days to assess their evidentiary response (and, if necessary, to retain their own expert) before filing their cross-motion for summary judgment and opposition to Plaintiffs' motion for summary judgment. That brief is currently due by March 7, 2025. *See* Order, ECF No. 59. If the Court considers the subjects of the Garthwaite Declaration to be relevant to the Court's task, Defendants may, for example, wish to retain their own expert to respond fully to Dr. Garthwaite's flawed characterizations and prognostications. Retaining an expert, who would then be tasked with developing an expert declaration, would require more time than currently allotted in the schedule, particularly in light of current budget realities facing the Department of Justice and the Department of Health and Human Services. Defendants therefore respectfully request in the alternative that, if the Court were to deny the primary relief requested in this motion, it at least allow Defendants 60 days from the date of that order to file their combined cross-motion and opposition.[4]

CONCLUSION

For the foregoing reasons, the Court should exclude the expert declaration of Craig Garthwaite. In the alternative, Defendants respectfully request 60 additional days to assess their evidentiary response (and, if necessary, to retain their own expert) before filing their cross-motion for summary judgment and opposition to Plaintiffs' motion for summary judgment.

[4] In the parties' joint scheduling submission, Defendants expressly contemplated that they may wish to seek such relief after reviewing Plaintiffs' then-forthcoming expert declaration. *See supra* at 6.

Dated: February 13, 2025

Respectfully submitted,

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