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

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| NATIONAL INFUSION CENTER ASSOCIATION *et al.*,<br><br>Plaintiffs,<br><br>vs.<br><br>ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services, *et al.*,<br><br>Defendants. | Civil Action No. 1:23-cv-00707 |

**PLAINTIFFS' OPPOSITION TO DEFENDANTS'**
**MOTION TO EXCLUDE EXPERT DECLARATION**

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## INTRODUCTION

The Court should deny the Government's motion to exclude the Declaration of Professor Craig Garthwaite because it is relevant and reliable, and, anyway, "[m]ost of the safeguards provided for in *Daubert* are not as essential in a case such as this where a district judge sits as the trier of fact in place of a jury." *Gibbs v. Gibbs*, 210 F.3d 491, 500 (5th Cir. 2000). In his Declaration, Professor Garthwaite analyzes the economic effects of the so-called "Drug Price Negotiation Program" (Drug Pricing Program or Program) of the Inflation Reduction Act of 2022 (IRA). The Government moves to exclude the Declaration, but its arguments fall far short of establishing that this is the exceptional case where such an extreme measure is warranted.

*First*, the Program's economic effects are relevant to numerous issues in this case, including whether: (i) the "excise tax" is punitive and disproportionate (implicating Plaintiffs' excessive fines claim); (ii) the so-called "tax" would inflict irreparable harm on manufacturers (implicating the Anti-Injunction Act); (iii) the Program upends protected property interests (implicating due process); and (iv) manufacturers have no option but to participate in the Program (implicating the coercion issue). Indeed, the Government has responded to similar challenges in other cases by emphasizing the plaintiffs' supposed *failure to provide* "any factual support." So the Government can hardly complain that Plaintiffs here *have provided* factual support.

*Second*, Professor Garthwaite does not offer "legal conclusions." As a basis for his opinions on the Program's economic effects, Professor Garthwaite explains his understanding of how the Program works, including the relevant features of the statutory and regulatory scheme. That utterly unremarkable feature of his Declaration provides appropriate context for his opinions about how the statutory and regulatory scheme will likely affect market participants. And insofar as the Court disagrees with his understanding of the Program's operation, it will be free to discount his opinions.

*Third*, the Government's perfunctory "reliability" objection—citing a small handful of

individual paragraphs and footnotes in Professor Garthwaite's 134-paragraph economic analysis—is incorrect and, in any event, an insufficient basis to exclude his Declaration. At most, the Government disputes the weight to be given Professor Garthwaite's testimony, not its admissibility.

*Finally*, the Court has wide discretion to admit expert testimony, and this case will not go before a jury. There is accordingly no reason for the Court to act as a gatekeeper *for itself*, when it can simply assess the relevance and weight of Professor Garthwaite's opinions as it decides the summary judgment issues.

The Court should deny the Government's motion to exclude and—as with the Government's motion to stay—should deny its alternative request to modify the briefing schedule.

## ARGUMENT

### I. The Court Should Not Exclude Professor Garthwaite's Declaration

"Rule 702 of the Federal Rules of Evidence governs the admissibility of expert testimony and reports." *Puga v. RCX Sols., Inc.*, 922 F.3d 285, 293 (5th Cir. 2019). The Rule "sets forth a broad 'helpfulness' standard." *Barrett v. Atl. Richfield Co.*, 95 F.3d 375, 382 (5th Cir. 1996). "When evaluating expert testimony, the overarching concern is generally whether the testimony is relevant and reliable." *Id.* (citing *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993)). "Most of the safeguards provided for in *Daubert* are not as essential in a case such as this where a district judge sits as the trier of fact in place of a jury." *Gibbs*, 210 F.3d at 500; *see 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.").

#### A. Professor Garthwaite's Declaration Is Relevant

The "helpfulness threshold is low: it is principally a matter of relevance." *Puga*, 922 F.3d at 294 (cleaned up). "Evidence is relevant if '(a) it has any tendency to make a fact more or less probable than

it would be without the evidence; and (b) the fact is of consequence in determining the action.'" *Lucid Grp. USA, Inc. v. Johnston*, 2024 WL 3404624, at *4 (W.D. Tex. July 11, 2024) (quoting Fed. R. Evid. 401). "The Rule's basic standard of relevance thus is a liberal one." *Daubert*, 509 U.S. at 587; *see Lucid Grp.*, 2024 WL 3404624, at *4 (admitting expert testimony to "explain the economic harm that results from" the challenged statute).

***1. Professor Garthwaite's Declaration Will Assist The Court***

The Government contends (at 7–9) that Professor Garthwaite's economic analysis "has little or no relevance to the legal questions at issue." Not so.

In his Declaration, Professor Garthwaite "describe[s] the economic impact of the [Drug Pricing Program]." Garthwaite Decl. ¶ 7. He does so by "evaluat[ing] the 'negotiation' process" and "the impact of setting prices for certain selected drugs on innovative behavior by manufacturers and the corresponding potential impacts on current and future patients." *Id.* Professor Garthwaite's Declaration is relevant to numerous issues in this case.

*First*, the Program's economic impact is relevant to Plaintiffs' excessive fines claim. One feature of a fine that evinces a punitive purpose is that it "promote[s] the traditional aims of punishment—retribution and deterrence." *Kennedy v. Mendoza-Martinez*, 372 U.S. 144, 168 (1963). Here, the "catastrophic" economic effect of the IRA's excise tax, Garthwaite Decl. ¶ 85, is evidence of its retributive and deterrent aims and effects. Likewise, the economic impact of the excise tax is relevant to whether it is "disproportionate." *United States v. Bajakajian*, 524 U.S. 321, 335 (1998).

Professor Garthwaite's expert economic analysis also supports Plaintiffs' point—and the statements of their fact declarants—that the excise tax "would cause significant financial harm to manufacturers." ECF No. 60 at 19 (citing Garthwaite Decl. ¶¶ 68, 85–86; Bernie Decl. ¶ 10). As Professor Garthwaite explains, "[f]rom an economic perspective, manufacturers (particularly those that sell multiple products) would be better off accepting an offer close to a zero price (or even a

negative price, i.e., pay CMS for the right to provide the drug to Medicare participants)." Garthwaite Decl. ¶ 15. Professor Garthwaite illustrates this point with the following example: "[I]f the [Maximum Fair Price]-eligible drug accounts for approximately 13 percent or more of its manufacturer's total net revenues, applying the excise tax over a full year (beginning at 186 percent and escalating to 1,900 percent by day 272) would result in an excise tax liability of 100 percent of the manufacturer's total net revenues." *Id.* at ¶ 86. This economic analysis shows that the so-called "tax" serves at least "*in part* to punish" and deter, *Tyler v. Hennepin Cnty., Minnesota*, 598 U.S. 631, 648 (2023) (Gorsuch, J., concurring) (cleaned up), and that it would inflict a disproportionate burden on manufacturers vis-à-vis their purported "offense" of declining to "negotiate."

Indeed, not only is Professor Garthwaite's economic analysis relevant to the excessive fines issue, it responds directly to arguments that the Government has made in similar litigation. The Government has disputed the IRA's economic effects in response to other excessive fines challenges. Citing "project[ions]" by "[o]utside experts," it has argued that "[s]ome manufacturers" actually "may find it to be in their business interest to continue to make Medicare-reimbursable sales of their selected drugs and to pay a portion of that Medicare reimbursement back in the form of the excise tax." Defs.' Opp. to Pls.' Mot. for Summary Judgment, *Novartis Pharms. Corp. v. Becerra*, No. 23-CV-14221, ECF No. 24 at 60 n.14 (D.N.J. Jan. 12, 2024); *see* Defs.' Mot. to Dismiss, *Dayton Area Chamber of Com. v. Becerra*, No. 23-CV-156, ECF No. 71 at 70 n.22 (S.D. Ohio Dec. 15, 2023) (same). The Court should allow Plaintiffs' expert to address this same issue.

*Second*, Professor Garthwaite's Declaration is relevant to whether the Anti-Injunction Act (AIA) applies. As Plaintiffs note in their motion for summary judgment, one exception to the AIA requires the plaintiff to show that the "tax" would inflict "irreparable injury." *Bob Jones Univ. v. Simon*, 416 U.S. 725, 737 (1974); *see Hosp. Res. Pers., Inc. v. United States*, 860 F. Supp. 1554, 1556 (S.D. Ga. 1994) (granting preliminary injunction, despite AIA, because evidence showed that "the collection

efforts threatened . . . would effectively force Plaintiff out of business"). Citing Professor Garthwaite's Declaration, Plaintiffs note that "attempting to pay the excise tax before suing would cause irreparable economic injury, in some cases 'liability of 100 percent of the manufacturer's total net revenues.'" ECF No. 60 at 23 (quoting Garthwaite Decl. ¶ 86).

Again, the point is also responsive to arguments the Government has made elsewhere. The Government has argued in other cases that the AIA bars an excessive fines challenge to the excise tax where a manufacturer "cannot establish that [it] will suffer irreparable harm" if required to pay. *Novartis*, No. 23-CV-14221, ECF No. 24 at 45; *Dayton*, No. 23-CV-156, ECF No. 71 at 28 (same). Indeed, the Government has disputed other manufacturers' claims of irreparable economic harm in part because those manufacturers "offer[ed] no factual support for that assertion." *Dayton*, No. 23-CV-156, ECF No. 71 at 30; *see id.* at 28 (arguing that the manufacturers failed to submit "any factual support" for irreparable harm argument); Defs.' Opp. to Pls.' Mot. for Summary Judgment, *Boehringer Ingelheim Pharms., Inc. v. HHS*, 23-CV-1103, ECF No. 48-1 at 16 (D. Conn. Dec. 20, 2023) (same). Professor Garthwaite's Declaration provides "factual support" for the irreparable harm manufacturers would face if subjected to the excise tax. *See* Garthwaite Decl. ¶¶ 82–91.

*Third*, Professor Garthwaite's Declaration supports the property-interest element of Plaintiffs' due process claim. To take one example, Plaintiffs note that "[i]n some instances, the economic viability of a product may turn *entirely* on HHS's decision whether the product is selected for 'negotiation'—or is grouped with other products as one qualifying single source drug." ECF No. 60 at 27 (citing Garthwaite Decl. ¶¶ 73, 106–07). Professor Garthwaite provides a detailed explanation of the economics underpinning this point. *See* Garthwaite Decl. ¶¶ 73, 106–07.

Plaintiffs also explain that the IRA upends manufacturers' property interests by reducing the value of their patents. To support this point—citing Professor Garthwaite's analysis—Plaintiffs observe that "the long lead times for developing cutting-edge medicines" mean "manufacturers must

make investment decisions based on the prospect of *future* sales." ECF No. 60 at 26 (citing Garthwaite Decl. ¶¶ 15, 17, 78(d)). Professor Garthwaite provides a detailed economic analysis supporting this reasoning as well. *See* Garthwaite Decl. ¶¶ 15, 17, 78(d).

*Finally*, Professor Garthwaite's Declaration walks through the economics of how the Program coerces participation. In the Fifth Circuit's words, "the consequences of failing to reach an agreement with HHS are [so] severe" that "[m]anufacturers are all but certain to adopt the price" HHS imposes, even when doing so would "ma[k]e sales of a particular drug unprofitable." ECF No. 60 (quoting *Nat'l Infusion Ctr. Ass'n v. Becerra*, 116 F.4th 488, 500 (2024)). Professor Garthwaite explains why this is so, including an economic analysis of how the purported option to withdraw from Medicare and Medicaid is illusory because it would devastate manufacturers' businesses—including in the commercial market. *See* Garthwaite Decl. ¶ 88 (explaining "spillover effects in the commercial market"); *see also id.* ¶¶ 89–91. He also explains how "[e]xiting from Medicare and Medicaid[,] . . . could stifle providers' and patients' access to the most-frequently prescribed medicines" and "devastate millions of patients, contradict manufacturers' core mission, and tarnish manufacturers' reputations." ECF No. 60 at 29–30 (citing Garthwaite Decl. ¶ 89; Bernie Decl. ¶ 14); *see* Garthwaite Decl. ¶ 89 ("[Medicare and Medicaid] insure millions of older and financially needy patients. Withdrawing all products from coverage would eliminate access to many safe and effective medications, including those not subject to MFP-setting. Not only would this be devastating for millions of patients, but this decision would harm manufacturers' reputations, which could lead to further financial repercussions.") (footnote omitted). This analysis underscores *why* manufacturers have no "cognizable" option other than to participate in the Program. *Valancourt Books, LLC v. Garland*, 82 F.4th 1222, 1235 (D.C. Cir. 2023). Professor Garthwaite's Declaration thus will be "helpful[]" in resolving numerous issues in the parties' summary judgment briefing. *Puga*, 922 F.3d at 294.

The Government's counterarguments are meritless. While it is true that this case, like all cases,

"presents legal questions," Br. 7 (citation omitted), that does not make Professor Garthwaite's Declaration *irrelevant*, *see, e.g.*, *Vogler v. Blackmore*, 352 F.3d 150, 156 (5th Cir. 2003) (observing that expert "testimony [can be] relevant" even "if not necessary"); *In re Richardson*, 273 A.3d 342, 351 (D.C. 2022) (rejecting argument that "confuse[d] relevance with strict necessity"). To the extent the Court considers factual issues—such as whether Plaintiffs satisfy the AIA exception for "irreparable injury" or whether the Program coerces participation—Professor Garthwaite's economic analysis certainly will "assist" with those determinations. Fed. R. Evid. 702 Advisory Committee Notes. And if the Court concludes that there are no disputes of material fact, it can simply disregard Professor Garthwaite's Declaration because—again—there is no jury to potentially prejudice. *See, e.g.*, *Gibbs*, 210 F.3d at 500; *Whitehouse Hotel*, 615 F.3d at 330.

Finally, the Government's observation (at 8) that other plaintiffs challenging the Drug Pricing Program have not submitted expert testimony has no bearing on the admissibility of Professor Garthwaite's Declaration. Plaintiffs here are not required to litigate this case in the same way as plaintiffs in other cases. Indeed, as noted, the Government has emphasized in several of those other cases that the plaintiffs did *not* submit "any factual support" for their arguments. Defs.' Mot. to Dismiss, *Dayton*, No. 23-CV-156, ECF No. 71 at 30; *see Boehringer Ingelheim*, 23-CV-1103, ECF No. 48-1 at 16. Plaintiffs here can hardly be faulted for providing the factual support that the Government has claimed was lacking in other cases.

#### *2. Professor Garthwaite's Discussion Of The Relevant Statutory Provisions Is An Appropriate Basis For His Economic Opinions*

The Government also urges the Court (at 8) to exclude Professor Garthwaite's Declaration on the theory that it offers "an evaluation of the statutory provisions at issue." While the Government says this objection applies to "much of" the Declaration, it provides only one example of a single paragraph—a paragraph that Plaintiffs do not cite in their summary judgment motion. *See* Br. 8 (citing Garthwaite Decl. ¶ 49). At any rate, the Government's superficial objection to Professor Garthwaite's

detailed economic analysis provides no basis to exclude any part of his testimony, let alone his Declaration as a whole.

Federal Rule of Civil Procedure 26 mandates that an expert provide "the basis and reasons for" his opinions. Fed. R. Civ. P. 26(a)(2)(i). Further, "an expert witness can 'educate the factfinder about general principles' relevant to the case." *U.S. ex rel. Ruscher v. Omnicare, Inc.*, 2015 WL 5178074, at *7 (S.D. Tex. Sept. 3, 2015) (quoting Fed. R. Evid. 702), *aff'd*, 663 F. App'x 368 (5th Cir. 2016). "Such testimony is particularly helpful where, as here, the case concerns a complex industry governed by a number of federal statutory and regulatory schemes." *Id.*

As discussed, Professor Garthwaite's Declaration analyzes the economic effects of a statutory and regulatory scheme on participants in a complex, heavily regulated market. So a key basis for his opinions is an understanding of how that statutory and regulatory scheme works. Indeed, Professor Garthwaite is up-front about the fact that his economic "opinions are based on"—among other things—his "own understanding of the Inflation Reduction Act, CMS Guidance, and IRS Guidance." Garthwaite Decl. ¶ 10. Without first "evaluat[ing] the 'negotiation' process required by the Medicare Drug Pricing Provision," Professor Garthwaite would lack the necessary foundation for his ultimate conclusions about the "impact" of that Program "on innovative behavior by manufacturers and the corresponding potential impacts on current and future patients." *Id.* ¶ 7.[*] Professor Garthwaite's Declaration thus does not offer "legal conclusion[s]," as the Government claims, Br. 9; it describes his understanding of a statutory and regulatory scheme as a basis for his expert analysis of the economic effects of that scheme.

In any event, as discussed, this case is not going to a jury. The Court does not need to parse

[*] Without citation, the Government claims (at 8) that Professor Garthwaite describes the "effects of the program on entities and people who are not party to this litigation." But Plaintiffs represent manufacturers (PhRMA), providers (NICA), and patients (GCCA).

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. *See, e.g.*, *Gibbs*, 210 F.3d at 500; *Whitehouse Hotel*, 615 F.3d at 330.

**B. Professor Garthwaite's Declaration Is Reliable**

"Evidentiary reliability, or trustworthiness, is demonstrated by a showing that the knowledge offered is 'more than [subjective] belief or unsupported speculation.'" *United States v. Posado*, 57 F.3d 428, 433 (5th Cir. 1995) (quoting *Daubert*, 509 U.S. at 590). To "prove by a preponderance of the evidence that the testimony is reliable," the proponent of an expert declaration "need not prove to the judge that the expert's testimony is correct." *MM Steel, L.P. v. JSW Steel (USA) Inc.*, 806 F.3d 835, 850 (5th Cir. 2015). Further—as discussed—in cases where there is "no jury, there is no risk of tainting the trial by exposing a jury to unreliable evidence." *Whitehouse Hotel*, 615 F.3d at 330. Thus, "a court sitting as the trier of fact errs only by relying on unreliable evidence, not by simply admitting such evidence." *Wal-Mart Stores, Inc. v. Texas Alcoholic Beverage Comm'n*, 2017 WL 11715451, at *4 (W.D. Tex. May 22, 2017).

Professor Garthwaite's Declaration is reliable. To accomplish his economic analysis, Professor Garthwaite "relied on [his] training and research, relevant literature, and publicly-available information." Garthwaite Decl. ¶ 8. He also "directed a team from . . . an economics research and consulting group." *Id.* The Government does not challenge Professor Garthwaite's qualifications as an economist.

Instead, the Government objects (at 10) to Professor Garthwaite's discussion of the statutory and regulatory framework on the basis that "he is not a lawyer." Again, however, Professor Garthwaite's Declaration analyzes the Program's *economic effects*. In so doing, he provides necessary foundation for his analysis by describing his understanding of the Program. The Court, of course, does not need to defer to Professor Garthwaite's understanding of the law, and Professor Garthwaite

does not opine on whether the Drug Pricing Program is unconstitutional anyway. But in determining the weight of Professor Garthwaite's economic analysis of the Program's effects, the Court must assess his understanding of the Program.

The Government also improperly brings a "line-by-line" challenge to particular paragraphs in Professor Garthwaite's Declaration and "render[s] a conclusion on the merits of [his] opinions." *Lucid Grp.*, 2024 WL 3404624, at *5. First, the Government takes issue with Professor Garthwaite's assessment of manufacturers' and CMS's "best alternatives to negotiation" (BATNAs), claiming (at 10) that his declaration "is entirely devoid of any examination of the government's BATNA." But as the Government elsewhere acknowledges, Professor Garthwaite in fact analyzes manufacturers' BATNAs at length, *see* Garthwaite Decl. ¶¶ 84–90, and specifically explains that "CMS faces little risk of manufacturers rejecting the final MFP amount no matter how low it is," *id.* ¶ 91. While the Government may *disagree* with Professor Garthwaite's conclusions, "mere disagreement with the assumptions and methodology used does not warrant exclusion of expert testimony." *Synergetics, Inc. v. Hurst*, 477 F.3d 949, 956 (8th Cir. 2007); *cf. United States v. Gutierrez*, No. 21-13791, 2023 WL 3620891, at *4 (11th Cir. May 24, 2023) ("[M]ere disagreement among possible experts is not enough to prove an expert's methodology unreliable.").

Second, the Government challenges footnote six in the background section of Professor Garthwaite's seventy-eight-page Declaration, which says that "nothing in the IRA prevents" CMS from setting "prices of $0." Garthwaite Decl. ¶ 15 n.6. The Government asserts (at 11) that "market realities would prevent CMS from setting a MFP at zero dollars." Again, however, that the Government "simply disagrees with [some of Professor Garthwaite's] opinions" is not a reason to exclude his testimony. *Mars, Inc. v. TruRx LLC*, 2016 WL 4034790, at *3 (E.D. Tex. Apr. 18, 2016). And regardless, the Government *doesn't* actually dispute that "nothing in the IRA prevents" CMS from setting "prices of $0," which is, again, a single point in a single footnote in the Declaration.

Finally, the Government accuses Professor Garthwaite (at 11) of "largely ignor[ing] . . . the results of the first negotiation cycle under the program." That statement is remarkable: In its motion for a stay of the summary judgment schedule, the Government claimed it needed more time in part because, unlike the first Garthwaite declaration, "[t]he Garthwaite Declaration at issue here . . . purports to discuss the actual events of the first round of actual drug price negotiations." ECF 62 at 4. And indeed, after making that statement, the Government then cited (at 11) the section of Professor Garthwaite's Declaration titled: "The First Round of Price Setting Has Not Changed the Fundamental Uncertainty Associated with the IRA." *See* Garthwaite Decl. ¶¶ 92–95 & tbl.1; *see also id.* ¶¶ 78(a), 15 n.6, 85 n.190. The Government apparently thinks Professor Garthwaite should have drawn different conclusions from the first round of price setting, or weighed it differently in his analysis. But that is not a basis to exclude his testimony. *See, e.g.*, *Mars*, 2016 WL 4034790, at *3; *Synergetics*, 477 F.3d at 956; *Gutierrez*, 2023 WL 3620891, at *4.

## II. The Court Should Not Amend The Joint Briefing Schedule

The Government asks the Court (at 12) to delay the joint briefing schedule for two months if it denies the Government's motion to exclude. But as Plaintiffs explained in their opposition to the Government's stay motion, ECF No. 64, incorporated here by reference, and as this Court recently concluded in denying that stay motion, ECF No. 65 at 2, the Government has known about Professor Garthwaite's testimony for a year and a half, and they have known since September that they would likely need to engage with it during summary judgment briefing. Indeed, as the Government points out, "[f]rom 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.'" ECF No. 61 at 6, 8. While the parties agreed they did not need discovery, there was never a suggestion that they would not rely on evidence. To the contrary, the parties agreed they would file "cross-motions for summary judgment pursuant to Federal Rule of Civil Procedure 56," not motions to dismiss or

for judgment on the pleadings. ECF No. 33 ¶ 5. And even the updated version of Professor Garthwaite's Declaration has already been on the docket for well over a month. Parties regularly move simultaneously for summary judgment and to exclude the other side's experts.

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. Instead, the Government can respond to Plaintiffs' summary judgment motion by explaining to the Court why it thinks Plaintiffs' reliance on the Declaration is unpersuasive. And as the ultimate trier of fact, the Court can disregard or discount the weight of Professor Garthwaite's views as it deems appropriate. The Government's disagreement with those views does not justify further delay.

## CONCLUSION

For the foregoing reasons, this Court should deny the Government's motion to exclude the expert declaration of Professor Craig Garthwaite and the Government's alternative request to modify the joint briefing schedule.

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