No. 25-50661

In the United States Court of Appeals for the Fifth Circuit

NATIONAL INFUSION CENTER ASSOCIATION, on behalf of itself and its members; GLOBAL COLON CANCER ASSOCIATION, on behalf of itself and its members; PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, on behalf of itself and its members,

Plaintiffs-Appellants,

v.

ROBERT F. KENNEDY, JR., Secretary, U.S. Department of Health and Human Services, In his Official Capacity; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; MEHMET OZ, Administrator of the Centers for Medicare and Medicaid Services, In his Official Capacity; CENTERS FOR MEDICARE AND MEDICAID SERVICES,

Defendants-Appellees.

On Appeal from the U.S. District Court for the Western District of Texas
No. 1:23-cv-707 (Hon. David Alan Ezra)

APPELLANTS' UNOPPOSED MOTION TO EXPEDITE BRIEFING AND ARGUMENT

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CERTIFICATE OF INTERESTED PERSONS

Pursuant to Fifth Circuit Rules 27.4 and 28.2.1, undersigned counsel certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of these appeals. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

1. **Plaintiff-Appellant the National Infusion Center Association (NICA).** NICA does not have a parent corporation, and no publicly held corporation owns 10% or more of its stock. The following attorneys have represented NICA in this case:

> Tim Cleveland, Austin Krist, Ibituroko-Emi Lawson, McKenzie Edwards and Gerard Bifulco of Cleveland Krist LLC.

2. **Plaintiff-Appellant the Global Colon Cancer Association (GCCA).** GCCA does not have a parent corporation, and no publicly held corporation owns 10% or more of its stock. The following attorneys have represented GCCA in this case:

> Michael Kolber and Megan Thibert-Ind of Manatt, Phelps & Phillips LLP.

3. **Plaintiff-Appellant Pharmaceutical Research and Manufacturers of America (PhRMA).** PhRMA does not have a parent

corporation, and no publicly held corporation owns 10% or more of its stock.

The following attorneys have represented PhRMA in this case:

> Jeffrey Handwerker, John Elwood, Allon Kedem, William Perdue, and Allissa Pollard of Arnold & Porter Kaye Scholer LLP.

4. **Defendant-Appellees Robert F. Kennedy, Jr., the U.S. Department of Health and Human Services, Mehmet Oz, and the Centers for Medicare and Medicaid Services.** The following attorneys have represented the Government in this case:

> Lindsey Powell, Steven A. Myers, David L. Peters, Catherine Padhi, Samuel R. Bagenstos, Paul R. Rodríguez, Joel McElvain, Matthew A. Campbell, Lindsay S. Goldberg, Kenneth Whitley, Eric J. Hamilton, Justin R. Simmons, Brian M. Boynton, Cassandra M. Snyder, Michael Granston, Jaime Esparza, Michael J. Gaffney, Michelle R. Bennett, Stephen M. Pezzi, Christine L. Coogle, and Alexander V. Sverdlov.

Dated: August 15, 2025

/s/ *John Elwood*
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Pursuant to Fed. R. App. P. 2 and 5th Cir. R. 27.5 and 34.5, Plaintiffs-Appellants the National Infusion Center Association (NICA), the Global Colon Cancer Association (GCCA), and Pharmaceutical Research and Manufacturers of America (PhRMA) respectfully request that the Court expedite this appeal of the district court's order denying Plaintiffs' motion for summary judgment and granting the cross-motion for summary judgment of Defendants-Appellees Robert F. Kennedy, Jr., the United States Department of Health and Human Services, Dr. Mehmet Oz, and the Centers for Medicare and Medicaid Services (collectively, the Government). The Government does not oppose this motion but asks that argument not be scheduled during the week of October 6.

INTRODUCTION

This lawsuit challenges an unconstitutional statute that is poised to upend the U.S. healthcare economy on January 1, 2026, and which is already inflicting massive harm on Plaintiffs. As this Court recognized in expediting a prior appeal in this case, *Nat'l Infusion Center Ass'n v. Becerra*, No. 24-50180, Dkts. 23, 32, 36 (5th Cir. Mar. 22, 2024), prompt resolution is necessary given the impending statutory deadlines and the economic and procedural harms Plaintiffs are suffering already. The Government will not be prejudiced by

expedition; indeed, the Government did not oppose expediting the prior appeal, and the matter has only grown more pressing. And as the Government indicated earlier in this litigation, it "share[s] [Plaintiffs'] desire to get this all resolved as soon as we can."

In 2022, Congress passed the Inflation Reduction Act (IRA). The IRA created the so-called "Drug Price Negotiation Program" (Drug-Pricing Program or Program) which—as this Court explained last September—"shifts the price-setting mechanism for many of America's highest-selling drugs from the free market to a government-run process." *Nat'l Infusion Ctr. Ass'n v. Becerra*, 116 F.4th 488, 494 (2024) (*NICA*). The IRA mandates sham "negotiations" whereby the government sets a "maximum fair price" for certain selected drugs—some of the most innovative and widely used. Pharmaceutical manufacturers must either accept these government-imposed prices or face draconian penalties. Left in place, this new regime will dramatically slow innovation, reduce the availability of new medicines, and undermine public health, causing grave harm to patients, pharmaceutical manufacturers, and healthcare providers.

In four months, the first ten "maximum fair prices" are scheduled to take effect, costing manufacturers and providers billions of dollars in 2026

alone. Members of Plaintiffs' organizations manufacture or provide nine of those selected drugs, and thus face imminent injury.

Further, as this Court recognized last year, the IRA has already begun to harm Plaintiffs. The Act is inflicting "economic injury *now*" by limiting NICA's ability to "obtain necessary debt and equity capital," which "is critically important to their financial solvency." *NICA*, 116 F.4th at 502 (quotation marks omitted). And for manufacturers, the Drug-Pricing Program is causing quintessential procedural injuries by compelling participation in an unconstitutional administrative process. Every day the Program remains in effect, it forces manufacturers to make major business decisions that will have significant consequences for patients and the public for years to come.

In June 2023, Plaintiffs challenged the IRA's constitutionality in the Western District of Texas.[1] Given the IRA's impending deadlines, the parties

[1] Numerous other plaintiffs filed lawsuits challenging the IRA's constitutionality. *See Merck & Co. v. Becerra*, No. 23-CV-1615 (D.D.C.); *Dayton Area Chamber of Commerce v. Becerra*, No. 23-CV-156 (S.D. Ohio); *Bristol Myers Squibb Co. v. Becerra*, No. 23-CV-3335 (D.N.J.); *Astellas Pharma US, Inc. v. HHS*, No. 23-CV-4578 (N.D. Ill.); *Janssen Pharms., Inc. v. Becerra*, No. 23-CV-3818 (D.N.J); *Boehringer Ingelheim Pharms., Inc. v. HHS*, No. 23-CV-1103 (D. Conn.); *AstraZeneca Pharmaceuticals LP v. Becerra*, No. 23-CV-931 (D. Del.); *Novartis Pharmaceuticals Corp. v. Becerra*, No. 23-CV-14221 (D.N.J.); *Novo Nordisk, Inc. v. Becerra*, No. 23-CV-20814 (D.N.J.); *Teva Pharms. USA, Inc. v. Becerra*, 25-CV-113 (D.D.C.).

agreed to an expedited schedule in which they would proceed directly to cross-motions for summary judgment. The Government reneged on that schedule and successfully sought dismissal for lack of jurisdiction and venue. This Court granted Plaintiffs' motion to expedite the appeal. *Nat'l Infusion Center Ass'n v. Becerra*, No. 24-50180, Dkts. 23, 32, 36 (5th Cir. Mar. 22, 2024). The Court heard oral argument just six weeks after the appeal was docketed—and issued an expedited decision reversing the dismissal order. To clear a path for efficient proceedings on remand, the Court also held that Plaintiffs have Article III standing to challenge the Program.

Good cause exists to expedite this appeal as well. The IRA's first "maximum fair prices" take effect on January 1, 2026. Absent a ruling before then, Plaintiffs will suffer irreparable harm, and it will become increasingly difficult to unwind the Act's other harmful effects. Meanwhile, every day the Program remains in effect, it will continue to inflict economic and procedural harms on manufacturers and providers. Because Plaintiffs' proposed timeline will not prejudice the Government, and the Government does not oppose the proposed briefing schedule, this Court should grant Plaintiffs' motion.

BACKGROUND

A. The Inflation Reduction Act

As this Court observed last September, the IRA's Drug-Pricing Program "shifts the price-setting mechanism for many of America's highest-selling drugs from the free market to a government-run process." *NICA*, 116 F.4th at 494. Although the statute directs HHS to establish a "Drug Price *Negotiation* Program," 42 U.S.C. § 1320f(a) (emphasis added), it in fact empowers HHS to set drug prices by administrative *fiat*.

HHS Ranks and Selects "Negotiation-Eligible Drugs"

After "negotiation-eligible" drugs are identified and ranked, the IRA directs HHS to "select" an increasing number of the highest-ranked drugs for "negotiation" of "maximum fair prices." *Id.* § 1320f-1(a). HHS selected the first round of ten Part D drugs in 2023, with prices scheduled to take effect on January 1, 2026. *Id.* In 2025, the agency selected fifteen more Part D drugs, with prices scheduled for 2027. *Id.* Part B drugs will be added to the selection process beginning in 2026, with maximum prices taking effect in 2028. *Id.* § 1320f-1(a)(1), (3). Fifteen Part D and Part B drugs will be selected for 2028, and twenty Part D and Part B drugs will be selected for 2029 and each year thereafter. *Id.* § 1320f-1(a)(1)–(4).

HHS Sets "Maximum Fair Prices" Through Sham "Negotiations"

Once drugs are selected, the IRA directs HHS to "enter into agreements with manufacturers" to "negotiate to determine (and . . . agree to) a maximum fair price." *Id.* §§ 1320f-2(a), (a)(1). While the IRA's "negotiation" process includes a sham offer/counteroffer framework, *id.* § 1320f-3(b)(2)(C)–(D), that is where any resemblance to ordinary commercial negotiations ends. The IRA places a "ceiling" on how *high* a price HHS can offer. *Id.* § 1320f-3(c). But with one minor exception, the statute does not limit how *low* a price HHS can demand, *id.* § 1320f-3(b)(2)(F), and it directs HHS to "aim[] to achieve the lowest maximum fair price," *id.* § 1320f-3(b)(1). While HHS must "consider" specified "factors," the IRA sets no criteria for how HHS must weigh them. *Id.* § 1320f-3(e).

After a "maximum fair price" becomes effective, the manufacturer must provide "access to such price to" a wide array of individuals and entities participating in Medicare. *Id.* § 1320f-2(a)(1). Manufacturers that fail to do so must pay a penalty of ten times the difference between the price charged and the HHS-imposed price, multiplied by the number of units sold. *Id.* § 1320f-6(a)(2).

Noncompliant Manufacturers Must Pay a Crippling "Excise Tax"

The linchpin of the IRA's forced-negotiation scheme is a so-called "excise tax"—a steep, escalating penalty for every day the manufacturer has not, by the deadline, (1) entered into an "agreement" to "negotiate" a price, or (2) "agreed" to the price that HHS imposes. 26 U.S.C. § 5000D(b). While labeled an "excise tax," it is intended to coerce rather than to raise revenue.

The size of this "tax" is staggering. It applies to all U.S. sales of the drug in question—not just Medicare sales—and is calculated based on a formula representing an "applicable percentage" of the drug's total cost (price plus tax). *Id.* § 5000D(d). The tax is calculated based on a high "applicable percentage" of the drug's total cost (price plus tax) that increases for each quarter of noncompliance. *Id.* As this Court explained, the excise tax rate "starts at 185.71% of the drug's price and rises to 1,900% depending on the duration of noncompliance." *NICA*, 116 F.4th at 495 (citing 26 U.S.C. § 5000D(d) and CRS, *Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376)* 4 (Aug. 10, 2022)).

The excise-tax penalty will not be "[s]uspen[ded]," 26 U.S.C. § 5000D(c), unless the manufacturer withdraws *all* of its drugs from Medicare Part D, Medicare Part B, *and* Medicaid. *See id.*; 42 U.S.C. § 1396r-8(a)(1). That would

leave Medicare and Medicaid beneficiaries without access to badly needed medications. ECF No. 1 ¶¶ 118, 126.[2]

In August 2023, CMS selected the first ten drugs for "negotiation." CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (Aug. 2023), go.cms.gov/3NRYfmU. In August 2024, it announced the first list of maximum prices, which are scheduled to take effect on January 1, 2026. *See* CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* (Aug. 15, 2024), go.cms.gov/48yZiSl. CMS slashed the list prices of the first ten selected drugs by as much as 79%, with an average discount of 63%.

In January 2025, CMS selected the next fifteen drugs for "negotiation." CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2027* (Jan. 2025), http://bit.ly/4mxQ7Hr. Manufacturers of those drugs must "agree" to "maximum fair prices" by November 1, 2025. 42 U.S.C. § 1320f(b)(4)(B). The IRA requires CMS to issue prices for those drugs by November 30, 2025. *Id.* § 1320f-4(a)(1).

[2] All ECF citations are to the docket below, *Nat'l Infusion Ctr. Ass'n v. Becerra*, No. 23-CV-707 (W.D. Tex.).

B. The Proceedings Below

Plaintiffs filed their Complaint on June 21, 2023. ECF No. 1. Plaintiffs asserted three claims, arguing that the IRA violates (1) the separation of powers and the nondelegation doctrine, (2) the Eighth Amendment's Excessive Fines Clause, and (3) the Fifth Amendment's Due Process Clause.

In July 2023, the parties conferred regarding the case schedule. ECF No. 41 at 1–2. Plaintiffs explained the need to expedite the case given the IRA's impending deadlines. *Id.* To avoid the need to seek a preliminary injunction or other extraordinary relief, Plaintiffs suggested that the parties move directly to cross-motions for summary judgment. *Id.* at 2. The Government agreed and affirmed that it "share[d] [Plaintiffs'] desire to get this all resolved as soon as we can." *Id.*

The parties jointly proposed an expedited schedule, ECF No. 33, which the district court entered, ECF No. 34. That schedule would have seen briefing completed by November 2023—well before the IRA's key deadlines. On August 10, 2023, Plaintiffs moved for summary judgment, just seven weeks after filing the Complaint. ECF No. 35. Based on the parties' agreement, briefing was set to be completed by November 17, 2023. ECF No. 34.

But rather than cross-move for summary judgment, the Government reneged on the parties' agreement, successfully moved to vacate the joint scheduling order over Plaintiffs' opposition, and moved to dismiss for lack of jurisdiction and venue. *See* ECF Nos. 39–40, 45. The district court granted the Government's motion, ECF 53, and Plaintiffs immediately appealed, ECF No. 54.

When the appeal was docketed in this Court, Plaintiffs sought an expedited briefing schedule, which the Government did not oppose. *Nat'l Infusion Center Ass'n v. Becerra*, No. 24-50180, Dkt. 23 (5th Cir. Mar. 22, 2024). Recognizing that Plaintiffs' claims are time-sensitive, this Court granted the motion to expedite. *See id.* Dkts. 32, 36. At oral argument, Plaintiffs' counsel stressed the need for a resolution of their claims 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). Just over four months later, this Court published an opinion reversing the dismissal of Plaintiffs' suit. *Nat'l Infusion Ctr. Ass'n v. Becerra*, 116 F.4th 488 (5th Cir. 2024). The Court also concluded that Plaintiffs have Article III standing, thus allowing the case to proceed directly to the merits on remand. *See id.* at 496-504.

On remand, the Government refused to negotiate a briefing schedule until most of the ninety-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 would be completed by May 2025. ECF No. 58. While negotiating the briefing schedule, Plaintiffs again reaffirmed that time was of the essence.

The court entered the parties' agreed-upon schedule, ECF No. 59, and Plaintiffs filed their motion for summary judgment on January 10, 2025, ECF No. 60. More than a month later, the Government moved to exclude the declaration of Plaintiffs' longtime expert and to stay briefing pending resolution of that motion. ECF Nos. 61, 62. The district court granted a brief extension to the Government but denied its motion to exclude and its motion to stay the briefing. ECF Nos. 65, 67.

On August 7, 2025—just over four weeks after briefing was completed on the parties' cross-motions for summary judgment—the district court entered the order that is the subject of this appeal. ECF No. 90.

ARGUMENT

This Court may expedite an appeal, including entering an abbreviated briefing scheduling and advancing the case for hearing, for "good cause." 5th Cir. R. 27.5 and 34.5. Good cause exists here because the first IRA-imposed prices are scheduled to take effect on January 1, 2026; the IRA is causing ongoing, irreparable harm to Plaintiffs; the dispute presents purely legal questions; and the Government does not oppose and would not suffer prejudice.

I. Both Sides Have An Interest In Resolving Challenges To The IRA's Constitutionality Expeditiously

Expedited briefing and review are crucial in this case because the first IRA-imposed prices are scheduled to take effect in just over four months. Meanwhile, some "negotiations" have already concluded, others are well underway, and more and more manufacturers are being compelled to participate in an unconstitutional process. Providers likewise are seeing their interests harmed by that same unconstitutional process and are already facing barriers to raising capital as a result. With these concerns already apparent last April, this Court expedited the first appeal in this case. In reversing and remanding, the Court addressed the issue of standing to clear the way for immediate review of the merits. With the merits now before the Court and

"maximum fair prices" poised to take effect in January, the matter is all the more pressing, and an expedited schedule is again warranted.

First, January 1, 2026 is fast approaching. That is the date when manufacturers of the first ten drugs selected under the Program must begin providing "access" to government-imposed prices. 42 U.S.C. § 1320f-2(a)(1). Those prices reflect discounts of as much as 79%, with an average discount of 63%. CMS, *Negotiating for Lower Drug Prices Works, Saves Billions* (Aug. 15, 2024), https://bit.ly/3TJt408. The Government projects that these imminent price caps will impact the market to the tune of "an estimated $6 billion" in 2026 alone. *Id.* Come January, Plaintiffs' members—who manufacture or provide nine of the first ten drugs—are expected to begin footing the bill.

Second, the Drug-Pricing Program is already harming Plaintiffs' interests. As this Court held last year, the Program is "causing [providers] economic injury *now*." *NICA*, 116 F.4th at 502. That is because "the Program limits [their] ability to obtain necessary debt and equity capital." *Id.* Every day the Program remains in effect, it "impacts an aspect of [providers'] business that is critically important to their financial solvency." *Id.* (quotation marks omitted).

The Program also is already "harming manufacturers," *id.* at 504 n.12, by inflicting the "here-and-now injury," *Axon Enter. v. FTC*, 598 U.S. 175, 189, 192 (2023), of "being compelled to participate in an invalid administrative process," *Texas v. United States*, 497 F.3d 491, 496-97 (5th Cir. 2007). In fact, as this Court has already concluded, the "lack of input regarding unanswered implementation questions and inability to challenge particular determinations," coupled with the property interests at stake, "satisf[ies] the [*Mathews v. Eldridge*, 424 U.S. 319 (1976)] test" for finding a due process violation. *NICA*, 116 F.4th at 503. Manufacturers are being forced to participate in that unconstitutional process every day.

Third, prompt resolution of this case also will benefit the Government. The Government is defending numerous lawsuits challenging the drug-pricing regime, all of which consume significant resources. The Government also continues to commit substantial resources to implementing the Drug-Pricing Program, which will be wasted should Plaintiffs prevail.

II. The Government Cannot Show Prejudice From An Accelerated Timeline Involving Discrete Legal Questions

As noted, the Government does not oppose this motion and thus clearly will not suffer prejudice as a result of Plaintiffs' proposed briefing schedule.

Further, this appeal presents purely legal questions, and the Government has previously expressed its desire to resolve this dispute quickly.

First, this case presents purely legal issues the Government has been focused on for years. Indeed, the Government has already briefed those issues not only in the district court, but also in multiple other cases in federal courts of appeals. *See, e.g.*, Br. of Appellees, *AstraZeneca Pharms. LP v. HHS*, No. 24-1819, Dkt. 37 (3d Cir. Sept. 12, 2024) (briefing due process issues); Br. of Appellees, *Novo Nordisk Inc. v. HHS*, No. 24-2510, Dkt. 34 (3d Cir. Dec. 16, 2024) (briefing due process and separation of powers issues); Br. of Appellees, *Novartis Pharms. Corp. v. HHS*, No. 24-2968, Dkt. 25 (3d Cir. Feb. 19, 2025) (briefing excise tax issues).

Second, the Government agreed to an expedited briefing schedule in the district court, skipping the answer stage and discovery altogether and proceeding directly to summary judgment. ECF 33. The Government confirmed then that it "share[d] [Plaintiffs'] desire to get this all resolved as soon as we can." ECF 41 at 2. The Government also did not oppose expediting the prior appeal in this case, which occurred much further out from the January 1, 2026 maximum-price deadline. The Government has not indicated that it would suffer prejudice as a result of Plaintiffs' proposed briefing

schedule. And the public interest is served by a speedy ruling on the constitutionality of a process that will consume substantial public resources.

CONCLUSION AND PROPOSED SCHEDULE

For all these reasons, Plaintiffs respectfully request that the Court expedite the briefing schedule and oral argument in this case. Plaintiffs propose the following schedule:

- **Plaintiffs' Opening Brief:** September 2, 2025;
- **The Government's Opposition Brief:** September 19, 2025;
- **Plaintiffs' Reply Brief:** September 26, 2025;
- **Oral Argument:** at the Court's earliest convenience.

The Government does not oppose this motion but asks that argument not be scheduled during the week of October 6.

Dated: August 15, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 15, 2025, the foregoing document was electronically filed with the Court via the appellate CM/ECF system, and that copies were served on counsel of record by operation of the CM/ECF system on the same date.

Dated: August 15, 2025

/s/ *John Elwood*
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CERTIFICATE OF COMPLIANCE

This motion complies with the type-volume limitation of Fed. R. App. P. 27(d)(2)(A) because the motion contains 3,122 words excluding the parts of the motion exempted by Fed. R. App. P. 32(f) and Fifth Circuit Rule 32.2. This motion complies with the typeface and type style requirements of Fifth Circuit Rule 32.1 and Fed. R. App. P. 32(a)(5) and 32(a)(6), respectively, because this motion has been prepared in a proportionately spaced typeface using Microsoft Word in Century Expanded BT 14-point font.

Dated: August 15, 2025

/s/ *John Elwood*
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