No. 24-50180

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.

XAVIER BECERRA, Secretary, U.S. Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare and Medicaid Services; 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' OPENING BRIEF

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CERTIFICATE OF INTERESTED PERSONS

Pursuant to Fifth Circuit Rule 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 Xavier Becerra, the U.S. Department of Health and Human Services, Chiquita Brooks-LaSure, and the Centers for Medicare and Medicaid Services.** The following attorneys have represented the government in this case:

> Brian M. Boynton, Jaime Esparza, Michelle R. Bennett, Stephen M. Pezzi, Christine L. Coogle, and Alexander V. Sverdlov.

Dated: April 12, 2024

/s/ John P. Elwood
John P. Elwood

Counsel for Appellant Pharmaceutical Research and Manufacturers of America

STATEMENT REGARDING ORAL ARGUMENT

Appellants requested oral argument as part of their motion to expedite this appeal. The Court granted the motion and set oral argument for May 1, 2024.

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INTRODUCTION

Plaintiffs bring three facial constitutional challenges to an unprecedented program of government price-setting enacted as part of the Inflation Reduction Act of 2022 (IRA). This novel scheme imposes government-dictated prices on sales of innovative medicines between private parties involved in Medicare. As a direct price-regulation scheme, the IRA's drug pricing program is unlike the traditional Medicare reimbursement program, and Congress expressly codified this new program *outside* the Medicare statute. But the district court dismissed Plaintiffs' claims without reaching the merits, holding that their suit bringing facial constitutional challenges to provisions outside the Medicare statute constitutes an "action … to recover on a[] claim arising under" the Medicare statute. The district court thus concluded that Plaintiffs' claims must be channeled through an administrative process designed to evaluate requests for reimbursement. This Court should correct that erroneous decision so that this case can proceed to the merits.

The IRA ended decades of a market-based system for reimbursing prescription drugs in favor of government price-setting. The statute's so-called "Drug Price Negotiation Program" (Drug Pricing Program or

Program) mandates sham "negotiations" whereby the government imposes a "maximum fair price" for certain selected drugs—some of the most innovative and widely used. Contrary to its name, the Program involves no genuine "negotiation." Instead, it compels manufacturers to accept prices that the Centers for Medicare and Medicaid Services (CMS), a sub-agency of the Department of Health and Human Services (HHS), unilaterally chooses. There is no statutory standard to govern the agency's price-setting decision, no procedures to ensure public accountability and to protect against arbitrary or confiscatory prices, and no judicial review to ensure that the agency acts within the bounds of law. The statute establishes a ceiling that the price may not exceed, while affording the agency complete discretion to choose as *low* a price as it wants: The agency could decide that an innovative, lifesaving medicine that cost billions to develop is worth just $1 per dose. And manufacturers must either accept these government-imposed prices or face draconian, crippling penalties. Left in place, this new regime will stall innovation, reduce the availability of new medicines, and undermine public health—causing grave harm to patients, manufacturers, and healthcare providers.

Well before these "negotiations" began, the National Infusion Center Association (NICA), the Global Colon Cancer Association (GCCA), and Pharmaceutical Research and Manufacturers of America (PhRMA) filed this lawsuit, alleging that the Drug Pricing Program contravenes the separation of powers and nondelegation doctrine, the Eighth Amendment's Excessive Fines Clause, and the Fifth Amendment's Due Process Clause. The government moved to dismiss for lack of jurisdiction and improper venue, arguing that NICA—which resides in the relevant district—lacks Article III standing and failed to present its claims to the agency and thereby exhaust administrative remedies. The district court agreed with the government's exhaustion argument based on 42 U.S.C. §§ 405(h) and 1395ii, which require reimbursement claims for benefits under Medicare to be channeled through HHS and CMS before being brought in federal court.

The district court's ruling flies in the face of the statutory text. As incorporated into the Medicare statute, § 405(h) provides that "[n]o action … shall be brought … to recover on any claim arising under this subchapter"—that is, subchapter XVIII of chapter 7 of title 42 (also known as Title XVIII of the Social Security Act), which governs Medicare reimbursement. The relevant provisions of the IRA, however, are codified in subchapter XI of chapter 7, not

subchapter XVIII. Accordingly, under the Supreme Court's and this Circuit's caselaw, "the Medicare Act provides" neither "the substance [nor] the standing for [Plaintiffs'] claim[s]," *Heckler v. Ringer*, 466 U.S. 602, 620 (1984), and those claims are not "inextricably intertwined with a claim for Medicare benefits," *RenCare, Ltd. v. Humana Health Plan of Texas, Inc.*, 395 F.3d 555, 557 (5th Cir. 2004) (cleaned up). Plaintiffs challenge the constitutionality of provisions *outside* the Medicare subchapter and do not seek "to recover on any claim arising under" that statute.

In holding otherwise, the district court expanded the statutory text to encompass challenges to any "law *affecting* future reimbursements." ROA.622 (emphasis added). That is not what the statute says. If it were, even a constitutional challenge to a separately codified law prohibiting doctors from advising patients on certain topics would have to be channeled through the Medicare reimbursement process. Another court that has addressed the issue has rejected such absurdities, holding that a challenge to agency action taken under subchapter XI does not "aris[e] under subchapter XVIII" and thus is *not* subject to channeling—even if it could affect future reimbursements. *Ass'n of Cmty. Cancer Ctrs. v. Azar*, 509 F. Supp. 3d 482, 491 (D. Md. 2020) (*ACCC*).

Finally, although the district court did not address Article III standing, this Court should resolve that question now to avoid further delay and a possible second appeal on a preliminary jurisdictional question on which the parties agree the issue is fully joined. The issue is straightforward: By "depriv[ing] [NICA] of 'a procedural right to protect its concrete interests,'" the IRA inflicts "a cognizable injury." *Texas v. EEOC*, 933 F.3d 433, 447 (5th Cir. 2019) (citation omitted). Plaintiffs allege that the IRA adopts constitutionally deficient procedures that insulate agency decision-making from external input or scrutiny. As a result, NICA and its members are *already* experiencing constitutional harms: "The loss is not merely the subsequent deprivation, but the right not to suffer a deprivation without proper process." *Bertulli v. Indep. Ass'n of Cont'l Pilots*, 242 F.3d 290, 295 (5th Cir. 2001). And in any event, Plaintiffs plausibly allege that NICA will also suffer economic harm—a quintessential injury for standing purposes—under the Drug Pricing Program. This Court should reverse.

JURISDICTIONAL STATEMENT

The district court had jurisdiction under 28 U.S.C. §§ 1331 and 1346 and erroneously held that it lacked jurisdiction over NICA's claims under 42 U.S.C. §§ 405(h) and 1395ii. On February 12, 2024, the district court entered

a final order dismissing Plaintiffs' claims for lack of jurisdiction and improper venue. ROA.626. Plaintiffs timely appealed. ROA.612. This court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

1. Whether this case, which challenges the constitutionality of the Drug Pricing Program in subchapter XI of the Social Security Act, is an "action … to recover on a[] claim arising under [subchapter XVIII]" as provided in 42 U.S.C. §§ 405(h) and 1395ii.

2. Whether NICA has Article III standing to challenge the Program's constitutionality.

STATEMENT OF THE CASE

A. Prescription Drug Coverage Under Medicare

Medicare, the federal government's health coverage program for the elderly and disabled, is codified in subchapter XVIII of the Social Security Act (that is, title 42, chapter 7 of the U.S. Code). 42 U.S.C. § 1395 *et seq.* As an insurance program, Medicare does not directly control or regulate the prices that healthcare providers charge for their services or that pharmaceutical manufacturers charge for their products. Instead, Medicare provides reimbursement; it pays patients, or providers as their assignees, for incurred

covered medical expenses defined in subchapter XVIII. The Secretary for HHS administers Medicare through CMS. *Id.*

Medicare is divided into several parts, two of which are pertinent here. First, Medicare Part B covers medically reasonable and necessary medicines that are furnished incident to a physician's services. 42 U.S.C. §§ 1395k(a)(1), 1395x(s)(2)(A). Medicare Part B has, with certain exceptions, long provided drug reimbursement based on market prices. Part B reimbursement rates are generally based on the drug's "average sales price" (a weighted average of manufacturer sales prices to commercial U.S. purchasers) plus a specified percentage (generally 6%). 42 U.S.C. § 1395w-3a. By basing Part B payments on market transactions, Congress ensured that pharmaceutical companies would have the opportunity to earn competitive returns that encourage and fund future innovation.

Second, Medicare Part D allows beneficiaries to enroll in privately operated plans that cover outpatient drugs that are not physician-administered. 42 U.S.C. § 1395w-102. Part D drug prices are also market-based; Part D insurance plans are administered by private plan sponsors, which negotiate prices with manufacturers. ROA.564-66. When Congress created Part D, it prohibited HHS from "interfer[ing] with the negotiations

between drug manufacturers[,] pharmacies[,] and [private health plans]" regarding Part D drug prices. 42 U.S.C. § 1395w-111(i).

Medicare includes an elaborate administrative scheme for reviewing reimbursement claims made by patients and providers, ultimately leading to judicial review in federal court. *Id.* § 1395ff. To channel reimbursement claims through that administrative scheme, Medicare (subchapter XVIII) incorporates a jurisdiction-limiting provision from the Social Security disability insurance program (subchapter II). That provision limits federal-court jurisdiction over any "action … to recover on any claim arising under this subchapter"—as relevant here, subchapter XVIII. *Id.* § 405(h); *see id.* § 1395ii (incorporating § 405(h) into subchapter XVIII).

B. Prescription Drug Price Regulation Under the IRA

The IRA established a new price-regulation program that is codified in subchapter XI of the Social Security Act. Unlike the Medicare program in subchapter XVIII, this new program does not define government benefits that are payable for specific beneficiaries. Instead, it directly sets the prices that pharmaceutical manufacturers must offer to certain buyers involved in Medicare, on pain of extreme penalties. The statute directs HHS to establish a "Drug Price *Negotiation* Program." *Id.* § 1320f(a) (emphasis added). But in

reality, the statute empowers HHS to set drug prices not by negotiation, but by administrative *fiat*.

1. HHS Ranks and Selects "Negotiation-Eligible Drugs"

The IRA directs HHS to rank "negotiation-eligible drugs" based on Medicare's "total expenditures" for those drugs (first in Part D, later in Part B also) over a specified twelve-month period. *Id.* § 1320f-1(b)(1)(A). Drugs with the highest total Medicare expenditures are ranked highest. *Id.*

The "negotiation-eligible drugs" HHS must rank encompass many of the most innovative drugs and biological products available. The IRA defines "negotiation-eligible drugs" as the 50 "qualifying single source drugs" with the highest total expenditures under Parts B and D. *Id.* § 1320f-1(d)(1). A "qualifying single source drug" is defined as one that (1) is marketed under a new drug application or a biologics license application, (2) has been approved by FDA for at least 7 years for drugs or 11 years for biological products, and (3) is not the reference drug for an approved and marketed generic drug or biosimilar product. *Id.* § 1320f-1(e)(1).

Once "negotiation-eligible" drugs have been identified and ranked, the IRA directs HHS to "select" an increasing number of the highest-ranked drugs for negotiation and "publish a list of [them]." *Id.* § 1320f-1(a). The IRA

directed HHS to select ten Part D drugs in 2023, with "maximum fair prices" taking effect in 2026, and 15 Part D drugs will be selected for 2027. *Id.* § 1320f-1(a)(1)-(2). Part B drugs are 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 20 Part D and Part B drugs for 2029 and each year thereafter. *Id.* § 1320f-1(a)(3)-(4). This process is cumulative: A selected drug remains selected until a certain period of time after HHS determines that an approved generic or licensed biosimilar has been marketed. *Id.* § 1320f-1(c)(1).

The first ten drugs were selected on August 29, 2023. *See* HHS Selects the First Drugs for Medicare Drug Price Negotiation, bit.ly/4367QNC.

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

While the IRA nominally requires price "negotiation," that is a misnomer. Once drugs are ranked and selected, the IRA directs HHS to "enter into agreements with manufacturers" whereby the parties "negotiate to determine (and … agree to) a maximum fair price." 42 U.S.C. § 1320f-2(a)(1). Manufacturers of drugs included on the first list of selected drugs were required to sign these "agreements" by October 1, 2023, or else face punishing

excise taxes. *Id.* §§ 1320f(d)(2)(A), 1320f-2(a). The ensuing "negotiations" must conclude by August 1, 2024. *Id.* §§ 1320f(d)(5), 1320f-3(b)(2)(E).

The statute directs HHS to "aim[] to achieve the lowest maximum fair price for each selected drug." *Id.* § 1320f-3(b)(1). The "negotiation" process includes an HHS "offer," a manufacturer "counteroffer," and an HHS "[r]esponse." *Id.* § 1320f-3(b)(2)(C)-(D). But that is where any resemblance to genuine negotiation ends.

The IRA sets no meaningful constraints on what prices HHS can mandate. With one minor exception, the statute does not limit how low a price HHS can demand. *Id.* § 1320f-3(b)(2)(F). But it does place a "ceiling" on how high a price HHS can offer. *Id.* § 1320f-3(c). For the Program's first year, the ceiling generally is calculated as a percentage of a specified baseline price. The ceiling ranges from 75% of that benchmark for recently approved drugs, down to just 40% for drugs that have been approved for over 16 years. *Id.* § 1320f-3(b)(2)(F), (c)(1)(C)(i). In other words, the IRA mandates a first-year *minimum* discount of 25% to 60%. For subsequent years, the ceiling can be even more restrictive—the statute directs HHS to use either the calculation above or an alternative calculation if it results in a *lower* ceiling. *Id.* § 1320f-3(c)(1)(C)(ii).

Below the "ceiling," HHS has free rein to set prices as it pleases. At most, HHS must "consider" specified "factors," including research and development costs, production and distribution costs, prior federal financial support, data on patents and regulatory exclusivities, market data and revenue and sales volume data, and information about alternative treatments. *Id.* § 1320f-3(e). But the IRA sets no criteria for how to weigh these considerations, nor does it require HHS to disclose in any meaningful way how it balanced those factors in setting prices. And the statute's low-ceiling, no-floor design, coupled with the directive "to achieve the lowest maximum fair price for each selected drug," *id.* § 1320f-3(b)(1), gives HHS every incentive to drive prices as low as possible.

Once HHS has imposed a "maximum fair price" and that price takes effect, the manufacturer must provide "access to such price to" individuals, pharmacies, providers, and other entities that dispense to Medicare beneficiaries. *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(b).

3. Noncompliant Manufacturers Must Pay a Crippling "Excise Tax"

The hammer the IRA uses to force manufacturers to "agree" to HHS's chosen "maximum fair price" is a so-called "excise tax." In ordinary negotiations, parties that fail to reach agreement regarding price can walk away. *See* ROA.236-37, 260-61. But under the IRA, walking away is not an option. The statute imposes a steep penalty for every day the manufacturer has not, by the deadline, (1) entered into an "agreement" to "negotiate" a maximum fair price, or (2) "agreed" to the maximum fair price that HHS imposes. 26 U.S.C. § 5000D(b). While Congress labeled this penalty an "excise tax," it is intended to coerce rather than to raise revenue.

The size of this "tax" is staggering. By the statute's terms, it applies to all U.S. sales of the drug in question, not just Medicare sales. *Id.* The tax is calculated based on a formula representing an "applicable percentage" of the drug's total cost (price plus tax). *Id.* § 5000D(d). The applicable percentage starts at 65% and then increases 10% for each quarter of noncompliance until it reaches 95%. *Id.* As the Congressional Research Service explained, "[t]he excise tax rate" thus "range[s] from 185.71% to 1,900% of the selected drug's price depending on the duration of noncompliance." Cong. Rsch. Serv., *Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376)*, 4 (Aug. 10,

2022), https://bit.ly/3sbHYBy. In other words, the statutory tax *starts* at nearly double the manufacturer's total daily U.S. revenue for the drug and quickly escalates to *19 times* revenue.

A summary of predecessor legislation aptly described the excise tax as a "steep, escalating penalty." Nancy Pelosi, Summary of H.R. 3 (Sept. 19, 2019), https://politi.co/49wRcZb. Indeed, though the statute calls it a "tax," both the Joint Committee on Taxation and CBO estimated that the "tax" would raise "no revenue" because no manufacturer could afford to pay it. Joint Comm'n on Tax'n, *Estimated Budget Effects of the Revenue Provisions of Title XIII - Committee on Ways and Means, of H.R. 5376, The "Build Back Better Act,"* at 8 (Nov. 19, 2021), https://bit.ly/3plC4cd; *see* CBO, *Estimated Budgetary Effects of Public Law 117-169*, at 5 (Sept. 7, 2022), https://bit.ly/3JOiq3r (similar). Manufacturers will have no choice but to "agree" to whatever "maximum fair price" HHS imposes.

The IRA provides that the excise-tax penalty may be "[s]uspen[ded]," but only if the manufacturer terminates its agreements with HHS, eliminating coverage for its drugs under Medicare Part D, Medicare Part B, and Medicaid. 26 U.S.C. § 5000D(c). Opting out of the IRA does not merely terminate coverage for those of the manufacturer's drugs that are subject to the IRA's

Drug Pricing Program, but for *all* the manufacturer's drugs. *Id.*; *see* 42 U.S.C. § 1396r-8(a)(1).

Although the government has suggested that any manufacturer may withdraw from Medicare and Medicaid, "[t]he consequence of" doing so "would be catastrophic for almost any manufacturer," as well as for patients. ROA.263-65. "Through Medicare and Medicaid, [the federal government] pays for almost half the annual nationwide spending on prescription drugs." *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023). Medicare and Medicaid account for an outsized portion of many manufacturers' revenue, and withdrawing would cause millions of patients to lose access to medicines on which they depend. *See* ROA.264; ROA.327-28; ROA.351; ROA.365. Pulling the rug out from under patients who have come to rely on medicines for a course of therapy would raise ethical concerns and would be "anathema" to manufacturers' "mission." ROA.327-28; *see also* ROA.365; ROA.264-65.

Even if a manufacturer were able to bear those financial, ethical, and reputational costs, the Part D statute delays manufacturers' ability to exit from Medicare Part D—and thus compels them to participate—for between 11 and 23 months. 42 U.S.C. §§ 1395w-114a(b)(1)(C)(ii), 1395w-114c(b)(4)(B)(ii), 1395w-153(a)(1). CMS has issued nonbinding guidance

asserting that, if manufacturers withdraw, the agency will take administrative actions to reduce that exit delay down to 30 days. *See* CMS, *Medicare Drug Price Negotiation Program: Revised Guidance for Initial Price Applicability Year 2026* [hereinafter *Revised Guidance*], at 120-21 (June 30, 2023), https://bit.ly/3JLSSUH. But the agency's statutory basis for those promised administrative actions is dubious at best, and manufacturers cannot rely on them—particularly since the agency could change its mind at any time.[1]

4. The IRA Limits Notice-and-Comment Rulemaking and Judicial Review

In contrast to the Medicare program, the Drug Pricing Program contains no elaborate administrative and judicial review scheme. Indeed, despite the statute's sweeping delegation of authority to CMS—and the unprecedented burdens on manufacturers and serious repercussions for

[1] CMS says it intends to reduce the exit delay under the Secretary's authority to terminate manufacturers for "a knowing and willful violation of the requirements of the agreement or other good cause shown." 42 U.S.C. §§ 1395w-114a(b)(4)(B)(i), 1395w-114c(b)(4)(B)(i); *see* Revised Guidance at 120-21, 129-31. That contradicts the statute, which lays out two *separate* paths to termination—one after 11-to-23 months at the manufacturer's request, and another with 30 days' notice and a right to a hearing based on the agency's determination of manufacturer misconduct. Treating a manufacturer's *own* request for termination as the agency's would mean that a manufacturer receives a hearing on its own purportedly voluntary exit from the program. That is nonsensical.

providers and patients—affected parties have *no say* in how HHS implements key parts of the Program, and the statute bars judicial review of many of the agency's most critical decisions, eliminating an essential check on the exercise of regulatory powers.

On the front end, there is no right to participate in the implementation process. The Administrative Procedure Act sets forth requirements for notice-and-comment rulemaking, which the Social Security Act requires HHS to follow in substantive rulemaking under Medicare. 5 U.S.C. § 553(b), (c); 42 U.S.C. § 1395hh. The IRA, however, provides that HHS "shall implement [the Drug Pricing Program] for 2026, 2027, and 2028, by program instruction or other forms of program guidance." *Id.* § 1320f note. CMS has read that language to exempt the Drug Pricing Program from notice-and-comment requirements during the Program's formative years. *See Revised Guidance* at 8-11; CMS, *Medicare Drug Price Negotiation Program: Initial Guidance for Initial Price Applicability Year 2026*, at 1-2 (Mar. 15, 2023), https://bit.ly/3J9eYQm. Moreover, CMS told stakeholders that it was *not* taking comments on critical implementation issues, but that it "may make changes to any policies" at any time. *Id.* at 2.

On the back end, after implementation decisions are made, the IRA purports to insulate critical decisions from review. The statute provides that "[t]here shall be no administrative or judicial review" of key HHS determinations, including "[t]he selection of drugs," "the determination of negotiation-eligible drugs," "the determination of qualifying single source drugs," and "[t]he determination of a maximum fair price." 42 U.S.C. § 1320f-7(2)-(3).

C. NICA and Its Members

NICA is a non-profit Texas corporation headquartered in Austin, Texas. ROA.18. NICA is an association of non-hospital, community-based infusion providers that offer care to patients safely and efficiently in high-quality, lower-cost settings. *Id.* NICA's members include BioTek reMEDys. ROA.557-58. A full list of NICA's members is available on NICA's website. *See* Provider Members, NICA, https://bit.ly/3EsPN95.

"Infusion" or "infusion therapy" refers to the delivery of medications directly into a patient's veins. ROA.336. Millions of patients rely on infusion to treat a host of complex conditions, including Crohn's disease, rheumatoid arthritis, and multiple sclerosis. ROA.337; ROA.18-19. Infusion centers typically provide services more economically and conveniently than

hospitals. ROA.336. Infusion providers generally obtain reimbursement under Part B, but many also operate in-house pharmacies that bill Part D plans and dispense medications to patients to self-administer or to be administered by the infusion center. ROA.563; ROA.558. The Drug Pricing Program's first list of selected drugs includes Stelara®, which several NICA members dispense and administer, and for which they are reimbursed under Medicare. ROA.565; *see* HHS, *HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023), https://bit.ly/460imGp.

The IRA is already affecting and harming NICA's concrete interests by holding the prices of the drugs its members administer and dispense hostage to a novel and unconstitutional decisionmaking process in which NICA's members have no say. Indeed, the expected decrease in Part B and Part D reimbursements is already having "negative effects on NICA's members[']ability to raise debt and equity financing on favorable terms," and threatening to "throw their financial stability into peril." ROA.566-67.

D. Procedural History

On June 21, 2023, Plaintiffs sued HHS, its Secretary, CMS, and its administrator. ROA.11-69. Plaintiffs brought 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.

On August 1, 2023, the parties jointly proposed an expedited schedule for cross-motions for summary judgment. ROA.165-70. The district court entered the stipulated schedule, ROA.171-72, and Plaintiffs moved for summary judgment, ROA.173-210. But a few weeks later, the government reneged; it successfully moved (over Plaintiffs' opposition) to vacate the joint scheduling order, ROA.459-501, 524-27, and moved to dismiss, ROA.434-58. The government argued that NICA lacks standing because it has not suffered a cognizable injury and, regardless, did not exhaust administrative remedies. ROA.440-42. And because NICA is the only Plaintiff that "resides" in the Western District of Texas, the government argued that, without NICA, venue in that district is improper. *Id.*

On February 12, 2024, the district court granted the government's motion and dismissed the case for lack of subject-matter jurisdiction and improper venue. ROA.609-10. The court did not reach standing, ruling solely that NICA failed to exhaust administrative remedies. ROA.603-09. The court reasoned that, "even though the challenges are constitutional and the requested relief is injunctive," "Plaintiffs ask the Court to hold that a law

affecting future reimbursement is unconstitutional." ROA.606. In the court's view, "Plaintiffs would not have standing or a substantive basis for a claim for reimbursement without the Medicare Act," and "[t]herefore, these claims arise under the Medicare Act and Section 405(h) channeling applies." ROA.607. Because NICA did not submit its constitutional challenges to HHS before filing suit, the court concluded that it lacks subject-matter jurisdiction over NICA's claims. ROA.607-09. And without NICA, the court held that venue is improper. ROA.609-10.

In dismissing the case rather than transferring to another district, the court noted that "[n]either party offered a transferee venue." ROA.610. The court then added that "the same federal jurisdictional defect likely exists for PhRMA and GCCA"—even though the government had never even suggested that channeling applies to any plaintiff beyond NICA. *Id.*

SUMMARY OF ARGUMENT

I. Plaintiffs' constitutional challenges to the IRA's drug-pricing scheme are not subject to channeling under § 405(h). As incorporated into the Medicare Act, that provision bars lawsuits seeking "to recover on any claim arising under this subchapter [*i.e.*, subchapter XVIII]." Channeling is thus required only "if both the standing and the substantive basis for the

presentation of the claim is the Medicare Act" or if the claim is "inextricably intertwined with a claim for Medicare benefits." *RenCare*, 395 F.3d at 557. This lawsuit does not fall into any of those categories. NICA's *standing* is grounded in constitutional harm from the operation of the IRA; its *claims* are facial constitutional challenges under the separation of powers, Excessive Fines Clause, and Due Process Clause; and its *requested relief* is invalidation of the Drug Pricing Program, which is codified outside Medicare. Nor are NICA's claims "inextricably intertwined" with claims for Medicare benefits simply because a successful challenge to the IRA could affect NICA's reimbursements. The IRA's price-setting provisions say nothing about Medicare reimbursement or claims for reimbursement. Rather, they require the offer of a discounted price, an activity outside the purview of § 405(h). Channeling would be particularly inappropriate here given the IRA's preclusion of administrative review, the facial nature of Plaintiffs' challenges, and the constitutional doubts that would arise from shutting the courthouse doors to Plaintiffs' constitutional claims. The district court's holding that channeling is required for any claim challenging a law "affecting future reimbursements," ROA.606, misstates the inquiry and, if followed in other cases, would lead to untenable results.

II. NICA has Article III standing. NICA alleges that the Drug Pricing Program deprives its members of procedural rights, including "any opportunity to weigh in on key determinations," ROA.66, and subjects them to an unconstitutionally structured decision-making process, ROA.39-47. Those "here-and-now injur[ies]," *Axon Enter., Inc. v. FTC*, 598 U.S. 175, 189, 192 (2023), "cannot be remedied through the retroactive payment of Medicare benefits" or "through the [Medicare] Act's administrative review process," *Alvarado Hosp., LLC v. Price*, 868 F.3d 983, 997 (Fed. Cir. 2017). In addition, the IRA imminently will inflict economic injuries by reducing NICA's reimbursement payments and undermining its members' "ability to raise debt and equity financing on favorable terms." ROA.566.

STANDARD OF REVIEW

This court reviews de novo "the district court's determination that [Plaintiffs'] claims arise under the Medicare Act." *RenCare*, 395 F.3d at 557. This court likewise reviews de novo "questions of standing." *Texas v. EEOC*, 933 F.3d at 446.

ARGUMENT

I. Plaintiffs Are Not Required To Channel Their Claims Through HHS

Under Social Security and Medicare, Congress has channeled judicial review of certain claims—and *only* certain claims—through the relevant agency. Codified in subchapter II of the Social Security Act, which governs the Social Security disability insurance program, 42 U.S.C. § 405(h) provides that "[n]o action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of title 28 to recover on any claim arising under this subchapter." Instead, a plaintiff bringing such an action must invoke the jurisdiction conferred by 42 U.S.C. § 405(g), which provides that "[a]ny individual, after any final decision of the Commissioner of Social Security[,] … may obtain a review of such decision by a civil action commenced within sixty days."

Section 405(h) applies to certain Medicare claims. Codified in the Medicare Act (subchapter XVIII of the Social Security Act), 42 U.S.C. § 1395ii provides that "[t]he provisions of section[] … (h) of section 405 of this title[] shall also apply with respect to this subchapter to the same extent as they are applicable with respect to subchapter II." Reading § 405(h) in light of § 1395ii means that "[n]o action against the United States, the [HHS Secretary], or any

officer or employee thereof shall be brought under section 1331 or 1346 of title 28 to recover on any claim arising under this subchapter [XVIII]." But actions that do *not* seek "to recover on [a] claim arising under" that subchapter do not require exhaustion.

A. Plaintiffs' Suit Is Not an Action To Recover on a Claim Arising Under Subchapter XVIII

Plaintiffs' facial constitutional attack on the IRA's unprecedented Drug Pricing Program in subchapter XI is not an "action … to recover on any claim arising under" subchapter XVIII. 42 U.S.C. § 1395ii. A lawsuit is subject to channeling under § 405(h) only "if both the standing and the substantive basis for the presentation of the claim is the Medicare Act, or if the claim is inextricably intertwined with a claim for Medicare benefits." *RenCare*, 395 F.3d at 557 (cleaned up). None of those conditions is satisfied in this case. And channeling would be particularly inappropriate here given the IRA's limitation of administrative review and the facial constitutional nature of Plaintiffs' claims. The district court's contrary reasoning misunderstands the statute, distorts Plaintiffs' claims, and would lead to absurd results.

1. Subchapter XVIII Does Not Provide Plaintiffs' Standing or the Substantive Basis of Their Claims

A claim does not "aris[e] under" a subchapter unless the subchapter provides *both* the standing *and* the substantive basis for the claim. Here, the Medicare statute provides neither.

a. The Supreme Court has interpreted the key language four times. First, in *Weinberger v. Salfi*, 422 U.S. 749 (1975), a mother and daughter challenged the constitutionality of a Social Security eligibility requirement. *Id.* at 753-54. Despite not having exhausted administrative remedies, the plaintiffs sought "a judgment directing the Secretary to pay Social Security benefits." *Id.* at 761. The Supreme Court held that it was "fruitless to argue that th[e] action does not . . . arise under the Social Security Act," as "it [wa]s the Social Security Act which provide[d] both the standing and the substantive basis" for their claims. *Id.* at 760-61.

Second, in *Heckler v. Ringer*, 466 U.S. 602 (1984), patients asserted statutory challenges to HHS's policy of denying coverage for a particular surgery under Part B. *Id.* at 609-10. The Court held that it made "no sense to construe the claims … as anything more than, at bottom, a claim that they should be paid for their BCBR surgery." *Id.* at 614. Although the plaintiffs challenged procedural aspects of HHS's policy, those challenges were

"inextricably intertwined with [plaintiffs]' claims for benefits." *Id.* "Indeed, the relief that [the plaintiffs] s[ought] to redress their supposed 'procedural' objections [wa]s the invalidation of [HHS]'s current policy and a 'substantive' declaration … that the expenses of [the] surgery are reimbursable under the Medicare Act." *Id.*

Third, in *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986), doctors challenged an HHS regulation that authorized the payment of Part B benefits in different amounts for similar physicians' services but did not submit any claim to Part B reimbursement. *Id.* at 668. The Supreme Court held that the doctors were *not* required to channel that claim through HHS. *Id.* at 679-81. The Court relied on the legislative history of § 1395ii, while also noting that, due to the details of the Part B administrative and judicial review scheme, requiring channeling there would mean that the doctors could obtain "no review at all." *Id.* at 680. The Court thus held that §§ 405(h) and 1395ii foreclosed review "only of 'amount determinations'"—not of "substantial statutory and constitutional challenges to the Secretary's administration of Part B of the Medicare program." *Id.*

Finally, in *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1 (2000), the Court considered § 405(h) as it related to a challenge to certain

Medicare Part A regulations. Writing for a closely divided court, Justice Breyer read *Michigan Academy* to mean that "§ 1395ii does not apply § 405(h) where application of § 405(h) would not simply channel review through the agency, but would mean no review at all." *Id.* at 19. Because the *Illinois Council* plaintiffs could obtain review of their challenges, the Court held that their claims needed to be channeled. *Id.* at 20-21.

Four Justices dissented in an opinion by Justice Thomas. He explained that, "[u]nder *Michigan Academy*, a case involving an 'amount determinatio[n]' would trigger § 1395ii's incorporation of § 405(h), and thus bar federal-question jurisdiction; a 'challeng[e] to the validity of the Secretary's instructions and regulations' would not." *Id.* at 37-38. Also in dissent, Justice Stevens—the author of *Michigan Academy*—explained that a provider's challenge to HHS regulations is not "fairly characterized as an action 'to recover' on a claim that is parallel to a claim for Social Security benefits." *Id.* at 31 (Stevens, J., dissenting).

These cases (and their progeny) demonstrate that channeling is not required for *all* claims that simply implicate Medicare. Courts have repeatedly held that a lawsuit is not an action "to recover on a claim arising under" the Medicare Act merely because it *relates to* or *might affect* reimbursement or

benefits. *See, e.g.*, *ACCC*, 509 F. Supp. 3d at 491 (channeling not required for constitutional and procedural challenges to "new reimbursement scheme" undertaken under subchapter XI); *RenCare,* 395 F.3d at 557 (channeling not required for contract-related claims that were "based on state law," even though the claims stemmed from "a dispute over reimbursement"); *Alvarado Hosp., LLC*, 868 F.3d at 997 (channeling not required for breach-of-contract claim even though plaintiffs, "at bottom, … [we]re seeking reimbursement for services they provided to Medicare beneficiaries"); *Do Sung Uhm v. Humana, Inc.*, 620 F.3d 1134, 1145 (9th Cir. 2010) (channeling not required for claim that insurer misrepresented the scope of Part D coverage); *United States v. Blue Cross & Blue Shield of Ala., Inc.*, 156 F.3d 1098, 1104 (11th Cir. 1998) ("Nothing in subsection 405(h) … suggests that the third sentence of subsection 405(h) eliminates federal-question jurisdiction over all actions implicating the Medicare Act … .").

b. NICA's claims do not "aris[e] under" the Medicare Act because the Medicare Act does not provide "*both* the standing *and* the substantive basis for the presentation of the claim." *RenCare,* 395 F.3d at 557 (emphasis added). The Act provides neither.

Start with standing. NICA primarily alleges procedural harms based on the IRA's novel "negotiation" regime, which is codified in subchapter XI. As explained below, *see infra* § II.A., this "unconstitutionally structured decisionmaking process" inflicts a "here-and-now injury" on NICA. *Axon Enter.*, 598 U.S. at 189, 192. And this procedural "injury cannot be remedied through the retroactive payment of Medicare benefits" or "through the [Medicare] Act's administrative review process." *Alvarado Hosp.*, 868 F.3d at 997. While the IRA's economic consequences are *another* form of harm, NICA has standing even if none of its members ultimately lose a single cent of reimbursements. NICA's principal "cognizable injury" is that "it has been deprived of 'a procedural right *to protect* its concrete interests.'" *Texas v. EEOC*, 933 F.3d at 447 (cleaned up) (emphasis added). "[T]he Medicare Act" does not, therefore, "provide[] … the standing for [NICA's] claim[s]." *Ringer*, 466 U.S. at 620.

The Medicare Act also does not provide the "substantive basis for" NICA's claims. *RenCare*, 395 F.3d at 557 (cleaned up). To begin with, the law that created NICA's causes of action is not the Medicare Act, but the Constitution. As the Supreme Court has repeatedly noted, "[t]he most familiar definition of … 'arising under' … is the statement by Justice Holmes that a

suit 'arises under the law that creates the cause of action.'" *Jones v. R.R. Donnelley & Sons Co.*, 541 U.S. 369, 377 (2004) (quotation marks omitted).

Nor does this lawsuit challenge any provision of the Medicare Act governing reimbursement. Rather, Plaintiffs challenge the IRA's separate Drug Pricing Program, whereby the government dictates drug prices for individuals, providers, and dispensers under cover of a sham "negotiation" process. Although Medicare's channeling provisions are limited to claims arising under subchapter XVIII, Congress chose to codify this new program in subchapter XI:

> PROGRAM TO LOWER PRICES FOR CERTAIN HIGH-PRICED SINGLE SOURCE DRUGS.—Title XI of the Social Security Act is amended by adding after section 1184 (42 U.S.C. 1320e-3) the following new part: . . . .

IRA § 11001(a), 136 Stat. 1833. NICA's claims are facial constitutional challenges to provisions *outside* the Medicare Act, and its requested relief is invalidation of a program codified in a different subchapter. "Accordingly, the plain text of the relevant statutes demonstrates that [NICA is] not subject to the jurisdictional bar in section 405(h)." *ACCC*, 509 F. Supp. 3d at 491.

ACCC is instructive. There, NICA, GCCA, PhRMA, and another organization brought constitutional and statutory challenges to a "new reimbursement scheme" that "require[d] reimbursements made for certain

drugs covered by Medicare Part B to be based on the lowest price in a group of 'most favored nations' rather than the average U.S. sales price." *Id.* As here, the government argued that NICA needed to channel its claims through HHS. But the district court disagreed and halted the new reimbursement scheme. *Id.* at 491, 505. The court explained that, because "[t]his new reimbursement model was promulgated pursuant to 42 U.S.C. § 1315a," "which is in subchapter XI," NICA "d[id] not make any specific or individual claims for reimbursement under subchapter XVIII"—that is, under the Medicare Act. *Id.* at 488, 491. Its claims therefore "ar[o]se under 42 U.S.C. § 1315a," not the Medicare Act. *Id.* at 491.

The same is true here. Plaintiffs have not submitted reimbursement claims under subchapter XVIII, and their facial constitutional challenges to the IRA's Drug Pricing Program are substantively based in subchapter XI. *Cf. Alvarado Hosp.*, 868 F.3d at 999 (holding that a claim did not "arise under" the Medicare Act because it was "contract law, and not the Medicare Act, that provide[d] both the standing and the substantive basis for the presentation of [the plaintiffs'] breach of contract claim").

It is no accident that Congress enacted the Drug Pricing Program separately from the Medicare Act. The Medicare program in subchapter

XVIII is a longstanding public benefits program providing health insurance and prescription drug coverage. It does not directly control the prices that manufacturers or providers charge in the marketplace. When pharmacies and providers incur covered medical expenses, Medicare reimburses a specified sum. Subchapter XVIII sets the scope of healthcare benefits that are payable for Medicare beneficiaries, which is why Congress limited § 405(h) channeling to claims for benefits under subchapter XVIII. The Drug Pricing Program in subchapter XI, by contrast, is a novel price-setting regime that directly regulates the prices private parties can charge in transactions to which the government is not a party. A suit asserting facial constitutional challenges to provisions in subchapter XI cannot fairly be described as an "action … to recover on any claim arising under" subchapter XVIII.

2. Plaintiffs' Claims Are Not "Inextricably Intertwined" with Claims for Benefits

NICA's facial constitutional challenges to provisions in subchapter XI are not "inextricably intertwined" with claims for benefits under subchapter XVIII. A constitutional challenge to a statute is "inextricably intertwined with a claim for Medicare benefits" only where it is nothing "more than, at bottom," a claim that the plaintiff was "denied services or reimbursement for services." *RenCare*, 395 F.3d at 557-58 (citation omitted). Conversely, "claims are not

'inextricably intertwined' [when] the [plaintiffs] are *at bottom* not seeking to recover *benefits*." *Ardary v. Aetna Health Plans of Cal., Inc.*, 98 F.3d 496, 500 (9th Cir. 1996). That latter description fits Plaintiffs' claims here.

In enacting § 405(h), Congress determined that the "hardship" of channeling "was justified" to the extent that "Medicare, embodied in hundreds of pages of statutes and thousands of pages of often interrelated regulations, … may become *the subject* of a legal challenge." *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000) (emphasis added). And a plaintiff seeking reimbursement under Medicare must rely on one of the avenues for judicial review established under the Medicare statute. Relevant here, 42 U.S.C. § 1395ff(b)(1) authorizes "any individual dissatisfied with any initial determination" of their entitlement to Part B Medicare benefits to seek "judicial review" and to be "represented" by the provider who furnished the services. That makes sense: Those unhappy with the size of their reimbursement should first give the agency an opportunity to adjust it. Thus, "Section 405(h) prevents beneficiaries … from evading administrative review by creatively restyling their benefits and eligibility claims as constitutional or statutory challenges to Medicare statutes and regulations." *Blue Cross & Blue Shield of Ala.*, 156 F.3d at 1104.

But if plaintiffs are "able to prove the elements of the[ir] causes of action without regard to any provisions of the [Medicare] Act relating to provision of benefits," then their "claims are not subject to the Act's exhaustion provisions." *Do Sung Uhm*, 620 F.3d at 1145. Channeling is not required when plaintiffs "do not challenge provisions of the Medicare Act or its regulations as having denied them benefits," and their claims "involve[] separate issues and [are] completely separate from a substantive claim to benefits," such that "hearing their … claim[s] will not mean reviewing the merits of the underlying reimbursement claims decisions." *Alvarado Hosp.*, 868 F.3d at 997-98. If a challenge does not depend on "any specific or individual claims for reimbursement under subchapter XVIII," *ACCC*, 509 F. Supp. 3d at 491, then it is not intertwined with an "action … to recover on any claim under th[at] subchapter," 42 U.S.C. § 405(h); *see id.* § 1395ii.

Here, NICA's claims are *not*, at bottom, claims for the denial of Medicare benefits. "Medicare" is not the "subject" of NICA's "legal challenge." *Ill. Council*, 529 U.S. at 13. While NICA's claims may "implicate benefits determinations" in a very attenuated sense, NICA is not asserting "constitutional or statutory challenges to Medicare statutes and regulations," *Blue Cross & Blue Shield of Ala.*, 156 F.3d at 1104, and "do[es] not challenge

provisions of the Medicare Act or its regulations as having denied [it] benefits," *Alvarado Hosp.*, 868 F.3d at 997. NICA's members do not have any relevant "specific or individual claims for reimbursement," *ACCC*, 509 F. Supp. 3d at 491, and they do not contend that they are constitutionally entitled to any particular level of benefits. NICA's facial constitutional challenges are "completely separate from a substantive claim to benefits," and resolving its claims "will not mean reviewing the merits of [any] underlying reimbursement claims decisions." *Alvarado Hosp.*, 868 F.3d at 998. And Plaintiffs will be "able to prove the elements of the[ir] [constitutional] causes of action without regard to any provisions of the [Medicare] Act." *Do Sung Uhm*, 620 F.3d at 1145. As in *ACCC*, Plaintiffs bring a facial constitutional challenge to a "reimbursement model [that] was promulgated pursuant to" provisions in a *different* subchapter. 509 F. Supp. 3d at 488.

3. Channeling Would Be Particularly Inappropriate Here

Other features of the Drug Pricing Program and Plaintiffs' constitutional claims reinforce that channeling does not apply.

In stark contrast to the detailed administrative and judicial review mechanisms Congress established in subchapter XVIII, *see* 42 U.S.C. § 1395ff, the Drug Pricing Program in subchapter XI contains *no* administrative or

judicial review mechanisms. The IRA directs HHS and CMS initially to implement the program through "program guidance." *Id.* § 1320f note. The agencies have taken this as a license to evade ordinary notice-and-comment rulemaking, even while imposing new substantive obligations on regulated parties—an astonishing departure from protections against arbitrary executive action. *See Revised Guidance* at 8-11. Congress also expressly provided that "there shall be no administrative or judicial review" of critical implementation decisions, including "[t]he selection of drugs," "the determination of negotiation-eligible drugs," "the determination of qualifying single source drugs," and "[t]he determination of a maximum fair price." 42 U.S.C. § 1320f-7(2)-(3). Far from channeling legal challenges to the new price-setting scheme through the agency, the IRA's Drug Pricing Program evinces an intent to avoid administrative review and judicial scrutiny.

Furthermore, "agency adjudications are generally ill suited to address structural constitutional challenges" such as this, "which usually fall outside the adjudicators' areas of technical expertise." *Carr v. Saul*, 593 U.S. 83, 92 (2021); *see Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 491 (2010) (similar). While an agency "knows a good deal" about its subject area, it knows

"nothing special about," for example, "the separation of powers." *Axon Enter.*, 598 U.S. at 194.

The canon of constitutional avoidance resolves any doubt in Plaintiffs' favor. Reading §§ 405(h) and 1395ii to require channeling of Plaintiffs' facial constitutional claims would raise grave due process concerns. Plaintiffs currently have no claim for Medicare benefits that they can present to HHS and administratively exhaust. Plaintiffs will not have such a claim until, at the earliest, January 2026 (when Part D price mandates take effect). That will be long after Plaintiffs suffer the harms they allege. Even then, "the delay in the administrative process for Medicare reimbursement is incontrovertibly grotesque." *Cumberland Cnty. Hosp. Sys., Inc. v. Burwell*, 816 F.3d 48, 50 (4th Cir. 2016). And "the logjam of Medicare appeals shows no signs of abating anytime soon." *Fam. Rehab., Inc. v. Azar*, 886 F.3d 496, 500 (5th Cir. 2018). While the government below noted that CMS regulations offer expedited review of constitutional claims, 42 C.F.R. § 405.990(c)(2), the regulations make clear that the agency will *not* rule on any constitutional issues, *id* § 405.990(g), (h)—reinforcing that channeling Plaintiffs' claims here serves no purpose except delay.

In effect, the government argues that Plaintiffs cannot sue in federal court to enjoin the implementation of a facially unconstitutional statute for years, even though that statute is *already* harming Plaintiffs. That is constitutionally dubious. *See Michigan Acad.*, 476 U.S. at 681 (avoiding "the 'serious constitutional question' that would arise if [the Court] construed § 1395ii to deny a judicial forum for constitutional claims arising under Part B of the Medicare program" (citations omitted)); *Battaglia v. Gen. Motors Corp.*, 169 F.2d 254, 257 (2d Cir. 1948) ("[W]hile Congress has the undoubted power to give, withhold, and restrict the jurisdiction of courts other than the Supreme Court, it must not so exercise that power as to deprive any person of life, liberty, or property without due process of law …." (footnote omitted)).

B. The Reasoning of the Decision Below Is Erroneous

The district court concluded that Plaintiffs' challenges to the IRA "arise under" the Medicare Act even though Plaintiffs' suit concerns a separate law governing price-setting—not Medicare reimbursements. None of the district court's stated rationales justifies channeling Plaintiffs' claims.

Even though Plaintiffs challenge only the negotiation provisions of the Drug Pricing Program in subchapter XI, the district court reasoned that Plaintiffs' claims arise under the Medicare statute because "Plaintiffs ask the

Court to hold that *a law affecting* future reimbursements is unconstitutional." ROA.622 (emphasis added). That plainly misstates the inquiry. As noted, the channeling provision requires exhaustion only for suits seeking "to recover on a[] claim arising under" the Medicare statute, not for claims challenging a separate "law" that might "affect[]" Medicare reimbursements.

The district court's rationale is implausibly broad. Dozens of laws codified in different titles of the Social Security Act—or even titles of the U.S. Code—potentially "affect future reimbursements," including any law regarding medical services. *Cf. California Div. of Lab. Standards Enf't v. Dillingham Const., N.A., Inc.*, 519 U.S. 316, 335 (1997) (Scalia, J., concurring) ("[A]s many a curbstone philosopher has observed, everything is related to everything else."). That would include any law that regulates the services doctors provide, what medicines they prescribe, or any other aspect of how they do their job, as those all will have at least some effect on reimbursement payments. But facial constitutional challenges to such laws cannot possibly "arise under" Medicare simply because they indirectly affect reimbursements.

Consider a hypothetical statute prohibiting healthcare providers from transporting particular medical products via interstate mail. While such a law would impede providers' ability to conduct particular procedures and obtain

reimbursements, a constitutional challenge to the law obviously would not "arise under" the Medicare Act. Or, suppose Congress, in an attempt to lower healthcare expenditures, passed a law requiring physicians to prescribe patients only generic versions of prescription drugs while prohibiting them from speaking with patients about innovative drugs. Under the district court's rationale, a suit challenging that law on First Amendment grounds would "arise under" the Medicare Statute and require channeling because the statute's fate would "affect[] future reimbursements." ROA.622.[2]

The district court also opined that "Plaintiffs do in fact challenge portions of subchapter XVIII, where portions of the Drug Pricing Program were enacted, like Section 1395w-3a." ROA.606-07. That woefully misstates the nature of Plaintiffs' challenge. While the IRA's Drug Pricing Program added "conforming amendments" to subchapter XVIII, Plaintiffs are *not* challenging those provisions, which play no substantive role in this lawsuit. IRA § 11001(b). The Drug Pricing Program *itself* is codified in subchapter XI, and this lawsuit challenges only the unprecedented "negotiation" regime in that subchapter—nothing more.

[2] Indeed, the district court's rationale would require channeling in cases where nobody even considered the issue, such as *Alliance for Hippocratic Medicine v. FDA*, 78 F.4th 210 (5th Cir.), *cert. granted*, 144 S. Ct. 537 (2023).

The district court also concluded that "Plaintiffs would not have standing or a substantive basis for a claim for reimbursement without the Medicare Act." ROA.607. As discussed, *see supra* § I.A.1, this misconstrues Plaintiffs' Complaint. Again, NICA's *claims* are constitutional challenges under the separation of powers, Excessive Fines Clause, and Due Process Clause, *see* ROA.63-67; NICA's *standing* is grounded in procedural harm from the operation of the IRA, *see supra* § I.A.1; and NICA's *requested relief* is invalidation of the Drug Pricing Program, *see* ROA.67. The IRA harms NICA even if none of its members lose a penny of their reimbursements, and NICA can prevail without the court invalidating a single word of the Medicare Act.[3]

[3] *Community Oncology Alliance, Inc. v. OMB*, 987 F.3d 1137 (D.C. Cir. 2021), which the government invoked below, is not to the contrary. The plaintiff there challenged a "sequestration order" under the Balanced Budget Act that "required a two percent reduction in all Medicare reimbursements." *Id.* at 1140. While the challenged order was authorized by a provision codified outside the Medicare Act, the provision expressly cross-referenced the Medicare Act and did nothing more than reduce Medicare reimbursements. *See* 2 U.S.C. § 906(d)(1)(A) (directing OMB and the President to determine and implement reductions "with respect to the health insurance programs under title XVIII of the Social Security Act"). In that context, the D.C. Circuit concluded that the plaintiff's claims were "plainly ones 'arising under' the Medicare Act," emphasizing that the plaintiff's standing and merits arguments both were directed at securing "additional reimbursement under the Medicare Act." *Id.* at 1143. The D.C. Circuit also rejected the plaintiff's attempt to frame its suit as challenging only the Balanced Budget Act. That statute, the court noted, does not permit "as-applied challenges to individual sequestration orders," yet "[i]n

Finally, in dismissing the case rather than transferring to another district, the district court opined that "the same federal jurisdictional defect likely exists for PhRMA and GCCA, as nothing suggests that either party has presented its claims to [HHS]." ROA.610. But the government has *never* made this argument—in this case or any of the other manufacturer suits challenging the Drug Pricing Program—and for good reason.[4] Generally, § 405(h) "permit[s] non-providers to seek immediate review in federal court," even if the providers would be subject to channeling. *Council for Urological Ints. v. Sebelius*, 668 F.3d 704, 711 (D.C. Cir. 2011). Courts thus have allowed non-provider plaintiffs to invoke federal-question jurisdiction under § 1331 notwithstanding §§ 405(h) and 1395ii. *See id.* at 707, 713; *Am. Lithotripsy Soc. v. Thompson*, 215 F. Supp. 2d 23, 30 (D.D.C. 2002). At least one court has

its complaint, [the plaintiff] challenged 'the application of the sequestration to Medicare Part B drugs that was made effective April 1, 2013.'" *Id.* at 1141-42.

[4] Indeed, the government recently explained during oral argument in a similar lawsuit that the Medicare Act's channeling provision does not apply to manufacturers affected by the Program. *See* Hr'g Tr. 90:4-11, *Janssen Pharmaceuticals, Inc. v. Becerra*, No. 3:23-cv-3818 (D.N.J. Mar. 7, 2024) ("We have not raised the type of channeling arguments that were at issue in the [NICA] litigation, among other reasons, because that litigation involved providers.… [M]anufacturers are differently situated in a number of respects that, from our standpoint, means that we think that argument is not one that was worth raising here.").

applied this principle to a claim by a pharmaceutical manufacturer, which "itself could not access HHS'[s] administrative review process." *Baxter Healthcare Corp. v. Weeks*, 643 F. Supp. 2d 111, 115 (D.D.C. 2009).

The district court's mistaken, offhand reference to channeling non-providers' claims underscores its broader misapplication of the doctrine. Plaintiffs are not required to channel their claims under §§ 405(h) and 1395ii before bringing facial constitutional challenges to provisions codified outside subchapter XVIII.

II. NICA Has Standing

The government's primary basis for its motion to dismiss was that NICA lacks standing. ROA.446-51. Though the parties devoted the bulk of their briefing below to that issue, the district court declined to reach it. ROA.614-27. This Court should nevertheless resolve the parties' standing dispute—a threshold jurisdictional question—to avoid further protracting this litigation and delaying resolution of the merits.

The standing question here presents an issue of law based on undisputed facts. Because it is potentially an alternative basis to affirm, its resolution is necessary to fully dispose of this appeal. And its resolution would advance interests in conserving judicial resources and permit the district court on

remand to proceed directly to the merits. It also would avoid the risk of a second appeal on a preliminary issue.

A. NICA Alleges Procedural Injuries

Below, the government did not dispute that GCCA and PhRMA have standing. As to NICA, whose standing the government has challenged, the Complaint alleges two independent forms of injury sufficient for Article III: procedural and economic. On the procedural side, the Drug Pricing Program is already harming NICA's members by depriving them of constitutionally required due process, subjecting them to impermissibly delegated legislative power, and coercing compliance via excessive fines. These are quintessential procedural injuries: an unconstitutional decision-making scheme.[5]

"A plaintiff can show a cognizable injury if it has been deprived of 'a procedural right to protect its concrete interests.'" *Texas v. EEOC*, 933 F.3d at 447 (quoting *Summers v. Earth Island Inst.*, 555 U.S. 488, 496 (2009) (cleaned up)); *accord Lujan v. Defs. of Wildlife*, 504 U.S. 555, 573 n.8 (1992). "The loss is not merely the subsequent deprivation, but the right not to suffer a deprivation

[5] Although there is no requirement to name a particular member "to survive a Rule 12(b)(1) motion to dismiss based on a lack of associational standing," *Hancock Cnty. Bd. of Sup'rs v. Ruhr*, 487 F. App'x 189, 198 (5th Cir. 2012), Plaintiffs have identified a named NICA member suffering both forms of injury—BioTek reMEDys, *see* ROA.563, 565; ROA.558.

without proper process." *Bertulli*, 242 F.3d at 295. Because "'procedural rights' are special," a "person who has been accorded a procedural right to protect his concrete interests can assert that right without meeting all the normal standards for redressability and immediacy." *Lujan*, 504 U.S. at 572 n.7. A "litigant has standing if there is *some possibility*" that enforcing the procedural right "will prompt the [defendant] to reconsider the decision." *Mass. v. EPA*, 549 U.S. 497, 518 (2007) (emphasis added). Although a plaintiff asserting a "deprivation of a procedural right" must identify "some concrete interest that is affected by the deprivation," *Summers*, 555 U.S. at 496, the plaintiff need not "establish with any certainty" that the procedural error "will cause" harm and may challenge a process even though its outcome "will not be completed for many years," *Lujan*, 504 U.S. at 572 n.7.

Here, "[t]he loss" alleged "is not merely the subsequent deprivation" of property, "but the right not to suffer a deprivation without proper process." *Bertulli*, 242 F.3d at 295. NICA's members are *already* experiencing that harm. The IRA deprives them of any input into the effects on their businesses of a "negotiation" regime that (1) violates due process, (2) improperly delegates legislative power to an executive agency, and (3) excessively penalizes parties

who attempt to *actually* "negotiate." Those procedural defects assuredly affect NICA's members' concrete interests.

1. Due Process

The IRA is already inflicting quintessential procedural harms on NICA's members by depriving them of due process. The Act "affords manufacturers, providers, and patients *no* opportunity to be heard regarding key decisions that HHS needs to make in order to implement the Act during the first three years and simultaneously deprives them of any judicial review of those decisions." ROA.53. NICA's members lack "any opportunity to weigh in on key determinations," and these "constitutionally [de]ficient procedures" multiply "[t]he risk of erroneous deprivation" of their concrete interests: operating within lawful constraints under a program that governs much of their industry, "serving Medicare patients" fully and adequately, and even "stay[ing] in business." ROA.66. The procedural harm "is not merely the subsequent deprivation" of the full value of the products NICA's members dispense and administer, "but the right not to suffer a deprivation without proper process." *Bertulli*, 242 F.3d at 295.

The Complaint explains how IRA's constitutionally inadequate procedures are currently harming NICA's members. To begin with, the IRA

requires HHS to implement the program for the first few years through "program guidance," rather than notice-and-comment rulemaking that would permit public input. IRA §§ 11001(c), 11002(c). The IRA then compounds this front-end barrier by providing on the back end that "there shall be no administrative or judicial review" of key implementation determinations. 42 U.S.C. § 1320f-7(2)-(3); *see* ROA.38-39. That unusual combination of structural obstacles—which the agency is already invoking to insulate its decision-making from public input or accountability—constitutes a clear "deprivation of a procedural right." *Texas v. EEOC*, 933 F.3d at 447. And while manufacturers have at least *some* voice in "negotiations," providers such as NICA—whose interests are also at stake—do not even get *that* limited input.

2. Improper Delegation

The IRA also harms NICA through an unconstitutional delegation of legislative power to HHS. The Constitution's "separation of governmental powers" is "essential to the preservation of liberty." *Mistretta v. U.S.*, 488 U.S. 361, 380 (1989). And a "separation-of-powers violation," such as "being compelled to participate in an invalid administrative process," coupled with "a concrete interest in seeing the violation corrected," is an "injury in fact" under Article III. *Consumers' Rsch. v. Consumer Prod. Safety Comm'n*, 91 F.4th 342,

350 (5th Cir. 2024) (quotation marks omitted). In other words, "subjection to an unconstitutionally structured decisionmaking process"—such as "an agency … wielding authority unconstitutionally"—is an injury "irrespective of [the] outcome." *Axon Enter.*, 598 U.S. at 189, 192. Indeed, rights to a "[]constitutionally structured decisionmaking process … are 'effectively lost' if review is deferred," because being subject to improper decision-making is itself a "here-and-now injury," regardless whether it has yet produced financial harm. *Id.* at 192; *cf. Texas v. EPA*, 829 F.3d 405, 434 (5th Cir. 2016) (recognizing an "institutional injury … from the inversion of the federalism principles").

In *Texas v. United States*, 497 F.3d 491, 495 (5th Cir. 2007), for example, this Court held that Texas had standing to challenge a regulation requiring it to negotiate with Indian tribes regarding governance of gambling activities. This Court "agree[d]" with Texas that "standing exist[ed]" because the regulation allegedly "violate[d] the … nondelegation doctrine[]" and inflicted "the injury of being compelled to participate in an invalid administrative process." *Id.* at 499, 496-97. "Texas's only alternative to participating in this allegedly invalid process [was] to forfeit its sole opportunity to comment upon [tribal] gaming regulations, a forced choice that [was] itself sufficient to support standing." *Id.* at 497.

The IRA's improper delegation of legislative power inflicts a similar injury. "[T]he IRA's novel structure concentrates substantial power over a significant part of the economy in an administrative agency with no checks to ensure public accountability." ROA.43. Congress unconstitutionally "delegated unfettered discretion to HHS to set prices"—including by redefining key statutory terms—which is "a wholly legislative function." ROA.41-42. That nondelegation problem, moreover, is compounded by the fact that the statute strips away other protections—including public comment and judicial review—that are necessary to protect both private rights and the broader public interest. *See Seila L. LLC v. Consumer Fin. Prot. Bureau*, 140 S. Ct. 2183, 2196 (2020). The IRA's expansive delegation thus strikes at the core of separation-of-powers concerns, as it is an obvious effort to escape accountability while allowing CMS to exercise sweeping lawmaking powers: If Congress had been transparent about mandating sales at government-imposed prices, it would have faced "significant public criticism." ROA.13. Because the IRA imposes on NICA members legislative decisions rendered by an unaccountable agency, it inflicts a cognizable separation-of-powers injury. *See Axon Enter.*, 598 U.S. at 192.

3. Excessive Fines

The IRA's "negotiation" regime also incorporates an unconstitutionally excessive fine, which compounds its other procedural defects. In an actual "negotiation," each side has leverage because it can walk away from an unsatisfactory offer. But when one side can harm the other if the other leaves the table, the parties are no longer negotiating in any meaningful sense.

Here, the massive, escalating "excise tax" is the "hammer through which the Drug Pricing Program is enforced." ROA.33. Without it, manufacturers could decline unfairly low prices, and NICA's members would not have to suffer the consequences. But the excise tax prevents manufacturers from "walk[ing] away" from sham negotiations and "doing anything but acquiescing to whatever price HHS demands." ROA.33, 35. The excise tax thus harms NICA by transmuting the government's "offer[s]" for pricing drugs, 42 U.S.C. § 1320f-3(b)(2)(C), into inexorable commands, *see Clinton v. City of New York*, 524 U.S. 417, 432 (1998) (presidential veto conferred standing on plaintiffs where it "depriv[ed] them of their statutory bargaining chip").[6]

[6] Although the IRA's compliance mechanism works by exerting influence on manufacturers, a litigant has standing when complained-of harm results from "the predictable effect of Government action on the decisions of third parties." *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2566 (2019). Plaintiffs have alleged

4. Concrete Interests

In the district court, the government argued that NICA cannot rest its standing on the "procedural injuries" described above because "the deprivation of a procedural right without some concrete interest that is affected by the deprivation—a procedural right *in vacuo*—is insufficient to create Article III standing." ROA.585 (quoting *Dep't of Educ. v. Brown*, 600 U.S. 551, 562 (2023)) (cleaned up). But NICA is no mere bystander, complaining about an agency foot-fault committed toward some *other* regulated party. The IRA's deficiencies prevent NICA's members from protecting their *own* concrete interests. To establish standing, NICA need not show that inadequate procedures *will* lead to particular outcomes, or *when* they will do so—only "some possibility" that NICA would have benefited from adequate procedures. *EPA*, 549 U.S. at 518. That "possibility" is plain here, as two examples from CMS's Guidance implementing the program for 2026 illustrate.

First, "CMS adopted its interpretation of 'qualifying single source drug' and 'marketing' as final … , without notice or any opportunity for manufacturers, providers, patients, or the public to comment." ROA.47 (cleaned

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that manufacturers have "no choice" but to submit in view of the exorbitant excise tax. ROA.19, 32, 35-36.

up). In so doing, the agency misinterpreted "qualifying single source drug" to include "distinct drugs that treat two different diseases but share the same active moiety," and to treat as a single product all biological products with the same active ingredient. ROA.44. This definition harms NICA's members by covering "a broader swath of the treatments providers administer," so providers "have their reimbursement rates slashed" for more drugs. ROA.45-46.

Given the chance, NICA would have opposed that "broad interpretation," which "strays far from the statutory text." ROA.44. If Congress had considered how broadly to apply this program, rather than (purportedly) delegating that task to a politically insulated agency, NICA's members could have sought to hold responsible legislators accountable. And if not for the IRA's excessive fines, manufacturers could more effectively resist CMS's overreach during the "negotiation" process, shielding providers from the consequences.

Second, while "[t]he statute provides that a drug or biological product is not eligible for price setting if it faces competition from a generic drug or biosimilar that has been 'marketed,'" ROA.46 (quoting 42 U.S.C. § 1320f-1(e)(1)(A), (B)), CMS's Guidance adds a requirement that "the manufacturer of that drug or product is engaging in *bona fide* marketing of that drug or

product," Revised Guidance at 102 (emphasis added). According to the agency, it is not enough that the generic drug has been "marketed," which is all the IRA requires. Rather, CMS will analyze the strength of that marketing effort, a subject about which it has no expertise. This counter-textual agency rule never underwent notice-and-comment. Providers, manufacturers, and patients had no say. And now, the IRA requires NICA to sit by while HHS slashes the value of its property.

Nor was the district court correct to discount the harm to NICA's interests on the ground that "[a] provider's participation in the Medicare program is completely voluntary." ROA.615. Long before the IRA was enacted, providers invested billions of dollars building the infrastructure to furnish innovative medicines to patients. At the time, providers lacked any notice that pricing would later be set by the government. Now, even as Congress displaces market pricing in favor of government-dictated prices, it prevents providers from effectively protecting their investments and interests.

NICA's members in particular cannot escape the effects of the IRA's unconstitutional process. For a drug administered by NICA's members to be exempt, the drug's *manufacturer* would need to terminate its Medicare Part D agreements and its Medicaid rebate agreement for *all* its drugs. 26 U.S.C.

§ 5000D(c); *see id.* § 5000D(c)(1). Withdrawing from Medicaid would result in all of the manufacturer's products also losing Part B coverage, because for a drug to be payable under Part B, "the manufacturer must have entered into and have in effect a [Medicaid] rebate agreement." 42 U.S.C. § 1396r-8(a)(1). Thus, NICA's members cannot escape the IRA's unconstitutional process unless the manufacturers of the drugs they administer take the unlikely step of completely ending their participation in Medicare and Medicaid. Providers like NICA have no say in that decision.

In any event, manufacturers cannot protect NICA's interests because they lack the ability to withdraw as a legal and practical matter. Coercing submission to mandatory prices by threatening removal from Medicare and Medicaid "is a gun to the head." *NFIB v. Sebelius*, 567 U.S. 519, 581 (2012). "For an abandonment option to render" compliance with a government program "a voluntary choice, the option would have to at least be cognizable to [property] owners." *Valancourt Books, LLC v. Garland*, 82 F.4th 1222, 1235 (D.C. Cir. 2023). It is not enough "to characterize" the mandatory surrender of traditional protections "as part of a voluntary exchange." *Id.* In *NFIB*, for example, the federal government's "threat[] to withhold all of a State's Medicaid grants" did not give states the option to "voluntarily and knowingly" agree to "post-

acceptance or 'retroactive' conditions," which states "could hardly anticipate" when they "developed intricate statutory and administrative regimes over the course of many decades … under existing Medicaid." 567 U.S. at 575, 577, 582, 584. Because "Congress … threatened to withhold those States' existing Medicaid funds" "[i]nstead of simply refusing to grant new funds to States that will not accept the new conditions," the Affordable Care Act's mandate amounted to "coercion." *Id.* at 579-80.

By making a complete exit from Medicare and Medicaid a manufacturer's only alternative to fiat pricing, the drug-pricing regime is equally coercive. *Cf. Tenoco Oil Co. v. Dep't of Consumer Affs.*, 876 F.2d 1013, 1027 n.21 (1st Cir. 1989) (noting that the "freedom to temporarily leave the market may be largely illusory" if, "[i]n practice, such a course might very well be economically prohibitive"); *Doe v. Univ. of Scis.*, 961 F.3d 203, 213 (3d Cir. 2020) (recognizing that "total withdrawal of federal funding" can be "economic dragooning" and "a gun to the head").

The IRA foreclosed even this Hobson's choice during the first round of "negotiation." The Act expressly prevented manufacturers from withdrawing until at least December 2023, well after the first ten drugs had been selected

and manufacturers had been forced to sign "agreements" to "negotiate."[7] In other words, between the IRA's enactment and the deadline to contractually submit to the first "negotiation," *see* 42 U.S.C. § 1320f-2(a), there was not even an illusory option to withdraw. Manufacturers *had* to enter an unconstitutional "negotiation" or pay an unconstitutional penalty, and providers *had* to incur the consequences. Thus, for drugs selected in the first round—including eight drugs manufactured by members of PhRMA and at least one drug dispensed and administered by members of NICA—participation was compulsory as a matter of law. NICA therefore is already suffering due process injuries sufficient to confer Article III standing. *Cf. FEC v. Cruz*, 596 U.S. 289, 298 (2022) (standing exists when government "require[s] [the plaintiff] to subject itself to the very framework it says unconstitutionally burdens its [rights]").

[7] A manufacturer may exit the Drug Pricing Program and avoid the excise tax only if it terminates all "applicable agreements." 26 U.S.C. § 5000D(c). If a manufacturer terminates the relevant agreements after January of a given year, the termination generally will not be effective until the end of the following plan year. *See* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(ii), 1395w-114c(b)(4)(B)(ii). Thus, if a manufacturer terminated all applicable agreements when the IRA was enacted (August 16, 2022), the termination would not be effective until after December 31, 2023.

B. NICA Alleges Economic Injuries

Although NICA's procedural harms alone confer standing, the IRA also will imminently inflict economic harms on NICA's members. In fact, NICA's members dispense and administer a Part D drug that has *already* been selected.

1. To adequately plead economic injury, a plaintiff must allege that it will "likely" suffer financial harm. *Bryant v. Yellen*, 447 U.S. 352, 368 (1980); *see Babbitt v. United Farm Workers Nat. Union*, 442 U.S. 289, 298 (1979) ("a realistic danger"). "But one does not have to await the consummation of threatened injury to obtain preventive relief." 442 U.S. at 298 (cleaned up). Instead, the plaintiff need only show that "the threatened injury is certainly impending, or there is a substantial risk that the harm will occur." *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2565 (2019) (citation omitted). In other words, injury must be "fairly likely." *Crawford v. Hinds Cnty. Bd. of Supervisors*, 1 F.4th 371, 376 (5th Cir. 2021).

A sufficient likelihood exists when legislation upends a litigant's "concrete plans" based on the prior legal regime. Thus, "probable economic injury resulting from governmental actions that alter competitive conditions [i]s sufficient to satisfy the Article III 'injury-in-fact' requirement." *Clinton*,

524 U.S. at 433 (cleaned up). "It follows logically that any petitioner who is likely to suffer economic injury as a result of governmental action that changes market conditions satisfies this part of the standing test." *Id.* (cleaned up).

When a plaintiff alleges a financial harm that *will* occur, moreover, that confers associational standing even if the harm will manifest in the future. In *American Forest & Paper Association v. EPA*, 137 F.3d 291 (5th Cir. 1998), for example, a trade association had standing to challenge an EPA rule that would inflict future "costs of compliance." *Id.* at 296. Under the challenged rule, EPA required Louisiana to obtain its approval before granting discharge permits. The trade association challenged the rule even though it "ha[d] not alleged that any of its members ha[d] applied for a new permit or sought to modify an existing one." *Id.* But the Court "d[id] not find the permit holders' injuries speculative," since permits "must be renewed every five years," and "[m]odifications to existing permits must also be cleared with [the agencies]." *Id.* Permit holders' "need to comply, coupled with EPA's frank announcement of its intentions, belie[d] the agency's claim that any injury [was] speculative." *Id.*

2. The financial injury to NICA's members from lost Part B revenue for drugs subject to mandatory prices is just as "imminent" and non-

"speculative." *Id.* "[W]ithin ten years, *half* of all Medicare drug spending will be for drugs whose price is set under th[e] program." ROA.30. Because NICA members' businesses depend on dispensing and administering the most-used Part B drugs, there is no question that "a significant and growing number of" Part B drugs NICA members dispense *will be* subject to mandatory prices. ROA.19. This will occur no later than 2028, which is comparable to the "five year[]" period at issue in *American Forest*. 137 F.3d at 296.

And Part B is just the beginning. "NICA members that provide infusion services and pharmaceuticals to Medicare patients are reimbursed through both Part B and Part D." ROA.563. The Complaint thus alleges that the IRA will harm NICA's members not only through *Part B* price caps, but also through *Part D* price caps: "[M]embers of NICA" receive reimbursements for "operating *outpatient* facilities for administering biological treatments," ROA.13 (emphasis added), and these treatments are covered "under Medicare Part B *and Part D*," ROA.19 (emphasis added). "[C]onstru[ing] the complaint in favor of [Plaintiffs]" thus means "accept[ing] as true" the allegations that NICA's members also will suffer injury from Part D price caps. *Warth v. Seldin*, 422 U.S. 490, 501 (1975).

Indeed, this has already occurred. The first list of selected drugs for negotiation includes Stelara®, which several NICA members administer, and for which they "are reimbursed under both Part B and Part D." ROA.563, 565; *see* ROA.558; HHS, *HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023), https://bit.ly/460imGp. Stelara® will be subject to mandatory prices in 2026. When that occurs, "the margins that NICA members earn on those drugs will decrease, causing them to incur losses on services to Medicare patients." ROA.37.

Once a drug has been selected, "reimbursement rates … will be based on the IRA's 'maximum fair price,' and revenues will fall precipitously." ROA.18-19. Plaintiffs allege "that these reimbursement changes will cause major revenue decreases for many of NICA's members and that, as a result, a substantial number of NICA's members will have no choice but to scale back operations, to reduce or eliminate the services they provide to Medicare patients, or even to go out of business." ROA.19.

Although the 2026 price mandates apply only to Part D drugs, they will also lower providers' *Part B* reimbursements for selected drugs (including Stelara®) that are administered under both Parts. *See* ROA.563-65. Part B "providers generally are reimbursed by Medicare based on the average sales

price of the drug." ROA.18-19; ROA.562. For selected drugs that are reimbursed under both Part D and Part B, the 2026 price mandates will lower the "average sales price," which is calculated using sales *under both Parts*. *See* 42 U.S.C. § 1395w-3a; 86 Fed. Reg. 64,996, 65,220 (2021). When the price mandates take effect, amounts "paid to the provider [will] decrease[] in absolute terms, and the provider [will be] financially harmed as a result." ROA.564. Thus, the average sales price of Stelara® will drop when the price mandates take effect in 2026, and "the margins that NICA members earn with respect to Stelara® will shrink in absolute terms." ROA.564. "The upshot is that NICA's members will be affected by impending price negotiation … regardless of whether they are reimbursed for Stelara® under Part D or Part B." ROA.564.

Finally, because the IRA impairs NICA members' reimbursements, it "is *already* impacting the ability of NICA's members," some of whom "are currently courting private equity investments," "to raise debt and equity funding." ROA.566 (emphasis added). This loss of business opportunity is another concrete harm. *See, e.g.*, *El Paso Cnty. v. Trump*, 408 F. Supp. 3d 840, 851 (W.D. Tex. 2019) (injury-in-fact exists "where the economic injury stems

from the 'loss of a non-illusory opportunity' to obtain 'a benefit'" (citation omitted)).

3. Below, the government speculated that "it is possible that [a] provider's savings on drug-acquisition costs" under 42 U.S.C. § 1320f-2(a)(3) "would outweigh any losses caused by" the IRA's price mandates. ROA.450. But the government's speculation contradicts the Complaint's detailed allegations. *See* ROA.450. And even if drug-acquisition costs fall along with reimbursement rates, the overall amount providers are paid will decrease in absolute terms.

Presumably, NICA knows better than the government how to represent its own members' interests. In any event, "standing analysis is not an accounting exercise." *Texas v. United States*, 809 F.3d 134, 156 (5th Cir. 2015). "Once injury is shown, no attempt is made to ask whether the injury is outweighed by benefits the plaintiff has enjoyed from the relationship with the defendant." *Id.* at 155-56 (citation omitted). In stock-manipulation cases, for example, investors have standing without considering possible benefits from the defendant's price manipulation, because "the mere fact that an injury may be outweighed by other benefits, while often sufficient to defeat a claim for damages, does not negate standing." *In re Barclays Liquidity Cross & High*

Frequency Trading Litig., 390 F. Supp. 3d 432, 444 (S.D.N.Y. 2019); *see Alaska Elec. Pension Fund v. Bank of Am. Corp.*, 175 F. Supp. 3d 44, 53 (S.D.N.Y. 2016). NICA adequately alleges standing.

CONCLUSION

This Court should reverse.

Dated: April 12, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 12, 2024, 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: April 12, 2024

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CERTIFICATE OF COMPLIANCE

This document complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B)(i) because it contains 12,885 words excluding the parts exempted by Fed. R. App. P. 32(f) and Fifth Circuit Rule 32.2. This document 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 it has been prepared in a proportionately spaced typeface using Microsoft Word in Century Expanded BT 14-point font.

Dated: April 12, 2024

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