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' REPLY BRIEF

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INTRODUCTION

Plaintiffs' facial constitutional challenges to the IRA's Drug Pricing Program—which Congress codified in subchapter XI of chapter 7 of title 42 of the U.S. Code—fall squarely within federal-question jurisdiction, 28 U.S.C. § 1331, or U.S.-defendant jurisdiction, *id.* § 1346. The government strains to argue that Congress withdrew that jurisdiction under 42 U.S.C. §§ 405(h) and 1395ii, which provide that "[n]o action … shall be brought … to recover on any claim arising under this subchapter [XVIII]" of chapter 7 of title 42, also known as the Medicare Act. But Plaintiffs' facial constitutional challenges cannot fairly be characterized as an effort "to recover on any claim," and subchapter XI is not subchapter XVIII. Indeed, Congress's decision to codify the Drug Pricing Program outside of the Medicare Act underscores that what those novel provisions regulate is *not* Medicare reimbursements, but the prices offered in private transactions between nongovernmental parties.

The government makes no effort to justify its interpretation based on the statutory text; indeed, in its full-length brief, the government never quotes the text of § 405(h). Instead, the government relies on inapposite decisions that rejected thinly disguised Medicare reimbursement challenges, which the government (mis)construes as holding that parties must channel "virtually all legal

attacks concerning Medicare reimbursements." Opp. 17-18 (quotation marks omitted). But no prior case has *ever* required channeling for a facial constitutional challenge to provisions codified outside the Medicare Act. And this case is a poor candidate to be the first, since Plaintiffs challenge provisions that do not themselves control reimbursement; they allege "here-and-now" procedural injuries; and they assert facial constitutional claims that can be adjudicated without evaluating any reimbursement claim or determination. Ultimately, the government is seeking a radical extension of § 405(h) channeling that is not grounded in the statutory text or existing caselaw and has no limiting principle.

After this Court concludes that NICA is not required to channel its claims, the Court should uphold NICA's Article III standing to assert them. The government attempts to portray NICA's claims as limited to reductions in far-off reimbursements, ignoring procedural harms the IRA inflicts *now*—depriving NICA's members of constitutionally required due process, impermissibly delegating legislative power to the agency, and coercing compliance via excessive fines. NICA is no mere bystander to the IRA with a purely academic interest in the scheme's operation. Rather, the law's unconstitutional procedures upend NICA's members' businesses, directly threatening their concrete interests.

Regardless, the IRA also threatens NICA with economic injuries that are reasonably certain and imminent. The lower prices mandated by the Drug Pricing Program—under both Part B and Part D—will directly translate to lower revenue for providers. This process has already begun with the selection of Stelara®, which NICA members dispense and administer. The government's contrary arguments—that intervening events *might* exempt Stelara® from the Program, or that NICA's members *might* find ways to offset lower reimbursements—provide no basis to ignore the Complaint's well-pleaded allegations.

ARGUMENT

I. Plaintiffs Are Not Required To Channel Their Claims

Plaintiffs' facial constitutional attack on the Drug Pricing Program in subchapter XI is not an "action … to recover on any claim arising under" subchapter XVIII, as the plain text of §§ 405(h) and 1395ii require. Subchapter XVIII provides *neither* NICA's standing *nor* the substantive basis for Plaintiffs' claims, and no prior case has held that a facial constitutional challenge to a statute outside subchapter XVIII meets those requirements. Nor is Plaintiffs' attack on the IRA's upstream price regulation inextricably intertwined with any downstream claim for Medicare reimbursement. The government's responses ignore the statutory text, mischaracterize the caselaw, and misunderstand the IRA's unprecedented scheme.

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

Plaintiffs' facial challenge to the IRA's Drug Pricing Program in subchapter XI is not subject to channeling under the plain text of §§ 405(h) and 1395ii or any existing precedent, and the government's expansive interpretation would lead to absurd results.

1. Section 405(h), read in light of § 1395ii, provides 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]." That language channels retroactive reimbursement claims and anticipatory challenges to Medicare "rule[s] or regulation[s]" through the agency, *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 10 (2000), giving the agency the opportunity to resolve issues affecting payments before courts review claims. Here, however, Plaintiffs do not seek to "recover on any claim"—retroactively *or* anticipatorily. And their challenges "aris[e] under" the Constitution and subchapter XI, not subchapter XVIII. The statutory text simply does not apply here.

Nor does "the Medicare Act provide[] both the substance and the standing for [NICA's] claim[s]." *Heckler v. Ringer*, 466 U.S. 602, 620 (1984). If

either Plaintiffs' standing *or* the substance of their claims does not rest on the Medicare Act, then channeling is not required; here, neither do. Plaintiffs assert a facial constitutional challenge to provisions of a *separate* statute (the IRA) that is codified in a *separate* subchapter (subchapter XI). And they allege procedural "here-and-now injur[ies]" inflicted by the IRA's price-setting scheme itself, irrespective of any later effects on Medicare reimbursements. *Axon Enter., Inc. v. FTC*, 598 U.S. 175, 189, 192 (2023).

The government nevertheless argues that Plaintiffs' claims arise under subchapter XVIII because the challenged provisions codified in subchapter XI "have no significance apart from the Medicare Act." Opp. 24-26. But that fundamentally misunderstands Plaintiffs' challenge. While the IRA eventually will affect Medicare reimbursements (among other things), Plaintiffs do not challenge those downstream effects. Rather, they challenge the IRA's upstream *process*. That process has already inflicted "here-and-now injur[ies]," *Axon Enter.*, 598 U.S. at 189, 192, and threatens to inflict still more, as CMS continues to make important decisions without constitutionally required safeguards. Those procedural injuries "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).

The government's argument also misunderstands the operation of the IRA's Drug Pricing Program itself. The government asserts that "the Negotiation Program has significance only in connection with Medicare." But that overlooks the Program's unprecedented design. Opp. 25-26. As Plaintiffs have explained, traditional Medicare is an *insurance* scheme: It reimburses patients (or providers as their assignees) for covered medical expenses, but does not directly regulate prices. The IRA's Drug Pricing Program, by contrast, is a *price-setting* scheme: It does not merely define the scope of government benefits, but rather directly prescribes the prices private parties must offer in transactions to which the government is not a party. *See* Br. 6-9. This novel price-setting regime has its own elaborate administrative apparatus, including new rights, duties, and enforcement mechanisms that operate entirely separately from any claim for benefits under traditional Medicare. It is no wonder, then, that Congress codified the Drug Pricing Program outside of subchapter XVIII—it is a new, distinct program. In that context, it makes no sense to channel Plaintiffs' claims through HHS's reimbursement-review scheme; their claims are not about reimbursement.

Even insofar as the IRA *does* affect insurance reimbursements, it does not affect *only* Medicare reimbursements. The government has taken the position that eligible maximum prices will be incorporated into the drug's "average sales price." *See* ROA.27. *Private* insurance plans, in turn, use the average sales price as a benchmark in negotiations with providers. Thus, "[t]he IRA's [maximum price] will likely migrate from Medicare to the commercially insured population (i.e., 'spill over' from Medicare to the commercial market)." ROA.281. Furthermore, "[i]n some cases," this commercial-market spillover "will be statutorily imposed by State Prescription Drug Affordability Boards." ROA.281. The IRA's mandated discounts thus affect NICA in multiple respects, not merely through effects on Medicare reimbursements.

For similar reasons, the government's argument that Plaintiffs' filings are "replete with references to the Medicare Act" elevates form over substance. Opp. 25. Many of those references simply rebut the government's own Medicare-related arguments. Regardless, the question for this Court is whether this case is "an action … to recover on any claim arising under" the Medicare Act, 42 U.S.C. § 405(h), or whether "the Medicare Act provides both the substance and the standing for [Plaintiffs'] claims," *Ringer*, 466 U.S. at

620. The answer to those questions does not depend on how many times Plaintiffs reference Medicare.

Take *Alvarado Hospital*, for example. There, even though the plaintiffs expressly sought "Medicare reimbursement," the Federal Circuit held that channeling was not required, instead focusing on the *substance* of the claims. *Alvarado Hosp.*, 868 F.3d at 99. As the court explained, "[t]hat [the plaintiffs] also call this sum in their complaint 'Medicare reimbursement' does not change the fact that the damages they seek are *really* the bargained-for total sum under the settlement agreement." *Id.* (emphasis added).[1]

Stepping back, the government never explains why, if Congress wanted challenges to the Drug Pricing Program to be channeled through HHS's administrative process for Medicare reimbursement claims, Congress nevertheless chose to codify that Program in subchapter XI—*outside* the Medicare Act. Nor does the government address why, if Congress wanted

[1] Citing Plaintiff's discussion of *Community Oncology Alliance, Inc. v. OMB*, 987 F.3d 1137 (D.C. Cir. 2021), the government asserts that Plaintiffs "accept" that a challenge to a statute outside subchapter XVIII "ar[i]se[s] under the Medicare Act" if the statute cross-references Medicare. Opp. 27-28. Obviously not. As discussed below, *Community Oncology* did not turn on mere cross-references. The executive order challenged there did *nothing whatsoever* besides adjusting Medicare reimbursements. Here, the challenged provisions operate independently of reimbursement. *See* pp. 11-12, *infra*.

challenges to be channeled through an administrative-review scheme, Congress expressly *barred* "administrative … review" of key aspects of the law's implementation. 42 U.S.C. § 1320f-7. The government seems to take the view that, if Congress wants to allow a claim touching on Medicare to avoid channeling, nothing short of an express partial repeal of §§ 405(h) and 1395ii will suffice to open the courthouse doors. But courts "have never required that Congress use magic words." *FAA v. Cooper*, 566 U.S. 284, 291 (2012). And requiring magic words would be particularly inappropriate here, where channeling would serve no purpose except delay, and where the government's interpretation would raise constitutional concerns. *See* Br. 38-39.

2. The government makes no attempt to justify channeling under the text of § 405(h)—which the government references only incidentally, almost halfway into its brief. *See* Opp. 19. Instead, the government relies on its own characterization of prior cases that required channeling. But *none* of those cases addressed the type of claim presented here: a facial constitutional challenge to provisions Congress chose to codify *outside* the relevant subchapter. It is thus the government, not Plaintiffs, that fails to "attend[] to the particulars of the[] cases" it cites. Opp. 38.

First, the government cites *Weinberger v. Salfi*, 422 U.S. 749 (1975), for the proposition that channeling "applies to claims that arise under the Constitution … , as long as the action also arises under the Social Security or Medicare Acts." Opp. 21. But the constitutional claim in *Salfi* challenged a Social Security eligibility requirement that, like § 405 itself, was codified in subchapter II—*i.e.*, in "*this* subchapter." 42 U.S.C. § 405(h) (emphasis added); *see Salfi*, 422 U.S. at 754 (discussing 42 U.S.C. § 416(c)(5) and (e)(2)). *Salfi* had no occasion to address facial constitutional challenges to statutes *outside* the relevant subchapter.

Second, the government cites *Heckler v. Ringer*, where the plaintiffs challenged an HHS policy denying Medicare coverage for a particular surgery. *See* 466 U.S. at 609-10. But that case is doubly inapposite. To start, the plaintiffs there attacked not a statute, but an HHS policy adopted under authority granted in subchapter XVIII. *See id.* at 605 (discussing 42 U.S.C. § 1395ff(a)). And the *Ringer* challenge directly concerned reimbursement: The plaintiffs alleged that the surgery was entitled to reimbursement under the Medicare Act. *Id.* at 610 n.7.

Third, the government cites *Shalala v. Illinois Council on Long Term Care, Inc.* But there, too, the plaintiffs attacked not a statute but HHS

regulations—which, again, were promulgated under statutory authority within subchapter XVIII. *See* 529 U.S. at 6-7 (discussing 42 U.S.C. § 1395i-3).

Fourth, the government cites *Physician Hospitals of America v. Sebelius*, 691 F.3d 649 (5th Cir. 2012). But there, the plaintiffs asserted constitutional challenges to a provision that Congress chose to codify *within* subchapter XVIII. *See id.* at 652 (discussing 42 U.S.C. § 1395nn(i)). Even then, *Physician Hospitals* primarily addressed a different issue—whether the plaintiffs' delay-related hardship amounted to a "practical denial of judicial review," *id.* at 656, such that channeling was not required under *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986), as interpreted in *Illinois Council*.

Finally, the government relies heavily on *Community Oncology Alliance, Inc. v. OMB*, 987 F.3d 1137 (D.C. Cir. 2021), where the plaintiff challenged a sequestration order under the Balanced Budget Act. *Id.* at 1140. That out-of-circuit decision is an outlier, representing the *only* case where any court has required a plaintiff to channel a challenge to administrative action authorized by a provision codified outside the relevant subchapter. But even if *Community Oncology* were considered persuasive, it is readily distinguishable, as it involved an *as-applied* challenge to an executive order

that did nothing except adjust Medicare reimbursements. *Id.* at 1142. The sole function of that executive order, and the statutory provision authorizing it, was to institute "a two percent reduction in all Medicare reimbursements." *Id.* at 1140. The plaintiff's challenge was thus directed exclusively at Medicare reimbursements—the plaintiff alleged "that [the relevant drugs] must be reimbursed at the full amount specified by the Medicare Modernization Act." *Id.*[2]

In contrast to every one of those cases, Plaintiffs assert facial constitutional challenges to statutory provisions that do not themselves govern reimbursement and that Congress chose to codify outside the Medicare statute. Channeling therefore is not required for the reasons explained in *Association of Community Cancer Centers v. Azar*, 509 F. Supp. 3d 482 (D. Md. 2020) (*ACCC*). As the government acknowledges, *ACCC* held that channeling was not required precisely because the "new reimbursement model was promulgated pursuant to 42 U.S.C. § 1315a," which—like the IRA—is codified in subchapter XI. *Id.* at 488, 491. Since the Drug Pricing Program is

[2] The government cites *Retina Grp. of New England, P.C. v. Dynasty Healthcare, LLC*, 72 F.4th 488 (2d Cir. 2023). But there, the plaintiff sought "monetary damages" for "Medicare underpayments" under the theory that a Medicare Administrative Contractor "failed to comply with the Medicare Act and related regulations." *Id.* at 496.

not even a "reimbursement model," this case follows *a fortiori* from *ACCC*. The government does not even attempt to distinguish *ACCC*; it simply calls the decision "erroneous[]." Opp. 28-29.

3. Dismissing the statutory text, and unconcerned by the limits of existing caselaw, the government seeks a startlingly broad extension of § 405(h) channeling. In the government's view, lawsuits must be channeled if they "*concern*[] Medicare reimbursements," "*refer*[] to provisions codified in Title XVIII," or challenge "a statute or regulation [that] *may limit* [claimants]' future Medicare reimbursements," Opp. 17-19, 25 (emphases added). According to the government, those are all actions "to recover on a[] claim arising under" the Medicare Act, 42 U.S.C. § 405(h); *see* Opp. 17, 19.

The government does not dispute the implications of its sweeping position. It does not dispute that, under its approach, channeling would be required for a constitutional challenge to a "statute prohibiting healthcare providers from transporting particular medical products via interstate mail," and for a First Amendment challenge to a law "prohibiting [physicians] from speaking with patients about innovative drugs." Br. 40-41. Nor does the government dispute that, under its interpretation, channeling would have been required in cases where channeling was never even considered, such as

Alliance for Hippocratic Medicine v. FDA, 78 F.4th 210 (5th Cir.), *cert. granted*, 144 S. Ct. 537 (2023). *See* Br. 41 n.2. All of these examples involve "a statute or regulation [that] *may* limit [claimants'] future Medicare reimbursements." Opp. 19 (emphasis added).

In the end, while the government tries to paint Plaintiffs' arguments as overbroad, it is the government that "advance[s] a view … that fails to admit of any limits." Opp. 38. The government cannot bring itself to acknowledge *any* type of claim touching upon Medicare reimbursement in *any* way where channeling would not be required. The government's position has no apparent limiting principle.

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

Below, the district court asserted that Plaintiffs' claims were "inextricably intertwined" with claims for Medicare reimbursement, but without a word of supporting analysis. ROA.623. The government does the same. Opp. 27. But even a cursory examination of this judge-made doctrine shows that it does not apply here.

Even where plaintiffs do not "su[e] directly for reimbursement," their suits still must be channeled if they "s[eek] only an invalidation of the Secretary's policy against reimbursement" under particular circumstances, or

seek "a declaration that [particular] expenses … were reimbursable." *RenCare, Ltd. v. Humana Health Plan of Tex., Inc.*, 395 F.3d 555, 558 (5th Cir. 2004). In such cases, the plaintiff's claims—however characterized—"[a]re not anything more than, at bottom, a claim that they should be paid," and hence are "inextricably intertwined with a claim for benefits." *Id.* (quotation marks omitted). But claims are "*not* inextricably intertwined with … claims for Medicare benefits" if "hearing [the plaintiff's] claim will not mean reviewing the merits of [any] underlying reimbursement claims decision." *Alvarado Hosp.*, 868 F.3d at 998 (emphasis added). And that will be true where the plaintiff "may be able to prove the elements of [its] causes of action without regard to any provisions of the [Medicare] Act." *Do Sung Uhm v. Humana, Inc.*, 620 F.3d 1134, 1145 (9th Cir. 2010).

Such is the case here. A court can readily adjudicate NICA's constitutional attacks on the IRA without evaluating the validity of any provision of the Medicare Act or any agency decision thereunder. Nothing about the elements of these claims would change if, for instance, a manufacturer were the sole plaintiff in this suit. Indeed, the fact that "[m]anufacturers of selected drugs … have challenged the constitutionality of the Negotiation Program in cases that are pending around the country,"

Opp. 9, underscores that those facial constitutional challenges—like this one—are *not* inextricably intertwined with benefits claims.[3]

This lawsuit does not map onto the government's cases for a reason. "[T]he Supreme Court's justification for broadly construing the 'claims arising under' language of subsection 405(h) is to prevent beneficiaries from circumventing the administrative process by creatively styling their benefits claims as collateral constitutional or statutory challenges not 'arising under' Medicare." *United States v. Blue Cross & Blue Shield of Ala., Inc.*, 156 F.3d 1098, 1104 (11th Cir. 1998); *see Ringer*, 466 U.S. at 624 (beneficiaries might "characterize[]" their challenges "in a different way" to evade administrative review). But that justification does not apply here. Parties cannot plausibly dress up Medicare benefits disputes as facial constitutional challenges to statutes outside the Medicare Act. And NICA's concern is not, "at bottom, … that [its members] should be paid" a certain amount, or even that a particular reimbursement methodology should be used. *Ringer*, 466 U.S. at 614. NICA challenges the IRA's mechanism for setting the prices that private parties must offer for drugs via a novel administrative scheme that is unconstrained

[3] The government does not defend the district court's statement that "the same federal jurisdictional defect likely exists for PhRMA and GCCA." ROA.610. For good reason—it is indefensible.

by public input or judicial review. The IRA's unconstitutional process will injure NICA's members even if none of them loses a penny, and an increase in Medicare reimbursements will do nothing to remedy that injury. Channeling, accordingly, is not required.

II. NICA Has Standing

NICA has alleged multiple, independent injuries sufficient to establish standing—both procedural and economic. The government's arguments mischaracterize or simply ignore the Complaint's procedural allegations; contradict the government's own description of how the IRA will affect providers like NICA's members; and rest on speculation about future events that *might* relieve NICA of those effects.

The government argues that the Court "does not need to reach" standing in light of its channeling argument. Opp. 31. But the government does not dispute that, if the Court concludes channeling is *not* required—and as explained, it is not—the Court should also address the "second threshold matter" of "whether [Plaintiffs] ha[ve] standing." *Ortega Garcia v. United States*, 986 F.3d 513, 523 (5th Cir. 2021). Doing so will avoid further delay on preliminary jurisdictional matters and allow the district court on remand to proceed directly to the merits.

A. NICA Alleges Procedural Injuries

NICA has always maintained that its procedural injuries provide its principal basis for standing, but the government attempts to bury that point. When the government finally responds, Opp. 38-42, it does not dispute that "[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 433, 447 (5th Cir. 2019) (quoting *Summers v. Earth Island Inst.*, 555 U.S. 488, 496 (2009) (cleaned up)). Instead, the government argues that NICA "does not identify any concrete interest to which the alleged procedural harms relate," and that NICA "cannot avoid the need to demonstrate concrete injury by recharacterizing its members' injuries as procedural." Opp. 38-39. The government's argument misconstrues the Complaint and the relevant legal standard.

1. To start, NICA has not "recharacterized" anything; the Complaint primarily alleges procedural injuries. *E.g.*, ROA.38-39; ROA.66. It is *the government* that labors to recharacterize NICA's injuries in purely economic terms. While plaintiffs alleging procedural harm still must show that the challenged procedures threaten their "concrete interests," *Texas v. EEOC*, 933 F.3d 433, 447 (5th Cir. 2019), that threat need not independently rise to the level of an Article III injury. After all, "[i]f a plaintiff also had to prove a freestanding

substantive injury, there would be no reason to allow procedural-injury standing." *Kinetica Partners, LLC v. U.S. Dep't of the Interior*, 505 F. Supp. 3d 653, 672 (S.D. Tex. 2020).

Instead, where procedural harm is alleged, "the *risk* of real harm can[] satisfy the requirement of concreteness." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 341 (2016) (emphasis added). As Plaintiffs explained, a plaintiff need not show that inadequate procedures *will* lead to particular outcomes or *when* they will do so—it is enough to show that there is "some possibility" adequate procedures would have benefited the plaintiff. *Mass. v. EPA*, 549 U.S. 497, 518 (2007); *see* Br. 52-53. NICA has easily satisfied that requirement by identifying specific ways that "the IRA's constitutionally inadequate procedures are currently harming NICA's members," Br. 47; *see id.* at 52-54; and by connecting those procedural errors to risk that its members' interests will suffer, *see id.* at 59-63.

The government nevertheless argues that "NICA has failed to establish with sufficient concreteness whether or how the Negotiation Program will affect any member's profit margins on [selected] drugs." Opp. 39. Insofar as the government is suggesting that the Drug Pricing Program might not affect drug prices, that argument is ironic coming from the government: The whole point of the Program is to "lower prices for these drugs." The White House, *Interested*

Parties Memo: President Biden Takes On Big Pharma and Is Lowering Prescription Drug Prices (Feb. 1, 2024), https://bit.ly/3Uc4Ew9. In fact, the IRA *legally mandates* lower prices for selected drugs: at least a 25% reduction from the current baseline for recently approved drugs, and at least 60% for older drugs. *See* 42 U.S.C. § 1320f-3(b)(2)(F), (c)(1)(C)(i).

Insofar as the government is suggesting that lower drug prices will not translate into lower profits for NICA's members, that contradicts the Complaint, which alleges that "revenues *will* fall precipitously." ROA.18-19 (emphasis added); *see Warth v. Seldin*, 422 U.S. 490, 501 (1975) ("[R]eviewing courts must accept as true all material allegations of the complaint, and must construe the complaint in favor of the complaining party."). Moreover, as Plaintiffs have explained (Br. 61-62), the relevant pricing dynamics flow mechanically from the statute by operation of law. Those pricing dynamics independently establish NICA's standing based on economic harm. *See* Part II.B, *infra*. But at minimum, they raise a "risk of real harm" sufficient to establish NICA's concrete interests for purposes of procedural standing. *Spokeo*, 578 U.S. at 340.

2. The government attempts to defend the IRA's inadequate procedures on the merits, arguing that NICA "overlooks the extensive public

feedback that CMS solicited in developing its implementation guidance." Opp. 40. But that is like saying NICA has not lost *anything* because it has not lost *everything*. CMS solicited feedback on *some* issues—though it claimed it had no obligation to follow ordinary notice-and-comment procedures. *See* CMS, *Medicare Drug Price Negotiation Program: Revised Guidance for Initial Price Applicability Year 2026* (hereinafter, *Revised Guidance*), at 8-9 (June 30, 2023), https://bit.ly/3JLSSUH. And CMS restricted input on several crucial topics, including "its interpretation of 'qualifying single source drug' and 'marketing.'" ROA.47. The government cannot deprive providers of key procedural rights, then claim those providers have not been injured because they still have *other* procedural rights.

The government also insists that if NICA's procedural injuries "were sufficient to establish standing, any party whatsoever would have standing to bring the claims plaintiffs assert." Opp. 40. That is demonstrably untrue. NICA is no mere bystander, with a purely academic interest in the IRA's constitutionality; it is a trade association of healthcare providers whose businesses the IRA will upend. Indeed, the government's own channeling argument is that NICA must first present its constitutional claims to HHS precisely because resolving those claims will help "determine[]" how much its

members are "reimburse[d] for a selected drug." Opp. 25. That channeling argument, while mistaken, nevertheless confirms that NICA is a party concretely affected by the IRA—not "any party whatsoever."

The government further argues that because manufacturers ostensibly can "end their participation in Medicare and Medicaid," the harm the IRA inflicts on NICA "turns on those third parties' future decisions." Opp. 42-43 (cleaned up). Again, the government's argument boils down to the claim that the IRA is likely to accomplish nothing. But the possibility that the law will come to naught because all manufacturers will opt out is beyond outlandish. As Plaintiffs have explained, 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 Commerce v. New York*, 139 S. Ct. 2551, 2566 (2019); *see* Br. 51 n.6. Given the staggering "financial, ethical, and reputational costs" of withdrawing from Medicare, ROA.190, it is not only "predictable" that manufacturers will submit to the IRA's demands, but practically guaranteed. *See* The White House, *Biden-Harris Administration Takes Major Step Forward in Lowering Health Care Costs; Announces Manufacturers Participating in Drug Price Negotiation Program* (Oct. 3, 2023),

https://bit.ly/3JtAkbl (touting that "all manufacturers of all ten drugs selected for negotiation have signed agreements to participate").

The government asserts that "neither NICA nor any of its members is an object of the government action here," since "NICA's members are not themselves subject to the allegedly unconstitutional process or the allegedly excessive fines of which plaintiffs complain." Opp. 42. That misses the point. NICA's procedural injury is not that its members must themselves "negotiate" or pay fines; the injury is that the IRA forces NICA into silence while CMS harms its members' concrete interests. Thus, NICA *is* "an object" of the IRA: The statute prevents NICA from weighing in on key decisions via notice-and-comment; improperly delegates decision-making to an unaccountable agency whose decisions harm it; and, through the threat of massive fines, stymies the only entities that might otherwise protect NICA's interests. The IRA's "constitutionally [de]ficient procedures" multiply "[t]he risk of erroneous deprivation" of Plaintiffs' concrete interests. ROA.66.[4]

[4] The government argues that NICA lacks standing because its "members are themselves voluntary participants in the Medicare program and [thus] can choose whether to continue their participation." Opp. 43. The factual premise of that argument is incorrect, given Medicare's "commanding percentage" of the relevant market. ROA.58. But even if participation *were* voluntary, that would not undermine standing: Voluntary participants in governmental programs still

B. NICA Alleges Economic Injuries

If this Court concludes that NICA has standing based on procedural injury, it need not address the issue of economic injury. But if the Court reaches it, NICA has standing based on economic injury as well.

The government argues that NICA's economic injuries are too "speculative." Opp. 15. But the IRA unavoidably injures NICA's members by operation of law—through a process that is already underway. In hypothesizing ways that the IRA might not harm NICA's members, it is *the government* that is speculating.

1. The IRA mandates significantly lower prices for selected drugs. *See* 42 U.S.C. § 1320f-3(b)(2)(F), (c)(1)(C)(i). Lower prices, in turn, harm providers, which are compensated at a percentage of those prices. Part B "providers generally are reimbursed by Medicare based on the average sales price of the drug." ROA.18; *see* ROA.562. The typical Part B reimbursement is "106 percent" of the drug's "average sales price." 42 U.S.C. § 1395w-3a(b)(1)(B); *see* ROA.562. For example, consider a drug with a $100 average sales price. A provider acquiring the drug for $100 will be reimbursed $106 for

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may challenge procedures used to make decisions affecting their concrete interests. *See FEC v. Cruz*, 596 U.S. 289, 297 (2022).

administering it to patients in Part B, earning $6. If CMS sets the maximum price of that drug at $50, providers may be able to acquire it for $50, but they will be reimbursed only $53 when they administer it to patients—and thus will earn only $3 for the same treatment.

These effects will be felt, moreover, based on maximum prices under both Part D and Part B. For selected drugs, HHS maintains that the lower "Maximum Fair Price" will be incorporated into the "average sales price," which generally is calculated using sales under both Parts. *See* 42 U.S.C. § 1395w-3a; 86 Fed. Reg. 64,996, 65,220 (Nov. 19, 2021). For certain selected drugs reimbursed under both Parts, therefore, when government-imposed prices *for Part D* take effect in 2026, "the six percent margin paid to the provider" *for Part B sales* also will "decrease[] in absolute terms, and the provider [will be] financially harmed as a result." ROA.564.

These effects on NICA's members are not speculative; they are already starting. Plaintiffs' declarations have "identified a NICA member (BioTek) that administers an infusion drug (Stelara) that was selected for negotiation." Opp. 32-33.[5] While this so-called "negotiation" is still ongoing, any maximum

[5] Despite the government's repeated carping that Plaintiffs did not identify BioTek in the Complaint, *see* Opp. 2-3, 10-11, 14-15, 32-33, there is "no precedent holding that an association must set forth the name of a particular

fair price imposed on Stelara® *must* result in a substantial price reduction. Under HHS's view, that means not only reduced compensation for BioTek when Stelara® is dispensed under Part D, but also an immediate reduction in average sales price—and hence in Part B reimbursements as well.

2. The government disputes none of this. Instead, it argues that NICA's injury is "speculative" because a biosimilar to Stelara® "*could* enter the market," so "a negotiated price for Stelara *may* never take effect." Opp. 33 (emphases added). But the government's "speculation" argument inverts the legal standard. As things currently stand, Stelara® is a "selected drug," and thus the payments NICA's members receive for Stelara® "*will* be based on the IRA's 'maximum fair price,' and revenues *will* fall precipitously." ROA.19 (emphases added). That is an imminent injury. *See Am. Forest & Paper Ass'n v. EPA*, 137 F.3d 291, 296 (5th Cir. 1998) (injury from improper permitting requirement sufficiently imminent where permits "must be renewed every five years"). The government is the one speculating that potential intervening

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member in its complaint in order 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). Even if identifying a member were required, a plaintiff may do what Plaintiffs have done here: "supply … affidavits" containing "further particularized allegations of fact deemed supportive of plaintiff's standing." *Warth*, 422 U.S. at 501.

events "could" occur and "may" *prevent* imminent harm. That is the premise of a potential future mootness challenge, not a current standing challenge. *Cf. Church of Scientology of Cal. v. United States*, 506 U.S. 9, 15 (1992) (asking "whether an intervening event has rendered the controversy moot").[6]

Indeed, there is notable irony in the government's argument. NICA specifically alleges that the IRA has deprived it of input into the criteria CMS uses to determine *whether* a biosimilar has "enter[ed] the market." Opp. 33. While the IRA requires deselection of a biological if a biosimilar competitor is "licensed and marketed," 42 U.S.C. § 1320f-1(e)(1)(A)-(B), CMS has—without allowing input—added a "*bona fide* marketing" requirement. *See* ROA.46. The government's argument is thus that NICA lacks standing to challenge an unconstitutional process because Stelara® "may" be deselected under faulty criteria HHS developed *through that very process*.

3. The government further speculates that "NICA's members might *benefit* from reduced acquisition costs" because "providers' acquisition costs

[6] Contrary to the government's speculation, Stelara®'s manufacturer "does not anticipate the launch of a biosimilar version of STELARA before January 1, 2025 in the United States." Johnson & Johnson, Annual Report (Form 10-K) at 3, (Feb. 16, 2024), https://bit.ly/4aPA9mv. And even if a biosimilar launches sometime in 2025, Stelara® still will be subject to government price-setting for 2026. *See Revised Guidance* at 166.

for [selected] drugs will change along with the amount of the Medicare reimbursement." Opp. 34-35 (emphasis added). But this Court must credit the Complaint, which alleges that "revenues *will* fall precipitously." ROA.19 (emphasis added). As explained, because maximum prices for selected drugs reimbursed under both Part B and Part D will reduce Part B reimbursements, which are based on a percentage of the average sales price, NICA members will be injured by decreased revenue regardless of whether their acquisition costs decline. That suffices for standing. As Plaintiffs have explained, "[o]nce 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." Br. 63 (quoting *Texas v. United States*, 809 F.3d 134, 155-56 (5th Cir. 2015) (citation omitted)).[7]

The government wrenches out of context this Court's statement in *Texas* that standing analysis considers "offsetting benefits that are of the same type and arise from the same transaction as the costs." Opp. 35 (quoting

[7] Bizarrely, the government asserts that Plaintiffs "[t]acitly acknowledg[e] that NICA's members might benefit from reduced acquisition costs." Opp. 35. Actually, Plaintiffs explained that the government's "offsetting benefits" argument, in addition to "contradict[ing] the Complaint's detailed allegations," would fail "*even if* drug-acquisition costs fall along with reimbursement rates." Br. 63 (emphasis added).

809 F.3d at 155). But there, the Court *upheld* the State's standing to challenge the federal Deferred Action for Parents of Americans program (DAPA) based on evidence that the State "would incur significant costs in issuing driver's licenses to DAPA beneficiaries." 809 F.3d at 155. The Court *rejected* the federal government's claim "that the costs would be offset by other benefits to the state," such as "income" from "DAPA beneficiaries [newly] eligible for licenses," who might pay to "register their vehicles." *Id.* "Even if the government [were] correct" about those offsetting benefits, the Court explained, they were not "sufficiently connected to the costs to qualify as an offset." *Id.* at 155-56.

This Court emphasized, moreover, that "[o]ur standing analysis is not an accounting exercise." *Id.* at 156. The Court thus distinguished a case in which a taxpayer-plaintiff had challenged a law authorizing pro-life license plates, where any harm to the taxpayer from funding that speech was likely eliminated because the speech was funded by "extra fees paid by drivers who purchased the plates." *Id.* (discussing *Henderson v. Stalder*, 287 F.3d 374 (5th Cir. 2002)). Unlike that case, where "[t]he costs and benefits arose out of the same transaction," *id.*, here, providers acquire their drugs and obtain reimbursement in *separate* transactions.

The government also asserts that "any theory of financial harm depend[s] upon speculation about variables not addressed in plaintiffs' filings," such as the prices providers pay for particular drugs. Opp. 34. Again, however, NICA's allegations are based on the law's legal effect, not unaddressed variables. Providers under Part B generally acquire drugs at their average sales prices, then recover 106% of those prices for the drugs they administer. The IRA, in turn, requires CMS to set prices well below the market benchmark. 42 U.S.C. § 1320f-3(b)(2)(F), (c)(1)(C)(i). No further "variables" are necessary to show that providers will lose money. To be sure, *how much* money NICA's members will lose remains to be seen. But even "the loss of $1" would be "enough." *Jackson Mun. Airport Auth. v. Harkins*, 2024 WL 1394246, at *3 (5th Cir. Apr. 2, 2024) (en banc) (Ho, J., concurring) (citation omitted).[8]

[8] The government asserts that NICA has not been injured by its members' inability "to raise debt and equity." Opp. 35-36. But in the cited cases, the alleged injuries turned on "a conceivable yet 'hypothetical' scenario," *New England Power Generators Ass'n, Inc. v. FERC*, 707 F.3d 364, 369 (D.C. Cir. 2013) (citation omitted), and a "loss or diminishment of [the plaintiff's] incentive to do something," *AstraZeneca Pharm. LP v. Becerra*, 2024 WL 895036, at *8 (D. Del. Mar. 1, 2024). The Drug Pricing Program, by contrast, "is *already* impacting the ability of NICA's members to raise debt and equity funding." ROA.566 (emphasis added).

Unable to discredit Plaintiffs' allegations, the government accuses Plaintiffs of overgeneralizing from the caselaw. It attempts to distinguish *Clinton v. City of New York*, 524 U.S. 417 (1998), on the ground that Plaintiffs "identif[y] no individual [NICA] member that has or will suffer a specific loss as a result of the Negotiation Program." Opp. 36-37. But again, Plaintiffs have "identified a NICA member (BioTek) that administers an infusion drug (Stelara) that was selected for negotiation," affecting both Part B and Part D reimbursements. Opp. 32-33. Specific member, specific drug, specific loss.

The government attempts to distinguish *American Forest* on the theory that there, "[i]t was only because the Association's members would soon be required to apply for a new permit, thus subjecting them to the challenged requirement, that the Court held that the members had standing." Opp. 37-38. But "soon" meant the permits "must be renewed every five years." *Am. Forest*, 137 F.3d at 296. Here, mandatory prices (including for Stelara®) will take effect in 2026, affecting Part D reimbursements and also Part B reimbursements (via average sales prices); and Part B drugs will be added no later than 2028. All of those harms "will" materialize in less than five years. *Id.*

Again, NICA has standing based on present-day procedural injuries alone. But if the Drug Pricing Program is allowed to go into full effect—and

thus to inflict economic injuries as well—NICA's members will "ha[ve] been injured not once but *twice*." *Deanda v. Becerra*, 96 F.4th 750, 759 (5th Cir. 2024).

CONCLUSION

This Court should reverse.

Dated: April 24, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 24, 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 24, 2024

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This document complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B)(ii) because it contains 6,485 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 24, 2024

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No. 24-50180 Natl Infusion Center v. Becerra
USDC No. 1:23-CV-707

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