United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
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Lyle W. Cayce
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No. 24-50180

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,

versus

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.

Appeal from the United States District Court
for the Western District of Texas
USDC No. 1:23-CV-707

Before ELROD, DUNCAN, and RAMIREZ, *Circuit Judges*.

JENNIFER WALKER ELROD, *Circuit Judge*:

The Inflation Reduction Act directs the Department of Health and Human Services to establish a Drug Price Negotiation Program that shifts the price-setting mechanism for many of America's highest-selling drugs from the free market to a government-run process. The program requires HHS to select "negotiation-eligible drugs," and then negotiate a "maximum fair price" with the manufacturers of those drugs. HHS is statutorily required to offer a price between 40% and 75% of the existing market price. Manufacturers who fail to reach an agreement with HHS are subject to escalating fines ranging from 187.5% to 1,900% of the drug's price that can only be suspended if the manufacturer terminates Medicare coverage for all drugs that it produces.

National Infusion Center Association, whose members provide infusion treatments for cancer and chronic diseases, filed this lawsuit challenging the constitutionality of the Drug Pricing Program.

NICA claims that the Program violates its members' due process rights, contains an unconstitutional delegation of legislative power to HHS, and coerces compliance using excessive fines. The district court dismissed NICA's lawsuit for lack of subject-matter jurisdiction, reasoning that 42 U.S.C. § 405 required NICA to "channel" its constitutional claims through HHS. Channeling means having one's claims decided by the relevant agency before bringing them in federal court. Because NICA has standing to challenge the Drug Pricing Program and because NICA's claims arise under the IRA, not the Medicare Act, and therefore need not be channeled, we REVERSE.

I

We begin with background on the basic structure of the Medicare program, the Drug Pricing Program, and the procedural history of this case. Medicare reimburses patients and providers for healthcare costs covered in subchapter XVIII of the Social Security Act. 42 U.S.C. § 1395 *et seq*. The Centers for Medicare and Medicaid Services (CMS) administer the Medicare program on behalf of the Secretary of HHS. Medicare Part B covers medicines furnished incident to a physician's services, and Part B reimbursement is based on the drug's average sales price plus a specified percentage (generally 6%). *Id.* §§ 1395k(a)(1), 1395x(s)(2)(A), 1395w-3a. That specified percentage means that the reimbursement recipient will receive more than just the cost of the drugs, and the premium that the recipient receives creates a profit margin that helps cover operating costs. Medicare Part D reimburses the providers of privately operated plans who provide outpatient drugs. *See id.* § 1395w-101 *et seq*. Plan administrators negotiate prices with manufacturers, meaning that the prices paid for drugs covered by Part B and Part D are determined by the market.

The Inflation Reduction Act's Drug Pricing Program, codified in subchapter XI of the Social Security Act, alters the way that prices are determined for many drugs covered by Medicare Parts B and D. It does not, however, change the process for reimbursement or alter the way that reimbursement is calculated. At a high level, the Drug Pricing Program requires manufacturers to "negotiate"[1] with HHS the maximum price that they will charge buyers on pain of penalty. The Program can be broken down

[1] The parties dispute whether the process is accurately characterized as a negotiation.

into three phases: the drug selection phase, the negotiation phase, and (if necessary) the penalty phase.

First, as part of the drug selection phase, the IRA directs HHS to rank drugs with the highest total Medicare expenditures.[2] *Id.* § 1320f-1(b)(1)(A). HHS must then select the highest-ranked drugs for negotiation. *Id.* § 1320f-1(a). Next, as part of the negotiation phase, HHS must enter into agreements with manufacturers to negotiate the "maximum fair price" for those drugs. *Id.* at § 1320f-2(a)(1). Finally, as part of the penalty phase, manufacturers who decline to enter into agreements to negotiate are subject to financial penalties. 26 U.S.C. § 5000D(a), (b).

The negotiation phase and penalty phase are worth discussing in more detail. The IRA requires HHS to begin the negotiation by making a maximum offer of between 40% and 75% of a market-based benchmark; there is no limit to how low HHS's offer can be. 42 U.S.C. § 1320f-3(b)(2)(F), (c)(1)(C)(i), (c)(3). In making its determination, HHS must consider, *inter alia*, research and development costs, production and distribution costs, and market data, but there are no criteria for how to weigh these considerations. *Id.* § 1320f-3(e). Manufacturers must offer their products at the price "negotiated" with HHS or else face a penalty ten times the difference between the negotiated price and the price actually offered. *Id.* § 1320f-6(a).

If the manufacturer fails to reach an agreement with HHS, the penalty phase ensues. Manufacturers who "walk away" from negotiations face an escalating tax on all sales of the drug (not just Medicare sales) that starts at 185.7% of the drug's price and rises to 1,900% depending on the duration of

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[2] To be ranked, a drug must be marketed under a new drug application or biologics license application, have been approved by FDA for at least 7 years for drugs or 11 years for biological products, and not be the reference drug for an approved generic. 42 U.S.C. § 1320f-1(a).

noncompliance. *Id.* § 5000D(d); Cong. Rsch. Serv., R47202, *Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376)*, at 4 (Aug. 10, 2022), https://bit.ly/3sbHYBy. For this reason, the parties dispute whether the process can accurately be called a negotiation at all. The Congressional Budget Office estimated that the tax on selected drugs for which no agreement was reached would raise no revenue because no manufacturer could afford to pay it. Joint Comm'n on Tax'n, 117TH CONG., JCX-46-21 *Estimated Budget Effects of the Revenue Provisions of Title XIII – Committee on Ways and Means, of H.R. 5376, The "Build Back Better Act," as passed by the House of Representatives*, at 8 (Nov. 19, 2021), https://bit.ly/3plC4cd.

The only way for a manufacturer to avoid the tax (besides agreeing to HHS's price) is to opt out of Medicare Parts B and D entirely, meaning Medicare will not reimburse patients or providers for *any* of the drugs that the manufacturer sells (whether or not those drugs are part of the Drug Pricing Program). 26 U.S.C. § 5000D(c); *see* 42 U.S.C. § 1396r-8(a)(1). NICA claims that because Medicare covers such a large percentage of the drug market, opting out is no real option.

The Drug Pricing program also contains notable procedural features. First, the Drug Pricing Program is implemented through Program Guidance, which HHS has interpreted to mean that the Program's implementation and decisions are not subject to the Administrative Procedure Act's notice-and-comment requirements. 42 U.S.C. § 1320f; *see* CMS, *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026*, at 8–11 (June 30, 2023), https://bit.ly/3JLSSUH. The IRA also states that there shall be no administrative or judicial review of key HHS determinations, such as the selection of drugs for the Program or the determination of a maximum fair price. 42 U.S.C. § 1320f-7(2)–(3).

NICA, the Global Colon Cancer Association, and Pharmaceutical Research and Manufacturers of America filed this lawsuit against HHS, its Secretary, CMS, and its administrator. The plaintiffs claimed that the Drug Pricing Program violates the nondelegation doctrine, the Excessive Fines Clause of the Eighth Amendment, and the Due Process Clause of the Fifth Amendment.

After both parties moved for summary judgment, the district court determined that NICA's constitutional challenges to the Drug Pricing Program, codified in the Inflation Reduction Act, arose under the Medicare Act because NICA challenged a law "affecting future reimbursements." Based on that determination, the district court found that it lacked subject-matter jurisdiction over NICA's claims because all claims arising under the Medicare Act must be channeled through HHS. The district court then dismissed the remaining plaintiffs on the ground that, without NICA, venue was improper in the Western District of Texas.[3]

II

Before reaching the district court's channeling determination, we start with standing. *Murthy v. Missouri*, 144 S. Ct. 1972, 1985 (2024) ("[I]f a dispute is not a proper case or controversy, the courts have no business deciding it, or expounding the law in the course of doing so." (quoting *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 341 (2006)). Doing so is appropriate here because it informs the channeling analysis by identifying

[3] The district court opted to dismiss the case, as opposed to transferring the case, because none of the plaintiffs offered a transferee venue. The district court also suggested that the remaining plaintiffs would face the same subject-matter jurisdiction problem in any transferee district.

NICA's basis for standing and resolves a threshold jurisdictional question that is itself of paramount importance.

To establish standing, NICA must demonstrate "(i) that [its members] have suffered or likely will suffer an injury in fact, (ii) that the injury likely was caused or will be caused by the defendant, and (iii) that the injury likely would be redressed by the requested relief." *Food & Drug Admin. v. All. for Hippocratic Med.*, 602 U.S. 367, 380 (2024).

Each element of standing must be supported with the manner and degree of evidence required at the successive stages of litigation, *Murthy*, 144 S. Ct. at 1986, and we consider the "nature and source of the claim asserted," not whether the plaintiff's legal theory is correct. *Warth v. Seldin*, 422 U.S. 490, 500 (1975) ("[S]tanding in no way depends on the merits of the plaintiff's contention that particular conduct is illegal . . . .").

To invoke associational standing,[4] as NICA does, NICA must identify at least one member that has suffered or will suffer harm.[5] *Summers*

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[4] Though some have cast doubts on associational standing, *All. for Hippocratic Med.*, 602 U.S. at 398–99 (Thomas, J., concurring) (urging the Court to revisit associational standing in an appropriate case), we are required to leave to the Supreme Court "the prerogative of overruling its own decisions." *Agostini v. Felton*, 521 U.S. 203, 237 (1997).

[5] Here, NICA identified a member, BioTek, before the district court. The government takes issue with the fact that BioTek was only identified in an affidavit attached to NICA's opposition to the government's motion to dismiss. That is a nonissue for two reasons. First, NICA need not specifically identify the member who will be injured. *Bldg. & Constr. Trades Council of Buffalo, N.Y. & Vicinity v. Downtown Dev., Inc.*, 448 F.3d 138, 145 (2d Cir. 2006); *Nat'l Council of La Raza v. Cegavske*, 800 F.3d 1032, 1041 (9th Cir. 2015). As the Ninth Circuit has explained, that view is consistent with the Supreme Court's decision in *Summers v. Earth Island Institute* because *Summers* only requires that the plaintiff allege that there is a specific injured member. *Cegavske*, 800 F.3d at 1041; *see also Summers v. Earth Island Inst.*, 555 U.S. 488, 497–98 (2008). Alleging that a specific member exists does not require naming that member.

Second, even if NICA were required to identify a specific member, NICA would ordinarily be given the opportunity to cure any failure to do so because it involves an

v. Earth Island Inst., 555 U.S. 488, 498 (2009). NICA must also show that the interests it seeks to protect are germane to its organizational purpose and neither the claim asserted nor the relief requested require the participation of individual members of the organization. *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977).

Here, NICA alleges both economic injury and procedural injury. Economic injury is what it sounds like: financial harm. *E.g.*, *Czyzewski v. Jevic Holding Corp.*, 580 U.S. 451, 464 (2017). Procedural injury occurs when a plaintiff is deprived of a procedural right to protect its concrete interests. *Texas v. EEOC*, 933 F.3d 433, 447 (5th Cir. 2019). As we will explain, NICA has alleged sufficient facts to establish both economic injury and procedural injury.

A

We first consider economic injury. NICA alleges both future and present economic injury, and we start with the future injury. For an alleged future economic injury, NICA must 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*, 588 U.S. 752, 767 (2019) (citation omitted). Where, as here, a party alleges future injury from a regulation that does not directly regulate the party itself, "the causation requirement and the imminence element of the injury in fact requirement can overlap." *All. for Hippocratic Med.*, 602 U.S. at 385 n.2. In such cases, the question is whether the government's regulation will likely cause a concrete and particularized injury to the "unregulated plaintiff." *Id.* That question is the crux of this dispute. Because the other standing requirements, including those for

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incomplete "statement[] about jurisdiction that actually exists." *Newman-Green v. Alfonzo-Larrain*, 490 U.S. 826, 831 (1989); 28 U.S.C. § 1653.

associational standing, are satisfied here,[6] we train our focus on whether NICA has established that the Drug Pricing Program will likely injure its members.

In order to do so, we consider each step that NICA's theory of economic harm relies on to establish the overlapping elements of imminence and causation: (1) HHS has already selected a NICA-member-administered drug for the Program and more NICA-member-administered drugs will be selected going forward; (2) the selection of a drug will inevitably lead to a lower market price for that drug because the Drug Pricing Program, though characterized as a negotiation, effectively requires drug manufacturers to accept HHS's proposed price; and (3) lower drug prices reduce NICA members' revenue, a quintessential economic injury. We must evaluate each claim to determine whether HHS's actions are likely to cause a concrete and particularized economic injury to at least one of NICA's members.

1

We begin with NICA's contention that its members administer drugs that have been and will be selected for the Program.

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[6] NICA's alleged financial injury is plainly an injury in fact. It is also redressable. As the causation analysis will show, the injury would not occur absent participation in the Drug Pricing Program.

The dissenting opinion briefly contends that NICA's members have not suffered an economic injury because NICA's members are not statutorily entitled to a profit. We respectfully disagree with that characterization of NICA's challenge. NICA is challenging a statute that affects the revenue that its members earn through market transactions. Economic injuries resulting from such statutes have long been recognized as injuries in fact. *All. for Hippocratic Med.*, 602 U.S. at 384–85 (collecting cases). That NICA receives money through government reimbursement, rather than directly from the patients its members treat, does not change the fact that its injury is loss of revenue, not loss of a welfare benefit.

Stelara, a drug administered by BioTek, a NICA member, has already been selected for the Drug Pricing Program, straightforwardly satisfying the drug selection step in NICA's theory of economic harm.[7] HHS, *HHS*

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[7] The dissenting opinion would hold that NICA lacks standing because NICA filed its complaint before Stelara was selected. But even before Stelara was selected, selection of a NICA-member administered drug was sufficiently certain to establish standing based on future economic injury. Standing must be supported "with the manner and degree of evidence required at the successive stages of litigation." *Murthy*, 144 S. Ct. at 1986. This case is currently at the motion-to-dismiss stage, so we must take all of NICA's factual allegations as true and draw all reasonable inferences in its favor when assessing whether it was sufficiently certain that a NICA-administered drug would be chosen by HHS.

NICA alleged that drugs administered by its members would be chosen, and it extensively supported that allegation. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (explaining that while "naked assertions devoid of further factual enhancement" are insufficient, "detailed factual allegations" are not required (alteration adopted) (quotation marks omitted)). NICA explained that its members' drugs are used by millions of patients, are used to treat chronic diseases (meaning each patient uses the drug repeatedly), are innovative, and are covered by Medicare. Considered together and drawing all inferences in NICA's favor, as we must at the motion to dismiss stage, these facts establish that NICA's members administer some of the highest expenditure drugs on the market, meaning they administer drugs that will be chosen by HHS. *Cf. Clinton v. City of New York*, 524 U.S. 417, 433 (1998) ("'Even though [Plaintiffs] could not with certainty establish that they would be able to purchase excess lands' if the judgment were reversed, [the Court] found standing because it was 'likely that excess lands would become available at less than market prices.'" (quoting *Bryant v. Yellen*, 447 U.S. 352, 367, 68 (1980)) (internal citation omitted)).

NICA's allegation is further strengthened by the fact that the drug selection process is cumulative, meaning a larger and larger percentage of drugs on the market will be subject to the Program. In the first four years of the program, sixty drugs will be selected. *See* 42 U.S.C. § 1320f-1(a). To believe that no NICA-member drug will be selected during that period is to believe that NICA-member drugs are *all* some of the most obscure, rarely used drugs on the market. We cannot do that consistently with NICA's allegations about the characteristics of its drugs and our duty to make all inferences in NICA's favor. *Remijas v. Neiman Marcus Grp., LLC*, 794 F.3d 688, 694 (7th Cir. 2015) ("We recognize that the plaintiffs may eventually not be able to provide an adequate factual basis for the inference, but they had no such burden at the pleading stage. Their allegations of future injury are sufficient to survive a 12(b)(1) motion."). Lest there be any doubt, exactly what

Selects the First Drugs for Medicare Drug Price Negotiation (Aug. 29, 2023), https://bit.ly/460imGp. The government counters that generic versions of Stelara will soon be approved, which will make Stelara ineligible for the Drug Pricing Program. But the government has not established with sufficient certainty that the generics will enter the market because the government has not offered any information about the likelihood that the recently approved generics will satisfy the Drug Pricing Program's bona fide marketing requirement.[8] While third-party action can be sufficiently certain for purposes of standing, *cf. Dep't of Com.*, 588 U.S. at 768, the government has not shown here that CMS approval of a generic predictably follows from FDA approval of that drug.

And because CMS approval of a generic is speculative, the standing analysis must proceed based on the status quo: Stelara is currently subject to negotiation through the Drug Pricing Program. Because Stelara is currently subject to the Drug Pricing Program, NICA has established that at least one of its members' drugs will be subject to the program.

NICA alleged has come to pass, making it all the more difficult to discredit NICA's allegations.

"It's no small thing to tell a litigant that the court will not even consider the merits of their claim—that it doesn't matter if [the government] has broken the law and injured [the plaintiff]." *Jackson Mun. Airport Auth. v. Harkins*, 98 F.4th 144, 147–48 (5th Cir. 2024) (en banc) (Ho, J., concurring). That is all the more true here where exactly what NICA alleged would come to pass immediately came to pass.

[8] CMS guidance indicates that CMS will review a drug's total expenditures under Part D to determine whether it satisfies the bona fide marketing requirement. *See* CMS, *Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments*, at 10 (Mar. 15, 2023), https://tinyurl.com/3fkpmj6c. Because the criteria for that review are unclear, it is purely speculative to say how likely it is for a given drug to satisfy the bona fide marketing requirement after receiving FDA approval.

We next turn to NICA's contention that the negotiation process will inevitably lead to lower prices for selected drugs. The term "negotiation" usually implies a process with a variety of possible outcomes such that it is speculative to say what the result will be. Here, however, HHS is statutorily required to make a maximum offer of 40-75% of the baseline price for the drug. 42 U.S.C. § 1320f-3(b)(2)(F), (c)(1)(C)(i), (c)(3). So even if we do not know the exact price that the parties will negotiate, we know that HHS's price, if accepted, will result in lower prices and corresponding revenue loss for NICA's members.

It is no impediment that manufacturers, not NICA members, participate in the negotiations. While a theory of standing may not rest on *speculation* about the decisions of third parties, *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 411–14 (2013), it may rely on "the predictable effect of Government action on the decisions of third parties." *Dep't of Com.*, 588 U.S. at 768. Manufacturers are all but certain to adopt the price that HHS offers. First, manufacturers who accept HHS's price and then offer a higher price to customers are taxed at a multiple of the difference between the negotiated price and the price offered to customers, 42 U.S.C. § 1320f-6(a), meaning that basic economic self-interest precludes offering a different price than the one negotiated with HHS.[9]

[9] The Congressional Budget Office's estimate that the tax would raise *zero* revenue is itself strong evidence for assuming that manufacturers will not choose to charge a price higher than the negotiated price. Joint Comm. on Tax'n, 117TH CONG., JCX-46-21, *Estimated Budget Effects of the Revenue Provisions of Title XIII - Committee on Ways and Means, of H.R. 5376, The "Build Back Better Act," as Passed by the House of Representatives*, at 8 (Nov. 19, 2021), https://bit.ly/3plC4cd.

As for the negotiations, the consequences of failing to reach an agreement with HHS are severe. A manufacturer that chooses to walk away from negotiations without reaching an agreement must remove *every* drug that it produces from Medicare coverage, not just the drug that is the subject of the negotiation. 26 U.S.C. § 5000D(c); *see* 42 U.S.C. § 1396r-8(a)(1). That means that even if HHS offered a price that made sales of a particular drug unprofitable, the manufacturer still might agree to the unprofitable price because doing so is preferable to losing the Medicare market for all of its drugs.

We point this out merely to emphasize how likely it is that manufacturers will opt against walking away. The manufacturers are guided by basic economic rationality, and the penalties the Program imposes make reaching an agreement all but certain. *Clapper*, the Supreme Court's seminal case regarding standing theories that rely on third-party decisions, provides a helpful contrast. Consider just how different the third-party decisions in that case, which were too speculative to support standing, are to the third-party decisions here. In *Clapper*, the plaintiffs' standing theory turned on whether the federal government would choose to surveil particular foreign individuals, whether the federal government would choose a particular surveillance method to monitor those individuals, and whether the Foreign Intelligence Surveillance Court would authorize such surveillance. *Clapper*, 568 U.S. at 410–14. Predicting those decisions was necessarily speculative because they were discretionary and involved the weighing of a variety of unidentified values and goals. By contrast, predicting a profit-seeking business's response to changing economic incentives simply requires determining the direction in which the incentives are changing.

Because the third-party decisions in NICA's theory are guided by basic economic rationality, NICA has "thread[ed] the causation needle" and shown that its theory falls squarely within the bounds of *Department of*

Commerce, not *Clapper*. *See All. for Hippocratic Med.*, 602 U.S. at 383 ("[T]o thread the causation needle [when third parties are involved], the plaintiff must show that the third parties will likely react in predictable ways . . . ." (internal quotations omitted)). NICA has established with sufficient certainty that the selection of one of its members' drugs will lead to a lower price for that drug.

3

Finally, we consider NICA's claim that a lower drug price leads to lower revenue. The path from a decrease in market price to loss of revenue for NICA members is a predictable result of the formula for reimbursement, which pays providers 106% of the cost of the drugs for which they are reimbursed. 42 U.S.C. § 1395w-3a. That 6% premium means that, contrary to the government's contentions, the decrease in reimbursement will not be offset by a corresponding decrease in cost.

For example, suppose that a provider spends $100 per year on Drug A. The reimbursement for Drug A would be 106% of its expenditure, 42 U.S.C. § 1395w-3a, or $106. Suppose Drug A becomes part of the Drug Pricing Program, and the provider now spends $50 per year on Drug A for the same volume of Drug A. The provider would be reimbursed $53 for Drug A (106% x $50). So while the provider's expenses would decrease by $50 ($100 - $50), its revenue would decrease by $53 ($106 - $53). The $3 gap between the change in costs and change in revenue is a quintessential economic injury. *TransUnion LLC v. Ramirez*, 594 U.S. 413, 425 (2021) ("The most obvious [Article III injuries] are traditional tangible harms, such as physical harms and monetary harms.").

Alternatively, if a manufacturer chooses to remove the drug from Medicare coverage, NICA members will lose revenue. It is elementary economics that when the price of a product goes up, customers demand less

of it. If a manufacturer decided to remove the drug from Medicare coverage, the effective price of the drug for customers would increase because patients would no longer be reimbursed for its use. That increase in effective price for the patient would predictably lower demand and reduce NICA members' revenue. In addition, NICA members would no longer receive the 6% premium that they receive as part of Medicare reimbursement. Therefore, one way or the other, selection of a NICA-administered drug leads to lower revenue for NICA's members.

* * *

Taken together, each step of NICA's theory (as well as the steps considered as a whole) are sufficiently certain to satisfy the requirements of standing.[10] NICA has shown that at least one of its members' drugs will be subject to the Program, that the Program will lower the price for that drug, and that the lower price will lead to lower revenue for the member that administers the drug. It is no impediment that the causation chain involves multiple steps.[11] *Cf. Massachusetts v. EPA*, 549 U.S. 497, 523–25 (2007) (causation established based on allegation that EPA's non-action would cause drivers to choose less fuel-efficient vehicles, which would increase

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[10] The government has suggested that any theory of economic injury in this case, relying as it must on the Medicare Act, necessarily triggers the channeling provision discussed in more detail below. However, as we will explain, channeling is required when the Medicare Act supplies *both* the standing and the substantive basis for a claim, so standing based on economic injury does not automatically require channeling.

[11] The dissenting opinion characterizes NICA's allegations as a "speculative chain of possibilities." But its characterization of the negotiation process fails to account for the extreme incentives that make manufacturers "likely [to] react in predictable ways" to the government's actions. *Murthy*, 144 S. Ct. at 1986; *All. for Hippocratic Med.*, 602 U.S. at 383. As we have explained in detail, those predictable reactions to incentives are a far cry from the discretionary judgment calls that the Supreme Court found too speculative in *Clapper*. 568 U.S. at 410–14.

global warming, which would contribute to rising sea levels, which would cause erosion of Massachusetts's shoreline). Rather, this is one of the "familiar circumstances" where government regulation of a third-party business causes "downstream . . . economic injuries to others in the chain." *All. for Hippocratic Med.*, 602 U.S. at 384.

B

We next consider NICA's alleged current injury. NICA alleges that its members are currently suffering economic harm because the Program currently impacts their projected revenue and their corresponding ability to raise the debt and equity they need to run their businesses. According to NICA's CEO, its members operate on narrow margins and carry substantial overhead costs. They rely on the ability to raise capital on favorable terms to stay solvent. By putting NICA members' revenue in jeopardy, the Program threatens their ability to raise debt and capital *now*, regardless of whether their drugs have been selected or not.

Under the Supreme Court's precedent, that is enough to establish economic injury. *See Clinton v. City of New York*, 524 U.S. 417, 432 (1998) ("By depriving [Plaintiffs] of their statutory bargaining chip, the cancellation inflicted a sufficient likelihood of economic injury to establish standing under our precedents."). Here, the threat of regulation at the hands of the federal government reduces the bargaining power with which NICA can raise debt or equity capital. *See id.* at 433 ("The Court routinely recognizes probable economic injury resulting from [governmental actions] that alter competitive conditions as sufficient to satisfy the [Article III 'injury-in-fact' requirement] . . . . 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." (alterations in

original) (quoting 3 K. Davis & R. Pierce, Administrative Law Treatise 13–14 (3d ed. 1994))).

The government faults NICA's theory of present injury as too speculative. We disagree. NICA has specifically described the ways in which the Program limits its members' ability to obtain necessary debt and equity capital. The government's attempt to distinguish *Clinton* is unpersuasive, as NICA does specifically explain the mechanisms that are causing its members economic injury *now*. NICA's CEO explained that "the terms on which NICA's members can raise debt and equity capital are directly impacted by their economic prospects and projected margins, and the Drug Price Negotiation Program is already affecting . . . [those factors]."

The government also points us to *New England Power Generators Ass'n v. FERC* for the proposition that injuries like the one that NICA alleges here cannot confer standing because such injuries are "quintessentially conjectural" and because recognizing such injuries would confer standing in almost all circumstances. 707 F.3d 364, 369 (D.C. Cir. 2013). First, unlike in *New England Power Generators*, there is nothing conjectural about NICA's allegation that the Program is *currently* impacting its members ability to obtain debt and equity capital. Second, adopting NICA's standing theory here would not confer standing in all circumstances. This case does not concern a statute that applies generally to all participants in a given market. It concerns a statute that picks out specific drugs for special treatment. In addition, NICA does not allege that the statute has some marginal effect on its members' businesses. Rather, it impacts an aspect of their business that is "critically important to their financial solvency."

In short, NICA's present economic injury provides an independent basis for standing in addition to its future economic injury.

C

Having determined that NICA has standing based on economic injury, we next consider whether NICA also has standing based on procedural injury. A plaintiff can show a cognizable injury if it has been deprived of a procedural right to protect its concrete interests. *Texas*, 933 F.3d at 447 (citing *Summers*, 555 U.S. at 496). A procedural right can be asserted "without meeting all the normal standards for redressability and immediacy." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 572 n.7 (1992). A litigant has standing if there is "some possibility" that enforcing the procedural right "will prompt the [defendant] to reconsider the decision." *Massachusetts*, 549 U.S. at 518. The plaintiff must identify "some concrete interest that is affected by the deprivation," *Summers*, 555 U.S. at 496, but the plaintiff need not "establish with any certainty" that the procedural defect "will cause" harm. *Lujan*, 504 U.S. at 572 n.7. A plaintiff "generally must assert his own legal rights and interests, and cannot rest his claim to relief on the legal rights or interests of third parties." *Warth*, 422 U.S. at 499.

We start by considering NICA's concrete interest. NICA has demonstrated a concrete interest for the same reasons that it has demonstrated economic injury: it has a concrete interest in not seeing its members' revenue decrease as a result of allegedly unconstitutional government action. We note, however, that because the concrete interest analysis is subject to a looser standard than the economic injury analysis, NICA could demonstrate a concrete interest, even if its economic injury theory failed.

NICA's concrete interest is connected to the alleged deprivation of procedural rights. NICA claims that it has been deprived of due process, subjected to impermissibly delegated legislative power, and will be subjected to coercive and excessive fines.

NICA alleges a due process violation based on its lack of opportunity to weigh in on the front end or the back end of a process that substantially affects its members' businesses. Specifically, NICA alleges that because key determinations—such as when HHS can reject a manufacturer's counteroffer and the selection of particular drugs—are made without notice and comment and insulated from administrative or judicial review, there is a substantial risk that NICA members will be erroneously deprived of important property interests. *See Matthews v. Eldridge*, 424 U.S. 319, 335 (1976) (explaining that a determination of adequate due process is based on the private interest affected, the risk of an erroneous deprivation, and the government's interest in the burdens of alternative procedures).

NICA has alleged sufficient facts to satisfy the *Matthews* test. The Drug Pricing Program substantially impacts NICA members' revenue and ability to stay in business. The lack of input regarding unanswered implementation questions and inability to challenge particular determinations create a substantial risk of erroneous deprivation. The government has not countered NICA's contention that the burden on the government consists of the fiscal and administrative burdens inherent in any review process.

The government's primary objection is that NICA is asserting the procedural rights of manufacturers, not its members. But its due process claim concerns the lack of a notice-and-comment period, a process which it would be able to participate in. The clear link between the decisions being made and NICA's concrete interests rebuts the concern that a procedural injury based on lack of notice and comment is not particularized.

That procedural deficiency connects to NICA's alleged concrete interest. With a notice-and-comment period, a provider like NICA could explain to HHS the impact that drug price reductions would have on its margins (and corresponding ability to offer particular treatments or remain

in business at all). The demonstration that a price reduction would eliminate the availability of a drug or treatment altogether certainly creates "some possibility" that HHS would reconsider its decision to negotiate a lower price for that drug or treatment. *Massachusetts*, 549 U.S. at 518. Therefore, NICA has standing based on its procedural injury.[12]

"Article III requires a plaintiff to first answer a basic question: 'What's it to you?'" *All. for Hippocratic Med.*, 602 U.S. at 379 (quoting A. Scalia, *The Doctrine of Standing as an Essential Element of the Separation of Powers*, 17 Suffolk U. L. Rev. 881, 882 (1983)). Because NICA's allegations adequately demonstrate its economic and procedural interest in the case, NICA has established two independent bases for standing: economic injury and procedural injury.

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[12] NICA also alleges procedural injury based on its nondelegation claim and its excessive fines claim, but it has not established standing based on those alleged injuries.

First, consider NICA's nondelegation claim. While this court has held that a separation-of-powers violation, coupled with a concrete interest, satisfies standing, *Consumers' Rsch. v. Consumer Prod. Safety Comm'n*, 91 F.4th 342, 349–50 (5th Cir. 2024), NICA's members do not participate in negotiations under the Drug Pricing Program. While the purported nondelegation issue may enable HHS to negotiate lower prices than it would otherwise be able to (thus harming manufacturers), that still does not establish a procedural injury *to* NICA.

So too with the allegedly excessive fines. On NICA's theory of the case, the excise tax is not really a tax that manufacturers may choose to pay. Rather, it is a "hammer" that forces manufacturers to agree to HHS's price. Because the threat of the excise tax allows HHS to offer less favorable terms than it could if manufacturers were truly free to walk away from the negotiation, its absence creates at least some possibility that HHS would make a different offer. *Cf. Clinton*, 524 U.S. at 432 ("By depriving [plaintiffs] of their statutory bargaining chip, the [government action] inflicted a sufficient likelihood of economic injury to establish standing under our precedents."). NICA does not connect that reasoning to *its own* procedural rights, rather than those of the manufacturers with which it does business. *See Warth*, 422 U.S. at 499. Just as with the nondelegation claim there is a plausible procedural injury that connects to NICA's concrete interest, but it is not *NICA's* procedural injury and so does not provide standing for NICA.

III

Having addressed standing, we turn to the question of whether NICA was required to channel its claims through HHS. Claims arising under the Medicare Act must be "channeled" through the relevant agency (in this case HHS) before they can be challenged in federal court. That means the plaintiff must first bring its claims before the agency and can only bring its claims in federal court after the agency has made a final determination.[13] 42 U.S.C. § 405(g), (h); *id.* § 1395ii; *see also Am. Hosp. Ass'n v. Azar*, 895 F.3d 822, 825–26 (D.C. Cir. 2018) (explaining how the statutes combine to create the requirement). Specifically, channeling applies to actions "to recover on any claim arising under" the Medicare Act. 42 U.S.C. § 405(h).

The Supreme Court has interpreted that language to mean that a lawsuit is subject to § 405(h), known as the channeling provision, if the Medicare Act provides both the standing and the substantive basis for the presentation of the claim. *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 11 (2000).

The district court determined that channeling was required because the plaintiffs challenged a law "affecting future reimbursements." And because channeling was required, the district court determined that it lacked

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[13] 42 U.S.C. §§ 405(g), (h) and 42 U.S.C. § 1395ii combine to create this requirement. Section 405(h), which is codified in subchapter II of the Social Security Act, divests federal courts of federal-question jurisdiction (28 U.S.C. § 1331) and federal defendant jurisdiction (28 U.S.C. § 1346) for any "action . . . to recover on any claim *arising under* this subchapter." 42 U.S.C. § 405(h) (emphasis added).

Section 405(g) provides the jurisdiction that plaintiffs must instead invoke, allowing plaintiffs to challenge any final decision of the Commissioner of Social Security within sixty days. *Id.* § 405(g). Section 1395ii, which is codified in subchapter XVIII of the Social Security Act, applies these Social Security requirements to Medicare. *Id.* § 1395ii. Specifically, it states that § 405(h) applies to "this subchapter to the same extent as [it is] applicable with respect to subchapter II." *Id.*

subject-matter jurisdiction over the case. The district court's determination that it lacked subject-matter jurisdiction is reviewed *de novo*. *Davila v. United States*, 713 F.3d 248, 255 (5th Cir. 2013).

A

Here, NICA challenges a provision of the Inflation Reduction Act, not the Medicare Act. At bottom, NICA's claim is not that its members should be reimbursed a particular amount (or that it is eligible for such reimbursement). Rather, its claim is that the prices of drugs on which its members' businesses rely should not be determined by allegedly unconstitutional government processes.[14] Though channeling may be required when multiple sources of law are involved, *e.g.*, *Cmty. Oncology All., Inc. v. Off. of Mgmt. & Budget*, 987 F.3d 1137, 1140, 1142–43 (D.C. Cir. 2021), three facts make clear that the Medicare Act does not provide the substantive basis for NICA's claims. First, Medicare is not the only vehicle through which the Drug Pricing Plan harms NICA's members; it also does so through the private market. NICA alleges that the maximum fair price will alter the average sales price, and that the average sales price is also used to determine private insurance reimbursements. As NICA put it, the Drug Pricing Program "[sets] rules for the entire ecosystem."

Second, a manufacturer, who would not participate in the reimbursement process, could bring substantively identical constitutional claims to those brought here, illustrating that though the Medicare Act plays a key part in the standing analysis, it does not provide the substantive basis

[14] The government has argued that NICA's members do not have the right to sell their drugs at the price that they wish. But NICA takes issue with the processes that will lead to a particular price, not the price itself. NICA does not claim freedom from any government influence on drug prices, only freedom from the particular mechanisms the government chose to implement through the Inflation Reduction Act.

for NICA's claims. We cannot see how the Medicare Act could supply the substantive basis for NICA's challenges to the IRA if those same challenges could be brought without reference to the Medicare Act.

Third, the Supreme Court in *Illinois Council* explained that channeling "assures the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes" without interference from individual courts. 529 U.S. at 13. The provisions at issue here are not provisions that HHS would need to apply or interpret when processing a reimbursement claim, and the government has not pointed to any interest that would be served by requiring channeling in this case.

B

The government urges us to follow the reasoning of the district court by determining that channeling is required because a drug cannot be selected without reference to total expenditures under the Medicare Act and because maximum fair price need only be offered to individuals covered by Medicare. But NICA is not challenging the way that drugs are selected or the scope of whom the maximum fair price applies to. Therefore, the fact that those determinations connect to the Medicare Act does not mean that NICA's claims arise under the Medicare Act. The government also argues that the Medicare Act provides the substantive basis for the claim because the injury will only be felt when a NICA member seeks reimbursement. The question, however, is the source of the injury, not when it is felt.

Put simply, the government's theories require a view of channeling that is too broad.[15] The caselaw demonstrates that there are two types of

[15] The government's theory is also inconsistent with cases from several of our sister circuits. *United States v. Blue Cross & Blue Shield of Ala., Inc.*, 156 F.3d 1098, 1104 (11th Cir. 1998) (explaining that nothing in § 405 "eliminates federal-question jurisdiction over

claims for which channeling is required: disputes about how reimbursement is calculated and disputes about whether a particular entity or drug is eligible for reimbursement.

Illinois Council focused on calculation and eligibility. The Court determined that channeling was not limited to "amount determinations," meaning disputes about how much someone should be reimbursed, as the Court's *Michigan Academy* decision could have been read to suggest. *Ill. Council*, 529 U.S. at 15; *see also Bowen v. Mich. Acad. of Fam. Physicians*, 476 U.S. 667 (1986). Based on *Heckler v. Ringer*, 466 U.S. 602 (1984), and *Weinberger v. Salfi*, 422 U.S. 749 (1975), the Court determined that channeling also applied to eligibility claims—claims about whether a particular person, company, or type of treatment is eligible for reimbursement. *Ill. Council*, 529 U.S. at 11–12.

So too in *Physician Hospitals of America v. Sebelius* where the plaintiffs asked for a declaratory judgment regarding whether they would be eligible for reimbursement if they expanded their hospitals. 691 F.3d 649, 652 (5th Cir. 2012). We held that channeling was required because plaintiffs' eligibility claims fell squarely within the ambit of *Illinois Council* and *Salfi*. *Id.* at 655–56. While the question turned on the interpretation of a provision of the Affordable Care Act, *id.* at 652–53, the case was plainly about eligibility for reimbursement.

In *Community Oncology*, the D.C. Circuit held that claims about whether particular drugs were subject to sequestration under the Balanced Budget Act (resulting in a 2% reduction in all Medicare reimbursements for those drugs) were subject to channeling. 987 F.3d at 1140, 1142–43. The

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all actions implicating the Medicare Act"); *see also Do Sung Uhm v. Humana, Inc.*, 620 F.3d 1134, 1145 (9th Cir. 2010); *Alvarado Hosp., LLC v. Price*, 868 F.3d 983, 998 (Fed. Cir. 2017).

plaintiff's claim was a claim about how reimbursement was to be calculated—namely, whether a 2% reduction should be applied.[16]

There is no dispute that the case here is not about calculation of reimbursement or eligibility for reimbursement. Here, the injury arises from statutes that impact market prices, not the way reimbursement is calculated. The fact that the Drug Pricing Program affects the *amount* a provider is reimbursed does not mean that it affects the *calculation* of reimbursement. The effect is occurring upstream, before reimbursement is calculated.

The district court held that channeling was required because the challenged law affects the amount of reimbursement. The government's arguments are of a similar type. But adopting the principle relied on by the district court and urged by the government—a challenge to any law affecting reimbursement requires channeling—would effectively create a new category of claims for which channeling is required. There are strong reasons against doing so.

First, the type of relationship between the claim and the Medicare Act urged here is inconsistent with the Supreme Court's admittedly purpose-

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[16] The government likens this case to *Community Oncology* because both involve challenges based on other statutes. But *Community Oncology* does not stand for the proposition that any claim involving multiple sources of law must be channeled. *Cmty. Oncology All.*, 987 F.3d at 1143. In that case, as in this one, the type of relationship between the claim and the Medicare Act was key. In *Community Oncology*, the question was fundamentally about how the plaintiffs' reimbursements should be calculated, so channeling was required. *Id.* at 1140.

The same is true of the government's discussion of NICA's constitutional claims. The government correctly notes that constitutional challenges to statutes whose claims otherwise arise under the Medicare Act are subject to channeling; they do not arise under the Constitution instead. *Ill. Council*, 529 U.S. at 10–11. The district court also focused on this point. Again, that does not mean that any constitutional claim that involves the Medicare Act in any way is subject to channeling. The question here is whether NICA's claims bear the type of relationship to the Medicare Act such that channeling is required.

based rationale for its decision in *Illinois Council*, which explained that expansive channeling "assures the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes" without interference from individual courts. *Ill. Council*, 529 U.S. at 13. Because an agency determination regarding reimbursement necessarily involves determining eligibility and calculating the amount owed, *Illinois Council*'s rationale applies to those types of claims. By contrast, selecting drugs for the Program and conducting pricing negotiations are not part of a reimbursement determination, so the rationale is inapplicable.

Second, consider what requiring channeling in any case affecting reimbursement would entail. Under such a rule, channeling would presumably be required for challenges to the following: an antitrust challenge to a manufacturer's allegedly anticompetitive practices; tariffs or trade restrictions impacting a key, non-substitutable drug ingredient; and tax subsidies for new drug development. Though "arising under," the operative term used in § 405(h), is an admittedly elusive phrase, we are skeptical of an interpretation that would require channeling in these cases and leave the test without any limiting principle.[17]

The government's additional arguments in favor of channeling are unavailing. First, the government leans heavily on broad language taken from *Illinois Council*. To be sure, there is expansive language in *Illinois Council*

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[17] The dissenting opinion seems to overlook the same problem. The dissenting opinion states that NICA's claims must be channeled because they are, at bottom, claims that NICA members should be reimbursed more. Taken at face value, that principle would require channeling for any claim that affects the market price of a drug.

It matters *why* NICA claims it should be reimbursed more. Not because it claims eligibility for a reimbursement for which it has been denied or because it claims its reimbursement was calculated improperly. Those would be within the requirement's purview. But because an allegedly unconstitutional regulation is distorting market prices.

suggesting that the channeling provision applies broadly. *Ill. Council*, 529 U.S. at 12 ("[T]he bar of § 405(h) reaches beyond ordinary administrative law principles of 'ripeness' and 'exhaustion of administrative remedies . . . .'"); *id.* at 13 (considering whether channeling applies to "virtually all legal attacks"); *id.* at 13–14 (foreclosing distinctions based on "the 'potential future' versus the 'actual present' nature of the claim, the 'general legal' versus the 'fact-specific' nature of the challenge, the 'collateral' versus 'noncollateral' nature of the issues, or the 'declaratory' versus 'injunctive' nature of the relief sought."). However, this broad language does not signify breadth in terms of the *types* of claims for which channeling is required. Rather, the broad language refers to the way the claim is *styled*. The Supreme Court's language merely indicates that it will look past form to evaluate substance when making channeling determinations.

And none of that language, nor anything else in *Illinois Council*, suggests that the test extends beyond the categories of eligibility and calculation recognized in the caselaw. Rather, that language indicates that *within* the categories of eligibility and calculation, the test applies regardless of the procedural distinctions listed.

That distinction—between breadth within categories and breadth across categories—is also shown by the Supreme Court's articulation of the question before it in *Illinois Council*: "The statute plainly bars § 1331 review in . . . a case [involving the denial of benefits], irrespective of whether the individual challenges the agency's denial on evidentiary, rule-related, statutory, constitutional, or other legal grounds. But does the statute's bar apply when one who *might* later seek money . . . challenges in advance . . . the lawfulness of a policy, regulation, or statute that *might* later bar recovery of that benefit . . . ?" *Id.* at 10. The question is not about the types of claims to which channeling applies. The question is about whether, for a claim that

channeling presumptively applies to, procedural distinctions change the analysis.

C

One final point regarding the *Illinois Council* test. The government also argues that channeling is required in this case because NICA's claims are "inextricably intertwined" with the Medicare Act. We have at times suggested that channeling is required when the Medicare Act provides the standing and substantive basis for the claim *or* when the claim is "inextricably intertwined" with the Medicare Act. *See RenCare, Ltd. v. Humana Health Plan of Tex., Inc.*, 395 F.3d 555, 557–58 (5th Cir. 2004). We do not read the "inextricably intertwined" language as a separate test. Rather, the development of the Supreme Court's channeling jurisprudence demonstrates that the "inextricably intertwined" analysis is a particular application of the standing-and-substantive-basis test.

The "inextricably intertwined" language comes from the Supreme Court's decision in *Ringer*. That case predated *Illinois Council*, and *Illinois Council* defines the channeling test in terms of standing and substantive basis alone. *Ill. Council*, 529 U.S. at 11–12. The "inextricably intertwined" language is not listed as a separate test. *See generally id.* We understand that omission to mean that the "inextricably intertwined" analysis in *Ringer* is a specific application of the standing-and-substantive-basis test. Therefore, in a case involving multiple sources of law, to ask whether the Medicare Act provides the standing and substantive basis for a claim is to ask whether the claims are inextricably intertwined with the Medicare Act.

Even if the inextricably intertwined language did point to an independent test, which we do not think it does, that test would not be met here. We hold that NICA's claims are not inextricably intertwined with the Medicare Act for the same reasons that the Medicare Act does not

provide the substantive basis for the claim: (1) because NICA's claims do not challenge eligibility for reimbursement or the calculation for reimbursement, they fall outside decades of application of the requirement; and (2) we decline to extend the requirement beyond those well-recognized categories because to do so would be to go beyond what the text of the channeling statute and the Supreme Court's interpretation of it can bear.[18]

In short, the relationship between the claims brought here and the Medicare Act is categorically different than the cases for which channeling has been required. And as we have explained, there are strong reasons against creating a new high-water mark for channeling by recognizing a new category of cases for which channeling is required. Because the Medicare Act does not supply the substantive basis for NICA's claims, NICA was not required to channel them through HHS, and the district court had subject-matter jurisdiction over those claims.

* * *

Because NICA has standing and because the district court has subject-matter jurisdiction over NICA's claims, we REVERSE and REMAND for further proceedings consistent with this opinion.

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[18] Here, the Medicare Act does not provide the substantive basis for NICA's claims. Even assuming *arguendo* that it did, we would still need to determine whether the *Michigan Academy* exception precludes channeling. *See Mich. Acad.*, 476 U.S. at 678. As the Supreme Court has explained, channeling does not apply when it would lead to no judicial review whatsoever. *Ill. Council*, 529 U.S. at 19. *Illinois Council* set the bounds of whether judicial review is available when it explained that a plaintiff may "contest in court the lawfulness of any regulation or statute upon which an agency determination depends," regardless of whether the agency considered, or could consider, that regulation or statute in its determination. *Id.* at 23. However, because it is clear that channeling is inappropriate in this case and because there is limited briefing regarding the *Michigan Academy* exception, we abstain from answering whether a particular reimbursement decision *depends* on the Drug Pricing Program.

IRMA CARRILLO RAMIREZ, *Circuit Judge*, concurring in part and dissenting in part:

An association of providers challenges the Drug Price Negotiation Program. Because the association lacks standing to bring its due process challenge and because its claims must be channeled, I respectfully dissent.

I

Medicare provides federally funded health coverage for people over the age of 65 and people with disabilities. 42 U.S.C. § 1395 *et seq*. Under the Drug Price Negotiation Program (the Program), drug manufacturers and HHS[1] can negotiate the prices of drugs that account for the highest Medicare expenditures, have no generic or biosimilar competitors, and have been on the market for at least seven years. *Id*. § 1320f-1.

These negotiations have the characteristics of a typical negotiation: an offer, counteroffer, response to the counteroffer, and acceptance or declination. *Id*. § 1320f-3(b). They are also voluntary. Once HHS has selected and announced the drugs eligible for negotiations for a given year, drug manufacturers can agree to negotiate with HHS by a certain deadline—and must do so before any negotiations can begin. *Id*. § 1320f-2(a). If a manufacturer declines to negotiate or cannot reach an agreement with HHS regarding the maximum fair price of a drug, it can withdraw from the Medicare program, transfer its interest in the drug to another entity, or continue to participate in the program and sell its drug to Medicare beneficiaries subject to an excise tax. 26 U.S.C. § 5000D(a)–(c); CMS, MEDICARE DRUG PRICE NEGOTIATION PROGRAM: REVISED GUIDANCE 120–21, 129–32 (June 30, 2023), https://perma.cc/984W-

[1] HHS, its Secretary, and CMS are collectively referred to as "HHS."

N6HW [REVISED GUIDANCE]. When a maximum fair price has been agreed to, manufacturers must sell their drug at that price to individuals, pharmacies, providers, and other entities participating in Medicare. 42 U.S.C. § 11320f-2(a)(1).

On August 29, 2023, HHS announced the ten drugs selected for the first cycle of negotiations.[2] The negotiated prices for the first and second cycles will take effect on January 1, 2026, and January 1, 2027, respectively, and will only apply to reimbursements under Part D of the Medicare program.[3] The third cycle will be the first to affect Part B reimbursements. Those negotiated prices will take effect in 2028.[4]

NICA is a non-profit association headquartered in Austin, Texas whose members are non-hospital, infusion therapy providers.[5] The Global Colon Cancer Association (GCCA) is a non-profit advocacy and membership-based association dedicated to advocating for colon cancer patients that is headquartered in Washington, D.C. Pharmaceutical Research and Manufacturers of America (PhRMA), also headquartered in D.C., is a non-profit association; its members are pharmaceutical and biotechnology companies dedicated to developing new medications.

On June 21, 2023, NICA, GCCA, and PhRMA sued HHS, the HHS Secretary, CMS, and its Administrator, challenging the

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[2] *See* CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (August 2023), https://perma.cc/SWH8-LF52.

[3] *See* CMS, *Fact Sheet: Medicare Drug Price Negotiation Program Draft Guidance for 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027* (May 2024), MEDICARE DRUG PRICE NEGOTIATION, https://perma.cc/JNP8-C696.

[4] *See* CMS, *Inflation Reduction Act: CMS Implementation Timeline*, RESOURCES, https://perma.cc/U98Q-UHMD.

[5] Infusion therapy is the delivery of medication directly into a patient's veins.

constitutionality of the Program. The complaint claims that (1) Congress violated the nondelegation doctrine when it delegated the authority to "set" prices within Medicare to HHS, (2) the Program's excise tax violates the Eighth Amendment's Excessive Fines Clause, and (3) the Program violates the Fifth Amendment's Due Process Clause because it was implemented through program guidance instead of notice-and-comment procedures.[6] The plaintiffs request a judgment that declares the Program and excise tax unconstitutional and enjoins HHS from (1) implementing the Program, (2) enforcing the excise tax, and (3) implementing the Program without "adequate procedural processes."

On August 1, 2023, the parties proposed an expedited schedule for cross-motions for summary judgment, the district court agreed, and the plaintiffs moved for summary judgment. On August 29, 2023, however, the defendants moved to vacate the joint scheduling order and to dismiss the case for lack of subject matter jurisdiction and improper venue. They argued that NICA lacked standing, and that because it was the only plaintiff residing in the Western District of Texas, venue was improper. The district court granted the motion to dismiss. It did not determine whether NICA had standing. Instead, it held that it lacked subject matter jurisdiction because NICA was required to channel its claims through HHS. Because the plaintiffs had not offered a transferee venue, the district court dismissed the remaining plaintiffs' claims without prejudice. NICA appealed.

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[6] HHS initially issued guidance for the Program on March 15, 2023, and then issued revised guidance on June 30, 2023. *See* CMS, *Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments* (Mar. 15, 2023), https://perma.cc/S9KJ-9Q49; *see also* REVISED GUIDANCE.

On appeal, NICA argues that its constitutional challenges to the IRA's Drug Price Negotiation Program need not be channeled because its claims do not arise under the Medicare Act. It also asks this court to determine whether it has standing to assert its challenges.

II

We review a district court's dismissal for lack of subject matter jurisdiction *de novo*. *Physician Hosps. of Am. v. Sebelius*, 691 F.3d 649, 652 (5th Cir. 2012). "[T]he proponents of federal-court jurisdiction carry the burden of establishing it." *Id.* At the pleadings stage, NICA must "allege a plausible set of facts establishing jurisdiction." *Id.*

III

The courthouse doors open only for a plaintiff with a "personal stake" in the outcome of a case. *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 379 (2024) (quoting *TransUnion LLC v. Ramirez*, 594 U.S. 413, 423 (2021)). A plaintiff must be more than a "mere bystander"—it must have standing. *Id.* at 379. "[S]tanding is not dispensed in gross; rather, plaintiffs must demonstrate standing for each claim that they press and for each form of relief that they seek." *Consumers' Rsch. v. Consumer Prod. Safety Comm'n*, 91 F.4th 342, 349 (5th Cir. 2024) (quoting *TransUnion*, 594 U.S. at 431). Because it seeks injunctive relief, NICA must establish that one of its members (1) will likely suffer an injury in fact, (2) caused by the defendant, (3) that is likely to be "redressed by the requested judicial relief." *All. for Hippocratic Med.*, 602 U.S. at 380.

"Foremost" among the standing requirements is the first, an injury in fact. *Gill v. Whitford*, 585 U.S. 48, 65 (2018). An injury in fact must be "concrete and particularized." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). This means the injury is "real and not abstract," *All. for Hippocratic Med.*, 602 U.S. at 381, and "affect[s] the plaintiff in a personal and individual

way," *Lujan*, 504 U.S. at 560 n.1. "At the pleading[s] stage, allegations of injury are liberally construed." *Little v. KPMG LLP*, 575 F.3d 533, 540 (5th Cir. 2009). Nevertheless, "allegations of *possible* future injury," *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013) (brackets omitted), or allegations of "injury that is merely conjectural or hypothetical" are insufficient, *Little*, 575 F.3d at 540. Generally, an injury "is too conjectural or hypothetical to confer standing when the injury's existence depends on the decisions of third parties not before the court." *Id.*

NICA must also establish causation and redressability. These requirements "are often 'flip sides of the same coin'" because when "a defendant's action causes an injury, enjoining the action or awarding damages for the action will typically redress that injury." *All. for Hippocratic Med.*, 602 U.S. at 381 (citation omitted). Even so, it "must show a predictable chain of events leading from the government action to the asserted injury." *Id.* at 385.

NICA is not itself the "object" of the program it challenges. *Lujan*, 504 U.S. at 562. The Drug Price Negotiation Program regulates drug manufacturers who choose to participate in Medicare and whose drugs are selected for negotiations. *See* 42 U.S.C. § 1320f *et seq.* "When . . . a plaintiff's asserted injury arises from the government's allegedly unlawful regulation (or lack of regulation) of someone else, *much more is needed*." *Lujan*, 504 U.S. at 562 (emphasis added). This is because, "[i]n that circumstance, causation and redressability ordinarily hinge on the response of the regulated (or regulable) third party . . . . Thus, when the plaintiff is not himself the object of the government action or inaction he challenges, standing is not precluded, but it is ordinarily 'substantially more difficult' to establish." *Id.* (citations omitted).

A

NICA first asserts standing based on a procedural injury. It contends that the Program's implementation through program guidance, instead of notice-and-comment rulemaking, is violative of the Due Process Clause. It argues that its members are injured by being subjected to this "unconstitutional decision-making scheme" that deprives them of any input into the Program's effect on their businesses. It claims the IRA exacerbates this procedural deficiency by precluding administrative or judicial review of key implementation determinations, like the selection of negotiation-eligible drugs, determination of qualifying single source drugs, and determination of the maximum fair price of a drug. *See* 42 U.S.C. § 1320f-7(2)–(3).

As noted, a plaintiff deprived of a procedural right to protect its concrete interests has standing to assert that right. NICA alleges the Program deprives its members of their interest in "adequate reimbursement." Because it does not identify any other concrete interest, NICA's standing therefore depends on whether its members have a concrete interest in profiting from Medicare reimbursements.[7]

> To have a property interest in a [welfare] benefit, a person clearly must have more than an abstract need or desire for it. He must have more than a unilateral expectation of it. He must, instead, have a legitimate claim of entitlement to it. . . . Property interests, of course, are not created by the

[7] NICA argues that its members also have concrete interests in "operating within lawful constraints under a program that governs much of their industry" and serving Medicare patients. To the extent that NICA is asserting that its members have a concrete interest in participating in the Medicare program, this argument fails because "participation in the federal Medicare reimbursement program is not a property interest." *Shah v. Azar*, 920 F.3d 987, 998 (5th Cir. 2019).

> Constitution. Rather, they are created and their dimensions are defined by existing rules or understandings that stem from an independent source such as state law . . . that support[s] claims of entitlement to those benefits.

Bd. of Regents of State Colls. v. Roth, 408 U.S. 564, 577 (1972). Under 42 U.S.C. § 1395w-3a(b)(1)(B), providers will be reimbursed "106 percent of the maximum fair price" of drugs administered incident to their services. NICA's members therefore have a statutorily created interest in being reimbursed what section 1395w-3a(b)(1)(B) allows—106 percent of the maximum fair price of a drug administered incident to their services—and NICA does not identify another law that entitles its members to more. Because the text of the statute does not entitle NICA's members to a profit, it has not identified a concrete interest of which its members are deprived. *See also Garelick v. Sullivan*, 987 F.2d 913, 916–18 (2d Cir. 1993) (rejecting anesthesiologists' takings challenge to a statute that limited how much they could charge Medicare beneficiaries because "they voluntarily [chose] to provide services in the price-regulated Part B program").

NICA argues that it need only show there is "some possibility" that its members would have benefited from adequate procedures. "But 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." *Summers v. Earth Island Inst.*, 555 U.S. 488, 496 (2009). Indeed, a litigant granted a procedural right "can assert that right without meeting all the normal standards for redressability and immediacy." *Massachusetts v. EPA*, 549 U.S. 497, 518 (2007) (quoting *Lujan*, 504 U.S. at 572 n.7). The Supreme Court has made clear, however, that any laxity allowed regarding the last two elements of standing does not extend to the first. *Dep't of Educ. v. Brown*, 600 U.S. 551, 562 (2023) ("Regardless of the

redressability showing we have tolerated in the procedural-rights context, we have never held a litigant who asserts such a right is excused from demonstrating that it has a 'concrete interest that is affected by the deprivation' of the claimed right." (quoting *Summers*, 555 U.S. at 496–97)). Notably, several district courts have rejected similar constitutional challenges to the Drug Price Negotiation Program brought by drug manufacturers. *See, e.g.*, *Boehringer Ingelheim Pharms., Inc. v. U.S. Dep't of Health & Human Servs.*, No. 23-cv-01103, 2024 WL 3292657, at *12–15 (D. Conn. July 3, 2024) (holding the Program does not deprive drug manufacturers of a property interest because participation in Medicare is voluntary); *Novo Nordisk Inc. v. Becerra*, No. 23-20814, 2024 WL 3594413, at *5–6 (D.N.J. July 31, 2024) (denying due process claim because the Program does not deprive drug manufacturers of a protected interest); *see also Bristol Myers Squibb Co., v. Becerra*, No. 23-3335, 2024 WL 1855054, at *4–9 (D.N.J. Apr. 29, 2024) (finding no Fifth Amendment violation because drug manufacturers' participation in Medicare is voluntary); *AstraZeneca Pharms. LP v. Becerra*, No. 23-931-CFC, 2024 WL 895036, at *13–16 (D. Del. Mar. 1, 2024) (granting government's motion for summary judgment because drug manufacturer "does not have a protected interest in selling drugs to the Government at prices the Government will not agree to pay"). If the drug manufacturers that are the object of the Program's regulations have not been found to be deprived of any protected interests under the Program, it is unclear how these providers could be.

A due process violation "*plus* [a plaintiff's] concrete interest combine to satisfy the 'injury' element of standing." *Consumers' Rsch.*, 91 F.4th at 350. NICA's members are providers who may participate in the Medicare program, or decline to do so, but they do not have a concrete interest in profiting from Medicare reimbursements. Accordingly, because NICA has

not identified a concrete interest of which its members are deprived, it has failed to establish an injury in fact sufficient to confer standing.

B

NICA also asserts standing based on two economic injuries. First, it argues that its members' "revenues will fall precipitously" because before the Program was enacted, Medicare reimbursements of drugs administered under Parts B and D were based on market prices and providers profited financially from them. After the Program's implementation, Part B and Part D reimbursements will be based on a drug's maximum fair price starting in 2028 and 2026, respectively. It contends that its members may have to scale back operations, stop serving Medicare patients, or go out of business as a result.

This economic injury suffers from the same shortcoming as NICA's alleged procedural injury. Because the text of 42 U.S.C. § 1395w-3a(b)(1)(B) does not entitle NICA's members to profit from Part B reimbursements, NICA has not shown that its members have suffered or will suffer an economic injury sufficient to show it has standing to bring its due process claim. *See Wendt v. 24 Hour Fitness USA, Inc.*, 821 F.3d 547, 551 (5th Cir. 2016) (holding that plaintiffs did not suffer an economic injury because they were not entitled to disgorgement of their membership dues under Texas law).

NICA's second alleged economic injury also fails to confer it with standing. It argues that its members are presently experiencing economic harm because their ability to raise debt and equity funding is impacted by their profit margins. This purported injury is insufficiently concrete. NICA does not allege that investors have declined to invest in its members' businesses or that its members' profit margins have been impacted, only that its members' profit margins impact the "terms" on which they can raise

capital. The Program does not regulate investors. Investors are independent third parties who may decline to invest in NICA's members even if the Program is enjoined. NICA therefore cannot show "a predictable chain of events leading from [the Program] to the asserted injury," or that this economic injury would be redressed by enjoining the Program. *All. for Hippocratic Med.*, 602 U.S. at 385. NICA has not shown that it has standing to bring its due process claim based on this economic injury. *See also Clapper*, 568 U.S. at 415 n.5 (explaining that causation cannot depend "on speculation about 'the unfettered choices made by independent actors not before the courts'" (quoting *Lujan*, 504 U.S. at 562) (quotation marks omitted)).

C

Setting aside that NICA's members do not have a cognizable right to profit from Medicare reimbursements, standing did not exist when the suit was filed because NICA's complaint fails to show that any economic injury is "certainly impending." *Clapper*, 568 U.S. at 414.

Standing must exist at the time the suit is filed. *Lujan*, 504 U.S. at 571 n.5. In cases of associational standing, the "requirement of naming the affected members has never been dispensed with in light of statistical probabilities, but only where *all* the members of the organization are affected by the challenged activity." *Summers*, 555 U.S. at 498–99. "Although 28 U.S.C. § 1653 and [Rule] 15(a) allow amendments to cure defective jurisdictional allegations, these rules do not permit the creation of jurisdiction when none existed at the time the original complaint was filed." *Camsoft Data Sys., Inc. v. S. Elecs. Supply, Inc.*, 756 F.3d 327, 337 (5th Cir. 2014) (alteration in original) (citations omitted). And while monetary harms "readily qualify as concrete injuries under Article III," *TransUnion*, 594 U.S. at 425, an injury in fact must be concrete, particularized, and not "merely conjectural or hypothetical." *Little*, 575 F.3d at 540.

Because NICA filed its complaint before HHS announced the drugs selected for the first cycle of negotiations, it did not identify a specific member that would be injured by the Program—it had no way to know if one existed. NICA's identification of BioTek in an affidavit attached to its opposition to the Government's motion to dismiss—filed on September 25, after HHS published the list of drugs selected for negotiation—could only have cured this deficiency if standing *already* existed when the complaint was filed on June 21. But the allegations in its complaint amount only to a "highly speculative fear" that: (1) at least one of its members prescribed a drug that would be chosen for negotiations, (2) the drug's manufacturer would enter into an agreement to negotiate with HHS, (3) the negotiation would result in the parties agreeing on a maximum fair price, (4) that would go into effect before a generic version of the drug was approved by the FDA, and (5) that the maximum fair price would result in decreased Medicare reimbursements to that member. *Clapper*, 568 U.S. at 410. This "speculative chain of possibilities" does not establish that any injury is "fairly traceable" to the Drug Price Negotiation Program for three reasons. *Id.* at 414.

First, NICA did not adequately plead that a drug that at least one of its members administered would be chosen for negotiations. The complaint merely alleges that "NICA's members receive significant reimbursement revenue from drugs and treatments that are likely to be included in [the Program]." Detailed factual allegations are not required at the pleadings stage, but "mere conclusory statements[] do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Without more, the allegation that a NICA-member-administered drug would be selected for the Program was entirely speculative.[8]

[8] On appeal, NICA argues that its economic injury is imminent because, within ten years, half of all Medicare spending will be for drugs whose prices are negotiated under

Second, when the complaint was filed, NICA could only speculate as to whether drug manufacturers would agree to negotiate with HHS (they had the option not to), whether a negotiation would result in an agreement on a maximum fair price (it may not have), whether a generic alternative would become available before a drug's maximum fair price went into effect (it still could), and whether a manufacturer would find it more profitable to withdraw its products from the Medicare program or continue to sell its drugs subject to the excise tax. "Rather than guesswork, [NICA] must show that [drug manufacturers] 'will likely react in predictable ways' to [the Program.]" *Murthy*, 144 S. Ct. at 1986. The number of contingencies in this equation, makes it difficult to identify a predictable result.

Third and most importantly, even if drug manufacturers react "predictably," NICA's complaint does not show that a loss of revenue is a "certainly impending." *Clapper*, 568 U.S. at 414. It merely alleges that its members profit from reimbursements based on market prices and that those profits will suffer if drug prices are capped. NICA's complaint is devoid of even *general* allegations regarding how much its members pay for drugs and how much they are reimbursed. It does not address the IRA's requirement that drug manufacturers offer negotiated prices to Medicare beneficiaries *and* providers. A court need only accept a complaint's well-pleaded factual allegations as true—these allegations fall short. *Iqbal*, 556 U.S. at 678. Without this link, NICA cannot establish that injury based on lower

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the Program. While the cumulative nature of the Program may increase the odds that a drug administered by a NICA member will be selected, that a NICA-member-administered drug will be selected does not follow from the fact that eventually half of all Medicare spending will be for drugs subject to the Program. NICA has not established economic injury based on the future selection of drugs administered by its members. *See Murthy v. Missouri*, 144 S. Ct. 1972, 1994 (2024) (faulting a standing theory that relied on "no more than conjecture" in predicting the future actions of third parties).

Medicare reimbursements is "certainly impending or is fairly traceable to [the Drug Price Negotiation Program]." *Clapper*, 568 U.S. at 414.

Because HHS had not yet released the list of negotiation-eligible drugs, NICA did not have the information necessary to fill in these factual gaps when it filed its complaint. It could not identify a negotiation-eligible drug administered by one of its members or plead relevant information about reimbursements. Accordingly, because standing did not exist when NICA filed its complaint, any subsequent amendments would not cure this jurisdictional deficiency.[9]

In cases of "alleged future injuries to unregulated parties from government regulation"—like this one—"the causation requirement and the imminence element of the injury in fact requirement can overlap." *All. for Hippocratic Med.*, 602 U.S. at 385 n.2. Nevertheless, "when a plaintiff seeks prospective relief such as an injunction, the plaintiff must establish a sufficient likelihood of future injury." *Id.* at 381. "Although imminence is concededly a somewhat elastic concept, it cannot be stretched beyond its

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[9] Apart from lacking standing at the time the complaint was filed, even NICA's identification of BioTek is still insufficient to show that its purported economic injury confers it with standing for three reasons. First, BioTek's CEO fails to assert that BioTek has no viable alternative to prescribing Stelara. *See id.* at 416 ("[Plaintiffs] cannot manufacture standing merely by inflicting harm on themselves based on their fears of hypothetical future harm that is not certainly impending."). Second, the maximum fair price may never take effect for Stelara. The Government maintains that the FDA has already approved two biosimilar competitors to Stelara, which could enter the market before January 1, 2026. Third, the first and second cycle of the Program only impact Part D reimbursements. Part B reimbursements won't be impacted until 2028. Nevertheless, NICA argues that, because Part B reimbursements of Stelara will be based on its average sales price until 2028, Part D reimbursements of Stelara will lead to lower Part B reimbursements. But this alleged effect on the market is speculative and contingent upon the speculative chain of possibilities set out above. An injury in fact must be imminent. *Dep't of Com. v. New York*, 588 U.S. 752, 765 (2019) (citation omitted). It may not be abstract or conjectural. NICA cannot satisfy the first element of the standing analysis.

purpose, which is to ensure that the alleged injury is not too speculative for Article III purposes—that the injury is *certainly* impending." *Clapper*, 568 U.S. at 409 (quoting *Lujan*, 504 U.S. at 565 n.2). NICA has failed to do this for its due process claim.

IV

The second threshold question presented in this appeal is whether NICA's due process claim arises under the Medicare Act such that its members must channel it through HHS. As noted, they must do so if the Medicare Act provides both the standing and substantive basis of the claim.

NICA argues that its claims arise under the IRA and the Constitution, not the Medicare Act. It asserts that the channeling requirement only applies to claims that arise under subchapter XVIII of the Medicare Act and not subchapter XI of the Social Security Act, where the IRA is codified.[10] It also argues that this suit only challenges the constitutionality of the Drug Price Negotiation Program and not the Medicare provisions governing reimbursement.

Even if NICA could show it has standing, its standing would be provided by the Medicare Act. As discussed, NICA's standing to assert its claims depends on whether it has a concrete interest in profiting from Medicare reimbursements. This is because all of its theories of standing rest on the premise that once the negotiated prices are live, its members' profit margins will suffer due to lowered Part B and Part D reimbursements. A provider's reimbursements under Medicare Parts B and D are governed by 42 U.S.C. § 1395w-3a and § 1395w-102, respectively. NICA's claims are "at bottom" claims that they should be reimbursed more than § 1395w-3a and

[10] NICA specifically argues that, when reading § 405(h) in light of § 1395ii, "this subchapter" in § 405(h) refers only to subchapter XVIII of the Medicare Act.

§ 1395w-102 allow. *Heckler v. Ringer*, 466 U.S. 602, 614 (1984). And in 2022, § 1395w-3a and § 1395w-102, codified in subchapter XVIII of the Medicare Act, were amended to account for any maximum fair prices negotiated under the Program. *See* Inflation Reduction Act of 2022, H.R. 5376, 117th Cong., 136 Stat. 1818 (2022). The Medicare Act therefore also provides the substantive basis of NICA's claims. Under its own reading of § 405(h), NICA's claims arise under the Medicare Act.

Nevertheless, "even if [NICA's] claims could be described as arising under the Constitution or the [IRA], all that matters under section 405(h) is that the claims also arise under the Medicare Act." *Cmty. Oncology All., Inc. v. Off. of Mgmt. & Budget*, 987 F.3d 1137, 1143 (D.C. Cir. 2021); *see also Weinberger v. Salfi*, 422 U.S. 749, 760–61 (1975) ("It would . . . be fruitless to contend that [this] claim . . . does not arise under the Constitution . . . . But it is just as fruitless to argue that this action does not *also* arise under the Social Security Act . . . . which provides both the standing and the substantive basis for the presentation of their constitutional contentions." (emphasis added)). Nor does the constitutional nature of NICA's claims exempt it from the administrative process. *See Physician Hosps. of Am.*, 691 F.3d at 656 (noting that the "Supreme Court has . . . explicitly rejected the argument that constitutional challenges are free from Section 405(h)'s requirements"). The Supreme Court has stated that Section 405(h) "do[es] not preclude constitutional challenges." *See Salfi*, 422 U.S. at 762. It "simply require[s] that they be brought . . . in conformity with the same standards which are applicable to nonconstitutional claims arising under the [Medicare Act]." *Id.* Section 405(h)'s "bar applies 'irrespective of whether resort to judicial processes is necessitated by discretionary decisions of the Secretary or by his nondiscretionary application of allegedly unconstitutional statutory restrictions.'" *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 11 (2000) (quoting *Salfi*, 422 U.S. at 762); *see also Ringer*, 466 U.S. at 614

(concluding that a claim challenging the Secretary's alleged failure to comply with the rulemaking requirements of the APA in issuing instructions and a rule were "inextricably intertwined" with a party's claims for Medicare benefits). NICA's claims arise at least in part under the Medicare Act because it provides the standing and substantive basis of it claims, and that's enough to require channeling.[11]

* * *

NICA does not have standing to bring its due process claim because it has not established the existence of an imminent injury in fact. I concur with the majority's holding that NICA lacks standing to bring its nondelegation and excessive fines claims. Even if NICA had standing, its claims cannot be disentangled from the Medicare Act. For providers, the IRA has no significance outside of Medicare reimbursements. The Medicare Act therefore provides both the standing and the substantive basis for NICA's due process claim, and because it arises under the Medicare Act, it must be channeled through HHS. I respectfully dissent.

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[11] There is one relevant exception to the channeling requirement. The *Michigan Academy* exception provides that channeling is not required "where application of § 405(h) would not simply channel review through the agency, but would mean no review at all." *Ill. Council*, 529 U.S. at 19. NICA has not alleged that channeling its claims would amount to a total preclusion of review and even acknowledges that there are established avenues for the administrative review of requests for reimbursement, including expedited review of constitutional claims. *See* 42 C.F.R. § 405.990. Rather, it argues that channeling its claims would result in an unnecessary and harmful delay because HHS cannot *resolve* a constitutional challenge. But the Supreme Court has firmly rejected this argument and has acknowledged that channeling "comes at a price" that Congress may find "justified." *Ill. Council*, 529 U.S. at 13.