IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

United States Court of Appeals
Fifth Circuit

FILED
August 16, 2012

Lyle W. Cayce
Clerk

No. 11-40631

PHYSICIAN HOSPITALS OF AMERICA; TEXAS SPINE & JOINT HOSPITAL, LIMITED,

Plaintiffs-Appellants

v.

KATHLEEN SEBELIUS, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendant-Appellee

Appeal from the United States District Court
for the Eastern District of Texas

Before SMITH, GARZA, and SOUTHWICK, Circuit Judges.

LESLIE H. SOUTHWICK, Circuit Judge:

A trade group and a physician-owned hospital sued the Secretary of the Department of Health and Human Services. They sought injunctive relief to remedy multiple alleged constitutional infirmities with Section 6001 of the Patient Protection and Affordable Care Act of 2010. Section 6001 limits Medicare reimbursement for services furnished to a patient referred by a physician owner. Although it denied the Secretary's motion to dismiss for lack of jurisdiction, the district court granted summary judgment to the Secretary. The court concluded that Congress had a rational basis for enacting Section 6001, the new law does not constitute a real or regulatory taking, and the law's

requirements are not unconstitutionally vague. The plaintiffs appeal and challenge the district court's ruling as an erroneous evaluation of the taking claims and an improper application of rational-basis review. Concluding that the district court lacked subject-matter jurisdiction, we VACATE and DISMISS.

FACTUAL AND PROCEDURAL BACKGROUND

Starting in 1989 with what is known as the "Stark Law," Congress ended reimbursement for services provided to Medicare patients at a facility in which a referring physician had an ownership interest. *See* 42 U.S.C. § 1395nn. Congress expanded the ban in 1993 to cover hospitals where the referring physician had an ownership interest unless that interest was in the whole hospital. Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, §13562, 107 Stat. 312 (1993). During this period, there was a rise in the number of speciality hospitals. U.S. Gov't Accounting Office, GAO–03–683R, Specialty Hospitals: Information on National Market Share, Physician Ownership, and Patients Served 3 (2003). In 2003, Congress enacted an 18-month moratorium on reimbursements to new and certain expanded specialty hospitals while directing the Medicare Payment Advisory Commission (MedPAC) and the Department of Health and Human Services (HHS) to study a number of issues relating to the cost and type of care at speciality hospitals. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 507, 117 Stat. 2066 (2003). The moratorium expired after the initial 18-month period.

In 2010, Congress enacted the Patient Protection and Affordable Care Act. It contains Section 6001, the provision at issue in this case. Pub. L. No. 111-148, 124 Stat. 119 (2010). Soon after, Congress amended Section 6001 in the Health Care and Education Reconciliation Act. Pub. L. No. 111-152, 124 Stat. 1029 (2010). In its current form, Section 6001 provides that any physician-owned hospital licensed as of December 31, 2010, falls under the whole-hospital

exception. 42 U.S.C. § 1395nn(i)(1)(A). This subsection provides, however, that such grandfathered facilities may not expand unless first obtaining an exception from the Secretary. *Id.* § 1395nn(i)(1)(B), (i)(3).

One plaintiff is Physician Hospitals of America. It is an organization that supports physician-owned hospitals. The other plaintiff, Texas Spine & Joint Hospital (TSJH), is a physician-owned hospital that opened in Tyler, Texas in 2002. In 2008, TSJH decided to expand its facilities and spent about $3 million towards a planned $30 million expansion. Because TSJH would have been unable to complete its expansion before the statutory cutoff, it stopped construction after the passage of Section 6001. TSJH alleges that in order to file an administrative claim it would have to complete its new building and treat a patient in that building, thereby risking millions of dollars in investment and creating a potential of having a large, empty building. The Secretary does not appear to challenge this allegation. Physician Hospitals and TSJH brought this case in the Eastern District of Texas seeking declaratory and injunctive relief on the basis that Section 6001 violates the Due Process Clause generally, is void for vagueness, and violates the Equal Protection Clause of the Constitution. The Secretary moved to dismiss for lack of subject-matter jurisdiction, which the court denied. Instead, the court granted the Secretary's motion for summary judgment. The plaintiffs appealed.

DISCUSSION

We first determine whether the district court had subject-matter jurisdiction. Our review of jurisdictional issues is *de novo*. *Volvo Trucks N. Am., Inc. v. Crescent Ford Truck Sales, Inc.*, 666 F.3d 932, 935 (5th Cir. 2012). Generally, the proponents of federal-court jurisdiction carry the burden of establishing it. *Ramming v. United States*, 281 F.3d 158, 161 (5th Cir. 2001). The plaintiffs have not offered any basis on which to conclude the burden lies elsewhere in this case and we see none. Because the district court resolved this

issue at the Rule 12(b)(1) stage of the proceedings, the plaintiffs' burden is to allege a plausible set of facts establishing jurisdiction. *See Davis v. United States*, 597 F.3d 646, 649-50 (5th Cir. 2009). Thus, the plaintiffs carry the burden of establishing that statutory subject-matter jurisdiction exists and they have failed to do so.

The Medicare Act severely restricts the authority of federal courts by requiring "virtually all legal attacks" under the Act be brought through the agency. *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000). The government argues we lack jurisdiction because the plaintiffs failed to follow the statutorily mandated administrative procedures. In the alternative, the government argues the current suit should instead be one seeking compensation in the Court of Federal Claims.

As we will explain, the plaintiffs had to proceed with the available administrative procedures. Their failure to do so leaves us without subject-matter jurisdiction over the claims they have presented in this suit. Accordingly, we do not reach the other issues raised for review.

By statute, claims under Medicare must first be presented to the HHS Secretary. The first relevant statute mandates a procedure for another context:

> The findings and decision of the Commissioner of Social Security after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter.

42 U.S.C. § 405(h). Title 42, Section 1395ii makes Section 405(h) applicable to Medicare, substituting the HHS Secretary for the references to the Social Security Commissioner. Once the Secretary reaches a final decision, an

individual who was a party to the administrative proceeding "may obtain a review of such decision by a civil action commenced within sixty days after the mailing to him of notice of such decision or within such further time as the [Secretary] may allow." 42 U.S.C. § 405(g).

In summary, judicial review of such a claim is available only after a party first presents the claim to the Secretary and receives a final decision.

The Supreme Court has had four occasions to interpret Section 405(h). After its most recent such opinion, a few courts of appeals have also considered the application of this Section. These opinions acknowledge that bringing claims administratively comes "at a price, namely, occasional individual, delay-related hardship." *Ill. Council*, 529 U.S. at 13. The hardship is identified as one that Congress was aware it was imposing on health-care providers:

> In the context of a massive, complex health and safety program such as Medicare, embodied in hundreds of pages of statutes and thousands of pages of often interrelated regulations, any of which may become the subject of a legal challenge in any of several different courts, paying this price may seem justified. In any event, such was the judgment of Congress as understood [by the Court].

Id. Section 405(h) requires that short of a "*complete* preclusion of judicial review," a party must channel his or her claims to the Secretary prior to litigating in federal court. *Id.* at 22-23.

In the first of the four Supreme Court decisions, plaintiffs challenged the constitutionality of portions of the Social Security Act in federal court. *Weinberger v. Salfi*, 422 U.S. 749, 752-53 (1975). The district court exercised jurisdiction over all of the claims in the case, including those that had not been first pursued administratively. *Id.* at 755. The district court concluded that Section 405(h) "amounted to no more than a codification of the doctrine of exhaustion of administrative remedies." *Id.* at 757. The Supreme Court found this reasoning to be "entirely too narrow." *Id.* The Court elaborated: "That the

third sentence of § 405(h) is more than a codified requirement of administrative exhaustion is plain from its own language, which is sweeping and direct and which states that no action shall be brought under § 1331, not merely that only those actions shall be brought in which administrative remedies have been exhausted." *Id.*[1] The Court also concluded that a claim "arising under this subchapter" encompassed a constitutional challenge because "not only is it Social Security benefits which appellees seek to recover, but it is the Social Security Act which provides both the standing and the substantive basis for the presentation of their constitutional contentions." *Id.* at 760-61.

The Court then addressed an argument also presented by the plaintiffs here, which is that preclusion of judicial review requires Congress to manifest its intent by clear and convincing evidence. *Id.* at 761-63. Section 405(h) does not preclude judicial review, but instead channels it through the Secretary:

> [T]he Social Security Act itself provides jurisdiction for constitutional challenges to its provisions. Thus the plain words of the third sentence of § 405(h) do not preclude constitutional challenges. They simply require that they be brought under jurisdictional grants contained in the Act, and thus in conformity with the same standards which are applicable to nonconstitutional claims arising under the Act. The result is not only of unquestionable constitutionality, but it is also manifestly reasonable, since it assures the Secretary the opportunity prior to constitutional litigation to ascertain, for example, that the particular claims involved are neither invalid for other reasons nor allowable under other provisions of the Social Security Act.

Id. at 762.

In its next opinion analyzing Section 405(h), the Court considered whether Medicare claimants could bring a direct challenge in federal court to the Secretary's policy of not paying medical benefits for a particular surgery.

[1] This statute is the general congressional grant of jurisdiction which permits districts courts to hear cases arising under federal law. 28 U.S.C. § 1331.

Heckler v. Ringer, 466 U.S. 602, 604-05 (1984). The Court construed these claims as arising under the Medicare Act because of the broad language in Section 405(h). *Id.* at 615. "It is of no importance that respondents here, unlike the claimants in *Weinberger v. Salfi*, sought only declaratory and injunctive relief and not an actual award of benefits as well." *Id.*[2] The Court concluded that "Congress must have felt that cases of individual hardship resulting from delays in the administrative process had to be balanced against the potential for overly casual or premature judicial intervention in an administrative system that processes literally millions of claims every year." *Id.* at 627.

Two years after *Ringer*, the Court reviewed a challenge to the way HHS paid doctors providing treatment to Medicare Part B patients. *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 668 (1986). There was no judicial or administrative review available to the plaintiffs in *Michigan Academy* because all payment disputes were processed by insurance companies. *Id.* at 675-76. Thus, "*no* forum" would have existed for the plaintiffs. *Id.* at 678. Having no forum, not even a costly or impractical one, would have raised serious constitutional questions that the Court avoided by determining the plaintiffs could avail themselves of federal question jurisdiction. *Id.* at 681 & n.12.

The Court's fourth and most recent review of Section 405(h) came in a suit brought by an association of nursing homes against the Secretary challenging certain nursing-home regulations. *Ill. Council*, 529 U.S. at 6-7. The case presented an opportunity for the Court to resolve a circuit split over whether *Michigan Academy* had "significantly modified [the] Court's earlier case law."

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[2] One of the plaintiffs in *Ringer* had yet to have the relevant surgery. The Court considered whether this meant he lacked a claim that could arise under the Act. *Ringer*, 466 U.S. at 621. The Court found "that argument superficially appealing but ultimately unavailing"; the "claim for future benefits must be construed as a 'claim arising under' the Medicare Act because any other construction would allow claimants substantially to undercut Congress' carefully crafted scheme for administering the Medicare Act." *Id.*

Id. at 9. The Court held it had not. *See id.* at 19. It clarified that *Michigan Academy* should be interpreted to mean that Section 405(h) does not apply "where application of § 405(h) would not simply channel review through the agency, but would mean no review at all." *Id. Ill. Council* further noted that "Congress may well have concluded that a universal obligation to present a legal claim first to HHS, though postponing review in some cases, would produce speedier, as well as better, review overall." *Id.* at 20.[3]

The courts of appeals that have applied *Illinois Council* have done so relatively consistently, unlike the split that resulted after *Michigan Academy*. Channeling will be required unless plaintiffs can show there is "no way of having their claims reviewed," there is "*complete* preclusion," or there exists a "serious 'practical roadblock'" to having their claims reviewed in any capacity, administratively or judicially.[4]

We now apply these principles to resolve the following issues: whether the plaintiffs' claims here arise under the Medicare Act; whether Congress stopped or only delayed judicial review; can a constitutional challenge at least be brought; and do the plaintiffs' claims fit under the *Illinois Council* exception?

First, do these claims arise under the Medicare Act? The plaintiffs seek, among other things, a declaration that patients who one day would be treated in their expanded facility will be eligible for Medicare reimbursements. In *Illinois Council*, the Supreme Court answered a similar question. It recognized it had to decide whether the suit was one "to recover on any claim arising under"

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[3] The Court explicitly declined to reconsider this conclusion, noting that it had "crossed the relevant bridge long ago when it held that Congress, in both the Social Security Act and the Medicare Act, insisted upon an initial presentation of the matter to the agency." *Id.*

[4] *Fanning v. United States*, 346 F.3d 386, 400 (3d Cir. 2003) ("no way"); *Nat'l Athletic Trainers' Ass'n, Inc. v. U.S. Dep't of Health & Human Servs.*, 455 F.3d 500, 504 (5th Cir. 2006) ("complete preclusion"); *Council for Urological Interests v. Sebelius*, 668 F.3d 704, 712 (D.C. Cir. 2011) ("roadblock").

the Medicare Act when "a group . . . needing advance knowledge for planning purposes, together bring[s] a § 1331 action challenging . . . a rule or regulation on general legal grounds." *Ill. Council*, 529 U.S. at 10. The Court determined that such claims do arise under the Medicare Act. *Id.* at 25. We similarly conclude that the plaintiffs' claims in this case arise under the Medicare Act because the Act "provides both the standing and the substantive basis for the presentation of their constitutional contentions." *Salfi*, 422 U.S. at 760-61.

Second, the plaintiffs assert that because the Secretary argues that the "statutory scheme" eliminates judicial review of a constitutional question, "Congress' intent to do so [must be] manifested by 'clear and convincing' evidence." *Califano v. Sanders*, 430 U.S. 99, 109 (1977). As already discussed, the Supreme Court has explicitly rejected this very argument. *Salfi*, 422 U.S. at 762. Section 405(h) does not remove jurisdiction from the federal courts but only delays it.

Third, the plaintiffs argue that their claims "do not seek recovery under the Medicare Act; instead, they invoke the U.S. Constitution." The Supreme Court has also explicitly rejected the argument that constitutional challenges are free from Section 405(h)'s requirements. *Id.* at 760-61. The plaintiffs seek to distinguish *Salfi* as a case about the recovery of Social Security benefits, while their case pertains to declaratory and injunctive relief. Again, the Court has rejected this argument. *Ringer*, 466 U.S. at 615-16.

Finally, plaintiffs argue that their claims fall under the *Illinois Council* exception because "the channeling requirement would result in the practical denial of judicial review." *See Ill. Council*, 529 U.S. at 22. They assert that these are the necessary steps for TSJH to channel its protest: knock down two commercial buildings, perfect financing, borrow tens of millions of dollars, finish the architectural and construction plans, pay a contractor, take two years to build a new hospital, treat a patient in the expansion, bill Medicare, appeal the

denial of the payment administratively, receive a final denial of claim, and file a suit in federal court under Section 405(g).[5]

The Secretary responds in two ways. She argues the *Illinois Council* exception only applies when there is a "*complete* preclusion of judicial review," and the plaintiffs have not argued that a legal bar exists to their claim. *See id.* at 23. The Secretary also argues that even if the plaintiffs are unable to bring their claim, the courts are only concerned with whether no one may bring the claim. *See Council for Urological Interests*, 668 F.3d at 711-12. The Secretary insists there are other potential parties who could bring such a claim. We will examine both of these responses.

The *Illinois Council* exception has been limited to cases in which there is no other path for judicial review. For example, the D.C. Circuit held that "section 405(h) is inapplicable where the Medicare Act offers no avenue for review of a particular category of statutory or constitutional claims." *Id.* at 708. The plaintiffs argue that bringing the claim requires the enormously wasteful expense of constructing a large building first, a structure they will not be able to use if the claim ultimately is denied. According to the plaintiffs, they also risk losing Medicare reimbursements on their existing facility. These burdens allegedly leave them no legitimate and practical way to bring the claim.

There has not been an appellate court decision addressing the effect of such a large initial expense on the obligation to channel a claim. There certainly have been attendant costs to the operation of Section 405(h) that have not caused courts to waive the requirement. One example is having to forgo a desired surgery or pay for it out of pocket prior to bringing an administrative claim. *Ringer*, 466 U.S. at 620-21. The plaintiffs are asking us to expand the *Illinois Council* exception to Section 405(h) to include cases in which channeling

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[5] We do not take a position on what the factual prerequisites would be for bringing a claim to the Secretary.

would require extraordinary expenses that are unrecoverable if the plaintiff is unsuccessful after administrative and judicial review.

Even if an exception for severe economic impracticability would be a justified expansion of the existing caselaw, it is not enough for a plaintiff to allege that it cannot channel. The D.C. Circuit explained the necessary allegations this way:

> [A] party may not circumvent the channeling requirement by showing merely that "postponement of judicial review would mean added inconvenience or cost in an isolated, particular case." Rather, in determining whether the *Illinois Council* exception to section 405(h) applies, "the question is whether, as applied generally to those covered by a particular statutory provision, hardship likely found in many cases turns what appears to be simply a channeling requirement into complete preclusion of judicial review."

Council for Urological Interests, 668 F.3d at 708 (quoting *Ill. Council*, 529 U.S. at 22-23). The quoted Supreme Court language requires that a party go beyond showing its own hardship and indicate that the difficulty it encounters is sufficiently widespread as to threaten the loss of any judicial review.

The relevant hardship in *Illinois Council* was the possibility that the claimant nursing home would have to subject itself to the threat of termination from the Medicare program in order to contest the relevant regulation, a possibility the government denied. *Ill. Council*, 529 U.S. at 21-22.

The D.C. Circuit explained the hardship in its case by asking a question: "How does section 405(h) apply when the Medicare Act provides an avenue for administrative and judicial review of a particular claim . . . but not by the category of affected parties who wish to bring it?" *Council for Urological Interests*, 668 F.3d at 708. There, a group of joint venturers providing surgical equipment sought to challenge the Secretary's regulation under the Stark Law that prohibited arrangements where physician-owned joint ventures purchased surgical equipment, which hospitals used, and then reimbursed the doctors for

their services while using the equipment. *Id.* at 706. Because the plaintiffs were not providers they could not seek administrative review. *Id.* at 706-07. The court then examined whether third parties could bring the claim. Such parties, the court decided, were at best neutral and at worst stood to gain from the new regulation. *Id.* at 713. Thus, the third parties lacked the incentive to bring a challenge because they were categorically misaligned with the plaintiffs. *Id.* Consequently, there was a preclusion of administrative review that required an *Illinois Council* exception be made to Section 405(h) channeling. *Id.*

We have also analyzed Section 405(h) issues. In one such suit, the plaintiffs challenging a new Medicare rule did not have standing to bring an administrative claim, but there potentially were other parties with an interest and a right to seek administrative review. *Nat'l Athletic Trainers' Ass'n, Inc.*, 455 F.3d at 504. The plaintiffs in that case argued that no other party would bring a challenge because of the potential for fines, criminal penalties, and civil liability under the Act if improper claims were made. *Id.* at 505. The Secretary countered, explaining that third parties would be protected by the scienter requirements of the statutes that allegedly threatened such penalties. *Id.* at 505-06. We concluded there were third parties properly aligned to bring a challenge, that "sufficient incentive to challenge the rule" by those parties existed, that the Secretary's position on scienter was reasonable,[6] and that therefore "the *Illinois Council* exception does not apply." *Id.* at 507.

The plaintiffs in the present case argue that the facts here fit the *Illinois Council* exception. We have already listed the financial costs that plaintiffs claim they must incur to position themselves to bring a claim to the Secretary. What we are addressing now is a different point, namely, is the hardship these

[6] We noted that "a physician who disclosed to the government that the services were not reimbursable could not be said to have *knowingly* submitted a false claim." *Nat'l Athletic Trainers' Ass'n*, 455 F.3d at 507.

plaintiffs face so widespread that it "turns what appears to be simply a channeling requirement into *complete* preclusion of judicial review[?]" *Ill. Council*, 529 U.S. at 22-23.

The plaintiffs allege that Physician Hospitals has "over 166 member hospitals." Their member hospitals are "typically enrolled as providers under the Medicare and Medicaid programs with up to 70% of their case mix stemming from Medicare and Medicaid patients." They also allege that as of December 31, 2010, they anticipated there would be 294 physician-owned Medicare certified hospitals in the United States. Further, they allege that "39 hospitals that were previously under development . . . are currently not continuing the development process due to the Physician Hospital Law." These figures reveal that the hospitals potentially affected by Section 6001 are numerous. They are of different sizes and have different patient mixes. The plaintiffs do not address whether a lesser expansion than TSJH has planned would permit some other physician-owned hospital from challenging the law, whether there are physician-owned hospitals with a low enough Medicare and Medicaid case mix such that they would challenge the law (either among Physician Hospitals's membership or among the almost half of the physician-owned hospitals that it does not allege are members), or whether other expansions could have alternative uses such that a failed challenge to the law would not render an expansion worthless.

The Secretary argues that there are physician-owned hospitals that are not "so heavily dependent on Medicare payments that further construction would make no sense."[7] Such hospitals arguably could complete similar expansions, admit Medicare patients, and bring to the Secretary the arguments the plaintiffs wish to make here. The plaintiffs respond, in part, with the same argument we rejected in *National Athletic Trainers',* which is that every provider who files a

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[7] The evidence the Secretary cites is a report that identifies physician-owned nonorthopedic surgical hospitals as some with lower numbers of Medicare patients.

Medicare reimbursement claim that is found to be in violation of the Stark Law faces substantial penalties. We discussed the ways in which the Secretary explained such penalties could be avoided. *Nat'l Athletic Trainers'*, 455 F. 3d at 506. Both the potential criminal and civil liability had requirements that a claim be knowingly false. *Id.* at 507. We concluded that the ability to submit a claim along with a disclosure that the charged services were not reimbursable "greatly reduce[d] the disincentive to challenge the rule." *Id.*

The plaintiffs have failed to allege that their case is analogous either to *Michigan Academy* or *Council for Urological Interests*, or to provide another basis on which we could conclude that the challenges in this case present a "*complete* preclusion of judicial review." *Ill. Council*, 529 U.S. at 22-23.[8] In *Michigan Academy*, there was a legal impossibility that any claimant would obtain judicial or administrative review. *Michigan Academy*, 476 U.S. at 675-76. In *Council for Urological Interests*, the plaintiff presented sufficient allegations for the D.C. Circuit to conclude that while it had "no need to determine precisely at what point a third party's lack of incentive or misalignment of interests triggers the *Illinois Council* exception," it was "clear that given the particular circumstances of [that] case, the *Illinois Council* exception applie[d]." *Council for Urological Interests*, 668 F.3d at 713. Far from being clear, the plaintiffs' allegations in this case appear almost silent as to third parties. Thus, they have failed to meet their burden of establishing subject-matter jurisdiction.

The plaintiffs have not met their burden of alleging more than that TSJH cannot channel its claim. This is insufficient to constitute a "*complete* preclusion of judicial review." *Ill. Council*, 529 U.S. at 22-23.

The plaintiffs' arguments rely heavily on the seeming lack of purpose behind administrative channeling in this case. It certainly appears that the

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[8] Additionally, the Section 405 bar may not be waived by the Secretary. *Ill. Council*, 529 U.S. at 15.

plaintiffs will suffer a "delay-related hardship" by following this path. *See id.* at 13; *see Fanning*, 346 F.3d at 401 n.17. The unsatisfactory nature of channeling was identified by the dissent in *Illinois Council,* which forcefully argued that "[d]elayed review – that is, a requirement that a regulated entity disobey the regulation, suffer an enforcement proceeding by the agency, and only then seek judicial review – may mean no review at all." *Ill. Council*, 529 U.S. at 47 (Thomas, J., dissenting). The dissent continued that "when the costs of 'presenting' a claim via the delayed review route exceed the costs of simply complying with the regulation, the regulated entity will buckle under and comply, even when the regulation is plainly invalid." *Id.*

The majority agreed that the channeling requirement "comes at a price" but rejected the dissent's argument. The Court noted that "[i]n the context of a massive, complex health and safety program such as Medicare, embodied in hundreds of pages of statutes and thousands of pages of often interrelated regulations, any of which may become the subject of a legal challenge in any of several different courts, paying this price may seem justified." *Id.* at 13.

The ever-evolving landscape of health care in the United States may one day prompt a new structure for judicial review in a case such as this. "If the balance is to be struck anew, the decision must come from Congress" and not from the courts. *Ringer*, 466 U.S. at 627. Section 405(h) makes clear that "No action . . . shall be brought under section 1331." The district court lacked subject-matter jurisdiction over this case.

VACATED and DISMISSED.