No. 98-1109

IN THE SUPREME COURT OF THE UNITED STATES

DONNA A. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,
Petitioner

v.

ILLINOIS COUNCIL ON LONG TERM CARE, INC.,
Respondent

BRIEF FOR THE AMERICAN MEDICAL ASSOCIATION, AMERICAN ACADEMT OF DERMATOLOGY, AMERICAN ACADEMY OF FAMILY PHYSICIANS, AMERICAN ACADEMY OF OFTHOPAEDIC SURGEONS, AMERICAN ASSOCIATION MEDICAL COLLEGES, AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS, CONGRESS OF NEUROLOGICAL SURGEONS, AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, AMERICAN COLLEGE OF PHYSICIANS, AMERICAN SOCIETY OF INTERNAL MEDICINE, AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY, AND ILLINOIS STATE MEDICAL SOCIETY AS AMICI CURIAE IN SUPPORT OF RESPONDENT

Filed August 23, 1999

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INTEREST OF AMICI CURIAE[1]

The American Medical Association ("AMA"), a private, voluntary, nonprofit organization, is the largest association of physicians in the United States. The AMA was founded in 1847 to promote the science and art of medicine and the improvement of the public health. Its nearly 300,000 members practice in all fields of medicine.

The American Academy of Dermatology ("AAD"), a nonprofit organization representing 12,000 physicians specializing in the practice of dermatology, is the largest organization of dermatologists in the world. Founded in 1938, AAD is dedicated to maintaining the highest standards of clinical practice, education, and medical research pertaining to dermatology.

The American Academy of Family Physicians is a national medical specialty society representing over 88,000 family physicians, family practice residents and medical students. Its members provide comprehensive, coordinated and continuing care to all members of the family and serve as the patient's advocate in the changing health care system.

The American Academy of Orthopaedic Surgeons ("AAOS") is a nonprofit organization representing 18,000 board-certified orthopaedic surgeons. Founded in 1933, the AAOS provides continuing medical education for its members and allied health professionals to help maintain a high level of skill and competence in the practice of orthopaedic surgery.

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[1]The parties have consented to the submission of this brief. Their letters of consent have been filed with the Clerk of this Court. None of the parties authored this brief in whole or in part and no one other than *amici*, their members, or counsel contributed money or services to the preparation or submission of this brief. *See* Sup. Ct. R. 37.6.

The American Association of Neurological Surgeons-Congress of Neurological Surgeons ("AANS" and "CNS"), representing over 5,200 neurosurgeons, are the two largest nonprofit scientific and educational associations for neurosurgical professionals in the world. The AANS and CNS are dedicated to excellence in neurosurgical education to advance patient care.

The American College of Obstetricians and Gynecologists is a private, voluntary, not-for-profit organization of physicians who specialize in obstetric and gynecologic care. Founded in 1951, its more than 39,000 members represent approximately 90 percent of all obstetricians and gynecologists practicing in the United States.

The American College of Physicians-American Society of Internal Medicine is a nonprofit professional society, whose membership consists of over 115,000 physicians specializing in internal medicine, the largest medical specialty group.

The American Society of Cataract and Refractive Surgery ("ASCRS"), is a nonprofit organization, the membership of which consists of nearly 8,000 physicians specializing in cataract and refractive surgery. ASCRS is dedicated to promoting the advancement of clinical practice, education, and research in cataract and refractive surgery.

The Association of American Medical Colleges ("AAMC") is a national association of medical schools, hospitals, and physician practice groups that employ teaching physicians. Located in Washington, D.C., the AAMC it is actively involved in the development of national policy affecting payment to teaching physicians and hospitals.

The Illinois State Medical Society ("ISMS") is a voluntary professional association representing 12,000

physicians, residents and medical students in Illinois. ISMS membership includes practicing physicians from a broad range of specialties, geographic locations, and types of practice.

The Medicare Act, 42 U.S.C. § 1395 *et seq.*, establishes a federally subsidized health insurance program for the elderly and disabled that is administered by petitioner, the Secretary of Health and Human Services ("Secretary"). Medicare Part A, *id.* § 1395c *et seq.*, provides insurance for the cost of hospital and related post-hospital services, including skilled nursing care. Part B, *id.* § 1395j, *et seq.*, by contrast, provides a voluntary supplemental insurance program that covers physicians' charges and other medical services.[2] The overwhelming majority of *amici's* physician members receive reimbursement for medical treatment and services provided to patients enrolled in Part B of the Medicare Act. Physicians can agree to accept assignment of their patients' Medicare Part B claims and then seek reimbursement directly from Medicare. *Id.* §§ 1395u(h)(1) & (b)(3))(B)(ii), 1395*l*(a)(1). Physicians who do not accept assignment are paid directly by their patients, who in turn seek reimbursement from Medicare.

In their capacity as assignees of their patients' Medicare claims, *amici's* physician members have the right to administrative and judicial review of reimbursement denials. 42 C.F.R. § 405.801(a). Likewise, hospitals and other providers can seek administrative and judicial review for their claims under Part A. 42 U.S.C. §§ 1395*oo*(b)-(g); 42 C.F.R. § 405.801, *et seq.* Subsumed within the right to judicial review of claims under Parts A and B is, of course, an

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[2]Under Part C, beneficiaries obtain medical care through, among other options, managed care organizations that contract with Medicare. Balanced Budget Act of 1997, Pub. L. No. 105-33, Tit. IV, § 4001, 111 Stat. 276-327.

entitlement to challenge the validity of the Secretary's policies governing Medicare benefits reimbursement. Representing their members' shared interests, *amici* and other healthcare associations frequently bring challenges to Medicare rules and regulations that are of broad significance to the administration of the Medicare program. *See infra* n.18. Because individual doctors and patients may be ill-equipped to bring such challenges themselves, *amici* and other healthcare associations perform a critical function in ensuring that the Secretary's implementation of the Medicare program does not run afoul of the dictates of Congress or the Constitution.

Although this case involves a challenge to the Secretary's rules governing nursing homes' compliance with Medicare's health, safety, and quality-of-care requirements, it presents a fundamental question of district court jurisdiction over challenges to generally applicable rules and regulations in the Medicare program, including those governing the payment of benefits under Parts A and B. As a result of their role in bringing challenges to the Secretary's rules and regulations affecting benefits payment under Parts B, *amici* offer a unique perspective on the issues presented here.

At stake is the right of patients, physicians, and other providers to obtain timely and effective review of the Secretary's regulations and policies. The Secretary's position, moreover, poses a substantial threat to *amici's* and other healthcare associations' ability to obtain *any* judicial review of challenges to the Secretary's Medicare regulations. Because *amici* and other associations of providers may not bring a claim in the administrative review process, they cannot directly avail themselves of the Medicare Act's review provisions, and *must* rely on the general federal-question jurisdiction statute to initiate a challenge to the validity of the

Secretary's policies. Taken to its extreme, the Secretary's argument here would foreclose that option entirely.

STATEMENT

This case calls upon the Court to revisit the framework established in *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986), for determining when federal courts may exercise their general federal-question jurisdiction under 28 U.S.C. § 1331 to entertain constitutional and statutory challenges to the validity of the Secretary's Medicare rules and regulations. *Michigan Academy* held that broad-based legal challenges to the Secretary's rules and regulations, *e.g.*, the Secretary's methodology for determining benefits under Parts A and B, could be filed directly in district court under 28 U.S.C. § 1331. Conversely, the Court concluded that challenges to the application of those regulations, *e.g.*, individualized determinations as to the *amount* of benefits payable, are subject to the review provisions contained in the Medicare Act, and hence must first be channeled through the agency's review process. This case presents an opportunity to confirm the continuing vitality of *Michigan Academy*'s "amount/methodology" distinction.

Respondent challenges the Secretary's rules governing nursing homes' participation in Medicare Part A. The Secretary contends that respondent's challenge is foreclosed by the administrative and judicial review procedures of 42 U.S.C. §§ 1395cc(h) and 1395ii. It is *amici's* position that the court of appeals correctly held that these provisions do not preclude pre-enforcement judicial review of respondent's challenge under 28 U.S.C. § 1331. Rather than dealing with the direct reviewability of nursing home regulations, however, *amici* will focus more generally on the basic *Michigan Academy* distinction between challenges to individualized determinations, which must brought through

established administrative channels, and broad-based challenges to the Secretary's rules and regulations governing such determinations, which may be brought directly in district court. For the reasons stated here, that distinction remains the law and should provide the foundation for resolving this case.

The *Michigan Academy* amount/methodology distinction stems from the interplay of several statutory provisions. Section 1395ff of the Medicare Act addresses challenges to the Secretary's determinations of the amount of benefits under Parts A and B.[3] Section 1395ff has always provided judicial review procedures for Part A benefits claims; however, prior to January 1, 1987, it provided no judicial

[3]Section 1395ff states in relevant part:

(a) Entitlement to and amount of benefits

The determination of whether an individual is entitled to benefits under part A or part B of this subchapter, and the determination of the amount of benefits under part A or part B of this subchapter, and any other determination with respect to a claim for benefits under part A of this subchapter or a claim for benefits with respect to home health services under part B of this subchapter shall be made by the Secretary in accordance with regulations prescribed by him.

(b) Appeal by individuals; provider representation of beneficiaries

(1) Any individual dissatisfied with any determination under subsection (a) of this section as to * * *

(C) the amount of benefits under part A or part B of this subchapter (including a determination where such amount is determined to be zero)
* * *

shall be entitled to a hearing thereon by the Secretary to the same extent as is provided in section 405(b) of this title and to judicial review of the Secretary's final decision after such a hearing as is provided in section 405(g) of this title * * *.

review for disputes concerning the amount of Part B benefits, and no administrative review beyond a hearing by private insurance carriers with whom the Secretary contracts to evaluate Part B claims. 42 U.S.C. § 1395u. Congress amended § 1395ff in 1986, Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9341(a)(1)(B), 100 Stat. 203 ("1986 Amendments"), to provide judicial review and additional administrative review of Part B benefit determinations. As a result of these amendments, Part B benefits determinations are now subject to a five-part administrative review process and judicial review.[4] Disputes concerning the payment of benefits under Part A proceed along a separate, four-stage administrative appeals process within the Department of Health and Human Services and judicial review.[5] As the Secretary concedes, all of the decisionmakers in the Part A and B administrative appeals

[4]After receiving notice from an insurance carrier of a complete or partial denial of a Part B claim, dissatisfied beneficiaries or physicians with claims totaling at least $500 (or at least $100 for home health claims) may seek reconsideration by the carrier. 42 U.S.C. § 1395ff(b)(2)(B); 42 C.F.R. § 405.800, *et seq*. The next step in the administrative appeals process is a "fair hearing" before the carrier, 42 C.F.R. § 405.820, followed by a hearing before an administrative law judge ("ALJ"), and finally, an appeal to the Departmental Appeals Board. 42 U.S.C. § 1395ff(b)(2)(B).

[5]Under Part A, the Secretary contracts with fiscal intermediaries (generally insurance companies), which determine whether a particular medical expense is covered by Part A and, if so, the amount of reimbursement Medicare will provide. 42 U.S.C. § 1395h. A claimant dissatisfied with the intermediary's decision can seek reconsideration by the Health Care Financing Administration. If a dispute meets the threshold amount-in-controversy requirements, the claimant may then seek a hearing before an ALJ. *Id.* § 1395ff(b)(1)(C) & (b)(2). If the claim is denied, the claimant may proceed to the Appeals Council. 42 C.F.R. §§ 405.701(c), 405.724. A claimant who receives an adverse ruling from the Appeals Council may seek review in district court for claims of at least $1,000. 42 U.S.C. § 1395ff(b)(1) & (2)(B).

processes are bound to apply the Medicare Act and the Secretary's regulations and may not address challenges to their validity. *See* Pet. Br. at 44-45.

Congress has incorporated the hearing and judicial review provisions of the Social Security program, 42 U.S.C. §§ 405 (b) and (g), into the Medicare program via 42 U.S.C. §§ 1395ff and 1395cc(h), and various other provisions of the Medicare Act. *See, e.g., id.* §§ 1320a-7(f), 1395mm(c)(5)(B), 1395w-22(g)(5). Section 405(b) entitles an individual dissatisfied with an administrative determination to "notice and an opportunity for a hearing with respect to" the determination. *Id.* § 405(b). Section 405(g) authorizes "an individual" to file an action in district court within 60 days of a "final decision" issued following a "hearing to which he was a party." 42 U.S.C. § 405(g).[6]

Congress also incorporated the Social Security Act's requirements concerning exhaustion of administrative remedies and limitations on judicial review under 42 U.S.C. § 405(h) into the Medicare Act in § 42 U.S.C. § 1395ii.[7]

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[6]Section 405(g) provides in relevant part:

> Any individual, after any final decision of the [Secretary] made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action . . . . [in] district court[.]* * * The court shall have the power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the [Secretary], with or without remanding the cause for a rehearing.

[7]Section 1395ii provides:

> The provisions of sections 406 and 416(j) of this title, and of subsections (a), (d), (e), (h), (i), (j), (k), and (l) of section 405 of this title, shall also apply with respect to this subchapter to the same extent as they are applicable with respect to [Social Security cases], except that in applying such provisions with respect to this subchapter, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

Section 405(h), by its terms, restricts only judicial review of actions "to recover on" claims eligible for review under Parts A and B, namely individual benefit determinations.[8] Likewise, § 405(h) applies only to "decision[s] of the [Secretary]," which, as the Secretary has acknowledged, do not include the Secretary's regulations. *See* Pet. Br. at 41 n.22.

SUMMARY OF ARGUMENT

The Court should reaffirm *Michigan Academy's* holding that challenges to the validity of the Secretary's policies affecting Medicare benefits determinations can be brought directly in district court under 28 U.S.C. § 1331, whereas challenges to the Secretary's individual administrative determinations are subject to the Medicare Act's presentment and exhaustion requirements. That authoritative construction was not disturbed when Congress added judicial review of Part B amount determinations under § 1395ff(b)(1)(C) in 1986. While the Secretary contends this amendment rendered *Michigan Academy* a dead letter months after it was issued, she has failed to point to anything in the text or legislative

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[8]Section 405(h) provides:

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

history of this amendment remotely suggesting that Congress intended to "overrule" *Michigan Academy*.

To the contrary, it is apparent that Congress' intent in 1986 was enhancing, not creating barriers to, judicial review under Part B. The Secretary's argument that, following the 1986 Amendments, *all* Medicare cases must first be routed through the administrative process would serve only to frustrate that clear intent. Indeed, because in 1986 Congress chose not to amend § 405(h) as incorporated by § 1395ii, the statutory provisions on which the Secretary primarily relies are the same now as when *Michigan Academy* was decided. The meaning of a statutory provision cannot change, of course, unless *Congress* revises it. And, where, as here, Congress has amended a related provision (§ 1395ff) while leaving the critical language in §§ 405(h) and 1395ii untouched, inferring such an intent would be especially inappropriate.

In addition, as the court of appeals has further explained, if something significant happened in 1986, "the point has been lost" on this Court, Pet. App. at 5a, which relied heavily on *Michigan Academy's* distinction between individualized adjudication and broad legal challenges to regulatory action in *McNary v. Haitian Refugee Center, Inc.*, 498 U.S. 479 (1991), which concerned the availability of judicial review in immigration proceedings. In fact, the *McNary* Court not only affirmed *Michigan Academy's* holding, it extended its reasoning outside the Medicare context and broadened the applicability of the presumption of judicial review to situations in which no *meaningful* judicial review is provided.

In any event, the presumption of judicial review, while still applicable after the 1986 Amendments, was not the sole basis for the Court's ruling in *Michigan Academy*. The Court's decision was primarily grounded in the text of the statute, and the relevant language is unchanged. Likewise,

the addition of judicial review for Part B "amount" disputes in the 1986 Amendments did not, as the Secretary asserts, create an "irreconcilable conflict" between *Michigan Academy* and *Heckler v. Ringer*, 466 U.S. 602 (1984). Pet. Br. at 34. Not only did *Ringer*, in contrast to *Michigan Academy*, involve individual claims for benefits, the Court in *Michigan Academy* also expressly indicated that its reasoning applied to Part A and Part B benefits alike.

Finally, the Secretary's contention that broad-based challenges to her policies must be funneled through an administrative process where legal challenges cannot be adjudicated, factual findings and the compilation of an administrative record are unnecessary, and there is no agency expertise to apply is at odds with well-settled principles of administrative law, judicial economy, and associational representation. Pursuant to such principles, where exhaustion of an administrative process would be futile, as it undoubtedly would be here, courts routinely allow litigants to bring their claims directly in district court. The reasons for doing so are particularly compelling where, as here, doing so will establish at the outset the validity of the applicable legal standard for the numerous individual claims that will be adjudicated in administrative appeals. By allowing broad challenges to the Secretary's rules and regulations to proceed directly to district court, courts can avoid resolving legal challenges on a piecemeal basis as they percolate through the administrative review process.

The Secretary's argument would jeopardize *amici's* and other health care associations' ability to bring broad-based challenges to the validity of the Secretary's regulations and policies. Because associations cannot file a claim for benefits, they cannot avail themselves of the review provisions of the Medicare Act. If, as the Secretary contends, they are confined by those jurisdictional provisions, they

would *never* be able to initiate an action contesting the Secretary's policies. That position would clearly conflict with the presumption of judicial review on which the Secretary so heavily relies.

ARGUMENT

I. *MICHIGAN ACADEMY* CONTINUES TO PERMIT JUDICIAL REVIEW UNDER 28 U.S.C. § 1331 OF FACIAL CHALLENGES TO MEDICARE RULES AND REGULATIONS.

Bowen v. Michigan Academy of Family Physicians, 476 U.S. 667 (1986), sets forth the appropriate framework for determining the availability of judicial review under 28 U.S.C. § 1331 in this and other Medicare Act cases. Because the Medicare Act does not establish procedures for judicial review of challenges to the validity of the Secretary's regulations and instructions affecting benefits payments -- *i.e.*, challenges to the "methodology" for calculating Medicare benefits -- a plaintiff may bring such a challenge in district court under the general federal-question jurisdiction statute, 28 U.S.C. § 1331. Conversely, because Congress has provided administrative and judicial review of individual benefit determinations under the Medicare Act, those procedures are exclusive with respect to such determinations.

A. *Michigan Academy* Was Grounded In The Text And Legislative History Of The Medicare Act.

In *Michigan Academy*, an association of family physicians and several individual doctors challenged a regulation promulgated under Medicare Part B authorizing payments of different amounts for similar services. 476 U.S. at 668. Just a few years before deciding *Michigan Academy*, the Court had held that Congress had limited review of determinations of the amount of Part B benefits to the "fair

hearing by the carrier" provided in 42 U.S.C. § 1395u(b)(3)(C). *See United States v. Erika, Inc.*, 456 U.S. 201 (1982). Because Part B awards were "'substantially smaller'" and more numerous than Part A awards, *id.* at 208 n.11 (quoting S. Rep. No. 89-404, at 54-55 (1965)), judicial review of such awards risked "overloading the courts with trivial matters," which Congress sought to avoid. *Id.* at 210 n.13 (citations and internal quotations omitted).

Michigan Academy nevertheless held that broad-based statutory and constitutional challenges to the regulations governing Part B determinations were subject to judicial review under 28 U.S.C. § 1331. It rejected the contention that § 1395ff impliedly foreclosed judicial review of methodology challenges under 28 U.S.C. § 1331. Noting that administrative procedures were provided in Parts A and B for challenging individual determinations of "amounts" of benefits to be paid, the Court held that § 1395ff "does not speak to challenges mounted against the *method* by which such amounts are to be determined rather than the *determinations* themselves." *Michigan Academy*, 476 U.S. at 675. (emphasis added)[9] Because "an attack on the validity of a regulation is not the kind of administrative action that we described in *Erika* as an 'amount determination,'" the Court concluded that it was not covered by § 1395ff, and was consequently exempt from the judicial review provisions of § 405(g), which § 1395ff incorporated by reference. *Id.* at 676. That such legal challenges could not be entertained in the administrative appeals process further confirmed that

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[9]Although the plaintiffs in *Michigan Academy* challenged a regulation under Part B, the Court reasoned that, by their terms, the review provisions for Part B (§ 1395u(b)(3)(C)) *and* the review provision for Part A (§ 1395ff(b)(1)(C)) applied only to challenges disputing the "amount" of benefits due. *See* 476 U.S. at 675 (referring to the separate review provisions of both Parts A and B); *see also infra* at page 22.

Congress did not intend to bar their direct review under 28 U.S.C. § 1331. *See id.* at 678.

The Court found this conclusion perfectly consistent with the text and legislative history of § 1395ii, which incorporates § 405(h), and on which the Secretary had relied. It had previously held that the first two sentences of § 405(h), which limit the review available for any "final decision" of the Secretary "made after a hearing," required exhaustion of administrative remedies. *Weinberger v. Salfi*, 422 U.S. 749, 757 (1975) But *Michigan Academy* clarified that this exhaustion requirement did not apply to challenges to the validity of the Secretary's regulations, for which there was no administrative hearing available. *See* 476 U.S. at 679 n.8. The Court also rejected the notion that a regulation was a "decision of the Secretary," which is defined as a determination made by the Secretary "*after a hearing.*" 42 U.S.C. §§ 405(g) & (h) (emphasis added).

Section 405(h)'s third sentence bars all "actions" against the government under 28 U.S.C. § 1331 to "recover on any claim arising under" the Medicare Act. *Michigan Academy* found that this provision precludes review only of amount determinations -- "*i.e.*, those 'quite minor matters' remitted finally and exclusively to adjudication by private insurance carriers in a 'fair hearing.'" 476 U.S. at 680 (internal citation omitted). In addition, as the court of appeals explained, a challenge to the validity of a regulation governing the method for calculating benefits is "not an action to '*recover on*' a claim, even when per *Salfi* a constitutional objection to the regulation is a 'claim arising under this subchapter." Pet. App. at 6a (emphasis added). This restriction applies only to an individual demand for benefits.

In sum, the Court found that §§ 1395ff and 1395ii worked in tandem: for matters covered by § 1395ff (*i.e.*, amount determinations under Parts A and B), § 1395ii limited

the availability of judicial review; as for matters falling outside of § 1395ff, § 1395ii did not apply, and hence they could be reviewed under a district court's general federal-question jurisdiction. *See* 476 U.S. at 679-80.

B. *Michigan Academy* Was Not "Overruled" By The 1986 Amendments.

The Secretary and several courts of appeals[10] have mistakenly concluded that Congress "overruled" *Michigan Academy* in 1986, months after it was decided, by adding judicial review procedures for Part B "amount" determinations in § 1395ff(b)(1)(C). While the Secretary has seized upon this amendment as a basis for discarding *Michigan Academy*, there is, in fact, nothing that suggests that Congress intended to overturn that ruling.

If, as the Secretary asserts, Congress had sought to overrule *Michigan Academy*, it surely would have mentioned this objective in the legislative history. Yet the committee reports discussing the amendments to § 1395ff, drafted a year *before* this Court's decision, contain none. *See* H.R. Rep. No. 99-727 95 (1986), *reprinted in* 1986 U.S.C.C.A.N. 3607, 3685; H.R. Conf. Rep. No. 99-1012 351 (1986), *reprinted in* 1986 U.S.C.C.A.N. 3868, 3996. Far from repudiating *Michigan Academy*, the principal sponsor of the amendment to § 1395ff(b)(1)(C) stated that "[t]his legislation *strengthens* the rights established by the Supreme Court in its decision Bowen versus Michigan Academy of Family Physicians, earlier this year." 132 Cong. Rec. 32978 (1986) (statement of Rep. Wyden) (emphasis added). Congress' *expansion* of judicial review rights for Part B amount disputes is an odd

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[10] *See, e.g., Michigan Ass'n of Homes & Servs. for the Aging v. Shalala*, 127 F.3d 496, 501 (6th Cir. 1997); *St. Francis Med. Ctr. v. Shalala*, 32 F.3d 805, 812 (3d Cir. 1994); *National Kidney Patients Ass'n v. Sullivan*, 958 F.2d 1127, 1133 (D.C. Cir. 1992).

basis for inferring an intent to create new *limitations* on judicial review for Part B methodology claims.

The Secretary's interpretation of the 1986 Amendments also ignores Congress' original purpose in foreclosing judicial review for Part B amount disputes, a decision the 1986 Amendments were intended to undo. As the Court explained in *Erika*, Congress had precluded judicial review of relatively "trivial" Part B claims in order to prevent them from taxing the federal court system. 456 U.S. at 210; *see also id.* at 208-11. That bar on judicial review, however, extended only to "'matters *solely* involving *amounts* of benefits under Part B.'" *Id.* at 210 (quoting H.R. Conf. Rep. No. 92-1605 at 61 (1972)) (emphasis added). Just as Congress had intended to preclude judicial review of Part B amount disputes only, so, too, it amended § 1395ff in 1986 with the clear purpose of adding judicial review procedures solely for such claims. *See* H. Rep. No. 99-727 at 95, *reprinted in* 1986 U.S.C.C.A.N. at 3685. Nothing suggests that it intended these amendments to foreclose review of Part B methodology disputes under 28 U.S.C. § 1331.[11]

Nor is such an intent implicit in the amendments themselves. There is simply "no conflict between the decision in *Michigan Academy* and Congress' subsequent grant of jurisdiction to review certain Medicare Part B determinations in the 1986 Act." *Griffith v. Bowen*,

[11]The Secretary points to a statement in a 1965 Senate Report that the "remedies provided by these review procedures shall be exclusive." Pet. Br. at 33 (quoting S. Rep. No. 89-404 55 (1965)). But that statement hardly supports the Secretary's argument that Congress adopted the *1986* Amendments as a rejection of *Michigan Academy*. As the Court made clear in *Erika*, the statement simply reflects Congress' intent to bar other types of judicial review of matters covered by the review provisions provided in the Medicare Act, *e.g.*, disputes concerning the amount of Part B awards. *See* 456 U.S. at 208 n.11.

678 F. Supp. 942, 945 (D. Mass. 1988). *Accord Abbott Radiology Assocs. v. Sullivan*, 801 F. Supp. 1012, 1017-18 (W.D.N.Y. 1992) (by providing expanded review for Part B "amount" determinations, because Congress "did not touch upon challenges by individuals to the Secretary's regulations . . . . the 1986 amendments did not displace the reasoning of *Michigan Academy*"). Rather, as they did before the 1986 Amendments, disputes concerning Part B "amount" determinations and broad challenges to the Secretary's regulations proceed on different tracks: for the former, judicial review is subject to the Medicare Act's presentment and exhaustion requirements, 42 U.S.C. §§ 1395ff, 405(g) and (h); the latter cannot be considered in the administrative appeals process, but may be brought in district court under 28 U.S.C. § 1331.

C. *McNary* Affirmed *Michigan Academy's* Reasoning And Expanded The Presumption Of Judicial Review.

As the court of appeals observed, "if something important happened in 1986, the point has been lost on the Supreme Court, which in 1991 [in *McNary v. Haitian Refugee Ctr., Inc.*, 498 U.S. 479], reiterated its conclusion that § 1395ii does not affect regulatory challenges that are detached from any request for reimbursement." Pet. App. at 6a. *See also Reno v. Catholic Social Servs., Inc.*, 509 U.S. 43 (1993) (holding district court had jurisdiction over pre-enforcement challenge to immigration regulation under *McNary*). In fact, *McNary* went beyond *Michigan Academy*, extending its reasoning outside the Medicare context and expanding the applicability of the presumption of judicial review.

McNary involved a constitutional challenge to the Immigration and Naturalization Service's ("INS") procedures for granting amnesty applications under the Immigration

Reform and Control Act of 1986 ("IRCA"), Pub. L. No. 99-603, 100 Stat. 3359. As it had in *Michigan Academy*, the government argued that such a challenge could be raised only pursuant to IRCA's judicial review provisions, and that statutory language limiting judicial review of "a determination respecting an [amnesty] application" to deportation or exclusion proceedings barred jurisdiction under 28 U.S.C. § 1331 over other challenges. 498 U.S. at 490-500.

Relying extensively on *Michigan Academy*, the Court dismissed these contentions. *See id.* at 497-98. In noting that its decision in *McNary* was "supported by our unanimous holding in *Bowen [v. Michigan Academy]*," the Court affirmed the "critical" distinction between "an individual 'amount' determination" and a dispute concerning "the procedures for making such determinations." *Id.* Because IRCA's limitations on judicial review applied by their terms to a "*determination* respecting an application" for amnesty, 8 U.S.C. § 1160(e)(1) (emphasis added), the Court concluded they covered only *individual* amnesty applications, not "general collateral challenges to unconstitutional practices and policies used by the agency in processing applications." 498 U.S. at 492. Accordingly, Congress had not precluded direct judicial review of broad constitutional challenges under 28 U.S.C. § 1331 even though review of disputes over *individual* amnesty determinations was confined to IRCA's administrative and judicial review provisions. *See id.*

Although IRCA provided for some judicial review (in the context of a deportation or exclusion hearing), the Court found the presumption that Congress intends administrative rulemaking to be subject to judicial review to apply. *See id.* at 496. It made clear that the critical question is not, as the Secretary asserts, whether the statute affords any judicial review, no matter how delayed, Pet. Br. at 31-32, but whether

"as a *practical* matter" the statute offers "*meaningful* judicial review" of a collateral legal challenge. 498 U.S. at 496 (emphasis added). If the obstacles to judicial review are sufficiently substantial, it is the "practical equivalent of a total denial of judicial review," and the government must present "clear and convincing evidence" that Congress intended to bar judicial review under 28 U.S.C. § 1331. *Id.* at 497.

McNary's expansion of the presumption of review rebuts the Secretary's contention that the 1986 Amendments, by providing some form of judicial review for Part B benefit claims, albeit delayed, removed the sole basis for the Court's decision. *See* Pet. Br. at 31-32. Requiring individual physicians and beneficiaries, whose claims may be of relatively small dollar value, to proceed through a lengthy and ultimately futile administrative appeal is tantamount to an outright denial of meaningful judicial review for collateral constitutional and statutory challenges.[12] Thus, even if *Michigan Academy* had been decided after the 1986 Amendments, the presumption of review would still have applied, and the Court would still have required clear and convincing evidence that Congress intended to foreclose review of Part B methodology challenges. But the legislative history of the 1986 Amendments does not vaguely suggest such an intent, let alone offer the type of evidence necessary to satisfy this rigorous standard. *See supra* pages 15-17.

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[12]With respect to a trade or professional association, the issue is more than the *de facto* denial of judicial review. As discussed more fully below, *see infra* at pages 28-30, an association cannot file a claim for benefits in the administrative appeals process or initiate an action in district court under the Medicare Act's judicial review procedures in § 405(g). Consequently, an association would -- apart from the possibility of intervening in a lawsuit -- be precluded from obtaining *any* judicial review of the Secretary's rules and regulations.

In any event, the key to the Court's decision in *Michigan Academy* was that §§ 1395ff and 1395ii, by their terms, did not purport to address broad-based challenges to the Secretary's rules and regulations. Congress' addition of judicial review for Part B "amount" disputes in 1986 did not alter the fact that § 1395ff addresses only review of amount determinations and "simply does not speak" to challenges to the validity of the Secretary's regulations. *Michigan Academy*, 476 U.S. at 675. Congress, moreover, left the language of § 1395ii as well as the text of §§ 405(g) and (h), which § 1395ii incorporates, substantively untouched.

It is simply incorrect to suggest that *Michigan Academy* interpreted § 1395ii to bar judicial review of all claims arising under the Medicare Act, but, because of the presumption of judicial review, chose not to enforce that restriction where the Secretary's methodology was challenged. *Michigan Academy* did not create an "exception" to § 1395ii or § 1395ff based on the presumption of judicial review. Pet. App. at 6a. Nor could it, because "[t]he presumption of judicial review is, after all, a presumption" to which "Congress can, of course, make exceptions." 476 U.S. at 672-73. *Cf. Bank of Nova Scotia v. United States*, 487 U.S. 250, 254 (1988) (court's exercise of supervisory power may not conflict with statute). Rather, it was the text of § 1395ii, which "read in light of its 1972 legislative history, affects only 'amount determinations,'" that was dispositive. Pet. App. at 6a. Because "[n]either th[e] critical language from § 405(h) nor the history of § 1395ii changed in 1986," *Michigan Academy's* interpretation of those provisions retains its vitality. *Id.*

In addition, *McNary's* reliance on *Michigan Academy* leaves no doubt that *Michigan Academy* is not limited to the specific context in which it arose, or even limited to the Medicare Act. Although the amount/methodology distinction

does not apply to immigration cases, this Court invoked *Michigan Academy's* more fundamental distinction between individualized administrative determinations and legal challenges to the rules governing those determinations. *See McNary*, 498 U.S. at 491-92. Thus, even if, as the Secretary asserts, the amount/methodology distinction "has no logical place" here, Pet. Br. at 33, there clearly *is* a distinction for reviewability purposes between an individualized determination that a nursing does not satisfy the standards for Medicare participation, 42 U.S.C. § 1395cc(h), and a facial legal challenge to the Secretary's rules and regulations affecting such a determination. Likewise, the distinction between individualized determinations and collateral legal challenges is equally germane to other Medicare cases, such those involving civil monetary penalties for specified statutory violations, 42 U.S.C. § 1320a-7a, the Medicare Act's anti-fraud provisions, *id.* § 1320a-7b, and the financial disclosure requirements for providers under Part B. *Id.* § 1320a-3a.

D. The Court Of Appeals' Decision Is Consistent With *Ringer*.

The court of appeals' decision is perfectly consistent with *Heckler v. Ringer*, 466 U.S. 602 (1984), which did not even address the amount/methodology distinction subsequently articulated in *Michigan Academy*. *Ringer* required administrative exhaustion prior to a judicial challenge by Part A claimants seeking coverage for a surgical procedure that the Secretary had disallowed. Distinguishing between the two types of claimants involved in the case -- three of whom had undergone the surgery and the fourth who had not -- the Court concluded that neither group could proceed directly to district court. The Secretary has argued that the only basis for distinguishing *Michigan Academy* from *Ringer* is that the Medicare Act did not provide judicial

review of the Part B claims at issue in *Michigan Academy*, but did for the Part A claims at issue in *Ringer*. Pet. Br. at 29-34. Thus, the Secretary asserts, the 1986 Amendments *must* be read to overturn *Michigan Academy* to avoid an "irreconcilable conflict" between *Ringer* and *Michigan Academy*. *See* Pet. Br. at 34. This argument fails for several reasons.

As a threshold matter, the Secretary's argument rests on the mistaken premise that *Michigan Academy* would have been decided differently had the specific claim at issue arisen under Part A (as *Ringer* did) rather than Part B. While *Michigan Academy* did involve a Part B claim, the Court reasoned that both the Part B provision at issue in *Erika* (§ 1395u(b)(3)(C)), and the Part A provision at issue in *Ringer* (§ 1395ff(b)(1)(C)), applied only to challenges disputing the amount of benefits:

> The reticulated statutory scheme, which carefully details the forum and limits of review of *"any determination . . . of . . . the amount of benefits under part A*," 42 U.S.C. § 1395ff(b)(1)(C) (1982 ed. Supp. II), and of the *"amount of . . . payment" of benefits under Part B*, 42 U.S.C. § 1395u(b)(3)(C), simply does not speak to challenges mounted against the method by which such amounts are to be determined rather than the determinations themselves.

476 U.S. at 675 (emphasis added). Accordingly, *Michigan Academy* made clear that under *both* Part A and Part B, challenges to the Secretary's methodology governing benefit awards were not subject to the exclusive review provisions of the Medicare Act.

Michigan Academy could bridge the review processes for Parts A and B notwithstanding *Ringer*, because *Ringer* did not involve the kind of broad challenge to the Secretary's

rules and regulations raised in *Michigan Academy*. As the Court explained, *Ringer* involved individual "'claims for benefits'" and the "'amount determinations'" concerning such claims. 476 U.S. 667 n.7. Likewise, the Court found that *Ringer* was not controlling in *McNary* because the "essence" of the former case was a "claim of entitlement to payment for [a] surgical procedure." *McNary*, 498 U.S. at 494. As to the claims brought by the plaintiffs who had already had the procedure, *Ringer* itself held that they were "at bottom" nothing more than "claim[s] that they should be paid for their . . . surgery." *Ringer*, 466 U.S. at 614. To the extent they contested the validity of the Secretary's policies, their legal challenges were "'inextricably intertwined' with [their] claims for benefits." *Id.* (citations omitted). In addition, the administrative review process was "in no sense futile" because, with respect to these plaintiffs, ALJs were not bound by the regulation at issue and hence authorized to award the reimbursement they sought. *Id.* at 619.[13]

As for the plaintiff who had not had the surgery, the Court determined that his claim was also "essentially one requesting the payment of benefits and hence cognizable only under § 405(g)." *Id.* at 620. *See also id.* at 608 n.4 (characterizing all four *Ringer* plaintiffs' claims "essentially as claims for benefits"); *McNary*, 498 U.S. at 494-95 (discussing *Ringer*). Although he had no immediate claim to exhaust, that fact meant only that his challenge was

[13]In *Ringer*, the Secretary's regulations barring reimbursement for the surgery in question did not apply to individuals who had the surgery in reliance on prior ALJ rulings awarding such reimbursement. *Id.*

premature, not that the federal courts had jurisdiction to issue "advisory opinions." *Ringer*, 466 U.S. at 621-22.[14]

II. *MICHIGAN ACADEMY* COMPORTS WITH WELL-ESTABLISHED PRINCIPLES OF ADMINISTRATIVE LAW, JUDICIAL ECONOMY, AND ASSOCIATIONAL REPRESENTATION.

Michigan Academy's distinction between individual administrative determinations and collateral legal challenges offers a sound and workable approach for addressing the thorny jurisdictional questions so often raised by the Social Security Act and Medicare Act.[15] Indeed, lower courts that have applied the *Michigan Academy* distinction have done so with relative ease, readily sorting out those challenges worthy of immediate judicial review and those where exhaustion of administrative remedies was appropriate. *See, e.g.,Cosgrove*, 999 F.2d at 632; *McCuin v. Secretary of Health & Human Servs.*, 817 F.2d 161, 163-66 (1st Cir. 1987); *Kuritzky v. Blue Shield*, 850 F.2d 126, 128 (2d Cir. 1988); *Medical Fund-Philadelphia Geriatric Ctr. v. Heckler*, 804 F.2d 33 (3d Cir. 1986); *Mediplex., Inc. v. Shalala*, 39 F. Supp.2d 88, 92-94 (D. Mass. 1999); *Stewart v. Sullivan*, 816 F. Supp. 281, 287-88 (D.N.J. 1992); *Abbott Radiology Assocs. v. Sullivan*, 801 F. Supp. 1012, 1015-18 (W.D.N.Y. 1992); *Griffith*, 678 F. Supp. at 943-45.

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[14]Likewise, there is no "irreconcilable conflict" between *Michigan Academy* and *Salfi*. While *Salfi* involved a challenge to a provision of the Social Security Act, like *Ringer*, it was, at bottom, a simple claim for benefits. *See* 422 U.S. at 760-61. Consequently, the Medicare Act offered the exclusive source of district court jurisdiction.

[15]*See, e.g., Heckler v. Ringer*, 466 U.S. 602 (1984); *Mathews v. Eldridge*, 424 U.S. 319 (1976); *Weinberger v. Salfi*, 422 U.S. 749 (1975); *Cosgrove v. Sullivan*, 999 F.2d 630 (2d Cir. 1993).

Also, *Michigan Academy* comports with basic administrative law principles. As the Secretary acknowledges, *see* Pet. Br. at 18, an exhaustion requirement is designed to allow the agency to: (1) "develop the necessary factual background upon which decisions should be based," *McKart v. United States*, 395 U.S. 185, 194 (1969); (2) "compile a record which is adequate for judicial review," *Salfi*, 422 U.S. at 765; (3) give the agency a chance to exercise its expertise to the issues raised, *see McKart*, 395 U.S. at 194; and (4) allow an agency to "correct its own errors," thereby mooting the dispute. *See McCarthy v. Madigan*, 503 U.S. 140, 145 (1992).

Funneling facial legal challenges to the Secretary's regulations through the administrative process furthers none of these objectives. Contrary to the Secretary's claims, by its nature, a facial challenge to the validity of a regulation typically will not require the "development of a factual record," Pet. Br. at 18, at least not the type of record compiled in a § 405(g) hearing. Nor are such questions appropriately left to an agency's expertise, particularly since they cannot even be entertained in the administrative appeals process. And because the Secretary has already made up her mind regarding the legal questions at issue -- as embodied in the regulation challenged -- there is no realistic chance that the dispute in question will be mooted.

It is hardly "fair and sensible," as the Secretary has asserted, to require someone like respondent to go through the lengthy and necessarily futile process of administrative adjudication. Pet. Br. at 22. To the contrary, litigants are commonly excused from exhaustion where doing so would serve no legitimate objective. *See McCarthy*, 503 U.S. at 148. "Plainly," exhaustion would serve no valid purpose where the "only issue is the constitutionality of a statutory requirement, a matter which is beyond [the agency's]

jurisdiction to determine." *Salfi*, 422 U.S. at 765. Not only would such a requirement be "futile for the applicant," but it would also constitute a "commitment of administrative resources unsupported by any administrative or judicial interest." *Id.* at 765-66.

Moreover, where, as here, "inordinate delay is the hallmark of the [administrative] appeal process," Timothy J. Blanchard, *"Medical Necessity" Denials as a Medicare Part B Cost-Containment Strategy*, 34 St. Louis L.J. 939, 964 (1990), justice delayed is effectively justice denied. In 1998, for example, after the initial denial of a claim by a carrier, the process under Part B took an average of 1 year and 10 months. *See* Testimony of Mike Hash, Deputy Administrator, HCFA, before the House Ways & Means Subcommittee on Health, Medicare Cover Policy Determinations and Appeals (April 22, 1999) (http://www.hcfa.gov/testimony/1999 as of 6/25/99). Part A claimants fare little better. In 1998, the administrative appeals process for Part A claims took an average of 362.9 days after initial denial by carrier. *See id.* This "unreasonable [and] indefinite timeframe," *McCarthy*, 503 U.S. at 146, will inevitably deter numerous individual claimants from pursuing their constitutional or statutory challenges.

Allowing legal challenges to be brought initially in district court also promotes judicial economy. As the Court observed in *Michigan Academy*, the "'validity of a standard can be readily established, at times even in a single case.'" 476 U.S. at 680 n.11 (internal citations omitted). Contrary to the Secretary's argument, *see* Pet. Br. at 22, resolving such challenges at the outset is inherently more efficient than addressing them on a piecemeal basis after numerous individual claims have wound their way through the

administrative process.[16] Whether or not the regulation is upheld, a "pre-enforcement challenge" can "speed enforcement" of administrative policies. *Abbott Labs. v. Gardner*, 387 U.S. 136, 154 (1967). If the regulation is sustained, "its enforcement thereafter can be swift, efficient, and inexpensive." II Kenneth C. Davis & Richard J. Pierce, Jr., ADMINISTRATIVE LAW TREATISE § 15.14 at 376 (3d ed. 1994). Conversely, if the rule is invalidated, "the agency benefits from prompt resolution . . . . [because it] then can begin immediately to pursue an alternative means of performing its statutory missions." *Id.*

In addition, resolving facial challenges outside the administrative process will not, as the Secretary contends, result in lawsuits raising abstract claims that exceed "manageable proportions." Pet. Br. at 27, 28. Basic justiciability rules, *see, e.g., Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992), will ensure that challenges to the Secretary's policies are sufficiently concrete and ripe to be heard in district court. *See Reno v. Catholic Social Servs., Inc.*, 509 U.S. 43 (1993) (dismissing pre-enforcement challenge to immigration regulation as unripe). This case itself is proof of that principle: having determined the district court had jurisdiction, the court of appeals nonetheless declined to reach respondents' claim on the ground that it was premature. Pet. App. at 10a-11a.[17] *See also Stewart*,

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[16]Nor will such review "open the floodgates" to millions of Medicare claims. Dismissing any such concern in *Michigan Academy*, the Court explained that, "[u]nlike the determination of the amounts of benefits," a challenge to the method by which such amounts are calculated "ordinarily affects vast sums of money and thus differs qualitatively" from a dispute over the amount of benefits due. 476 U.S. at 680 n.11.

[17]The court of appeals also remanded to the district court to determine whether respondent's due process challenge was ripe. Pet. App. at 12a.

816 F. Supp. at 287-91 (dismissing pre-enforcement challenge to Secretary's policies as unripe).

The *Michigan Academy* distinction is also consonant with the basic structure of the APA, 5 U.S.C. § 551, *et seq.*, which separates an agency's adjudication of individual matters, *id.* § 554, and its establishment of generally applicable policies through rulemaking. *Id.* § 553. *See generally* Martin Shapiro, *Administrative Discretion: The Next Stage*, 92 Yale L.J. 1487, 1488 (1983) ("[t]he APA essentially divides administrative action into three parts: quasi-judicial adjudication; quasi-legislative rulemaking; and a residual category . . . . [of] 'informal action'"); David L. Shapiro, *The Choice of Rulemaking or Adjudication in the Development of Administrative Policy*, 78 HARV. L. REV. 921 (1965).

In this case, the Secretary seeks to collapse the two, effectively barring challenges under the APA's rulemaking requirements unless they can be raised along with an individual claim for benefits. But, by its very nature, a challenge to the Secretary's compliance with the APA, *e.g.*, its notice and comment rules, should be able to be raised outside the context of an individual dispute. The notice and comment rules serve broad purposes, and the right to receive notice of a proposed rulemaking and to submit comments does not belong solely to individuals who ultimately challenge the application of the agency's rule. Eliminating APA challenges other than those that can be brought in conjunction with an individual administrative claim would seriously limit the right to bring such a challenge, thereby substantially insulating the Secretary's regulations from review.

The Secretary's position would also jeopardize *amici's* and other associations' ability to challenge the legality of the Secretary's Medicare rules and regulations directly affecting

their members. Under Part B, for example, the claimants often are not hospitals or other institutions, but individual beneficiaries and healthcare providers. These individuals are far less suited to bring broad legal challenges to the administration of the Medicare program than associations representing the common interests of their members. Indeed, healthcare associations have done so for years; *Michigan Academy* itself involved such a challenge.[18]

As respondent has noted, *see* Br. in Opp. at 3, such associations cannot file a claim for benefits in the administrative review process. But § 405(g), which the Secretary contends is the exclusive avenue for judicial review, authorizes only "an individual" to file an action in district court for review of a "final decision of the [Secretary] made after a *hearing to which he was a party* * * *." 42 U.S.C. § 405(g) (emphasis added). And a regulation is not a "final decision of the Secretary" under § 405(g). *See Michigan Academy*, 476 U.S. at 679 n.8. Consequently, without the ability to sue under 28 U.S.C. § 1331, an association could *never* challenge the Secretary's rules and regulations.[19] Such a result would run counter to the "strong

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[18]*See, e.g., American Academy of Dermatology v. Department of Health & Human Servs.*, 118 F.3d 1495 (11th Cir. 1997); *American Hosp. Ass'n v. Bowen*, 857 F.2d 267 (5th Cir. 1988); *College of Am. Pathologists v. Heckler*, 734 F.2d 859 (D.C. Cir. 1984); *American Medic. Ass'n v. Weinberger*, 522 F.2d 921 (7th Cir. 1975); *American Medic. Ass'n v. Mathews*, 429 F. Supp. 1179 (N.D. Ill.1977); *Association of Am. Physicians & Surgeons v. Weinberger*, 395 F. Supp. 125 (N.D. Ill. May 1975).

[19]Associations might be able to intervene in an action under Rule 24 of the Federal Rules of Civil Procedure. However, intervention in a case following exhaustion of the administrative process is a poor alternative to bringing a facial challenge under 28 U.S.C. § 1331 because of the unreasonable delays discussed above. By the time an individual determination concerning benefit amounts finds its way to the district court,

presumption that Congress intends judicial review of administrative action," *Michigan Academy*, 476 U.S. at 670, the well-settled right of associations to bring suits on behalf of their members, *see United Food & Commercial Workers Union Local 751 v. Brown Group, Inc.*, 517 U.S. 544 (1996); and the critical role associations have played in challenging program-wide Medicare policies.[20]

CONCLUSION

For the foregoing reasons, the Court should affirm the decision of the court of appeals.

Respectfully submitted,

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the damage done by a defective national payment rule or other regulation could be irreparable.

[20]The Court has held that where administrative appeals will be futile, an individual who has satisfied the Medicare Act's presentment requirements may be excused from completing the administrative process. *Salfi*, 422 U.S. at 764-67. That, however, is not an option for associations, which cannot file a claim in the administrative appeals process.

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