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 TREM CARE, INC.,
Respondent

BRIEF FOR THE RESPONDENT

Filed August 23, 1999

QUESTION PRESENTED

Whether 42 U.S.C. § 405(h), incorporated into the Medicare Act by 42 U.S.C. § 1395ii, precludes jurisdiction under 28 U.S.C. §§ 1331 and 1346 over an action asserting constitutional and statutory challenges to Medicare regulations where the contentions alleged cannot be considered in the administrative review process and are unrelated to an individual claim.

RULE 29.1 STATEMENT

Respondent Illinois Council on Long Term Care, Inc., an Illinois not-for-profit corporation, in compliance with Supreme Court Rule 29.1, states that it has no affiliated corporations, either as a parent, subsidiary or otherwise.

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v.
ILLINOIS COUNCIL ON LONG TERM CARE, INC.

On Writ of Certiorari To The
United States Court of Appeals
For the Seventh Circuit

BRIEF FOR THE RESPONDENT

STATUTORY AND REGULATORY PROVISIONS INVOLVED

Pertinent statutory and regulatory provisions are set forth in the appendix to the Secretary's brief and in the appendix hereto.

STATEMENT OF THE CASE

The Illinois Council on Long Term Care, Inc.

The Illinois Council on Long Term Care, Inc. (the Council), is an Illinois not-for-profit trade association comprised of more than 180 nursing homes. J.A. 19. The Council is chartered to provide continuing education programs to nursing home professionals, problem resolution and advocacy with regulatory agencies and to develop public policy through membership on state and local advisory boards. It maintains a prominent role in representing the long term care community, and serves as a liaison between state, municipal and federal agencies. R. 24, ex. H & I. Its goal is to "foster and maintain a high standard of service to the residents and to the

public in the operation of long term care facilities managed by its members." R.24, ex. I. The Council's Board of Directors has authorized it to pursue this litigation and has deemed the purposes of this litigation as being consistent with the Council's mission. *Id.*

The Council's Complaint

In 1987, Congress amended the Social Security Act with the Omnibus Budget Reconciliation Act, Pub. L. No. 100-203, §§ 4201-4218, 101 Stat. 1330 (1987) (OBRA 87). See Pet. App. 14a. The amendments called for stricter guidelines and more severe penalties for providers not satisfying minimum health and safety standards. 42 U.S.C. § 1395i-3. The Secretary published regulations implementing the minimum health and safety standards on October 1, 1990. 42 C.F.R. § 483, Subparts E and F. The Council does not challenge or seek to overturn the health and safety standards. J.A. 17.

OBRA 87 directed the Secretary to develop enforcement regulations for nursing facilities participating in Medicare and Medicaid. 42 U.S.C. § 1395i-3(g)(1)(A). Implementing enforcement regulations for the 1987 amendments, however, did not take effect until July 1, 1995 (hereafter 1995 Regulations). Pet. App. 1a. Before the 1995 Regulations went into effect, 6% of nursing homes in Illinois were found to be out of compliance with the requirements to participate in Medicare and Medicaid. Pet. App. 14a. After the 1995 regulations went into effect, nearly 70% of nursing homes in Illinois were found deficient. Pet. App. 2a, 14a.

The Council filed suit in federal district court challenging the 1995 Regulations and seeking declaratory and injunctive relief. The Council asserts constitutional and statutory challenges to the 1995 Regulations and to a State Operations Manual (hereinafter SOM) used by government inspectors of nursing homes. J.A. 17, 49-53. The Council's Amended Complaint seeks declaratory and injunctive relief regarding the following statutory and constitutional claims:

a) The Secretary's 1995 enforcement regulations are void for vagueness;

b) The 1995 Regulations and SOM violate the APA because they are substantive rules that deviate from and exceed the legislative mandate of federal statutes;

c) The administrative review system contained in the 1995 regulations is so restrictive that it violates procedural due process; and

d) The Secretary has failed to adequately implement programs to measure and reduce inconsistency in survey results in violation of the Social Security Act.[1]

Statutory and Regulatory Framework

The Declaratory Judgment Act

From the founding of the nation, the federal courts have been viewed as the safeguard against unconstitutional laws passed by Congress. The courts also have been viewed as a check on the executive branch if it exceeded its authority in implementing the law. The Constitution, as signed in 1787, gave this Court (and other courts as Congress may establish) jurisdiction over cases arising under the Constitution and federal law, and jurisdiction over cases where the United States is a party.[2]

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[1] For additional information on the merits of the Council's claims, see the Joint Appendix which contains the Council's Amended Complaint and relevant portions of the SOM. See also Pet. Brief 8-13.

[2] Article III of the U.S. Constitution declares in pertinent part:
Section 1: The judicial Power of the United States, shall be vested in one Supreme Court, and in such inferior Courts as the Congress may from time to time ordain and establish.
Section 2: Clause 1: The judicial Power shall extend to all Cases, in Law and Equity, arising under the Constitution, the Laws of the United States, and . . . to Controversies to which the United States shall be a Party . . . .

The Council's jurisdictional bases in this case, 28 U.S.C. § 1331 (federal question), and 28 U.S.C. § 1346 (United States as a defendant),[3] derive ultimately from Article III of the Constitution. This Court and the lower federal courts have a long history of declaring statutes and regulations unconstitutional in appropriate cases.

In 1934, Congress enacted a federal declaratory judgment statute. See 28 U.S.C. § 2201.[4] During the enactment process, Congress recognized the declaratory judgment's utility in testing the validity of statutes. The Senate Report states that "now it is often necessary, in the absence of the declaratory judgment procedure, to violate or purport to violate a statute in order to obtain a judicial determination of its meaning or validity." S. Rep. No. 1005, 73rd Cong., 2d. Sess., at 2-3 (1934). The Report continues: "In jurisdictions having the declaratory judgment procedure, it is not necessary to bring about such social and economic waste and destruction in order to obtain a determination of one's rights." *Id.* at 3. Since its enactment in 1934, the Declaratory Judgment Act frequently has been used to challenge the validity of statutes or regulations in section 1331 cases.

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[3] 28 U.S.C. § 1331 provides: "The district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States."

28 U.S.C. § 1346 provides in pertinent part:

> (a) The district courts shall have original jurisdiction, concurrent with the United States Court of Federal Claims, of . . . (2) Any other civil action or claim against the United States, not exceeding $10,000 in amount, founded either upon the Constitution, or any Act of Congress, or any regulation of an executive department . . . .

[4] The current federal declaratory judgment statute reads in pertinent part:

> In a case of actual controversy within its jurisdiction, . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

28 U.S.C. § 2201 (original version at 28 U.S.C. § 400 (1934)).

The Social Security Act

Congress passed in 1935 the Social Security Act. See ch. 531, 49 Stat. 620. Its purpose is to provide benefits to protect against some of the burdens of modern existence through payments in the form of annuities to the elderly and compensation to workers during periods of unemployment. *E.g., United States v. Silk*, 331 U.S. 704, 710 & n.5 (1947) (citing legislative history).

In 1939, Congress amended the Social Security Act by adding administrative and judicial review provisions for individuals applying for benefits. Those provisions appear (as amended) at 42 U.S.C. § 405(b), (g) and (h). See Social Security Act Amendments of 1939, ch. 666, 53 Stat. 1360. Section 405(h) reads, in its entirety:

> The findings and decisions 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, United States Code, *to recover on any claim arising under this title.*

42 U.S.C. § 405(h) (emphasis added). As the highlighted language demonstrates, section 405(h) on its face encompasses only actions "to recover on any claim arising under this title."

The Administrative Procedure Act

Seven years later, in 1946, Congress enacted the Federal Administrative Procedure Act (APA), ch. 324, 60 Stat. 237 (codified as amended at 5 U.S.C. §§ 551-559, 701-706). It was "a new, basic and comprehensive regulation of procedures in many agencies," *Wong Yang Sung v. McGrath*, 339 U.S. 33, 36 (1950), and it provided minimum standards of administrative procedure. Section 703 of the APA provides that in the absence

or inadequacy of a special statutory forum to challenge administrative action, a party can bring any form of legal challenge, including declaratory judgments and injunctions, in a court of competent jurisdiction:

> The form of proceeding for judicial review is the special statutory review proceeding relevant to the subject matter in a court specified by statute or, in the absence or inadequacy thereof, any applicable form of legal action, including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus, in a court of competent jurisdiction. . . .

5 U.S.C. § 703. The legislative history for the APA contains the following statement by the Senate Committee on the Judiciary:

> Very rarely do statutes withhold judicial review. It has never been the policy of Congress to prevent the administration of its own statutes from being judicially confined to the scope of authority granted or to the objectives specified. Its policy could not be otherwise, for in such a case statutes would in effect be blank checks drawn to the credit of some administrative officer or board.

S. Rep. No. 752, 79th Cong., 1st Sess., at 26 (1945). Accord H.R. Rep. No. 1980, 79th Cong., 2d. Sess., at 41 (1946). The legislative history further establishes the "clear and convincing evidence" standard of proof to preclude judicial review when statutes are not specific in withholding review:

> To preclude judicial review under this bill a statute, if not specific in withholding such review, must upon its face give clear and convincing evidence of an intent to withhold it. The mere failure to provide specially by statute for judicial review is certainly no evidence of intent to withhold review.

H.R. Rep. No. 1980, 79th Cong., 2d. Sess., at 41 (1946). The legislative history of section 703 of the APA also reveals that Congress intended that pre-enforcement declaratory judgment actions would continue to be used to test the validity of administrative action:

> Declaratory judgment procedure, for example, may be operative before statutory forms of review are available and may be utilized to determine the validity or application of any agency action. By such an action the court must determine the validity or application of a rule or order, render a judicial declaration of rights, and so bind an agency upon the case stated and in the absence of a reversal.

Id. at 42 (1946). Accord S. Rep. No. 752, 79th Cong., 1st Sess., at 26 (1945).

The Medicare Act

In 1965, Congress amended the Social Security Act, adding Title XVIII -- the Medicare Act -- to provide medical insurance for the elderly and disabled. Pub. L. No. 89-97, 79 Stat. 291 (codified as amended at 42 U.S.C. § 1395 *et seq.*). The Medicare Act established an expansive new federal program with complex provisions, including requirements for program participation and amounts of benefits for many medical services. Regarding appeal rights and judicial review of administrative determinations, Medicare simply incorporated by reference the hearing and judicial review provisions of sections 405(b), (g) and (h) from the Social Security Act. See 42 U.S.C. §§ 1395ff(a) and (b) (if an individual participating in Part A of Medicare Program is not satisfied with entitlement or amount of benefits, that individual is entitled to hearing and judicial review as provided by sections 405(b) and (g)); 42 U.S.C. § 1395cc(h) (if provider is dissatisfied concerning compliance determinations, certification or termination of provider agreement, administrative appeal and judicial review is provided through sections 405(b) and (g)); and 42 U.S.C. § 1395ii (incorporating 42 U.S.C. § 405(h) into Medicare Act).[5]

[5] In 1965, Congress also amended the Social Security Act with Title XIX -- the Medicaid Act. Congress did not, however, incorporate into the Medicaid Act sections 1395ii or 405(h). See Pet App. 7a. Amount determinations and claims for benefits under Medicaid are not determined by Secretary, but by the state Medicaid agency.

On their face, these provisions pertain only to individual claims regarding benefits or provider status.

The District Court Decision

In its Amended Complaint, the Council asserted separate counts on behalf of its 75 members who participate solely in Medicaid, and separate counts for the remainder who participate in both Medicare and Medicaid. Pet. 7, n.5. The district court dismissed all counts of the complaint for lack of subject matter jurisdiction. Pet. App. 3a.[6]

The district court held that 42 U.S.C. § 405(h) deprived it of jurisdiction because the Council's claims "arise under" the Medicare act, relying on *Heckler v. Ringer*, 466 U.S. 602 (1984). Pet. App. 16a. The district court also construed the amended complaint as a "claim for benefits," Pet. App. 17a, even though the complaint was for "injunctive and declaratory relief." Pet. App. 13a. The district court also declined to follow *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986). It concluded that because Congress amended the Medicare Act to provide appeal rights under Part B, "the concern noted in *Michigan Academy*, no longer exists because all participants now have an avenue of judicial review within HHS." Pet. App. 18a.

The Seventh Circuit Decision

The Seventh Circuit reversed, holding that the Council's lawsuit is not an action "to recover" on a claim arising under Medicare within the meaning of section 405(h), and therefore, is not barred. Pet. App. 6a. The court followed the more recent precedent of *Michigan Academy* instead of *Heckler v. Ringer*. The court acknowledged that "*Ringer and Salfi* [422 U.S. 749 (1975)] treat [405(h)'s] language as channeling all *claims to benefits* through the administrative forum, no matter what legal theory underlies the claim." Pet. App. 4a (emphasis added). It recognized, however, that this Court more recently in *Michigan Academy*, 476 U.S. at 678-81, held "that § 1395ii (which incorporates 405(h)) does not foreclose Medicare providers' anticipatory challenge to implementing regulations." Pet. App. 4a. The Seventh Circuit also rejected the district court's conclusion that in *Michigan Academy* this Court carved out an "exception" to statutory exhaustion requirements. Writing for the panel, Judge Easterbrook explained that *Michigan Academy* does not say that a presumption of judicial review justifies an exception to exhaustion requirements. Pet. App. 6a. Rather, *Michigan Academy* says that section 1395ii, in light of its legislative history, pertains to individual amounts determinations. *Id.*

In addition, the Seventh Circuit rejected the Secretary's argument (and the conclusion of the district court) that "*Michigan Academy* ceased to have any precedential force a few months after it was issued." Pet. App. 4a. The Seventh Circuit explained that "[s]hortly after the Court decided *Michigan Academy*, Congress amended the Medicare Act to give providers an avenue of judicial review of amount determinations, 42 U.S.C. § 1395ff(b)(1), thus overturning the result of *United States v. Erika, Inc.*, 456 U.S. 201, 102 S. Ct. 1650, 72 L.Ed.2d 12 (1982)." Pet. App. 4a-5a. This amendment, however, did not cause *Michigan Academy's* entire holding to lose its precedential force. *Id.* at 5a. The Seventh Circuit observed that, after the amendments, this Court "in 1991 reiterated its conclusion that § 1395ii does not affect regulatory challenges that are detached from any request for reimbursement." *Id.* at 5a (citing *McNary v. Haitian Refugee Center, Inc.*, 498 U.S. 479, 497-98 (1991)). The Seventh Circuit recognized that the 1986 amendments allowed additional review for "*amount determinations*" under Part B. The Seventh Circuit explained that "[n]ow that Congress has authorized review of amount determinations through § 1395ff(b)(1), that part of *Michigan Academy's* rationale is gone--the invalidity of regulations would be a good reason for a reviewing court to

[6] The Seventh Circuit reversed the district court's dismissal of the Medicaid counts. Pet. App. 7a-9a. The Secretary does not challenge that part of the Seventh Circuit's decision. See Pet. 7, n.5; see also Pet. Brief 15-16, n.14. Accordingly, the Seventh Circuit's conclusion that a Medicaid provider is not prevented from bringing a pre-enforcement challenge under section 1331 to a Medicaid regulation is not before the Court. See Pet. App. 9a.

upset an *amount determination*." Pet. App. 5a (emphasis added). But the Seventh Circuit further explained that "[n]either this critical language from § 405(h) nor the history of § 1395ii changed in 1986. . . . The operative language is the same now as when *Michigan Academy* came down." Pet. App. 6a-7a.

The Seventh Circuit further concluded that the Council has standing as a trade association to bring its claims: "If some nursing homes may litigate on their own, they may litigate through their trade association; we don't see why the fact that other members of the Council have potential Medicare claims should cut off associational representation and compel independent litigation." Pet. App. 8a.[7]

The Seventh Circuit also reversed the district court's conclusion that jurisdiction did not exist under the Medicaid Act (which contains no provisions like sections 1395ii or 405(h)). Pet. App. 7a-8a. The Seventh Circuit recognized that general federal question jurisdiction under § 1331 exists and it

[7] There is no dispute that the Council has standing. This Court has long recognized that "[e]ven in the absence of injury to itself, an association may have standing solely as the representative of its members." *Warth v. Seldin*, 422 U.S. 490, 511 (1975). Several of the cases relied upon by the Secretary and the Council were brought by associations suing on behalf of their members. See *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986); *Abbott Laboratories v. Gardner*, 387 U.S. 136, 138 (1967); *McNary v. Haitian Refugee Center, Inc.*, 498 U.S. 479, 487 (1991). This Court's long-standing test regarding associational standing was articulated in *Hunt v. Washington Apple Advertising Comm'n*, 432 U.S. 333 (1977). That the Council satisfies the *Hunt* test has not been disputed by either court below. The Secretary's brief does not argue that the Council lacks standing. Therefore, standing is not an issue before this Court.

There also can be no argument that this case is mooted by the interim final rule promulgated by the Department of Health and Human Services on July 23, 1999. See Medicare and Medicaid Program; Appeal of the Loss of Nurse Aid Training Programs, 64 Fed. Reg. 39,934 (1999). This action by the Secretary remedies only a small subset of the Due Process violations complained of by the Council. The Council's APA claim remains unchanged. Moreover, "voluntary cessation of a challenged practice" does not deprive this Court of the power to hear this case. See *City of Mesquite v. Aladdin's Castle, Inc.*, 455 U.S. 283, 289 (1982).

supplies the avenue of judicial review. Pet. App. 7a.

The Seventh Circuit rejected "across the board" the Sixth Circuit's decision in *Michigan Association of Homes & Services for the Aging, Inc. v. Shalala*, 127 F.3d 496 (CA6 1997), *reh'g denied*, 1997 U.S. App. LEXIS 37154 (CA6 1997). Pet. App. 8a. The Sixth Circuit, in contrast with the Seventh Circuit decision below, concluded that: (1) so long as a plaintiff's standing and substantive bases for its claims arise under the Medicare Act, section 405(h) bars judicial review (following *Weinberger v. Salfi*, 422 U.S. 749 (1975) and *Heckler v. Ringer*, 466 U.S. 602, 622 (1984)); (2) *Michigan Academy* and *McNary* carve out an exception to 405(h) in cases of futility; (3) the "exception to exhaustion" of *Michigan Academy* did not apply, and that exhaustion was required; and (4) exhaustion is not futile because a nursing home could raise constitutional claims in a federal court after exhausting administrative remedies.[8]

The Seventh Circuit panel's decision was unanimous. On the Secretary's petition for rehearing, even though the decision created a split with the Sixth Circuit, the majority of active judges on the Seventh Circuit, including the three panel judges, voted against rehearing *en banc*. Pet. App. 22a-23a.

SUMMARY OF THE ARGUMENT

1. The plain language of sections 405(b), (g) and (h) of the Social Security Act demonstrates that Congress intended section 405(h) to preclude only *individual* claims for benefits for which there is an available administrative hearing under section 405(b), and which would result in a decision by the Secretary that could be reviewed meaningfully in an appeal to a

[8] The Sixth Circuit also held that jurisdiction over the Association's claims pertaining to Medicaid was precluded, even though the Medicaid Act did not incorporate the jurisdictional bar of section 405(h). *Michigan Association*, 127 F.3d at 502-3. By not contesting the Seventh Circuit's conclusion that jurisdiction exists for Medicaid, the Secretary is tacitly conceding the Sixth Circuit's error in concluding that jurisdiction is barred for claims arising under Medicaid. Even though the Secretary does not contest Medicaid jurisdiction here, this Court should overrule the Sixth Circuit's Medicaid holding to resolve the circuit split on that point.

district court under section 405(g). When sections 405(b), (g) and (h) were incorporated by reference into the Medicare Act through sections 1395ff, 1395cc(h) and 1395ii, the meaning and purpose of those provisions did not change. The plain language of the Medicare provisions again reveals congressional intent to require exhaustion only of individual claims regarding benefits or provider status. The legislative history confirms this conclusion. Moreover, this Court held in *Bowen v. Michigan Academy of Family Physicians,* 476 U.S. 667, 680 (1986), that section 1395ii pertains to individual "amount determinations," and that other claims, such as challenges to the validity of regulations, are not barred. The Seventh Circuit below simply followed that holding of *Michigan Academy*.

2. The Secretary's statutory construction would deny meaningful review of statutory and constitutional challenges to the validity of the Secretary's regulations. A district court considering an administrative appeal under section 405(g) is limited to the administrative record and may only affirm, modify or reverse a decision of the Secretary. The Secretary concedes that statutory and constitutional challenges to regulations cannot be raised in the administrative review process. Consequently, there will be neither a decision nor an administrative record regarding such issues for a federal court to review on appeal, as this Court observed in *McNary v. Haitian Refugee Center Inc.*, 498 U.S. 479, 496-97 (1991). Moreover, the plain language of section 405(g) reveals that a reviewing district court considers only the validity of Secretary's regulations regarding an individual's burden of proof in an administrative hearing. Neither the language nor legislative history of section 405(g) suggests that Congress intended for federal courts to consider broad statutory and constitutional challenges under section 405(g).

3. Properly construed, sections 1395ii and 405(h) do not divest federal courts of plenary jurisdiction over the Council's case. The Council asserts constitutional and statutory challenges to specific regulations and enforcement practices. This Court has long embraced the view that statutory or constitutional

challenges to regulations are collateral to a substantive claim of entitlement, and that jurisdiction exists for such claims. Here, the Council is not asserting an individual claim. The Council is a trade association; it has no provider agreement. Because the Council has no access to the administrative review process, and its constitutional and statutory challenges could not be considered in an administrative appeal in any event, section 405(h) does not bar its lawsuit.

4. *Michigan Academy* and *McNary* compel affirmance of the Seventh Circuit's decision. In *Michigan Academy* this Court rejected many of the Secretary's arguments here. This Court held that challenges to regulations cannot be considered in the administrative review process, and that such claims are cognizable in courts of law. 476 U.S. at 680. This Court recognized that a challenge to the validity of a regulation is not a challenge to a "decision" after a "hearing" as those words appear in section 405(h). *Id.* at 674, n.8. The Secretary's argument that *Michigan Academy* lost precedential value after the 1986 amendments lacks merit because this Court has continued to rely on *Michigan Academy* after 1986. As the Seventh Circuit concluded, the amendments did not change the operative language of sections 405(h) and 1395ii, nor the viability of *Michigan Academy*'s holding. *McNary* likewise supports affirmance. In *McNary*, this Court held that the words "a determination" describe "a single act rather than a group of decisions or a practice or procedure employed in making decisions." 498 U.S. at 492. This Court further held that federal court jurisdiction is available when a claimant "would not as a practical matter be able to obtain meaningful judicial review" after exhausting administrative remedies. *Id.* at 496.

5. The Secretary's policy arguments are irrelevant in this statutory construction case, and in any event, are meritless. The traditional justifications for exhaustion do not apply here. No agency expertise exists for the Council's challenges; nor would consideration of the Council's case be facilitated if raised in an individual administrative proceeding because ALJ's cannot consider such issues. The Declaratory Judgment Act and the

APA reveal congressional intent that challenges to the validity of regulations can be asserted pre-enforcement. Federal courts should exercise their traditional jurisdiction in such cases to: (a) deter administrative agencies from exceeding their legislative authority through unconstitutional rules and regulations; and (b) mitigate the widespread irreparable harm that occurs when agencies have done so.

ARGUMENT

I. CONGRESS DID NOT INTEND TO PRECLUDE INITIAL JUDICIAL REVIEW OF THE COUNCIL'S CHALLENGES TO THE SECRETARY'S REGULATIONS AND ENFORCEMENT PRACTICES.

The narrow issue before the Court is whether 42 U.S.C. § 405(h), (incorporated into the Medicare Act by 42 U.S.C. § 1395ii), which precludes initial judicial review of individual determinations regarding claims for benefits and provider status, also precludes initial judicial review of the Council's challenges to the Secretary's constitutional and statutory regulations and enforcement practices. See *McNary v. Haitian Refugee Center, Inc.*, 498 U.S. 479, 491 (1991) (defining the issue). Whether a statute is intended to preclude initial judicial review is determined from the statute's language, structure, and purpose, its legislative history, *Block v. Community Nutrition Inst.*, 467 U.S. 340, 345 (1984), and whether the claims can be afforded meaningful review. See, *e.g., Thunder Basin Coal Co, v. Reich, 510 U.S. 200, 207 (1994); Board of Governors, FRS v. MCorp Financial, Inc.*, 502 U.S. 32, 43 (1991); *Whitney Nat'l Bank in Jefferson Parish v. Bank of New Orleans & Trust Co.*, 379 U.S. 411, 420-21 (1965). An examination of these factors in this case compels the conclusion that the statutory provisions at issue were not intended to preclude initial judicial review of the Council's challenges to the Secretary's regulations and enforcement practices.

A. The Plain Language of the Statutes Demonstrates That Congress Did Not Intend to Divest the Federal Courts of Initial Jurisdiction Over the Council's Challenges to the Secretary's Regulations and Practices.

In a statutory construction case, the beginning point in the analysis must be the language of the statute. *Estate of Cowart v. Nicklos Drilling Co.*, 505 U.S. 469, 475 (1992). When a statute speaks with clarity to an issue, judicial inquiry into the statute's meaning, in all but the most extraordinary circumstance, is finished. *Demarest v. Manspeaker*, 498 U.S. 184, 190 (1991).

1. Section 405(h) requires exhaustion only of individual claims for Social Security benefits.

The plain language of Section 405(h) and its companion provisions demonstrates that they pertain only to *individual* claims for *benefits* that can be raised in the administrative review process. Section 405(h) precludes review of a "decision" of the Secretary after a "hearing . . . . except as herein provided." Pet. Brief App. 3a. The section 405(h) phrase "except as herein provided" in the second sentence refers to section 405(g). H.R. Rep. No. 728, 76th Cong., 1st Sess., at 43-44 (1939) (there shall be no review of the Board's decisions "except as provided in subsection (g)."). Section 405(g) in turn provides for district court review of any "final decision of the Secretary made after a hearing." The "hearing" referenced in both 405(g) and 405(h) is the administrative hearing provided in section 405(b), as the Secretary concedes. Pet. Brief 3.

The Secretary argues that section "405(h) renders the administrative and judicial review procedures under Section 405(b) and (g) exclusive." Pet. Brief 3. It is exclusive, however, only for the *types of claims* that can be brought in an administrative hearing under 405(b), namely, individual claims for benefits. This is made plain from the heading for section 405(b), which reads: "Administrative determination of *entitlement to benefits;* findings of fact; hearings;

investigations; evidentiary hearings . . . ." 42 U.S.C. § 405(b) (emphasis added). App., *infra*, 1a. Section 405(b)(1) reads: "The Secretary is directed to make findings of fact, and decisions as to the rights of *any individual applying for a payment* under this subchapter." (emphasis added). Section 405(g) reads: "Any *individual,* after any final decision of the Secretary . . . made after *a hearing* . . . may obtain a review of *such decision* . . . ." (emphasis added) App., *infra*, 4a. Thus, reading section 405(h) in context with 405(b) and 405(g), it is clear that 405(h) precludes only individual claims for benefits for which there is an administrative hearing and a decision by the Secretary.

The Secretary argues that Congress used the words "to recover" in some broad sense. (Pet. Brief 39 (citing dictionaries)). This argument, however, is defeated by the plain language of section 405(h) and sections 405(b) and (g). The conclusion is inescapable that section 405(h) as originally enacted pertained to individual claims for benefits for which there is an administrative hearing and final decision. Even though Congress subsequently has incorporated section 405(h) elsewhere, it still pertains to individual claims for some kind of entitlement for which there is an administrative hearing and a final decision.

The plain statutory language thus reveals that section 405(h) applies to the types of individual claims for benefits that can be raised in an administrative hearing under 405(b), and which can be reviewed on appeal by a district court under 405(g). Claims that cannot be raised in a hearing under 405(b), and that cannot be appealed under 405(g), are not subject to 405(h)'s preclusive effect. *Michigan Academy*, 476 U.S. at 478. No evidence exists in the statutory language that Congress intended that these provisions would preclude initial judicial review of statutory or constitutional challenges unrelated to individual benefits claims.

2. Medicare Act Section 1395ff requires exhaustion only of individual claims for benefits.

When Congress amended the Social Security Act in 1965 with the Medicare Act, Congress simply incorporated by reference the administrative review provisions of 405(b) and (g) via 42 U.S.C. §§ 1395ff(b) and 1395cc(h). The Medicare Act incorporates 405(h) in 42 U.S.C. § 1395ii. When Congress incorporated 405(b), (g) and (h) into Medicare, the meaning and purposes of those provisions did not change.

The plain language of 42 U.S.C. § 1395ff reveals that it also pertains only to individual claims for benefits. See 42 U.S.C. § 1395ff(a) ("The determination of whether an *individual* is entitled to *benefits* under part A or part B . . . shall be made by the Secretary . . . ." (emphasis added)), App., *infra*, 5a; 42 U.S.C. § 1395ff(b)(1) ("Any *individual* dissatisfied with any determination under subsection (a) . . . shall be entitled to *a hearing* thereon . . . as is provided in section 405(b) of this title and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title." (emphasis added)), App., *infra*, 5a. Section 1395ff's purpose to provide review of individual claims for benefits is further demonstrated by the amount in controversy thresholds found in section 1395ff(b)(2)(A): "[U]nder part A of this subchapter, a hearing shall not be available to an individual . . . if the amount in controversy is less than $100 and judicial review shall not be available to the individual . . . if the amount in controversy is less than $1,000 . . . ." App., *infra*, 6a-7a. Hence, section 1395ff pertains to individual claims for benefits.

3. Medicare Act Section 1395cc(h) requires exhaustion only of individual claims regarding provider status.

As the Secretary concedes: "If a provider wishes to dispute a determination concerning compliance or certification – or termination or non-renewal of its provider agreement – 42 U.S.C. 1395cc(h) provides that it may do so through the

hearing and review procedures under 42 U.S.C. 405(b) and (g)." Pet. Brief 4-5. Thus, section 1395cc(h) pertains to *individual* determinations regarding provider status. It speaks of *"a determination* by the Secretary that *it is not a provider* of services." App., *infra*, 9a (emphasis added), Section 1395cc(h) also references "a determination described in subsection (b)(2) of this section." *Id.* Subsection (b)(2), in turn, includes among other things, a refusal to enter into a provider agreement with, or termination of such an agreement with an individual provider. See § § 1395cc(b)(2); App., *infra*, 8a-9a. The language of sections 1395cc(b)(2) and (h), therefore, plainly demonstrates that they pertain to *individual* provider status claims.

B. The Legislative History Confirms That Congress Did Not Intend to Divest the Federal Courts of Initial Jurisdiction Over Constitutional and Statutory Challenges to the Secretary's Regulations.

The 1939 legislative history pertaining to sections 405(b), (g) and (h) is consistent with the plain language of the statutes. This Court has repeatedly looked to a statute's legislative history as an aid to determining its meaning, and has recognized the reliability of committee reports from the earlier part of this century. See, *e.g.*, *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 610 (1991) ("Our precedents demonstrate that the Court's practice of utilizing legislative history reaches well into its past. We suspect that the practice will likewise reach well into the future."); *Thornburg v. Gingles*, 478 U.S. 30, 44, n.7 (1986) ("We have repeatedly recognized that the authoritative source for legislative intent lies in the Committee Reports on the bill."); *Garcia v. United States*, 469 U.S. 70, 76-77 (1984), *reh'g denied*, 469 U.S. 1230 (1985) (relying on 1935 Committee Reports to examine congressional intent); *Michigan Academy*, 476 U.S. at 676-78 (relying on 1965 Committee Reports).

The Senate Report prefaces its discussion of section 405 by stating, "[t]his section of the bill provides a detailed procedure in connection with *benefit determination and payment."* S. Rep. No. 734, 76th Cong., 1st Sess., at 51 (1939) (emphasis added). It states that section 405(b) "outlines the general functions of the Board in determining *rights to benefits.* It requires the Board to offer opportunity for a hearing, upon request, *to an individual* whose rights are prejudiced by any decision of the Board." *Id.* (emphasis added). After stating that 405(g) allows judicial review of a final administrative decision, the report notes that "[t]he present provisions of the Social Security Act do not specify what remedy, if any, is open to *a claimant* in the event *his claim to benefits* is denied by the Board." *Id.* at 52 (emphasis added). Statements in the House Report regarding section 405 are virtually identical to the above report of the Senate. See H.R. Rep. No. 728, 76th Cong., 1st Sess., at 42-44 (1939). Compare *Weinberger v. Salfi*, 422 U.S. 749, 792, n.8 (1975) (Brennan, J., dissenting: "[A]t their inception, the exhaustion provisions which became §§ 405(g) and (h) were clearly intended to apply only to run-of-the-mill claims under the statutory provisions, in which factual determinations would be paramount.").

Similarly, the legislative history of section 1395ff confirms that section 1395cc(h) pertains to individual provider status claims. Section 1395cc(h) originally appeared at 42 U.S.C. § 1395ff(c). See 42 U.S.C. § 1395ff(c) (1976); see also Pet. Brief 5, n.3. The legislative history of section 1395ff states that current section 1395cc(h) provided hospitals, extended care facilities, and home health agencies with a hearing and judicial review "if they are dissatisfied with the Secretary's determination regarding their eligibility to participate in the program." S. Rep. No. 404, 89th Cong., 1st Sess., pt. 1, at 55 (1965); H.R. Rep. No. 213, 89th Cong., 1st Sess., at 47 (1965). Section 1395cc(h) thus pertains to individual provider status claims. No evidence exists that Congress intended section 1395cc(h) to prohibit broad statutory or constitutional challenges to regulations.

The Secretary relies heavily on a single sentence in a Senate Report from the Medicare Act's 1965 legislative history which reads: "It is intended that the remedies provided by these

review procedures *shall be exclusive."* Pet. Brief 22 (emphasis added). That sentence does not appear in the companion House Report. See H.R. No. 213, 89th Cong., 1st Sess., at 47 (1965). Moreover, the Secretary ignores the context of the paragraph. The full paragraph shows that the "review procedures" pertain to "individual" claims for benefits or provider status:

> The committee's bill provides for the Secretary to make determinations, under both the hospital insurance plan and the supplementary plan, as to whether *individuals* are entitled to hospital insurance *benefits* or supplementary medical insurance *benefits* and for hearings by the Secretary and judicial review where an *individual* is dissatisfied with the Secretary's determination. Hearings and judicial review are also provided for where an *individual* is dissatisfied with *a determination* as to the *amount of benefits* under the hospital insurance plan if the amount in controversy is $1,000 or more. (Under the supplementary plan, carriers, not the Secretary, would review beneficiary complaints regarding the *amount of benefits*, and the bill does not provide for judicial review of *a determination* concerning the *amount of benefits* under part B where claims will probably be for substantially smaller amounts than under part A.) Hospitals, extended care facilities, and home health agencies would be entitled to hearing and judicial review if they are dissatisfied with the Secretary's *determination regarding their eligibility to participate* in the program. It is intended that the remedies provided by these review procedures shall be exclusive.

S. Rep. No. 404, 89th Cong., 1st Sess., pt. 1, at 54-55 (1965) (emphasis added).

The sentence the Secretary quotes is no evidence that collateral statutory and constitutional claims are barred by section 405(h). The Senate Report shows only an intent to provide review of individual claims for benefits or provider status, and not any intent to exclude initial jurisdiction over collateral statutory and constitutional challenges.

C. The Broader Statutory Scheme Confirms That Congress Did Not Intend To Divest The Federal Courts of Jurisdiction Over Constitutional And Statutory Challenges to the Secretary's Regulations.

The Seventh Circuit's construction of the statutory provisions at issue is consistent with a broader scheme of relevant statutes. Passage of the federal declaratory judgment statute in 1934 confirmed Congress' intent that declaratory judgment actions could be used to test the validity of federal laws. Congress believed declaratory judgment actions would be used avoid the "social and economic waste and destruction" from having "to violate or purport to violate a statute in order to obtain a judicial determination of its meaning or validity . . . ." S. Rep. No. 1005, 73rd Cong., 2d. Sess., at 2-3 (1934). Five years later, in 1939, Congress amended the Social Security Act with the administrative and judicial review provisions of 42 U.S.C. § 405(b), (g) and (h) for individual benefits claims, but took no steps to withdraw traditional remedies in federal court for challenging the validity of regulations.

Seven years later, in 1945, Congress passed the Administrative Procedure Act ("APA"). The legislative history of the APA says that "[i]t has never been the policy of Congress to prevent the administration of its own statutes from being judicially confined . . . for in such a case statutes would in effect be blank checks drawn to the credit of some administrative officer or board." S. Rep. No. 752, 79th Cong., 1st Sess., at 26 (1945). Congress specifically provided in 5 U.S.C. § 703 that in the "absence or inadequacy" of a special statutory review proceeding, "any applicable form of legal action, including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus, [is available] in a court of competent jurisdiction . . . ." The legislative history to section 703 further reveals that both houses of Congress agreed that *pre-enforcement* declaratory judgment actions would continue to be used to test the validity of statutes:

> Declaratory judgment procedure, for example, may be operative before statutory forms of review are available and may be utilized to determine the validity or application of any agency action. By such an action the court must render a judicial declaration of rights, and so bind an agency upon the case stated and in the absence of a reversal.

H.R. Rep. No. 1980, 79th Cong., 2d. Sess., at 42 (1946); accord S. Rep. No. 752, 79th Cong., 1st Sess., at 26 (1945). Section 405(h) should be viewed in context with the Declaratory Judgment Act and the APA where Congress expressed its intent that jurisdiction would exist for pre-enforcement challenges to the validity of agency action. The Secretary's construction of 405(h) conflicts with those seminal acts.

D. The Secretary's Statutory Construction Would Deny Meaningful Judicial Review.

The Secretary argues that *Michigan Academy* does not support initial jurisdiction in this case because section 405(g) expressly confirms the district court's power to "review . . . the validity of . . . [the Secretary's] regulations" when it reviews the Secretary's final decision. Pet. Brief 47. However, if a district court cannot *meaningfully* review the validity of the Secretary's general regulations and practices, no exhaustion is required. *McNary*, 498 U.S. at 498-99.

In fact, the Secretary's position is undermined by "the strong presumption that Congress intends judicial review of administrative action." *Michigan Academy*, 476 U.S. at 670. See also, *e.g.*, *Barlow v. Collins*, 397 U.S. 159, 166-67 (1970); *Dunlop v. Bachowski*, 421 U.S. 560, 567 (1975); *Traynor v. Turnage*, 485 U.S. 535, 540 (1988); *Reno v. Catholic Soc. Servs.*, 509 U.S. 43, 63-64 (1993). These principles have been invoked time and again when considering whether the Secretary has discharged her "heavy burden" of overcoming the "strong presumption" of meaningful judicial review. *Michigan Academy*, 476 U.S. at 671-72 (quoting *Dunlop v. Bachowski*, 421 U.S. 560, 567 (1975)). See also, Louis Jaffe, The Right to

Judicial Review I, 71 Harv. L. Rev. 401, 432 (1958) ("[J]udicial review is the rule. It rests on the congressional grant of general jurisdiction to the Article III courts. It is a basic right; it is a traditional power and the intention to exclude it must be made specifically manifest."). The presumption of review is the starting point, and only upon a showing of clear and convincing evidence is it overcome. *Michigan Academy*, 476 U.S. at 670 ("We begin with the strong presumption . . . .") (emphasis added); *McNary*, 498 U.S. at 498-99 ("strong presumption . . . is not overcome by the language or the purpose of the relevant provisions of the Reform Act."). In *McNary*, this Court applied the strong presumption even though a review mechanism existed for individual SAW claims whereby a claimant could appeal to a circuit court. 498 U.S. at 485-86, 498-99. Thus, the strong presumption exists even when some review is provided for certain types of claims, because the review provided may be inadequate for the types of claims at issue.[9] See 5 U.S.C. § 703 (in the absence or inadequacy of a special statutory review proceeding any applicable form of legal action is available).

Under the Secretary's interpretation of the statute, the Council would not be able to obtain meaningful judicial review of its constitutional and statutory claims if it is forced to submit to the administrative review process. On its face, section 405(g) limits the scope of the district court's review to the administrative record, and gives "power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the Commissioner of Social Security, with or without remanding the cause for a rehearing." Pet. Brief App. 1a. Obviously, if the Secretary has

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[9] The Secretary erroneously relies on *Thunder Basin Coal Company v. Reich*, 510 U.S. 200 (1994) for the contention that the presumption does not apply here because there is post-enforcement judicial review of the Council's claims. In *Thunder Basin*, this Court declined to apply the presumption because there was meaningful "court of appeals review" of the relevant claims. 510 U.S. at 207 n.8, 212-214. Here, there is no *meaningful* post-enforcement federal court review of the Council's claims. See *McNary*, 498 U.S. at 498 (applying presumption where post-enforcement judicial review was not meaningful).

provided no "hearing" in which to adjudicate constitutional or statutory claims, there will be no "final decision" and no administrative record regarding such claims for a court to "affirm, modify or reverse." See *Michigan Academy*, 476 U.S. at 679, n.8. Administrative law judges lack authority to hear statutory or constitutional challenges to regulations.[10] The Secretary admits that "[n]either the Departmental Appeals Board nor individual ALJs are free to depart from statutory and regulatory requirements." Pet. Brief 45. Moreover, section 405(g) "contains no suggestion that a reviewing court is empowered to enter an injunctive decree whose operation reaches beyond the particular applicants before the court." *Weinberger v. Salfi*, 422 U.S. 749, 763, n.8 (1975).

Furthermore, the Secretary exaggerates the scope of a district court's powers in a section 405(g) appeal. The plain language of section 405(g) reveals that the "regulations" that can be reviewed pertain to an individual's burden of proof to establish his claim to benefits, rather than the agency's regulations and practices generally. The "regulations" referred to in section 405(g) are regulations promulgated under section 405(a), which requires the Secretary to establish rules and regulations for processing individual claims for benefits. Section 405(g) reads in pertinent part:

> where a claim has been denied by the Commissioner of Social Security or a decision is rendered under subsection (b) of this section which is adverse to an individual who was a party . . . because of failure *of the claimant* or such individual to *submit proof* in conformity with any *regulation prescribed under subsection (a)* of this section, the court shall review only the question of conformity with *such regulations* and the validity of *such regulations*.

App., *infra*, 4a (emphasis added). Contrary to the Secretary's

[10] *E.g., Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 676, n.6 (1986); *American Ambulance Service, Inc. v. Sullivan*, 911 F.2d 901, 905 (CA3 1990), *aff'd without opinion*, 947 F.2d 934 (CA3 1991); 42 C.F.R. § 1005.4(c)(1), (4).

contentions, section 405(g)'s language shows that Congress intended section 405(g) courts to review individual claims and "such regulations" that bear on whether an individual has met his burden of proof in the specific individual hearing being reviewed. Indeed, a precondition to reviewing the validity of the regulation is an individual's failure to submit proof in such a hearing. The plain language does not establish that Congress intended section 405(g) courts to review broad statutory and constitutional challenges unrelated to an individual claim for benefits. Moreover, the legislative history of section 405(g) confirms this. It reads in pertinent part: "Where a decision of the Board is based on a failure to submit proof in conformity with a regulation, the court may review only the question of *conformity of the proof with the regulation* and the validity of *the regulation*." H.R. Rep. 728, 76th Cong., 1st Sess., at 43 (1939); Accord S. Rep. No. 734, 76th Cong., 1st Sess., at 51 (1939) (emphasis added). The legislative history gives no indication that Congress was considering statutory or constitutional challenges to regulations generally.

This Court rejected in *McNary* the Secretary's argument that constitutional and statutory claims adequately can be "deferred." In *McNary*, the Immigration and Naturalization Act ("INA") provided for administrative review and thereafter judicial review by the court of appeals regarding decisions on amnesty applications. This Court concluded that the limited post-exhaustion judicial review provided could not adequately address the statutory and constitutional claims at issue. *McNary*, 498 U.S. at 484, 496-97. Administrative and judicial review of an agency decision "is almost always confined to the record made in the proceeding at the initial decisionmaking level . . . ." *Id.* at 496. The lack of an adequate administrative record at the initial decision making level meant that the court of appeals would have no "meaningful basis upon which to review application determinations." *Id.* By contrast, a district court exercising section 1331 jurisdiction as a trial court with its "fact finding and record-developing capabilities," is an adequate forum for challenges to the validity of regulations. *Id.* at 497.

The same analysis applies here. In a section 405(g) appeal, the district court is limited to the administrative record of a hearing. The Council's statutory and constitutional claims cannot be considered in an administrative hearing. There accordingly would be no evidence taken and no administrative record compiled regarding the Council's statutory and constitutional claims for a federal court to review in a 405(g) appeal. As in *McNary,* restricting judicial review to the limited scope of section 405(g) "is the practical equivalent of total denial of judicial review of generic constitutional and statutory claims." *Id.* at 497. Therefore, even if Congress did intend to preclude all review of statutory and constitutional claims until a 405(g) appeal, which it did not, section 1331 jurisdiction is available because a district court in a 405(g) appeal is an inadequate forum.

Practical considerations of cost and delay in the administrative process further underscore the inadequacy of the Secretary's review scheme. Administrative appeal rights are triggered only by imposition of a "remedy." See 42 C.F.R. § 498.3(b)(12). If a provider cures the alleged deficiency before a remedy is imposed, it loses its appeal rights. Thus, when an inspection results in deficiencies, a provider must choose between: (a) refusing to correct the alleged deficiency and risking termination of its provider agreement in order to appeal the deficiency; or (b) remedying the alleged deficiency and thereby forfeiting appeal rights. Providers rarely refuse to comply just so that they can appeal. Because nursing facilities generally "knuckle under" rather than appeal, challenges to the validity of a regulation will rarely, if ever, reach the 405(g) appeal stage.

For this reason, the Secretary's argument that "post-enforcement review" is available and adequate rings hollow. During the first six months after the effective date of the 1995 Regulations, literally thousands of nursing homes had sanctions proposed against them. But only 3.6% of those providers received a penalty such that any *administrative*

review was available, much less judicial review.[11] This fact belies the Secretary's argument that a 405(g) appeal is adequate for statutory and constitutional claims. The Secretary's proposed system simply does not work for statutory and constitutional claims. For over four years, the Secretary has had the kind of "blank check" that Congress deplores. S. Rep. No. 752, 79th Cong., lst Sess., at 26 (1945); H.R. Rep. No. 1980, 79th Cong., 2d. Sess., at 41 (1946).

The Secretary also contends that other provisions of the Medicare Act, like 42 U.S.C. §§ 1395cc(f)(1) and 1395ff(b)(3), provide a mechanism for meaningful review of the Council's claims. Pet. Brief 47-48. The Secretary ignores, however, that section 1395oo(f)(1) "certification" by the Provider Reimbursement Review Board (PRRB) is not available here because the Council is not a provider bringing a reimbursement claim. Nor does the Council's suit raise "national coverage decisions" within the meaning of section 1395ff(b)(3). Pet. Brief 47-48. Thus, the provisions relied on by the Secretary provide no mechanism available to the Council for meaningful review of its statutory and constitutional challenges to the Secretary's regulations and enforcement practices.

Because the statutory scheme does not permit meaningful post-enforcement review of the Council's claims, the Secretary's position boils down to the obviously untenable contention that there is no federal court review of the constitutionality of rules and regulations that the Secretary herself enacted. The Constitution does not permit the fox to guard the hen house in this manner, but instead ensures that the federal judiciary will be the ultimate arbiter of the legitimacy of administrative rulemaking action. *Gutierrez De Martinez v. Lamagno*, 515

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[11] Between July 1, 1995 and January 1, 1996, there were 21,351 nursing home surveys (8711 "standard surveys" plus 12,640 "complaint surveys"). J.A. 77; Brief of Amicus Curiae American Association of Homes and Services for the Aging 18 (AAHSA Brief). Penalties were proposed in 14,386 of these cases. J.A. 78; AAHSA Brief at 18. Of these, a sanction was imposed in only 523 cases (3.6%), triggering the provider's administrative appeal right.

U.S. 417, 424 (1995) (quoting *United States v. Nourse*, 34 U.S. (9 Pet.) 8, 28-29 (1835)). For that reason, there must be clear and convincing evidence of legislative intent for a court to restrict access to meaningful judicial review. *Lindahl v. Office of Personnel Management*, 470 U.S. 768, 779 (1984). "[O]nly upon a showing of 'clear and convincing evidence' of a contrary legislative intent should the courts restrict access to judicial review." *Abbott Laboratories v. Gardner*, 387 U.S. 136, 141 (quoting *Rusk v. Cort*, 369 U.S. 367, 379-80 (1961)); see also *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 410 (1970); *Johnson v. Robison*, 415 U.S. 361, 373-74 (1974); *Gutierrez De Martinez v. Lamagno*, 515 U.S. 417, 424 (1995); H.R. Rep. No. 1980, 79th Cong., 2d. Sess., at 41 (1946) ("To preclude judicial review . . . a statute, if not specific in withholding such review, must upon its face give clear and convincing evidence of an intent to withhold it.").

Here, the Secretary has identified no evidence -- either from the plain language of the statutes, the pertinent legislative history or from any other source -- that Congress intended to deprive the federal courts of plenary jurisdiction over the types of constitutional and statutory challenges brought by the Council here. Rather, the evidence points unmistakably to the conclusion that the exhaustion of administrative remedies is not a precondition to federal court review of these claims.

E. Properly Construed, the Statutes Afford Initial Judicial Review Over the Council's Claims As Set Forth In Its Amended Complaint.

The Amended Complaint alleges no individual provider status claim and makes no individual benefits claim. The Council asserts a facial challenge to statutory procedures and practices. The Council contends: (a) that the 1995 Regulations are unconstitutionally vague; (b) that the 1995 Regulations and SOM violate the APA; (c) that the administrative review

mechanism of the 1995 Regulations is so restrictive that it violates due process; and (d) that the Secretary has failed to take adequate steps to reduce inconsistency in survey results in violation of the Social Security Act. See J.A. 17-19, 51-52.

This Court has long embraced the view that statutory or constitutional challenges to a regulation or policy, like those asserted by the Council in this case, are collateral to a substantive claim of entitlement, and that federal courts have jurisdiction for such claims. See *Johnson v. Robison,* 415 U.S. at 373 (jurisdiction exists for action challenging constitutionality of veterans benefits legislation); *Abbott Laboratories v. Gardner*, 387 U.S. at 148 (jurisdiction exists for pre-enforcement review of pharmaceutical regulations); *Mathews v. Eldridge,* 424 U.S. 319, 330-32 (1976) (upholding federal question jurisdiction over systemic and constitutional challenge to administrative procedures established by the Secretary); *Bowen v. New York*, 476 U.S. 467, 483-86 (1976); *Michigan Academy*, 476 U.S. at 670; *McNary*, 498 U.S. at 497-98. This Court has thus recognized that there is a difference between a collateral constitutional challenge and an individual claim of entitlement. *E.g., Mathews*, 424 U.S. at 330-31.

To illustrate, the class action complaint in *McNary* alleged that the INS had engaged in unlawful practices and policies in administering one of its programs and that the interview process was arbitrary, depriving applicants of due process. 498 U.S. at 487-88. This Court held that the claim was collateral to any individual determination of an application. *McNary*, 498 U.S. at 492; see also *id.* at 497-98 ("[in *Michigan Academy*] [w]e recognized that review of individual determinations of the amount due on particular claims was foreclosed, but upheld the *collateral attack* on the regulation itself, emphasizing the critical difference between an individual 'amount determination' and a challenge to the procedures for making such determinations. . . ."). (emphasis added) See also *Bowen v. New York*, 476 U.S. at 483 ("[t]he claims in this lawsuit are collateral to the claims for benefits . . . [t]he class members neither sought nor were awarded benefits in the

District Court, but rather challenged the Secretary's failure to follow the applicable regulations.").

Likewise, the Council facially attacks certain aspects of the enforcement program, allegations which are "beyond the scope of administrative review." *McNary*, 498 U.S. at 488. The Council's lawsuit falls squarely within this Court's precedents recognizing jurisdiction over collateral challenges. Sections 405(g) and (h) are tailored to individual determinations and do not refer to general collateral challenges. *Id.* at 492-93.

The Secretary's position is based on the erroneous contention that the Council is asserting a claim for benefits, and that therefore the Council's claims are "indistinguishable" from those asserted in *Ringer* and *Salfi*. Pet. Brief 42. However, as this Court has concluded before, *Ringer* and *Salfi* have no bearing on the issues here. In *Ringer* itself, this Court characterized the claims "essentially as claims for benefits." *Heckler v. Ringer*, 466 U.S. 602, 609, n.4 (1984). In *McNary* this Court discussed *Ringer* at length and found that it did not apply. *McNary*, 498 U.S. at 494-96 (concluding that claims in *Ringer* were claims for benefits). In *Michigan Academy*, this Court clarified that in *Ringer* the preclusion of judicial review was not extended beyond the Part B "amount determinations" at issue there. *Michigan Academy*, 476 U.S. at 677, n.7. The Secretary's claim that the Seventh Circuit's reading of *Michigan Academy* is in "irreconcilable conflict" with *Ringer* is hyperbole, because *Ringer* is not relevant to the issue here. Pet. Brief 34.

Likewise, in *Weinberger v. Salfi*, this Court referred to "suits, such as this one, which seek to recover Social Security benefits." 422 U.S. at 757. In describing the proceedings below, this Court noted that the district court granted a judgment "directing the Secretary to pay Social Security benefits." *Id.* at 761. *Salfi*, therefore, addressed only the availability of judicial review of an individual benefits determination. In contrast with *Ringer* and *Salfi*, the Council is not pursuing an individual benefits claim, just as in *McNary*,

New York, Michigan Academy and *Reno*. Indeed, it is difficult to imagine how claims could be more "collateral" than the Council's here.

The Secretary also cites *United States v. Erika, Inc.*, 456 U.S. 201 (1982), contending that review mechanisms are exclusive. Pet. Brief 24. However, the respondent in *Erika* was asserting a "claim for benefits." It argued that reimbursement under Part B for certain medical supplies should be based on the cost of the goods sold, including recent price increases. *Erika*, 456 U.S. at 204-05. The carrier instead used the price in its catalog as of July 1 of the previous calendar year. *Id.* at 209. After an unsuccessful hearing before the carrier, respondent filed suit in the U.S. Court of Claims. The Court of Claims accepted jurisdiction and found in respondent's favor on the merits. *Id.* This Court reversed, concluding that the Court of Claims lacked jurisdiction.

After analyzing the statutory provisions and the legislative history of the Medicare Act, this Court concluded that Congress intended to preclude jurisdiction over amounts determinations under Part B. *Erika*, 456 U.S. at 208. This Court quoted several statements in the legislative history whereby Congress clarified its determination that Part B amounts determinations were too insignificant for administrative and judicial review. *Id.* at 208-9. Significantly, respondent did not assert any constitutional or statutory challenges to the applicable regulations before this Court. Thus *Erika* is immaterial to the Council's collateral constitutional and statutory challenges.

Equally misplaced is the Secretary's reliance on this Court's recent decision in *Your Home Visiting Nurse Services, Inc. v. Shalala*, 119 S. Ct. 930 (1999). See Brief in Opp. 7-9. In that case, this Court held that the Provider Reimbursement Review Board ("PRRB") lacked jurisdiction to review a fiscal intermediary's refusal to reopen a reimbursement determination. This Court rejected petitioner's "fallback argument" that judicial review of the refusal to reopen was available under either

section 1331, mandamus or the APA's judicial review provision. *Your Home*, 119 S. Ct. at 935-36. The petitioner in *Your Home* was seeking reimbursement of certain Medicare claims upon "new and material evidence." *Id.* at 933. It was not asserting a collateral constitutional or statutory claim. Of course, the Secretary is not blind to the difference between an individual claim for benefits and a collateral attack to the validity of a regulation. As the Secretary recognized in her merits brief in *Your Home:*

> [Petitioner's claim] does not attack the underlying validity of a regulation; it simply avers that the intermediary misapplied a regulation when determining the amount of reimbursable owners' compensation costs owed to petitioner. Thus, petitioner's contentions do not resemble the sort of facial challenge that the Court in *Michigan Academy* found to be beyond the scope of Section 405(h)'s preclusive effect.

Your Home Visiting Nurse Services, Inc. v. Shalala, Resp. Brief at 31, 1998 WL 644663.

The fallacy of the Secretary's "claim for benefits" argument is more apparent when considering that the Council, a trade association, has no access at all to the Secretary's administrative review mechanism. Because of its status, the Council could not assert a claim for benefits even if it wanted to. The Council likewise is not a "provider of services" that has or seeks a provider agreement within the meaning of 42 U.S.C. § 1395cc(h). On their face, therefore, the administrative review provisions of the Medicare Act do not apply to the Council.

Because the Council has no access to the administrative review process, section 405(h) does not bar its claims. *Michigan Academy of Family Physicians v. Blue Cross and Blue Shield of Michigan,* 757 F.2d 91, 94 (CA6 1985), *aff'd, Michigan Academy,* 476 U.S. 667 (1986). In *Michigan Academy,* this Court granted certiorari twice. "We first granted . . . certiorari to allow the Court of Appeals to consider its jurisdictional ruling in light of *Heckler v. Ringer." Michigan*

Academy, 476 U.S. at 669, n.2. On remand, the Sixth Circuit specifically addressed whether the academy of physicians, a non-profit corporation, was entitled to challenge the regulation at issue since section 405(g) was not available to it, as it was to individual claimants. The Sixth Circuit held that *Heckler v. Ringer* did not proscribe review where challenge is made by a party other than a claimant for benefits. *Michigan Academy of Family Physicians,* 757 F.2d at 94. This Court affirmed in *Bowen v. Michigan Academy of Family Physicians,* 476 U.S. 667 (1986) ("[The Association's] attack on the regulation here is not subject to [an exhaustion] requirement because there is no hearing, and thus no administrative remedy, to exhaust."). *Id.* at 679, n.8.

Similarly in *Rosado v. Wyman,* 397 U.S. 396 (1970), *reh'g denied,* 398 U.S. 914 (1970), this Court held that exhaustion was inapplicable where petitioners could not have obtained an administrative ruling because "HEW has no procedures whereby welfare recipients may trigger and participate in the Department's review of state welfare programs." *Id.* at 406 (citing *Abbott Laboratories,* 387 U.S. 136). See also *Nader v. Alleghany Airlines, Inc.,* 426 U.S. 290, 302 (1976) (individual consumers are not entitled to initiate administrative proceedings, which indicates that Congress did not intend to require consumers to exhaust before proceeding with common law remedies). The same reasoning applies here. The Secretary's contention that the Council is seeking to "bypass the express statutory mechanisms for judicial review provided by the Medicare Act" is insupportable. See Pet. Brief 26-27.

II. *MICHIGAN ACADEMY* AND *McNARY* COMPEL AFFIRMANCE OF THE DECISION BELOW.

A. *Michigan Academy*

1. *Michigan Academy* Rejects Arguments Made By the Secretary Here.

In *Michigan Academy,* this Court confronted and rejected many of the Secretary's arguments here. *Michigan Academy* involved a challenge to the validity of a regulation by a trade association of physicians. The regulation authorized the payment of benefits in different amounts for similar physicians' services. *Michigan Academy,* 476 U.S. at 668. However, the lower courts struck down the regulation. On certiorari, the Secretary contested jurisdiction. The Secretary argued that Congress precluded federal question jurisdiction through 42 U.S.C. §§ 1395ff and 1395ii (which incorporates section 405(h)). *Id.* at 668. This Court considered the language and legislative history of both sections 1395ff (see *id.* at 674-678) and 1395ii (*id.* at 678-681). This Court held that federal question jurisdiction existed and affirmed the lower courts. Those same statutes, particularly section 1395ii and section 405(h), are at issue here.

The Secretary contended in *Michigan Academy* that section 1395ff(b) "impliedly" foreclosed administrative or judicial review of any action taken under part B. 476 U.S. at 674. This Court disagreed:

> Section 1395ff on its face is an explicit authorization of judicial review, not a bar. As a general matter, "[the] mere fact that some acts are made reviewable should not suffice to support an implication of exclusion as to others. The right to review is too important to be excluded on such slender and indeterminate evidence of legislative intent."

Id. at 674 (quoting *Abbott Laboratories,* 387 U.S. at 141 (citations omitted)). Significantly, when *Michigan Academy* was decided, section 1395cc(h), which authorizes administrative review under section 405(g) of individual provider status claims, was included within section 1395ff at subsection (c). See Pet. Brief 5, n.3. Thus, this Court's analysis of section 1395ff in *Michigan Academy* is probative of congressional intent regarding section 1395cc(h). See 476 U.S. at 680, n.10 ("[I]t bears mention that the legislative history

summarized in the preceding section speaks to provisions for appeal generically, and is thus as probative of congressional intent in enacting § 1395ii as it is of § 1395ff." (citing legislative history)).

This Court recognized in *Michigan Academy* that judicial review existed because certain claims cannot be considered during the administrative review process. 476 U.S. at 676 ("the legality, constitutional or otherwise, of any provision of the Act or regulations relevant to the Medicare Program is not considered in a "fair hearing" held by a carrier to resolve a grievance related to a determination of the amount of a Part B award."). The same applies here. Administrative law judges, like the hearing officers in *Michigan Academy,* cannot use "hearing decisions as a vehicle for commenting upon the legality, constitutional or otherwise, of any provision of the Act or regulations relevant to the Medicare Program." *Id.* at 667, n.6. This Court concluded that "matters which Congress did not leave to be determined in a 'fair hearing' conducted by the carrier--including challenges to the validity of the Secretary's instructions and regulations--are not impliedly insulated from judicial review by 42 U.S.C. 1395ff." *Id.* at 678.

This Court in *Michigan Academy* also construed the language and legislative history of sections 1395ii and 405(h). This Court rejected the Secretary's contention that sections 1395ii and 405(h) bar challenges to regulations. As she does here, the Secretary relied heavily on the "arising under" analysis of *Ringer* and *Salfi*. 476 U.S. at 679. This Court declined to apply the "abstract" and over-simplified "arising under" analysis and instead relied on the language and legislative history of the statutes:

> Whichever may be the better reading of *Salfi* and *Ringer*, we need not pass on the meaning of § 405(h) in the abstract to resolve this case. . . . The legislative history of both the statute establishing the Medicare program and the 1972 amendments thereto provides specific evidence of Congress' intent to foreclose 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." By the same token, matters which Congress did not delegate to private carriers, such as challenges to the validity of the Secretary's instructions and regulations, are cognizable in courts of law. 476 U.S. at 680.

This Court further rejected the Secretary's argument that a challenged regulation is a "decision of the Secretary" which the second sentence of section 405(h) excepts from review. 476 U.S. at 674, n.8. This Court stated that such an argument "ignores the contextual definition of 'decision' in the first sentence as those determinations made by 'the Secretary after a hearing.'" *Id.* Clearly, the Council here is *not* challenging through this lawsuit a "decision" of the Secretary after a "hearing." The Secretary holds no "hearings" to determine the constitutionality of her regulations. This Court also rejected the Secretary's contention that its decision would "open the floodgates." *Id.* at 681, n.11. This Court recognized that permitting review only of a particular statutory or administrative standard would not result in a costly flood of litigation, because the validity of a standard can be readily established, at times even in a single case. *Id.* (quoting Note, 97 Harv. L. Rev. 778, 792 (1984)).

The Seventh Circuit below simply followed, in straightforward fashion, this Court's interpretation of particular statutes and their legislative history in *Michigan Academy*. The Seventh Circuit declared: "As the Court read § 1395ii and therefore § 405(h) in *Michigan Academy,* pre-enforcement review of a regulation's validity 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. 6a. As its opinion indicates, the Seventh Circuit carefully considered *Salfi* and *Ringer,* but it chose to follow the more recent and more precise holding of *Michigan Academy*.

2. The Secretary's Attempt To Avoid *Michigan Academy* Does Not Survive Scrutiny.

In an attempt to avoid *Michigan Academy,* the Secretary argues that the case lost value as precedent soon after it was decided because of Medicare amendments passed as part of the Omnibus Budget Reconciliation Act of 1986 (OBRA 86), Pub. L. No. 99-509, § 9341, 100 Stat. 2037-38. Pet. Brief 36-37. This argument is meritless, as the Seventh Circuit concluded. This Court often has relied on *Michigan Academy* even after the 1986 OBRA amendments. Moreover, both the textual changes to 42 U.S.C. § 1395ff in 1986 and the legislative history reveal that the amendments did not alter the force and viability of *Michigan Academy's* reasoning and holding. Contrary to the Secretary's contentions, the Seventh Circuit's conclusion regarding the vitality of *Michigan Academy* is not an anomaly. See Pet. Brief 33-34.

Two years after *Michigan Academy* (and after the 1986 amendments), this Court repeatedly quoted from *Michigan Academy* in *Traynor v. Turnage,* 485 U.S. 535 (1988), concluding that jurisdiction existed for a challenge over whether a Veteran's Administration regulation violated the Rehabilitation Act. 485 U.S. at 543. Five years after *Michigan Academy,* this Court revisited its holding in *McNary v. Haitian Refugee Center, Inc.,* 498 U.S. 479 (1991), and confirmed that federal question jurisdiction existed over systemic and constitutional challenges to regulatory procedures under the Immigration Reform and Control Act of 1986 ("IRCA").

Since 1991, this Court has approved the holdings of *Michigan Academy* and *McNary* in other cases, including *Reno v. Catholic Social Services, Inc.,* 509 U.S. 43, 64 (1993) (following *McNary* and citing to *Michigan Academy)*; *Thunder Basin Coal Company v. Reich,* 510 U.S. 200, 213-14 (1994) (citing *Michigan Academy* and discussing but distinguishing *McNary)*; and *Gutierrez De Martinez v. Lamagno,* 515 U.S. 417, 424 (1995) (citing *Michigan Academy*). Hence, *Michigan Academy* has retained its precedential value and the Seventh

Circuit was obliged to follow it.

The amendments upon which the Secretary relies to avoid the holding of *Michigan Academy* were adopted as part of OBRA 86. The amendments granted Part B claimants the same hearing and appeal rights previously enjoyed by Part A claimants, subject to certain amount-in-controversy restrictions. They remedied a gap in judicial review for individual benefit claims recognized in *United States v. Erika, Inc.*, 456 U.S. 201 (1982).

As the Seventh Circuit explained, OBRA 86 did not amend either section 405(h) or 1395ii. The amendments, on their face, granted only *greater* judicial review to certain Part B claims and certainly did not expressly take jurisdiction away regarding other claims. The legislative history confirms this. The House Report explains why Part B claimants had not previously enjoyed administrative and judicial review (in large part because of the volume and small amounts of money involved). It then concludes that additional review nevertheless is necessary because of concerns regarding the fairness and adequacy of carrier "fair hearings." H.R. Rep. No. 99-727, at 95 (1986), *reprinted in* 1986 U.S.C.C.A.N. 3607, 3685. Similarly, the Conference Report only addresses judicial review of coverage determinations. It does not address statutory or constitutional challenges to regulations. H.R. Conf. Rep. No. 99-1012, at 350 (1986), *reprinted in* 1986 U.S.C.C.A.N. 3868, 3995. The author of the Medicare amendments 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. And it ensures that beneficiaries and providers who feel wronged by Medicare's decisions have access to appeal." 132 Cong. Rec. E3799 (1986) (statement of Rep. Ron Wyden) (emphasis added). This statement demonstrates an intent to provide *additional* protection (administrative and judicial) to what this Court recognized in *Michigan Academy*.

This Court encountered a similar situation in *Lindahl v. Office of Personnel Management*, 470 U.S. 768 (1984). There, this Court held that an amendment to a statute did not eliminate judicial review: "There is certainly nothing on the face of the . . . amendment suggesting that Congress intended to discard [judicial] review generally while expanding upon it in a particular category of cases." *Lindahl*, 470 U.S. at 782. This Court further stated that "[i]f Congress had intended by the 1980 amendment not only to expand judicial review . . . but to abolish the standard in all other cases as well, there would presumably be some indication in the legislative history to this effect." *Id.* at 787. The same rationale applies here. There is no hint in either the text or legislative history of OBRA 86 that Congress intended to restrict or rescind jurisdiction for collateral statutory and constitutional challenges. Thus, under the analysis in *Lindahl*, the 1986 amendments do not bar the Council's statutory and constitutional claims.

The Secretary's attempt to paint the Seventh Circuit's analysis of *Michigan Academy* as an aberration also is belied by numerous lower court opinions that have correctly reached the same conclusion as the opinion by Judge Easterbrook. See, *e.g.*, *Vermont Assembly of Home Health Agencies, Inc. v. Shalala*, 18 F. Supp.2d 355, 362 (D. Vt. 1998) (even though the statutory scheme has been altered, this Circuit still recognizes that courts have subject matter jurisdiction over a challenge to a rule of general applicability); *Abbott Radiology Associates v. Sullivan*, 801 F. Supp. 1012, 1017-1018 (W.D.N.Y. 1992) ("the 1986 amendments did not displace the reasoning in *Michigan Academy*, and courts have explicitly acknowledged *Michigan Academy's* continuing vitality."); *Abbey v. Sullivan*, 788 F. Supp. 165, 168 n.2 (S.D.N.Y. 1992) ("Contrary to defendant's assertions, the 1986 amendments to Medicare Part B do not render *Michigan Academy* a 'dead letter.'") *aff'd*, 978 F.2d 37 (CA2 1992); *Griffith v. Bowen*, 678 F. Supp. 942, 945 (D. Mass 1988) (there is no tension between *Michigan Academy* and the 1986 amendments). See also *United States, Qui Tam Body v. Blue Cross and Blue Shield of Alabama*, 156 F.3d 1098 (CA11 1998) (following *Michigan Academy* without suggesting that

the 1986 amendments affected its holding).

The circuit court decisions, which the Secretary cites (Pet. Brief 36-37) in arguing that *Michigan Academy* no longer is good law, did not involve collateral statutory or constitutional challenges. The conclusions in those cases that the 1986 amendments gave administrative review for the individual benefits claims at issue do not support the conclusion that jurisdiction is eliminated for collateral statutory and constitutional claims. See *National Kidney Patients Ass'n. v. Sullivan,* 958 F.2d 1127 (CADC 1992), *cert. denied,* 506 U.S. 1049 (1993) (the plaintiffs challenge a decision to change the level of benefits awarded under a program for dialysis patients; no statutory or facial constitutional challenge asserted); *American Academy of Dermatology v. Dept. of Health and Human Services,* 118 F.3d 1495, 1499 (CA11 1997) (court determined that the case was really a "claim for benefits" under the Medicare Act which implicated section 405(g)); *Martin v. Shalala,* 63 F.3d 497, 503 (CA7 1995) (involved a claim for benefits and not systemic statutory and constitutional challenges); *Farkas v. Blue Cross and Blue Shield of Michigan,* 24 F.3d 853, 854 (CA6 1994) (plaintiff challenged a decision by an insurance carrier to place him under "Medicare Prepayment Utilization Review"; case did not involve a broad statutory or constitutional challenge); *Abbey v. Sullivan,* 978 F.2d 37, 41-42 (CA2 1992) (concerned claims for medical benefits and the procedure followed on appeal from a specific benefit decision).

Because the Secretary has failed to establish any error in the Seventh Circuit's decision and because *Michigan Academy* remains good law, this Court should affirm the Seventh Circuit's judgment.

B. *McNary* Also Compels Affirmance of the Decision Below.

This case also is closely analogous to *McNary v. Haitian Refugee Center,* 498 U.S. 479 (1991). There, this Court analyzed section 210(e)(1) of the amended Immigration and

Naturalization Act and determined that the words "of a determination respecting an application" and "a determination" regarding SAW status described "a single act rather than a group of decisions or a practice or procedure employed in making decisions." 498 U.S. at 492. This Court concluded that such language described "the process of direct review of *individual* denials of SAW status, rather than . . . general collateral challenges to unconstitutional practices and policies used by the agency in processing applications. *Id.* (emphasis added); accord *Reno v. Catholic Social Services,* 506 U.S. 43, 56 (1993) (following *McNary,* concluding that "a determination respecting an application" precludes review of denials of individual applications, and rejecting argument that it precludes challenges to the legality of a regulation).

Significantly, this Court affirmed jurisdiction in *McNary* even though some judicial review ostensibly existed under IRCA. Under the administrative review mechanism in *McNary,* an individual SAW claimant could appeal to a circuit court. See 8 U.S.C. § 1160(e)(3). The review provided by section 1160(e)(3), however, was so limited that without section 1331 jurisdiction "the respondents would not as a practical matter be able to obtain meaningful judicial review. . . ." *McNary,* 498 U.S. at 496. This conclusion thus forecloses the Secretary's argument that *Michigan Academy* was limited to its facts, wherein no review was available for challenges under Part B of Medicare. *McNary* in fact expanded the holding of *Michigan Academy* to encompass instances where limited judicial review exists, but would not adequately address statutory and constitutional claims at issue. *McNary's* holding is completely consistent with section 703 of the APA which allows judicial review in the "absence or inadequacy" of a special statutory review proceeding.

III. THE SECRETARY'S POLICY ARGUMENTS ARE BETTER DIRECTED TO CONGRESS THAN THIS COURT.

The Secretary argues that it is "fair and sensible" to

require exhaustion for this case. Pet. Brief 22. This is a policy argument better directed to Congress. Before this Court, this case only "concern[s] the construction of existing statutes. The relevant question is not whether, as an abstract matter, the rule advocated by petitioners accords with good policy. . . . Courts are not authorized to rewrite a statute because they deem its effects susceptible of improvement." *Badaraco v. Commissioner of Internal Revenue*, 464 U.S. 386, 398 (1984); see also *TVA v. Hill*, 437 U.S. 153, 194-95 (1978) ("Our individual appraisal of the wisdom or unwisdom of a particular course selected by the Congress is to be put aside in the process of interpreting a statute. . . .We do not sit as a committee of review, nor are we vested with the power of veto.")

Even if the Secretary's policy arguments were somehow relevant to this statutory construction case, they are unpersuasive because the traditional justifications for exhaustion do not apply here. The Secretary has failed to assert any "agency expertise" for the issues raised in the Amended Complaint. "Nor is there any reason to believe that the [Secretary] has any special expertise in assessing the validity of [her] regulations . . . ." *Traynor*, 485 U.S. at 544 .

The Secretary argues that "challenges [should] be brought in the context of a specific enforcement action." Pet. Brief 22. This argument is undermined by the federal declaratory judgment statute itself, a primary purpose of which was to enable parties to challenge the validity of statutes and avoid the "waste and destruction" that comes from having to violate a statute to test its validity. S. Rep. No. 1005, 73 Cong., 2d. Sess., at 2-3 (1934). See also Schwartz, *Administrative Law* 537 (2d ed. 1984) ("In federal administrative law, the injunction and/or declaratory judgment has become the general-utility remedy by which the legality of an administrative act may be determined . . . ."). Furthermore, in enacting the APA, both houses of Congress expressed an intent that pre-enforcement declaratory judgment actions may continue to be used to test the validity of statutes. H.R. Rep. No. 1980, 79th Cong., 2d. Sess., at 42 (1946); accord S. Rep. No. 752, 79th Cong., 1st Sess., at

26 (1945) (declaratory judgment procedure may be operative before administrative review is available). This expression of congressional intent defeats the Secretary's argument that claims must be brought in specific enforcement actions. This Court has recognized that the "legislative material elucidating that seminal act manifests a congressional intention that it cover a broad spectrum of administrative actions." *Abbott Laboratories*, 387 U.S. at 140.

Moreover, the Secretary fails to offer any evidence of congressional intent that a regulatory challenge like this cannot be brought in a representational setting. As the Seventh Circuit stated, "[i]f some nursing homes may litigate on their own, they may litigate through their trade association; we don't see why the fact that other members of the Council have potential Medicare claims should cut off associational representation and compel independent litigation." Pet. App. 8a.

This is not a situation in which consideration of the underlying legal issues would necessarily be facilitated if they were raised in the context of a specific attempt to enforce the regulations. *Gardner v. Toilet Goods Ass'n.*, 387 U.S. 158, 165-66 (1967). Exhaustion would be futile because the only issues in *this* type of case cannot be raised in an administrative hearing, there will be no factual findings made, and no agency expertise to apply. It is simply implausible that Congress intended such futility and delay. The Council has asserted systemic, facial challenges, not challenges to the regulations "as applied" to a single nursing facility. For the Council's type of claims, a court is not reviewing factual and discretionary decisions of an administrative law judge or Appeals Board in a run-of-the-mill benefits determination. *Oestereich v. Selective Service Bd.*, 393 U.S. 233, 241 (Harlan, J., concurring) (a claim of facial invalidity of a procedure does not require a court to review the factual and discretionary decisions inherent in the classification or processing of registrants). "Where the constitutionality of a statute or other act is challenged as facially invalid, the administrative process is unlikely to contribute anything to the resolution of

the challenge." Schwartz, *supra*, 518.

The Secretary also contends that exhaustion prevents "overly casual . . . judicial intervention in an administrative process." Pet. Brief 22 (quoting *Ringer* and *Salfi*). The language quoted from *Ringer* contains the phrase (omitted by the Secretary) "overly casual *or premature* judicial intervention in an administrative system." *Ringer*, 466 U.S. at 627 (emphasis added); see also *Salfi*, 422 U.S. at 749 (exhaustion generally required "as a matter of preventing *premature interference* with agency processes . . ." (emphasis added)). There is nothing "premature or overly casual" about a federal court considering systemic statutory or constitutional challenges to regulations already being applied. This becomes clearer when considering the dual roles of administrative agencies.

"[A]dministrative agencies typically have both legislative and judicial powers concentrated in them. They have authority to issue rules and regulations that have the force of law (power that is legislative in nature) and authority to decide cases (power judicial in nature)." Schwartz, *supra*, 10. In the exercise of the legislative function (issuing rules and regulations) administrative agencies pose the greatest danger for infringing the rights of the greatest number. If an agency's "rules of the game" are bad, constitutional violations proliferate. Congress understood this danger and therefore established the notice-and-comment requirements of the APA as one check on the legislative activities of agencies. See 5 U.S.C. § 553; see also H.R. Rep. No. 1980, 79th Cong., 2d. Sess., at 17 (1946) (the APA "provides quite different procedures for the 'legislative' and 'judicial' functions of administrative agencies. In the 'rule making' (that is 'legislative') function it provides that with certain exceptions agencies must publish notice and at least permit interested parties to submit their views in writing before . . . the issuance of general regulations (sec 4).").

After an agency has completed the legislative function, and rules and regulations have been established, there is nothing "premature" about a court considering their facial validity. A

facial/collateral challenge to a regulation's validity is a challenge to an agency's legislative work. Nothing is gained by waiting for the agency to perform its quasi-judicial function of deciding individual cases.

In arguing for an independent federal judiciary, Alexander Hamilton aptly stated: "From a body which had had even a partial agency in passing bad laws, we could rarely expect a disposition to temper and moderate them in application . . . [s]till less could it be expected that men who had infringed the constitution, in the character of legislators, would be disposed to repair the breach, in the character of judges." *The Federalist* No. 81, at 543-44 (Alexander Hamilton) (Jacob Cooke ed., 1961). This all the more true here, where the bureaucrats who must bear the administrative inconvenience of conferring greater due process are the ones who would be expected to "repair the breach". This Court has agreed with this view. "It is unrealistic to expect that the Secretary would consider substantial changes in the current administrative review system at the behest of a single aid recipient raising a constitutional challenge in an adjudicatory context." *Mathews*, 424 U.S. at 330. The availability of immediate judicial review is critical whenever an agency promulgates unconstitutional regulations with widespread effect.

In contrast, when an agency is performing its judicial function (deciding individual benefit cases), immediate judicial review may be inappropriate until after a final decision, just as interlocutory appeals can be inappropriate disruptions to the trial process. See Schwartz, *supra*, 503. In such situations, agency expertise and the compilation of an administrative record can serve a useful purpose prior to judicial review. *Salfi*, 422 U.S. at 765. No similar useful purpose exists where, as here, a claimant asserts broad statutory and constitutional challenges. Indeed, when the agency's unconstitutional conduct causes widespread harm, initial judicial review is beneficial.

The Secretary's argument that exhaustion "may avert the need for judicial review altogether" (Pet. Brief. 23) pertains

again to an agency's quasi-judicial role of determining individual claims. Exhaustion should never be allowed to thwart "judicial review altogether" of an agency's improper regulatory actions having widespread impact. If so, the agency has a "blank check." If an agency enacts a compliance program that violates due process, judicial review is necessary to check the proliferation of constitutional violations that will result. The Secretary's apocalyptic suggestion of "devastating consequences" from "judicial interference" is an exaggeration, and an insult to the federal judiciary. Claims of interference are no reason for federal courts to abdicate their responsibility. The judiciary -- not the Secretary -- decides whether the Secretary has exceeded her powers. "[U]nder Article III, Congress established courts to adjudicate cases and controversies as to claims of infringement of individual rights . . . by the exertion of unauthorized administrative power." *Stark v. Wickard*, 321 U.S. 288, 310 (1944). If the Secretary exceeds her powers, the federal courts are constitutionally permitted to "interfere."

Finally, the Secretary cites the distinguishable *Lujan* case in favor of her policy argument that this Court should "reduce the scope of the controversy." Pet. Brief 22. In *Lujan*, the claims were much broader than the Council's here. The National Wildlife Federation asserted an amorphous challenge to the "entirety" of the "land withdrawal review program." *Lujan v. National Wildlife Federation*, 497 U.S. 871, 890 (1990). That program encompassed "1250 or so individual classification terminations and withdrawal revocations." *Id.* The Council's claims are much more focused than in *Lujan*. Moreover, the Court in *Lujan* expressly recognized that regulations with "across the board" applicability can be challenged. *Lujan*, 497 U.S. at 890-91, n.2 ("If there is in fact some specific order or regulation, applying some particular measure across the board . . . it can of course be challenged under the APA . . . ."). Thus, *Lujan* does not undermine the Seventh Circuit's judgment below.

CONCLUSION

The plain language of the statute, its structure and purpose, and its legislative history, all confirm that Congress did not intend to preclude initial judicial review of the Council's constitutional and statutory challenges to the Secretary's regulations and enforcement practices. For these reasons, this Court should affirm the judgment of court of appeals.

Respectfully submitted,

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