No. 03-1339

In the Supreme Court of the United States

UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY, ET AL., PETITIONERS

v.

DARA CORRIGAN, ACTING INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether the Inspector General Act prohibits the Inspector General of the Department of Health and Human Services from conducting an audit or investigation of potential fraud or abuse by a Medicare provider absent a referral from the providers' Medicare carrier or other particularized evidence of fraud.

2. Whether the Inspector General's decision to undertake an investigation of potential fraud or abuse by recipients of Medicare funds is final agency action subject to judicial review prior to any enforcement action.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-32a) is reported at 347 F.3d 57. The opinion of the district court (Pet. App. 35a-69a) is not reported.

JURISDICTION

The judgment of the court of appeals was entered on October 17, 2003. A petition for rehearing was denied on December 18, 2003 (Pet. App. 70a-71a). A petition for a writ of certiorari was filed on March 16, 2004. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. a. Title XVIII of the Social Security Act (Medicare Act), 42 U.S.C. 1395 *et seq.*, establishes a federally subsidized health insurance program primarily for persons over age 65. The program is administered by the Centers for Medicare and Medicaid Services (CMS), previously known as the Health Care Financing Administration (HCFA), within the Department of Health and Human Services (HHS). CMS, in turn, contracts with insurance companies throughout the nation, called carriers, which are responsible for communicating Medicare policy in the locale they serve, processing and paying claims, and conducting post-payment audits. The Medicare program has two principal parts. This case relates to circumstances in which these two parts overlap, presenting a risk that Medicare providers will bill the program twice for the same services.

Part A of Medicare, 42 U.S.C. 1395c-1395i, provides insurance for the costs of institutional care. Part A payments contribute to the costs of training residents and interns, including their salaries and the salaries of teaching physicians. 42 U.S.C. 1395ww(d) and (h). In 1996, Medicare Part A paid over $8 billion to teaching hospitals for the costs of training their residents and interns, or approximately $100,000 per resident or intern. C.A. App. A309.

Part B of Medicare, 42 U.S.C. 1395j-1395w, provides insurance to reimburse for specific medical services provided to a patient. Because Medicare already contributes to teaching supervision through Part A, teaching physicians may not seek reimbursement under Part B for merely providing general supervision to residents. Rather, in order to receive compensation under

Part B, a teaching physician must "render[] sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which the payment is sought." 42 U.S.C. 1395u(b)(7)(A)(i)(I).

During the time period covered by the audits here at issue, the Secretary's regulations authorized payment under Medicare Part B only where the teaching physician both was the "attending physician" and "furnishe[d] personal and identifiable direction to interns or residents who [we]re participating in the care of the patient." 42 C.F.R. 405.521(b)(1) (1993). The Secretary interpreted that regulation, together with a general requirement that Medicare will pay only where "[t]he services are personally furnished for an individual patient by a physician," 42 C.F.R. 405.550(b)(1), to require that the teaching physician must at least be physically present at the time the services were performed in order to be eligible for payment under Part B. See, *e.g.*, Centers for Medicare & Medicaid Services, HHS, *Carriers Manual* § 8201(A) (visited May 19, 2004) <http://www.cms.hhs.gov/manuals/14_car/3b8201.asp> (if teaching physician did not personally perform the service, medical record should indicate that the "physician was physically present when the service" was rendered).[1]

b. Congress enacted the Inspector General Act (the IG Act), 5 U.S.C. App. 1 *et seq.*, at 12, in 1978 in order to

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[1] The Secretary revised the regulations effective July 1, 1996. The current regulation eliminates the "attending physician" requirement, but carries forward and makes explicit in the text of the regulations themselves the requirement that "services * * * furnished by a resident [must be performed] in the presence of a teaching physician." 42 C.F.R. 415.170 (2002).

curb "fraud, abuse and waste in the operations of Federal departments and agencies and in federally-funded programs." S. Rep. No. 1071, 95th Cong., 2d Sess. 4 (1978). The IG Act created an Office of Inspector General (OIG) for numerous agencies, into which Congress consolidated various audit and investigation responsibilities, see 5 U.S.C. App. 2(1), 3(a), 9(a), at 12, 13, 32. In the case of HHS (then the Department of Health, Education, and Welfare), Congress had previously created an Inspector General (IG), with responsibilities and powers similar to those conferred by the IG Act. Act of Oct. 15, 1976, Pub. L. No. 94-505, Tit. II, 90 Stat. 2429. The IG Act, as amended by Pub. L. 100-504, transferred that pre-existing office to a new HHS OIG. 5 U.S.C. App. 9(a)(1)(F), at 32.

Sections 4 and 6 of the IG Act vest the IG with broad authority to "conduct, supervise, and coordinate audits and investigations relating to [HHS] programs," such as Medicare, 5 U.S.C. App. 4(a)(1), at 15, as well as to conduct activities designed to "promot[e] economy and efficiency" and "prevent[] and detect[] fraud and abuse" in the agency's "programs and operations," 5 U.S.C. App. 4(a)(3), at 15. See also 5 U.S.C. App. 2(1) and (2), at 12 (same). The IG enjoys broad discretion "to make such investigations * * * relating to the administration of the programs and operations of [HHS] as are, in the judgment of the Inspector General, necessary or desirable." 5 U.S.C. 6(a)(2), at 19.

c. In 1996, an audit by the HHS OIG of the University of Pennsylvania Health System revealed a dramatic lack of documentation that teaching physicians were physically present during services for which Medicare had been billed and, further, that Medicare was being billed for a more complex level of care than was actually provided. The University of Pennsylvania

audit resulted in a $30 million settlement. Pet. App. 7a. In light of that audit, the HHS OIG developed the Physician at Teaching Hospital (PATH) initiative to focus on the two forms of potential over-billing discovered at the University of Pennsylvania. *Id.* at 8a. PATH audits are conducted by HHS-OIG at its own cost. Alternatively, if a provider so chooses and OIG agrees, the provider may hire an independent reviewer to conduct a "self-audit" and report the findings to the HHS OIG. *Ibid.*

In 1996, the HHS OIG informed petitioners and other teaching hospitals of its intent to conduct a PATH audit of their Medicare reimbursements. After certain providers objected that the Secretary and his carriers had not sufficiently made clear the "physical presence" requirement for teaching physicians, the HHS OIG conducted a broad review of the guidance that the agency and carriers had provided on the subject. Pet. App. 7a-8a. The HHS OIG found that the Secretary and the "overwhelming majority" of regional carriers had "consistently * * * read [the regulatory language] to require the attending physician's physical presence when a resident performed a service," in order to qualify for Part B reimbursement. C.A. App. A322. The HHS OIG acknowledged, however, that "some carriers did not enforce a 'physical presence' standard." *Ibid.* The HHS OIG therefore announced that it would undertake PATH audits "only where carriers * * * issued clear explanation[s] of the rules regarding reimbursement for the services of teaching physicians." *Id.* at A323.

In response to the teaching hospitals' objections, HHS's General Counsel, Harriet Rabb, also reviewed the issue of Part B payments to teaching physicians. On the same day that the HHS OIG issued its PATH

Overview, the General Counsel sent a letter to the Association of American Medical Colleges and the American Medical Association (the Rabb Letter), responding to their concerns. The letter endorsed the approach adopted by the HHS OIG—to investigate those providers whose carriers had provided clear instruction of the physical presence requirement. Pet. App. 9a.

The Rabb Letter first observed that no physician could reasonably have believed he could be compensated under Medicare Part B for a merely supervisory role. "It would be absurd to assert that physicians could receive the significant remuneration that characterizes Part B reimbursement for supplying the same level of services that qualifies and was paid for as Part A services." Pet. App. 109a. The Rabb Letter noted several HCFA publications that had specifically referred to the physical presence requirement, but recognized that the standard had been stated in various ways. *Id.* at 110a-112a. In the General Counsel's view, because HCFA's own guidance was "not unambiguously clear," providers would have had to look to the carriers for clarification, and "that guidance would be controlling." *Id.* at 113a. "[I]ndeed," the General Counsel observed, "carriers across the country did provide very clear guidance on this subject," and she quoted several that stated the "physician's presence" requirement quite explicitly. *Ibid.* The Rabb Letter further stated the General Counsel's agreement with the HHS OIG's decision only to undertake PATH audits where the carrier had adopted a clear position that the treating physician's physical presence was required. *Id.* at 115a.

The HHS OIG has informed this Office that, pursuant to the PATH initiative, it has undertaken audits of 32

teaching hospitals. Of those audits, 29 have been completed. The HHS OIG has also informed this Office that PATH audits have recovered nearly $130 million for the Medicare program, in addition to another roughly $100 million recovered in non-PATH audits that encompassed PATH-related issues.

d. In 1997, the HHS OIG reviewed the written policies of petitioners' Medicare carrier and determined that they showed a clear policy of requiring a teaching physician's physical presence as a condition for reimbursement under Medicare Part B. See, *e.g.*, C.A. App. A285 ("The supervising physician * * * *should personally provide* all services reported for Medicare Part B payment or *be present* when the resident renders the services.") (emphases added). The HHS OIG also determined that petitioners had adequate notice of the carrier's interpretation through manuals that directed the providers to the appropriate publication for guidance concerning Part B payments to teaching physicians. *Ibid.*

Petitioners initially agreed to cooperate with the PATH audits and voluntarily elected to employ an independent auditor, rather than having the HHS OIG conduct the audit directly. Instead of going forward with the audits, however, petitioners filed this action, challenging the audits. The HHS OIG subsequently issued administrative subpoenas to petitioners to produce the necessary documents, and counter-claimed to enforce the subpoenas. Pet. App. 11a.

2. The district court dismissed petitioners' suit and granted the government's motion for enforcement of the subpoenas. Pet. App. 39a-69a. The district held that petitioners' challenge to the HHS OIG's audit failed to satisfy at least three separate requirements for review under the Administrative Procedure Act (APA),

5 U.S.C. 551 *et seq.* First, the IG's decision to initiate an audit was neither "final agency action" nor ripe for review, because it was merely the beginning of an investigation without immediate impact on petitioners' day-to-day operations. Pet. App. 52a-53a, 56a-57a. Further, petitioners had an adequate alternative remedy because any challenge to the IG's interpretation of the Medicare regulations could be raised in defense against any enforcement action, if one were ever brought. *Id.* at 54a-55a. Finally, the IG Act committed the decision whether to perform an audit to the HHS OIG's sole discretion. *Id.* at 55a-56a. In granting the government's motion to enforce the administrative subpoenas, the court found that the investigation was within the authority conferred on the IG by Section 6(a)(2) of the IG Act. *Id.* at 56a, 64a-68a.

3. The court of appeals affirmed. Pet. App. 1a-32a. The court held, as petitioners conceded, that the HHS OIG's statutory charge "to prevent and detect fraud and abuse" in the Medicare program encompassed the authority to audit not only the agency's own operations, but also to audit directly the recipients of Medicare funds. *Id.* at 17a. The court rejected petitioners' attempt to circumscribe that authority to instances where "the inspector general has received a referral from a carrier, or is otherwise responding to a specific allegation of fraud." *Ibid.* The court held that "[t]he inspector general's mandate to prevent and detect fraud and abuse is not limited by HHS's—or its agents'—own efforts to prevent and detect fraud and abuse." *Id.* at 19a.

The court further held that it lacked jurisdiction over petitioners' challenge to the standard that the IG intended to use in her audit. Two members of the panel held, following *FTC* v. *Standard Oil Co.*, 449 U.S. 232

(1980), that the IG's decision to conduct an investigation and to utilize a particular standard in her audit was not sufficiently ripe or final for judicial review. The court recognized that the decision to initiate an investigation is "a *preliminary* step—non-final by definition—leading toward the possibility of a 'final action' in the form of an enforcement" that may never materialize. Pet. App. 24a. In response to petitioners' reliance on the immediate need to comply with the IG's audit requests, the court observed that "[a]lthough this burden certainly is substantial, it is different in kind and legal effect from the burdens attending what heretofore has been considered to be a final action." *Id.* at 28a (quoting *Standard Oil*, 449 U.S. at 242).

Judge Ambro concurred. Pet. App. 31a-32a. He declined to join the majority's analysis concerning finality but viewed the IG's decision to undertake an audit as unreviewable because it was "committed to agency discretion," 5 U.S.C. 701(a)(2), by Section 6(a)(2) of the IG Act, which authorizes the IG "to make such investigations * * * relating to the administration of the programs and operations of [HHS] as are, in the judgment of the [IG] necessary or desirable." Pet. App. 32a.

ARGUMENT

The decision of the court of appeals is correct and does not conflict with any decision of this Court or any other court of appeals. Accordingly, the petition for a writ of certiorari should be denied.

1. a. Petitioners argue that the HHS OIG may audit Medicare providers only when there has been a fraud referral from a carrier. Pet. 11-24. That contention lacks merit. The IG Act provides that the inspector general is "to provide leadership * * * for activities designed * * * to promote economy, efficiency, and

effectiveness * * * and * * * to prevent and detect fraud and abuse" in her agency's programs. 5 U.S.C. App. 2(2), at 12. See also 5 U.S.C. App. 4(a)(3), at 15 ("It shall be the duty and responsibility of each Inspector General * * * to conduct, supervise, or coordinate * * * for the purpose of promoting economy and efficiency in the administration of, or preventing and detecting fraud and abuse in [the agency's] programs."). The IG Act thus assigns to the inspectors general an active and *leading* role in combating fraud, waste and abuse, and, more generally, in promoting economy and efficiency in their respective agency's programs. In fulfilling that mission, an inspector general must exercise independent initiative to investigate possible fraud and abuse, rather than wait for other offices or individuals to bring such accusations to her. The statute's use of the verbs "prevent" and "detect" also necessarily signify authority to investigate potential fraud or abuse even when the IG has no specific evidence that fraud or abuse has occurred. The court of appeals correctly held that Congress did not restrict the IG to acting only when another office or individual had discovered evidence of fraud.

Petitioners also argue (Pet. 11-24) that the HHS OIG's PATH audits are unlawful because HHS's carriers audit providers to ensure that reimbursement complies with the Medicare Act, and Section 9(a)(2) of the IG Act prohibits the IG from exercising agency "program operating responsibilities." Nothing in that Section, however, precludes the IG from exercising her mandated functions whenever her investigatory authority overlaps with that of the carrier.

Section 9(a)(1) immediately transferred into the newly-created inspector general offices numerous preexisting investigative offices. 5 U.S.C. App. 9(a)(1), at

32. Section 9(a)(2), in turn, provides that "[t]here shall be transferred * * * to the office of Inspector General * * * such other offices or agencies, or functions, powers, or duties thereof, as the head of the establishment involved may determine are properly related to the functions of the Office * * *, except that there shall not be transferred to an Inspector General under paragraph (2) program operating responsibilities." 5 U.S.C. App. 9(a)(2), at 32-33. As is clear from the plain text, Section 9(a)(2)'s reference to "program operating responsibilities" imposes a limit only on the agency head's ability to "transfer[] to an Inspector General under paragraph (2)" additional offices or functions beyond those already conferred by Congress. 5 U.S.C. App. 9(a)(2), at 33. It is inconceivable that Congress, which created the OIG precisely because of the failure of agencies to combat fraud and abuse effectively, would then make the IG's authority to investigate waste depend upon the agency's own ability to detect it.

The PATH initiative is undertaken pursuant to HHS OIG's independent authority to detect and prevent fraud. The carriers have not relinquished their powers to conduct routine compliance audits, nor has the Secretary transferred that function to the IG.

The 1989 Opinion of the Office of Legal Counsel (OLC) upon which petitioners rely, Pet. 13-14 (citing 13 Op. Off. Legal Counsel 54 (1989)), explicitly disclaims any application to investigations such as the PATH audits. The OLC opinion both begins and concludes by stressing that "[t]he significant investigat[ory] authority granted to Inspectors General * * * includes the authority to investigate recipients of federal funds * * * to determine if they are complying with federal laws and regulations." 13 Off. Legal Counsel at 54; *id.* at 66 (same). OLC expressly limited its opinion to "in-

vestigations pursuant to statutes that provide the Department with regulatory jurisdiction over private individuals and entities *that do not receive federal funds*," *id.* at 54 (emphasis added), such as the Fair Labor Standards Act of 1938 and Occupational Safety and Health Act of 1970, "which impose restrictions on individuals and entities * * * who are not * * * recipients of federal funds distributed by the Department," *id.* at 55-56. In fact, the OLC opinion specifically defined the term "regulatory investigation"—a phrase petitioners attempt to invoke here—as "investigations [that] generally have as their objective regulatory compliance by private parties," as distinguished from investigations aimed at eliminating "waste and fraud among * * * recipients of federal funds." *Id.* at 54 n.1.

The legislative history of the IG Act also is fully consistent with the court of appeals' decision. Petitioners cite a House Report that states that the IGs will not have direct responsibility for conducting audits such as those "conducted by USDA's Packers and Stockyards Administration in the course of its regulation of livestock marketing" or Department of Labor investigations aimed at "enforcing the Fair Labor Standards Act." Pet. 4 (quoting H.R. Rep. No. 584, 95th Cong., 1st Sess. 12-13 (1977)). The salient characteristic of those two examples is that they, like the investigations discussed in the OLC opinion, concern the enforcement of regulatory schemes that, unlike benefit programs, do not involve the potential for "waste of federal funds." See 13 Op. Off. Legal Counsel at 60-61 (discussing House Report).

Moreover, the legislative history of the IG Act specifically endorses the kind of investigative initiative undertaken by the HHS OIG here. The Senate Report commended the HEW Inspector General's "Project

Integrity," in which the IG "spearhead[ed] a nationwide effort to deal systematically with Medicaid fraud." S. Rep. No. 1071, *supra*, at 8. "Using computer screening to identify doctors and pharmacists performing services which appeared unusual when compared with certain norms," the IG had identified over 1000 cases warranting criminal or administrative action. *Ibid.* That initiative, which Congress held up as an example, is indistinguishable in salient respects from the present PATH audits.

b. Petitioners also argue that the court of appeals' decision conflicts with *Burlington Northern Railroad Co.* v. *Office of Inspector General, Railroad Retirement Board*, 983 F.2d 631 (5th Cir. 1993), and *Truckers United for Safety* v. *Mead*, 251 F.3d 183 (D.C. Cir. 2001). Pet. 17-24. That is not correct.

Burlington Northern did not endorse petitioners' construction of the IG Act. As the Fifth Circuit explained in the subsequent case of *Winters Ranch Partnership* v. *Viadero*, 123 F.3d 327 (1997), *Burlington Northern* held only that an agency may not "relinquish its own performance of [a] function" such that there is an effective "transfer of function" that would be precluded by Section 9(a)(2). *Id.* at 334-335 (explaining that, in *Burlington Northern*, the Railroad Retirement Board had "never exercised its statutory duty" to investigate railroad companies' payment of taxes to an employee insurance account, and the IG "assumed the agency's primary duty" in its place, including adopting a plan to "conduct[] regular tax collection audits of substantially all major railroads on a continuing long-term basis"); accord *United States* v. *Chevron U.S.A., Inc.*, 186 F.3d 644, 648 (5th Cir. 1999) (*Burlington Northern* inapplicable where agency "continues to keep

the relevant records" and "subpoenas do not displace any agency responsibilities").

Petitioners do not suggest that the Medicare carriers have "relinquish[ed their] own performance of [the audit] function." *Winters Ranch*, 123 F.3d at 334. Nor could they. The carriers continue to have primary responsibility for ensuring that Medicare providers are entitled to the reimbursement they claim. The PATH initiative covers only a specified period of time in the past, is directed at a small subset of providers (teaching hospitals), and focuses only on two discreet issues that the HHS OIG has reason to believe were susceptible to large-scale fraud and abuse.

The D.C. Circuit's decision in *Truckers United for Safety* is similarly inapposite. There, the IG was engaged in a joint program with the Office of Motor Carriers within the Department of Transportation "to create a greater deterrence to motor carrier violations of * * * Safety Regulations." 251 F.3d at 187. The target companies received no federal funds, and the IG was not "engaged in an investigation relating to abuse" of DOT's programs. *Id.* at 189. Like the safety investigations at issue in the 1989 OLC opinion, the DOT IG's investigation was merely "to determine whether individual trucking companies were complying with federal motor carrier safety regulations." *Ibid.* *Truckers United* has no application to the investigation of fraud and abuse by recipients of federal Medicare funds.[2]

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[2] It also is not clear that *Truckers United* remains good law on its own facts. Congress subsequently enacted legislation to clarify that the DOT IG can investigate any fraud on the agency by an entity regulated by DOT. Act of Oct. 9, 1999, Pub. L. No. 106-69, 113 Stat. 1013; Motor Carrier Safety Improvement Act of 1999, Pub. L. No. 106-159, § 228(a) and (b), 113 Stat. 1773. The D.C. Cir-

2. Petitioners also argue that the court of appeals erred in concluding that the IG's interpretation of the Medicare Act and regulations as requiring physical presence of an attending physician was not subject to judicial review at this time. Pet. 24-29. That contention also lacks merit.

One of several "prerequisite[s]" for judicial review under the APA is that the challenged conduct constitute "final agency action." *Dalton* v. *Specter*, 511 U.S. 462, 469 (1994); 5 U.S.C. 704. "[T]he action must mark the 'consummation' of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature"—and "must be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Bennett* v. *Spear*, 520 U.S. 154, 177-178 (1997) (citations omitted).

In *Standard Oil*, *supra*, the Court held that the FTC's issuance of an administrative complaint, which alleged that the Commission had "reason to believe" that the respondents were engaged in unfair trade practices, was not "final agency action." 449 U.S. at 234, 238. The decision to investigate served only to initiate the matter; it was not a definitive ruling, and had no legal force or practical effect on Standard Oil's day-to-day operations other than the costs and disruptions of the proceeding, which were similar to those that accompany any major litigation. *Id.* at 241-242.

Based on those same considerations, the court of appeals correctly held that the HHS OIG's decision to undertake a PATH audit is not final agency action. Pet. App. 23a-29a. Moreover, in this case, unlike in *Stan-*

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cuit declined to address whether the DOT IG could, in the future, undertake similar investigations in light of this new statutory authority. *Truckers United*, 251 F.3d at 191-192.

dard Oil, the IG's decision to undertake a PATH audit does not even amount to a threshold determination of "reason to believe" that petitioners are in violation of Medicare law, let alone any definitive determination of petitioners' liability. Indeed, it is still quite uncertain whether any enforcement action will be taken against petitioners. In the past, in a third of the then-completed PATH audits, "no enforcement action was taken." C.A. App. A251-A252; *Physicians at Teaching Hospitals (PATH) Audits: Hearing Before a Subcomm. of the Senate Comm. on Appropriations*, 105th Cong., 1st Sess. 396 (1998) (PATH reviews have been terminated at institutions where few errors have been identified during audits).

The IG's initiation of an audit does not determine any rights or obligations or have legal consequences for petitioners' primary conduct or day-to-day operations. "[A]n administrative investigation adjudicates no legal rights." *SEC* v. *Jerry T. O'Brien, Inc.*, 467 U.S. 735, 742 (1984). Even assuming that the IG refers petitioners for proceedings to assess administrative penalties or commencement of a False Claims Act case, petitioners will have ample opportunity to raise all their arguments as defenses to an enforcement action. "[T]he extent to which the respondent may challenge the complaint and its charges proves that the averment of reason to believe is not 'definitive' in a comparable manner to the regulations in *Abbott Laboratories* [v. *Gardner*, 387 U.S. 136 (1967)]." *Standard Oil*, 449 U.S. at 241.

The court of appeals' decision also is consistent with the decisions of other courts that have dismissed pre-investigation challenges to the PATH initiative on ripeness and finality grounds. *Association of Am. Med. Colls. (AAMC)* v. *United States*, 217 F.3d 770, 781 (9th

Cir. 2000); *Temple Univ.* v. *Brown*, No. 00-CV-1063, 2001 WL 185535 (E.D. Pa. Feb. 23, 2001), aff'd *sub nom. Temple Univ.* v. *Rehnquist*, No. 01-3862, 2002 WL 31012237 (3d Cir. Aug. 20, 2002) (46 Fed. Appx. 124) (not precedential); *Greater N.Y. Hosp. Ass'n* v. *United States*, No. 98 Civ. 2741 (RLC), 1999 WL 1021561, at *5-*7 (S.D.N.Y. Nov. 9, 1999). As the Ninth Circuit succinctly stated, "[a]n investigation, even one conducted with an eye to enforcement, is quintessentially non-final as a form of agency action." *AAMC*, 217 F.3d at 781.

Abbott Laboratories, upon which petitioners rely (Pet. 24-26), is not to the contrary. That decision involved final agency action in the form of formally issued regulations that forced drug manufacturers to risk serious penalties for noncompliance, or undertake costly changes in labeling and advertising materials. See *Standard Oil*, 449 U.S. at 242. Petitioners make no claim that the HHS OIG's decision to undertake a PATH audit, which focuses exclusively on past conduct (billings prior to 1996), has any impact on petitioners' present or future primary conduct. Petitioners are simply required to cooperate with the audit, an entirely reasonable aspect of participating in receiving large amounts of federal funds under the vast Medicare program. *Standard Oil* makes clear that the initiation of an investigation—even one in which the cost and burden of responding is "substantial"—does not qualify as the kind of immediate impact on day-to-day activities that will satisfy the *Abbott Laboratories* finality requirement. See *id.* at 243 (such costs are no more "than the disruptions that accompany any major litigation"). "[T]he expense and annoyance of litigation is part of the social burden of living under government." *Id.* at 244. Finally, even if the HHS OIG's initiation of the investigation constituted final agency action, neither that

initiation nor the IG's interpretation of the Medicare Act and regulations would be ripe for judicial review at this stage. See, *e.g.*, *Ohio Forestry Ass'n* v. *Sierra Club*, 523 U.S. 726, 732-737 (1998).[3]

b. Even if the IG's determination of how to conduct her investigation constituted final agency action and were ripe for review, the decision whether and how to investigate recipients of Medicare payments is one "committed to agency discretion by law," 5 U.S.C. 701(a)(2), and therefore not subject to judicial review. Pet. App. 32a (Ambro, J., concurring); *Webster* v. *Doe*, 486 U.S. 592, 599-600 (1988).

The IG Act confers on the IG authority "to make such investigations and reports relating to the administration of the programs and operations of [HHS] as are, *in the judgment of the Inspector General, necessary or desirable*." 5 U.S.C. App. 6(a)(2), at 19 (emphasis added). See *NASA* v. *FLRA*, 527 U.S. 229, 239 (1999) (Section 6(a)(2) confers "discretion" on the

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[3] Petitioners also err in asserting (Pet. 27) a conflict between the court of appeals' decision and the D.C. Circuit's decisions in *General Electric Co.* v. *EPA*, 290 F.3d 377 (2002), and *Mountain States Tel. & Tel. Co.* v. *FCC*, 939 F.2d 1035 (1991). Those decisions did not involve instigation of an IG audit but simply permitted judicial review when a regulated entity was required to comply with a new regulation adopted by the agency. *General Elec.*, 290 F.3d at 381-382 (review of EPA Guidance Document that "purports on its face to bind both applicants and the Agency" with respect to clean up and disposal of PCB waste); *Mountain States*, 939 F.2d at 1038-1039 (review of "new accounting rules" adopted by the FCC after notice and comment). Moreover, in each case, the D.C. Circuit noted that the relevant judicial review provisions *required* petitioners to seek judicial review within sixty days of the new rule's adoption. See *General Elec.*, 290 F.3d at 381 (Toxic Substances Control Act, 15 U.S.C. 2618(a)(1)(A)); *Mountain States*, 939 F.2d at 1040 (Hobbs Act, 28 U.S.C. 2344).

Inspectors General in the conduct of their investigations).

The language of Section 6(a)(2) is similar to the grant of discretion that barred APA review in *Webster*, *supra*. See 486 U.S. at 600 (statutory language authorizing the Director of Central Intelligence to terminate an employee "whenever the Director 'shall deem such termination necessary or advisable in the interests of the United States,'" foreclosed APA review). Section 6(a)(2) of the IG Act similarly reflects Congress's intent to foreclose review. Other provisions of the Act reinforce that conclusion. See, *e.g.*, 5 U.S.C. App. 3(a), at 13 (prohibiting agency head from interfering with IG audit, investigation, or subpoena), 5 U.S.C. App. 6(a)(4), at 19 (granting IG broad subpoena power to obtain evidence "necessary in the performance of the [IG's] functions").

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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