

UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

August Term, 2005

(Argued: February 6, 2006 Decided: November 16, 2006)

Docket Nos. 05-1224-cv-LEAD, 05-1434-cv-XAP

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YALE-NEW HAVEN HOSPITAL, GIOVANNI  
AVALLONE, FARDI BAIK, LOUIS BONAVENTURA,  
JOSEPH BOTTONI, CHARLES BRADBURY, MARY  
CACCONI, SALLY CASSIDY, JOHN CHRISTIE,  
MARY COONS, STANLEY CORNELL, CHARLES  
DELUCA, THEODORE DEMMERTE, RALPH  
DERUBERTIS, RICHARD FLAIG, KARL FRITZ,  
EDWARD GROSSO, ALFRED HAMANN, WILLIAM  
HORODECK, WARREN IVEY, MARION JOHNSON,  
ALVIN KARCHERE, ANDREW MANCUSO, CHARLES  
MATTIA, VINCENT MCCARTHY, JAMES MILLER,  
JOHN NURCZYK, ROMANO ORLANDO, BERT SCOTT,  
JOSEPH TELESCO, STANLEY GINGOLASKI, EDITH  
HOWARD, RAYMOND IOVINO, EDWARD JURCZAK,  
JOHN KING, SHERMAN PLATT, PHILIP KISHEL,  
LOUISE KOCAK, STEPHANIE LEBELL, THOMAS  
PRALL, SOLON ROBBINS, HARRY SANDS, FELIX  
SNOPKOSKI, DAVID SPRAGUE, JOSEPH VANEK,  
JACK WARREN, JAMES WATERS,

Plaintiffs-Appellees, Cross-Appellants,

- v. -

MICHAEL O. LEAVITT, U.S. Department of  
Health Human Services,

Defendant-Appellant, Cross-Appellee.

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Before: JACOBS, Chief Judge, POOLER, and GIBSON,\*  
Circuit Judges.

Judge Pooler concurs in a separate opinion.

Appeal from the judgment of the United States District Court for the District of Connecticut (Dorsey, J.), reversing a decision by the Secretary of Department of Health and Human Services that denied Medicare reimbursement claims. We vacate and remand to the district court so that it may remand to the Secretary for further proceedings consistent with this opinion.

JEFFREY CLAIR, Barbara C. Biddle, Attorneys, Appellate Staff Civil Division, Department of Justice, Washington, DC (Peter D. Keisler, Assistant Attorney General, Kevin J. O'Connor, United States Attorney, on the brief), for Defendant-Appellant, Cross-Appellee.

LEONARD C. HOMER (Ray M. Shepard, on the brief), Ober, Kaler, Grimes & Shriver, Baltimore, MD, for Plaintiffs-Appellees, Cross-Appellants.

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\*The Honorable John R. Gibson, Circuit Judge, United States Court of Appeals for the Eighth Circuit, sitting by designation.

DENNIS JACOBS, Chief Judge:

Michael O. Leavitt, the Secretary of the United States Department of Health and Human Services (the "Secretary" of "HHS"), appeals from the decision of the United States District Court for the District of Connecticut (Dorsey, J.), which reversed on motion for summary judgment a final decision of the Secretary denying to Yale-New Haven Hospital ("Yale") Medicare coverage for treatment involving investigational cardiac devices provided to 48 patients. The Secretary denied reimbursement on the ground that the devices had not received premarket approval from the FDA; in the district court, Yale successfully argued that the denial of the claims on the categorical ground of FDA classification was predicated on a rule altering the previous Medicare practice of conducting device-by-device review of safety and efficacy, and that the rule change was improperly adopted. We agree with the district court that the new rule is unenforceable because the Secretary did not satisfactorily explain his reasons for its promulgation. Nevertheless, we vacate the judgment of the district court (which reversed) and remand the case to the district court with instructions to remand to the Secretary for proceedings

consistent with this opinion.

## I

### A. Medicare Reimbursement Procedures

Medicare, which at the time of the events at issue was administered by the Health Care Financing Administration ("HCFA")<sup>1</sup> on behalf of the Secretary, see Cedars-Sinai Med. Ctr. v. Shalala, 939 F. Supp. 1457, 1460 (C.D. Cal. 1996), is the federally subsidized health insurance program for the elderly and disabled established by Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. ("Medicare Act"). Part A of the Medicare program, 42 U.S.C. §§ 1395c et seq., provides basic insurance protection "against the costs of hospital, related post-hospital, home health services, and hospice care," see also Huntington Hosp. v. Thompson, 319 F.3d 74, 76 (2d Cir. 2003). Under Part A, service providers such as hospitals, see 42 U.S.C. § 1395x(u), are paid the lesser of the "reasonable cost" of covered services provided to program beneficiaries or "the customary charges with respect to such services," 42 U.S.C.

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<sup>1</sup>HCFA has been known since 2001 as the Centers for Medicare and Medicaid Services. See Matthews v. Leavitt, 452 F.3d 145, 148 n.5 (2d Cir. 2006).

§ 1395f(b)(1), and agree not to charge beneficiaries for these services, see 42 U.S.C. § 1395cc(a)(1)(A).<sup>1</sup> Medicare reimbursement to service providers is generally made through “fiscal intermediaries”: private entities, often insurance companies, that process, review, and pay claims submitted by providers. See 42 U.S.C. § 1395h. Fiscal intermediaries must only pay claims for services that are covered by Medicare, see 42 C.F.R. § 421.100(a); this responsibility includes the contractual obligation (to Medicare) to make coverage determinations in accordance with (i) the Medicare statutes, (ii) formal agency regulations and rulings, and (iii) less-formal agency instructions such as instructional manuals and intermediary letters. See Adventist Living Centers, Inc. v. Bowen, 881 F.2d 1417, 1419 (7th Cir. 1989); Yale-New Haven Hosp., Inc. v. Thompson, 162 F. Supp. 2d 54, 57-58 (D. Conn. 2001).

## **B. Recourse for Dissatisfied Providers**

Under certain circumstances, see 42 C.F.R. § 405.710(b), a provider may seek administrative and judicial

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<sup>1</sup>Beneficiaries are, however, responsible for certain deductible and coinsurance payments. See 42 U.S.C. § 1395e.

review of a fiscal intermediary's initial coverage determination, see 42 U.S.C. § 1395ff; see also 42 C.F.R. §§ 405.702, 405.704(b), (c)(1); 421.100(a), (b). The successive levels of administrative review available to a provider are [i] reconsideration by the fiscal intermediary, see 42 C.F.R. §§ 405.710, 405.711; [ii] review before an administrative law judge, see 42 C.F.R. §§ 405.720, 405.722; and [iii] review before the Medicare Appeals Council ("Appeals Council"), which may also review the ALJ's decision sua sponte, see 20 C.F.R. §§ 404.967-404.969. A provider that has exhausted its administrative remedies may seek judicial review of the Secretary's final decision under 42 U.S.C. § 1395ff(b) (incorporating 42 U.S.C. § 405(g)). See Weinberger v. Salfi, 422 U.S. 749, 762-65 (1975).

### **C. Medicare Coverage Standards**

With a few exceptions, the Medicare Act does not specify which devices are covered or excluded from coverage. Broad wording excludes from Medicare Part A coverage "any expenses incurred for items or services [which] are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a

malformed body member." 42 U.S.C. § 1395y(a)(1)(A); see also 42 C.F.R. § 411.15(k)(1). The Secretary is responsible for specifying those services that are covered under the "reasonable and necessary" standard, see 42 U.S.C. § 1395ff(a); he has wide discretion in selecting the means for doing so, see Heckler v. Ringer, 466 U.S. 602, 617 (1984), and has traditionally acted through formal regulations and (informal) instructional manuals and letters.

The Medicare reimbursement manuals issued to fiscal intermediaries in July 1986, see Yale-New Haven Hosp., 162 F. Supp. 2d at 59, announced that only medical devices that had received FDA premarket approval for commercial distribution were covered under Medicare. The FDA is authorized to regulate medical devices by the Medical Devices Amendments Act of 1976 ("MDA"), 21 U.S.C. § 360 et seq. See Medtronic, Inc. v. Lohr, 518 U.S. 470, 476-77 (1996). Under the MDA, each medical device is classified according to the stringency of regulatory control necessary to ensure safety and effectiveness. See 21 U.S.C. § 360c(a). Certain devices, such as those at issue in this case, require FDA "premarket approval" before they may be commercially distributed to the general public. Such "Class

III" devices are so designated if (i) the controls provided for under Classes I and II are insufficient to guarantee the device's safety and effectiveness and (ii) the device (a) is "purported or represented to be for a use in supporting or sustaining human life or . . . of substantial importance in preventing impairment of human health" or (b) "presents a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C)(ii)(II). To obtain premarket approval, the manufacturer must furnish "detailed information about the device's testing, design, components, performance standards, manufacturing, packaging, and labeling" sufficient to reasonably assure the FDA that the device is safe and effective. Martello v. Ciba Vision Corp., 42 F.3d 1167, 1168 (8th Cir. 1994) (citing 21 U.S.C. § 360e(c)(1); 21 C.F.R. § 814.20 (1994)); 21 U.S.C. § 360c(a)(1)(C).

In 1980, the FDA promulgated regulations establishing an investigational device exemption ("IDE"), which authorizes the lawful sale--to hospitals and physicians, for use in clinical trials--of certain devices that have not obtained premarket approval. See 21 U.S.C. § 360j(g). The IDE exemption is intended "to encourage . . . the discovery

and development of useful devices" by generating the data necessary to determine safety and effectiveness. Id.

The 1986 Manual Provision explained Medicare's policy with respect medical devices that had received IDEs but had not been accorded premarket approval. The provision, identified as a "New Policy," instructed intermediaries to adopt a per se rule against reimbursement for these devices:

Devices Not Approved by FDA.--Medical devices which have not been approved for marketing by the FDA are considered investigational by Medicare and are not reasonable and necessary for the diagnosis or treatment of illness or injury . . . . Program payment, therefore may not be made for medical procedures or services performed using devices which have not been approved for marketing by FDA.

Yale-New Haven, 162 F.Supp.2d at 59. Prior to the FDA's adoption of the IDE in 1980 (and promulgation of the per se rule against IDE reimbursement in the 1986 Manual Provision), Medicare had issued coverage guidelines for "investigational" (or "experimental") medical devices in a letter to fiscal intermediaries in 1977 ("1977 intermediary letter"). The letter instructed Medicare fiscal intermediaries to respond to coverage inquiries concerning investigational medical devices by explaining that:

a basic consideration [in making a coverage

decision] is whether the service has come to be generally accepted by the professional medical community as an effective and proven treatment for the condition for which it is being used. If it is, Medicare may make payment. On the other hand, if the service or treatment is one that is not yet generally accepted, is rarely used, novel or relatively unknown, then authoritative evidence must be obtained to establish it is safe and effective before Medicare may make payment.

The 1986 Manual Provision, or similar initiatives, evidently provoked some congressional disapproval. A (non-retroactive) 1987 amendment to the Medicare Act, 42 U.S.C. § 1395hh(a)(2), explicitly forbade the Secretary from promulgating any "rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter . . . unless it is promulgated by the Secretary" through notice-and-comment rulemaking. See Warder v. Shalala, 149 F.3d 73, 79 n.4 (1st Cir. 1998). This reframing of settled law under the Administrative Procedure Act (see id. at 79) can be read as a congressional shot across the bow: The House Budget Committee noted its

concern that "important policies are being developed without benefit of the public notice and comment period and, with growing frequency, are being transmitted, if at all, through manual instructions and other informal means." H.R. Rep. No. 100-391, at 430 (1987).

In 1995, the 1986 Manual Provision was superseded by published final regulations governing coverage of IDE devices ("1995 Regulations"). Under the 1995 Regulations, the Medicare coverage determination was made to depend on an exquisite adjustment in the FDA status-classification system, which was developed by the FDA in conjunction with HCFA. See 42 C.F.R. §§ 405.203, 405.205, 405.211; see also 61 Fed. Reg. 7011 (Feb. 23, 1996). As long as all other coverage requirements were met, the 1995 Regulations extended coverage to IDEs classified by the FDA as Category B (non-experimental/non-investigational), which included those Class III devices that constituted refinements or replications of technologies that had already been demonstrated as being safe and effective.<sup>3</sup> 42 C.F.R. §§

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<sup>3</sup>Specifically, Category B devices are those "for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example,

405.201(b), 405.211(b). The FDA classified all other devices in Category A (experimental/investigational), which continued to be excluded from Medicare coverage. Over ninety percent of all devices sold for use in FDA-approved clinical trials under an IDE were in Category B. See 61 Fed. Reg. 15,491, 15,501-04 (Apr. 8, 1996).

#### **D. The Present Case**

This case arises out of the efforts of the Secretary to recover \$1.5 million paid to reimburse Yale for 49 Medicare claims (involving 48 individual beneficiaries) that Yale submitted between 1994 and 1995. All the claims were on behalf of patients participating in clinical trials who had received implantable cardioverter-defibrillator devices (ICDs), which are cardiac devices for treatment of an irregular heart rhythm. The FDA had granted these devices IDEs, but had not conferred premarket approval.

These claims have been embroiled in prolonged litigation. Yale, along with 131 other hospitals, was a defendant in a sealed qui tam action brought in 1994,

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other manufacturers have obtained FDA approval for that device type." 42 C.F.R. 405.201(b).

alleging that the hospitals violated the False Claims Act by knowingly submitting false Medicare claims for payment of services involving investigational cardiac devices.<sup>4</sup> In addition, Yale and 24 other hospitals filed a separate action challenging the 1986 Manual Provision as unlawful under the Administrative Procedure Act ("APA"). See Cedars-Sinai, 939 F. Supp. at 1459. In an April 1996 decision, the district court agreed with the hospitals, ruling that the 1986 Manual Provision was a legislative rule that was invalid because the Secretary failed to promulgate it pursuant to notice-and-comment rule-making under 5 U.S.C. § 553(b). See id. at 1465. That ruling was vacated on appeal without consideration of the validity of the regulation. See Cedars-Sinai Medical Ctr. v. Shalala, 125 F.3d 765, 771 (9th Cir. 1997). On remand, the district court dismissed the hospitals' claims for non-compliance with the requisite statute-of-limitations, see Cedars-Sinai Med. Ctr. v. Shalala, 177 F.3d 1126, 1128 (9th Cir. 1999).

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<sup>4</sup>The government intervened in that case in 2002; the opinion in an appeal of a decision in that case, see In re Cardiac Devices Qui Tam Litig., 221 F.R.D. 318 (D. Conn. 2004) (Goettel, J.), is being issued in tandem with this opinion. See United States of America v. The Baylor University Medical Center et al., 05-2951 (2d Cir. filed [ ])

The allegations in the qui tam action prodded the Secretary to seek information from Yale about Medicare claims submitted for services involving ICDs. Yale's Medicare fiscal intermediary ultimately determined that Yale had been improperly reimbursed for treatment involving the ICDs, and informed Yale that the erroneous payments would be recouped from the ongoing stream of Medicare reimbursements. Yale, joined by the Medicare beneficiaries who received ICDs, successfully requested hearings before an ALJ. In June 1996, the ALJ--observing that the 1986 Manual Provision had been held invalid in Cedars-Sinai--found that Yale had presented sufficient evidence to demonstrate that the ICDs were "reasonable and necessary" to each beneficiary's treatment. Accordingly, the ALJ ruled in favor of Yale and the beneficiaries on each of the claims. The Appeals Council reviewed the ALJ's decision sua sponte, and reversed the ALJ in a single consolidated decision issued in October 1999. By that time, the Ninth Circuit had vacated the district court decision in Cedars-Sinai that had invalidated the 1986 Manual Provision (the Appeals Council having stayed its decision to await the Ninth Circuit ruling). The Appeals Council sustained the denial of Medicare

reimbursement on the grounds that the 1986 Manual Provision (i) remained in effect as a valid rule, (ii) was applicable to the devices at issue, and (iii) was entitled to deference. See Appeals Council Decision at 5-6. In the alternative, the Appeals Council ruled that a remand to the ALJ would otherwise be needed because the record evidence did not support the conclusion that the devices had been shown to be "safe and effective" or "generally accepted." Id. at 6 n.3.

Yale and the Medicare beneficiaries sought judicial review of the Secretary's decision. On cross-motions for summary judgment, the district court granted judgment for Yale, reversed the Secretary's recoupment decision, and directed the Secretary to reimburse Yale. See Yale-New Haven Hosp., Inc. v. Shalala, 3:99cv2546 (D. Conn. Dec. 29, 2004) (order granting summary judgment) (Dorsey, J.). As a threshold matter, the district court (following its reasoning in In re Cardiac Devices, 221 F.R.D. at 350-51) decided that the manual provision was promulgated and applied as a rule that was interpretive, and as a result was not subject to the procedures governing notice-and-comment rulemaking. However, the district court went on to hold

that: (i) the 1986 Manual Provision was entitled to little deference because the categorical reliance on FDA premarket approval in determining Medicare coverage of medical devices constituted a shift from historical practice (i.e., the 1977 letter) that the Secretary did not adequately explain; (ii) in light of the limited deference owed to the 1986 Manual Provision, the Appeals Council failed to explain adequately its reasons for following the FDA's premarket approval decision in determining that Yale's claims were not covered by Medicare, thus rendering that determination arbitrary and capricious; and (iii) substantial evidence did not support denial of Yale's claims because the unrebutted evidence submitted by Yale was sufficient to demonstrate that the ICDs in question had achieved the requisite level of safety and acceptance in the medical community. Finally, the court ruled that remand for further evidentiary findings by the agency was not warranted because, under the circumstances, it would be inappropriate to afford the agency "a second bite at the apple."

The Secretary appeals the district court judgment, arguing that (i) it is not arbitrary and capricious for the Secretary to have denied Yale's reimbursement claims on the

ground that the devices lacked FDA premarket approval; (ii) substantial evidence supports the Secretary's conclusion that Yale failed to show that the devices were safe and effective; and (iii) even if the Secretary's determination is arbitrary and capricious and unsupported by substantial evidence, the appropriate remedy would be remand to the agency for further proceedings rather than reversal (per the district court judgment). Yale and the 48 individual beneficiaries cross-appeal the specific holding of the district court that because the 1986 Manual Provision was an interpretive--not legislative--rule, its promulgation did not require notice-and-comment rulemaking.

## II

"On appeal from a grant of summary judgment in a challenge to agency action under the APA, we review the administrative record and the district court's decision de novo." Bellevue Hosp. Ctr. v. Leavitt, 443 F.3d 163, 173-74 (2d Cir. 2006); see Abbott Radiology Assocs. v. Shalala, 160 F.3d 137, 139 (2d Cir. 1998).

The district court's jurisdiction over Yale's challenge to the Secretary's determination arises under 42 U.S.C. §

1395ff(b), which authorizes a provider or supplier of services who represents an individual beneficiary to appeal adverse claims determinations under the Act.<sup>5</sup> See N.Y. State Dep't of Soc. Servs. v. Bowen, 846 F.2d 129, 130 (2d Cir. 1988) ("A . . . provider of health care can take an administrative appeal, with judicial review, from a denial

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<sup>5</sup>Yale represents the individual beneficiaries who received ICDs pursuant to 42 U.S.C. § 1395pp(d), which establishes that "[i]n any case arising under subsection (b) . . ., the provider . . . shall have the same rights that an individual has under [§ 1395ff(b)] . . . when the amount of benefit or payments is in controversy." Highland Dist. Hosp. v. Sec'y of Health & Human Servs., 676 F.2d 230, 237-38 (6th Cir. 1982) ("[A] provider may seek judicial review under § 1395pp(d) of a determination by its fiscal intermediary that certain cost reimbursements are excluded [as] not reasonable and necessary for the diagnosis or treatment of illness or injury or expenses for custodial care . . . [if] the beneficiary or the provider knew or should have known the services were excluded and the Secretary determines the beneficiaries will not exercise their appeal rights under § 1395ff(b)."); see also Chaves County Home Health Serv., Inc. v. Sullivan, 931 F.2d 914, 921 (D.C. Cir. 1991) ("[Section] 1395pp(d) accords providers the same rights as individuals."). Section 1395pp(b) provides that if the individual beneficiary did not know (and could not reasonably have been expected to know) that a service was not covered, but the provider of services did know (or could have been expected to know) of the noncoverage, then Medicare will deny payment to the provider, but the individual beneficiary will have no liability to the provider or to Medicare. Subsection (b) clearly applies: The individual beneficiaries here were informed by Medicare that they "did not have any way of knowing" that the ICD implantations were not covered, and no party challenges that determination.

of Medicare coverage.”). Since (i) Yale’s challenge to the Secretary’s determination represents the beneficiaries’ interests and (ii) the 1986 Manual Provision has been superseded by the 1995 Regulations, it is altogether unclear what interest the individual beneficiaries retain in this action. On remand, the district court should determine whether their continued presence as parties is warranted.

Section 1395ff(b) specifies 42 U.S.C. § 405(g) as “the sole avenue for judicial review for all ‘claim[s] arising under’ the Medicare Act.” Heckler, 466 U.S. at 615 (establishing that specification of § 405(g) is “to the exclusion of 28 U.S.C. § 1331”). We therefore review the Secretary’s actions pursuant to the specific provisions of § 405(g) where applicable; where no provision of § 405(g) is on point, we apply the judicial review provisions of the APA, see 5 U.S.C. § 559 (“[A] [s]ubsequent statute may not be held to supersede or modify . . . [the APA]. . . except to the extent that it does so expressly.”); see also Dickinson v. Zurko, 527 U.S. 150, 154-55 (1999).

### III

Yale has challenged the validity of the 1986 Manual

Provision on the grounds that

(i) it is a legislative rule that is void because its promulgation did not comply with the notice-and-comment rulemaking requirements of the APA, 5 U.S.C. § 553;

(ii) it is an impermissible interpretation of the Medicare Act, see Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984); Skidmore v. Swift & Co., 323 U.S. 134, 139-40 (1944); United States v. Mead Corp., 533 U.S. 218, 228 (2001); and

(iii) in promulgating the 1986 Manual Provision, the Secretary acted arbitrarily and capriciously, 5 U.S.C. § 706(2)(A); see Motor Vehicle Mfr's Ass'n of the United States, Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29 (1983).<sup>6</sup>

We conclude that the 1986 Manual Provision was adopted

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<sup>6</sup>Although the analyses are related, we conduct separate inquiries into whether a rule (i) is a permissible interpretation of the governing statute and (ii) was promulgated arbitrarily or capriciously. See Bellevue Hosp. Ctr. v. Leavitt, 443 F.3d 163, 174 (2d Cir. 2006); see also Arent v. Shalala, 70 F.3d 610, 619 (D.C. Cir. 1995) (Wald, J., concurring).

in a manner that is arbitrary and capricious. This conclusion moots Yale's other challenges.<sup>7</sup>

**A. Arbitrary and Capricious Review Under State Farm**

The inquiry into whether the promulgation of the 1986 Manual Provision was arbitrary and capricious is guided by the criteria established in State Farm:

the agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made. . . . Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise. The reviewing court should not attempt itself to make up for such deficiencies; we may not supply a reasoned basis for the agency's action that the agency itself has not given. We will, however, uphold a decision of less than ideal clarity

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<sup>7</sup>Because the APA requires that legislative rules (unlike interpretive rules) be promulgated pursuant to notice-and-comment rulemaking, and the Secretary concedes that notice-and-comment procedures were not followed in this case, the 1986 Manual Provision would be invalid ab initio if it were legislative. We do not decide whether the 1986 Manual Provision is legislative or interpretive, but assume for the purposes of the following discussion that it is interpretive.

if the agency's path may reasonably be discerned.

463 U.S. at 43 (internal citations omitted); see also Martin v. Occupational Safety and Health Review Comm'n, 499 U.S. 144, 158 (1991) (holding that "Secretary's interpretation of an ambiguous regulation is subject to the same standard of substantive review as any other exercise of delegated lawmaking power," including review of "quality of the Secretary's elaboration of pertinent policy considerations" under State Farm); Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971), overruled on other grounds by Califano v. Sanders, 430 U.S. 99 (1977) (applying arbitrary and capricious review under § 706(2)(a) to agency action outside of ambit of 5 U.S.C. § 553(b), (c)); Sentara-Hampton Gen. Hosp. v. Sullivan, 980 F.2d 749, 755 (D.C. Cir. 1992) (per curiam) (applying State Farm to review of interpretive rule promulgated by Secretary under Medicare Act).

Our review is particularly searching in this instance because the record indicates that the 1986 Manual Provision altered historical practice. "A settled course of behavior embodies the agency's informed judgment that, by pursuing that course, it will carry out the policies committed to it

by Congress"; therefore, "an agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance." State Farm, 463 U.S. at 41-42 (internal quotation marks omitted); see Huntington Hosp. v. Thompson, 319 F.3d 74, 80 (2d Cir. 2003) ("While an agency is not locked into the first interpretation of a statute it embraces, it cannot simply adopt inconsistent positions without presenting some reasoned analysis.") (internal quotation marks omitted). As we have explained,

when an agency reverses its course, a court must satisfy itself that the agency knows it is changing course, has given sound reasons for the change, and has shown that the rule is consistent with the law that gives the agency its authority to act. In addition, the agency must consider reasonably obvious alternatives and, if it rejects those alternatives, it must give reasons for the rejection, sufficient to allow for meaningful judicial review. . . . Even in the absence of cumulative experience, changed circumstances or judicial criticism, an agency is free to change course after reweighing the competing statutory policies. But such a flip-flop must be accompanied by a reasoned explanation of why the new rule effectuates the statute as well as or better than the old rule.

N.Y. Council, Ass'n of Civilian Technicians v. Fed. Labor Relations Auth., 757 F.2d 502, 508 (2d Cir. 1985) (internal

citations and quotation marks omitted).

The record reflects that, prior to the 1986 Manual Provision, fiscal intermediaries exercised some discretion (albeit narrow) in determining coverage for investigational medical devices. The 1977 intermediary letter instructed fiscal intermediaries that, in determining coverage of an investigational device that was neither specifically covered nor excluded from coverage, the primary consideration is whether the device has been demonstrated as "generally accepted by the professional medical community as an effective and proven treatment for the condition for which it is being used." However, this letter also explained that Medicare would pay for an investigational or experimental treatment upon the receipt of authoritative evidence that the treatment is "safe and effective." Thus coverage was available for a device that was safe and effective even if the device was not generally accepted within the medical community.

The 1986 Manual Provision--telling intermediaries that there is no coverage unless treatments received FDA premarket approval--was an evident change of course.

Despite some hedging elsewhere,<sup>8</sup> the 1986 Manual Provision was cast in per se terms, and would at minimum contractually bind fiscal intermediaries and be entitled to deference from the Secretary in claim adjudications. See Appeals Council Decision at 6; see also Warder v. Shalala, 149 F.3d at 82 (“ “[A]n interpretative rule binds an agency’s employees, including its ALJs, but it does not bind the agency

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<sup>8</sup>The 1995 Regulations observed that, historically,

a device categorized by the FDA as being investigational served as an indication that it was not “reasonable” and “necessary” within the meaning of the Medicare program. As a general rule, these devices currently are not covered.

60 Fed. Reg. 48418 (emphasis added). Since the 1986 Manual Provision would not have bound the Secretary, the Secretary could (if he liked) characterize the superseded rule as a mere presumption against coverage for investigational devices. However, the Secretary has brought to our attention no instance in the period 1986-95 in which a beneficiary or provider successfully challenged an adverse coverage decision with respect to a device covered by an IDE. Moreover, in denying Yale’s reimbursement claim, the Secretary invoked the 1986 Manual Provision without conducting any independent assessment of the safety and efficacy of the devices at issue. The Secretary’s ruling in the alternative, which accepted arguendo that the 1986 Manual Provision is invalid, engaged in some individual assessment; but that assessment was said to require remand to the ALJ for further fact-finding, and thus does not support rejection of the claims (the ruling under review on this appeal).

itself.'" (quoting Kenneth C. Davis & Richard J. Pierce, Jr., Administrative Law Treatise § 6.3, at 104 (3d ed. 1996 & Supp. 1997))).

In 1977-86, providers could justify reimbursement by giving fiscal intermediaries evidence sufficient to establish safety and efficacy; after the 1986 Manual Provision, no prudent provider would treat a Medicare beneficiary with a device that was investigational unless the provider was charitable, or looking for litigation, or had alternative funding. Beneficiaries (or their provider representatives) could appeal adverse coverage determinations, and theoretically could obtain payment by demonstrating that an investigational device was safe and effective despite its not having received FDA premarket approval; but it is unlikely that many beneficiaries would undertake the effort and expense (even assuming they outlived the proceedings). Thus, even if the 1986 Manual Provision was merely interpretive in nature, and therefore lacked the force of law over the agency, it operated with nearly undiminished force on beneficiaries because it was binding on the fiscal intermediaries who paid for treatment.

The Secretary contends that 1986 marked no change of

position, that the 1986 Manual Provision merely expressed Medicare's historical de facto practice, and that therefore nothing required explanation. According to the Secretary, Medicare coverage determinations were made on a device-by-device basis prior to 1976; however, as of that year--when Congress's enactment of the MDA conferred statutory authority on the FDA to regulate new medical devices--fiscal intermediaries were instructed to make coverage determinations for medical devices according to the FDA's premarket determinations.

This narrative seems at odds with the timeline in this case: why did ten years elapse between the conferral of authority on the FDA by the MDA (in 1976) and the promulgation of the 1986 Manual Provision? To answer that question, the Secretary moved in the district court to supplement the administrative record with declarations from senior agency officials.<sup>9</sup> The district court granted Yale's

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<sup>9</sup>For example, Robert A. Streimer, former director of the Bureau of Eligibility, Reimbursement, and Coverage, explained in his declaration that "[o]nce FDA began exercising its statutory authority to determine the safety and effectiveness of devices, HCFA began advising its intermediaries that a device would have to meet the FDA's standards of safety and effectiveness and be legally marketable under the Food and Drug Act." According to the declaration of Thomas E. Hoyer, Director, Office of Chronic

motion to strike the declarations, see Yale-New Haven Hosp., Inc. v. Thompson, 198 F.Supp.2d 183, 184 (D.Conn. 2002) (order granting motion to strike), and we affirm on the ground that the declarations are not admissible to supplement a record that is otherwise devoid of explanation for the Secretary's action.

Generally speaking, after-the-fact rationalization for agency action is disfavored. See SEC v. Chenery Corp., 318 U.S. 80, 87 (1943) ("The grounds upon which an administrative order must be judged are those upon which the record discloses that its action was based."); Citizens to Preserve Overton Park, 401 U.S. at 419 (internal citations omitted) (criticizing lower court's reliance on "post hoc" litigation affidavits in reviewing agency action); see also Forest Watch v. United States Forest Serv., 410 F.3d 115, 119 (2d Cir. 2005); Envntl. Def. Fund, Inc. v. Costle, 657

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Care and Insurance Policy ("Hoyer Declaration"): "[i]n those instances in which FDA approval or clearance of drugs or devices is required before general marketing, it has generally been HCFA's policy that such items are not covered by Medicare unless they have been approved or cleared by the FDA." The Hoyer Declaration also avers that HCFA labeled the 1985 Manual Provisions a "NEW POLICY" because "although HCFA's policy [of following the FDA's determinations] had been expressed previously in intermediary letters and other sources prior to 1986, it had not been included in the manuals."

F.2d 275, 284 (D.C. Cir. 1981) ("It is well settled that judicial review of agency action is normally confined to the full administrative record before the agency at the time the decision was made. . . . not some new record completed initially in the reviewing court."). At the same time, an agency may supplement the administrative record before the reviewing court in some circumstances--among them, if "the absence of formal administrative findings makes such investigation necessary in order to determine the reasons for the agency's choice." Nat'l Audubon Soc'y v. Hoffman, 132 F.3d 7, 14 (2d Cir. 1997) (citing Overton Park, 401 U.S. at 420); see also Camp v. Pitts, 411 U.S. 138, 143 (1973) ("If . . . there was such failure to explain administrative action as to frustrate effective judicial review, the remedy [is] . . . to obtain from the agency, either through affidavits or testimony, such additional explanation of the reasons for the agency decision as may prove necessary."); Action on Smoking & Health v. Civil Aeronautics Bd., 713 F.2d 795, 798 n.2 (D.C. Cir. 1983) ("Where, as in Camp . . . , the agency's explanation is required to be responsive to the purposes of the enabling statute, rather than to a record developed through mandatory hearings or public

comments, post hoc explanations, while undesirable, are not fatal.") (internal citation omitted); see also Shalala v. Ill. Council on Long Term Care, 529 U.S. 1, 23--24 (2000) ("[A] court reviewing an agency determination under § 405(g) has adequate authority to resolve any statutory or constitutional contention that the agency does not, or cannot, decide, including, where necessary, the authority to develop an evidentiary record."); Citizens to Preserve Overton Park, 401 U.S. at 419.

Some tension is evident between the general principle (disfavoring the after-the-fact rationalization of agency action) and the exceptions. The District of Columbia Circuit resolves the tension by positing that "[t]he new materials should be merely explanatory of the original record and should contain no new rationalizations." Env'tl. Def. Fund, 657 F.2d at 285; see also Bunker Hill Co. v. EPA, 572 F.2d 1286, 1292 (9th Cir. 1977) ("[T]he augmenting materials were merely explanatory of the original record. No new rationalization of the . . . regulations was offered by the EPA. Instead, the augmenting materials clarified a dispute that we felt was less than clear from the original record and were clearly admissible."). That analysis is

persuasive, and gives effect to all the precedents. We therefore hold that to the extent that an agency may supplement the record on judicial review of the validity of a rule that is interpretive, it may do so only if the proffered evidence illuminates the original record and does not advance new rationalizations for the agency's action.

True, a rule that is interpretive is subject only to the basic procedural requirements imposed by arbitrary and capricious review under § 706(2)(A) (as elucidated in State Farm), and not the more extensive procedures required by § 553 for a rule passed pursuant to notice-and-comment rulemaking. So the agency's obligation to explain its reasoning on the record is less extensive for an interpretive rule. See Ass'n of Data Processing Serv. Orgs., Inc. v. Bd. of Governors of Fed. Reserve Sys., 745 F.2d 677, 684 (D.C. Cir. 1984) (observing that the requirement for "the most critical factual material that is used to support the agency's position on review" to "have been made public in the proceeding and exposed to refutation" only applies in rulemaking and not in other informal agency action such as promulgation of interpretive rules). We need not draw the contours of that requirement

because the Secretary supplied no contemporaneous explanation at all in promulgating the 1986 Manual Provision.<sup>10</sup> The proffered affidavits sponsor a new rationalization--historical continuity--for the agency's action, and are therefore not admissible.<sup>11</sup>

## **B. The Secretary's Rationales Are Not "Clearly**

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<sup>10</sup>The Secretary also argues that his failure to submit the declarations at the 1995 hearing on Yale's reimbursement claims was due to Yale's failure to argue in that proceeding that the 1986 Manual Provision constituted a deviation from the Secretary's historical practice. The Secretary relies on Edison Elec. Inst. v. Occupational Safety & Health Admin., 849 F.2d 611, 618 (D.C. Cir. 1988), which permitted supplementation of the record because the petitioner's challenge went to an issue that was not directly addressed in the "proceedings below"; but the "proceedings below" referred to were the rulemaking, not a subsequent adjudication of an individual claim.

<sup>11</sup>The Secretary also cites the congressional testimony of Thomas Ault, the Director of Policy Development in the Health Care Financing Administration. See Improper Medicare Billing by Hospitals Nationwide for Investigational Devices and Procedures: Hearing of the Permanent Subcomm. on Investigations of the S. Comm. on Governmental Affairs, 104th Cong. (1996) ("In the case of medical devices, since the 1970s Medicare has looked to the . . . FDA."). We need not decide whether this material is admissible to supplement the administrative record on review. It predates this litigation and therefore (unlike the affidavits) stirs no credibility issue as an after-the-fact rationalization; but even if it is admissible, this short and vague statement is hardly sufficient to establish that the practice prior to 1986 was strict adherence to FDA premarket approval determinations.

## **Discernible"**

The Secretary asserts that the rationales for the 1986 Manual Provision are "clearly discernible." See also State Farm, 463 U.S. at 43. In light of the more searching review occasioned by the Secretary's shift in course, we disagree.

### **1. The Secretary's Failure to Explain Linkage to FDA Standard**

We cannot clearly discern why the standard adopted by the Secretary was FDA premarket approval, given that such a standard likely excludes numerous devices that would be the most appropriate treatments for certain patients.

The Secretary argues that his reasons for relying on the FDA are sufficient because they are implicit in the nature and scope of the FDA's regulatory power. This argument has some force. The Medicare statute itself does not limit the Secretary's choice of experts, and reliance on the FDA would make sense: the FDA is within HHS, and thus subject to the Secretary's direct supervision and control, cf. Marsh v. Oregon Nat. Res. Council, 490 U.S. 360, 378 (1989) ("[The] agency must have discretion to rely on the reasonable opinions of its own qualified experts . . . ."); more important, the FDA exercises exclusive regulatory

authority to determine--through a process that is "rigorous"--whether Class III medical device such as the ICDs at issue in this case are sufficiently safe and effective to be permitted on the market. Medtronic, 518 U.S. at 477 ("Before a new Class III device may be introduced to the market, the manufacturer must provide the FDA with a 'reasonable assurance' that the device is both safe and effective.") (quoting 21 U.S.C. § 360e(d)(2)); see also S. Rep. No. 94-33, at 2 (1975) (stating that Senate's goal in passing the MDA was to ensure that "the FDA has the proper authority to regulate th[e] process [of medical device research and development] so that Americans are not put at risk from the use of unsafe and ineffective medical devices").

Moreover, Congress has shown interest in reining in Medicare's rapidly rising costs.<sup>12</sup> So it would have been

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<sup>12</sup>See Tucson Med. Ctr. v. Sullivan, 947 F.2d 971, 974 (D.C. Cir. 1991) ("Congress discovered that the problem with a system of reimbursement based on a retrospective calculation of reasonable costs [as was established in the original Medicare Act] was that it provided little incentive for hospitals to keep costs down. . . . So Congress set about gradually to change the system of hospital reimbursement."); see also Soc. Sec. Amendments of 1972, Pub. L. No. 92-603, § 223(b), 86 Stat. 1329, 1393 (authorizing Secretary to set limits on the "direct or indirect overall incurred costs or [on] costs incurred for

reasonable for the Secretary to have considered cost-control in determining that Medicare should not cover potentially expensive and unproven investigatory treatments. See Bodnar v. Sec. of Health and Human Serv., 903 F.2d 122, 125 (2d Cir. 1990) (observing that cost-effectiveness is consideration in determining whether services are "not reasonable and necessary"). At the same time, the force of a cost-control rationale for the 1986 Manual Provision is undercut by legislation in 1983 that, through implementation of the Prospective Payment System ("PPS"), see 42 U.S.C. § 1395ww, ended the practice of reimbursing hospitals for their actual (reasonable) costs in treating beneficiaries.<sup>13</sup>

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specific [or groups of] items or services to be recognized as reasonable based on estimates of the costs necessary in the efficient delivery of needed health services"); Section 101 of the Tax Equity and Fiscal Responsibility Act ("TEFRA"), Pub. L. No. 97-248, § 101(b)(1)(A), (B), 96 Stat. 324, 331 (codified as amended at 42 U.S.C. § 1395ww(b)) (requiring HCFA to incentivize hospitals that kept their costs below a "target amount" and to penalize those that exceeded their target amounts).

<sup>13</sup>The PPS categorizes particular classes of patients and treatments into "Diagnostically Related Groups" ("DRGs") and establishes the amount that Medicare will pay for each DRG. See id.; see also Rye Psychiatric Hosp. Ctr. v. Shalala, 52 F.3d 1163, 1167 (2d Cir. 1995). "The PPS seeks to promote efficiency by permitting hospitals to keep the difference between actual costs and the DRG amount, and by denying hospitals payment for costs over the DRG amount." Rye, 52 F.3d at 1167 n.4. The effect of the PPS system is that hospitals absorb the extra costs associated with more

In any event, "reasonable and necessary" is not obviously the same standard as "safe and effective," and the authority to determine which devices are reasonable and necessary (an inchoate and value-laden standard) is conferred by Congress upon Medicare, see 42 U.S.C. § 1395ff(a) (according Secretary authority to promulgate regulations governing benefits eligibility); 42 U.S.C. § 1395ff(f)(1)(A) (delineating scope of judicial review of Secretary's national coverage determinations for items or services), not the FDA--an agency with a separate statutory purpose and agenda. Further, as the Secretary concedes, FDA approval is required even for investigational use under an IDE, and the requirements for FDA approval of an IDE do address the safety and efficacy of the device. The FDA may disapprove an IDE application for a "significant risk device," 21 C.F.R. 812.3(m), if it determines that "[t]here is reason to believe that the risks to the subjects are not outweighed by the anticipated benefits to the subjects and the importance of the knowledge to be gained," 21 C.F.R.

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expensive treatments; that reform thus tends to erode the force of an argument that denial of coverage for devices that have not received FDA premarket approval is needed to contain the costs of the Medicare program.

812.30(b)(4). Use of significant risk devices in clinical trials under an IDE also requires approval by an Institutional Review Board--i.e., "any board, committee, or other group formally designated by an institution to review biomedical research involving subjects," 21 C.F.R. 812.3(f)-which must determine that the "[r]isks to subjects are reasonable in relation to anticipated benefits," 21 C.F.R. 56.111(a)(2).<sup>14</sup>

No doubt, these inquiries are less exacting than the premarket approval process, which considers at least four factors in determining the safety and efficacy of a device: (1) the condition of the device's intended beneficiaries, (2) the circumstances of the device's use, (3) the probable risks and benefits of the device, and (4) the device's reliability, see 21 C.F.R. 860.7(b); that is unsurprising because the very purpose of the IDE is to facilitate the collection of data on safety and effectiveness. Nevertheless, successful completion of the IDE approval process could plausibly serve as the basis for Medicare

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<sup>14</sup>This review is to "consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research)." 21 C.F.R. § 56.111(a)(2).

coverage in certain circumstances. From time to time, the Secretary has adopted policies supported by comparable alternative rationales, as demonstrated by (i) the Secretary's policy with respect to investigational drugs and (ii) the 1995 Regulations.

The Secretary's investigational drug policy, as set out in the 1977 intermediary letter, allowed Medicare coverage for investigational drugs lacking FDA premarket approval that had been approved by a hospital committee and that were administered to inpatients as part of a course of treatment that was itself covered. The 1995 Regulations, which afforded coverage for IDE devices that are refinements or replications of approved technology, were issued in light of the "increasing recognition . . . that there are devices that are refinements of existing technologies or replications of existing technologies by other manufacturers" that "could be viewed as 'reasonable' and 'necessary' under Medicare." 60 Fed. Reg. 48418. We recognize that the Secretary cannot be expected to forecast "increasing recognition" of emerging trends and that the FDA classification of IDE devices into Categories A and B--upon which the 1995 Regulations rely--first became effective in

September of 1995 (pursuant to an agreement between the FDA and the HCFA). See 61 Fed. Reg. 7011. Nevertheless, it seems unlikely that the Secretary was unaware in 1986 of a possible basis for affording coverage to the class of investigational devices that are refinements or replications of existing technologies. More generally, it is hard to say (in light of these alternative coverage methodologies) that the rationale for the Secretary's sole focus on FDA premarket approval, although unexpressed, should be intuited and deemed obvious.

## **2. The Secretary's Failure to Explain Adoption of a Per Se Rule**

The Secretary also fails to explain how adoption of a per se coverage standard comports with congressional purposes in enacting the Medicare Act.

It may well be that sound considerations justify the adoption of a per se approach to coverage determinations. As we reasoned in Goodman v. Sullivan, considerations of administrative convenience afford the Secretary leeway to promulgate such per se rules. 891 F.2d 449, 451 (2d Cir. 1989) ("Because the government could not possibly adjudicate on a case-by-case basis whether a given procedure is 'not

reasonable and necessary,' the Secretary, in order to execute faithfully the mandates of the Medicare statute, necessarily must paint with a broad brush by issuing regulations specifying certain services as per se not reasonable or necessary . . . ."). But there are other considerations. Legislative history of the Medicare Act suggests that Congress wanted Medicare patients to have access to the medical care most suited to their individual needs, see S. Rep. No. 89-404, at 1989 (1965) (explaining how determination as to whether specific treatments are reasonable and necessary is based on needs of individual patient), including innovative treatments, see S. Rep. No. 89-404, at 1967 (stating that, under Medicare, "[t]he reasonable cost of service ordinarily provided to inpatients by hospitals (other than certain items discussed subsequently), including new services and techniques as they are adopted in the future, would be paid for"). This legislative history does not bind the Secretary to provide Medicare coverage for every or any new medical device that is suited to an individual patient's needs, see Goodman, 891 F.2d at 451; but the statute arguably reflects a legislative preference to afford coverage, in the absence of a

substantial reason to the contrary.

The unanswered questions raised by the 1986 Manual Provision--particularly in light of the Secretary's historical practice--demonstrate that it was not the type of self-explanatory, unremarkable application of governing law that would allow a reviewing court to exercise its limited authority to uphold an agency's action based on justifications that the court discerns for itself. See State Farm, 463 U.S. at 43. And while an agency is obliged neither to answer all questions nor to pose them, the 1986 Manual Provision constituted the type of policy choice that Medicare--while it likely has the authority to undertake--must explain.

#### **D. Remedy**

Because the Secretary acted arbitrarily and capriciously under § 706(2)(A) in promulgating the 1986 Manual Provision, we conclude that it is invalid and unenforceable. In adjudicating Yale's claims, the Secretary stated that the 1986 Manual Provision was "entitled to deference," and then concluded simply that Yale's services were not covered "because they were related to the

implantation of investigational device[s] which had not been approved for marketing by the FDA." Appeals Council Decision at 6. The Secretary thus relied on an invalid and unenforceable rule--and in the absence of that rule the Secretary's decision appears "seriously contestable," NLRB v. Wyman, 394 U.S. 759, 766 n.6 (1969) (plurality opinion). The decision therefore must be vacated.<sup>15</sup> See Chenery, 318 U.S. at 94 ("[I]f the [agency's] action is based upon a determination of law as to which the reviewing authority of the courts does come into play, an order may not stand if the agency has misconceived the law. . . . [T]he orderly functioning of the process of review requires that the grounds upon which the administrative agency acted be clearly disclosed and adequately sustained."); Indep. U.S. Tanker Owners Comm. v. Lewis, 690 F.2d 908, 921 (D.C. Cir. 1982); see also Wyman, 394 U.S. at 782 ("[W]e are obliged to

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<sup>15</sup>The Appeals Council held in the alternative that, even in the absence of the 1986 Manual Provision, remand to the Administrative Law Judge for further consideration would be necessary because "[t]he record in these cases contains insufficient evidence to support a conclusion that the devices in question, at the time they were implanted, had been proven safe and effective." Contrary to the Secretary's suggestion, we may not uphold the Appeals Council's reversal on the basis of its alternative holding that the appropriate remedy is remand.

remand a case if the agency has relied upon an improper reason to justify its action.”) (Harlan, J., dissenting).

We remand to the district court with instructions to remand to the Secretary for proceedings consistent with this opinion. On remand to the Secretary, Yale’s claims must be adjudicated under the rules and procedures in place at the time Yale submitted those claims, without reference to the 1986 Manual Provision.<sup>16</sup>

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<sup>16</sup>Yale argues that the Secretary should have applied the 1995 Regulation because it was the “regulation in effect at the time of his final decision.” A regulation may not be applied “to conduct that took place before its enactment in the absence of clear congressional intent where the regulation would impose new duties with respect to transactions already completed.” Sweet v. Sheahan, 235 F.3d 80, 89 (2d Cir. 2000) (quoting Rock of Ages Corp. v. Sec’y of Labor, 170 F.3d 148, 158 (2d Cir. 1999)); see also Landgraf v. USI Film Prods., 511 U.S. 244, 280 (1994) (holding that if statute would, inter alia, “impose new duties with respect to transactions already completed,” then “traditional presumption teaches that it does not govern absent clear congressional intent favoring such a result”). Here, the new payment obligation would fall (ultimately) on the Secretary (i.e., the government) rather than a private party; but the distinction is immaterial. See Landgraf, 511 U.S. at 271 n.25 (1994) (indicating that government and private parties are subject to same anti-retroactivity presumption); see also United States v. Magnolia Petroleum Co., 276 U.S. 160, 162-63 (1928) (holding that the date of allowance of a claim for the refund of internal revenue taxes paid is when the tax commissioner approves the refund, not the date of later-enacted statute at time of appeal, on ground that “[s]tatutes are not to be given retroactive effect or construed to change the status of claims fixed in accordance with earlier provisions unless the legislative

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The judgment of the district court is vacated, and the case is remanded to the district court with instructions to remand to the Secretary for proceedings consistent with this opinion.

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purpose so to do plainly appears"). Because application of the 1995 Regulation, to the extent that it would result in a different disposition of Yale's claims, would impose "new duties" on the Secretary "with respect to transactions already completed," and there is no indication that Congress intended Medicare regulations to have retroactive effect, see Bowen v. Georgetown Univ. Hosp., 488 U.S. 204 (1988), the 1995 Regulation will not govern on remand.

POOLER, Circuit Judge, concurring:

I concur in the judgment and in the analysis of the majority opinion with the exception of its basis for holding that the district court properly excluded declarations of former Health and Human Services officials. See Majority op. **[at 30-31]**. I believe the holding on this issue—that extra-record materials may be admitted only if they “illuminate[] the original record and do[] not advance new rationalizations for the agency’s action”—creates an unnecessary tension with Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402 (1971).<sup>1</sup> Id. **[at 31]**. In Overton Park, petitioners contended that a decision of the Secretary of Transportation was invalid because the Secretary failed to make formal findings. Id. at 408. The Supreme Court rejected this argument. Id. at 409, 417. However, it also directed remand to the district court. Id. at 420. The Court held that on remand “it may be necessary for the District Court to require some explanation in order to determine if the Secretary acted within the scope of his authority and if the Secretary’s action was justifiable under the applicable standard.” Id. The Court explained that where the administrator

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<sup>1</sup> Overton Park was subsequently overruled in part for reasons not pertinent to the issues before us. See Califano v. Sanders, 430 U.S. 99, 105-07 (1977) (overruling Overton Park to the extent that it implicitly held that the APA is an independent grant of subject matter jurisdiction).

has made findings, it is ordinarily not permissible to look outside the record but added "here there are no such formal findings and it may be that the only way there can be effective judicial review is by examining the decisionmakers themselves." Id.; see also Nat'l Audubon Soc'y v. Hoffman, 132 F.3d 7, 14 (2d Cir. 1997) ("[A]n extra-record investigation by the reviewing court may be appropriate . . . where the absence of formal administrative findings makes such investigation necessary in order to determine the reasons for the agency's choice.").

There are no formal findings explaining the Secretary's adoption of the 1986 Manual Provision. Therefore, Overton Park would give the district court discretion to admit and consider the declarations even if the declarants urge reasons for promulgating the provision that are not in the administrative record. Thus, I believe that the majority's reason for upholding the district court's evidentiary ruling is incorrect.

However, the district court did not abuse its discretion by excluding the declarations at issue in this case. See Nat'l Audubon Soc'y, 132 F.3d at 16 ("We review a district court's consideration of matters outside the administrative record under an abuse of discretion standard."). In the case of the 1986 Manual Provision, the agency had not one but three opportunities to make its reasoning public: (1) in conjunction with the promulgation of the 1986 Manual Provision; (2) before the

administrative law judge in the adjudicatory proceedings relevant to plaintiffs; and (3) before the Appeals Council in the same proceedings. Although defendant argues that he had no cause to believe the reasons for his change in position were at issue in those proceedings, his argument is belied by the record. The Secretary argued before the Appeals Council as he argues here that the 1986 Manual Provision is a simple implementation of "long-standing policy" not to cover experimental and investigational devices. **[A72]** The Secretary therefore had ample reason to submit to the administrative adjudicators the declarations that he attempted to submit to the district court.

Further, the declarations are somewhat conclusory; the declarants contend that the Health Care Financing Administration, before 1986, notified its intermediaries that devices would not be covered if they were not approved for marketing by the Food and Drug Administration but fail to indicate when the notices were made, to whom they were made, or by whom they were made.

**[A221]** Because the declarations could and should have been offered at an earlier juncture and because they are too conclusory to be probative of the Secretary's policy prior to the 1986 Manual Provision, the district court did not abuse its discretion by excluding them. See Overton Park, 401 U.S. at 419 (disapproving the use of litigation affidavits on administrative review); Cf. Parker v. Reda, 327 F.3d 211, 215 (2d Cir. 2003)

(indicating that better practice under Federal Rules of Evidence would be to exclude conclusory statements); Hillside Amusement Co. v. Warner Bros. Pictures Distrib. Corp., 224 F.2d 629, 630 (2d Cir. 1955) (holding that district court did not abuse its discretion under Federal Rules of Evidence by excluding conclusory statements).

Because the district court's decision not to admit the declarations was not an abuse of discretion, it is not a basis for disturbing the judgment.