United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued December 12, 2003 Decided February 13, 2004

No. 03-5046

AMGEN INC.,
APPELLANT

v.

DENNIS G. SMITH, IN HIS OFFICIAL CAPACITY AS ACTING ADMINISTRATOR, CENTERS FOR MEDICARE & MEDICAID SERVICES, ET AL.,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 02cv02259)

Jonathan L. Abram argued the cause for appellant. With him on the briefs were *Stuart Langbein*, *William H. Johnson*, *C. Boyden Gray*, *Edward C. DuMont*, and *Andrew R. Varcoe*. *Louis R. Cohen* entered an appearance.

Bills of costs must be filed within 14 days after entry of judgment. The court looks with disfavor upon motions to file bills of costs out of time.

William C. Crenshaw and *Anie Elizabeth Wulkan* were on the brief for *amicus curiae* Biotechnology Industry Organization in support of appellant.

Sharon Swingle, Attorney, U.S. Department of Justice, argued the cause for appellees. With her on the brief were *Peter D. Keisler*, Assistant Attorney General, *Roscoe C. Howard, Jr.*, U.S. Attorney, *Gregory G. Katsas*, Deputy Assistant Attorney General, *Mark B. Stern* and *Michael S. Raab*, Attorneys, *Alex M. Azar II*, General Counsel, U.S. Department of Health & Human Services, *Henry R. Goldberg*, Deputy Associate General Counsel, and *Lawrence J. Harder*, Supervisory Trial Attorney.

Steven A. Zalesin, *Eugene Tillman*, and *Helen G. Kirsch* were on the brief for appellee Ortho Biotech Products LP.

Before: HENDERSON and ROGERS, *Circuit Judges*, and WILLIAMS, *Senior Circuit Judge*.

Opinion for the Court filed by *Circuit Judge* ROGERS.

ROGERS, *Circuit Judge*: The principal issue on appeal is whether the court has jurisdiction of a complaint filed by Amgen, Inc., the manufacturer of an anemia treatment, Aranesp, challenging an adjustment to the Medicare Part B rate at which the federal government pays hospitals for using its product. The district court dismissed Amgen's complaint for lack of prudential standing. Although we hold that Amgen has prudential standing, we affirm the dismissal of the complaint for lack of jurisdiction.

I.

Title XVIII of the Social Security Act of 1935, 42 U.S.C. § 1395 *et seq.*, establishes the Medicare program, which provides federally funded medical insurance to the elderly and disabled. Part A of the Medicare program provides insurance coverage for inpatient hospital care, home health care, and hospice services. *Id.* § 1395c. Part B of Medicare is a voluntary program that provides supplemental coverage for other types of care, including outpatient hospital care. *Id.* §§ 1395j, 1395k. The Medicare program is subject to both

fiscal limits and restrictions on administrative and judicial review. We address the former as applied to Amgen in Part I and the latter in Part III.

A component of the Medicare B program is the Outpatient Prospective Payment System ("OPPS"), which pays hospitals directly to provide outpatient services to beneficiaries. To control costs, OPPS, rather than reimbursing providers after-the-fact for their reasonable expenses in any given year, as was done prior to 1997, pays hospitals prospectively for their services in each upcoming year, thus requiring payments for outpatient hospital care to be made based on predetermined rates. *See* Balanced Budget Act of 1997, Pub. L. No. 105–33, 111 Stat. 251 (1997). As relevant here, OPPS payments governed by 42 U.S.C. § 1395*l*(t) are calculated through a formula setting payment weights for the provision of certain services (or certain groups of clinically similar services) based on the mean or median costs of providing such services in past years, with adjustments for regional cost variations. *Id.* at §§ 1395*l*(t)(2)(C) & (t)(2)(D). Pursuant to amendments to the outpatient prospective payment system in the Balanced Budget Refinement Act of 1999, Pub. L. No. 106–113, 113 Stat. 1501 (1999), the Secretary of the Department of Health and Human Services ("the Secretary") then additionally modifies those resulting payment amounts. Hospitals facing actual costs significantly above their prospective payment amounts receive outlier adjustments. 42 U.S.C. §§ 1395*l*(t)(2)(E) & (t)(5). Hospitals also receive supplemental payments, called "pass-through" payments, to help cover the cost of providing certain treatments, including new drugs, biologicals and medical devices. *Id.* § 1395*l*(t)(6) (hereafter, "§ (t)(6)"). Under § (t)(6), when a drug, biological, or medical device becomes eligible for pass-through status, hospitals providing it to beneficiaries receive supplemental payments equal to 95% of the wholesale cost of the treatment minus whatever amount the hospital would otherwise receive through the prospective payment system, §§ (t)(6)(D)(i) & 1395(u)(*o*), for a period of two to three years. § 1395*l*(t)(6)(C). At the end of that period, the treatment is factored into the normal prospective payment system. More

generally, the Secretary also has authority, in light of his or her "significant expertise" and "judgment grounded in policy concerns" over Medicare's "complex and highly technical regulatory program," *see Tenet Health Systems HealthCorp. v. Thompson*, 254 F.3d 238, 248 (D.C. Cir. 2001) (quoting *Thomas Jefferson Univ. v. Shalala*, 512 U.S. at 512 (1994) (internal quotation omitted)), to make "other adjustments as determined to be necessary to ensure equitable payments." 42 U.S.C. § 1395*l*(t)(2)(E) (hereafter, "§ (t)(2)(E)"). No supplemental funding is available for these three types of adjustments: when the Secretary makes any of the three — outlier adjustments, pass-through adjustments, or other equitable adjustments — any additional projected expenses must be offset by a reduction in all prospective payment rates. § (t)(2)(E). Supplemental pass-through payments are additionally subject to a cap; they may not exceed a fixed percentage of OPPS payments, and must be reduced pro rata in the event they exceed that limit. § (t)(6)(E).

Amgen is the manufacturer of darbepoetin alpha, also known as Aranesp, a relatively recent biological product used to treat anemia in chemotherapy and kidney disease patients. 67 Fed. Reg. 66718, 66758 (Nov. 1, 2002). A similar product, epoetin alpha, was developed in the late 1980s, and is presently marketed both as Amgen's own predecessor product, Epogen, and the product of its competitor (and intervenor here) Ortho Biotech Products, Procrit. *Id.* Providers are presently compensated for providing epoetin alpha to beneficiaries through the regular prospective payment system. While the parties disagree about the significance of molecular differences between darbepoetin alpha and epoetin alpha, Aranesp differs clinically in that it has a longer half-life, such that many patients require less frequent dosages and therefore fewer hospital visits. *Id.*

Amgen applied on November 30, 2001, to the Centers for Medicare and Medicaid Services ("CMS") (known prior to July 1, 2001 as the Health Care Financing Administration), which, as relevant here, administers the Medicare Part B program, for transitional pass-through new-drug status so that hospitals would receive supplemental payments for pro-

viding Aranesp to Medicare Part B beneficiaries. *See* § (t)(6)(A)(iv). According to the complaint, in September 2001 and July 2002, respectively, the Federal Drug Administration approved Aranesp for marketing as a treatment for kidney disease-related anemia and for chemotherapy-related anemia. CMS sent Amgen an approval letter on February 5, 2002, and on March 1, 2002, CMS included Aranesp in the reimbursement rates for 2002, to be effective April 1, 2002. 67 Fed. Reg. 9556, 9562 (March 1, 2002). CMS's proposed 2003 OPPS rates, published on August 9, 2002, also included pass-through payments for Aranesp. 67 Fed. Reg. 52092, 52119 (Aug. 9, 2002). The proposed rule stated, however, that the pass-through provisions had "been exceptionally difficult to implement" and that CMS was "actively seeking comment on all aspects of these [proposed] rates," explaining that it was "open to making changes, perhaps significant" to the proposed rates based on comments received. *Id.* at 52093. Ortho Biotech, the manufacturer of Procrit, submitted comments questioning the pass-through payments for Aranesp in light of its purported similarity to Procrit. 67 Fed. Reg. 66718, 66757 (Nov. 1, 2002). Amgen responded that the two biologicals were not substitutes, and that reimbursement amounts for Aranesp should not be determined in reference to Procrit.

On November 1, 2002, the Secretary published the final rule setting 2003 OPPS rates. 67 Fed. Reg. 66718 (Nov. 1, 2002). Claiming to act pursuant to the authority in § (t)(2)(E) to make "adjustments . . . to ensure equitable payments," CMS adjusted payments for Aranesp to the level hospitals would receive under the prospective payment system, effectively eliminating the supplemental pass-through payment for the biological. *Id.* at 66758. The decision to reduce payments was predicated on the availability of the clinically similar yet cheaper Procrit, and noted that it was not "an equitable or efficient use of Medicare funds to pay for these two functionally equivalent products at greatly different rates." *Id.* Because no historical cost data were available to calculate Aranesp's reimbursement level under the prospective payment system pursuant to § (t)(2)(C), CMS calculated

a reimbursement amount using what it determined to be the equivalent dosage ratio between Procrit and Aranesp. *Id.* at 66758–59. As an alternative ground for the decision, the final rule stated that Aranesp is not "new" for pass-through purposes under § (t)(6)(A)(iv) because it is "functionally equivalent" to Procrit and Epogen. *Id.* at 66759.

Amgen sued the Administrator of CMS and the Secretary on the ground that the rule reducing its pass-through payments violated the plain language of the Medicare Act. Amgen argued that under § (t)(6) the Secretary is required to make pass-through payments for new treatments and can only reduce those payments when necessary to keep total pass-through payments under the statutory cap, and then only on a pro rata basis for all pass-through products. Alleging violations of its procedural rights as well, Amgen argued that the rule was arbitrary and capricious, and that procedural irregularities violated Amgen's rights under the Administrative Procedure Act and the Due Process Clause of the Fourteenth Amendment to the Constitution. The district court allowed Ortho Biotech to intervene on the question of whether Amgen had standing to bring the suit. Relying in large part on the Fourth Circuit's decision in *TAP Pharmaceuticals v. U.S. Dept. of Health*, 163 F.3d 199 (4th Cir. 1998), the district court ruled that Amgen, as a drug manufacturer not itself regulated by or within the zone of interests of the relevant portion of the Medicare Act, lacked prudential standing, and dismissed the complaint. *Amgen v. Scully*, 234 F. Supp. 2d 9 (D.D.C. 2002).

II.

Amgen appeals the dismissal of its complaint on the ground that the district court's ruling that it lacks prudential standing to challenge OPPS payment amounts for its product conflicts with this court's precedent as well as that of the Supreme Court. The court reviews de novo the dismissal of a complaint, accepting as true the allegations of the complaint. *See American Federation of Gov't Employees AFL–CIO v. Rumsfeld*, 321 F.3d 139, 142 (D.C. Cir. 2003).

Section 10(a) of the Administrative Procedure Act, 5 U.S.C. § 702 (2004) ("APA") provides that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." The Supreme Court has held that to qualify as " 'adversely affected or aggrieved . . . within the meaning' of a statute, a plaintiff must establish that the injury he complains of . . . falls within the 'zone of interests' sought to be protected by the statutory provision whose violation forms the legal basis for his complaint." *Lujan v. Nat'l Wildlife Found.*, 497 U.S. 871, 883 (1990) (quoting *Clarke v. Securities Industry Assn.*, 479 U.S. 388, 396–97 (1987)). A party's claimed injury from administrative action, therefore, will be considered "within the meaning" of the relevant statute for purposes of 5 U.S.C. § 702 only if the party can meet the so-called "zone of interests" test. Qualified plaintiffs include not only those who are themselves the "subject of the contested regulatory action," *Clarke*, 479 U.S. at 399, but also those whose interests are not "so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit." *Id.* Amgen contends that it is the subject of the Secretary's action and that its interests are consistent with the statutory scheme. We hold that Amgen's interests are congruent with interests underlying the Medicare Act and do not reach the question whether it is a regulated party.

The Supreme Court has explained that "[t]he [zone of interests] test is not meant to be especially demanding." *Clarke*, 479 U.S. at 399. Thus, "there need be no indication of congressional purpose to benefit the would-be plaintiff." *Id.* at 399–400. Not only need a party not be a beneficiary of a statute, a putative party's "objectives in [the] action" need not be "eleemosynary in nature;" whether they are is "beside the point." *Nat'l Cred. Union Admin. v. First National Bank*, 522 U.S. 479, 498 (1998). Congruence of interests, rather than identity of interests, is the benchmark; the zone of interests test serves to exclude only those "parties whose interests are not consistent with the purposes of the statute

in question," *Ethyl Corp. v. EPA*, 306 F.3d 1144, 1148 (D.C. Cir. 2002), because lawsuits by such plaintiffs "[c]arr[y] a considerable potential for judicial intervention that would distort the regulatory process." *Hazardous Waste Treatment Council, Inc. v. EPA*, 861 F.2d 277, 282–86 (D.C. Cir. 1988).

Parties motivated by purely commercial interests routinely satisfy the zone of interests test under this court's precedents. As the court observed in *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060, 1075 (D.C. Cir. 1998), the salient consideration under the APA is whether the challenger's interests are such that they "in practice can be expected to police the interests that the statute protects." *See also Animal Legal Defense Fund v. Glickman*, 154 F.3d 426, 444–45 (D.C. Cir. 1998) (en banc); *cert. denied sub nom.*, *Nat'l Ass'n for Biomedical Research v. Animal Legal Defense Fund, Inc.*, 526 U.S. 1064 (1999). Manufacturers' challenges to agency actions, then, fall within the zone of interests of a statute when their interests appear congruent with those of the statute. For instance, in *Ethyl Corp.,* 306 F.2d at 1148, a manufacturer of fuel additives had prudential standing, under the Clean Air Act, to challenge regulations applied to automobile manufacturers because, as the developer of products that will "reduce harmful air pollutants," the company's interests "appear congruent with those of the statute." *Id.* Similarly, in *Motor & Equipment Mfrs. Ass'n v. Nichols*, 142 F.3d 449, 458 (D.C. Cir. 1998), the court held that the manufacturers of replacement automobile parts could challenge, under the Clean Air Act, the agency's order permitting California to prohibit tampering with pollution monitors, reasoning that the manufacturers' commercial interest in selling replacement parts was "congruent" with those of mechanics and ultimately of the statute. And in *Nat'l Cottonseed Products Ass'n v. Brock*, 825 F.2d 482, 492 (D.C. Cir. 1987), the manufacturers of respirators had prudential standing to challenge the effectiveness of OSHA regulations in filtering cotton dust "on the basis of the vendor-vendee relationship alone." *Id.* (quoting *FAIC Securities v. Federal Deposit Insurance Corporation*, 768 F.2d 352, 359 (D.C. Cir. 1985)).

Amgen's commercial interest in a full statutory reimbursement rate for Aranesp is neither incidental nor antagonistic to the purposes of § (t)(6), the "statutory provision whose violation forms the basis for the complaint," *Bennett v. Spear*, 520 U.S. 154, 199 (1997). Congress adopted § (t)(6) as an amendment to the Medicare Act in 1999 because the proposed outpatient prospective payments did "not adequately address issues pertaining to the treatment of drugs, biologicals and new technology," and to prevent "restricted beneficiary access to drugs, biologicals and new technology." H.R. REP. 106–436(I) at 53 (1999). Amgen's commercial interest in selling Aranesp is congruent with the interests of beneficiaries in obtaining access to the technology because Congress' reason for providing supplemental pass-through payments was that hospitals inadequately reimbursed for new drugs or biologicals are less likely to provide them and more likely to steer beneficiaries towards older, less expensive treatments. The required offset to other reimbursements caused by supplemental payments for Aranesp under § (t)(2)(E)'s budget-neutrality requirement does not create a disqualifying conflict between Amgen and beneficiaries. There would be such an offset as a result of any successful challenge brought by any eligible plaintiff seeking access to a new treatment. Moreover, just as beneficiaries desiring access to Aranesp and hospitals desiring reimbursement for providing it would have prudential standing to challenge pass-through payment amounts, Amgen as a vendor does as well, *cf. Nat'l Cottonseed Products Ass'n*, 825 F.2d at 492. This is true irrespective of whether hospitals or beneficiaries could file lawsuits; whether Amgen's claim is ultimately precluded is a separate question from whether it has prudential standing to file a lawsuit. Unlike *Hazardous Waste Treatment Council*, 861 F.2d 277, where the court held that an association of pollution equipment providers lacked standing to challenge the agency's adoption of allegedly too weak regulations and that the statute did not manifest "congressional intent to improve the competitive position" of suppliers of more expensive pollution control devices, *id.* at 284, here the purpose of the pass-

through provision is precisely to attract supply of higher-priced items, making Amgen a suitable challenger.

The district court concluded that Amgen's "competitive interest in financial gain" was "not closely aligned with the federal health care insurance act." *Amgen*, 234 F. Supp. 2d at 21. In reaching this conclusion the court focused on the broad purpose of the Medicare Act "to provide more adequate and feasible health insurance protection for the elderly," *id.* at 18, and neglected the more specific interest protected by § (t)(6) itself, namely, preventing "restricted beneficiary access to drugs, biologicals and new technology." H.R. REP. 106–436(I) at 53. Under the precedents discussed, the fact that Amgen's motives were commercial is not disqualifying, and in distinguishing this circuit's precedent, the district court did not give adequate weight to Amgen's financial alignment with Congress' purpose in § (t)(6) of increasing beneficiary access to new medical technology. The district court's reliance on *TAP Pharmaceuticals v. U.S. Dept. of Health*, 163 F.3d 199 (4th Cir. 1998), was also misplaced, for in holding that drug manufacturers lack prudential standing to challenge the Medicare B rates at which providers are reimbursed for their drugs, the Fourth Circuit limited the standing of commercial entities to regulated firms, their competitors, and other firms whose interests put them in the "same position," *id.* at 208, a test that this court has rejected. *See Tax Analysis & Advocates v. Blumenthal*, 566 F.2d 139, 142 (D.C. Cir. 1977), *cert. denied*, 434 U.S. 1086 (1978). Adopting a more flexible approach that focuses instead on whether a party "in practice can be expected to police the interests that the statute protects," *Mova Pharmaceutical Corp.*, 140 F.3d at 1075, is more faithful to the Supreme Court's teachings, in *Clarke*, 479 U.S. at 399, that parties are denied a right to judicial review only when their interests are "marginally related to or inconsistent with" the statute at issue, and in *Nat'l Credit Union Admin.*, 522 U.S. at 499, rejecting as "beside the point" whether a putative plaintiff's objectives are the same as those intended by Congress. The "commercial competitor[s]" of regulated parties, *TAP Pharma-*

ceuticals, 163 F.3d at 208, and those in the "same position," *id.*, may be examples of parties whose interests sufficiently align with some statutory schemes to confer prudential standing, but the court sees no reason to consider them the only parties so situated.

Accordingly, we hold that Amgen's interests are sufficiently aligned with the purpose of § (t)(6) in ensuring the access of Medicare beneficiaries to new technology, and, consequently, it has prudential standing to sue the Secretary and the Administrator.

III.

That Amgen has prudential standing does not resolve this appeal, however. Another threshold issue is whether the court has jurisdiction to entertain Amgen's complaint. The Administrator and Secretary contend that adjustments to OPPS rates are not subject to judicial review. This court may affirm the dismissal of a complaint on different grounds than those relied upon by the district court. *See Bennett v. Spear*, 520 U.S. 154, 166 (1997). The court's jurisdiction is a pure question of law, and as the merits do not hinge on any fact-finding or discretionary balancing of competing interests, a remand to the district court is unnecessary. *Compare McGraw–Hill Cos., Inc. v. Proctor & Gamble Co.*, 515 U.S. 1309, 1311 (1995); *EEOC v. Nat'l Children's Ctr., Inc.*, 98 F.3d 1406, 1411 (D.C. Cir. 1996).

Under § (t)(2)(E), the Medicare Act authorizes the Secretary to make adjustments to the payments hospitals receive under the outpatient prospective payment system:

> (E) The Secretary shall establish, in a budget neutral manner, outlier adjustments under paragraph (5) and transitional pass-through payments under paragraph (6) and other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals.

42 U.S.C. § 1395*l*(t)(2)(E). Regarding judicial review of the Secretary's adjustments, the Medicare Act provides, in pertinent part:

> There shall be no administrative or judicial review under section 1395ff, 1395oo, of this title, or otherwise, of —
>
> (A) The development of the [prospective payment] classification system under paragraph (2), including the establishment of groups and relative payment weights for covered OPD [outpatient department] services, of wage adjustment factors, other adjustments, and methods described in paragraph (2)(F) [regarding measures to control "unnecessary increases in the volume of covered OPD services"];

Id. § 1395*l*(t)(12)(A) (hereafter "§ (t)(12)(A)"). In order to determine whether the court has jurisdiction to consider Amgen's complaint, the court must determine first, whether the "other adjustments" of which § (t)(12)(A) precludes review include the "other adjustments as determined to be necessary to ensure equitable payments" authorized by § (t)(2)(E), and second, whether the Secretary may use the equitable adjustment authority under § (t)(2)(E) to alter a payment amount to which a hospital would have been otherwise been entitled pursuant to the pass-through provision in § (t)(6). Because we hold that § (t)(12)(A) precludes review of the equitable adjustments made pursuant to § (t)(2)(E), and that the Secretary, through CMS, acted within the authority under § (t)(2)(E) in adjusting the pass-through payment amount for Aranesp, our review of DHHS's decision is at an end.

There is a "strong presumption that Congress intends judicial review of administrative action," *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 670 (1986), and it can only be overcome by a "clear and convincing evidence" that Congress intended to preclude the suit. *Abbott Laboratories v. Gardner*, 387 U.S. 136, 141 (1967) (quoting *Rusk v. Cort*, 369 U.S. 367, 380 (1962)). The presumption is particularly strong that Congress intends judicial review of agency action taken in excess of delegated authority. *See Leedom v. Kyne*, 358 U.S. 184, 190 (1958); *Aid Ass'n for Lutherans v. U.S. Postal Service*, 321 F.3d 1166, 1173 (D.C. Cir. 2003). Such review is favored, the court stated in *Dart v. United*

States, 848 F.2d 217, 221 (D.C. Cir. 1988), "if the wording of a preclusion clause is less than absolute."

The court therefore turns to the statute's "language, structure and purpose, its legislative history, and whether the claims can be afforded meaningful review." *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 206 (1994). That Congress intended to preclude judicial review of the Secretary's adjustments to prospective payment amounts is "clear and convincing" from the plain text of § (t)(12) alone. The text of § (t)(12)(E) stipulates that "there shall be no administrative or judicial review" of "other adjustments." The legislative history reflects this stipulation. *See* H.R. REP. 105–149 at 724. That Congress would use such language of prohibition is unsurprising, for piecemeal review of individual payment determinations could frustrate the efficient operation of the complex prospective payment system. *Cf. Block v. Community Nutrition Inst.*, 467 U.S. 340, 348 (1984). Payments to hospitals are made on a prospective basis, and given the length of time that review of individual payment determinations could take, review could result in the retroactive ordering of payment adjustments after hospitals have already received their payments for the year. Moreover, both the pass-through and equitable adjustments to payment rates are subject to a budget-neutrality requirement under § (t)(2)(E), such that judicially mandated changes in one payment rate would affect the aggregate impact of the Secretary's decisions by requiring offsets elsewhere, and thereby interfere with the Secretary's ability to ensure budget neutrality in each fiscal year. Other circuits have noted the havoc that piecemeal review of OPPS payments could bring about, *see Skagit County Pub. Hosp. Dist. No. 2 v. Shalala*, 80 F.3d 379, 386 (9th Cir. 1996); *American Soc'y of Cataract & Refractive Surgery v. Thompson*, 279 F.3d 447, 454 (7th Cir. 2002), and this court has noted similar concerns with respect to the prospective payment system the Medicare A program utilizes to reimburse hospitals for the costs of providing inpatient care. *See Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1232–33 (D.C. Cir. 1994); *County of Los Angeles v.*

Shalala, 192 F.3d 1005, 1019 (D.C. Cir. 1999), *cert. denied*, 520 U.S. 1204 (2000).

In light of the presumption that Congress rarely intends to foreclose review of action exceeding agency authority, however, *see Leedom*, 358 U.S. at 190; *Aid Ass'n*, 321 F.3d at 1173; *Dart*, 848 F.2d at 221, we construe § (t)(12)(E) to prevent review only of those "other adjustments" that the Medicare Act authorizes the Secretary to make; in other words, the preclusion on review of "other adjustments" extends no further than the Secretary's statutory authority to make them. First, the reference to "other adjustments" in § (t)(12)(A) appears alongside other components of outpatient prospective payments that are contemplated by the Act, such as the establishment of "relative payment weights" and "wage adjustment factors." The canon of statutory construction, *noscitur a sociis*, i.e., a word is known by the company it keeps, *cf. Washington State Dept. of Social and Health Services v. Guardianship Estate of Keffeler*, 537 U.S. 371, 384–85 (2003), which is "often wisely applied where a word is capable of many meanings in order to avoid giving unintended breadth to the Acts of Congress," *Jarecki v. G.D. Searle & Co.*, 367 U.S. 303, 307 (1961), suggests that the reference to "other adjustments" in § (t)(12)(A) should similarly be confined to those "other adjustments" otherwise provided for in the Act, and at least creates sufficient ambiguity to trigger the presumption that judicial review of allegedly *ultra vires* agency action is favored. Second, the text in § (t)(12)(A) — "other adjustments" — matches the language of "other adjustments as determined to be necessary to ensure equitable payments" in § (t)(2)(E), implying that Congress intended to reference adjustments made pursuant to that subsection. Third, the interference with the administration of the Medicare B program that would result from judicial review pertaining to the overall scope of the Secretary's statutory adjustment authority, as opposed to case-by-case review of the reasonableness or procedural propriety of the Secretary's individual applications, would be sufficiently offset by the likely gains from reducing the risk of systematic misinterpretation in the administration of the Medicare B program. In the similar

context of prospective payments to hospitals providing inpatient services under the Medicare A program, which also operates under budget-neutrality constraints, review of the validity of certain system-wide determinations by the Secretary has been held to be available notwithstanding an express preclusion on review of individual determinations, *see Universal Health Services of McAllen, Inc. v. Sullivan*, 770 F. Supp. 704, 711–12 (D.D.C. 1991), *aff'd*, 978 F.2d 745 (table) (D.C. Cir. 1992).

Proceeding, then, on the basis that § (t)(12)(A) precludes judicial review of any adjustment made by the Secretary pursuant to the equitable adjustment authority under § (t)(2)(E), but not of those for which such authority is lacking, the court turns to the question of whether § (t)(2)(E) authorizes the type of adjustment the Secretary, acting through CMS, made here. This requires consideration of the merits of Amgen's claim that the Secretary's decision to eliminate pass-through payments for Aranesp violated § (t)(6), which dictates the manner in which such payments are to be calculated. If a no-review provision shields particular types of administrative action, a court may not inquire whether a challenged agency decision is arbitrary, capricious, or procedurally defective, but it must determine whether the challenged agency action is of the sort shielded from review. Otherwise, agencies could characterize reviewable or unauthorized action as falling within the scope of no-review provisions whose application to such action Congress did not intend. In such cases, the determination of whether the court has jurisdiction is intertwined with the question of whether the agency has authority for the challenged action, and the court must address the merits to the extent necessary to determine whether the challenged agency action falls within the scope of the preclusion on judicial review.

Most apposite is *Comsat Corp. v. FCC*, 114 F.3d 223 (D.C. Cir. 1997). The Communications Act of 1934 provides the Federal Communications Commission with authority to make certain amendments to fees, and includes in the same paragraph a provision stipulating that "amendments pursuant to this paragraph shall not be subject to judicial review." 47

U.S.C. § 159(b)(3) (2004). The court held that it had jurisdiction to review whether the Commission's fee changes fell within the scope of the Commission's authority under the paragraph, and that the Commission's position that it was acting pursuant to authority shielded from review did not end the matter: "the statute merges consideration of the legality of the Commission's action with consideration of this court's jurisdiction in cases in which the challenge to the Commission's action raises the question of the Commission's authority to enact a particular amendment. Where, as here, we find that the Commission has acted outside the scope of its statutory mandate, we also find that we have jurisdiction to review the Commission's action." 118 F.3d at 226–27. Similarly, in *E.I. du Pont de Nemours & Co v. Train*, 430 U.S. 112, 124–25 (1977), involving a challenge to regulations promulgated by the Environmental Protection Agency pursuant to the Federal Water Pollution Control Act, the Supreme Court faced a statutory scheme whereby review was available in the Court of Appeals for agency action taken pursuant to a particular section of the Act, but the parties were in disagreement regarding whether that section authorized the agency to issue regulations. The Supreme Court held that "the issue of jurisdiction is intertwined with the issue of EPA's power to issue the regulations" and proceeded to address the merits. *Id.* at 125.

The court therefore must determine whether § (t)(2)(E) authorizes the Secretary to alter a pass-through payment otherwise required by § (t)(6). If it does, review is precluded. If it does not, because the court construes § (t)(12)(A) as only shielding from review "other adjustments" contemplated by the Medicare Act, the preclusion of review would not apply to shield the Secretary's unauthorized action. The effect of the interplay of these statutory provisions is also to render irrelevant Amgen's contentions that the Secretary's elimination of the pass-through payment for Aranesp was arbitrary, capricious, and procedurally deficient. If the Secretary is authorized to alter pass-through payments, judicial review is precluded and it does not matter how the Secretary made the decision. If the Secretary is not so authorized, even a

procedurally proper and reasonably explained decision would be contrary to law because it would be *ultra vires*.

On the merits, Amgen's statutory claim is defeated by the text of § (t)(2)(E). The plain meaning of the Secretary's equitable adjustment authority permits the type of adjustment that the Secretary, acting through CMS, made here. Under § (t)(2)(E), the Secretary may make "other adjustments" to hospital payments beyond those already allowed under by the statute, "as determined to be necessary to ensure equitable payments." It is difficult to see how a decision by the Secretary to adjust pass-through payments for a specific treatment downward, based on the Secretary's conclusion that the treatment is too costly relative to its benefits, would not lie at the heart of such authority. The text of § (t)(2)(E), by authorizing the Secretary to adjust payments where "necessary to ensure equitable payments," manifests Congress's recognition that the payment system might otherwise sometimes produce inequitable results. The House and Conference Reports to the Balanced Budget Act of 1997, Pub. L. No. 105–33, 111 Stat. 251 (1997), state that that Act "giv[es] the Secretary discretion in determining the adjustment factors that will be applied to OPD prospective rates." H.R. REP. 105–149 at 1323 (1997), H.R. CONF. REP. No. 105–217 at 785 (1997). That discretion is what was exercised here.

Amgen presents several arguments for why the Secretary's decision to alter Aranesp pass-through payments is not the sort of "adjustment" authorized under § (t)(2)(E), but none are persuasive. It relies primarily on a textual argument relating to the words "shall" and "other." Amgen maintains that § (t)(6), which sets forth the means for calculating pass-through payments, provides in § (t)(6)(A) that the Secretary "shall" make pass-through payments, as does § (t)(2)(E), and describes the manner of their calculation. Focusing on the specificity of § (t)(6)'s instructions — that pass-through payments shall equal 95% of the wholesale cost of the drug or biological minus the payment amount under the prospective payment system, §§ (t)(6)(D) & 1395(u)(*o*); that the payments shall continue for no fewer than two years and no more than

three, § (t)(6)(C); and that all pass-through payments shall be reduced pro rata in the event that total pass-through payments exceed a fixed percentage of total payments for that year, § (t)(6)(E) — Amgen contends that the Secretary acted unlawfully in using the equitable adjustment authority to override the "clear statutory mandate" to make pass-through payments in the prescribed manner. Amgen points to the pro rata reductions required by § (t)(6)(E) and shielded from review by § 1395*l*(t)(12)(E), and contends that because pro rata reductions to avoid budgetary overruns are the only reductions to pass-through payments addressed in § (t)(6), the Secretary's authority to reduce pass-through payments is correspondingly limited. Amgen also contends that the legislative history of § (t)(2)(E) supports its reading of the word "shall." Prior to 1999, § (t)(2)(E) provided that "the Secretary shall establish other adjustments, in a budget neutral manner, as determined to be necessary to ensure equitable payments, such as outlier adjustments or adjustments for certain classes of hospitals." This language was changed in the Balanced Budget Refinement Act of 1999, Pub. L. No. 106–113, 113 Stat. 1501 (1999), so that § (t)(2)(E) now provides that "the Secretary shall establish . . . outlier payments . . . pass-through payments . . . and other adjustments as determined to be necessary to ensure equitable payments." Amgen contends that the new language, by changing outlier payments from an example of an equitable adjustment the Secretary may consider into an adjustment the Secretary "shall establish," reduced the Secretary's discretion, both for outlier payments and pass-through payments. The Secretary's discretionary authority, Amgen maintains, is therefore limited to "other" adjustments — adjustments to rates "other" than those already adjusted by the outlier and pass-through payment provisions.

This line of reasoning reads too much into the "shall" in §§ (t)(2)(E) and (t)(6)(A). In the Balanced Budget Refinement Act, Congress made outlier and pass-through payments mandatory, but they are mandatory only in the same sense that regional adjustments in § (t)(2)(D) and the use of past cost data in § (t)(2)(C) are mandatory: they are part of

default OPPS rate calculations subject to later adjustment. Congress' amendments to § (t)(2)(E) do not mean that Congress also eliminated the Secretary's discretion to make further equitable adjustments to payment rates already adjusted through the outlier or pass-through provisions. Similar uses of the statutory term "shall" elsewhere for the Medicare B program suggest the opposite. Almost every provision in § 1395*l*(t)(2) governing OPPS payments requires that the Secretary "shall" compute payment amounts in a certain manner: the Secretary "shall" develop a classification system for covered services, § (t)(2)(A); "shall" use median or mean cost data to establish payment weights for those services, § (t)(2)(C); "shall" determine wage adjustment factors, § (t)(2)(D). Other than the Secretary's authority to group clinically similar services together for payment purposes pursuant to § (t)(2)(B), OPPS payments are calculated almost entirely based on steps the Secretary "shall" take. If use of the word "shall" makes those payments final, there would be nothing left for the Secretary to adjust pursuant to § (t)(2)(E), for "other" adjustments would violate a "shall" provision. Congress' use of the term "shall" to describe OPPS calculations throughout § (t)(2) thus contemplates the qualification that initial payment amounts are subject to later adjustment, subject to the Secretary's "discretion." H.R. REP. 105–149 at 1323, H.R. CONF. REP. No. 105–217 at 785. The Balanced Budget Refinement Act used the same terminology in adding pass-through and outlier payments to the initial calculation of OPPS payments, and there is nothing in the Act to suggest that Congress intended to bar adjustments by the Secretary.

Congress' recent amendment to § 1395*l*(t)(6) in § 622 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108–173, highlights the Secretary's flexibility under § (t)(2)(E). As amended, § (t)(6)(F) bars the Secretary, after the date of enactment (December 8, 2003), from calculating pass-through payments for drugs or biologicals in future rates using a "functional equivalence" standard, although determinations of "functional equivalence" made prior to the date of enactment may still be

used in future rates so long as they are made only to determine eligibility for pass-through adjustments and not to calculate other OPPS payments. *Id.* at § 622; 42 U.S.C. § 1395*l*(t)(6)(F)(ii). The amendment only applies "on or after December 8, 2003", *id.*, so it does not apply retroactively of its own force to the 2003 OPPS rates at issue here. The new limitation on the future application of a "functional equivalence" standard to pass-through payments, however, by permitting the continuation of some such calculations made "prior to December 8, 2003," § (t)(6)(F)(ii)(I), contemplates the Secretary's authority to apply such a standard in the first instance. Yet if Amgen's interpretation of §§ (t)(2)(E) and (t)(6)(A) were correct, and the "clear statutory mandate" by which § (t)(6) sets pass-through payments cannot be altered, there would be no opportunity to apply a "functional equivalence" standard to pass-through payments to begin with: payment amounts would have been finally set under § (t)(6)(D), which sets total payments for pass-through drugs and biologicals at 95% of wholesale costs. Congress did not enact such an inflexible system.

Nor, as Amgen contends, does a flexible understanding of the Secretary's equitable adjustment authority under § (t)(2)(E) render superfluous § (t)(12)(E), which prevents review of only certain decisions related to the calculation of pass-through payments. Amgen maintains that if the Secretary could make equitable adjustments to pass-through payments, it would be redundant for the Medicare Act also to exempt decisions about matters such as the duration of payments or the application of any pro rata reduction from judicial review, because the Secretary could make all such decisions as "equitable adjustments" under § (t)(2)(E) and shield them from review under § (t)(12)(A). This is not a redundancy at all; the initial setting of OPPS rates and later adjustments are different decisions. Amgen does not point to any concrete way in which the Secretary could use the equitable adjustment authority to shield a calculation or decision for which the Medicare Act contemplates review. Section (t)(12)(E) is not exhaustive; it lists calculations the

Secretary would make while setting pass-through payments in the first instance. The fact that Congress also used § (t)(12)(A) to shield any later adjustments to those initial rates pursuant to § (t)(2)(E) is not a redundancy. Nor, for that matter, is the breadth of the no-review provisions surprising, given Congress' reasons for limiting review. *See Skagit County Pub. Hosp. Dist. No. 2 v. Shalala*, 80 F.3d 379, 386 (9th Cir. 1996); *American Soc'y of Cataract & Refractive Surgery v. Thompson*, 279 F.3d 447, 454 (7th Cir. 2002); *cf. Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1232–33 (D.C. Cir. 1994); *County of Los Angeles v. Shalala*, 192 F.3d 1005, 1019 (D.C. Cir. 1999), *cert. denied*, 520 U.S. 1204 (2000).

The Secretary's equitable adjustment authority that enables the adjustment of OPPS payments otherwise set by the Medicare Act, including pass-through payments, would not, as Amgen contends, give the Secretary the absurdly broad power to make drastic adjustments, such as the elimination of the entire pass-through program, and term it an "equitable adjustment," thereby undermining the mandatory nature of the pass-through payment system while evading judicial review. Limitations on the Secretary's equitable adjustment authority inhere in the text of § (t)(2)(E), which only authorizes "adjustments," not total elimination or severe restructuring of the statutory scheme. As in *MCI Telecommunications Corp. v. American Tel. & Tel. Co.*, 512 U.S. 218, 225 (1994), where the Supreme Court held that the Federal Communication Commission's authority to "modify" certain requirements could not reasonably be read to encompass the power to make "basic and fundamental changes in the scheme" such as eliminating them entirely, similar limits inhere in the term "adjustments" to those the Supreme Court found in the word "modify." The statutory requirement that the Secretary "shall" develop certain aspects of the payment system is qualified by the Secretary's authority to "adjust[ ]" those payment amounts, but a more substantial departure from the default amounts would, at some point, violate the Secretary's statutory obligation to make such payments and cease to be an "adjustment[ ]." Because the Secretary would, in that

event, exceed his statutory authority under § (t)(2)(E), the preclusion on judicial review in § (t)(12)(A) would not apply. *Cf. Leedom v. Kyne*, 358 U.S. at 190; *United States v. Dart*, 848 F.2d at 223. But because the adjustment to which Amgen objects, involving only the payment amount for a single drug, does not work "basic and fundamental changes in the scheme" Congress created in the Medicare Act, *MCI Telecommunications Corp.*, 512 U.S. at 225, but is rather of the sort contemplated by the plain text of § (t)(2)(E), the court has no occasion to engage in line drawing to determine when "adjustments" cease being "adjustments."

Finally, the court does not reach the question of whether review of Amgen's constitutional claim is barred, as it is not properly before us. Amgen contends in its reply brief that the court has jurisdiction to review Amgen's constitutional claim that the administrative process violated its due process rights under the Fourteenth Amendment irrespective of whether § (t)(12)(A) shields the adjustment from review. The court has "repeatedly held that an argument first made in a reply brief ordinarily comes too late for our consideration." *Students Against Genocide v. Department of State*, 257 F.3d 828, 842 (D.C. Cir. 2001); *see also Bd. of Regents of the Univ. of Washington v. EPA*, 86 F.3d 1214, 1221 (D.C. Cir. 1996). There is no reference in the district court's opinion to Amgen's constitutional claim, and Amgen's main brief mentions neither its constitutional claim nor the district court's failure to address it. Instead, Amgen's main brief seeks reversal only of the district court's ruling on prudential standing under the Medicare Act and the APA, notwithstanding the irrelevance of such a requirement to constitutional claims, *see Clarke*, 479 U.S. at 400 n.16, and its awareness of the Secretary's arguments in the district court that judicial review of Amgen's complaint, which included a constitutional claim, was precluded. The Secretary's brief on appeal does not address whether the court has jurisdiction of the constitutional claim made in Amgen's complaint, as Amgen mentions that claim for the first time in its reply brief. Under these circumstances, the court has no occasion to make exception to

its usual refusal to address contentions raised for the first time in a reply brief.

Accordingly, we affirm the dismissal of Amgen's complaint. Although we hold that Amgen has prudential standing to bring its complaint, we also hold that the court lacks jurisdiction under § (t)(12)(A) to consider Amgen's complaint challenging the Secretary's exercise of the equitable adjustment authority under § (t)(2)(E).