No. 12-356

In the Supreme Court of the United States

MONIQUE D. ALMY, CHAPTER 7 TRUSTEE FOR THE BANKRUPTCY ESTATE OF BIONICARE MEDICAL TECHNOLOGIES, INC., PETITIONER

v.

KATHLEEN SEBELIUS, SECRETARY OF HEALTH AND HUMAN SERVICES

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

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

Whether the Secretary of Health and Human Services has discretion to determine Medicare coverage for a medical device through case-by-case adjudication.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-32a) is reported at 679 F.3d 297. The opinions of the district court (Pet. App. 33a-84a) are reported at 749 F. Supp. 2d 315.

JURISDICTION

The judgment of the court of appeals was entered on April 26, 2012. A petition for rehearing was denied on June 25, 2012. The petition for a writ of certiorari was filed on September 21, 2012. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

Petitioner sought review of several final decisions of the Secretary of Health and Human Services (Secre-

tary) that denied claims for Medicare coverage of a medical device known as the "BIO-1000." The district court granted summary judgment for the Secretary (Pet. App. 33a-72a) and denied petitioner's motion for reconsideration (Pet. App. 73a-84a). The court of appeals affirmed. Pet. App. 1a-32a.

1. Medicare is a federally funded health insurance program for the aged and disabled. 42 U.S.C. 1395 *et seq.* Part B of the Medicare Act establishes a supplemental "voluntary insurance program" that provides coverage "for medical and other health services," including "durable medical equipment." 42 U.S.C. 1395j, 1395k(a)(1), 1395x(s)(6). But the Act forbids payment "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) (Supp. IV 2010).

The Secretary contracts with private insurance carriers to administer the Part B claims process. 42 U.S.C. 1395u (2006 & Supp. IV 2010). Claims relating to durable medical equipment are handled by four contractors, each covering a different geographic region. 42 U.S.C. 1395m(a)(12); 42 C.F.R. 421.210(c), 421.404(c)(2).

Those contractors make the initial determination of whether a particular item of equipment is covered under Part B for a particular patient. The Secretary can choose to issue a "national coverage determination" mandating that the contractors deem a specified item to be "reasonable and necessary" if certain conditions are satisfied. 42 U.S.C. 1395ff(f)(1)(B) (describing "a determination by the Secretary with respect to whether or

not a particular item or service is covered nationally").[1] Absent such a pronouncement, however, each contractor may either (1) make a "local coverage determination," which states "whether or not a particular item [of equipment] * * * is covered" throughout that contractor's region, 42 U.S.C. 1395ff(f)(2)(B); Dep't of Health & Human Servs., Ctr. for Medicare & Medicaid Servs., *Medicare Program Integrity Manual* (*MPIM*) §§ 13.1.3 (Oct. 26, 2006), 13.1.4 (May 27, 2008) (explaining that a local coverage determination "specif[ies] under what clinical circumstances" an item "is considered to be reasonable and necessary"), or (2) proceed on a purely case-by-case basis, applying the "reasonable and necessary" requirement and other coverage criteria to the factual circumstances of each individual claim, see 68 Fed. Reg. 63,693 (Nov. 7, 2003).

In either event, a contractor deems an item of equipment "reasonable and necessary" if it is "[s]afe and effective," "[n]ot experimental or investigational," and "appropriate" in various respects in relation to the needs of the patient. *MPIM* §§ 13.3, 13.5.1, 13.7.1 (Apr. 9, 2004). If an item is covered under this standard, Medicare pays the claimant—typically, the equipment supplier—the lesser of 80% of the actual charge for the item or the amount set in a Medicare fee schedule. 42 U.S.C. 1395m(a) (2006 & Supp. IV 2010); 42 C.F.R. 414.210(a). If coverage is denied, Medicare will nevertheless pay the claim if neither the supplier nor the beneficiary knew or had reason to know that the item would not be covered.

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[1] A procedure is available for a party to request that the Secretary make a national coverage determination with respect to an item, and the Secretary must act on such a request within a defined period of time. See 42 U.S.C. 1395ff(f)(4)-(5); 68 Fed. Reg. 55,634-55,641 (Sept. 26, 2003).

42 U.S.C. 1395pp; 42 C.F.R. 411.400(a). If the supplier does have reason to know of a risk of coverage denial, the supplier can shift that risk to the beneficiary by providing the beneficiary with advance written notice of the specific rationale for the probable denial. 42 C.F.R. 411.404(b); Dep't of Health & Human Servs., Ctr. for Medicare & Medicaid Servs., *Medicare Claims Processing Manual*, Ch. 30, §§ 40.3.6.1 (Oct. 1, 2003), 50.2.1 (Sept. 4, 2012).

A claimant dissatisfied with a contractor's determination is entitled to numerous layers of review. First, the claimant may request that the contractor undertake a "redetermination." 42 U.S.C. 1395ff(a); 42 C.F.R. 405.920, 405.940. Second, the claimant may then ask for "reconsideration" by a "qualified independent contractor"—that is, "an entity or organization that is independent of any organization under contract with the Secretary that makes initial determinations." 42 U.S.C. 1395ff(b)(1)(A) and (c); 42 C.F.R. 405.960. Third, the claimant may appeal the reconsideration decision by requesting a hearing before an administrative law judge (ALJ), who issues a decision based on evidence presented at the hearing or otherwise admitted into the administrative record. 42 U.S.C. 1395ff(b)(1)(A) and (d); 42 C.F.R. 405.1000-1002, 405.1042, 405.1046. Finally, the claimant may appeal the ALJ's decision to the Medicare Appeals Council (MAC), a division of the Departmental Appeals Board of the Department of Health and Human Services. 42 U.S.C. 1395ff(b)(1)(A) and (d)(2); 42 C.F.R. 405.1100.

The MAC makes a de novo assessment of the administrative record, and its ruling is the Secretary's final decision on coverage. 42 U.S.C. 1395ff(d)(2)(B); 42 C.F.R. 405.1130, 405.1136. As such, the ruling is subject

to judicial review in federal district court—a forum where the Secretary's findings of fact "shall be conclusive" so long as they are "supported by substantial evidence." 42 U.S.C. 405(g), 1395ff(b)(1)(A).

2. Petitioner is the bankruptcy trustee of an equipment supplier called BioniCare Medical Technologies, Inc. (BioniCare). BioniCare distributed the "BIO-1000," a device used to treat osteoarthritis of the knee by delivering electrical pulses to the knee joint. Pet. App. 6a-7a.

The BIO-1000 was developed by Murray Electronics, which sought approval of the device from the Food and Drug Administration (FDA). Originally, Murray Electronics submitted an application for pre-market approval—the most rigorous form of pre-market review under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.* The FDA "spends an average of 1,200 hours reviewing" such an application and approves it only if clinical testing gives "reasonable assurance" that the device is safe and effective. *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312, 317-318 (2008). Ultimately, however, Murray Electronics decided to seek "510(k) clearance" instead. Pet. App. 6a-7a, 25a. Such clearance requires no clinical testing; rather, it permits marketing based on a showing that the device is "substantially equivalent" to another device that is already legally on the market. *Id.* at 6a-7a; 21 U.S.C. 360c(f)(1)(A)(ii); 21 C.F.R. 807.100(b)(2)(ii)(B); *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 479 (1996) ("[I]n contrast to the 1,200 hours necessary to complete a [pre-market approval] review, the § 510(k) review is completed in an average of 20 hours."); *id.* at 477-478, 493 (explaining that the predicate device, to which the device submitted for 510(k) clearance is asserted to be substantially equivalent,

would not necessarily have been subject to any safety investigation by the FDA). The FDA granted marketing approval to the BIO-1000 on the ground that it was substantially equivalent to a legally marketed device called a transcutaneous electric nerve stimulator.

BioniCare eventually took over manufacture and distribution of the BIO-1000 and began submitting claims to Medicare contractors. Pet. App. 7a, 39a. There is no national or local coverage determination with respect to the BIO-1000, so those claims were adjudicated on a case-by-case basis. Some contractors covered the device; others frequently denied coverage. *Id.* at 7a. BioniCare sought administrative review of the coverage denials. *Id.* at 7a, 27a.

This case involves eight groups of individual claims as to which BioniCare appealed to the MAC from ALJ decisions that were wholly or partially unfavorable. Pet. App. 7a, 40a-41a. In seven of the resulting final decisions, the MAC denied coverage for the BIO-1000 on the ground that the administrative record did not establish that the device met the statutory "reasonable and necessary" requirement. *Id.* at 7a-8a, 101a. In the eighth decision, that requirement was not at issue, because BioniCare had obtained a favorable contractor determination as to coverage of the BIO-1000 and had appealed only with respect to the amount of payment. *Id.* at 8a. The MAC affirmed the contractor's payment calculation. *Ibid.*

3. After BioniCare filed for bankruptcy, petitioner sought judicial review of all eight MAC decisions. Pet. App. 42a. The district court granted the Secretary's motion for summary judgment. See *id.* at 33a-72a; *id.* at 73a-84a (denying motion for reconsideration). The court held that variations in coverage outcomes at the lower

levels of the Medicare appeals process did not constitute "any material inconsistency" in the agency's decision-making, because the "lower-level components"—which process a huge volume of claims—issue only non-precedential decisions. *Id.* at 49a-50a, 54a-55a. The court also held that the MAC's determinations on the "reasonable and necessary" issue were supported by substantial evidence. *Id.* at 58a. In particular, the court found that the MAC had given adequate weight to the FDA's 510(k) clearance of the BIO-1000—especially in light of BioniCare's insistence that the device used a different "method[ ] of operation" and targeted a different "medical condition[ ]" than the transcutaneous electric nerve stimulator to which the BIO-1000 was compared during the clearance process. *Id.* at 62a. The court also found that the MAC "properly assessed the evidence in the record," including BioniCare submissions, which were "produced or supported by biased sources," suffered from "methodological shortcomings," or constituted "identical boilerplate." *Id.* at 63a-67a.[2]

The court of appeals affirmed, noting the substantial deference that is due to the Secretary in administering a highly complex statutory and regulatory regime that involves "a significant degree of medical judgment." Pet. App. 11a. First, the court held that the Secretary was entitled to use case-by-case adjudication to assess whether the BIO-1000 was "reasonable and necessary." The court explained that nothing in the Medicare statute required the Secretary to adopt a general coverage policy for the device, and that *Heckler* v. *Ringer*, 466 U.S.

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[2] In addition, the district court upheld the MAC's payment-related decision and its rejection of notices by which BioniCare attempted to shift the risk of coverage denial to beneficiaries. See Pet. App. 67a-72a.

602 (1984), had specifically held that the Secretary has discretion to decide whether to assess the reasonableness and necessity of "a particular medical service" by "promulgating a generally applicable rule or by allowing individual adjudication." Pet. App. 12a (quoting *Ringer*, 466 U.S. at 617); see *id.* at 13a (stating that Congress has given the Secretary flexibility in "deal[ing] with hundreds of millions of Part B claims").

Second, the court of appeals found no impermissible inconsistency in the Secretary's decisions as to coverage of the BIO-1000. Pet. App. 27a-30a. All of the MAC's own decisions were consistent with each other, since "in every instance in which the question of whether the device was 'reasonable and necessary' was before the MAC" it "reached the same conclusions about the inadequacy of BioniCare's proffered evidence." *Id.* at 28a. And while some lower-level administrative adjudications reached a different conclusion, those decisions were binding only on the particular parties involved, and the Secretary did not need to defer to them or seek to have them overturned. See *id.* at 27a-28a. The court explained that requiring the Secretary to "reverse any decision at a lower level of adjudication either through promulgation of [a national coverage decision] or through MAC review" would "impose massive resource costs" and severely constrain the Secretary's broad discretion "to administer the Medicare system." *Id.* at 29a.

Third, the court of appeals concluded that the MAC had given adequate consideration to the FDA's clearance of the BIO-1000. Pet. App. 22a-25a. The court explained that the FDA and the Secretary make different determinations, and that the Secretary's independent role in determining coverage is particularly important for devices that were "only cleared by the FDA under

the abbreviated 501(k) process" and thus have "'never been formally reviewed . . . for safety or efficacy.'" *Id.* at 23a (quoting *Lohr*, 518 U.S. at 493).

Finally, the court of appeals held that substantial evidence supported the MAC decisions denying coverage for the BIO-1000. Pet. App. 19a. Rejecting petitioner's suggestion that the MAC relied on the wrong evidentiary standards and allocated the burden of proof incorrectly, see *id.* at 15a-17a, the court found that the MAC had identified serious flaws in each of the studies and other documents on which petitioner relied, see *id.* at 17a-20a.[3]

ARGUMENT

The court below and the Ninth Circuit are the only two courts of appeals to have considered the propriety of final determinations by the Secretary regarding coverage of the BIO-1000, and both upheld those determinations. The Fourth Circuit's decision thus does not conflict with the decision of any other court of appeals. It also correctly applies long-standing principles of administrative law in a manner fully consistent with this Court's decisions. Accordingly, further review is not warranted.

1. The Ninth Circuit recently upheld four MAC decisions denying Medicare coverage for the BIO-1000—a ruling that petitioner mentions only in a footnote. See Pet. 35 n.9; *International Rehabilitative Scis., Inc.* v. *Sebelius*, 688 F.3d 994 (9th Cir. 2012). One of those MAC decisions—which resolved claims submitted by

[3] The court also noted that the existence of a billing code for the BIO-1000 in the Medicare system did not suggest any error in the MAC's decisions, see Pet. App. 20a n.3, and rejected a variety of other challenges to the Secretary's rulings, see, *e.g.*, *id.* at 25a-26a, 30a n.4.

BioniCare as well as by another supplier—was also among the eight decisions upheld by the Fourth Circuit in this case. See Pet. App. 88a-118a.

The Ninth Circuit's decision agrees with the Fourth Circuit's decision in every respect. Invoking the Fourth Circuit's reasoning, the Ninth Circuit held that "while the agency *may* make coverage determinations via up-front rules, it is not *required* to do so; rather, the agency has discretion in whether to make coverage determinations by up-front rulemaking or by case-by-case adjudication." *International Rehabilitative Scis.*, 688 F.3d at 1001. The court also concluded that the Secretary had not acted inconsistently with respect to coverage of the BIO-1000, since no MAC decision "has granted coverage" for that device and "inconsistency" cannot properly be "measured * * * across different levels of agency adjudication." *Id.* at 1000-1001. Finally, the court upheld the MAC's decisions as supported by substantial evidence, noting that "the studies * * * purporting to show the BIO-1000's effectiveness suffered from methodological flaws," and that the FDA's marketing approval did not constitute an independent assessment of the BIO-1000's safety and effectiveness. *Id.* at 1002-1004.

The fact that the Fourth and Ninth Circuits have reached such similar conclusions on the same coverage issue counsels strongly against review here.

2. The decision below (like the decision in *International Rehabilitative Sciences*) does not conflict with any precedent of this Court. Indeed, the Fourth and Ninth Circuits reached their consistent results in reliance on the very decisions of this Court to which petitioner points (Pet. 30-35) in an effort to identify such a conflict. See Pet. App. 12a, 17a, 23a, 25a (citing *SEC* v.

Chenery Corp., 332 U.S. 194 (1947); *Heckler* v. *Ringer*, 466 U.S. 602 (1984); *Director* v. *Greenwich Collieries*, 512 U.S. 267 (1994); *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996); and *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312 (2008)); *International Rehabilitative Scis.*, 688 F.3d at 1001-1002 (citing *Ringer* and *Riegel*).

a. Petitioner suggests (Pet. 30-33) that the holding by the court of appeals that the Secretary was entitled to use individual adjudications to assess whether the BIO-1000 should be covered by Medicare conflicts with this Court's decisions in *Chenery* and *Ringer*. But petitioner does not actually contend that this case is controlled by those decisions; instead, she argues that the decisions can be *distinguished*. See Pet. 31 ("But in *Chenery* and *Ringer*, there was no disavowal of the agency's responsibility ultimately to arrive at some uniform approach. * * * [T]hose cases do not provide a license to perpetuate a regime of inconsistency."); Pet. 32 ("*Ringer* does not address, much less foreclose, Petitioner's challenge to the Secretary's inconsistency."). That argument does not establish the existence of any conflict warranting this Court's review.

Moreover, despite petitioner's effort to distinguish *Chenery* and *Ringer*, those decisions strongly support the decision below. Both stand for what the court of appeals called "[o]ne of the earliest principles developed in American administrative law" (Pet. App. 12a): that "the choice made between proceeding by general rule or by individual, *ad hoc* litigation is one that lies primarily in the informed discretion of the administrative agency." *Chenery*, 332 U.S. at 203; see *Ringer*, 466 U.S. at 617. And *Ringer* articulated that principle when addressing the statutory provisions and regulations governing the Secretary's decision whether to grant Medicare cover-

age to beneficiaries who undergo a particular procedure—the exact administrative framework at issue in this case. See *id.* at 606-611; see also, *e.g.*, *Shalala* v. *Guernsey Mem'l Hosp.*, 514 U.S. 87, 97 (1995) ("The Secretary's mode of determining [Medicare] benefits by both rulemaking and adjudication is, in our view, a proper exercise of her statutory mandate.").

To be sure, as petitioner points out (Pet. 32), the argument rejected in *Ringer* was the inverse of petitioner's argument. The *Ringer* plaintiffs did not seek a uniform, binding coverage determination; they argued that the Secretary had erred by making such a determination rather than permitting case-by-case adjudication. 466 U.S. at 614; see *id.* at 610 (noting argument that Secretary's uniform policy conflicted with various decisions rendered by ALJs). But that distinction does not make the reasoning of *Ringer* any less applicable here. Congress has granted the Secretary broad discretion to choose a mode of making coverage decisions: "The Secretary's decision as to whether a particular medical service is 'reasonable and necessary' and the means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions." *Id.* at 617. The Secretary cannot be forced to alter her choice merely because a claimant believes that there is some more efficient way for administrative decisionmaking to proceed.

b. Petitioner's attempt (Pet. 33-34) to identify some conflict between the decision below and this Court's decisions in *Riegel* and *Lohr* fares no better. Petitioner asserts that those decisions indicate that every FDA marketing decision necessarily requires "a determination by the FDA of some level of safety and efficacy,"

Pet. 33—which, in petitioner's view, means that the court below gave insufficient weight to the FDA's 510(k) clearance of the BIO-1000. That assertion misdescribes *Riegel* and *Lohr* and rests on a faulty premise.

Riegel and *Lohr* do not establish that 510(k) clearance constitutes an independent determination by the FDA that a device is safe and effective. In those cases, the Court held that the rigorous pre-market approval process preempts state-law tort claims against a manufacturer, but mere 510(k) clearance does not. See *Riegel*, 552 U.S. at 322-323; *Lohr*, 518 U.S. at 492-494. That is because "510(k) is 'focused on *equivalence*, not safety,'" while "premarket approval is focused on safety, not equivalence." *Riegel*, 552 U.S. at 323 (quoting *Lohr*, 518 U.S. at 493); see *id.* at 322-323 (explaining that while 510(k) clearance is "an exemption from federal safety review," pre-market approval "*is* federal safety review"); *Lohr*, 518 U.S. at 477-478, 493. Under *Riegel* and *Lohr*, then, the FDA's 510(k) clearance process cannot be said to impose a "requirement" on an equipment manufacturer that "relates to safety or effectiveness." *Lohr*, 518 U.S. at 482, 492 (quoting 21 U.S.C. 360k(a)).

Moreover, even if *Riegel* and *Lohr* did indicate that 510(k) clearance reflected a considered judgment about safety, that judgment would not dictate the outcome of the "reasonable and necessary" determination in the separate Medicare context. As the Secretary has explained, Medicare "contractors make coverage determinations and the FDA conducts premarket review of products under different statutory standards and different delegated authority." Pet. App. 22a (quoting 68 Fed. Reg. 55,636 (Sept. 26, 2003)). Accordingly, while "FDA approval may * * * inform the Secretary's decision as to whether a device is 'reasonable and necessary,' it

cannot tie the Secretary's hands." *Id.* at 23a. *Riegel* and *Lohr*, which are silent on the subject of Medicare coverage determinations, do not suggest otherwise.

c. Finally, contrary to petitioner's argument (Pet. 34-35), there is no conflict between the decision below and *Greenwich Collieries*, which held in the context of a formal agency adjudication that "when the party with the burden of persuasion establishes a prima facie case supported by 'credible and credited evidence,' it must either be rebutted or accepted as true." 512 U.S. at 280 (citation omitted); see *id.* at 269; 5 U.S.C. 554(a), 556(a) and (d). Petitioner says that the agency "'arbitrarily disbelieve[d]'" evidence submitted by BioniCare showing that the BIO-1000 was reasonable and necessary, without ever "rebut[ting] or contradict[ing]" it. Pet. 34-35 (quoting 512 U.S. at 279). But as the court of appeals correctly held (Pet. App. 17a), the condition that triggers the need for some rebuttal under *Greenwich Collieries* was not present here, because the agency properly concluded that BioniCare had not submitted sufficiently credible evidence to "'establish[] a prima facie case.'" 512 U.S. at 280; see Pet. App. 17a (noting in addition that "it is doubtful" that standards for formal adjudication "even apply to these informal proceedings under the Medicare Act"). That is an assessment of the record, not a legal ruling in any tension with *Greenwich Collieries*.

3. Petitioner argues on the merits that the Secretary has acted arbitrarily and capriciously because decision-makers at lower-levels of the claims process approved claims for coverage of the BIO-1000 both before and after the MAC decisions at issue here. See Pet. 1-6, 26-30. Petitioner does not suggest that there is any conflict in the lower courts or any uncertainty in the law in this ar-

ea requiring clarification by this Court; she simply contends (*e.g.*, Pet. 26) that the court of appeals overlooked her argument or did not apply the law correctly. Even if that were so, it would not warrant this Court's review. See Sup. Ct. R. 10. In any event, the court below (like the Ninth Circuit in *International Rehabilitative Sciences*) correctly applied well-established principles of administrative law in rejecting petitioner's contention concerning inconsistent agency decision-making.

As an initial matter, contrary to petitioner's suggestion (Pet. 26), the MAC decisions at issue in this case were fully consistent with each other, as the court below held. See Pet. App. 28a. One of those decisions left undisturbed a determination that the BIO-1000 was reasonable and necessary, because no one had appealed that portion of the ALJ's ruling. But that does not mean that the resulting MAC decision—which was confined to payment issues—somehow endorsed the safety and efficacy of the BIO-1000. The MAC proceeded as an appellate tribunal typically does; it ruled only on the issues that were before it. Cf. *Webster* v. *Fall*, 266 U.S. 507, 511 (1925).

In addition, as the Fourth Circuit explained, it is not correct to characterize lower-level rulings that preceded the MAC's decisions as "inconsistent" with the MAC's conclusions. The MAC issues "final decisions of the Secretary," and it need not "defer to the outcomes of prior decisions below" that "did not carry the full imprimatur of the Secretary's authority." Pet. App. 28a, 30a; see *National Ass'n of Home Builders* v. *Defenders of Wildlife*, 551 U.S. 644, 658-659 (2007). Such deference would prevent the MAC from exercising its independent judgment as to the claims before it. See Pet. App. 30a; *International Rehabilitative Scis.*, 688 F.3d at 1001 (ex-

plaining that "[b]ecause [the MAC decisions] explained the reasons for their disagreement" with "the lower agency adjudicatory decisions granting coverage," and because "agency inconsistency" should not be measured "across different levels of agency adjudication," the MAC's "coverage denials were not impermissibly arbitrary"); *Community Care Found.* v. *Thompson,* 318 F.3d 219, 227 (D.C. Cir. 2003).

Subsequently issued lower-level coverage decisions also do not suggest that the MAC decisions at issue here were arbitrary. It is difficult to see how any lower-level result that post-dates the MAC decisions can cast doubt on their conclusions—and the propriety of the subsequent decisions is of course not at issue in this case. See, *e.g.*, *Amor Family Broad. Group* v. *FCC*, 918 F.2d 960, 961-963 (D.C. Cir. 1990) (rejecting inconsistency argument where lower-level administrative decisions were "decided *after* the [Federal Communications] Commission's dismissal of the case at hand" and "are not binding on the Commission as a decisionmaker"). In any event, the MAC decisions that the Fourth Circuit upheld do not purport to establish a generally applicable policy that lower-level administrative decision-makers are disregarding. See Pet. App. 12a-13a; *NLRB* v. *Wyman-Gordon Co.*, 394 U.S. 759, 765-766 (1969). The MAC decisions were based on the record before that body with respect to particular claims; subsequent cases involve different claims and give the parties a chance to compile different records. See *Amor Family Broad. Group*, 918 F.2d at 961-963.

In the end, petitioner's argument that the Secretary has acted arbitrarily boils down to the contention that the Secretary *should have* employed various specific means to ensure completely uniform results as to every

claim involving the BIO-1000: institution of a national coverage policy, deference to the FDA 501(k) clearance process, or appeal of every contractor decision permitting Medicare coverage of the device. See, *e.g.*, Pet. 26, 28-29; Pet. 32 (arguing that the Secretary can proceed by adjudication if she "*first* set[s] forth the coverage policy at issue in a *sub-regulatory* document and then consistently applie[s] and defend[s] it during the appeals process"). But the Secretary has broad discretion in administering the Medicare statute, and—as this Court has held—should not be forced to select any particular mode of carrying out her authority. See *Ringer*, 466 U.S. at 617; see also *Guernsey Mem'l Hosp.*, 514 U.S. at 97; *Thomas Jefferson Univ.* v. *Shalala*, 512 U.S. 504, 512 (1994) (explaining that agency is entitled to substantial deference in administering Medicare, "'a complex and highly technical regulatory program,' in which the identification and classification of relevant 'criteria necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns'") (quoting *Pauley* v. *BethEnergy Mines, Inc.*, 501 U.S. 680, 697 (1991)).

The court of appeals cogently explained why that conclusion is apt in this case. Nothing in the Medicare Act requires the Secretary to establish a national coverage policy with respect to every conceivable item of durable medical equipment. See Pet. App. 13a-14a ("Congress has not seen fit to set mandatory conditions for the use of [national or local coverage decisions], and we refuse to craft such requirements out of whole cloth."). Nothing requires the Secretary to defer in the Medicare context to an FDA decision about substantial equivalence between the equipment at issue and a different device for purposes of certain provisions of the Federal

Food, Drug and Cosmetic Act. *Lohr*, 518 U.S. at 493; Pet. App. 22a-25a; see *id.* at 62a (noting BioniCare's argument that the predicate device is distinct from the BIO-1000 in significant ways). And nothing requires the Secretary to participate as an adversary at lower levels of adjudication (something she "rarely" does) in an attempt to "reverse" a certain class of decisions on appeal—an approach that would "impose massive resource costs." *Id.* at 29a; see *ibid.* ("The Secretary has simply not seen fit to invoke her final authority in every case in which there is an argument over whether the evidence adequately supports a finding that a device was 'reasonable and necessary.'"). Constraining the Secretary in any of these ways would hamper her in "decid[ing] how to deal with [the] hundreds of millions of Part B claims" made "every year." *Id.* at 13a; see *id.* at 29a (noting that "there were 970 million Medicare Part B claims in 2008 alone"); Gov't C.A. Br. 54 n.19 (noting that in 2008 "benefits for durable medical equipment alone totaled $8.584 billion, or 4.7% of all Part B benefits").

Finally, the court of appeals correctly rejected petitioner's argument (Pet. 28-29) that the MAC's ruling on the "reasonable and necessary" issue was not supported by substantial evidence. See Pet. App. 17a-20a. The court delved into that highly fact-bound question and held that the MAC's rejection of BioniCare's evidence was justified because the evidence suffered from a number of serious flaws.[4] See *ibid.* That decision does not warrant review by this Court.

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[4] The court of appeals also correctly explained why petitioner is wrong to contend (Pet. 29) that the existence of a billing code or a fee schedule for the BIO-1000 somehow required the MAC to reach a different coverage conclusion. See Pet. App. 20a n.3. The agency issues codes and fee schedules with an express disclaimer stating that those

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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NOVEMBER 2012

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administrative steps provide no basis for any inference of Medicare coverage. See *ibid.* (citing 42 U.S.C. 1395y(a)(1)(A) (Supp. IV 2010)); *id.* at 65a-66a.