No. 16-808

In the
# Supreme Court of the United States

VITREO RETINAL CONSULTANTS OF THE PALM BEACHES, P.A.,

*Petitioner*,

v.

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES,

*Respondent*.

**On Petition for Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit**

## REPLY BRIEF FOR PETITIONER

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## REPLY BRIEF

The government's brief in opposition conveniently ignores virtually everything that makes this case cert-worthy. In the decision below, the Eleventh Circuit cleanly and clearly broke with the D.C. Circuit over whether the Secretary of Health and Human Services has authority to rewrite the payment formula that Congress dictated for physicians who administer drugs that are covered under Part B of the Medicare program. The Eleventh Circuit's decision to grant the Secretary such authority parts ways with the D.C. Circuit and allows him to defy the unambiguous limits that Congress (and the D.C. Circuit) placed on his payment power. The Eleventh Circuit's refusal to abide by the statute is all the more indefensible because the Secretary's intransigence does not yield any benefit for the government or Medicare beneficiaries. None. If petitioner followed the government's preferred methodology to a tee, the government would be out of pocket the exact same amount. The only entity that would benefit is the drug manufacturer that insisted that physicians discard *75%* of each vial of Lucentis they purchased.

The government does not seriously engage with any of these arguments. It does not acknowledge the D.C. Circuit's decision in *Hays v. Sebelius*, 589 F.3d 1279 (D.C. Cir. 2009), until nearly the final page of its brief—and even then, its lead response is that any conflict with that case need not be resolved because the Eleventh Circuit's detailed 27-page decision was unpublished. The government *never* acknowledges that the Secretary's position would not actually save

Medicare any money, but would just force physicians to purchase three times more medicine than they actually need in order to receive the full statutory payment rate. Nor does the government ever acknowledge the problem that the Secretary never included in his published coverage decisions the medicine-wasting labeling instruction that he belatedly insists VRC was unequivocally bound to follow. And while the government blithely regurgitates the Eleventh Circuit's conclusion that only the "first" dose from a repackaged vial of Lucentis is "medically reasonable," it does not and cannot explain how anyone could even determine which of the identically repackaged doses is the "first" one. Such a thin argument confirms that the physician's acquisition costs, not the physician's medical practices (which in all events should be left to the States), are really driving the Secretary's payment policy.

In the end, then, there is no escaping the conclusion that the decision below squarely conflicts with the D.C. Circuit's decision in *Hays*. The Eleventh Circuit now allows the Secretary to do precisely what the D.C. Circuit prohibits: reduce Medicare payments whenever the Secretary thinks paying the rate mandated by Congress would be unreasonable. By empowering the Secretary to pick and choose when to abide by Congress' payment rates, the Eleventh Circuit not only has ignored a clear statutory command, but also has introduced untenable uncertainty into an already exceedingly complex and massive government program. This Court should grant certiorari and resolve the circuit split that the decision below creates.

## I. The D.C. And Eleventh Circuits Are Divided Over Whether The Secretary May Ignore Medicare Part B's Statutory Payment Rates For Covered Drugs.

The decision below is in clear conflict with the D.C. Circuit's decision in *Hays*. In the Eleventh Circuit, whenever the Secretary deems a physician's profit margins too high, he can now refuse to pay the physician at Congress' statutorily mandated rates, or (as here) demand repayment—years after the fact—to make up the difference. By contrast, the D.C. Circuit has expressly refused to recognize any such power. In the D.C. Circuit, the Secretary may not consider a physician's acquisition costs, but instead must pay physicians who administer drugs covered under Medicare Part B exactly as Congress specified. The irreconcilability of the two decisions is clear, and the Eleventh Circuit's thinly veiled "alternative holding" serves only to reinforce it.

### A. The Eleventh Circuit's "Overstated Expense" Theory Conflicts with the D.C. Circuit's Decision in *Hays*.

As the government acknowledges, the decision below squarely holds that the Secretary may dock physicians' payments if he concludes that a physician "impermissibly overstated its expenses." Opp.4, 9. That holding directly conflicts with the D.C. Circuit's decision in *Hays*. There, the D.C. Circuit held that the Secretary "may determine only whether [a given drug] is reasonable and necessary; if it is, Medicare must reimburse based on the 106% statutory formula." *Hays*, 589 F.3d at 1280-81. The court thus squarely rejected the Secretary's argument that "the

reimbursement formulas [are] either discretionary or based on the cost of an item or service[]." *Id.* at 1282. Instead, all that matters is if the drug is medically "reasonable and necessary" to treat the patient's condition; if so, then the Secretary *must* pay the physician the rate Congress mandated, regardless of what the physician paid to acquire the drug. *Id.*

The government confirms the conflict between that decision and the decision below simply by describing the Eleventh Circuit's holding: that the Secretary can find a drug covered, yet nonetheless conclude that a physician who administers it is "not entitled to have the [statutorily mandated] per-milligram price" if that price yields a payment exceeding the physician's acquisition costs. Opp.11. Allowing the Secretary to condition payments on a consideration found nowhere in the statute allows the exact "end-run around the statute" that the D.C. Circuit foreclosed in *Hays*. 589 F.3d at 1282; *see also id.* ("[W]e think it quite unlikely that 'Congress, having minutely detailed the reimbursement rates for covered items and services, intended that the Secretary could ignore these formulas whenever she determined that the *expense* of an item or service was not reasonable or necessary.'" (citation omitted)).

The government's cursory discussion of *Hays*—10 pages into an 11-page brief—half-heartedly tries to resist that conclusion by claiming that the Secretary "did not reimburse petitioner at less than the statutory rate for the vials that petitioner actually purchased." Opp.11. But Congress' payment scheme does not turn on how many vials of a drug the physician *purchased*; it turns on how many units of

the drug the physician *administered*. Pet.5-7. The Secretary's focus on vials purchased is thus just another attempt to consider the same acquisition costs that *Hays* held off-limits.

The government alternatively tries to limit *Hays* to the specific "least costly alternative policy" that the court rejected there. Opp.11. But it would make no sense at all to read the Medicare statute as foreclosing a policy that (as in *Hays*) was at least designed to save the program money, while permitting a policy that (as here) is concededly fiscally neutral to Medicare. It would be bizarre indeed for Congress to have prohibited the Secretary from reducing rates when doing so will help the agency's bottom line (as in *Hays*), but to have empowered him to reduce rates when doing so would maximize drug manufacturers' profits while yielding zero benefit to the public fisc (as here). But in all events, whatever the details of the policy at issue in *Hays* may have been, there is no reconciling the D.C. Circuit's holding that the Secretary may not reduce payments based on "the *expense* of an item or service," *Hays*, 589 F.3d at 1282, with the Eleventh Circuit's holding that the Secretary may limit payments based on "the expense incurred by VRC in purchasing the drug," Pet.App.13.

### B. The Eleventh Circuit's Alternative "Medical Reasonableness" Holding Also Conflicts with *Hays*.

The government fares no better with its attempt to reconcile *Hays* with the Eleventh Circuit's "medical reasonableness" rationale. In reality, that "alternative" rationale is no alternative at all, but is

just a backdoor way of getting at the same cost considerations as the "overstated expense" theory. There is no better evidence of that than the fact that the Secretary concocted his "medical reasonableness" theory only *after* the D.C. Circuit's decision in *Hays*. Before that, the Secretary's own contractors made explicit that they were not driven by concerns about *medical* reasonableness; indeed, they did not even *review* VRC's medical records when investigating whether any "overpayment" was made. *See, e.g.*, Pet.App.63 ("[M]edical necessity is not at issue in this case. Medical records were not the source of this review." (quoting 2009 contractor redetermination)). It was only after *Hays* that the Secretary came up with the novel notion that the "first" dose of a multi-dosed vial of Lucentis is medically reasonable, but the "second" and "third" doses are not.

That late-blooming argument "sounds absurd, because it is." *Sekhar v. United States*, 133 S. Ct. 2720, 2727 (2013). Even accepting the Secretary's utterly unsubstantiated claim that the "second" and "third" doses carry a heightened risk of infection, Opp.7, it is not even *possible* to distinguish between the "first," "second," and "third" doses drawn from a multi-dosed vial, as each dose is drawn from the same vial and repackaged in identical fashion. Pet.22-23. Even if there were some way to distinguish among the repackaged doses, moreover, there is certainly nothing in the record to suggest that the Secretary actually attempted to do so. Instead, the Secretary just arbitrarily declared two-thirds of VRC's payment submissions "unreasonable" for the simple reason that VRC did not purchase as much Lucentis as the drug manufacturer insisted

that it purchase. That has nothing to do with medical reasonableness, and everything to do with the very *cost* considerations that *Hays* forecloses.

The Secretary's "medical reasonableness" rationale is as unprecedented as it is implausible. The Secretary has never said that any departure from a drug label renders a practice *per se* medically unreasonable. In fact, he routinely pays for drugs that are administered "off-label" when a physician's medical judgment leads him to disregard some or all of a manufacturer's FDA-approved instructions. Indeed, the Secretary routinely pays for the use of Avastin, a molecular cousin of Lucentis, to treat AMD through injections into the eye—even though Avastin is not approved to treat AMD and is sold only in "single-use" vials that are far too large to treat AMD. *See* Pet.27-28. The only conceivable difference between that situation and this one is the same cost considerations that *Hays* held foreclosed by the statute. Accordingly, the Eleventh Circuit's "alternative" holding is no more consistent with the D.C. Circuit's decision than its principal holding.

## II. The Decision Below Is Wrong.

This Court's review is all the more important because the decision below is wrong. Indeed, the government all but gives its case away on the merits by conceding that, during the time period at issue, the statute as applied to Lucentis yielded a payment rate "of approximately $405 per 0.1 mg *administered*." Opp.3 (emphasis added). There is no dispute that VRC properly billed Medicare for every 0.1 mg it administered. Under the government's own telling, then, VRC was entitled to payment of $405

for each 0.1 mg of Lucentis it administered. This case should have been that simple.

Instead, the government insists that VRC "impermissibly overstated its expenses." Opp.4. But while that assertion may sound good at first blush, it powerfully underscores the conflict between the Secretary's position and the legal and practical considerations that govern the Medicare payment regime. As a legal matter, the D.C. Circuit correctly concluded that Congress' statutory scheme does not allow the Secretary to consider how much a physician paid to acquire a drug that has been deemed covered. "Expenses" are irrelevant. And as a practical matter, precisely because acquisition cost is irrelevant to payment for covered drugs, *physicians are not even asked to state their expenses* when billing Medicare Part B for a drug like Lucentis; they are asked only how many units of the drug they *administered*. In other words, "expenses" are so completely irrelevant to the Secretary's legal regime that physicians seeking payment are not required to state them at all.[1] Complaining that VRC "impermissibly overstated" expenses it was not required to "state" at all is just dangerous rhetoric.

Ignoring the statutory scheme Congress actually created, the government insists that a physician's "reimbursement" should be capped at his actual expenses. *E.g.*, Opp.9. Yet that is a sleight of hand

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[1] The standard Medicare CMS-1500 claim form does not ask physicians to state their expenses. *E.g.*, Form CMS-1500 (08-05), *available at* http://go.cms.gov/2mULy06 (version effective Aug. 2005 through Feb. 2012).

as well, for the governing statute—42 U.S.C. §1395w-3a—does not even use the word "reimbursement," let alone make a physician's expenses relevant to his payment rate. While expenses are relevant under a completely separate part of the Medicare statute that deals with inpatient hospital services, *see id.* §1395x(v)(1)(A); Pet.20, they have nothing to do with the statutory payment framework applicable here. Under that framework, "[t]he Secretary may determine only whether [a given drug] is reasonable and necessary; if it is, Medicare must reimburse based on the 106% statutory formula." *Hays*, 589 F.3d at 1280-81. Whether a cost-based "reimbursement" scheme would be sensible is therefore entirely beside the point, as that is simply not the scheme that Congress created.

Moreover, to the extent that the Secretary's payment decisions turn on judgments about the frequency of off-label use or the relative risk of infection, the Secretary is not only exceeding his statutory authority but wandering into the forbidden territory of the regulation of medicine, which has been reserved to the States. *See* 42 U.S.C. §1395 ("Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided ...."); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 351 (2001) (the Food, Drug, and Cosmetic Act "expressly disclaims any intent to directly regulate the practice of medicine"). It is one thing for the Secretary to refuse payment for a service that is not medically necessary and thus designed just to facilitate payment, but the Secretary

has no warrant to deem a medically necessary procedure "unreasonable" because a doctor chooses to deviate from the label in order to avoid wasting medicine—especially when doing so has no net effect on the public fisc.

## III. The Decision Below Threatens To Destabilize The Administration Of The Medicare Program.

The government does not even bother to dispute the wide-ranging, pernicious consequences the decision below will wreak on the administration of Medicare. *See* Pet.26-29. In particular, the decision below gives the Secretary the unilateral power to deny claims based only on a physician's decision to administer a drug without heeding every requirement in the manufacturer's instructions—even when, as here, the physician is using the drug "on-label" for the treatment approved by the FDA.

Congress did not create a scheme that empowers the Secretary to make arbitrary determinations about whether to treat a drug manufacturer's labels as sacrosanct. To the contrary, part of the point of having a fixed payment rate scheme is to make payments predictable for physicians. Yet the Secretary's approach leaves physicians at the whim of the Secretary, who may now unilaterally declare that certain *on*-label uses are "medically unreasonable" and thus not payable, while continuing to make payments for materially indistinguishable *off*-label uses.

It will only be a matter of time before similar arbitrariness infects the Secretary's willingness to pay for *off*-label uses as well. "Off-label" use is a

common and perfectly legitimate practice that is essential to sound medical treatment, giving doctors flexibility in tending to patients and fostering innovative care. *See Buckman*, 531 U.S. at 349-51; Pet.27-28. Yet in the Eleventh Circuit, the Secretary can now potentially withhold payment—or demand repayment years after the fact—for any off-label drug use that he sees fit, even without advance notice to physicians, even if his extra-statutory intervention has no fiscal value to Medicare, and even if his doing so merely shifts profits from physicians to pharmaceutical companies.

That alone is enough to destabilize the medical practice of physicians who treat Medicare Part B beneficiaries. The fact that the Secretary enjoys such power in the Eleventh Circuit but not in the D.C. Circuit only makes matters worse. It is not tolerable to have a festering split on such a critical issue between two circuits that resolve a sizable portion of Medicare payment disputes.

Finally, the government simply ignores the relationship between this case and *Menendez v. United States*, No. 16-755. As explained in the petition, Pet.28-29, the government has belittled the substantial legal and policy questions surrounding the Secretary's payment policy as part of its effort to deny Senator Menendez the protections of the Speech or Debate Clause. Yet as the division between the D.C. Circuit and the Eleventh Circuit confirms, those legal and policy questions are real. The government thus wisely does not even try to deny that the Court's consideration of this petition may inform its

consideration of the *Menendez* petition, and vice versa.

## CONCLUSION

For the foregoing reasons, this Court should grant the petition.

Respectfully submitted,

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