In The Supreme Court of the United States

LESLIE RUTLEDGE, in her official capacity as Attorney General of the State of Arkansas,

Petitioner,

v.

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,

Respondent.

On Petition For A Writ Of Certiorari To The Court Of Appeals For The Eighth Circuit

REPLY BRIEF FOR PETITIONER

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TABLE OF CONTENTS

Page

ARGUMENT	1
I. The Eighth Circuit's decision conflicts with this Court's precedent	3
II. The Eighth Circuit's decision deepens a circuit split	8
III. This case is an ideal vehicle	10
CONCLUSION	14

i

TABLE OF AUTHORITIES

Page

CASES

Azar v. Allina Health Servs., 139 S. Ct. 51 (2018) 13
Cal. Div. of Labor Standards Enf't v. Dillingham Constr., N.A., Inc., 519 U.S. 316 (1997)7
Gobeille v. Liberty Mut. Ins. Co., 136 S. Ct. 936 (2016)9
Ingersoll-Rand Co. v. McClendon, 498 U.S. 133 (1990)
New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645 (1995)
PCMA v. D.C., 613 F.3d 179 (D.C. Cir. 2010)9, 10
<i>PCMA v. Gerhart</i> , 852 F.3d 722 (8th Cir. 2017) <i>passim</i>
PCMA v. Rowe, 429 F.3d 294 (1st Cir. 2005)9, 10
Yee v. City of Escondido, 503 U.S. 519 (1992)12

STATUTES

Ark. Code Ann. 17-92-507(a)(7)4, 6	
Ark. Code Ann. 17-92-507(a)(9)4	
Ark. Code Ann. 17-92-507(f)(2)7	
Employee Retirement Insurance Security Act (ERISA), 29 U.S.C. 1001 et seqpassim	

TABLE OF AUTHORITIES—Continued

Page

OTHER AUTHORITIES

M. Miller Baker & Sarah P. Hogarth, ERISA	
Broadly Preempts State Regulation of PBM-	
Pharmacy and PBM-Plan Agreements, https://	
perma.cc/3PVL-Z6SE (July 26, 2018)5,	6
Brief of Appellant, <i>PCMA v. Tufte</i> , No. 18-2926 (8th Cir. Nov. 29, 2018)	.5

iii

REPLY BRIEF

Faced with an indefensible opinion that both flouts this Court's precedent and deepens a circuit split, respondent resorts to an unusual strategy for opposing certiorari: It argues that the decisions below are *too* poorly reasoned for this Court to review them. Their reasoning is so "opaque," respondent complains, that it doesn't know why it won. BIO 18. Their judgments are so "enigmatic," respondent claims, that it doesn't even know *what* it won. BIO 16 n.10. But whatever it won, and for whatever reason, respondent is sure that the Eighth Circuit's decision is consistent with this Court's precedent, does not conflict with any circuit's decisions, and presents no issues worthy of review.

Respondent is right about one thing: The Eighth Circuit's decision was poorly reasoned. But as illreasoned as it was, what happened below is no great mystery. Respondent claimed that ERISA preempted four related provisions of Arkansas's pharmacyreimbursement law, and on summary judgment, the district court held those provisions preempted. The Eighth Circuit affirmed, holding that under its previous decision in *PCMA v. Gerhart* it was required to find those provisions referred to, and had impermissible connections with, ERISA plans. Two holdings in *Gerhart* compelled that decision: (1) that a state PBM law refers to ERISA plans if it defines PBMs in a way that *includes or excludes* PBMs serving ERISA plans, and (2) that a PBM law has impermissible connections with ERISA plans if it removes, in any way, PBMs' ability to conclusively determine reimbursements.

Neither holding can be reconciled with this Court's precedent. Respondent effectively concedes as much by conjuring a pair of alternative rationales that fare no better. To start, under respondent's referenceto theory, ERISA plans are essential to a PBM law's operation whenever the law defines PBMs as entities that service prescription drug plans. This is true, respondent says, because an ERISA plan's mere existence (or any other prescription drug plan's) triggers the law's application. That argument makes a mockery of the word "essential" and would require overruling this Court's reference-to precedent. No less problematic is respondent's connection-with theory that states can set PBMs' reimbursement rates, but cannot give pharmacies a right to appeal reimbursement amounts or to decline to sell drugs to a PBM that refuses to pay the rates the state sets.

Moreover, even if respondent's salvage job had some purchase, review would still be warranted to resolve the growing split discussed in the petition. The Eighth Circuit's reference-to rule squarely conflicts with decisions from the First and D.C. Circuits upholding materially identical PBM laws against reference-to attacks. The Eighth Circuit's connectionwith rule likewise contrasts with both: 1) the First Circuit's conclusion that PBMs are such peripheral ERISA players that no law regulating them is preempted; and 2) the D.C. Circuit's conclusion that everything PBMs do is \mathbf{SO} central to plan administration that PBMs are impervious to state regulation. Respondent's protestations otherwise are inaccurate in every respect.

Ultimately, the decision below immunizes the central players in the retail pharmaceutical market from state regulation, conflicting with this Court's precedent and widening a circuit split. Its winner refuses to defend its reasoning and claims not to understand it in this Court, while simultaneously urging its continued application in the Eighth Circuit. And thirty-two States and the District of Columbia, almost all with laws like Arkansas's, ask this Court to review and reverse that decision lest their laws meet a similar fate. This Court should grant certiorari.

I. The Eighth Circuit's decision conflicts with this Court's precedent.

Below, the Eighth Circuit held that ERISA preempted four provisions of Arkansas's PBM-reimbursement law, each implementing Arkansas's policy of setting a pharmacy-acquisition-cost floor for PBM reimbursements. It held that under its earlier decision in *PCMA v. Gerhart*, 852 F.3d 722 (8th Cir. 2017), those provisions were preempted because they both referred to and had "a connection with" ERISA. App. 7a.

In particular, the Eighth Circuit held *Gerhart* compelled that conclusion for two reasons. First in language respondent does not cite—that court reasoned that under *Gerhart*, a PBM regulation references ERISA where it regulates "PBMs who administer benefits for [entities that] *include* . . . entities [that] are necessarily subject to ERISA regulation." App. 6a (emphasis added) (internal quotation marks omitted) (quoting *Gerhart*, 852 F.3d at 729). Under that standard, the Arkansas provisions at issue here impermissibly referenced ERISA plans because they regulate PBMs who manage "pharmacy benefit plans" that *include* ERISA plans. *See* Ark. Code Ann. 17-92-507(a)(7), 17-92-507(a)(9).

Second, on the theory that "making disbursements for [prescription drug] benefits" is an "area central to plan administration," *Gerhart* held that a law that "removes [PBMs'] ability to conclusively determine final drug benefit payments" to pharmacies impermissibly connects with ERISA plans. 852 F.3d at 731. Under that rule, Arkansas's law—even more than the Iowa law at issue in *Gerhart*—had an impermissible connection with plans because it removed PBMs' ability to conclusively determine drug reimbursements by establishing reimbursement floors based on drugs' acquisition cost.

Both holdings squarely conflict with this Court's reference-to and connection-with precedents, which hold, respectively, that a law does not refer to plans unless plans are essential to its operation or its exclusive object of regulation, and that a law that prescribes generally applicable reimbursement rates for healthcare providers does not impermissibly connect with ERISA plans. *See* Pet. 17–19, 21–23. Understandably, then, respondent does not defend them, resorting instead to claiming that the decision below contains too "little

analysis" to say why it won. BIO 19, 22. The decision below may contain little analysis, but there is a reason for that; the Eighth Circuit concluded it was "completely bound by [*Gerhart*'s] reasoning on the exact question before [it]." App 7a. Little more analysis was necessary.

Until recently respondent (and its counsel) understood the Eighth Circuit's reasoning in Gerhart and the decision below. Indeed, just three months before responding to the petition, respondent told the Eighth Circuit that if a state law defines PBMs as servicers of "entities that necessarily include ERISA plans," then under Gerhart and the decision below, the law refers to ERISA. PCMA Br. at 14, PCMA v. Tufte, No. 18-2926 (8th Cir. Nov. 29, 2018). More directly still, respondent's counsel wrote last year that under *Gerhart* and the decision below, "[w]here a state law regulates PBMs and defines the scope of the law to either expressly or implicitly include those PBMs administering pharmaceutical benefits for entities that are subject to ERISA regulation, the state law impermissibly refers to ERISA-governed plans and is preempted." M. Miller Baker & Sarah P. Hogarth, ERISA Broadly Preempts State Regulation of PBM-Pharmacy and PBM-Plan Agreements, https://perma.cc/3PVL-Z6SE (July 26, 2018). Regarding connection-with preemption, respondent successfully argued below that Gerhart held preempted any "limits on PBMs' ability to calculate reimbursements" at their chosen rates. PCMA Response Br. at 19-20 (8th Cir. July 18, 2017). And respondent's counsel has accurately observed that

the decision below held ERISA preempts laws that "[m]andat[e] particular pharmacy reimbursement rates." Baker & Hogarth, *supra*.

But realizing those rules conflict with this Court's precedent, respondent simply declines to defend them. Instead, respondent conjures a pair of alternative rationales—neither of which it claims actually motivated the decision below—that it hopes can justify the Eighth Circuit's result. In one sense, whether respondent is correct does not matter; a denial of certiorari would leave the Eighth Circuit's actual precedentflouting rules in place, not respondent's modestly narrower rationales. Yet in any event, even those rationales equally conflict with this Court's precedent.

Respondent's reference-to theory goes as follows. Arkansas's law regulates PBMs, defining them as "entit[ies] that administer[] or manage[] a pharmacy benefits plan or program." Ark. Code Ann. 17-92-507(a)(7). *Some* "pharmacy benefits plans" are ERISA plans; others are not. To prove that an entity is a PBM, the state must prove "the existence" of a pharmacy benefits plan, which sometimes will happen to be an ERISA plan. BIO 29. Thus, "the very existence of [an] ERISA plan" (or any other prescription drug plan) can trigger the law's application and ERISA plans are therefore essential to the law's operation. BIO 30.

That argument is both sophistic and foreclosed by precedent. This Court has held that a law refers to ERISA plans if the existence of ERISA plans is essential to the law's operation. But the fact that a PBM-ERISA plan relationship is one of a law's *many* regulatory triggers does not make an ERISA plan's existence *essential* to its operation. To the contrary, under Arkansas law, so long as a PBM manages *any* prescription drug plan—even Arkansas's Medicaid program's—it is subject to the challenged regulations. *See* Ark. Code Ann. 17-92-507(f)(2). That does not make a PBM-ERISA plan relationship essential to that regulation, just one on-ramp to it.

Unsurprisingly, this Court has already rejected respondent's semantic approach to reference-to preemption. In Dillingham, California permitted approved apprenticeship programs to pay lower wages than unapproved ones. See Cal. Div. of Labor Standards Enf't v. Dillingham Constr., N.A., Inc., 519 U.S. 316, 320 (1997). The trigger for that law's application, necessarily, was the existence of an approved apprenticeship program. Some of those programs were ERISA plans, but not all were. See id. at 325. Therefore, this Court concluded that the law "'function[ed] irrespective of the existence of an ERISA plan'" and did not refer to them, even though a plan's existence was one possible trigger for the law's application. Id. at 328 (alteration omitted) (quoting Ingersoll-Rand Co. v. McClendon, 498 U.S. 133, 139 (1990)). The relationship between Arkansas's law and ERISA plans is the same.

No less outlandish is respondent's novel connectionwith theory, which concedes that states can set pharmacies' reimbursement rates but would forbid states from enforcing them. According to respondent, ERISA bars Arkansas from requiring PBMs to give pharmacies a way to appeal reimbursements below Arkansas's rate floor, or even from permitting pharmacies to decline to sell drugs to a PBM that refuses to meet it. BIO 32. In other words, whatever state law *says* the rates are, pharmacies must accept whatever rates respondent's members are willing to pay.

This theory too flouts precedent. This Court has held that "ERISA was not meant to pre-empt basic rate regulation," New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Insurance Co., 514 U.S. 645, 667 n.6 (1995), or "intended to squelch" it. Id. at 665. That cannot have meant that ERISA did preempt any recourse states might give providers to insist on the states' rates. Such a rule would eviscerate Arkansas's acquisition-cost-based regulation; acquisition-cost pricing is only enforceable through post-reimbursement appeals and adjustments since PBMs do not know individual pharmacies' wholesale costs ex ante.

II. The Eighth Circuit's decision deepens a circuit split.

The Eighth Circuit's decision categorically shields PBMs from state regulation. There is *no* PBM law that can escape its rule that PBM laws that include ERISA-plan-serving PBMs within their coverage are preempted, because this Court's precedent forbids states from exempting plans from generally applicable law. *See* Pet. 12. The circuits are split on whether such a categorical rule is correct, and on the subsidiary questions of reference-to and connection-with preemption.

The First Circuit has held that ERISA never preempts generally applicable PBM regulations. Indeed, respondent told this Court so when it sought review of that decision. See Pet. 27. Yet respondent now claims that the First Circuit's holding turned on "the specific effect of the state-law provisions before it[.]" BIO 37. But the First Circuit barely described what those provisions said and actually held that since "PBMs . . . are not fiduciaries under ERISA, there can be no preemption" of PBM regulation. PCMA v. Rowe, 429 F.3d 294, 301 (1st Cir. 2005). Respondent alternatively suggests that Gobeille abrogated the First Circuit's holding because it held that ERISA preempted a reporting requirement imposed on plans through their general-purpose third-party administrators. BIO 37-38. That distinction, however, rests on the dubious assumption—on which Gobeille is silent—that a plan's general-purpose third-party administrator is not a plan fiduciary.

By contrast, the D.C. Circuit has expressly rejected *Rowe* and held that any PBM regulation that cannot be waived by ERISA plans is connection-with preempted. Respondent denies that, observing that the D.C. Circuit held some provisions of D.C.'s PBM law were not preempted. BIO 35. But that is solely because *plans could waive them. See PCMA v. D.C.*, 613 F.3d 179, 182 (D.C. Cir. 2010). Otherwise, finding that everything PBMs do for plans involves an "area of core ERISA concern," that court held that any law that "requir[es] a PBM to follow a specific practice in administering pharmaceutical benefits on behalf of an [ERISA plan]" is preempted. *Id.* at 185.

Further, respondent does not even deny the existence of a subsidiary reference-to split. All three laws at issue in *Rowe, D.C.*, and *Gerhart* only regulated PBMs that served "covered entities," and defined that term to include ERISA plans. The First and D.C. Circuits held that did not suffice for reference-to preemption because "the statute would still be operable" were ERISA plans not covered. *Rowe*, 429 F.3d at 304; *D.C.*, 613 F.3d at 189–90 (same). The Eighth Circuit, by contrast, held that because Iowa's "covered entities'... include[d]" ERISA plans, its law referred to them. *Gerhart*, 852 F.3d at 729. The decision below then followed suit. Both sets of decisions cannot be correct, and this Court's review is warranted to resolve the split in authority.

III. This case is an ideal vehicle.

Besides claiming that it cannot comprehend the decision below, respondent's principal submission is that the Court should deny review due to an array of supposed vehicle problems. BIO 18–28. None are real.

Respondent's first objection is that it is unclear which provisions of Arkansas's law the Eighth Circuit held preempted. Not so. In the district court, respondent sought summary judgement on four provisions. Dist. Ct. R. 75-1 at 35; BIO 9–10.¹ The district court granted that motion on respondent's ERISA theory. App. 17a. The Eighth Circuit affirmed, App. 11a, discussing only the provisions respondent challenged, as respondent notes. BIO 18 n.11. What, then, is the mystery? Respondent claims the district court may have granted it more relief than it sought because that court briefly analogized unchallenged and unrelated disclosure provisions of Arkansas's law to those in *Gerhart*. BIO 15–16. But that hardly suggests—let alone establishes—that the district court set aside provisions respondent never even challenged. And in any event, it is immaterial. This petition is limited to those provisions all parties agree were held preempted—the ones respondent challenged.

Respondent also raises a series of waiver objections. For instance, it claims Arkansas never argued below that its law was not preempted because it regulated reimbursement. BIO 22–23. Yet an entire subsection of Arkansas's opening Eighth Circuit brief was entitled "State regulation of reimbursement methodologies is not a proper subject for a preemption finding." Cross-Appellant's Br. at 74–76 (8th Cir. June 15, 2017). Respondent further claims Arkansas did not argue that its law's general applicability precluded a reference-to finding until its reply brief. BIO 33. But respondent's own brief belies that claim. *See* PCMA Response Br. at 32 ("[Arkansas] argues that the law does not make a 'reference to' ERISA because the law

¹ Respondent claims that it also challenged the law's definition of pharmacy acquisition cost, BIO 9, but that is incorrect.

covers non-employment based pharmacy benefit programs.").

Along the same lines, respondent claims the question presented fails to include important issues. For instance, respondent claims that the question presented fails to consider two of the provisions that it challenged because the question characterizes Arkansas's law as "regulating drug-reimbursement rates." BIO 20. In particular, respondent claims that phrase excludes review of Act 900's provisions permitting pharmacies to decline to sell drugs to a PBM that refuses to pay acquisition-cost rates, and requiring PBMs to update their reimbursement rates if acquisition costs significantly rise. But those provisions *regulate drug-reimbursement rates*, or implement that regulation.

Most fancifully, respondent claims the entire issue of reference-to preemption is waived because the question notes the Eighth Circuit's holding was "in contravention of this Court's precedent that ERISA does not preempt rate regulation." BIO 24–27. Aside from ignoring the petition's extensive discussion of reference-to preemption, that claim is doubly wrong.

First, this is not a case like *Yee v. City of Escondido*, where the petitioner limited an otherwise broad question by literally asking whether it was "error for the [lower] court to disregard the rulings" of two circuits that solely addressed one subsidiary issue. 503 U.S. 519, 536 (1992). Rather, Arkansas's question simply asks "[w]hether the Eighth Circuit erred in holding that Arkansas's statute . . . is preempted by ERISA[.]" Pet. i. The balance of the question merely highlights the Eighth Circuit's contravention of one aspect of this Court's ERISA precedent as particularly review-worthy. Second, contrary to respondent's suggestions, "this Court's precedent that ERISA does not preempt rate regulation" in fact includes a reference-to holding; in *Travelers*, this Court held that generally applicable rate regulation "cannot be said to make 'reference to' ERISA plans in any manner." 514 U.S. at 656.

In any event, respondent cannot claim that the petition failed to put it (or the Court) on notice of an issue it seeks to raise. Respondent fully understood—and addressed—the State's reference-to argument. Moreover, if the Court concludes that the question's "in contravention" clause could be read to exclude that issue, it could rewrite the question to omit that clause. *See Azar v. Allina Health Servs.*, 139 S. Ct. 51 (2018) (rewriting question to include issue argued in petition and addressed by respondent but omitted from petitioner's question presented).

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CONCLUSION

The questions this petition raises are fundamental: whether states may ever regulate PBMs, and whether, if they may, states may regulate the punishingly below-cost rates PBMs too often pay pharmacies. The laws of thirty-six States—thirty-two of which have asked this Court to grant review—hang in the balance. This Court should grant certiorari.

Respectfully submitted,

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