

No. _____

**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**

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Thirty-six States have enacted legislation to curb abusive prescription drug reimbursement practices by claims-processing middlemen—known as pharmacy benefit managers (PBMs)—who make money on the spread between the rates at which they reimburse pharmacies and the drug prices they charge health plans. In response, Respondent Pharmaceutical Care Management Association (PCMA), a PBM trade association, has launched a barrage of litigation across the country arguing that state regulations of PBMs generally, and state drug-reimbursement regulations specifically, are categorically preempted by the Employee Retirement Income Security Act of 1974 (ERISA). Disregarding this Court’s ERISA precedent (and contrary to the First Circuit’s conclusion that PBM regulations are categorically *not* preempted by ERISA), the Eighth Circuit embraced that argument.

The question presented here is:

Whether the Eighth Circuit erred in holding that Arkansas’s statute regulating PBMs’ drug-reimbursement rates, which is similar to laws enacted by a substantial majority of States, is preempted by ERISA, in contravention of this Court’s precedent that ERISA does not preempt rate regulation.

PARTIES TO THE PROCEEDING BELOW

Petitioner is Arkansas Attorney General Leslie Rutledge, the defendant-cross-appellant below.

Respondent is Pharmaceutical Care Management Association, the plaintiff-cross-appellee below.

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PETITION FOR A WRIT OF CERTIORARI

Petitioner Arkansas Attorney General Leslie Rutledge, in her official capacity as a constitutional officer of the State of Arkansas, respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Eighth Circuit in this case.

**OPINIONS BELOW**

The opinion of the court of appeals (App. 1a–11a) is reported at 891 F.3d 1109. The decision of the district court (App. 12a–36a) is reported at 240 F. Supp. 3d 951.

**JURISDICTION**

The judgment of the court of appeals was entered on June 8, 2018. On August 3, 2018, Justice Gorsuch extended the time to file a petition for certiorari to and including October 8, 2018. On October 1, 2018, Justice Gorsuch extended the time to file a petition for certiorari to and including October 22, 2018. The jurisdiction of this Court is invoked pursuant to 28 U.S.C. 1254(1).



STATUTORY PROVISIONS INVOLVED

The Supremacy Clause of the U.S. Constitution provides:

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

U.S. Const. art. VI, cl. 2.

The “other laws” provision of the Employee Retirement Income Security Act (ERISA), 29 U.S.C. 1144, is set forth at App. 37a–44a.

Arkansas’s Maximum Allowable Cost Lists statute, Ark. Code Ann. 17-92-507, is set forth at App. 45a–50a.



INTRODUCTION

Pharmacists are important frontline healthcare providers. Indeed, in rural America and inter-city communities, a person’s only regular interaction with a healthcare provider may be with a pharmacist. But in recent years, abusive prescription drug reimbursement practices by PBMs have driven more than 16% of independent rural pharmacies from the healthcare

marketplace, and in many communities, nothing has replaced them.

In response, thirty-six States have enacted legislation designed to curb the abusive PBM reimbursement practices that have driven independent pharmacies from the marketplace. Arkansas, for instance, enacted a statute that regulates the rates at which PBMs reimburse pharmacies for drugs and gives pharmacies a right to appeal a PBM's reimbursement rate. Other States have enacted similar regulations. *See, e.g.*, Cal. Bus. & Prof. Code 4440; Ohio Rev. Code Ann. 3959.111; Tex. Ins. Code Ann. 1369.351–62.

This case concerns whether ERISA broadly preempts those regulations. ERISA preempts state laws that “relate to” employee benefit plans within ERISA’s coverage, 29 U.S.C. 1144(a), and under this Court’s precedents, that language preempts two classes of laws. *First*, ERISA preempts laws that make impermissible explicit reference to ERISA plans, exclusively act on ERISA plans, or regulate in such a way that ERISA plans are essential to their operation. *Second*, ERISA preempts laws that have impermissible connections with ERISA plans, assessed in light of ERISA’s objectives. By contrast, this Court has held ERISA does not preempt state regulation of the *rates* that ERISA plans pay for medical services.

Applying prior circuit precedent on a materially similar statute regulating PBM reimbursement, the Eighth Circuit held ERISA preempted Arkansas’s statute because: (1) it impermissibly referred to ERISA

plans, given that PBMs' customers *include* ERISA plans; and (2) it had an impermissible connection with ERISA plans, given a prior panel's reasoning that the rates at which plans or their intermediaries reimburse pharmacies for prescription drugs are an "area central to plan administration," sacrosanct from state regulation. Because that decision conflicts with this Court's precedent, a decision in a substantially similar First Circuit case, and the reasoning of other circuits, this Court should grant review and ultimately reverse the decision below.

◆

STATEMENT

In 1974, Congress enacted ERISA to protect the participants and beneficiaries of employee welfare and pension benefit plans. *See* 29 U.S.C. 1001, 1002(3). "ERISA does not guarantee substantive benefits," *Gobeille v. Liberty Mutual Insurance Co.*, 136 S. Ct. 936, 943 (2016); instead, it secures the benefits an employer promises to provide by regulating certain plan-administration procedures. *Id.* The plan-administration procedures ERISA regulates fall into essentially four categories: reporting and disclosure, conditions of plan participation and benefit-vesting, plan funding, and plan administrators' basic fiduciary duties to their plans. *See N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 641 (1995).

“One of [ERISA’s] principal goals . . . [wa]s to enable employers ‘to establish a uniform administrative scheme, which provides a set of standard procedures to guide processing of claims and disbursement of benefits.’” *Egelhoff v. Egelhoff*, 532 U.S. 141, 148 (2001) (quoting *Fort Halifax Packing Co. v. Coyne*, 482 U.S. 1, 9 (1987)). In pursuit of that aim, ERISA contains an express preemption clause. It states that ERISA preempts “any and all State laws insofar as they may now or hereafter relate to any employee benefit plan.” 29 U.S.C. 1144(a).

The course of this Court’s ERISA preemption doctrine has not run smooth. By 1997, only twenty-three years after ERISA’s enactment, this Court had already taken sixteen cases to “resolve [circuit splits] regarding ERISA pre-emption of various sorts of state law,” and it has taken six more since.¹ *Cal. Div. of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc.*, 519 U.S. 316, 334 (1997) (Scalia, J., concurring). In large part this is due to “the unhelpful text” of 1144(a), *Travelers*, 514 U.S. at 656, under which, if read literally, “pre-emption would never run its course, [as] ‘really, universally, relations stop nowhere.’” *Id.* at 655 (alteration omitted) (quoting Henry James, Roderick Hudson xli (World’s Classics 1980)).

In the mid-90s, however, this Court succeeded in imposing a measure of order on ERISA preemption

¹ See *Gobeille*, 136 S. Ct. 936 (2016); *Aetna Health Inc. v. Davila*, 542 U.S. 200 (2004); *Ky. Ass’n of Health Plans, Inc. v. Miller*, 538 U.S. 329 (2003); *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355 (2002); *Egelhoff*, 532 U.S. 141 (2001); *UNUM Life Ins. Co. of Am. v. Ward*, 526 U.S. 358 (1999).

law. It did so by describing two categories of state laws that ERISA preempts: laws that “make ‘reference to’ ERISA plans,” *Travelers*, 514 U.S. at 656, and laws that have “an impermissible connection with ERISA plans.” *Egelhoff*, 532 U.S. at 147.

This Court’s test for reference-to preemption is relatively simple. Absent express references to ERISA-covered plans, *see Dillingham*, 519 U.S. at 324, a law only impermissibly refers to ERISA plans if it “acts immediately and exclusively upon ERISA plans . . . or where the existence of ERISA plans is essential to the law’s operation[.]” *Id.* at 325.

What qualifies as an impermissible connection with ERISA plans is somewhat more opaque. The farthest this Court has gone in offering a general standard is instructing lower courts to look to “‘the objectives of the ERISA statute as a guide to the scope of the state law that Congress understood would survive,’ and ‘the nature of the effect of the state law on ERISA plans.’” *Gobeille*, 136 S. Ct. at 943 (citation omitted) (quoting *Dillingham*, 519 U.S. at 325). At a minimum, “state law[s] that ‘govern a central matter of plan administration’” have such impermissible connections. *Id.* (alteration omitted) (quoting *Egelhoff*, 532 U.S. at 148).

Yet critically for present purposes, one application of this standard is clear. Because ERISA did not begin to regulate the rates at which employee health benefit plans reimbursed medical providers—and was enacted against a backdrop of abundant state regulation of

those rates—this Court has “conclu[ded] that ERISA was not meant to pre-empt basic rate regulation.” *Travelers*, 514 U.S. at 667 n.6.

* * *

Enter pharmacy benefit managers, or PBMs. Barely on the horizon when ERISA was enacted, they were first mentioned in a federal or state-court opinion in 1998, a year after this Court issued its last landmark opinion on ERISA preemption. Since then, they have appeared in 640 of them, often as defendants in complex litigation over their sharp reimbursement and billing practices.²

PBMs are prescription-drug middlemen. They reimburse pharmacies on behalf of healthcare plans, and in turn, bill those plans for their beneficiaries’ prescriptions. PBMs serve ERISA health plans, non-ERISA group health plans, insurers in the individual marketplace, federal and state employees’ health

² See, e.g., *In re Pharm. Benefit Managers Antitrust Litig.*, 582 F.3d 432 (3d Cir. 2009) (multidistrict antitrust action alleging that PBM used the market power of its ERISA plan sponsors to reduce the prices it paid to pharmacies below prices that would prevail in a competitive market); *In re Express Scripts/Anthem ERISA Litig.*, 285 F. Supp. 3d 655 (S.D.N.Y. 2018), *appeal filed*, No. 18-346-cv, 2d Cir. Feb. 5, 2018 (putative class action alleging that PBM’s inflationary drug pricing breached its fiduciary duty under ERISA to employer plans); *Anthem, Inc. v. Express Scripts, Inc.*, 16 Civ. 2048 (ER), 2017 WL 1134765, at *3 (S.D.N.Y. Mar. 23, 2017) (\$15 billion breach-of-contract action against PBM for overcharging); *In re Express Scripts, Inc., PBM Litig.*, 522 F. Supp. 2d 1132 (E.D. Mo. 2007) (multidistrict breach-of-fiduciary-duty action against PBM).

plans, Medicare Part D, and many state Medicaid programs. Few healthcare plans administer their prescription drug benefits without a PBM's assistance; indeed, "the vast majority of insured Americans receive their pharmaceutical benefits through" one. *Pharm. Care Mgmt. Ass'n v. Dist. of Columbia*, 613 F.3d 179, 182 (D.C. Cir. 2010).

PBMs make "[m]uch of [their] revenue . . . on the 'retail spread'" between the rates at which they reimburse pharmacies for drugs and the prices they receive from their healthcare plan customers. Dep't of Labor, Advisory Council on Emp. Welfare & Pension Benefit Plans (ERISA Advisory Council), *PBM Compensation and Fee Disclosure* at 7 (2014), available at <https://perma.cc/F4ZY-MNC7>. PBMs' spread profits are substantial; a study commissioned several months ago by the Ohio Department of Medicaid found that in a single year Ohio Medicaid's PBMs billed Ohio \$223.7 million more than they reimbursed pharmacies for the same drugs.³ HealthPlan Data Solutions, LLC, *Executive Summary: Report on MCP Pharmacy Benefit Manager Performance* at 3 (June 15, 2018), available at <https://perma.cc/6KR8-MXNX>.

On the individual-drug level, another study of PBM spreads found that PBMs billed \$215 for a drug that they reimbursed at only \$15 and \$80 for a drug

³ Ohio responded to this discovery by terminating its contracts with its PBMs. See Lucas Sullivan & Catherine Candisky, *Ohio firing pharmacy middlemen that cost taxpayers millions*, The Columbus Dispatch, Aug. 14, 2018, available at <https://perma.cc/FB73-MS75>.

that they reimbursed at only \$7. Robert I. Garis & Bartholomew E. Clark, *The Spread: Pilot Study of an Undocumented Source of Pharmacy Benefit Manager Revenue*, 44 J. Am. Pharm. Ass'n 15, 18 (2004), available at <https://perma.cc/U3V9-VBJ6>. A more recent investigative report found spreads between PBM pharmacy reimbursement and PBM plan billing for some drugs of \$0.67 and \$8.64, or \$0.30 and \$5.80—a factor of nineteen. Lucas Sullivan & Catherine Candisky, *'Cost-cutting' middlemen reap millions via drug pricing, data show*, The Columbus Dispatch, June 17, 2018, available at <https://perma.cc/L5LA-5S8D>.

Some of PBMs' spread is attributable to aggressive billing markups, a problem that has caused four States, and the District of Columbia, to regulate the relationship between PBMs and plans.⁴ But some of it is attributable to aggressively low pharmacy reimbursement rates—rates that in many cases are exceeded by pharmacies' drug acquisition costs. In Iowa, the state insurance commissioner found that twenty-three community pharmacies closed due to below-cost PBM reimbursement rates, Video Remarks on Iowa H.F.

⁴ See Iowa Code 510B.4 (requiring PBMs to perform their services for their customers with good faith and fair dealing, and to disclose conflicts of interest to their customers); Nev. Rev. Stat. 683A.178 (imposing fiduciary duties and conflict-of-interest disclosure obligations on PBMs vis-à-vis their customers); S.D. Codified Laws 58-29E-3-4 (imposing duty of good faith and fair dealing, duty to disclose payments from drug manufacturers upon request); Vt. Stat. Ann. tit. 18, 9472 (imposing disclosure and pass-back obligations on PBMs); D.C. Code 48-832.01-03 (same). Two of these states, Iowa and Vermont, also regulate PBMs' pharmacy reimbursement practices. See n.6, *infra*.

2297, at 10:20–21 A.M. (Mar. 4, 2014) (statement of Rep. Linden);⁵ a subsequent legislative study found that in some cases pharmacies were reimbursed forty cents a pill for drugs that they purchased from wholesalers for one dollar. *Id.* at 10:23 A.M. (statement of Rep. Ourth).

Similarly, in Arkansas, one pharmacist attested to receiving below-cost reimbursements for 856 prescriptions over a three-month period in 2015 at a net loss of \$6.67 per prescription; another attested to receiving below-cost reimbursements for 307 prescriptions over the same period at a net loss of \$5.96 per prescription. Dist. Ct. R., Docs. 19-1 at 4 ¶ 14, 19-2 at 3 ¶ 11.

Such below-cost reimbursements have left marks on the pharmacy industry, and particularly so on independent rural pharmacies. In the last fifteen years, 16.1 percent of independently owned rural pharmacies in the United States have closed, and 630 rural communities that had one or more pharmacies, independent or otherwise, lost their only pharmacy. Aboidun Salako, Fred Ullrich & Keith J. Mueller, *Update: Independently Owned Pharmacy Closures in Rural America, 2003–2018*, Rural Pol’y Brief (July 2018), at 1, available at <https://perma.cc/54YD-X9BM>. One hundred and ten of those communities are located in the six states comprising the Eighth Circuit. *Id.* at 5.

The plight of small pharmacies has not gone unnoticed in the halls of state government. To date,

⁵ <http://www.legis.state.ia.us/dashboard?view=video&chamber=H&clip=934&offset=6646&bill=HF%202297&dt=2014-03-04>.

thirty-six States and counting have enacted legislation regulating PBMs' pharmacy reimbursement practices.⁶ Iowa and Arkansas are just two recent examples.

In 2014, Iowa enacted a law regulating PBM pharmacy reimbursement. *See* Iowa Code 510B.8. The statute required PBMs to report, on request, their pricing methodology to the state insurance commissioner, and to give pharmacies an opportunity to appeal their reimbursement rates to the PBM. *See id.* The statute provided no rule of decision for those appeals, or administrative or judicial review of PBMs' decisions.

Two months after that provision went into effect, Respondent, a trade association of PBMs, brought an action seeking a declaratory judgment that ERISA preempted Iowa's law. *See Pharm. Care Mgmt. Ass'n v. Gerhart*, 852 F.3d 722, 727 (8th Cir. 2017), *reh'g denied*.

⁶ *See* Alaska Stat. 21.27.950; Ark. Code Ann. 17-92-507; Cal. Bus. & Prof. Code 4440; Colo. Rev. Stat. Ann. 25-37-103.5; Del. Code Ann. tit. 18, 3323A; Fla. Stat. Ann. 465.1862; Ga. Code Ann. 33-64-9; Haw. Rev. Stat. 328-106; Iowa Code 510B.8; Kan. Stat. Ann. 40-3830; Ky. Rev. Stat. Ann. 304.17A-162; La. Rev. Stat. Ann. 22:1864; Me. Rev. Stat. Ann. tit. 24-A, 4317; Md. Code Ann., Ins. 15-1628.1; Minn. Stat. Ann. 151.71; Mo. Rev. Stat. 376.388; Mont. Code Ann. 33-22-170-73; N.H. Rev. Stat. Ann. 420-J:8; N.J. Stat. Ann. 17B:27F-2-4; N.M. Stat. Ann. 59A-61-4; N.Y. Pub. Health Law 280-a; N.C. Gen. Stat. 58-56A-5; N.D. Cent. Code 19-02.1-14.2; Ohio Rev. Code Ann. 3959.111; Okla. Stat. Ann. tit. 59, 360; Or. Rev. Stat. 735.534; Pa. Stat. Ann. tit. 40, 4531-35; R.I. Gen. Laws 27-41.38.2; S.C. Code Ann. 38-71-2110-40; Tenn. Code Ann. 56-7-3104-11; Tex. Ins. Code Ann. 1369.351-62; Utah Code Ann. 31A-22-640; Vt. Stat. Ann. tit. 18, 9473; Wash. Rev. Code Ann. 19.340.100; Wis. Stat. 632.865; Wyo. Stat. Ann. 26-52-104.

The district court held that the statute did not “impermissibly reference ERISA, concluding that the existence of ERISA plans [wa]s not essential to the law’s operation and, further, that the statute d[id] not act ‘immediately and exclusively’ on ERISA plans.” *Id.* at 727–28. The district court also held the statute did not have a prohibited connection with ERISA plans, reasoning that it did not dictate any particular rates or pricing methodology. *See id.* at 727.

In an opinion by District Judge Catherine Perry, sitting by designation, the Eighth Circuit reversed. That court first held that Iowa’s statute was preempted because it expressly exempted PBMs that represented “certain ERISA plans.” *Id.* at 729. That counterintuitive result was compelled by this Court’s decision in *Mackey v. Lanier Collection Agency & Service, Inc.*, 486 U.S. 825 (1988), which held that otherwise generally applicable laws that specifically exempt ERISA plans are preempted by ERISA. *See id.* at 828–30.

The Eighth Circuit next held that Iowa’s statute also made a prohibited implicit reference to ERISA plans by defining them as managers of benefits provided by plans and insurers that “include . . . entities [that] are necessarily subject to ERISA regulation,” *Gerhart*, 852 F.3d at 729 (emphasis added), as well as entities outside ERISA’s coverage, such as nonprofit hospitals, individual insurers, and government employee plans. *See id.* (citing Iowa Code 510B.1(2)). Because *some* of the PBMs covered by the statute represented ERISA plans, the Eighth Circuit concluded

that the statute made impermissible reference to those plans.

Finally, that court concluded that Iowa's statute had an impermissible connection with ERISA plans, both because of its reporting obligations, which this Court deemed preempted under *Gobeille*, and because of its reimbursement appeal provision. *See id.* at 731. The latter, the Eighth Circuit claimed, "implicat[ed] another area central to plan administration—that is, the calculation of prescription benefit levels and making disbursements for these benefits," and "remove[d] [plans'] ability to conclusively determine final drug benefit payments and monitor funds." *Id.*

In 2013, Arkansas enacted a PBM reimbursement statute much like Iowa's, Ark. Code Ann. 17-92-507; in 2015, it amended the statute to specify a standard for PBM reimbursement rates. Unlike Iowa's provision, that statute does not explicitly exempt PBMs working with ERISA plans from regulation; nor does it impose reporting obligations on PBMs. Like Iowa's statute, it does create an appeal procedure for pharmacies to challenge their reimbursement rates. *See* Ark. Code Ann. 17-92-507(c)(4). As in Iowa, PBMs themselves—not agencies or courts—decide those appeals. As amended, however, Arkansas's statute provides a standard for deciding those appeals and requires PBMs to raise their reimbursement rate for a drug if that rate is below a pharmacy's primary wholesaler's price. *See* Ark. Code Ann. 17-92-507(c)(4)(C)(iii). Thus, under Arkansas's statute, pharmacies are protected against below-cost reimbursements.

Weeks after this amendment to Section 17-92-507 went into effect, Respondent filed suit in the Eastern District of Arkansas, claiming that provision was preempted by both ERISA and Medicare Part D and that it violated the dormant Commerce Clause, Contract Clause, and Due Process Clause. App. 16a. The district court held that because Section 17-92-507 “regulate[d] PBMs in ways fundamentally similar to the Iowa statute in *Gerhart*,” it was preempted by ERISA, solely as applied to PBMs’ service of ERISA plans. App. 19a. That court rejected the balance of Respondent’s claims. App. 36a.

Respondent appealed the district court’s ruling on Medicare Part D preemption, abandoning its constitutional claims, and Petitioner cross-appealed the district court’s ruling on ERISA preemption. App. 5a. In an opinion by Circuit Judge C. Arlen Beam, the Eighth Circuit affirmed the district court’s ERISA conclusion and reversed on Medicare Part D. App. 11a.

On her cross-appeal, Petitioner argued that *Gerhart*’s implicit-reference and connection-with holdings were—given *Gerhart*’s express-reference holding—unnecessary dicta that were inconsistent with this Court’s decisions in *Dillingham* and *Travelers*. The Eighth Circuit disagreed, holding it was “completely bound by [*Gerhart*’s] reasoning on the exact question before us,” and affirmed the district court’s holding that Section 17-92-507 was partially preempted by ERISA. App. 7a. Moreover, that court stressed that under circuit precedent, PBM regulations impermissibly make implicit reference to ERISA plans because

PBMs’ customers “*include* . . . entities [that] are necessarily subject to ERISA regulation.” App. 6a (emphasis added) (quoting *Gerhart*, 852 F.3d at 729). That court also found *Gerhart*’s connection-with holding binding on the permissibility of regulating PBM reimbursement. App. 7a (“[H]ere, the state law both relates to and has a connection with employee benefit plans.”). On PCMA’s appeal, the court separately held that Section 17-92-507 was preempted by Medicare Part D, as applied to PBMs’ service of Medicare Part D plans. App. 7a–11a.



REASONS FOR GRANTING THE WRIT

I. The Eighth Circuit’s decision squarely conflicts with this Court’s ERISA preemption precedents.

In *Gerhart* and in the decision below, the Eighth Circuit first adopted and then reaffirmed two rules of ERISA preemption. First, any generally applicable state regulation of PBMs implicitly refers to ERISA and is preempted because the universe of PBMs *includes* PBMs that administer benefits for ERISA plans. Second, any generally applicable state regulation of PBM provider reimbursement rates has an impermissible connection with ERISA and is preempted.

Those rules squarely conflict with this Court’s precedent. Indeed, both rules would vastly expand ERISA preemption beyond the limits that this Court has set, and unsurprisingly, this Court has already

rejected them. Thus, this Court should grant review and ultimately reverse the decision below.

a. The Eighth Circuit’s implicit-reference rule conflicts with this Court’s implicit-reference precedents.

It is undisputed that Arkansas’s pharmacy reimbursement law covers far more than those PBMs that administer benefits for ERISA plans. It defines a PBM as any “entity that administers or manages a pharmacy benefits plan or program,” Ark. Code Ann. 17-92-507(a)(7), and explicitly includes PBMs “employed by the Arkansas Medicaid Program or the [Arkansas] Employee Benefits Division”—neither of which administer ERISA plans. *See* 29 U.S.C. 1003(b)(1) (exempting “governmental plan[s]” from ERISA coverage). Likewise, Iowa’s pharmacy reimbursement law in *Gerhart* expressly applied to PBMs that administered benefits for non-ERISA plans or insurers, including both individual insurers and HMOs, as well as “a health program administered by a department or the state[.]” *Gerhart*, 852 F.3d at 729 (quoting Iowa Code 510B.1(2)).⁷

⁷ On a national level, Respondent claims that only 35.7% of the 266 million Americans who purchase prescription drugs through PBMs do so under the auspices of an ERISA plan. *See* Pharmaceutical Care Management Association, *Pharmacy Benefit Managers (PBMs): Reducing Costs and Improving Quality* at 5 (May 18, 2018), available at <https://perma.cc/JS9D-BLSA> (lobbying presentation to National Conference of State Legislatures).

The Eighth Circuit could not, then, claim that Iowa’s and Arkansas’s pharmacy reimbursement laws implicitly referred to ERISA by exclusively regulating ERISA plans or entities that dealt with them. Instead, it held those laws “ma[de] implicit reference to ERISA” because they regulated “PBMs who administer benefits for . . . entities, which, by definition, *include* health benefit plans and employers, labor unions, or other groups . . . subject to ERISA regulation.” App. 6a (emphasis added) (quoting *Gerhart*, 852 F.3d at 729) (internal quotation marks omitted).

As Respondent itself recently argued in an Eighth Circuit district court, the decision below cemented “a new rule regarding the ‘reference to’ inquiry”: “that an implicit reference to ERISA exists even where the law does not *only* regulate entities necessarily subject to ERISA regulation,” so long as it is “broad enough to encompass ERISA plans within its scope[.]” *Pharm. Care Mgmt. Ass’n v. Tufte*, ___ F. Supp. 3d ___, No. 1:17-cv-141, 2018 WL 4222870, at *5 (D.N.D. Sept. 5, 2018), appeal filed, No. 18-2926, 8th Cir. Sept. 7, 2018 (quoting Respondent’s supplemental brief on the decision below).

But that is not the test for ERISA implicit-reference preemption. Rather, as this Court recently reaffirmed, a state law implicitly refers to ERISA if it “acts immediately and exclusively upon ERISA plans[,] or where the existence of ERISA plans is essential to the law’s operation[.]” *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 943 (2016) (alterations omitted) (quoting *Cal. Div. of Labor Standards Enforcement v.*

Dillingham Constr., N.A., Inc., 519 U.S. 316, 325 (1997)). If a law regulates a class of third-party administrators or claim processors whose customers merely *include* ERISA plans, it logically follows that the law does not act immediately and exclusively upon ERISA plans, and that the existence of ERISA plans is not essential to the law’s operation.

Indeed, applying that commonsense proposition, in *Dillingham*, this Court rejected the test adopted by the Eighth Circuit for implicit-reference ERISA preemption. There, California had enacted a law providing that public works contractors could pay an apprenticeship wage to apprentices in apprenticeship programs that met national standards. *See Dillingham*, 519 U.S. at 319. A contractor subcontracted with an apprenticeship program that did not meet those standards. *See id.* at 321–22. That program, like many but not all apprenticeship programs, satisfied ERISA’s broad definition of employee welfare benefit plans. *See id.* at 323–24. The contractor, therefore, argued to this Court that California’s law “ma[de] ‘reference to’ ERISA plans” by regulating the wages paid in a class of apprenticeship programs that *included* ERISA plans. *Id.* at 325.

This Court made short work of this argument, reasoning that California’s law did not refer to ERISA because the regulated “apprenticeship programs *need not necessarily be ERISA plans*[.]” *Id.* (emphasis added). Whether an apprenticeship program was an ERISA plan turned on whether it was “funded through a separate fund.” *Id.* at 326. California’s law was “indifferent

to the funding, and [thus the] attendant ERISA coverage, of apprenticeship programs.” *Id.* at 328. Therefore, it “function[ed] irrespective of the existence of an ERISA plan,” *id.* (alteration omitted) (quoting *Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 139 (1990)), and “[a]ccordingly, [it] d[id] not make reference to ERISA plans.” *Id.*

Likewise, in *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Insurance Co.*, 514 U.S. 645 (1995), this Court disposed of a suggestion that a state-mandated hospital surcharge on certain insurers referred to ERISA plans, though ERISA plans were among the purchasers of their insurance and were affected by the surcharges in the form of increased insurance rates. This Court explained that the surcharges were imposed on insurers “regardless of whether [their] coverage . . . is ultimately secured by an ERISA plan, private purchase, or otherwise, with the consequence that the surcharge statutes cannot be said to make ‘reference to’ ERISA plans in any manner.” *Id.* at 656.

The upshot of *Dillingham* and *Travelers* is simple: a law that regulates a class of entities that *includes* ERISA plans (*Dillingham*), or that regulates a class of entities whose customers include ERISA plans (*Travelers*), does not refer to ERISA plans. Yet despite that obvious rule, the Eighth Circuit has twice held just the opposite: that so long as *some of the customers* of a class of regulated entities are ERISA plans, their regulation impermissibly refers to ERISA plans.

In fact, the Eighth Circuit’s implicit-reference rule is so wildly at odds with this Court’s precedent that district courts in the Eighth Circuit have questioned whether that court really meant what it has said in two published opinions. Just last month, in an action brought by Respondent to enjoin enforcement of North Dakota’s PBM laws, a district court wrote that Respondent’s literal reading of the Eighth Circuit’s holdings was inconsistent with *Gobeille* and *Dillingham*, and “would vastly expand the scope of . . . ERISA preemption . . . ‘to the furthest stretch of its indeterminacy’” to cover virtually any commercial regulation. *Tufte*, 2018 WL 4222870, at *5–6 (quoting *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 813 (1997)). Declining to impute “such an intent” to the Eighth Circuit, *id.* at *5, it therefore chose to “apply the test set out in *Dillingham*” instead.⁸ *Id.* at *6. Predictably, Respondent immediately appealed.

But despite its reluctance to apply the Eighth Circuit’s rule, the North Dakota district court was entirely correct about its breadth: the Eighth Circuit’s implicit-reference test *would* not only preempt any regulation of PBMs, but any generally applicable state law that regulated *any* class of entities or professionals that

⁸ This decision does not suggest that a narrower reading of *Gerhart* and the decision below is truly available. The North Dakota district court’s only rationale for concluding the Eighth Circuit did not mean what it said was the Eighth Circuit’s insistence below that *Gerhart* was not “inconsistent with the Supreme Court’s precedent.” *Id.* at *5 (quoting App. 7a). But merely *saying* that a rule is not inconsistent with this Court’s precedent does not make it so.

provide services for, among other clients, ERISA plans. Indeed, even an ethics regulation of lawyers, or accountants, would be preempted because some lawyers and accountants assist ERISA plans with plan administration. Because that approach plainly conflicts with this Court's precedents, as even district courts in the Eighth Circuit have recognized, this Court should grant review and ultimately reverse the decision below.

b. The Eighth Circuit's "connection with" rule conflicts with this Court's precedents on "connection with" ERISA preemption.

In *Gerhart*, the Eighth Circuit held that Iowa's regulation of how PBMs calculated pharmacies' reimbursement rates had "a prohibited connection with ERISA," *Gerhart*, 852 F.3d at 730, reasoning that an ERISA plan's PBM's "ability to conclusively determine final drug benefit payments" was an "area central to plan administration" on which state regulation could not encroach. *Id.* at 731. Faced with a similar regulation of PBMs' drug reimbursement rates below, the Eighth Circuit found that same reasoning applied here and held that Arkansas's drug-reimbursement-rate regulation "ha[d] a connection with employee benefit plans." App. 7a.

Like the Eighth Circuit's implicit-reference holding, this rule too directly conflicts with this Court's precedent on ERISA preemption. For this Court has

held that “ERISA was not meant to pre-empt basic rate regulation.” *Travelers*, 514 U.S. at 667 n.6.

In *Travelers*, this Court reviewed a rate regulation that required hospitals to bill insurers at differential rates depending on whether the insurer was favored by New York’s legislature. New York had long regulated hospital billing rates generally, requiring hospitals to bill at diagnostic related group rates—rates based on the average cost of treating a given medical condition rather than the actual cost of individual patients’ treatment—since ERISA’s enactment, and that regulation was never challenged as preempted. *See id.* at 649–50, 665.

The statute that was challenged in *Travelers* supplemented its generally applicable diagnostic related group rates regulation with a scheme of differential rates, providing that Blue Cross/Blue Shield insurers would be billed at diagnostic related group rates, while non-Blue Cross/Blue Shield insurers would be billed a 13% surcharge on top of those rates. *See id.* at 650. The challenged provision’s conceded purpose was to encourage ERISA plans and other health insurance consumers to purchase insurance from Blue Cross/Blue Shield, whose practice of open enrollment New York wished to reward with new customers. *See id.* at 658–59. Other insurers argued, and then-Judge Freeh and the Second Circuit agreed, that the surcharge’s indirect economic effects on ERISA plans functionally regulated ERISA plan administration. *See id.* at 652–54.

But in a unanimous opinion, this Court reversed, holding that even this form of rate regulation was not preempted by ERISA. “Cost uniformity,” it explained, “was almost certainly not an object of preemption,” and even state cost regulations engineered to induce plans to deal with particular insurers “[le]ft plan administrators right where they would be in any case, with the responsibility to choose the best overall coverage for the money.” *Id.* at 662.

In a lengthy—and for these purposes, critical—coda to its opinion, this Court observed that the statute’s challengers’ position “would bar any state regulation of hospital costs,” including New York’s “basic [diagnostic related group] system” that existed before the Blue Cross/Blue Shield-favoring surcharges. *Id.* at 664. That, this Court explained, “would be an unsettling result,” and a “startling” one given that many states regulated hospital and medical billing rates at the time ERISA was enacted. *Id.* at 665. Indeed, this Court noted, Congress itself, in legislation enacted contemporaneously with ERISA, expressly “envisioned state experiments with comprehensive hospital reimbursement regulation.” *Id.* at 667 n.6 (noting that in the Medicare program, Congress authorized “physician and hospital reimbursement according to approved state payment schedules”). All this, this Court stressed, militated in favor of “[its] conclusion that ERISA was not meant to pre-empt basic rate regulation.” *Id.*

“Basic rate regulation,” of course, is all Arkansas’s PBM-reimbursement law is. The heart of that law is a

requirement that all PBMs reimburse all pharmacies at (at least) pharmacies' wholesale cost; it does not even have the differential-rate features that led the lower courts in *Travelers* to mistakenly conclude New York's surcharge law was preempted. Wholesale-cost reimbursement is merely one form of the generally applicable rate regulation that this Court deemed uncontestedly safe from ERISA preemption in *Travelers*; another form is the underlying diagnostic related group regulation in *Travelers* that the *Travelers* Court specifically blessed.

Arkansas's PBM-reimbursement law is indistinguishable, for all purposes relevant to ERISA preemption, from New York's basic rate regulation. The fact that it turns on actual costs rather than average diagnostic costs is immaterial. The *Travelers* Court favorably cited legislative history showing that Congress sought to encourage states to innovate beyond "traditional [diagnostic related group]-based reimbursement systems," *Travelers*, 514 U.S. at 667 n.6, and even contemplated the possibility of rates based on "the cost of [patients'] individual treatment[.]" *Id.* at 649.

The fact that Arkansas's statute regulates pharmacy reimbursement, rather than "physician and hospital reimbursement," *id.*, as the regulations discussed in *Travelers* did, is likewise immaterial. Nothing in ERISA's text or history suggests that pharmacy reimbursement regulation is uniquely susceptible to preemption. If anything, the opposite is the case; prescription drug benefits are not mentioned in ERISA once, unlike "surgical or hospital care or benefits,"

which are baked into the definition of an ERISA plan. 29 U.S.C. 1002(1).

In short, pharmacy reimbursement regulation is basic rate regulation; ERISA does not preempt it, and this Court should grant review to reverse the Eighth Circuit's holding that ERISA does so.

II. The decision below deepens a circuit split over whether ERISA categorically preempts PBM regulation.

Three Circuits—the First Circuit, the D.C. Circuit, and now the Eighth—have addressed the application of ERISA's preemption provision to various forms of PBM regulation. Each has reached the unhelpful conclusion that ERISA either preempts *all* PBM regulation or none.

Two circuits—the D.C. and the Eighth Circuits—have held that ERISA preempts all regulation of how PBMs manage pharmaceutical benefits. By contrast, the First Circuit has held that ERISA preempts no PBM regulation at all because PBMs “are outside of the ‘intricate web of relationships among the principal players in the ERISA scenario.’” *Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 305 (1st Cir. 2005) (quoting *Carpenters Local Union No. 26 v. U.S. Fid. & Guar. Co.*, 215 F.3d 136, 141 (1st Cir. 2000)).

Both categorical rules are badly mistaken. PBMs administer plans' drug benefits, and some of their choices in that capacity—for example, their selection of

drugs a plan covers at all, if made by a PBM⁹—are protected from regulation by ERISA preemption. But not everything they do is, no more than everything an ERISA plan itself does is immune from state regulation. This Court should grant certiorari to make plain that PBM regulation—like regulation of ERISA plans themselves—is neither categorically immune from ERISA preemption nor categorically prohibited by it.

The first challenge to a PBM regulation was brought in Maine. Like this case, it was brought by Respondent. Maine’s law targeted payments that PBMs received from drug manufacturers for “therapeutic interchange,” a euphemism for PBMs substituting “a more expensive brand name drug for an equally effective and cheaper generic drug . . . so that the PBM can collect a fee from the manufacturer for helping to increase the manufacturer’s market share.” *Rowe*, 429 F.3d at 299. The law required PBMs to disclose these payments to their customers, including ERISA plans, and to pass them on in full to those customers—again, including ERISA plans. *See Pharm. Care Mgmt. Ass’n v. Rowe*, No. Civ. 03-153-B-H, 2005 WL 757608, at *3 (D. Me. Feb. 2, 2005).

The First Circuit held this statute was not preempted. It easily rejected Respondent’s argument in that case that the challenged statute referred to ERISA plans, because it “applie[d] regardless of

⁹ *See Saltzman v. Indep. Blue Cross*, 634 F. Supp. 2d 538, 556–58 (E.D. Pa. 2009) (holding that a drug formulary, *i.e.*, a list of covered drugs, is part of an ERISA plan), *aff’d*, 384 F. App’x 107 (3d Cir. 2010).

whether PBMs are serving ERISA plans.” *Rowe*, 429 F.3d at 304. It also held that the law did not have a prohibited connection with ERISA plans on such broad grounds as to save *all* PBM regulation from preemption.

Without any regard for the law’s content, which the court barely described, the First Circuit simply held that the law did not regulate plan administrators. It only regulated PBMs, which were “not ERISA fiduciaries” and, “[a]s such, [were] outside of the ‘intricate web of relationships among the principal players in the ERISA scenario.’” *Id.* at 305 (quoting *Carpenters*, 215 F.3d at 141).

Plan administrators, the First Circuit reasoned, formally remained “free . . . to structure the[ir] plans as they wish[ed],” *id.* at 303, and could “reevaluate their working relationships with the PBMs if they wish[ed]” to avoid dealing with PBMs on Maine’s prescribed terms. *Id.* As Respondent accurately described the First Circuit’s reasoning in its subsequent petition for certiorari, the First Circuit flatly held that “because PBMs are non-fiduciaries [under ERISA], ERISA preemption principles cannot apply.” Petition for Writ of Certiorari, *Pharm. Care Mgmt. Ass’n v. Rowe*, 547 U.S. 1179 (2006) (No. 05-1297), 2006 WL 938621, at *17. In the First Circuit, this case would have come out the other way.

Next, Respondent challenged “a nearly identical” disclosure/pass-back law in the District of Columbia. *Pharm. Care Mgmt. Ass’n v. Dist. of Columbia*, 613 F.3d

179, 190 n.* (D.C. Cir. 2010). Indeed, the District’s law was so close to Maine’s that the district court initially entered summary judgment against Respondent on the ground that its loss in *Rowe* precluded it from challenging the District’s “virtually identical” law on preemption grounds. *Pharm. Care Mgmt. Ass’n v. Dist. of Columbia*, 477 F. Supp. 2d 86, 93 (D.D.C. 2007), *vacated*, 522 F.3d 443 (D.C. Cir. 2008). But when the D.C. Circuit reached the merits of Respondent’s claims, Respondent won, creating an acknowledged circuit split. *See Dist. of Columbia*, 613 F.3d at 190 n.* (“This holding differs from that of the First Circuit in *Rowe*[.]”).

Like the First Circuit, the D.C. Circuit rejected Respondent’s reference-to arguments—the same arguments that would gain acceptance below here—reasoning in a paragraph that under *Dillingham*, the existence of ERISA plans was nonessential to the District’s law’s operation because the law covered PBMs that dealt with non-ERISA customers. *See id.* at 189–90 (citing *Dillingham*, 519 U.S. at 325). But it held that the District’s law had a prohibited connection with ERISA plans on such broad grounds as to preempt *all* PBM regulation, with the sole exception of PBM regulation that ERISA plans can contractually waive.

The D.C. Circuit’s reasoning proceeded in two stages. First, it reasoned that “the administration of employee benefits is an area of core ERISA concern” and that “PBMs administer benefits on behalf of [ERISA plans]” when they manage ERISA plans’ pharmaceutical benefits. *Id.* at 185. Thus, *any* regulations of how PBMs served ERISA plans “touch[ed] upon ‘a

central matter of plan administration,’ and [would be] pre-empted if they also ha[d] an impermissible effect upon an [ERISA plan].” *Id.* at 186 (quoting *Egelhoff*, 532 U.S. at 148). In the D.C. Circuit’s view, even the District’s requirement that PBMs merely disclose to plans on request the quantity and cost of drugs a plan purchased through them touched on central matters of plan administration. *See id.* at 183, 186 (citing D.C. Code 48-832.01(c)(1)(A)).

Second, absent power on plans’ part to exempt their PBMs from regulation—a power which the District’s law gave plans in part and which therefore saved parts of the law, including the permissive disclosure obligation mentioned above, *see id.* at 186–87—any regulation of PBMs had an impermissible effect on ERISA plans. This was because, according to the D.C. Circuit, plans had “no choice at all” but to deal with PBMs and avail themselves of their “economies of scale, purchasing leverage, and network[s] of pharmacies[.]” *Id.* at 188. Thus, any non-waivable regulation of PBMs necessarily “function[ed] as a regulation of an ERISA plan itself.” *Id.* (quoting *Travelers*, 514 U.S. at 659). In the D.C. Circuit, this case would come out the way it did below; plans have no power under Arkansas’s statute to exempt their PBMs from regulation.

At the broadest level, the Eighth Circuit’s decision below aligns with the D.C. Circuit’s decision on PBM-regulation preemption and diverges from the First Circuit’s decision. Where the First Circuit deems no PBM regulation preempted, the Eighth and D.C. Circuits deem *all* PBM regulation preempted absent plan

waivability, though the Eighth Circuit slightly differs from the D.C. Circuit in that plan waivability makes no difference to preemption on its theory. In the Eighth Circuit, *all* PBM regulation, regardless of its effects on ERISA plans, impermissibly makes implicit reference to them.

Analyzed in terms of the two theories of ERISA preemption, the circuits are aligned differently. Whereas both the First and D.C. Circuits have held that generally applicable regulations of PBMs invariably do not make reference to ERISA plans, emphatically rejecting Respondent's arguments to the contrary, the Eighth Circuit has held that generally applicable regulations of PBMs invariably *do* make preempted reference to ERISA plans.

As to prohibited connections with ERISA plans, the First Circuit has held that no PBM regulation has such connections; the Eighth Circuit has held that at least regulations of PBM reporting or PBM reimbursement have them; and the D.C. Circuit has held that any regulations of how PBMs administer plans' drug benefits (which is to say, any regulations of PBMs at all) have such connections. However precisely the split is analyzed, the circuits are badly and irrevocably split on the elemental question of whether states may regulate PBMs at all.

III. The question presented is important.

As noted, thirty-six States have adopted regulations similar to Arkansas's designed to curb abusive

reimbursement practices that have strangled the Nation's independent pharmacies. Whether or not those regulations are preempted is an important question warranting this Court's review.

Moreover, this case presents important federalism questions, asking whether the Eighth and D.C. Circuits are correct that ERISA broadly preempts *all* state regulation of PBMs—entities that thirty-eight States and the District of Columbia regulate,¹⁰ and through which virtually every insured American purchases their prescription drugs. Indeed, the Department of Labor has previously recognized as much, having filed an amicus brief in the D.C. Circuit's case arguing that the District's disclosure and pass-back law was not preempted, and stating “a strong interest . . . in expressing [its] disagreement with the district court's conclusion that ERISA preempt[ed]” that law. Br. of the Sec'y of Labor at 1, *Pharm. Care Mgmt. Ass'n v. Dist. of Columbia*, 613 F.3d 179 (D.C. Cir. 2010) (No. 09-7042), 2009 WL 6613547. Unfortunately, the Department of Labor's arguments were rejected, leaving the circuits split over the elemental question of whether states may regulate PBMs at all, a split the Eighth Circuit's decision below has deepened.

¹⁰ See nn.4, 6 and accompanying text, *supra*.

Consequently, this Court's review is warranted to give both States and lower courts guidance about what regulations of the central players in prescription drug markets are and are not preempted by ERISA.



CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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