No. 18-540

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 UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

BRIEF FOR THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, GEORGIA, HAWAII, IDAHO, INDIANA, IOWA, KANSAS, KENTUCKY, LOUISIANA, MAINE, MARYLAND, MASSACHUSETTS, MINNESOTA, MONTANA, NEBRASKA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OHIO, OKLAHOMA, OREGON, TEXAS, UTAH, VERMONT, VIRGINIA, WASHINGTON, WYOMING, AND THE DISTRICT OF COLUMBIA AS AMICI CURIAE IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether the Eighth Circuit erred in holding that Arkansas's statute regulating pharmacy benefit managers' drug-reimbursement rates, which is similar to laws enacted by a substantial majority of States, is preempted by the Employee Retirement Income Security Act of 1974, in contravention of this Court's precedent that ERISA does not preempt rate regulation.

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INTERESTS OF AMICI STATES[1]

The States of California, Colorado, Connecticut, Delaware, Georgia, Hawaii, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Montana, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Oregon, Texas, Utah, Vermont, Virginia, Washington, Wyoming, and the District of Columbia have a compelling interest in protecting the health and well-being of their residents. In furtherance of that interest, many States have enacted laws regulating pharmacy benefit managers (PBMs), which act as intermediaries between pharmacies, health insurance plans, and patients. The court of appeals' expansive interpretation of ERISA preemption in this case threatens to interfere with States' ability to exercise their long-standing authority to regulate PBM conduct, causing confusion and uncertainty for regulators and market participants, and ultimately harming patients.

INTRODUCTION

Pharmacy benefit managers play a central role in the healthcare market. As middlemen between insurers, drug makers, and pharmacies, they negotiate drug prices, including discounts and rebates, with pharmaceutical manufacturers; conduct drug-utilization reviews and disease management; determine the composition of pharmacy and wholesaler networks;

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[1] Pursuant to Rule 37.2(a), counsel for all parties received notice of the States' intention to file this brief at least 10 days before the due date of the brief.

and run mail-order and affiliated specialty pharmacies that often compete with brick-and-mortar pharmacies. They also process the vast majority of all prescriptions issued in the United States.[2]

PBMs have taken on an increasingly important role in recent years, as prescription drug costs have risen rapidly throughout the United States. In 2016, Americans spent $328.6 billion on prescription drugs—more than double the amount spent in 2002.[3] Annual consumer spending on prescription drugs is expected to increase by 6.3% over the next decade, the fastest rate of growth of any major health care sector.[4] At the same time, certain PBM reimbursement and billing practices have raised significant concerns about healthcare affordability and access, including PBMs' impact on rural pharmacies.

In response, States have sought to employ their traditional police and regulatory powers to improve the transparency and operation of prescription drug markets. At least 38 States have enacted laws regulating the conduct of PBMs in a variety of ways. Pet.

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[2] Oversight Hearing of the S. Comm. on Bus., Professions and Econ. Dev., *Pharmacy Benefit Managers 101* (Cal. Mar. 20, 2017), at 1, https://sbp.senate.ca.gov/sites/sbp.senate.ca.gov/files/PBM%20Background%20paper.pdf.

[3] Ctrs. for Medicare & Medicaid Servs. (CMS), NHE Fact Sheet (2017), tbl. 2, https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html.

[4] CMS Office of the Actuary, Press Release, Projections of National Health Expenditures (Feb. 14, 2018), https://cms.gov/newsroom/mediareleasedatabase/press-releases/2018-press-releases-items/2018-02-14.html.

11 n.6.[5] Arkansas, for example, seeking to reverse the loss of independent and rural pharmacies across the State, mandated that PBMs reimburse pharmacies for generic drugs at a price at least equal to a pharmacy's cost for the drug—unless the drug could have been acquired at a lower cost from a wholesaler that serves the pharmacy in question. Pet. 13; *see* Ark. Code Ann. §17-92-507. California has a similar law. *See* Cal. Bus. & Prof. Code §4440. Earlier this year California also enacted Assembly Bill (AB) 315, which requires PBMs to exercise good faith and fair dealing, including notifying health insurers of any conflicts of interest. Many other States have enacted similar laws to safeguard the health and welfare of their residents.

The court of appeals' decision invalidating Arkansas's PBM statute has created confusion and uncertainty regarding States' power to regulate these significant market participants. The decision departs sharply from this Court's precedent, and conflicts with published authority in the First Circuit. The unbounded approach to ERISA preemption reflected in the court's opinion raises serious federalism concerns, making it more difficult for States to perform their traditional role as healthcare regulators. And the decision comes at a time when many States are grappling with how best to address the challenges presented by the conduct of PBMs and rising prescription drug costs.

In construing ERISA's preemption provision, this Court has emphasized the need to "avoid[] the clause's

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[5] *See also* Oversight Hearing of the S. Comm. on Bus., Professions and Econ. Dev., *Table of State Regulation of Pharmacy Benefit Managers (PBMs)* (Cal. Mar. 20, 2017), https://sbp.senate.ca.gov/sites/sbp.senate.ca.gov/files/Table%20of%20State%20Regulation%20of%20Pharmacy%20Benefit%20Managers.pdf.

susceptibility to limitless application." *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 943 (2016). ERISA preempts only state laws that have either (1) an impermissible "reference to" ERISA plans—*i.e.*, where a State seeks to single out ERISA plans for regulation, or (2) an impermissible "connection with" ERISA plans—*i.e.*, where a State seeks to regulate in a way that would undermine ERISA's scheme of "nationally uniform plan administration." *Id.*

Arkansas's law, like other similar state statutes, has neither forbidden feature. First, as a generally applicable law regulating both ERISA and non-ERISA plans alike, it does not make "reference to" ERISA plans. *See Cal. Div. of Labor Standards Enforcement v. Dillingham Constr., N.A. Inc.*, 519 U.S. 316, 325 (1997). Yet the decision below wrongly holds that ERISA preempts any state law that regulates a group of entities whose customers "include" ERISA plans. Pet. App. 6a. Second, Arkansas's statute seeks to regulate the reimbursement rates PBMs pay to pharmacies. This Court has held that such "rate regulation" does not have an impermissible "connection with" ERISA. *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 662, 667 n.6 (1995). Yet here, the court of appeals has held just the opposite. This Court's review is warranted to correct these errors and bring clarity and uniformity to the law of ERISA preemption in this important area.

ARGUMENT

I. A SIGNIFICANT MAJORITY OF STATES REGULATE PBMS TO PROMOTE HEALTHCARE ACCESS AND AFFORDABILITY

State regulation of pharmacy benefit managers responds to a complex health delivery system that has changed enormously in recent decades. States have played a key role in monitoring costs, accessibility, and utilization of pharmacy benefits, including through oversight of PBMs. As this Court has repeatedly recognized, healthcare (and prescription drugs in particular) are traditional subjects of state regulation. *See, e.g.*, *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (noting the "historic primacy of state regulation of matters of health and safety"); *Wyeth v. Levine*, 555 U.S. 555, 565 & n.3 (2009); *Travelers*, 514 U.S. at 661; *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 715 (1985).

Some background helps explain why so many States regulate PBMs. Before reaching the patient, prescription drugs make their way through a web of intermediaries with various and sometimes competing incentives. Normally, a prescription drug is made by a manufacturer, delivered by a wholesale distributor to a pharmacy, and then dispensed at the pharmacy to a patient, according to terms set by the patient's health insurer, including the applicable formulary (*i.e.*, list of covered drugs). At the first stage, the manufacturer sells a drug to distributors at a list price it sets, which reflects any discounts that have been negotiated.[6] The distributor will then sell the drug to a

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[6] U.S. Government Accountability Office, Generic Drugs Under Medicare: Part D Generic Drug Prices Declined Overall, but

pharmacy at a price stemming from the list price. A patient buys the drug at the pharmacy, after paying any cost-sharing required by his or her health insurer.

While PBMs have existed since the 1970s, they have grown in influence in recent decades. They originally functioned as claims processors for health insurers, which generally entailed only verifying that a patient had coverage, determining whether a drug was on the plan formulary, and calculating the appropriate copayment.

Over time, however, PBMs expanded in both their size and role. Now, nearly every health insurer contracts with a PBM, which often manages all aspects of the pharmaceutical benefit portion of the health plan.[7] In their modern form, PBMs operate as middlemen between insurers, drug makers, and pharmacies. They develop and maintain formularies; contract with pharmacies; negotiate discounts and rebates with drug manufacturers; manage chronic conditions of high-risk, high-cost patients; conduct drug-utilization reviews by compiling information regarding projected volume of health plan beneficiaries who use a given drug; process and pay prescription drug claims; and

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Some Had Extraordinary Price Increases (Aug. 2016), at 6, https://www.gao.gov/assets/680/679022.pdf; MedPAC, Overview: The Drug Development and Supply Chain (June 2016), at 12, http://www.medpac.gov/docs/default-source/fact-sheets/overview-of-the-drug-development-and-supply-chain.pdf.

[7] Oversight Hearing of the S. Comm. on Bus., Professions and Econ. Dev., *Pharmacy Benefit Managers 101* (Cal. Mar. 20, 2017), at 2, https://sbp.senate.ca.gov/sites/sbp.senate.ca.gov/files/PBM%20Background%20paper.pdf.

operate mail-order and specialty pharmacies.[8] Because nearly every health insurer relies on a PBM, it is "essential" for pharmacies' "survival" to work with them.[9] And PBMs have significant market power in these dealings because of their immense size: The largest three (CVS Health; Express Scripts; and OptumRx, a division of UnitedHealth Group) combine to serve approximately 80% of the market, translating to coverage of 180 million Americans.[10]

Significant recent increases in the cost of many prescription drugs have brought widespread attention to PBMs' role in setting drug prices. Drug prices increased by 12.4% in 2014 and 9% in 2015, outpacing the rate of increase for all other health services.[11] As drug prices rise, so too does consumer spending, which increased by $65 billion from 2012 to 2015, and is projected to grow an average of 6.7% per year through 2024.[12] These price increases have direct consequences for consumer access to medicine: In 2016, approximately 14% of *insured* Americans failed to fill a prescription or skipped a dose because of cost.[13]

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[8] *Id.*

[9] *Id.* at 2-3.

[10] Health Affairs, Health Policy Brief, Pharmacy Benefit Managers (Sept. 14, 2017), at 2, https://www.healthaffairs.org/do/10.1377/hpb20171409.000178/full/healthpolicybrief_178.pdf.

[11] California Senate Health Committee Analysis, SB 17 (Apr. 19, 2017), at 5, https://leginfo.legislature.ca.gov/faces/billAnalysisClient.xhtml?bill_id=201720180SB17.

[12] *Id.*

[13] Sarnak et al., The Commonwealth Fund, Paying for Prescription Drugs around the World: Why Is the U.S. an Outlier? (Oct. 5, 2017), at 6, https://www.commonwealthfund.org/sites/default/

A Senate special committee recently investigated notable drug price increases—including for such medications as Sovaldi, Epipens, and insulin—and found that many price increases bore little relation to improvements in the drug or the cost of research and development.[14] To help address this phenomenon, the committee recommended "improve[d] transparency" in drug prices.[15]

Amici States' experience has been that improving transparency in drug pricing requires regulation of PBMs. Unlike other actors in the drug market, PBMs feature in almost all of the key transactions that drive the price of a drug. PBMs also face incentives that often do not align with patients' interest in obtaining prescription drugs at reasonable cost. As U.S. Secretary of Health & Human Services Alex Azar noted earlier this year, a "PBM actually wins when list price goes up."[16] Secretary Azar explained:

> Imagine you take a $1,000 drug. The PBM working for your insurance plan negotiates a 30

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files/documents/___media_files_publications_issue_brief_2017_oct_sarnak_paying_for_rx_ib_v2.pdf.

[14] U.S. Senate Special Committee on Aging, Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System (Dec. 2016), at 39, https://www.aging.senate.gov/imo/media/doc/Drug%20Pricing%20Report.pdf.

[15] *Id*. at 10, 123-124.

[16] Alex M. Azar II, U.S. Secretary of Health & Human Services, "Fixing Healthcare: Driving Value Through Smart Purchasing and Policy" (May 16, 2018), https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/fixing-healthcare-driving-value-through-smart-purchasing-and-policy.html.

> percent rebate, $300, which gets sent back to your employer, minus a percentage cut for the PBM. Now imagine the list price goes up to $1,500—now the rebate would be $450, allowing the PBM to keep the added $150, while the patient pays significantly more in cost-sharing.[17]

Apart from drug costs, PBMs also play an outsized role in controlling drug access. In designing their formularies they commonly create a three-tiered system, whereby a drug with "preferential placement" has a lower co-payment compared to other (non-preferred) drugs.[18] PBMs negotiate with manufacturers for rebates in return for placing the manufacturers' drug on their formularies' preferential placement lists. PBMs thus have become the "medication gatekeepers" between doctors and patients. Without proper formulary placement, many patients will lack access to certain drugs.[19]

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[17] *Id.*

[18] U.S. Senate Special Committee on Aging, Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System (Dec. 2016), at 15, https://www.aging.senate.gov/imo/media/doc/Drug%20Pricing%20Report.pdf; Oversight Hearing of the S. Comm. on Bus., Professions and Econ. Dev., *Pharmacy Benefit Managers 101* (Cal. Mar. 20, 2017), at 3, https://sbp.senate.ca.gov/sites/sbp.senate.ca.gov/files/PBM%20Background%20paper.pdf.

[19] Winegarden, *It's Generics Not PBMs that Keep Pharmaceuticals Affordable*, Forbes (July 12, 2018), https://www.forbes.com/sites/waynewinegarden/2018/07/12/its-generics-not-pbms-that-keep-pharmaceuticals-affordable.

PBMs not only control certain aspects of the prescription drug market, they also participate in that same market by operating their own mail-order and retail pharmacies. They are thus particularly susceptible to self-dealing and unfair advantage. For example, while the PBM operated by CVS reimburses a CVS pharmacy $400.65 for a fentanyl patch, it reimburses non-CVS pharmacies only $75.74 for the same patch.[20] Similarly, CVS pharmacies were reimbursed $5.86 for Ibuprofen, while non-CVS pharmacies were paid only $1.39.[21]

PBMs' actions have had significant adverse consequences for underserved patients in rural or isolated areas in particular. Over the last 16 years, 16.1% of rural pharmacies have closed.[22] PBM conduct, including unfair PBM payment and list pricing practices, is a major cause.[23] For example, in Iowa alone, 23 community pharmacies closed due to PBMs reimbursing

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[20] Lopez, *What CVS is Doing to Mom-and-Pop Pharmacies in the U.S. Will Make Your Blood Boil*, Business Insider (Mar. 30, 2018), https://www.businessinsider.com/cvs-squeezing-us-mom-and-pop-pharmacies-out-of-business-2018-3.

[21] *Id*.

[22] Salako, et al., Ctr. for Rural Health Policy Analysis, Brief No. 2018-2 (July 2018), https://www.public-health.uiowa.edu/rupri/publications/policybriefs/2018/2018%20Pharmacy%20Closures.pdf; Firozi, *The Health 202: Here's Why Rural Independent Pharmacies Are Closing Their Doors*, Washington Post (Aug. 23, 2018), https://www.washingtonpost.com/news/powerpost/paloma/the-health-202/2018/08/23/the-health-202-here-s-why-rural-independent-pharmacies-are-closing-their-doors/5b7da33e1b326b7234392b05.

[23] Salako, et al., *Issues Confronting Rural Pharmacies After a Decade of Medicare Part D, Rural Policy Research Institute* (Apr. 2017), Brief No. 2017-3, https://www.public-health.uiowa.edu/

at below-cost rates.[24] This is especially troubling because pharmacies are often the main (or only) healthcare providers in rural areas, so when rural pharmacies close there are "grave implications for the population's access to health services."[25]

In response to these issues plaguing consumers, States, and the market, policymakers at the state level have taken legislative action to regulate drug market behavior in their States and to protect residents. For example, California's recently enacted law, AB 315, requires PBMs to exercise "good faith and fair dealing," and to disclose conflicts of interest.[26] AB 315 also prohibits "gag clauses," through which PBMs require pharmacies to refrain from informing patients of a less costly alternative to a prescription medication.[27] In enacting AB 315, the California Legislature reasoned that these regulations would help "lower drug costs by requiring more extensive transparency."[28]

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rupri/publications/policybriefs/2017/Issues%20confronting%20rural%20pharmacies.pdf.

[24] Iowa State Legislature, Remarks on Iowa H.F. 2297 at 10:20-21 (Mar. 4, 2014) http://www.legis.state.ia.us/dashboard?view=video&chamber=H&clip=934&offset=6646&bill=HF%202297&dt=2014-03-04.

[25] Salako, et al., Ctr. for Rural Health Policy Analysis, Brief No. 2018-2 (July 2018), at 1, https://www.public-health.uiowa.edu/rupri/publications/policybriefs/2018/2018%20Pharmacy%20Closures.pdf.

[26] AB 315, ch. 905 (Cal. 2018) (enacted Sept. 29, 2018) (to be codified in relevant part at Cal. Bus. & Prof. Code §4441), https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201720180AB315.

[27] *Id.*

[28] California Assembly Floor Analysis, AB 315 (Aug. 28, 2018), at

Like California and Arkansas, a clear majority of States have enacted legislation to address PBM conduct. Some laws aim to combat self-dealing or other anticompetitive practices, either by imposing fiduciary duties or requiring disclosure of potential conflicts of interest. *See, e.g.*, Nev. Rev. Stat. Ann. §683A.178; R.I. Gen. Laws §27-29.1-7; Vt. Stat. Ann. tit. 18, §9472(c)(2). Others attempt to undo barriers for rural and isolated patients in obtaining affordable drugs and place limits on "gag clauses."[29] *See, e.g.*, Ark. Code Ann. §23-92-507; Cal. Bus. & Prof. Code §4441(k);[30] Md. Code Ann., Ins. §15-1611; N.C. Gen. Stat. Ann. §58-56A-3; Tenn. Code Ann. §56-7-3114. And many other States also require PBMs to provide an appeal process for pharmacies to contest reimbursement rates, with the PBM obligated to increase the reimbursement unless it can identify a source for the drug in question at or below the appealed rate. *See, e.g.*, Pet. App. 47a-49a; Cal. Bus. & Prof. Code §4440(f); Ga. Code Ann. §33-64-9(d); Md. Code Ann., Ins. §15-1628.1(f)-(i); Ohio Rev. Code Ann. §3959.111(A)(3); Tex. Ins. Code Ann. §1369.357; Wash. Rev. Code Ann. §19.340.100(3). These measures, and others, reflect traditional state policy goals of promoting healthcare

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9-10, https://leginfo.legislature.ca.gov/faces/billAnalysisClient.xhtml?bill_id=201720180AB315.

[29] National Conference of State Legislatures, *Prohibiting PBM "Gag Clauses" that Restrict Pharmacists from Disclosing Price Options: Recent State Legislation 2016-2018* (Aug. 22, 2018), http://www.ncsl.org/Portals/1/Documents/Health/Pharmacist_Gag_clauses-2018-14523.pdf.

[30] Newly added by AB 315. *See* AB 315, ch. 905 (Cal. 2018) (enacted Sept. 29, 2018) https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201720180AB315.

affordability and access, in a manner consistent with the unique experiences and needs of each State.

II. THIS COURT SHOULD GRANT CERTIORARI TO CLARIFY THE LAW REGARDING ERISA PREEMPTION AS IT RELATES TO STATE REGULATION OF PBMS

Under well-established ERISA preemption law, States retain the ability to enact generally applicable legislation that does not single out ERISA plans for regulation or interfere with ERISA's policies, even if the law imposes certain economic costs on ERISA plans. That is especially true where, as here, a State acts in an area of traditional state regulation.

The decision below in this case departs sharply from these principles. It adopts a far-reaching theory of ERISA preemption that contravenes this Court's precedent, creates significant uncertainty for States in their efforts to regulate PBMs, and conflicts directly with authority from the First Circuit. This Court should grant certiorari and should reverse.

A. THE EIGHTH CIRCUIT'S DECISION CONFLICTS WITH THIS COURT'S PRECEDENT

ERISA expressly 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). As this Court has observed on numerous occasions, "'if 'relate to' were taken to extend to the furthest stretch of its indeterminacy, then for all practical purposes [ERISA] preemption would never run its course.'" *Gobeille*, 136 S. Ct. at 943; *see also Travelers*, 514 U.S. at 656; *Egelhoff v. Egelhoff*, 532 U.S. 141, 146 (2001). Because "[t]hat is a result 'no sensible person could have in-

tended,'" *Gobeille*, 136 S. Ct. at 943 (quoting *Dillingham*, 519 U.S. at 336 (Scalia, J., concurring)), this Court has developed "workable standards" that "reject 'uncritical literalism' in applying the [ERISA preemption] clause," *id.* (quoting *Travelers*, 514 U.S. at 656). These standards seek to "avoid[] the clause's susceptibility to limitless application." *Id.*

This Court thus has identified two categories of state laws that ERISA preempts:

> (1) where the state law has an impermissible "reference to" ERISA plans, meaning
>
> (a) where the state law "acts immediately and exclusively upon ERISA plans," or
>
> (b) "where the existence of ERISA plans is essential to the law's operation," and
>
> (2) where the state law has an impermissible "connection with ERISA plans," meaning
>
> (a) where the state law "governs a central matter of plan administration," or
>
> (b) where the state law "interferes with nationally uniform plan administration."

Gobeille, 136 S. Ct. at 943; *see* Pet. 5-6.

This Court applies this framework with the "starting presumption" that the "historic police powers of the States were not superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Travelers*, 514 U.S. at 655. "That approach is consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety." *Medtronic*, 518 U.S. at 485. "[N]othing in the language of [ERISA] or the context of its passage indicates that Congress chose to displace general

health care regulation, which historically has been a matter of local concern." *Travelers*, 514 U.S. at 661.

In this case, the court of appeals held that Arkansas's law is preempted under both the "reference to" and "connection with" prongs of the ERISA preemption test. Pet. App. 6a-7a. On the "reference to" prong, the decision below holds that the Arkansas law impermissibly makes "implicit reference" to ERISA plans because it regulates entities whose customers "by definition[] include" ERISA plans. Pet. App. 6a. The court considered itself "completely bound" by its prior opinion in *Pharmaceutical Care Management Ass'n v. Gerhart*, 852 F.3d 722, 729 (8th Cir. 2017), which had held—also in the context of PBM regulation—that an Iowa law impermissibly made reference to ERISA where it regulated entities whose customers necessarily "include[d]" ERISA plans. Pet. App. 6a-7a; *see Gerhart*, 852 F.3d at 729. On the "connection with" prong, the decision below holds, without any analysis apart from another citation to *Gerhart*, that the Arkansas law has an impermissible "connection with" ERISA plans. Pet. App. 7a.

Neither of these holdings can be squared with this Court's ERISA case law. On the first prong, the court of appeals' holding that a state law makes "reference to" ERISA plans simply because it regulates a set of entities whose customers *include* ERISA plans, Pet. App. 6a, directly contradicts *Dillingham* and *Travelers*, among other cases. *See* Pet. 18-19. In *Dillingham*, the Court held that a California law did not make "reference to" ERISA plans because the regulated entities "need not necessarily be ERISA plans," although they might be. 519 U.S. at 325. Likewise, in *Travelers*, the Court held that a New York law regulating hospital pricing to health insurers did not make "reference to"

ERISA plans because it applied "regardless of" whether the insurer was "ultimately secured by an ERISA plan" or a non-ERISA plan. 514 U.S. at 656.

On the second prong, the decision below relies entirely on the court of appeals' previous holding in *Gerhart* that Iowa's PBM statute had an impermissible "connection with" ERISA plans. Pet. App. 7a. The *Gerhart* court reached that conclusion because, in its view, "all facets" of the Iowa law at issue "interfere[d] with the structure and administration of ERISA plans in Iowa and require[d] administrative processes unique to that state." 852 F.3d at 730.

That conclusion was wrong in *Gerhart* and is even more so here. A central component of Arkansas's law is regulation of provider reimbursement rates: The law "mandates that pharmacies be reimbursed for generic drugs at a price equal to or higher than the pharmacies' cost for the drug." Pet. App. 4a. As this Court explicitly has held, "ERISA was not meant to pre-empt basic rate regulation." *Travelers*, 514 U.S. at 667 n.6; *see* Pet. 21-25. Thus, in *Travelers*, the Court upheld New York's law mandating different hospital reimbursement rates for different types of health insurers. 514 U.S. at 661-662. Yet the court of appeals here determined that Arkansas's rate regulation has an impermissible "connection with" ERISA plans. Pet. App. 7a. The court reached the same conclusion, without any analysis, regarding multiple other distinct provisions of the statute. *Id.* That approach to ERISA preemption finds no support in this Court's case law.

More broadly, the court of appeals disregarded the principle that the "connection with" analysis requires courts to "consider[] 'the objectives of the ERISA statute as a guide to the scope of the state law that Congress intended would survive.'" *Gobeille*, 136 S. Ct. at

943 (quoting *Travelers*, 514 U.S. at 656). Regulation of PBM reimbursement rates and practices is not an objective of ERISA. Arkansas (and many other States) have chosen to regulate PBMs' reimbursement rates and interactions with health insurers and pharmacies. That is a space Congress has not occupied, and such state laws do not affect the core obligations of ERISA plan administrators.

At most, Arkansas's regulation may have an "indirect economic influence" on some ERISA plans; but that is insufficient to result in preemption. *Travelers*, 514 U.S. at 659. "[M]yriad state laws of general applicability … impose some burdens on the administration of ERISA plans but nevertheless do not 'relate to' them within the meaning of the governing statute." *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 816 (1997) (some internal quotation marks omitted). "Indeed, if ERISA were concerned with any state action—such as medical-care quality standards or hospital workplace regulations—that increased costs of providing certain benefits, and thereby potentially affected the choices made by ERISA plans, we could scarcely see the end of ERISA's pre-emptive reach, and the words 'relate to' would limit nothing." *Dillingham*, 519 U.S. at 329. This Court has repeatedly rejected that result, but the court of appeals in this case has embraced it.

B. The Eighth Circuit's Opinion Will Create Uncertainty and Undermine States' Ability to Regulate Prescription Drug Markets

The court of appeals' expansive interpretation of ERISA preemption in this case will create significant uncertainty for States, undermining their ability to

regulate PBMs and prescription drug markets, ultimately harming patients. States within the Eighth Circuit are already confronting this uncertainty, and the court of appeals' opinion invites discord in other jurisdictions as well.

Within the Eighth Circuit, the decision below is already causing substantial confusion. In *Pharmaceutical Care Management Ass'n v. Tufte*, 326 F. Supp. 3d 873 (D.N.D. 2018), the same trade association that is the respondent here sued North Dakota over that State's regulation of PBMs. The court reasoned that interpreting the court of appeals' opinions in this case and in *Gerhart* to mean what they say on their face would "vastly expand the scope of the ERISA preemption doctrine" and would conflict with this Court's opinions in *Travelers* and *De Buono*. *Id.* at 883-884. The court instead applied the test laid out in this Court's cases and found North Dakota's statute *not* preempted, *id.* at 885-888, but respondent has appealed. States within the Eighth Circuit are thus left to guess whether their PBM regulations will be invalidated (as in Iowa and Arkansas) or upheld (as, so far, in North Dakota), since district courts there are asked to perform the impossible task of reconciling this Court's precedent with directly contradictory circuit authority.

That confusion may spread beyond the Eighth Circuit as well. The provisions of the Arkansas law that the court of appeals held preempted have direct parallels in the laws of numerous other States. These include regulation of PBM reimbursement rates and practices, *see, e.g.*, La. Rev. Stat. Ann. §22:1860.3; Md. Code Ann., Ins. §15-1612; mandated disclosure of certain pricing information, *see, e.g.*, Cal. Bus. & Prof. Code §4440(b)-(c); Ga. Code Ann. §33-64-9(a); Minn.

Stat. Ann. §151.71(2)(a); N.J. Stat. Ann. §17B:27F-2; Okla. Stat. Ann. tit. 59, §360A; and a requirement that PBMs provide an effective appeal procedure for pharmacies, *see, e.g.*, Haw. Rev. Stat. §328.106(f); Ky. Rev. Stat. §304.17A-162(1)(b); N.J. Stat. Ann. §17B:27F-4; N.M. Stat. Ann. §59A-61-4(A)(5); *supra* at 12 (citing other state statutes). These provisions all fall comfortably within States' traditional authority as "regulat[ors] of matters related to health and safety." *Automated Med. Labs.*, 471 U.S. at 715. Yet the court of appeals' erroneous opinion in this case suggests they could be subject to ERISA preemption.

Moreover, as Arkansas notes (Pet. 25-30), the decision below conflicts directly with authority from the First Circuit, which has rejected an ERISA preemption challenge to PBM regulation. *See Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 302-304 (1st Cir. 2005). The Eighth Circuit's opinion in this case compounds the existing conflict between the First Circuit and the D.C. Circuit's opinion in *Pharmaceutical Care Management Ass'n v. District of Columbia*, 613 F.3d 179 (D.C. Cir. 2010). Certiorari is warranted for this reason as well.

CONCLUSION

This petition for a writ of certiorari should be granted.

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November 21, 2018

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