No. 18-540

IN THE Supreme Court of the United States

LESLIE RUTLEDGE, IN HER OFFICIAL CAPACITY AS ARKANSAS ATTORNEY GENERAL,

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 OF THE AMERICAN MEDICAL ASSOCIATION, THE ARKANSAS MEDICAL SOCIETY, AND THE LITIGATION CENTER OF THE AMERICAN MEDICAL ASSOCIATION AND THE STATE MEDICAL SOCIETIES AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

> JACK R. BIERIG *Counsel of Record* APHRODITE KOKOLIS SCHIFF HARDIN LLP 233 S. Wacker Dr., Suite 7100 Chicago, IL 60606 (312) 258-5500 jbierig@schiffhardin.com

March 2, 2020

Counsel for Amici Curiae

294767



COUNSEL PRESS (800) 274-3321 • (800) 359-6859

TABLE OF CONTENTS

INTERESTS	S OF AMICI CURIAE1
SUMMARY	OF THE ARGUMENT4
ARGUMEN	Γ8
I.	The Decision Below Conflicts With This Court's Precedent8
	A. The Arkansas Statute Does Not Impermissibly "Refer To" ERISA Plans10
	B. The Arkansas Statute Does Not Have An Impermissible "Connection With" ERISA Plans
II.	ERISA's Preemption Provision Should Be Construed In Light Of The Historic Federal Deference To State Regulation Of Health Care
III.	In Enacting ERISA, Congress Intended To Impose Uniform Federal Regulation Of Retirement Plans, But Not Health Care Plans
CONCLUSI	ON27

TABLE OF AUTHORITIES

Cases

Aetna Health Inc. v. Davila, 542 U.S. 200 (2004)
Alessi v. Raybestos-Manhattan, Inc., 451 U.S. 504 (1998)21, 22
De Buono v. NYSA-ILA Med. & Clinical Servs. Fund, 520 U.S. 806 (1997)passim
California Div. of Labor Stds. Enf't v. Dillingham Constr., N.A., Inc., 519 U.S. 316 (1997)9, 10, 11, 17
Gobeille v. Liberty Mut. Ins. Co., 136 S. Ct. 936 (2016)passim
Hillsborough Cty. v. Automated Med. Labs, Inc., 471 U.S. 707 (1985)19
Ingersoll-Rand Co. v. McClendon, 498 U.S. 133 (1990)12
Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996)19, 20, 21
Metropolitan Life Ins. Co. v. Massachusetts, 471 U.S. 724 (1985)18
New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Insurance Co., 514 U.S. 645 (1995)passim

Pharmaceutical Care Mgmt. Ass'n v. Gerhart, 852 F.3d 722 (8th Cir. 2017)10, 12, 13
Taggart Corp. v. Life & Health Benefits
Admin., Inc.,
617 F.2d 1208 (5th Cir. 1980), cert. denied
sub nom. Taggart Corp. v. Efros, 450 U.S.
1030 (1981)
Wyeth v. Levine,
555 U.S. 555 (2009)

Statutes

29 U.S.C. § 1001(a)21, 24
29 U.S.C. § 1001(c)
29 U.S.C. § 1002(1)5
29 U.S.C. § 1002(2)(A)
29 U.S.C. § 1003(a)(1)11
29 U.S.C. § 1003(a)(2)11
29 U.S.C. §§ 1052-105325
29 U.S.C. § 105425
29 U.S.C. § 105525
29 U.S.C. § 1056
29 U.S.C. § 105825
29 U.S.C. § 105925
29 U.S.C. § 1060
29 U.S.C. §§ 1082-1085

iii

29 U.S.C. § 1144(a)	.3, 5, 7, 15
29 U.S.C. §§ 1201-1203	25
29 U.S.C. §§ 1221-1222	25
29 U.S.C. §§ 1301-1303	
29 U.S.C. §§ 1305-1309	
29 U.S.C. §§ 1321-1322	
29 U.S.C. §§ 1341-1348	
29 U.S.C. §§ 1361-1368	
Ark. Code Ann. § 17-92-507(a)(6)	9
Ark. Code Ann. § 17-92-507(a)(7)	11
Ark. Code Ann. § 17-92-507(a)(9)	11
Ark. Code Ann. §§ 17-92-507(b)-(d)	11
Ark. Code Ann. § 17-92-507(c)(2)	9
Ark. Code Ann. § 17-92-507(c)(4)	9
Ark. Code Ann. § 17-92-507(c)(4)(A)(i)	9
Ark. Code Ann. § 17-92-507(c)(4)(C)	9
Ark. Code Ann. § 17-92-507(c)(4)(C)(iii)	9
Ark. Code Ann. § 17-92-507(e)	9

Legislative Materials

Pub. L. No. 93-406, 88 Stat. 829 (1974)25
H.R. Rep. No. 93-533 (1974), reprinted in 1974
U.S.C.C.A.N. 4639

S. Rep. No. 93-127 (1974), reprinted in 1974	
U.S.C.C.A.N 4838	23

Other Authorities

American Medical Association, The Impact of
Pharmacy Benefit Managers on Patients and
Physicians D-110.987, https://policysearch
.ama-assn.org/policyfinder/detail/pharmacy
%20benefit%20managers?uri=%2FAMADoc%
2Fdirectives.xml-D-110.987.xml3
American Medical Association, The Impact of
Pharmacy Benefit Managers on Patients and
Physicians (Report 5 of the Council on
Medical Service), https://www.ama-
assn.org/system/files/2019-07/a19-cms-report-
5.pdf3
Karen Van Nuys, Ph.D., et al., Frequency and
Magnitude of Co-payments Exceeding
Prescription Drug Costs, Journal of American
Medical Association, Mar. 13, 2018, available
at https://jamanetwork.com/journals/jama/
fullarticle/26746553
Donald T. Bogan, Protecting Patient Rights
Despite ERISA: Will the Supreme Court Allow
States to Regulate Managed Care?, 74 Tul. L.
Rev. 951 (2000)24

INTERESTS OF AMICI CURIAE 1

Amici Curiae are the American Medical Association (AMA), the Arkansas Medical Society (AMS), and the Litigation Center of the American Medical Association and the State Medical Societies (Litigation Center).

The AMA is the largest professional association of physicians, residents, and medical students in the United States. Founded in 1847, its mission is to promote the science and art of medicine and the betterment of public health. Its members practice in every state and in every medical specialty. Substantially all U.S. physicians, residents, and medical students are represented in the AMA's policymaking process, through state and specialty medical societies and other physician groups seated in the AMA's House of Delegates. AMA members practice and reside in all states and in all areas of medical specialization.

The AMS is a statewide professional association representing physicians, residents, and medical students in Arkansas. The AMS is dedicated

¹ Pursuant to Supreme Court Rule 37.3, *amici* state that all parties have provided written consent to the filing of this brief. Pursuant to Rule 37.6, *amici* state that no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity other than *amici*, their members, or their counsel made such a monetary contribution.

to improving the practice of medicine for physicians and patients by, among other things, addressing issues that affect the practice of medicine and access to health care.

The AMA and AMS submit this brief on their own behalf and as representatives of the Litigation Center. The Litigation Center is a coalition among the AMA and the medical societies of each state and the District of Columbia. The purpose of the Litigation Center is to represent the interests of organized medicine in the courts.

Amici are committed to the provision of quality, fairly priced health care to all Americans. In this connection, amici have been concerned over the increasing influence of pharmacy benefits managers (PBMs) in the provision of health care. PBMs play a pivotal role not only in the pricing of prescription drugs for patients, but also in the administration of patient drug benefits. Yet without the sort of state legislation that the Court of Appeals held to be preempted, PBMs would be free to operate with at most minimal transparency regarding drug pricing and other decisions.

This lack of transparency makes it difficult for physicians to determine which treatments are preferred by a particular payor, what level of costsharing their patients will bear, and whether medications are subject to sometimes unreasonable utilization management requirements. This lack of transparency in patients' drug coverage can interfere with sound medical practice and may lead to delays in and other disruptions to necessary medication treatment.² Thus, the ability of patients and their physicians to have the information and even the latitude they need to make key decisions regarding medication has been hampered by the sort of practices that state legislation of PBMs can properly address.

For these reasons, *amici* have actively advocated for the regulation of PBMs by the states.³ We respectfully submit that the Court of Appeals' expansive interpretation of the preemption provision in Section 514 of the Employee Retirement Income Security Act (ERISA), 29 U.S.C. § 1144(a), (a) is contrary both to the language and intent of that statute, (b) wrongly interferes with the traditional police powers of each state to regulate the delivery of health care to its citizens, and (c) given the absence of

² Karen Van Nuys, Ph.D., et al., *Frequency and Magnitude of Copayments Exceeding Prescription Drug Costs*, Journal of American Medical Association, Mar. 13, 2018, available at https://jamanetwork.com/journals/jama/fullarticle/2674655

^{(&}quot;Cost-related nonadherence is common and associated with increased medical services use and negative health outcomes.").

³ See American Medical Association, The Impact of Pharmacy Benefit Managers on Patients and Physicians D-110.987, https://policysearch.ama-

assn.org/policyfinder/detail/pharmacy%20benefit%20managers? uri=%2FAMADoc%2Fdirectives.xml-D-110.987.xml; American Medical Association, *The Impact of Pharmacy Benefit Managers on Patients and Physicians* (Report 5 of the Council on Medical Service), https://www.ama-assn.org/system/files/2019-07/a19cms-report-5.pdf.

comprehensive federal regulation of PBMs in ERISA or elsewhere, will leave a regulatory vacuum—to the detriment of patients and their physicians.

SUMMARY OF THE ARGUMENT

In recent years, PBMs have played an increasingly important role in the pricing and delivery of pharmaceuticals in the United States. PBMs serve essentially as intermediaries between pharmacies and health benefit plans, including ERISA plans, non-ERISA group health plans, insurers in the individual marketplace, and federal and state employee health plans. PBMs contract with pharmacies to establish pharmacy networks, and separately contract with health benefit plans to provide access to those pharmacy networks. Pet. App. 2a-3a; JA66, 68-69.

Most significantly for this case, PBMs create maximum allowable cost lists, which set the reimbursement rates to pharmacies dispensing generic prescription drugs. Those reimbursement rates are sometimes lower than the wholesale cost at which the pharmacy purchases the drugs, causing the pharmacy to lose money on any given transaction. Many independent pharmacies, particularly those serving rural areas, have closed as a result, often leaving those communities unserved. Pet. App. 2a-3a, 12a, 24a.

To address these issues—and other issues related to effective delivery of health care—a substantial majority of states, like Arkansas, have enacted legislation to regulate PBMs. Notably, this legislation is not directed at ERISA plans. Rather, as the Arkansas statute exemplifies, the legislation regulates PBMs. Specifically, it regulates the prices at which PBMs reimburse pharmacies for generic drugs (no lower than the pharmacy's acquisition cost of the drug) and requires disclosure and transparency in the PBMs' price-setting process. *See* pp. 8-9, *infra*. This sort of legislation is directly within the traditional police powers of the states to regulate in the interests of promoting the health and safety of their residents.

The Eighth Circuit's decision that the Arkansas PBM preempted under statute is ERISA is inconsistent with this Court's precedent and congressional intent (see pp. 8-17, infra), pays inadequate regard to the states' historic police powers to regulate health care (see pp. 18-20, infra), and would, contrary to the intent of Congress, leave a significant gap in the regulation of PBMs, to the detriment of patients and their physicians (see pp. 20-27, infra).

First, as a textual matter, 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). An "employee benefit plan" can be a "pension plan" (providing for employee retirement income, *see id.* § 1002(2)(A)), or a "welfare plan" (providing for medical benefits through the purchase of insurance or otherwise, *see id.* § 1002(1)).

This Court has recognized that a literal reading

of the broad "relate to" language in ERISA's preemption provision could invalidate state legislation to an extent not intended by Congress. Yet that is precisely what the decision below does. In so doing, the decision conflicts with this Court's longstanding precedent, including its decision in New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Insurance Co., 514 U.S. 645 (1995).

Like the statute at issue in *Travelers*, the Arkansas statute does not "relate to" ERISA plans because it does not make "reference to" or have a "connection with" ERISA plans. The statute regulates only PBMs—not ERISA plans. Notably, the statute does not attempt to impose any requirements on ERISA plans or otherwise dictate their health care choices. At most, the Arkansas statute might arguably have an indirect effect on an ERISA plan's choice of insurance. But this Court has held that state laws of general application, like the Arkansas statute here, are not preempted by ERISA simply because they could indirectly affect ERISA plans.

Second, the decision below fails to take into account the historic federal deference to state regulation of health care. Congress did not intend ERISA to undermine the police powers of the states in this area. As this Court has repeatedly recognized, these historic state powers should not be superseded unless that was the "clear and manifest purpose of Congress." *Id.* at 655 (internal quotations omitted). There is no such "clear and manifest" intent to preempt here. To the contrary, Congress could not have intended the sweeping displacement of traditional state health care regulation created by the Eighth Circuit's decision.

Third, the decision below ignores that, in enacting ERISA, Congress distinguished between regulation of retirement plans and regulation of health care plans. ERISA's legislative history and its comprehensive regulation of pension plans demonstrate that Congress intended to "occupy the field" when it came to retirement plan regulation. Congress imposed detailed federal requirements on retirement plans because state regulation had proved inadequate, and also because Congress determined that employers operating in more than one state should not be subject to different regulations depending on the location of their employees. By contrast, when enacting ERISA, Congress did not impose substantive federal requirements on health plans. ERISA's preemption provision must be interpreted in light of this dichotomy.

Federal preemption of laws regulating PBMs would result in a substantial regulatory gap, with insufficient laws in place to protect the health and safety of patients. Congress could not have intended ERISA's preemption provision to invalidate state consumer protection laws without corresponding comprehensive federal regulation.

This Court has recognized that a literal reading of Section 514's "unhelpful text" could not have been what Congress intended, and that courts must instead look to the objectives of ERISA to determine which state laws Congress intended to preempt. *Travelers*, 514 U.S. at 656. *Amici* therefore join "the rising judicial chorus urging that Congress and [this] Court revisit what is an unjust and increasingly tangled ERISA regime." *Aetna Health Inc. v. Davila*, 542 U.S. 200, 222 (2004) (Ginsburg, J., concurring) (internal quotations omitted). *Amici* request that this Court make clear that, in enacting ERISA, Congress did not preempt the laws of a significant majority of states enacted to protect the health and safety of their citizens without corresponding federal regulation.

The decision below should be reversed.

ARGUMENT

I. The Decision Below Conflicts With This Court's Precedent.

The Arkansas PBM statute does not regulate ERISA plans. The statute does not dictate an ERISA plan's choice of coverage or insurer. It does not affect the processing of health care claims by ERISA plans. It does not even mention ERISA plans. Instead, the statute regulates the prices at which PBMs reimburse pharmacies for generic prescription drugs—without regard to whether the payor is an ERISA plan.

The Arkansas statute requires PBMs to reimburse pharmacies for generic drugs at a price at least equal to the pharmacy's cost for the drug, unless the drug could have been acquired at a lower cost from a wholesaler that serves the pharmacy. Ark. Code Ann. §§ 17-92-507(a)(6), (c)(4). The statute also addresses the transparency problem in PBM pricesetting, requiring PBMs to update their price lists within seven days from the date of a specified increase in drug acquisition costs. *Id.* § 17-92-507(c)(2); Pet. App. 3a-4a.

The statute also requires PBMs to create a reasonable appeal procedure for pharmacies to challenge their reimbursement rates. The PBMs themselves decide those appeals, however. Ark. Code Ann. §§ 17-92-507(c)(4)(A)(i), (c)(4)(C). If, as part of that appeal, a pharmacy demonstrates that it is unable to purchase the drug "below the pharmacy acquisition cost from the pharmaceutical wholesaler" from whom the pharmacy purchases the majority of its prescription drugs, the pharmacy may "reverse and rebill each claim affected by the inability to procure the drug at a cost that is equal to or less than the previously challenged maximum allowable cost." Id. § 17-92-507(c)(4)(C)(iii). Finally, the statute allows a pharmacy to decline to dispense a drug when the pharmacy will lose money on that transaction. See id. § 17-92-507(e); Pet. App. 4a.

The Court of Appeals held that the Arkansas statute was preempted under both the "reference to" and "connection with" prongs of this Court's ERISA preemption framework. Pet. App. 5a-6a; see Gobeille v. Liberty Mut. Ins. Co., 136 S. Ct. 936, 943 (2016); California Div. of Labor Stds. Enf't v. Dillingham Constr., N.A., Inc., 519 U.S. 316, 324-25 (1997). Notably, however, the decision below contains little analysis of these issues. Rather, the Court of Appeals considered itself "completely bound" by its earlier decision holding that an Iowa PBM statute was preempted because it regulated entities whose customers could include ERISA plans. Pet. App. 6a-7a; see Pharmaceutical Care Mgmt. Ass'n v. Gerhart, 852 F.3d 722, 728-31 (8th Cir. 2017) (articulating this framework in holding that Iowa PBM law was preempted by ERISA).

The decision below squarely conflicts with this Court's ERISA preemption precedent. The Arkansas statute does not impermissibly "refer to" or have an impermissible "connection with" ERISA plans.

A. The Arkansas Statute Does Not Impermissibly "Refer To" ERISA Plans.

A state law has an impermissible "reference to" ERISA plans if it "acts immediately and exclusively upon ERISA plans" or if "the existence of ERISA plans is essential to the law's operation." *Gobeille*, 136 S. Ct. at 943 (internal quotations omitted); *see Dillingham*, 519 U.S. at 325.⁴ Neither criterion is satisfied here.

First, the Arkansas statute does not act "immediately and exclusively" on ERISA plans. Indeed, the Act does not impose any regulation *at all*

 $^{^4}$ It is undisputed that the Arkansas statute does not expressly "refer to" ERISA plans.

on ERISA plans. The Act regulates only PBMs. See Ark. Code Ann. §§ 17-92-507(b)-(d). Although a PBM "administers or manages a pharmacy benefits plan," id. § 17-92-507(a)(7), that plan need not be an ERISA plan. Under the Arkansas statute, a "pharmacy benefits plan" includes any plan "that pays for, reimburses, covers the cost of, or otherwise provides for pharmacist services to individuals who reside in or are employed in this state." Id. § 17-92-507(a)(9). Thus, a pharmacy benefits plan can include non-ERISA plans, such as plans sold in the individual health insurance market and government-sponsored plans. See 29 U.S.C. §§ 1003(a)(1), (2) (ERISA applies only to employee benefit plans established or maintained by employer or employee organization).

the pharmacy benefit Because plans administered by PBMs "need not necessarily be ERISA plans," the Arkansas statute does not act "immediately and exclusively" on ERISA plans. Dillingham, 519 U.S. at 325 (California prevailing wage statute did not make "reference to" ERISA plans because entities regulated "need not necessarily be ERISA plans"). The Arkansas statute applies "regardless of whether" the PBM's customer is an ERISA plan. See, e.g., Travelers, 514 U.S. at 656 (upholding New York statute that imposed surcharges on patients and HMOs but did not "make reference to" ERISA plans, because surcharges were imposed "regardless of whether" benefits were "ultimately secured by an ERISA plan, private purchase, or otherwise").

Second, the "existence of ERISA plans" is not "essential" to the operation of the Arkansas statute. The statute applies regardless of the identity of a PBM customer, and therefore "functions irrespective of ... the existence of an ERISA plan." Ingersoll-Rand Co. v. McClendon, 498 U.S. 133, 139 (1990).Act does The not impose different requirements on PBMs in the management of their pharmacy benefit plans depending on whether the plan is an ERISA plan. The statute therefore does not require any "inquiry" that is "directed to" any ERISA plan. See id. at 140.

Relying on *dicta* from its earlier decision in *Gerhart*, the Court of Appeals held that the Arkansas statute makes "*implicit* reference" to ERISA plans because the statute regulates PBMs, and PBMs administer benefits for entities that can *include* ERISA plans. Pet. App. at 6a-7a (emphasis added).⁵ This ruling is contrary to this Court's precedent holding that a state law "refers" to an ERISA plan only if it applies "immediately *and exclusively*" to ERISA plans. *See Gobeille*, 136 S. Ct. at 943.

The "implicit reference" standard invites precisely the sort of "limitless application" of ERISA preemption that this Court has rejected. *See, e.g., id.* As this Court has noted, the "relates to" language in

⁵ The Iowa statute at issue in *Gerhart* expressly referred to ERISA. *See* 852 F.3d at 726-27, 729. Accordingly, the Eighth Circuit's "implicit reference" analysis in *Gerhart*, which the Court of Appeals believed it was bound to follow here, was *dicta*.

ERISA's preemption provision cannot be read literally, because if that phrase "were taken to extend to the furthest stretch of its indeterminacy, then for all practical purposes pre-emption would never run its course, for [r]eally, universally, relations stop nowhere." *Travelers*, 514 U.S. at 655 (internal quotation omitted).

B. The Arkansas Statute Does Not Have An Impermissible "Connection With" ERISA Plans.

A state law has an impermissible "connection with ERISA plans" if the state law "governs . . . a central matter of plan administration" or "interferes with nationally uniform plan administration." *Gobeille*, 136 S. Ct. at 943 (internal quotations omitted). Neither "connection with" prong is satisfied here.

First, the Arkansas statute does not "govern a central matter of plan administration." Indeed, the statute does not govern *any* matter of plan administration, because its provisions apply only to PBMs, not to ERISA plans. *See* pp. 8-9, *supra*. The Court of Appeals did not appear to hold the Arkansas law preempted on this ground.

Second, the Arkansas statute does not "interfere with nationally uniform plan administration." Other than a citation to its decision in *Gerhart*, the Court of Appeals provided no explanation for its conclusion that the Arkansas statute was preempted for this reason. Pet. App. at 5a-6a.

At most, the Arkansas statute has an indirect economic effect on an ERISA plan by potentially affecting the prices of prescription drugs generally. But as this Court repeatedly has held, states may enact generally applicable laws that do not single out ERISA plans, even if the laws indirectly impose economic costs on such plans. See, e.g., Travelers, 514 U.S. at 659-60; De Buono v. NYSA-ILA Med. & Clinical Servs. Fund, 520 U.S. 806, 814-16 (1997) (ERISA did not preclude state from imposing gross receipts tax on ERISA-funded health care facilities).

In *Travelers*, for example, this Court upheld a New York statute that required hospitals to collect surcharges from patients insured by commercial insurers and certain HMOs, but not from patients insured under a Blue Cross/Blue Shield plan. The state regulation made Blue Cross/Blue Shield plans more attractive than other insurance, and therefore had "an indirect economic effect on choices made by insurance buyers, including ERISA plans." 514 U.S. at 659.

Despite the law's "indirect economic effect" on ERISA plans' choices of insurance, this Court held that the New York statute did not "bear the requisite 'connection with' ERISA plans to trigger preemption." *Id.* at 662. The Court explained that the law did not "bind plan administrators to any particular choice" and, therefore, did not "function as a

regulation of an ERISA plan itself." Id. at 659.

The Court concluded:

the pre-emption provision [T]o read as displacing all state laws affecting costs and charges on the theory that they indirectly relate to ERISA plans that purchase insurance policies or HMO memberships that would cover such services would effectively read the limiting language in § 514(a) out of the statute, a conclusion that would violate basic principles of statutory interpretation and could not be squared with our prior pronouncement that [p]re-emption does not occur . . . if the state law has only a tenuous, remote, or peripheral connection with covered plans, as is the case with many laws of general applicability.

Id. at 661 (internal quotations omitted).

The decision below directly conflicts with this Court's decision in *Travelers*. Both the New York law and the Arkansas statute could potentially affect the cost of providing health care benefits, and therefore could influence an ERISA plan's purchasing decisions. Yet like the New York law, the Arkansas statute is not preempted, because it does not mandate employee benefit structures or their administration, *id.* at 654; nor does it "bind plan administrators to any particular choice," *id.* at 659, or "force an ERISA plan to adopt a certain scheme of substantive coverage or effectively restrict its choice of insurers," *id.* at 668, or "function as a regulation of an ERISA plan itself," id. at 659.

Neither *Davila* nor *Gobeille* requires a contrary result. In both cases, the state law directly regulated the conduct of ERISA plans.

In Davila, the plaintiffs alleged that their ERISA-governed health maintenance organizations had violated a Texas statute by failing to exercise ordinary care in the handling of medical coverage decisions. See 542 U.S. at 204. This Court held that the plaintiffs' state causes of action were preempted by ERISA: "[I]f an individual brings suit complaining of a denial of coverage for medical care, where the individual is entitled to such coverage only because of the terms of an ERISA-regulated employee benefit plan, and where no legal duty (state or federal) independent of ERISA or the plan is violated," the state claims are preempted. See id. at 210. Thus, in Davila, "interpretation of the terms of [the plaintiffs'] benefit plans form[ed] an essential part" of the plaintiffs' claims. Id. at 213.

Here, by contrast, the Arkansas statute does not purport to regulate the relationship between ERISA beneficiaries and their ERISA plans or require any interpretation of the terms of an ERISA plan. Indeed, it does not purport to regulate ERISA plans at all. The Arkansas statute simply regulates PBMs in regard to the prices at which they reimburse pharmacies for prescription drugs.

In Gobeille, the state statute and regulation

required all health insurers, including those whose plans were subject to ERISA, to file detailed reports with state regulators disclosing payments relating to health care claims and other detailed information relating to health care services. 136 S. Ct. at 940. This Court held that ERISA preempted the state laws insofar as they applied to ERISA plans. Id. at 943-45. The Court held that ERISA's reporting, disclosure, and recordkeeping requirements were "central to, and an essential part of," ERISA plan administration, id. at 945, and that the state laws interfered with these federal requirements, id. at 945-46. Here, by contrast, the Arkansas statute does not regulate any aspect of an ERISA plan, and there are no PBM-related ERISA requirements with which the Arkansas statute could interfere.

The decision below, if affirmed, would sweep so broadly as to invalidate all manner of traditional state health care regulation that has some indirect effect on ERISA plans, no matter how remote. Yet "myriad state laws of general applicability . . . impose some burden on the administration of ERISA plans but nevertheless do not 'relate to' them within the meaning of the governing statute." De Buono, 520 U.S. at 815 (internal quotations 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.

II. ERISA's Preemption Provision Should Be Construed In Light Of The Historic Federal Deference To State Regulation Of Health Care.

The conclusion that the Arkansas PBM statute is not preempted under ERISA is reinforced by the fact that the statute regulates in the field of health care, an area "traditionally occupied by the States." *De Buono*, 520 U.S. at 814 (internal quotations omitted).

This Court has "never assumed lightly that Congress has derogated state regulation." *Travelers*, 514 U.S. at 654. Instead, the Court has addressed preemption issues "with the starting presumption that Congress does not intend to supplant state law." *Id.*; *see, e.g., De Buono*, 520 U.S. at 813-14 (ERISA preemption provision not intended to modify presumption against preemption).

This reluctance to find congressional intent to preempt is particularly strong when "federal law is said to bar state action in fields of traditional state regulation." *Travelers*, 514 U.S. at 655. The states "traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985) (internal quotations omitted).

Moreover, in non-ERISA preemption cases, this Court repeatedly has recognized the "historic primacy of state regulation in matters of health and safety," including the regulation of pharmaceuticals and medical devices. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (medical devices); *see Wyeth v. Levine*, 555 U.S. 555, 564-81 (2009) (prescription drugs); *Hillsborough Cty. v. Automated Med. Labs, Inc.*, 471 U.S. 707, 719 (1985) (blood plasma collection and testing).

Accordingly, this Court has assumed that "the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Travelers*, 514 U.S. at 655 (internal quotations omitted). Here, there is no congressional "clear and manifest purpose" to preempt state regulation of PBMs.

When Congress enacted ERISA, it did so against the backdrop of decades of state regulation of health care, as well as the judicial reluctance to interfere with the states' police powers to legislate in that realm. That context must be taken into account when assessing congressional intent regarding ERISA's preemption provision.

There is no evidence that Congress intended to interfere with state regulation of the provision of health care when it enacted ERISA. As this Court has held, "nothing 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." *Id.* at 661. Indeed, this Court repeatedly has upheld state regulation of health care against ERISA preemption challenges, including state regulation of health care pricing. *See, e.g., id.* at 667 n.6 ("ERISA was not meant to pre-empt basic rate regulation."). As demonstrated in the following section, this conclusion is confirmed by the legislative history and structure of ERISA itself.

III. In Enacting ERISA, Congress Intended To Impose Uniform Federal Regulation Of Retirement Plans, But Not Health Care Plans.

Congressional intent not to preempt state health care legislation like the Arkansas PBM statute is further evidenced by ERISA's legislative history and structure. In enacting ERISA in 1974, Congress imposed comprehensive federal regulation of retirement plans. Significantly, however, it provided no substantive federal regulation of health care plans. The absence of any such corresponding regulation strongly suggests a congressional intent not to displace state regulation of health care plans.

This Court justifiably has called ERISA's preemption language "opaque." *De Buono*, 520 U.S. at 809. Courts therefore must "go beyond the unhelpful text and the frustrating difficulty of defining its key term, and look instead to the objectives of the ERISA statute as a guide to the scope of the state law that Congress understood would survive." *Travelers*, 514 U.S. at 656; *see, e.g., Medtronic*, 518 U.S. at 485-86 ("[A]ny understanding of the scope of a pre-emption

statute's scope must rest primarily on a fair understanding of *congressional purpose*.") (internal quotations omitted; emphasis in original). Courts should consider "the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law." *Medtronic*, 518 U.S. at 486.

The circumstances surrounding the passage of ERISA, and the objectives set forth in that statute, confirm that, unlike the situation with respect to retirement plans, Congress did not intend the preemption provision to be interpreted broadly to displace state health care regulation with substantive federal regulation of welfare benefit plans.

Congress enacted ERISA "after careful study of private retirement pension plans." Alessi v. Raybestos-Manhattan, Inc., 451 U.S. 504, 510 (1998) (emphasis added). Indeed, the very name of the statute demonstrates that Congress' overriding concern was with employee retirement income security. Congress intended to address the inadequate and conflicting state standards in this area, which failed to ensure the soundness and stability of retirement plans; the lack of vesting provisions, causing employees to be deprived of anticipated retirement benefits; and the impact of those inadequate standards on federal tax revenues, given the preferential tax treatment accorded to such plans. See 29 U.S.C. § 1001(a).

In enacting ERISA, Congress therefore intended "to depart from its previous legislation that

envisioned the exercise of state regulation power over pension funds, and meant to establish pension plan regulation as exclusively a federal concern." Alessi, 451 U.S. at 523 (internal quotations omitted); see, e.g., Taggart Corp. v. Life & Health Benefits Admin., Inc., 617 F.2d 1208, 1211 (5th Cir. 1980) ("ERISA's legislative history demonstrates that its drafters were principally concerned with abuses occurring in respect of private pension assets."), cert. denied sub nom. Taggart Corp. v. Efros, 450 U.S. 1030 (1981).

For example, the House Education and Labor Committee Report defined ERISA's purposes to be concerned with pension plans:

> (1) to establish minimum standards of fiduciary conduct for Trustees, Administrators and others dealing with *retirement plans*, to provide for their enforcement through civil and criminal sanctions, to require adequate public disclosure of the plans' administrative and financial affairs, and (2) to improve the equitable character and soundness of private *pension plans* by requiring them to: (a) vest the accrued benefits of employees with significant periods of service with an employer, (b) meet minimum standards of funding and (c) guarantee the adequacy of the plan's assets against the risk of plan termination prior to the completion of the normal funding cycle by insuring the unfunded portion of the benefits promised.

H.R. Rep. No. 93-533, at 17-18 (1974), *reprinted in* 1974 U.S.C.C.A.N. 4639, 4655-4656 (emphasis added).

The Senate Committee on Labor and Public Welfare reiterated Congress' concern with the regulation of private pension plans:

> The provisions of S.4 are addressed to the issue whether American working men and women shall receive private pension plan benefits which they have been led to believe would be theirs upon retirement from working lives. It responds by mandating protective measures and prescribing minimum standards for promised benefits.

> The purpose of S.4 is to prescribe legislative remedies for the various deficiencies existing in the private pension plan systems which have been determined by the Senate Subcommittee's comprehensive study of such plans.

S. Rep. No. 93-127, at 1 (1974), reprinted in 1974 U.S.C.C.A.N. at 4838.

There is simply no evidence in the legislative history of any such congressional concern with welfare benefit plans:

ERISA's legislative history is remarkable . . . for what it does not contain. ERISA's legislative

history provides no evidence that Congress seriously investigated, studied, or debated any issues or concerns with nonpension employee benefit plans....

... There is no documentation anywhere in ERISA's legislative history of any study or investigation of the history or growth of nonpension employee benefit plans, or of any specific concern with the management of nonpension plan assets. Further, ERISA's legislative history fails to disclose any concerted investigation of any complaints about nonpension benefits, such as inadequate health care, accident, death, or disability coverage, or problems with health, life, or disability benefits claims. In short, Congress just was not dealing with nonpension benefit plans when it enacted ERISA.

Donald T. Bogan, Protecting Patient Rights Despite ERISA: Will the Supreme Court Allow States to Regulate Managed Care?, 74 Tul. L. Rev. 951, 972, 976-77 (2000).

Furthermore, the express statutory findings and declaration of policy confirm that Congress was concerned with regulating retirement plans and ensuring employee retirement income security. See 29 U.S.C. § 1001(a); *id.* § 1001(c) ("It is hereby further declared to be the policy of this chapter to protect

. . .

interstate commerce, the Federal taxing power, and the interests of participants in private pension plans and their beneficiaries by improving the equitable character and the soundness of such plans by requiring them to vest the accrued benefits of employees with significant periods of service, to meet minimum standards of funding, and by requiring plan termination insurance.").

To that end, when Congress enacted ERISA it put in place a series of regulatory provisions that impose specific, substantive federal requirements on retirement plans. See Pub. L. No. 93-406, 88 Stat. 829 (1974). For example, there were detailed provisions regarding participation and vesting of pension plans, including minimum participation and vesting standards (29 U.S.C. §§ 1052-1053), benefit accrual requirements (*id.* 1054), a requirement of joint and survivor annuity and preretirement survivor annuity (id. \S 1055), specifications regarding the form and payment of benefits (id. § 1056), regulation of merger and consolidation of plans or transfers of plan assets recordkeeping (id. § 1058), and reporting requirements (id. § 1059), and rules regarding multiple employer plans (id. § 1060). There were detailed provisions regarding the funding of pension plans (e.g., id. §§ 1082-1085), federal tax regulation (e.g., id. §§ 1201-1203), including significant revisions to the Internal Revenue Code, and the establishment of a Joint Pension Task Force (id. §§ 1221-1222). There were also detailed provisions regarding pension plan termination insurance, including the creation of the Pension Benefit Guaranty Corporation. E.g., id.

§§ 1301-1303, 1305-1309, 1321-1322, 1341-1348, 1361-1368.

By contrast, Congress did not impose substantive federal regulation of health care plans.⁶ Accordingly, state regulation of PBMs, such as the Arkansas statute at issue here, simply does not implicate the congressional concerns for federal uniformity of regulation of retirement plans that underlie ERISA's preemption provision.

Further, despite the increasing importance and pervasiveness of PBMs in recent years, Congress has not sought to interfere with regulation of PBMs by the states. A holding that state statutes regulating PBMs are preempted by ERISA would directly undermine that approach. Preemption of state PBM legislation like the Arkansas statute would do a disservice both to congressional intent and to the welfare of patients that such legislation is designed to advance.

Amici have outlined some of the problems state PBM legislation has attempted to address regarding transparency in the area of PBM drug pricing and administration of drug benefits. See pp. 2-3, supra. Petitioner and others have noted the adverse effect of PBMs on the viability of independent pharmacies, and

⁶ Congress did enact reporting, disclosure, and recordkeeping requirements applicable to employee benefit plans, *see Gobeille*, 136 S. Ct. at 944, but did not impose anything like the comprehensive substantive federal regulation on welfare plans that it did on pension plans.

the consequent statewide health care crises caused by their closures. The ERISA preemption provision was not intended, and should not be interpreted, to strike down state legislation that was enacted to address these concerns.

CONCLUSION

The decision below should be reversed.

Respectfully submitted,

Jack R. Bierig *Counsel of Record* Aphrodite Kokolis SCHIFF HARDIN LLP 233 S. Wacker Dr., Suite 7100 Chicago, IL 60606 (312) 258-5500 jbierig@schiffhardin.com

Counsel for Amici Curiae

March 2, 2020