NO. 18-540

In the
Supreme Court of the United States

LESLIE RUTLEDGE, Attorney General of Arkansas,
Petitioner,
v.

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Eighth Circuit

BRIEF OF FMI AND TWENTY-THREE RETAIL TRADE ASSOCIATIONS AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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INTEREST OF *AMICI CURIAE*[1]

Amicus curiae FMI is a trade association representing the food industry, including nearly 1,000 supermarket member companies that collectively operate almost 33,000 food retail outlets and employ approximately 6 million workers. Those companies also operate approximately 12,000 pharmacies inside retail grocery stores throughout the United States. The additional *amici* are twenty-three state-level trade associations representing the interests of retailers, including operators of supermarket pharmacies.[2] *Amici* represent the interests of members ranging from independent stores to regional supermarket chains to some of the

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[1] Pursuant to Rule 37.6, *amici* affirm that no counsel for a party authored this brief in whole or in part and that no person other than *amici*, their members, or their counsel made any monetary contributions intended to fund the preparation or submission of this brief. All parties have consented in writing to the filing of this brief.

[2] Those *amici* are the Alabama Grocers Association, Arkansas Grocers and Retail Merchants Association, California Grocers Association, Idaho Retailers Association, Illinois Food Retailers Association, Indiana Grocery & Convenience Store Association, Iowa Grocery Industry Association, Kentucky Retail Federation, Louisiana Retailers Association, Maryland Retailers Association, Massachusetts Food Association, Minnesota Grocers Association, Missouri Retailers Association, Nebraska Industry Association, New Jersey Food Council, Ohio Grocers Association, Pennsylvania Food Merchants Association, Tennessee Grocers & Convenience Store Association, Texas Retailers Association, Utah Food Industry Association, Utah Retail Merchants Association, Washington Food Industry Association, and Wisconsin Grocers Association.

country's best-known retailers with locations in all fifty States.

The diversity of *amici*'s membership gives *amici* a unique and particularly strong interest in this case. *Amici*'s members both operate pharmacies and sponsor multi-state healthcare plans regulated by the Employee Retirement Income Security Act of 1974 ("ERISA"). As a result, *amici*'s members have interests both in constraining the kind of abusive practices that the Arkansas statute at issue is designed to address, and in protecting the uniform administration of ERISA plans as Congress intended when it provided for preemption.

Pharmacy benefit managers ("PBMs") leverage their concentrated market power to the detriment of both pharmacies and the healthcare plans that the PBMs serve. The Arkansas statute at issue, 2015 Ark. Laws Act 900 (S.B. 688) (codified at Ark. Code Ann. § 17-92-507) ("Act 900"), addresses just one type of such conduct. Act 900 is designed to curtail PBMs' ability to reimburse a pharmacy for generic drugs below the pharmacy's cost to acquire those drugs. PBMs leverage their market power in other ways that similarly hinder the ability of *amici*'s members to provide access to healthcare through pharmacies in their retail locations. As a result, some of *amici*'s members have stopped operating pharmacies, and many others struggle to maintain the financial viability of their pharmacies. *Amici* therefore have a strong interest in preserving the ability of States to regulate abusive PBM practices.

Amici's members, which include Fortune 500 companies, have an equally strong interest in

ensuring that state regulations do not interfere with the uniform administration of ERISA plans. *Amici*'s members include multi-state employers that Congress sought to protect when it enacted ERISA Section 514(a) (codified at 29 U.S.C. § 1144(a)) to "minimize the administrative and financial burden of complying with conflicting directives among States or between States and the Federal Government ..., [and to prevent] the potential for conflict in substantive law ... requiring the tailoring of plans and employer conduct to the peculiarities of the law of each jurisdiction." *New York State Conference of Blue Cross & Blue Shield Plans* v. *Travelers Ins.* Co., 514 U.S. 645, 656-57 (1995) (quoting *Ingersoll-Rand Co.* v. *McClendon*, 498 U.S. 133, 142 (1990)) (alterations in *Travelers*).

If Act 900 and similar laws required plan sponsors to tailor plan administration or benefits to the laws of a particular State, *amici*'s members would feel that burden acutely and *amici* could not support such laws. Act 900 presents no such concern. It imposes obligations only on PBMs, not on ERISA plans. As a result, *amici* have an interest in preserving the ability of States to enact similar laws that curtail PBM abuses of their concentrated market power and protect public access to healthcare through pharmacies without burdening the uniform administration of ERISA plans.

SUMMARY OF ARGUMENT

I. Act 900 is one of many state laws designed to address abuses by PBMs that have made it difficult, and in some cases financially infeasible, for *amici*'s members to operate pharmacies and provide

healthcare to their communities (or to expand pharmacy operations to other store locations). Act 900 reflects a recognition, shared by many States in addition to Arkansas, that PBM abuses of their concentrated market power should be restrained to preserve affordable access to healthcare through pharmacies.

In Arkansas, independent pharmacies were closing at an alarming rate. The Arkansas General Assembly responded by enacting Act 900 as a "general health care regulation, which historically has been a matter of local concern." *See Travelers*, 514 U.S. at 661. The purpose of Act 900 is to ensure that what a PBM pays a pharmacy for a generic drug is at least as much as a pharmacy's actual cost to acquire that drug.

Below-cost pricing is just one of many abusive practices enabled by the concentration of market power in three PBMs that allows them to operate outside of the normal constraints of market forces. PBMs, for example, charge large retroactive fees to pharmacies well after the point of sale, supposedly to dictate incentives to pharmacies. The federal government recently reported that these fees increased by more than 45,000 percent from 2010 to 2017. There is no market justification for the exponential explosion of such fees. These PBM practices already have caused some of *amici*'s members to stop operating pharmacies at numerous retail locations, and if left unchecked, they likely will force many more of *amici*'s members to exit the pharmacy business.

This challenge to Act 900 by the Pharmaceutical Care Management Association ("PCMA") threatens to hamstring States' efforts to combat PBMs' documented abuses of their concentrated market power. Those practices harm *amici*'s members, "mom and pop" shops and Fortune 500 companies alike. As an organization representing pharmacy operators, *amici* have a strong interest in preserving the power of States to enact similar laws to constrain PBMs' abuses of their market power.

II. *Amici*'s members include many employers that sponsor multi-state ERISA plans. As such, *amici* have an equally strong interest in preserving the purpose of ERISA's preemption clause—to protect plan sponsors and administrators from having to tailor their plans to comply with conflicting state laws.

Fortunately, Act 900 does not burden uniform plan administration in any way. It imposes requirements only on PBMs, not on ERISA plans. The Eighth Circuit below did not even attempt to explain pragmatically how Act 900 could bind ERISA plans, much less require such a plan to tailor its administration or benefits to accommodate a requirement unique to Arkansas.

The Eighth Circuit erred in holding that Act 900 makes "reference to" ERISA plans, because this Court has held consistently that generally applicable laws do not make such a prohibited "reference." This case therefore turns on whether Act 900 has a "connection with" ERISA plans—in other words, whether Act 900 imposes requirements that interfere with the uniform administration of multi-state

ERISA plans. This Court has held that ERISA does not preempt basic state rate regulations in the field of healthcare. *Travelers*, 514 U.S. at 662, 667 n.6. Act 900 is indistinguishable from the rate regulation upheld in *Travelers*. For purposes of preemption, a State telling a commercial insurer that administers an ERISA plan what it must pay a hospital for health care services is no different than a State telling a PBM what it must pay a pharmacy for a drug. Neither regulation constrains or burdens ERISA plan administration.

Act 900 does not resemble the kinds of state laws that this Court has held preempted. Act 900 does not impose direct requirements on ERISA plans or dictate benefit or beneficiary decisions in any way. *See, e.g., Shaw* v. *Delta Air Lines, Inc.*, 463 U.S. 85, 97 (1983); *Egelhoff* v. *Egelhoff ex rel. Breiner*, 532 U.S. 141, 148 (2001). It also does not impose reporting requirements or otherwise duplicate an "essential part of[] the uniform system of plan administration contemplated by ERISA." *See Gobeille* v. *Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 945 (2016).

Finally, Act 900 has at most modest incidental economic effects on the prices PBMs ultimately charge to ERISA plans. Any such effects are precisely the kind of "indirect economic effect on the relative costs of various health insurance packages in a given State" that this Court has held are "a far cry from those 'conflicting directives' from which Congress meant to insulate ERISA plans." *Travelers*, 514 U.S. at 662.

In short, Act 900 is a "general health care regulation, which historically has been a matter of

local concern" that does not impinge upon uniform plan administration in any demonstrable way. *See id.* at 661. This Court therefore should reverse the judgment of the Eighth Circuit holding that ERISA preempts Act 900.

ARGUMENT

I. Laws Like Act 900 Are Needed to Limit PBM Abuses of Concentrated Market Power and to Preserve Patient Access to Pharmacies.

A. Supermarket Pharmacies Are Important Providers of Healthcare to Millions of Americans.

Food retailers play a unique and important role in providing American consumers with convenient access to the full range of pharmacy services. Supermarket pharmacies provide medication counseling, fill prescriptions, offer reduced price or free generic drug programs, and administer vaccinations; and they are among the most efficient and lowest cost competitors in the pharmacy market.

Food retailers also are uniquely positioned to offer integrated health and wellness services as a complement to their pharmacy services. For example, many supermarkets today offer dietary educational programs and carry products specific to personalized health and wellness goals. The majority of *amicus curiae* FMI's members report that their pharmacists, dietitians, and culinary teams collaborate frequently to meet customers' health needs.

Furthermore, as drug store chains merge and vertically integrate (including with PBMs and insurance companies), supermarket pharmacies have largely remained independent. They therefore provide an important check on market power in an increasingly consolidated pharmacy industry. *See* Ellen Gabler, *How Chaos at Chain Pharmacies Is Putting Patients at Risk*, N.Y. Times, Jan. 1, 2020, https://nyti.ms/2Oiw42e.

B. States Have Compelling Reasons to Regulate How PBMs Leverage Concentrated Market Power.

PBMs leverage concentrated market power to dictate terms to pharmacies and health plans alike that are divorced from market pressures. Act 900 is a straightforward rate regulation that, at base, requires PBMs to pay at least a pharmacy's actual acquisition cost for a generic drug it dispenses. Below-acquisition-cost pricing, however, is just one of many ways that PBMs leverage concentrated market power to the detriment of pharmacies, health care plans, and beneficiaries. The outcome of this case could affect the ability of States to legislate limits on a variety of different PBM abuses of concentrated market power.

PBMs operate as middlemen in the prescription drug distribution chain. Health plans, both those that ERISA regulates and those that ERISA does not, contract for PBMs to organize networks of pharmacies at which their participants can purchase prescription drugs. PBMs earn money on the spread between the prices they pay to pharmacies and the amounts they bill to health plans on every drug

purchase, and by charging pharmacies additional "performance-based pharmacy incentive" fees (also referred to as a type of "direct and indirect remuneration" or "DIR" fees), which PBMs contend are designed to incentivize pharmacies to perform better. They also profit from rebates that drug manufacturers pay to have their drugs placed and preferred on drug formularies. PBMs also operate their own pharmacies from which they can sell prescription drugs directly to patients.

1. PBMs Wield Concentrated Market Power.

Act 900, like similar laws enacted by other States, is designed to constrain predatory practices enabled by PBMs' concentrated market power. The current administration has found that "[t]hree PBMs account for 85 percent of the market, which allows them to exercise undue market power against manufacturers and against the health plans and beneficiaries they are supposed to be representing, thus generating outsized profits for themselves." Counsel of Economic Advisers, *Reforming Biopharmaceutical Pricing at Home and Abroad* 10 (Feb. 2018).[3] This market concentration empowers the big three PBMs to offer pharmacies a Hobson's choice. The pharmacy must either accept the PBM's mandated contract terms (including allowing the PBM to set prices for generic drugs unilaterally and then later impose retroactive DIR fees based on an

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[3] https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf.

opaque methodology), or give up the ability to serve the many customers whose health plans contract with the PBM.

PBMs consistently have resisted state and federal efforts to regulate how they leverage concentrated market power, including taking contradictory positions before federal regulators and this Court. When the Department of Labor considered federal regulations that would impose transparency requirements on how PBMs calculate drugs prices and administrative fees, PBMs argued that existing state laws were sufficient to constrain their ability to abuse concentrated market power. *See* Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* 18 (Nov. 2014) ("ERISA Advisory Council Report").[4] Yet in this case and in several other similar cases around the country, PCMA argues that ERISA preempts those same state laws. The combined effect of PCMA's irreconcilable positions is to provide PBMs with unconstrained freedom to exploit concentrated market power to the detriment of healthcare plans, beneficiaries, and pharmacies.

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[4] https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/about-us/erisa-advisory-council/2014-pbm-compensation-and-fee-disclosure.pdf.

2. PBMs Leverage Concentrated Market Power to Force Pharmacies to Accept Below-Cost Pricing and Other Financially Oppressive Practices.

PBMs' profit model is dependent upon their ability to dictate prices and impose upon pharmacies arbitrary and often below-cost reimbursement terms for generic drugs through maximum allowable cost ("MAC") price lists. Unlike with on-patent drugs, where PBM reimbursements typically are based on the actual prices paid by drug wholesalers to manufacturers, PBM reimbursements to pharmacies for generic drugs are based on PBMs' "proprietary" MAC lists, which bear no necessary relation to pharmacies' acquisition costs. *See* ERISA Advisory Council Report 10; BIO 6.

PBMs profit by maximizing the difference between what they pay pharmacies for a drug and the inflated amount they charge a healthcare plan for that same transaction. To take just one reported example, an Iowa county was billed by its PBM $198.22 for a drug that the PBM reimbursed the dispensing pharmacy just $5.73—a markup of more than 3,400 percent. *See* Robert Langreth et al., *The Secret Drug Pricing System Middlemen Use to Rake in Millions*, Bloomberg, Sept. 11, 2018.[5] As a result, many States impose limits on such practices to protect themselves and private plans from

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[5] https://www.bloomberg.com/graphics/2018-drug-spread-pricing/.

excessively inflated markups. *See id.*; California et al. Cert. *Amicus* Br. 12-13.

Act 900 is not, as PCMA suggests, designed to prop up inefficient businesses. *See* BIO 7. PCMA asserts that below-cost reimbursement is a problem only for "[p]oorly run pharmacies," and that low PBM reimbursement rates "create a powerful incentive for less-well-run pharmacies to improve their purchasing practices, which in turn increases competition by wholesalers and manufacturers to sell to such pharmacies." *Id.* Although PCMA declares that "the whole point of a MAC program is to pay the average cost incurred by well-run pharmacies," *id.*, the PBM industry has resisted attempts to force price transparency that would reveal the basis for these claims. *See, e.g.*, ERISA Advisory Council Report 17-20. Pharmacy operators generally—not just "poorly run" ones—are suffering as a result of PBMs' below-cost MAC pricing. Even some of *amici*'s largest members—Fortune 500 companies with efficiencies, expertise in supply chain logistics, and economies of scale—struggle to operate financially viable pharmacies.

Below-cost pricing is just one way that PBMs systematically leverage their market power. They also impose opaque retroactive DIR fees. PBMs charge these fees to pharmacies without warning or market justification weeks or months after the pharmacy dispenses a drug to a beneficiary.

The Centers for Medicare & Medicaid Services ("CMS") tracks DIR fees and has reported an increase in such post-sale fees charged to pharmacies by PBMs of more than 45,000 percent from 2010 to

2017. *See* Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses, 83 Fed. Reg. 62,152, 62,174 (Nov. 10, 2018). There is no competitive market justification for such an exponential growth in these fees.

As with MAC pricing, PBMs tout these post-sale fees as disincentives to "poor performance" by pharmacies. *See id.* In reality, they are just another example of PBMs leveraging their market power to maximize their profits. Charges for "poor performance" far exceed incentive payments to pharmacies intended to reward "high performance." *See id.* As a result, beneficiaries pay higher costs and drug prices become less transparent. Pharmacies report that these retroactive fees are a key reason for recent closures. Xil Consulting, *Payers and PBMs Profit from Obscure Pharmacy Fees, While Seniors See No Relief in Prescription Costs* (Feb. 11, 2020) (*"Pharmacy Fees*").[6] As a result, below-cost MAC pricing is just one of potentially numerous manifestations of PBMs' concentrated market power that States have a legitimate interest in regulating.

3. PBMs' Exploitation of Concentrated Market Power Harms Healthcare Plans and Beneficiaries.

How PBMs wield market power does not just harm pharmacies. States also have a legitimate interest in regulating PBM practices that exploit inherent conflicts of interest to the detriment of

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6 https://www.xilangconsulting.com/post/policy-alert.

health care plans and beneficiaries. The Court's decision in this case likely will impact States' ability to legislate to constrain such practices.

PBMs often are responsible for developing healthcare plan formularies—lists of drugs that a plan will cover. Drug companies compete to have their drugs listed on those formularies by offering compensation to PBMs in the form of rebates. *See* Joanna Shepherd, *Pharmacy Benefit Managers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs*, 38 Yale L. & Pol'y Rev. (forthcoming).[7] PBMs may be incentivized to obtain more expensive drugs, to the extent their rebates correlate with the cost of the drugs they include on formularies. *See id.* Plans typically have little visibility into these rebates, making it difficult for them to monitor whether their contracted PBMs are choosing drugs to reduce plan costs or to increase the PBMs' own compensation. *See id.*

Rebates and other price concessions have been steadily increasing in recent years, with PBMs taking the lion's share. Between 2012 and 2016, "over half of the increase in list price purchases was paid to PBMs as higher rebates," meaning that "although drug list prices are increasing, drug makers are keeping a decreasing share of the revenue while PBMs are keeping an increasing share." *Id.*

PBMs also own or have financial interests in pharmacies, and they frequently drive patients to those outlets as the sole source for pharmaceuticals.

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[7] https://ssrn.com/abstract=3313828.

Again, PBMs have incentives in these circumstances to provide patients with more expensive drugs. *See* Applied Policy, *Concerns Regarding the Pharmacy Benefit Management Industry* (Nov. 2015).[8] They also reduce competition when they steer patients toward their own captive retailers. *See* Katie Thomas, *Specialty Pharmacies Say Benefit Managers Are Squeezing Them Out*, N.Y. Times, Jan. 9, 2017, https://nyti.ms/2jmugmO. As CMS has recognized, "[m]arket competition is best achieved when a wide variety of pharmacies are able to compete in the market for selective contracting with plan sponsors and PBMs," not when PBMs can simply direct patients to themselves. 83 Fed. Reg. at 62,176.

Act 900 is just one example of efforts by States to curb these practices. PCMA has attempted to invalidate state laws promoting patients' ability to choose their own pharmacies, allowing pharmacies to disclose information about drug alternatives and PBM compensation, allowing brick-and-mortar pharmacies to deliver drugs by mail, limiting PBMs' ability to charge certain retroactive fees, and prohibiting copayments that exceed the cost of medication. *See, e.g.*, Compl., *Pharmaceutical Care Mgmt. Ass'n* v. *Mulready*, No. 5:19-cv-00977 (W.D. Okla. Oct. 25, 2019), ECF No. 1; *Pharmaceutical Care Mgmt. Ass'n* v. *Tufte*, 326 F. Supp. 3d 873, 880 (D.N.D. 2018).

PBM practices have also attracted the attention of the federal government. The current

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[8] http://www.ncpa.co/pdf/applied-policy-issue-brief.pdf.

administration has identified as problems, for example, the massive increase in DIR fees imposed on pharmacies and PBMs' tactic of steering patients to their own pharmacy operations, or those in which they have a financial interest. *See* 83 Fed. Reg. at 62,174-76. It also has acknowledged how PBMs' conflicted rebate-based compensation structures contribute to high prescription costs. See Dep't of Health and Human Servs., *American Patients First, The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs* (May 2018)[9] ("Because health plans, pharmacy benefit managers (PBMs), and wholesalers receive higher rebates and fees when list prices increase, there is little incentive to control list prices. Consumers, however, pay higher copayments, coinsurance, or pre-deductible out-of-pocket costs when list prices rise.").

C. PBMs' Practices Risk Driving Food Retailers Out of the Pharmacy Business.

The PBM practices described above have put independent pharmacy operations at risk. Unlike standalone pharmacies, *amici*'s members that operate supermarket pharmacies generally are not dependent solely on their pharmacy operations for survival. PBM abuses may not threaten to force integrated food retailers to close their doors. Instead, PBM practices make it likely that food retailers will be forced to continue leaving the pharmacy

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[9] https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf.

business—either by outsourcing their pharmacy operations to the biggest players in the market, or worse, by abandoning pharmacy operations altogether.

Neither of these scenarios is merely hypothetical. Some stores already have sold their pharmacy operations to PBM-operated chains. The number of pharmacies in supermarkets decreased by more than seven percent between 2007 and 2017. *See* National Association of Chain Drug Stores, *Chain Member Fact Book 2018-2019* at 10;[10] Sharon Terlep & Jaewon Kang, *The Pharmacist Is Out: Supermarkets Close Pharmacy Counters*, Wall St. J., Jan. 27, 2020.[11] Food and mass-market retailers have experienced the worst impact of PBMs' practices, accounting for more than 45 percent of the pharmacy closures from July 2018 to July 2019. *See Pharmacy Fees*.[12] At the same time, consumers are expressing increasing interest in integrated health and wellness. Supermarket pharmacy closures, and abandoned expansions, thus contribute to the overall trend of decreased access to pharmacies. The effect of such closures is particularly acute in some rural communities, where closures are more prevalent and more detrimental to a community's access to healthcare. *See* RUPRI Center for Rural Health

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10 https://www.nacds.org/wp-content/uploads/2019/05/2018_ChainDrugFactbook.pdf.

11 https://www.wsj.com/articles/the-pharmacist-is-out-supermarkets-close-pharmacy-counters-11580034600.

12 https://www.xilangconsulting.com/post/policy-alert.

Policy Analysis, *Update: Independently Owned Pharmacy Closures in Rural America*, *2003-2018* at 1-2 (July 2018).[13] The closure of pharmacies in recent years has created "pharmacy deserts" in some underserved urban communities as well. *See*, *e.g.*, Ese Olumhense & Nausheen Husain, *'Pharmacy deserts' a growing health concern in Chicago, experts, residents say*, Chi. Trib., Jan. 22, 2018.[14]

II. Act 900 Does Not Interfere with the Uniform Administration of ERISA Plans.

Congress's primary goal when it preempted state laws that "relate to" ERISA plans was to ensure that plan sponsors that have employees in multiple States, like many of *amici*'s members, could offer uniform benefits nationwide without the burden of tailoring their plans to as many as fifty sets of conflicting state laws. Act 900 serves its purpose—to ensure that pharmacies in addition to those run by PBMs remain financially viable—without undermining that goal. Act 900 imposes obligations only upon PBMs, not ERISA plans, and it does not require an ERISA plan to tailor plan administration or benefits in any way.

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[13] https://rupri.public-health.uiowa.edu/publications/policybriefs/2018/2018%20Pharmacy%20Closures.pdf.

[14] https://www.chicagotribune.com/news/breaking/ct-met-pharmacy-deserts-chicago-20180108-story.html.

A. Congress's Primary Purpose When It Enacted ERISA's Preemption Provision Was to Protect Uniform Plan Administration.

Section 514(a) of ERISA preempts state laws "insofar as they may now or hereafter relate to any employee benefit plan." 29 U.S.C. § 1144(a). Recognizing that this language on its own is "unhelpful" for determining the outer bounds of preemption, *Travelers*, 514 U.S. at 656, this Court has held that a "law 'relate[s]' to a covered employee benefit plan for purposes of § 514(a) 'if it [1] has a connection with or [2] reference to such a plan.'" *California Div. of Labor Standards Enf't* v. *Dillingham Constr., N.A., Inc.*, 519 U.S. 316, 324 (1997) (alterations in original).

The Eighth Circuit's contrary decision below notwithstanding, Act 900 plainly does not make "reference to" an ERISA plan. Act 900 imposes obligations only on PBMs, not on healthcare plans, as part of a statute that regulates the use of MAC price lists for generic drugs. *See* Ark. Code Ann. § 17-92-507. As a result, it does not "act immediately and *exclusively*" upon ERISA plans, nor is "the existence of an ERISA plan essential to the law's operation." *See Dillingham*, 519 U.S. at 325 (emphasis added). Every ERISA plan could disappear tomorrow, and the statute would apply unabated to PBMs' management of prescription drug benefits for other types of health plans.

This case therefore primarily is about whether Act 900 has a "connection with" an ERISA plan. This Court has acknowledged that "'connection with' is

scarcely more restrictive than 'relate to'" and "cautioned against 'uncritical literalism' that would make pre-emption turn on 'infinite connections.'" *Egelhoff*, 532 U.S. at 147. Instead, this Court has held that "to determine whether a state law has the forbidden connection, we look both to 'the objectives of the ERISA statute as a guide to the scope of the state law that Congress understood would survive,' as well as to the nature of the effect of the state law on ERISA plans." *Id.*

Congress's principal goal when it enacted Section 514(a) was to ensure that plan sponsors are not required to tailor plan administration and benefits to comply with as many as fifty sets of state laws:

> We have found that in passing § 514(a), Congress intended "to ensure that plans and plan sponsors would be subject to a uniform body of benefits law; the goal was to minimize the administrative and financial burden of complying with conflicting directives among States or between States and the Federal Government ..., [and to prevent] the potential for conflict in substantive law ... requiring the tailoring of plans and employer conduct to the peculiarities of the law of each jurisdiction."

Travelers, 514 U.S. at 656-57 (quoting *Ingersoll-Rand*, 498 U.S. at 142) (alterations in *Travelers*); *see also Egelhoff*, 532 U.S. at 150 (explaining that "[r]equiring ERISA administrators to master the relevant laws of 50 States" undermines Congress's goals). Congress sought to enable employers to "establish a uniform administrative scheme," and to

protect employers from having "to keep certain records in some States but not in others; to make certain benefits available in some States but not in others; to process claims in a certain way in some States but not in others; and to comply with certain fiduciary standards in some States but not in others." *Fort Halifax Packing Co.* v. *Coyne*, 482 U.S. 1, 9 (1987).

The multi-state employers that *amici* represent, which sponsor plans that provide healthcare to employees in several States, are precisely the parties that Congress intended ERISA preemption to protect. Absent a strong preemption regime, they would have to contend with these hurdles to providing benefits to their employees. *Amici* therefore have a strong interest in preserving ERISA's protection for the uniform administration of benefit plans.

B. Act 900 Does Not Require Plan Sponsors to Tailor Plan Administration or Benefits in Any Way.

Amici support laws like Act 900 that constrain PBMs' abuses of their concentrated market power to the detriment of *amici*'s pharmacy-operating members without infringing upon their members' ability to uniformly administer their plans and formulate benefits nationwide. No provision in Act 900 requires an ERISA plan sponsor to tailor the plan's administration or benefits.

The Eighth Circuit accurately summarized Act 900 as follows: "the Act mandates that pharmacies be reimbursed for generic drugs at a price equal to or higher than the pharmacies' cost for the drug based on the invoice from the wholesaler." *Pharmaceutical*

Care Mgmt. Ass'n. v. *Rutledge*, 891 F.3d 1109, 1111 (8th Cir. 2018). The Eighth Circuit's use of the passive voice notwithstanding, Act 900 makes clear that it imposes obligations only on PBMs. It requires nothing from healthcare plans—ERISA plans and non-ERISA plans alike—that contract with PBMs.

Act 900 also creates enforcement mechanisms to allow pharmacies to protect themselves from below-cost MAC prices. Specifically, the law requires PBMs to:

(i) update MAC lists within seven days of certain wholesale price changes for prescription drugs, Ark. Code Ann. § 17-92-507(c)(2);

(ii) provide an administrative appeal procedure that pharmacies can use to challenge below-cost MAC prices and seek retroactive reimbursement for underpayments, *id.* § 17-92-507(c)(4)(A)(i); and

(iii) adjust MAC pricing when a pharmacy wins an appeal, *id.* § 17-92-507(c)(4)(C)(iii).

Act 900 also authorizes pharmacies to decline to dispense a generic drug when a PBM's MAC price is below the pharmacy's acquisition cost for the drug. *Id.* § 17-92-507(e).

None of those provisions apply to ERISA plans, much less bind an ERISA plan sponsor or administrator to provide a particular benefit, recognize a particular beneficiary, or take on additional reporting or other administrative burdens.

Thus, a comparison of the "objectives of the ERISA statute" to the "nature of the effect of the state law on ERISA plans" reveals that Act 900 does not impact ERISA plan administration or benefits in a manner that contravenes Congress's goals. *Egelhoff*, 532 U.S. at 147.

1. Act 900 Is Rate Regulation Indistinguishable from the Law Upheld in *Travelers*.

At its core, Act 900 regulates pharmacy reimbursement rates for prescription medications. It sets a pharmaceutical wholesaler's price for a generic drug as the floor for how much a PBM must pay the pharmacy for that same drug. For preemption purposes, a law setting a floor for how much a PBM must pay a pharmacy for a drug is no different than a law regulating how much a plan administrator must pay a hospital for a health care service.

Travelers specifically held that "ERISA was not meant to pre-empt basic rate regulation" in the field of healthcare. 514 U.S. at 665-67 & n.6; *cf. Dillingham*, 519 U.S. at 330 ("The wages to be paid on public works projects and the substantive standards to be applied to apprenticeship training programs are, however, quite remote from the areas with which ERISA is expressly concerned—"'reporting, disclosure, fiduciary responsibility, and the like.'"'). In *Travelers*, the law at issue was a New York statute, Section 2807-c, requiring hospitals to "collect surcharges from patients covered by a commercial insurer but not from patients insured by a Blue Cross/Blue Shield plan." 514 U.S. at 649. Those surcharges were intended to compensate

nonprofit insurers for providing coverage to patients "whom the commercial insurers would reject as unacceptable risks." *Id.* at 658.

The conclusion in *Travelers* that Section 2807-c was not preempted was bolstered by the fact that, only months after passing ERISA, Congress passed a law making States eligible for grants "'[f]or the purpose of demonstrating the effectiveness of State Agencies regulating rates for the provision of health care ... within the State.'" *Id.* at 666 (alteration in original). This Court concluded that Congress's "provision for comprehensive aid to *state health care rate regulation* is simply incompatible with pre-emption of the same by ERISA." *Id.* at 667 (emphasis added).

For preemption purposes, Act 900 is indistinguishable from the rate regulation in Section 2807-c. Both laws regulate what third parties must pay to facilitate a healthcare plan's provision of benefits to participants. Section 2807-c regulates what a commercial insurer must pay a hospital for a health care service. Act 900 similarly regulates what a PBM must pay to a pharmacy for a generic drug, specifically a price equal to or higher than the "[p]harmacy acquisition cost." Ark. Code Ann. § 17-92-507(a)(6). Act 900, like Section 2807-c, does not "bind plan administrators to any particular choice," *Travelers*, 514 U.S. at 659.

This Court noted in *Travelers* that treating a regulation of hospital costs as a regulation of ERISA plan administration for purposes of preemption—based on the argument that the costs of such regulation inevitably will be passed to ERISA

plans—would "bar any state regulation of hospital costs." 514 U.S. at 665. It referred to such a result as "unsettling" and "startling," particularly because "there is not so much as a hint in ERISA's legislative history or anywhere else that Congress intended to squelch these state efforts." *Id.* at 665.

The same is true with respect to state laws that regulate PBMs. Such laws are "general health care regulation" of a kind that "historically has been a matter of local concern." *Id.* at 662. If ERISA could preempt a law like Act 900 that sets a floor for what a PBM must pay a pharmacy for a generic drug, even though that law does not regulate a PBM's relationship with a healthcare plan in any way, it is difficult to conceive how a State ever could regulate a PBM. "Nothing in the language of [ERISA] or the context of its passage indicates that Congress chose to displace" such laws. *Id.*

2. Act 900 Does Not Impose Direct Requirements on ERISA Plans or Dictate Benefit or Beneficiary Decisions.

Act 900 regulates only PBMs' relationships with pharmacies. It does not regulate healthcare plans' relationships with PBMs or with plan participants. As a result, it does not resemble the kinds of state laws that this Court has held to be preempted by ERISA. Those laws generally have imposed direct requirements on ERISA plans that required them to provide a particular kind of benefit, or pay benefits to a particular beneficiary.

For example, in *Shaw*, this Court held that ERISA preempted the New York Human Rights Law

because it required employers to provide pregnancy benefits in ERISA plans. 467 U.S. at 97. In contrast, Act 900 does not require health care plans to provide coverage for any particular drug. Rather, the law simply requires a PBM to pay at least a pharmacy's actual acquisition cost to acquire a drug covered by a health care plan's formulary.

Similarly, in *Egelhoff*, this Court held that ERISA preempted a Washington statute that revoked a spouse's designation as beneficiary upon divorce because the statute "binds ERISA plan administrators to a particular choice of rules for determining beneficiary status." 532 U.S. at 148. As this Court recognized in *Egelhoff*, ERISA preempts such state laws because they "interfere[] with nationally uniform plan administration." *Id.* There is no credible argument in this case that Act 900 dictates plan benefit choices or administration in a similar manner.

3. Act 900 Does Not Require Reporting or Target Information Central to Plan Administration.

Act 900 does not impose new reporting requirements on ERISA plans or even concern information central to plan administration, distinguishing the law from the Vermont statute struck down in *Gobeille*, 136 S. Ct. at 943-44. Act 900 requires no reporting, and it does not concern

matters central to plan administration that are subject to federal regulation.[15]

The law that this Court struck down in *Gobielle* required "health insurers, health care providers, health care facilities, and governmental agencies to report any 'information relating to health care costs, prices, quality, utilization, or resources required' by the state agency, including data relating to health insurance claims and enrollment." 136 S. Ct. at 941. This Court held that ERISA preempted that law. "ERISA's extensive reporting, disclosure, and recordkeeping requirements are central to, and an essential part of, this uniform plan administration system." *Id.* at 945. Because the Vermont statute, "by necessary implication," governed "recordkeeping," it risked "regulations from multiple jurisdictions [that] could create wasteful administrative costs and threaten to subject plans to wide-ranging liability." *Id.*

Act 900, by contrast, is concerned only with the price a PBM will pay a pharmacy for each generic drug on its MAC list. It does not require any reporting, and this Court established in *Travelers*, 514 U.S. at 665-67 & n.6, that a State's regulation of rates in the field of healthcare is not a matter central to uniform plan administration that Congress intended ERISA to preempt.

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[15] Act 900 requires PBMs to update MAC lists on a timely basis, Ark. Code Ann. § 17-92-507(c)(2), but not to report information about plan benefits or administration.

4. Any Secondary Economic Effects of Act 900 Fall Far Short of the Kind of De Facto Regulation that Could Warrant ERISA Preemption.

PCMA argues primarily for preemption based on the indirect economic effect that Act 900 could have on ERISA plans and beneficiaries if PBMs are required to pay at least a pharmacy's acquisition cost for a prescription drug. For example, PCMA argues that "Act 900 will increase ERISA plans' pharmaceutical spending by undermining the utility of MAC pricing." BIO 13. It asserts that "Act 900 will increase plan members' out-of-pocket contributions by increasing premiums and copayments, which are computed based on the actual cost of the dispensed drug." *Id.* And it claims that "Act 900 will cause employers to change their plan design to offset the lost value of MAC pricing, including by modifying covered benefits or changing co-payments and deductibles." *Id.*

At base, PCMA argues that Act 900 is preempted because PBMs may charge ERISA plans and their beneficiaries more for certain generic drugs to make up the revenue that PBMs lose by not being able to force pharmacies to accept below-cost MAC prices. But this Court has already held in *Travelers* that such indirect economic influences do not warrant preemption:

> An indirect economic influence ... does not bind plan administrators to any particular choice and thus function as a regulation of an ERISA plan itself .... Nor does the indirect influence ... preclude uniform plan

> administrative practices or the provision of a uniform interstate benefit package if a plan wishes to provide one. It simply bears on the costs of benefits and the relative costs of competing insurance to provide them. It is an influence that can affect a plan's shopping decisions, but it does not affect the fact that any plan will shop for the best deal it can get, surcharges or no surcharges.

514 U.S. at 659-60. In other words, the surcharges in *Travelers* were just another generally applicable factor affecting ERISA plans' prices, no different than other non-preempted state laws like "[q]uality standards" or "basic regulation of employment conditions." *Id.* at 660. Indeed, even non-regulatory factors like "the geographically disparate burdens of providing for the uninsured" cause prices to vary across different States. *Id.*

PCMA's reliance upon indirect economic effects underscores that there is no legitimate impingement of uniform plan administration that could warrant ERISA preemption. PCMA argues, for example, that "Act 900 will increase ERISA plans' pharmaceutical spending," will "increase plan members' out-of-pocket contributions by increasing premiums and co-payments," and may even lead employers to "modify[] covered benefits." BIO 13. As this Court held in *Travelers*, 514 U.S. at 660, these are precisely the kind of "shopping decisions" that do not warrant ERISA preemption.

Virtually any regulation a State issues in the field of healthcare—a traditional subject of state regulation—has the theoretical potential to indirectly

increase the price an ERISA plan or its members pay for health benefits, and "the existence of other common state action with indirect economic effects on a plan's costs leaves the intent to pre-empt even less likely." *Id.* at 660. In both *Travelers* and in this case, the payer subject to higher payment requirements—whether commercial insurers or PBMs—might theoretically "pass[] on" those prices "at least in part to those who purchase commercial insurance." *Id.* at 659. To be sure, this Court has left open the possibility that a state law's indirect economic influences might be so acute that they act as a de facto regulation by "forc[ing] an ERISA plan to adopt a certain scheme of substantive coverage or effectively restrict its choice of insurers." *Gobeille*, 136 S. Ct. at 943; *see also Travelers*, 514 U.S. at 668. PCMA has not established that Act 900 will have any significant secondary economic influence on ERISA plans, much less the kind of acute economic effects that operate as a de facto regulation that the Court has suggested might trigger ERISA preemption.

PCMA's argument that Act 900 automatically will require ERISA plans to pay more for certain generic drugs also ignores a primary component of its members' profit model. Most PBMs currently make a substantial portion of their profits by maximizing the spread between the price they pay a pharmacy for a drug and the higher price they charge an ERISA plan or beneficiary for that same drug. PBMs treat information about that spread as confidential, in many cases refusing to disclose to ERISA plans their MAC list of prices they pay to pharmacies for generic drugs, unless compelled by state law to do so.

As a result, there is no direct correlation between the price a PBM pays to a pharmacy in a drug transaction and the price that the PBM charges to an ERISA plan for that same transaction. As the First Circuit has recognized, "'[w]hether and how a PBM actually saves an individual benefits provider customer money with respect to the purchase of a particular prescription drug is largely a mystery to the benefits provider.'" *Pharmaceutical Care Mgmt. Ass'n* v. *Rowe*, 429 F.3d 294, 298 (1st Cir. 2005) (alteration in original). PCMA cannot establish that Act 900 has any significant economic influences on healthcare plans, much less influences so acute that they "bind plan administrators to any particular choice and thus function as a regulation of an ERISA plan itself." *Travelers*, 514 U.S. at 659.

CONCLUSION

The judgment below of the court of appeals should be reversed.

Respectfully submitted,

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