No. 23-1213

In the Supreme Court of the United States

GLEN MULREADY, IN HIS OFFICIAL CAPACITY AS INSURANCE COMMISSIONER OF OKLAHOMA, ET AL., PETITIONERS

v.

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

BRIEF FOR AMERICAN PHARMACIES, INC., THE AMERICAN PHARMACISTS ASSOCIATION, THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES, INC., THE NATIONAL COMMUNITY PHARMACISTS ASSOCIATION, AND THE OKLAHOMA PHARMACISTS ASSOCIATION AS AMICI CURIAE SUPPORTING PETITIONERS

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INTEREST OF AMICI CURIAE

Amici collectively represent a broad coalition of pharmacists and pharmacy owners functioning at both the state and national level.[1] Its members have witnessed

[1] Pursuant to Rule 37.6, amici affirm that no counsel for any party authored this brief in whole or in part, and that no person other than amici, their members, or their counsel made a monetary contribution intended to fund the preparation or submission of this brief. Pursuant to Rule 37.2, amici further affirm that counsel of record for all parties received timely notice of the intent to file this brief.

firsthand how pharmacy benefit managers (PBMs) have affected all aspects of pharmacy care and operations, while experiencing the negative effects from leaving PBMs unregulated. These groups have a direct interest in preventing the profound impact on patients and patient care from improper PBM practices.

American Pharmacies, Inc., is a cooperative of independent pharmacies serving the professional, economic, and advocacy needs of its members. It represents the interests of more than 600 member pharmacies in 36 States and is the fastest-growing independent pharmacy group in the nation. Its mission is to protect and promote the growth of independent community pharmacies through collective-buying power, advocating for beneficial legislation, and promoting common-sense regulation to address issues vital to the success of independent pharmacy.

The American Pharmacists Association (APhA) is the voice for pharmacists, advancing the profession of pharmacy. APhA delivers invaluable leadership and support to pharmacists across all practice settings, including its nearly 50,000 member pharmacists, scientists, students, and technicians.

The National Association of Chain Drug Stores, Inc. (NACDS) is comprised of chains of diverse sizes that operate standalone pharmacies and pharmacies in grocery and mass retail settings. NACDS members include regional chains, with as few as four stores, as well as national chains.

The National Community Pharmacists Association (NCPA) represents the interests of the owners, managers, and employees of more than 19,000 independent community pharmacies across the United States. NCPA's members employ over 239,000 individuals on a full or part-time basis and dispense roughly 40% of the nation's retail prescriptions.

The Oklahoma Pharmacists Association (OPhA) is a state-level association representing the interests of pharmacists in Oklahoma. OPhA includes more than 500 pharmacist members located in over 130 cities across Oklahoma directly affected by the challenged legislation.

These organizations—representing stakeholders at the core of the healthcare system—have a significant interest in this case. Oklahoma has enacted a series of common-sense reforms designed to combat PBM abuse. Its regulatory scheme targets PBMs at the intermediary level; it does not require *actual* ERISA plans "to provide any particular benefit to any particular beneficiary in any particular way." *Rutledge* v. *Pharm. Care Mgmt. Ass'n*, 592 U.S. 80, 90 (2020). And amici can attest these reforms are necessary: PBMs routinely use market leverage to benefit their own bottom line while hurting the interests of everyone else—patients, plans, and providers. And PBM practices have devastating effects on pharmacies and pharmacy access for those patients who need it most. States have an urgent need to protect their core interests in patient care and the healthcare market, and amici have a distinct interest in preserving the full range of regulatory options to counteract PBM abuse.

The Tenth Circuit's aggrandized view of both PBMs and ERISA preemption would interfere with legitimate state regulation in matters of traditional local concern, and jeopardize important state interests without promoting ERISA's objectives. Indeed, if allowed to stand, the decision below would leave PBMs unregulated in broad areas critical to patient access and medical care.

Amici, representing key industry interests, agree that Oklahoma's modest regulations are not preempted for the reasons ably articulated in the petition. And amici likewise agree that this Court's guidance is urgently needed. Exaggerating the scope of ERISA preemption effectively

means that no one can regulate at all. It deters States from acting—since there is little point in absorbing the staggering costs of administering a new scheme only to discover it is preempted. All stakeholders need clear ground rules in this area. And yet the decision below leaves a cloud hanging over all provisions of PBM reform. State legislatures are left guessing whether States can regulate PBMs at all or enact any meaningful checks on PBM abuse—producing palpable confusion and uncertainty in this critical area.

There is an obvious need for clarity on the bounds of federal preemption, and amici have a clear interest in conveying the full scope of PBM misconduct that prompted the safeguards below and in every other State nationwide.

SUMMARY OF ARGUMENT

PBMs engage in harmful practices that impair patient care, distort the free market, and impose serious costs on everyone in the healthcare industry—aside from themselves. States are ideally positioned to attack PBM misconduct; the regulation of healthcare is a traditional state function, and States routinely address market inefficiency and abuse, as Oklahoma did here. The State's targeted regulation benefits all legitimate market participants, and does so without interfering with ERISA's regulatory scheme. The decision below injects intolerable uncertainty over all States' efforts to combat this staggering national problem.[2]

A. PBMs exercise overwhelming control in the "lucrative" prescription-drug industry. *Pharmaceutical Care Mgmt. Ass'n* v. *Rowe*, 429 F.3d 294, 298 (1st Cir. 2005).

[2] This brief focuses on ERISA preemption, but the same regulatory void is left by the Tenth Circuit's holding on Medicare Part D. Both holdings wrongly handcuff important state regulation, and both equally warrant this Court's review.

PBMs act as intermediaries between insurers, drugmakers, and pharmacies, managing drug benefits for both ERISA and non-ERISA plans. David Dayen, American Prospect, *The Hidden Monopolies that Raise Drug Prices* (Mar. 28, 2017). In theory, PBMs should benefit patients and plans alike: they have tremendous market power—created by "pool[ing]" together massive groups of "providers" into networks of approved pharmacies—and they could leverage that power to extract discounts and reduce costs. *Rowe*, 429 F.3d at 298; see also Advisory Council on Employee Welfare and Pension Benefit Plans, U.S. Dep't of Labor, *PBM Compensation and Fee Disclosure* 6 (2014).

But in practice PBMs opt for a different course. While PBMs do indeed extract discounts and concessions, PBMs do not pass along the bulk of these concessions to patients or plans; they instead retain the savings for themselves. They construct "formularies" (lists of covered drugs) to give preferential treatment to manufacturers who pay the highest rebates and fees. Those payments are again diverted to the PBMs' bottom line, rather than defraying costs for plans or patients. These profit-driven activities distort the healthcare market and limit patient access to drugs—especially where formulary decisions are dictated by a PBM's profit potential over medical necessity or clinical standards. Yet PBMs avoid scrutiny by resisting transparency and hiding conflicts of interest—making it difficult for market-participants alone to address PBMs' abuse of power. Thus the need for state regulation.

The end result is the opposite of what PBMs were originally designed to accomplish: PBMs have become massive profit centers while (ironically) increasing patient costs, interfering with doctor-patient relationships, impairing patient access to appropriate treatments, and driving PBM-disfavored pharmacies out of business (and

out of town)—leaving countless citizens without local access to neighborhood drugstores or expert pharmacists.

B. In a unanimous decision, this Court recently upheld Arkansas's effort to curb certain aspects of PBM abuse. Like other States, Oklahoma enacted similar legislation to attack related PBM misconduct. These state reforms are essential to protect traditional state and local interests. Yet despite both schemes addressing comparable PBM practices, the Tenth Circuit refused to follow this Court's lead, instead invalidating crucial state laws under a sweeping and outdated view of ERISA preemption.

That decision urgently cries out for review. State regulation has proved essential in this area. It does not affect any core ERISA concern—but it does affect a fundamental aspect of the States' historic police powers. The decision below creates a massive regulatory gap over PBM practices that undermine a functioning healthcare system. It renders States powerless to address serious PBM-related harms, and generates confusion and uncertainty over the viability of existing state schemes. This undermines the necessary confidence for States to enact and enforce important regulatory reforms.

All stakeholders have a desperate need to know the relevant baseline. If state regulation is not an option, that determination should be made immediately at a national level—so States can instead seek recourse in Congress. Only this Court can provide that necessary guidance, and its review is urgently warranted.

ARGUMENT

A. PBMs Are Engaged In Abusive Practices With Serious Consequences For Consumers, Industry Stakeholders, And A Functioning Healthcare Market

According to the Tenth Circuit, PBMs act as helpful "intermediaries" between plans, drugmakers, and pharmacies. Pet. App. 4a. The Tenth Circuit highlighted PBMs' "economic efficiencies and administrative savvy," touting their "'economies of scale, purchasing leverage, and network of pharmacies'" to "promote a higher quality of care" and "reduce [beneficiaries'] costs." *Id.* at 5a, 20a. Indeed, in the Tenth Circuit's view, far from creating problems, PBMs "wield their market power" for the benefit of both plans and patients. *Id.* at 4a-7a.

The Tenth Circuit's rosy narrative is both gratuitous and false. In reality, PBMs are not good for anyone but themselves. They leverage market power to benefit their bottom line. In pursuit of extreme profit, they distort the healthcare market, favoring abusive practices with serious consequences (for both pocketbooks and well-being) for the very patients and plans these systems were designed to serve.

Congress has always had the option to regulate PBMs directly. But it instead has chosen to defer to the States. At this point, "[a]ll 50 States have enacted some form of PBM regulation" to restore a working healthcare system and curb widespread PBM abuse. Pet. 2. The decision below casts intolerable doubt on these essential state re-

forms. As described below, that doubt threatens to entrench significant harm at each corner of the nation's healthcare system.[3]

1. Years ago, PBMs started as small companies focused on "financial and administrative aspect[s] of pharmaceutical benefit administration." Katie Dwyer, Risk & Insurance, *The PBM Evolution* (Nov. 2, 2015) <https://tinyurl.com/dwyer-pbm>. But the industry quickly evolved as small entities were replaced by market behemoths. The PBM world is now consolidated into three major players: Express Scripts (a Cigna Corporation subsidiary), CVS Caremark (a CVS Health subsidiary), and OptumRX (a UnitedHealth Group subsidiary).[4] These three PBMs control 80-85% of the relevant market (Pet. App. 6a), covering more than 260 million prescription-drug patients. Health Affairs, Health Policy Brief, *Pharmacy Benefit Managers* 1-2 (Sept. 14, 2017) <https://tinyurl.com/health-affairs-pbm>. Their sheer size has led to extraordinary wealth and market power. These three PBMs rank higher on the Fortune 500 than every drugmaker and nearly every insurance company. See Fortune 500 <https://fortune.com/fortune500/>. In 2017, for example, the PBM industry boasted revenues between $350 to $400 billion, exceeding the returns ($300 billion) of the top ten drugmakers (those actually *producing* the drugs)

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[3] The Oklahoma provisions here focus predominantly on PBMs' interaction with pharmacies; but the same preemption framework also applies to PBMs' interaction with drugmakers and millions of patients. Amici thus outline the full spectrum of problems created by PBM abuse.

[4] Several PBMs have merged with some of the nation's leading pharmacies and insurance companies to further consolidate market power. While there is at least some oversight when a payor and PBM are distinct entities, that oversight disappears when both fall under a single roof.

combined. Lucas Sullivan, et al., Columbus Dispatch, *Ohio leads way as states take on 'pharmacy benefit manager' middlemen* <https://tinyurl.com/columbus-pbm>.

2. Rather than use their leverage to reduce prices and improve healthcare, PBMs have instead used their market power to benefit themselves. Without regulation, PBMs "engage[] in a wide range of deceptive and anticompetitive conduct that ultimately harms consumers and denies them access to affordable medicines." Ltr. from David A. Balto on Behalf of Consumer Action to Federal Trade Commission 4 (Dec. 6, 2017) <https://tinyurl.com/balto-ltr> (Balto). Until this Court clarifies the outer boundaries of federal preemption, these harmful practices will persist—and States will be chilled from pursuing safeguards against PBM misconduct.

a. One common form of PBM abuse arises when PBMs construct "formularies"—their lists of covered prescription drugs. See Dep't of Health & Human Servs., Office of Inspector General, *Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees*, 84 Fed. Reg. 2,340, 2,341 (Feb. 6, 2019) (*Fraud & Abuse*).

In developing formularies, PBMs catalog drugs into "preferred" and "non-preferred" tiers; patients pay higher "copays" on non-preferred tiers, which encourages use of the preferred drug. *Ibid.* One would think PBMs would construct the formularies on medical considerations (a drug's cost, safety, effectiveness, etc.). But PBMs instead sell access to the highest bidder. They demand so-called "rebates" from manufacturers—a payment for each prescription filled—and assign preferential treatment to those offering the highest rebates. See *id.* at 2,241

& n.8, 2,341-2,342; see also Balto, *supra*, at 2. The result is unseemly: "formulary decisions" turn "on rebate potential, not [the] quality or effectiveness of the drug." *Fraud & Abuse*, 84 Fed. Reg. at 2,342 (citing Arlene Weintraub, Fierce Pharma, *Shire, Pfizer antitrust lawsuits could rewrite the rules for formulary contracts: report* (Oct. 10, 2017)).

Nor do PBMs demand that rebates go to benefit plans or patients. This is all about PBM self-interest: in "the vast majority of cases," PBMs pass along nothing to plans, but instead "pocket some or all of the savings" themselves. Mark Meador, *Squeezing the Middlemen: Ending Underhanded Dealing in the Pharmacy Benefit Management Industry Through Regulation*, 20 Annals of Health Law 77, 82 (2011). And this pattern is found even when PBM customers *require* rebates returned to the plans. PBMs simply shield the information: they mark drugmaker contracts as "proprietary" and refuse to disclose them. *Fraud & Abuse*, 84 Fed. Reg. at 2,343; Henry C. Eickelberg, et al., Am. Health Policy Inst., *The Prescription Drug Supply Chain "Black Box"—How it Works and Why You Should Care* 7, 11-12 (2015) <https://tinyurl.com/eickelberg> (flagging the "[s]harp limitations on client access to data" and the "[non-]disclosure" of "financial incentives" PBMs "receive from manufacturers"). This frustrates a plan's ability to verify PBM "compliance with program rules." *Fraud & Abuse*, 84 Fed. Reg. at 2,343.

Even when PBMs make disclosures, they often manipulate the information. One example: some PBMs flip-flop on how to classify a drug (generic versus brand) to maximize the PBMs' bottom line. Linda Cahn, Managed Care, *When is a brand a generic? In a contract with a PBM* (Sept. 1, 2010) <https://tinyurl.com/cahn-pbm>. When "invoic[ing] clients," these PBMs shift "drugs into the

brand category"; but when it otherwise benefits the PBM, "they magically recharacterize the drugs as generics." *Ibid.* PBMs have even been found treating the *same* drug differently—"for one purpose in one way, and for another purpose in another way"—under the same contract. *Ibid.*

In short, PBMs use discounts, rebates, and concessions not to limit cost or spare plans, but as a giant source of profit. And according to experts, this is where "the real money is made" (Meador, *supra*, at 6)—nearly $120 billion annually according to some estimates. Wharton Public Policy Initiative, *Pharmacy Benefit Management: How the Middlemen Have Leverage in the U.S. Healthcare System* (Aug. 7, 2019); see also Joanna Shepherd, *Pharmacy Benefit Managers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs*, 38 Yale L. & Pol'y Rev. 360, 361-362 (2020). That massive sum reflects systemic costs that could otherwise offset research and development (for manufacturers) or improve health and wellbeing (for patients). Balto, *supra*, at 5. These amounts are instead extracted solely for the PBMs' economic gain.[5]

b. Aside from arrogating all savings to themselves, PBMs also exert *upward* pressure on drug prices. The abuse has reached a level where experts believe (ironically) that eliminating rebates could *lower* costs. See generally Neeraj Sood, Ph.D, et al., Leonard D. Schaeffer

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[5] These are just some of the ways that PBMs line their pockets at others' expense. As one example: "Medicaid audits have also found that [PBMs] sometimes drive up costs by charging health plans more for pharmacy reimbursement than what they ultimately pay pharmacies, and pocketing the difference." U.S. Senate Finance Committee, *A Bipartisan Framework for Reducing Prescription Drug Costs by Modernizing the Supply Chain and Ensuring Meaningful Relief at the Pharmacy Counter*, at 2 (Apr. 20, 2023) <https://www.finance.senate.gov/imo/media/doc/pbm_framework.pdf>.

Ctr. for Health Policy & Economics, *The Association Between Drug Rebates and List Prices* (Feb. 11 2020) <https://tinyurl.com/sood-pbm> (Sood).

The explanation is straightforward: because PBMs sell formulary placement to the highest (rebate) bidder, manufacturers artificially increase the list price to *create a margin for rebates*. *Fraud & Abuse*, 84 Fed. Reg. at 2,341; see also Sood, *supra*, at 1-3. Manufacturers are "discourage[d]" to lower prices because a "lower * * * list price" usually means a lower rebate, which could trigger PBM "remov[al * * * from the formulary" or "place[ment] in a less-preferred formulary tier." *Ibid.* The PBMs' scheme thus forces manufacturers to raise prices only to drop them—with the PBM pocketing the difference. *E.g.*, Madelaine A. Feldman, M.D., The Center Square, *Op-Ed: Debate over pharmacy benefit managers a matter of price vs. cost* (June 27, 2019) <https://tinyurl.com/feldman-pbm>.[6]

Nor is this risk theoretical. In testimony before Congress, a Pfizer executive admitted that Pfizer would not drop certain drug prices to avoid "jeopardiz[ing]" its "formulary access." See *Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain: Hearing Before the House Energy & Comm. Health Subcomm.*, 116

[6] These practices also increase drug costs for patients. Rebates are usually applied after the point of sale and "do not flow through to consumers at the pharmacy counters." See *Fraud & Abuse*, 84 Fed. Reg. at 2,341; see also *Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program*, 82 Fed. Reg. 56,336, 56,419 (Nov. 28, 2017) (rebates do not reduce "the amount [beneficiaries] must pay in cost-sharing, and thus, [they] end up paying a larger share of the actual cost of a drug"). Patients are thus stuck with the higher list price and no rebate. See, *e.g.*, Sood, *supra*, at 1, 3-5.

Cong., at 2:29:40–2:30:48 (May 9, 2019) <https://tinyurl.com/house-pbm-hearing>. At the same hearing, an Amgen executive explained what happens if a company ignores the PBM scheme: when Amgen cut the price of its flagship drug by 60%, it lost formulary access—because a competitor's higher list price promised a bigger rebate for the PBM. *Id.* at 2:37:55–2:42:34. In this distorted market, competition *increases* prices—hurting plans and consumers while benefiting PBMs. See S. Pociask, Real Clear Health, *You Can Blame Pharmacy Benefit Managers for Higher Drug Prices* (Mar. 28, 2017) <https://tinyurl.com/pociask-pbm>.

The result again is predictable: these PBM business practices are a major factor behind the constant rise in drug prices. Stephen W. Schondeleyer, et al., AARP Policy Institute, *Trends in Retail Prices of Prescription Drugs Widely Used by Older Americans: 2006 to 2015 at AARP Policy Institute* 3 (Dec. 2017) <https://tinyurl.com/aarp-policy-pbm>. Nor can respondents excuse these increases as happenstance or a product of inflation: unlike PBM profits, manufacturers' net drug prices, on average, are flat or decreasing.[7]

As experts have confirmed, the problem rests with PBMs themselves: "most of the increase[s] in drug spending were rebates pocketed by PBMs." Robert Goldberg, Center for Medicine in the Public Interest, *Drug Costs Driven by Rebates* 2 <https://tinyurl.com/goldberg-

[7] For example, Bristol-Myers Squibb's CEO testified that, in 2018, the average net pricing across the company's U.S. portfolio "did not increase and we anticipate the same in 2019." Giovanni Caforio, M.D., Testimony before the Senate Finance Comm. (Feb. 26, 2019) <https://tinyurl.com/bristol-myers-pbm>. And Merck's CEO testified that its "average net price declined in 2017 by almost 2 percent." Testimony of Kenneth Frazier, Chairman and CEO, Merck <https://tinyurl.com/merck-pbm>.

pbm>; see also *Fraud & Abuse*, 84 Fed. Reg. at 2,340 (PBM "rebate arrangements" were a major barrier to reducing costs, creating "significant distortions in the [drug] distribution chain"). And while PBMs are maximizing profits, Americans are paying the highest prices for medications anywhere in the world. See, *e.g.*, Dayen, *supra*; Pet. App. 6a ("the PBM market generated $28 billion in gross profits in 2019").[8]

It is no surprise that an industry profiting from suspect practices seeks to preserve a regulatory void.

3. Aside from increasing cost, abusive PBM practices also impair the quality of care and access to drugs.

First, PBMs refuse to cover some safe, effective drugs because a manufacturer refuses to match a competitor's rebate. This can cause patients to lose access to drugs proven effective in ongoing treatment—as when PBMs alter a formulary midyear based on profit-based considerations, not medical justification. The effects can be grave on the quality of care: certain conditions may take years to identify the most effective treatment—and it does patients little good to drop their optimal medication from the formulary.

PBMs also undermine patient care by steering patients to preferred medications—those garnering the highest rebates. PBMs employ a host of tactics—*e.g.*, "utilization controls," "step therapy," and "non-medical

[8] An example is instructive: In 2015, PBMs received $291 of the $2,914 list price for Humira, a drug to treat rheumatoid arthritis and other conditions. By 2019, the list price had increased to $5,174, with PBMs pocketing $2,070 of that amount. See Lisa L. Gill, *The Shocking Rise of Prescription Drug Prices*, Consumer Reports (Nov. 26, 2019) <https://tinyurl.com/gill-pbm>.

switching"[9]—to support a formulary that maximizes profits.

Take step therapy for instance. With this "utilization control," PBMs drive patients toward drugs with the greatest concessions. The detrimental effect on patient care is profound: one study found a 27% reduction in treatment effectiveness. See N. Boytsov, et al., *Impact of Plan-Level Access Restrictions on Effectiveness of Biologics Among Patients with Rheumatoid or Psoriatic Arthritis*, 4 PharmacoEconomics Open 105-117 (2020) <https://tinyurl.com/step-therapy-pbm>. Yet PBMs still use step therapy to favor PBM profits over patient health.

Finally, PBMs' pharmacy-side practices—such as those at issue in *Rutledge* and below—have run pharmacies out of business, which imposes "system-level barriers" to care. D.M. Quato, et al., JAMA Network Open, *Association Between Pharmacy Closures and Adherence to Cardiovascular Medications Among Older US Adults* 4-5 (Apr. 19, 2019) <https://tinyurl.com/quato-pbm> (recounting findings that adults who had previously filled prescriptions at now-closed pharmacies were less likely to follow treatment plans for cardiovascular health).

The impact is especially harmful for specialty pharmacies integrated at the point of care, such as in oncologists' or urologists' offices. These pharmacies provide im-

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[9] In simple terms, utilization-management tools tell patients what they can and cannot have; step therapy—also known as "fail first"—requires patients to first try (and fail) the PBMs' preferred treatment, even if against the prescriber's professional judgment, before "stepping up" to the medication deemed optimal by the treating professional; and non-medical switching involves swapping a patient's medication for reasons other than the patient's health and safety—such as placing the medication on a different "tier" of a health plan or dropping the medication from a formulary altogether.

portant care coordination, patient education, and side-effect management that improve the quality of care and reduce wasteful spending from unnecessary refills (see https://communityoncology.org/issue-brief-in-house-and-specialty-pharmacies/). Without such specialty options or corner drugstores, patients are often stuck using mail-order pharmacies for medications that should be available in person right in the neighborhood.

Patients suffer when PBMs drive these critical access points out of business. And yet PBMs have done just that: PBMs have now caused more than 1,200 pharmacies to close, with the worst effects in rural communities, including in Oklahoma. Abiodun Salako et al., *Update: Independently Owned Pharmacy Closures in Rural America, 2003-2018*, at 1, 5, RUPRI Center for Rural Health Policy Analysis (July 2018) <https://tinyurl.com/rupri-salako>.

4. Confronted with this extraordinary market abuse, States have responded with action. PBMs have now been sued by at least 28 state attorneys general, securing settlements compelling PBMs to correct deceptive trade practices. *In re Express Scripts, Inc., Assurance of Voluntary Compliance and Discontinuance* (entered May 27, 2008) <https://tinyurl.com/express-scripts-pbm>.[10] And all 50 States have now enacted legislation regulating PBMs. See, *e.g.*, States' Amicus Br. 5 (filed June 10, 2024); States' Amicus Br. 14-21, *Rutledge* v. *PCMA*, No. 18-540 (filed March 2, 2020). Congress is surely aware of these expansive legislative efforts, and yet there is no indication

[10] States have also modified their own relationships with PBMs servicing their Medicaid programs. Lucas Sullivan, et al., Columbus Dispatch, *West Virginia a possible model for cheaper prescription drug prices* (Dec. 10, 2019) (noting that West Virginia's Medicaid program fired its PBM); Johanna Butler, NASHP, *States Assert their Drug Purchasing Power to Capture Savings for Medicaid* (Nov. 18, 2019) (noting that Ohio audited its Medicaid PBM).

Congress views state enforcement as inconsistent with ERISA's uniform national scheme.

Moreover, these legislative efforts transcend party lines. Even conservative legislators, traditionally reluctant to interfere with free markets, have recognized that the PBM market is dysfunctional. Indeed, when Governor Hutchinson signed the Arkansas law upheld in *Rutledge*, he explained the need to combat PBMs' anticompetitive practices: "'We're conservatives. Nobody likes more regulations than what is necessary, but I reflect back at times in history, and we have needed to have rules in the marketplace to assure freedom of the marketplace, and to make sure the free market system operates fairly.'" Steve Brawner, *Gov. Hutchinson signs pharmacy legislation; critiques marijuana process*, Talk Business & Politics (Mar. 15, 2018) <https://tinyurl.com/brawner-pbm>.

Experience emphatically confirms that market forces alone will not cure PBM misconduct. Yet with "little federal regulation" in play (Pet. App. 7a), the States stand alone as the single bulwark against PBM abuse. The decision below undermines that important legislative tool, and this Court's review is necessary to restore state power in this mission-critical industry.

B. The Scope of ERISA Preemption Is Exceptionally Important And Warrants Immediate Review

The question presented is exceptionally important, and this Court's immediate guidance is needed. The decision below leaves a massive regulatory gap over PBMs. It expands ERISA preemption into areas where ERISA has nothing to say, and leaves PBMs free to exert staggering market power in ways that distort and impair a functioning healthcare system. Nor are these dangers merely theoretical: as outlined above, PBMs have undermined virtually every core aspect of a system that is vital to the nation's health (literally). These issues are as serious as any

in the country, and the decision below has thrown into serious disarray all aspects of how this industry functions at a basic level.

The challenged Oklahoma provisions target a core of these problems in a modest fashion, and the Tenth Circuit still struck down the State's bipartisan legislation. Oklahoma's regulations are representative of the important reforms found nationwide in an overwhelming number of States. And yet all States now have no idea if their regulatory efforts will survive. It is untenable to cast that type of federal cloud over critical state efforts in an area of traditional local concern. States cannot effectively regulate PBMs—or responsibly invest significant resources to enforce new PBM-related schemes—without real confidence their reforms will survive. The Tenth Circuit's decision obliterates that confidence.

Even in the short period since the Tenth Circuit ruled, amici's members have seen the damage from that decision on the ground. In direct dealings with state regulators, amici's representatives have been informed by States *in other circuits* that the Tenth Circuit's decision serves as an immediate deterrent to enforcement action. And it surely will deter future state legislation: New regulatory regimes are expensive to develop and require extraordinary resources to implement. States cannot responsibly invest finite public resources in the face of such uncertainty.

Only this Court can restore the necessary baseline to eliminate the profound confusion introduced by the decision below. Immediate review is warranted.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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