No. 18-540

In the Supreme Court of the United States

LESLIE RUTLEDGE, ATTORNEY GENERAL OF ARKANSAS,
PETITIONER

v.

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

BRIEF FOR THE ALLIANCE FOR TRANSPARENT AND AFFORDABLE PRESCRIPTIONS AS AMICUS CURIAE SUPPORTING PETITIONER

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INTEREST OF AMICUS CURIAE

The Alliance for Transparent and Affordable Prescriptions (ATAP) is a coalition of patient and provider organizations, functioning at both the state and national level, who have joined together to address pharmacy benefit managers' (PBMs) negative impact on prescription drug costs and patient access to affordable treatment.[1] The goal of ATAP is two-fold: (i) to educate physicians,

[1] Pursuant to Rule 37.6, amicus curiae affirms that no counsel for any party authored this brief in whole or in part and that no person other than amicus, its members, or its counsel made a monetary contribution intended to fund the preparation or submission of this brief. The parties have provided written consent to the filing of this brief.

healthcare professionals, patients, federal and state lawmakers, and the public about PBMs and their role in the prescription drug market, thus bringing awareness to the serious impact PBMs have on drug costs and access to treatment; and (ii) to ensure patients have access to effective and affordable therapies by increasing transparency and regulating harmful PBM business practices through legislation and public policy at both the state and federal levels.

ATAP has a significant interest in this case. ATAP has been at the forefront of efforts to combat PBM abuse. It works with Congress and federal agencies to implement balanced policies at the federal level to protect patients and plans. And ATAP's state policy team has developed a model state bill that focuses on mandated disclosures and increased state regulation to counter PBM misconduct that distorts the healthcare market, drives up patient and plan costs, and interferes with patient access to medications they desperately need—all while generating staggering profits for PBMs alone.

While the Arkansas law at issue targets PBMs' improper leverage vis-à-vis pharmacies, PBMs exact similar leverage vis-à-vis drug manufacturers. PBMs use this leverage to exact significant price concessions that add to their own bottom line while damaging the interests of patients, plans, and the manufacturers themselves. To further increase their own profitability, PBMs place burdensome restrictions on patients' ability to access the medicines prescribed by their physicians. Because these restrictions are not based on the clinical profile of a medicine, but rather on the potential of that medicine to maximize rebates and other price concessions for the PBM, patients suffer significant harm as a result. States have an urgent need to regulate in this area to protect core state interests, and ATAP has a distinct interest in preserving

the full range of regulatory options to counteract PBM abuse.

The court of appeals' sweeping view of ERISA preemption would interfere with legitimate state regulation in matters of traditional local concern, and leave exposed important state interests without promoting any of ERISA's objectives. ATAP agrees that Arkansas's pharmacy-based regulations are not preempted, but it offers a broader picture of PBMs' bad practices on the manufacturing side so the Court can take into account the full picture when construing ERISA's preemptive scope.

SUMMARY OF ARGUMENT

PBMs are engaged in harmful practices that undermine the free market with serious consequences for every major stakeholder in the healthcare industry. States are the perfect actors to attack that misconduct and restore ordinary market forces for the benefit of all legitimate market participants. And they can do so without interfering at all with ERISA's regulatory scheme.

A. Pharmacy benefit managers (PBMs) are an overwhelming force in the "lucrative" prescription drug industry. *Pharmaceutical Care Mgmt. Ass'n* v. *Rowe*, 429 F.3d 294, 298 (1st Cir. 2005). They act as middlemen between insurers, manufacturers, and pharmacies, managing drug benefits for "health plan sponsors" as large as the federal government and as small as single-employer ERISA plans. David Dayen, American Prospect, *The Hidden Monopolies that Raise Drug Prices* (Mar. 28, 2017). In theory, PBMs use their massive market power to benefit patients and plans alike: they "pool" together huge groups of "health benefit providers" and create networks of approved pharmacies, using volume to negotiate discounts with pharmacies and manufacturers and drive down 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 PBMs operate differently in practice. While PBMs are indeed successful in extracting discounts and other price concessions, PBMs do not pass along the bulk of these concessions to patients or plans, instead retaining much of those savings for themselves as profits. They construct formularies (lists of covered drugs) to give preferential treatment to manufacturers who pay the highest rebates, administrative fees, and other price concessions based on a percentage of the list price of a drug. Much of these fees are again diverted to the PBMs' own bottom line, rather than defraying the costs of care. These profit-driven activities distort the healthcare market to the detriment of those PBMs are intended to serve, are riddled with conflicts of interest, and limit patient access to drugs to maximize PBMs' own profit potential, even where formulary decisions depart from accepted clinical standards or medical necessity. And PBMs avoid scrutiny by resisting transparency and threatening to raise premiums if the status quo is threatened, which makes it difficult for those in the industry to correct PBMs' abuse of market power.

The end result is the opposite of what PBMs were originally designed to do, which was manage pharmacy-claims adjudication and control drug costs for patients and payers. PBMs instead have become staggering profit centers while (ironically) increasing patients' out-of-pocket drug costs, interfering with the doctor-patient relationship, spurring higher list prices, and impairing patient access to appropriate treatments.

Arkansas enacted legislation to attack one common feature of PBM abuse: increasing their own spread on generic prescriptions by maximizing the difference between what the plan pays the PBM and what the PBM pays the

pharmacy for dispensing a drug. This may result in negative reimbursements for pharmacies forced to provide medication at a price below cost—even while plans reimburse PBMs at higher levels.[2] But PBMs also engage in misbehavior on the manufacturer side of the equation. ATAP respectfully submits that the Court should take into account the full context of PBM abuse in deciding the appropriate scope of ERISA preemption—and in understanding the vital need for regulation to protect traditional state and local interests.

B. Contrary to the Eighth Circuit's view, States can regulate PBMs without running afoul of ERISA. Congress framed ERISA's preemption provision in sweeping terms, but its broad text is limited by ERISA's core objectives. Under this Court's decisions, PBM regulation does not implicate any of those objectives.

First, PBM regulation (in its common and standard form) does not reference ERISA itself. These laws leave all plans on equal footing; they do not single out ERISA plans for preferred or disfavored coverage, and they do not change the playing field for ERISA plans alone. Such evenhanded regulation has no conceivable effect on ERISA's core underlying purpose.

Second, PBM regulation does not have any prohibited connection with ERISA plans. These regulations do not require plans to do anything. They do not dictate their choices or scope of coverage, or mandate that any plans exist or disband. The regulations affect only how PBMs—

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[2] This tactic also results in States—and patients—paying more for generics than they should: an audit by the Ohio Auditor of State found that PBMs charged the State a spread of more than 31% for generic drugs. See Ohio Auditor of State, *Auditor's Report: Pharmacy Benefit Managers Take Fees of 31% on Generic Drugs Worth $208M in One-Year Period* (Aug. 16, 2018) <https://tinyurl.com/ohio-auditor-pbm>.

who are third-party intermediaries in the system—happen to operate. And while those laws may indeed affect the economics of certain plan transactions, that still is not regulation of the plan itself, nor does it directly require any action or limit any decision the plan is otherwise entitled to make. These laws simply restrict an intermediary's activities in the economic marketplace. As long as plan administrators are left free to structure the plans as they wish, PBM regulation does not interfere with ERISA's core aims.

In the end, PBM regulation does not address or affect any core ERISA concern—but it does affect a core aspect of the States' historic police powers. There is a strong presumption against displacing the States' ability to regulate in matters of traditional local concern, and PBM regulation falls squarely within the core of that authority. Courts should presume that Congress would speak clearly before disarming States and leaving them powerless to address PBM activities as harmful as these.

ARGUMENT

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

PBMs were designed to benefit patients and plans by driving down costs and serving as effective intermediaries between plans, drug manufacturers, and pharmacies. Instead, however, PBMs have leveraged their incredible market power to benefit themselves, through constructing formularies that increase their profits and implementing practices to ensure those formularies will continue to prefer drugs that confer the highest price concessions. Put simply, they have distorted the healthcare market and adopted abusive practices with serious consequences

(both economic and health-related) for the patients these systems are ultimately designed to serve. Regulation is desperately needed to correct these destructive practices and restore cost savings and patient access to medical treatment.

While the federal government has the authority to regulate PBMs directly in some markets, the States are in an optimal position to address these issues with responsible regulation. A broad coalition of States have already passed laws to restore a working healthcare system and curb widespread PBM abuse.

1. In their earliest form, PBMs were small companies primarily focused on the "financial and administrative aspect of pharmaceutical benefit administration." Katie Dwyer, Risk & Insurance, *The PBM Evolution* (Nov. 2, 2015) <https://tinyurl.com/dwyer-pbm>. But these entities have since evolved into market behemoths. The PBM industry has consolidated into three major players: Express Scripts (a Cigna Corporation subsidiary), CVS Caremark (a CVS Health subsidiary), and OptumRX (a UnitedHealth Group subsidiary).[3] These three PBMs control between 75% and 80% of the prescription-drug market, 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 size equates to extraordinary wealth and market power. In 2018, those three PBMs ranked higher on the Fortune 500 than every drug manufacturer and nearly every insurance company. See Fortune 500 <https://fortune.com/fortune500/2018>.

[3] Several PBMs have merged with some of the nation's leading pharmacies and insurance companies to further consolidate their market power. And while there is at least limited oversight when a payer and PBM are distinct entities, that oversight disappears when both fall under a single parent company's roof.

In 2017, the PBM industry boasted revenues between $350 to $400 billion, exceeding the returns of the top ten drug manufacturers (those actually *producing* the drugs), which generated $300 billion combined. Lucas Sullivan, et al., Columbus Dispatch, *Ohio leads way as states take on 'pharmacy benefit manager' middlemen* <https://tinyurl.com/columbus-pbm>.

These PBMs are larger financially than all but the tiniest fraction of plan sponsors or drug manufacturers. Their oligopolistic power permits them to exert tremendous pressure on all other industry stakeholders, including manufacturers and pharmacies. But rather than use their market power to drive down prices and improve healthcare, PBMs have instead used their power and influence for their own benefit.

2. Left unregulated, PBMs have leveraged their market power in ways prone to abuse. "The largest PBMs [have] engage[d] 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). In particular, they leverage their power to extract rebates and discounts for the PBMs' bottom line, while increasing the cost of consumer medicine and limiting access to necessary treatments.

a. On the manufacturer side, PBMs take advantage of their power to maximize profits when constructing PBM "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 these formularies, PBMs divide similar drugs into "preferred" and "non-preferred" tiers; patients must pay higher "copays" for drugs on the non-preferred tiers, which encourages use of the preferred drug. *Ibid.* PBMs demand rebates—a payment a drugmaker makes each time a prescription is filled—to secure preferred access on the formulary, with drugmakers paying the highest rebates given preferential positions. See *id.* at 2,241 & n.8, 2,341-2,342; see also Balto, *supra*, at 2. The result is unseemly: instead of constructing formularies based on the effectiveness, safety, or ease of administration of competing drugs, PBMs favor those manufacturers willing to pay the most for better access and increased sales—making "formulary decisions based 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 these price concessions necessarily translate into savings for plans or patients. In "the vast majority of cases," PBMs do not pass rebates on to plans, but instead "pocket some or all of the savings" for 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 there is evidence this occurs even when PBM customers *require* that any rebates be returned to the plans. PBMs have asymmetric access to information; they shield contracts with manufacturers as "highly proprietary" and often declare the agreements off-limits "to the plans." *Fraud & Abuse*, 84 Fed. Reg. at 2,343; see also 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> (recognizing the "[s]harp limitations on client access to data" and the "[non-]disclosure" of the "financial incentives" that PBMs "receive from manufacturers"). This impairs the ability of plan providers to verify PBM "compliance with program rules." *Fraud & Abuse*, 84 Fed. Reg. at 2,343.

Making matters worse, PBMs manipulate what little information they do provide to their customers. Sometimes this is through definitional sleight-of-hand, treating brand-name drugs as generics (or generics as brands) where it helps 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>. Thus, "when it is in the PBMs' interests to classify more drugs as brands—for instance, when determining how to invoice clients—they use their ambiguous definitions to shift more drugs into the brand category"; yet "when it is in PBMs' interests to classify more drugs as generics, they magically recharacterize the drugs as generics." *Ibid.* Indeed, PBMs will occasionally treat the *same* drug differently—"for one purpose in one way, and for another purpose in another way"—under the same contract. *Ibid.*

PBMs also shield rebates using accounting tricks to "hide their profits," Balto, *supra*, at 5, by doing things such as classifying rebates as "administrative expenses" charged to the manufacturer. For example, a recent lawsuit between one PBM (Express Scripts) and a drugmaker (kaléo, Inc.) revealed that the PBM was charging an "administrative fee" for an opioid-overdose treatment nearly *15 times higher* than the associated rebates, and that "administrative fee" soared immediately after the manufacturer hiked the drug's price, strongly suggesting these "fees" were actually rebates by another name.

Cmplt. 15-16, *Express Scripts, Inc., et al.* v. *kaléo, Inc.*, No. 17-cv-01520 (E.D. Mo. May 16, 2017) (reporting in a four-month period that Express Scripts invoiced a total of $26,812.50 for "formulary rebates" while charging $363,160.04 for "administrative fees"); see also Nat'l Prescription Coverage Coalition, *Express Scripts Lawsuit Should Raise Everyone's Eyebrows* <https://tinyurl.com/npcc-pbm> (tracing rise in the "administrative fee" to a price increase for the drug). Because such profits are disguised, it is difficult for plans to exercise what little leverage they have to resist unfair contractual terms or the PBMs' anti-competitive conduct.[4]

In short, the PBMs use manufacturer discounts, rebates, and other price concessions as a giant source of profit, making even more than their take from pharmacy discounts. Indeed, as some have concluded, this is where "the real money is made." Meador, supra, at 6. By certain estimates, PBMs collect nearly $120 billion in annual rebates and discounts that were not passed along to plans or beneficiaries. Wharton Public Policy Initiative, *Pharmacy Benefit Management: How the Middlemen Have Leverage in the U.S. Healthcare System* (Aug. 7, 2019) (quoting Dr. Robert Goldberg of the Center of Medicine in the Public Interest). That amount reflects increased costs that could be used for research or development (on the manufacturer side) or better health and wellbeing (on the patient side). Balto, *supra*, at 5. But rather than ben-

[4] One study by the Medicare Office of the Inspector General suggested that similar schemes allowed PBMs servicing Medicare Plan D plans to "underestimat[e] rebates" they would otherwise pass along in "69 percent of their bids." Dep't of Health & Human Servs., Office of Inspector General, *Concerns with Rebates in the Medicare Part D Program* 17 (Mar. 2011).

efit either end of the healthcare system, these amounts instead typically accrue only to the bottom line of the PBM intermediary.

b. PBMs' abusive practices with rebates and other price concessions do more than reduce the significant savings that could otherwise go to plans and patients; these practices also exert *upward* pressure on drug list prices, leading some to suggest that eliminating rebates could result in *lower* list prices—and thus reduced out-of-pocket costs for patients. See generally Neeraj Sood, Ph.D, et al., Leonard D. Schaeffer Ctr. for Health Policy & Economics, *The Association Between Drug Rebates and List Prices* (Feb. 11 2020) <https://tinyurl.com/sood-pbm> (Sood).

The process is predictable: because PBMs give the best formulary placement to those paying the highest price concessions, manufacturers increase drug prices to create a margin to offer higher rebates. *Fraud & Abuse*, 84 Fed. Reg. at 2,341; see also Sood, supra, at 1-3. Conversely, the same PBM pressure "discourage[s] manufacturers from reducing their list prices" (even "penaliz[ing]" manufacturers that do) because a "lower * * * list price" often translates to a lower rebate, which could trigger a PBM to "remove [the drug] from the formulary" or "place[the drug] in a less-preferred formulary tier." *Ibid.* Simply put, the scheme encourages manufacturers to raise list prices only to immediately discount them—with the PBM pocketing the difference. See, *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>.

This is no mere theoretical risk. A Pfizer senior executive testified before Congress that it had been dissuaded from dropping certain drug prices to avoid "jeop-

ardiz[ing]" its "formulary access." See *Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain: Hearing Before the House Energy & Comm. Health Subcomm.*, 116 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 the consequences of ignoring the PBM system: after his company cut the price of its flagship cardiovascular drug by 60%, the drug 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 deeply broken market, competition actually *increases* prices because it is not based on the lowest price, but on the highest percentage-based price concession.

3. All of these activities maximize benefits for the PBMs—and has contributed to their record profits in recent years. See S. Pociask, Real Clear Health, *You Can Blame Pharmacy Benefit Managers for Higher Drug Prices* (Mar. 28, 2017) <https://tinyurl.com/pociask-pbm> (noting that largest PBMs experienced 70% profit growth between 2015 and 2017); see also Balto, supra, at 2 (noting that the adjusted profit-per-prescription for one large PBM went up 500% between 2003 and 2017). But these PBM gains ultimately come at the expense of other stakeholders in the prescription-drug industry: the prescription-drug plan sponsors that do not receive what they contracted for, the manufacturers and pharmacies that feel the squeeze from PBM practices, and, most egregiously, the patient at the end of this flawed supply chain.

a. First, these PBM abuses lead to higher costs for patients. "[M]any rebates do not flow through to consumers at the pharmacy counters as reductions in price," because the consumer's point-of-sale payments—*e.g.*, co-pays, co-insurance amounts, etc.—are often keyed to *list prices*,

and do not reflect manufacturer rebates, which are applied *after* the point of sale. 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) (noting that rebates do not result in a "reduction in the amount [beneficiaries] must pay in cost-sharing, and thus, [they] end up paying a larger share of the actual cost of a drug"). When a manufacturer's list price goes up, the price a beneficiary pays at the pharmacy also goes up, no matter what the rebate might be. See, *e.g.*, Sood, supra, at 1, 3-5. Thus, PBM business practices mean that pharmaceutical benefit coverage costs *more* and covers *less* than it should.

Second, these egregious PBM business practices are a driving factor behind the constant rise in drug prices. Those price gains have been steady for at least a decade. 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>. And evidence suggests that prices are rising fastest on the most expensive medicines—those needed to

treat the sickest people.[5] And yet, on average, manufacturers' net drug prices are flat or decreasing.[6] As experts have confirmed, the PBMs are a main source of the problem: "most of the increase[s] in drug spending were rebates pocketed by PBMs."[7] HHS has also found PBM "rebate arrangements" as one of the largest barriers to bringing costs down, and noted the PBMs' role in creating "significant distortions in the distribution chain" for drugs. *Fraud & Abuse*, 84 Fed. Reg. at 2,340. While these practices are useful for PBM profits, they are one of the main reasons that Americans pay the highest price for

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[5] For instance, a study of Part D Medicare beneficiaries showed that "high-price drugs were responsible for almost two-thirds of the total drug spending in catastrophic coverage. This is a significant increase from 2010, when high-price drugs were responsible for one-third of the spending." Dep't of Health & Human Servs., Office of Inspector Gen., *High-Price Drugs Are Increasing Federal Payments for Medicare Part D Catastrophic Coverage* (Jan. 4, 2017).

[6] 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>.

[7] Robert Goldberg, Center for Medicine in the Public Interest, *Drug Costs Driven by Rebates* 2 <https://tinyurl.com/goldberg-pbm>; see also Aaron Vandervelde, et al., Berkeley Research Group, *The pharmaceutical supply chain: gross expenditures realized by stakeholders* 10 (noting that between 2013 and 2015, the share of the gross branded drug expenditures from fees, retrospective rebates, and discounts grew by 5.2%, more than offsetting the 4.4% decline in the manufacturers' share).

medications of anyone in the world. See, *e.g.*, Dayen, supra.[8]

b. Abusive PBM business practices also frustrate patient access to prescription drugs.

First, PBMs may not cover needed drugs because a drug that is safe and effective is manufactured by a company unwilling to match a kickback paid by another manufacturer. When PBMs construct formularies based on price concessions instead of quality care, the patients will ultimately suffer. And they suffer both when medications are not available in the first instance and when they lose access to drugs that have proven effective in their treatment—as when PBMs alter a formulary mid-year based on their own bottom-line economics notwithstanding the lack of any medical basis for the change.

The harmful fallout from PBM business practices has grave effects on the quality of care received by patients. For certain conditions, it may take years for a physician to find the most effective treatment for a patient. Access to the full array of medically indicated treatments for a particular condition is essential, yet utilization controls, mid-year formulary changes, and non-medical switching[9]

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[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 several 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>.

[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 try (and fail) the PBMs' preferred medication before "stepping up" to the medication preferred by the actual professional who prescribed the medicine; and non-medical switching involves swapping a patient's medication for reasons other than the pa-

are among the tactics leveraged by PBMs to maintain a formulary that brings in the highest revenues, regardless of the disruption to patient care.[10]

Take step therapy for example. This is one of the utilization controls frequently used by PBMs to ensure that patients are driven toward the product that ensures the greatest price concession. Step therapy, otherwise known as "fail first," requires patients to first try the PBM's preferred treatment, even if it is not what the prescriber, in her professional judgment, believes is best for that patient. These types of controls have a direct impact on patient care: one study found that the odds of treatment effectiveness were 27% lower for the patient group in plans with step therapy, as compared to those in plans without. 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 step therapy is still used to usher patients toward the drugs that maximize a PBM's profits, regardless of impact on patient care.

Finally, aside from manufacturer-side abuses, PBMs' pharmacy-side abuses have caused many pharmacies to

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tient'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.

[10] These tactics are so pervasive and so disruptive that some have questioned whether they amount to the practice of medicine without a license. Cf., *e.g.*, William E. Bennett Jr., *Opinions: Insurance companies aren't doctors. So why do we keep letting them practice medicine?*, Wash. Post (Oct. 22, 2019) <https://tinyurl.com/bennett-pbm>. This is the result of taking away the determination of the optimal medical treatment from the healthcare provider (who has a duty of care to the patient before him or her), and entrusting it instead to an entity that has a duty to maximize profit for its anonymous shareholders.

close, which (quite literally) 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 study's findings that adults who had previously filled prescriptions at now-closed pharmacies were less likely to follow treatment plans for cardiovascular health). Patients obviously suffer when PBM practices drive local access points out of business.

4. The States have started the process of confronting and ending PBMs' market abuse. PBMs have now been sued by at least 28 state attorneys general, producing settlements that compel certain PBMs to correct various deceptive trade practices. *In re Express Scripts, Inc., Assurance of Voluntary Compliance and Discontinuance* (entered May 27, 2008) <https://tinyurl.com/express-scripts-pbm>.[11] States have also enacted legislation specifically addressing PBM abuse—with 54 pieces of legislation passed in the last two years alone.[12] Some of these reforms focus exclusively on the pharmacy-side of the PBM industry, like the Arkansas law at issue here, which

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[11] States have also altered 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).

[12] "[I]n 2018, 21 states passed 32 bills to shed light" on PBM practices. Nat'l Academy for State Health Policy, *Comparison of State Pharmacy Benefit Managers Laws* <https://tinyurl.com/nashp-pbm>. And in 2019, at least 22 PBM-regulation bills passed in 20 States. Nat'l Academy for State Health Policy, *In 2019, State Legislatures Took Targeted, Aggressive Steps to Curb Drug Spending* <https://tinyurl.com/nashp-pbmII>.

combats PBM "spread pricing" abuse. See Pet. Br. 10-11 (discussing 2015 Ark. Laws Act 900). Other state reforms focus on the manufacturing-side—for example, promoting transparency by requiring that PBMs disclose rebates and fees to clients and regulators, see, *e.g.*, Cal. Bus. & Prof. Code 4441(e); Conn. Gen. Stat. 38a-479ppp(a); Iowa Code 510C.1(2) & (11); or allowing customers to demand similar information, see Utah Code 31A-46-301. Others provide PBM customers the option of choosing plans where rebates are automatically passed along to plan sponsors. *E.g.*, Vt. Stat. Ann. 9421. Still others regulate PBMs as a whole—imposing licensure and registration requirements to lawfully operate in the State. *E.g.*, Vt. Stat. Ann. 9421(a) (requiring PBMs to register with the commissioner to do business in Vermont); S.D. Codified Laws 58-29E-4 (requiring that PBMs obtain a license to conduct business in South Dakota). And many more reforms are currently under consideration in state legislatures nationwide.

These legislative efforts by States transcend party lines. Even conservative legislators, who are usually wary of government interference in free markets, have recognized the fact that the market at issue here is deeply dysfunctional. In fact, when Governor Hutchinson signed the Arkansas law at issue here, he explained the need to combat the 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 has confirmed that market forces alone will not cure PBM misdeeds. Legislative and regulatory efforts are necessary to reverse and prevent the widespread and devastating healthcare and market harms caused by PBMs' abusive practices.

B. States Can Exercise Their Traditional Regulatory Power To Curb PBM Abuse Without Triggering ERISA Preemption

States can regulate PBMs without running afoul of ERISA. There is a strong presumption against preemption in areas touching on traditional state concern (*New York State Conference of Blue Cross & Blue Shield Plans* v. *Travelers Ins. Co.*, 514 U.S. 645, 655 (1995)), and PBM regulations fall squarely within the heartland of traditional state regulation. And while Congress framed ERISA's preemption provision in sweeping terms (see 29 U.S.C. 1144(a)), its broad text is limited by ERISA's core objectives. *Travelers*, 514 U.S. at 656. Under this Court's decisions, unless a state regulation references ERISA or has an impermissible connection to ERISA, it survives federal preemption. See, *e.g.*, *Shaw* v. *Delta Air Lines, Inc.*, 463 U.S. 85, 96-97 (1983). PBM regulations do neither of those things. They target PBM interaction with *any* plan, without singling out ERISA plans; it makes no difference whether the contracting party is covered by ERISA or not. And state laws regulating third-party PBMs (and their interaction with other third-party drugmakers and pharmacies) lack the necessary connection to ERISA and thus fall outside ERISA's ambit.

The court of appeals extended ERISA preemption far beyond its intended scope, and intruded in an area where state regulation is both appropriate and urgently needed. See Pet. App. 5a-7a. Its decision should be reversed, and this Court should adopt a bright-line rule making clear (for the benefit of state and federal lawmakers alike) that

States retain their traditional power to address harms inflicted by improper PBM practices in local markets.

1. There is no genuine dispute that laws regulating PBM relationships and practices target *PBMs*, not ERISA plans. See *California Div. of Labor Standards Enforcement* v. *Dillingham Constr., N.A., Inc.*, 519 U.S. 316, 325 (1997) (asking whether state laws "act[] immediately and exclusively upon ERISA plans" or if "the existence of ERISA plans is essential to the law's operation"). These laws restrict how PBMs leverage their own market power, and they limit PBMs' ability to abuse that power to distort the market and take advantage of other parties. Those laws apply irrespective of the nature or character of any plan contracting with a PBM. A PBM inflicts the same harm whether a contracting plan is an ERISA plan or not, and whether a pharmacy or drug manufacturer is serving an ERISA or non-ERISA beneficiary. Every time a patient, for example, suddenly loses access to an effective drug—because a PBM pocketed a bigger rebate from a competing manufacturer—there is the same cost whether or not the patient's coverage is ERISA-based.

Laws of general applicability that evenhandedly regulate PBMs' dealings with *all* entities—without any feature necessarily turning on anything to do with ERISA—do not "reference" ERISA and thus fall comfortably outside its scope. See, *e.g.*, *Dillingham*, 117 S. Ct. at 837-838.

2. PBM regulations do not have any prohibited "connection" with ERISA. *Dillingham*, 519 U.S. at 325. These regulations again regulate the PBMs, not the plans. They have no effect on actual plan administration—the restrictions affect upstream or downstream issues regarding PBMs' conduct with other parties. See, *e.g.*, *Pharmaceutical Care Mgmt. Ass'n* v. *Rowe*, 429 F.3d 294, 305 (1st Cir. 2005). A rule prohibiting self-dealing, for example,

does not dictate the scope or nature of any plan's coverage. *Travelers*, 514 U.S. at 668. It does not require any employer to create or drop a plan, to cover or not cover any medical procedures or medications, to include or exclude any particular beneficiaries, to alter the terms or conditions for vesting rights under the plan, or to modify anything else involving the plan's coverage. Compare, *e.g.*, *Rush Prudential HMO, Inc.* v. *Moran*, 536 U.S. 355, 365 (2002); *Egelhoff* v. *Egelhoff*, 532 U.S. 141, 147-150 (2001).

While it is certainly true that state regulations may require PBMs to alter their own practices—and thus offer different services or new rates to plans interested in coverage—those alterations occur *outside* the plan, and have nothing to do with *internal* plan administration. See *Rush Prudential*, 536 U.S. at 381 n.11; *Egelhoff*, 532 U.S. at 148. A plan always has the option of refusing to deal with a PBM. See *Travelers*, 514 U.S. at 662. It has long been settled that ERISA does not interfere with rate regulation or any rules that might affect the marketplace options of ERISA (and other) plans, even if they indirectly affect the plan's choices. See, *e.g.*, *De Buono* v. *NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 816 (1997); *Travelers*, 514 U.S. at 659, 667 n.6. It is difficult to see how state laws requiring PBM transparency and prohibiting PBM self-dealing change anything—besides PBM bad behavior.

Nor do these PBM regulations invite any positive conflict with any affirmative ERISA provision. Unlike the Vermont provisions at issue in *Gobeille* v. *Liberty Mut. Ins. Co.*, 136 S. Ct. 936 (2016), the typical PBM regulation does not require a plan itself to do anything, and it does not replicate, displace, or supplant any ERISA rule or standard dictating the substance or uniform administration of an ERISA plan. See 136 S. Ct. at 945. It merely dictates how PBMs—non-ERISA entities offering ser-

vices on the open market—may interact with other entities in the healthcare space. See, *e.g.*, *De Buono*, 520 U.S. at 816; *Dillingham*, 519 U.S. at 329, 334; *Rowe*, 429 F.3d at 303.

3. This measured understanding of ERISA preemption respects historic state police powers in core areas of traditional state concern. See, *e.g.*, *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 485 (1996); *Travelers*, 514 U.S. at 661. It preserves local authority to regulate healthcare in the State, and preserves regulatory options for targeting abusive PBM practices—including those that distort proper market function and impair access to safe medical treatment. And given the lack of any demonstrable impact on any federal interest in ERISA, there is especially no reason to presume that Congress set aside widespread state regulation in this area.

4. While the Eighth Circuit's rule invites difficult line-drawing, ATAP's views offer an administrable, workable rule. It sets clear boundaries for the States and Congress: unless a regulation references ERISA plans, targets a core feature of those plans (*e.g.*, scope of coverage), or conflicts with an express ERISA provision, then state regulations checking PBM abuse should categorically survive ERISA preemption.[13]

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[13] Laws such as those at issue in *Metropolitan Life Ins. Co.* v. *Massachusetts*, 471 U.S. 724 (1985), are distinguishable because they effectively mandated additional coverage by making it impracticable *not* to extend certain benefits to plan participants. See 471 U.S. at 739. Congress left that choice of plan coverage to employers and plan sponsors, not the States. But a law limiting the effective rates and costs of a third-party service (like PBMs) fall safely outside ERISA's core objectives. Directing that PBMs cannot demand rebates for themselves is little different from saying that hospitals can demand surcharges from certain patients (cf. *Travelers*, 514 U.S. at 659, 667 n.6); the effect is external to plan administration.

Clarity is essential here to provide necessary latitude for state regulators—and to ensure that those regulators are aware that ERISA did not withdraw their traditional powers to combat healthcare and market abuse. And, of course, while Congress is always free to override inconsistent state regulation (if it so chooses), bright lines reduce the potential for federal-state friction. A clear rule would avoid chilling critical state regulatory efforts and would preserve joint responsibility for addressing new and deleterious PBM practices in areas that stay clear of ERISA's core functions.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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MARCH 2020