No. 18-2926

In the United States Court of Appeals for the Eighth Circuit

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,
Plaintiff-Appellant,

v.

NIZAR WEHBI, IN HIS OFFICIAL CAPACITY AS THE STATE HEALTH OFFICER OF NORTH DAKOTA; MARK J. HARDY, IN HIS OFFICIAL CAPACITY AS THE EXECUTIVE DIRECTOR OF THE NORTH DAKOTA BOARD OF PHARMACY; TYLER G. LANNOYE, IN HIS OFFICIAL CAPACITY AS PRESIDENT OF THE NORTH DAKOTA BOARD OF PHARMACY; AND WAYNE STENEHJEM, IN HIS OFFICIAL CAPACITY AS THE ATTORNEY GENERAL OF NORTH DAKOTA,
Defendants-Appellees.

On Appeal from the United States District Court for the District of North Dakota

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BRIEF FOR THE ALLIANCE FOR TRANSPARENT AND AFFORDABLE PRESCRIPTIONS, THE COMMUNITY ONCOLOGY ALLIANCE, AND AMERICAN PHARMACIES AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS-APPELLEES AND URGING AFFIRMANCE

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1, counsel for amici curiae certifies that the Alliance for Transparent and Affordable Prescriptions (ATAP), the Community Oncology Alliance (COA), and American Pharmacies each has no parent corporation and no publicly held corporation owns ten percent or more of any amici's stock.

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INTEREST OF AMICI CURIAE

The Alliance for Transparent and Affordable Prescriptions is a broad coalition of patient and provider organizations functioning at both the state and national level. Its members have witnessed firsthand the negative impacts and abuse that often occur when pharmacy benefit managers (PBMs) are left unregulated. ATAP relies on its extensive knowledge and expertise to shine a light on PBM practices that increase prescription drug costs and impair patient access to affordable treatment—and its members have united to reverse those negative outcomes.[1]

ATAP's organizational goals are two-fold. First, ATAP educates physicians, healthcare professionals, patients, lawmakers, and the public about PBMs and their role in the prescription-drug market, calling attention to the serious impact PBMs have on drug costs and access to treatment. Second, ATAP strives to secure patients access to effective and affordable therapies by increasing transparency and checking harmful PBM practices via sensible regulation.

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[1] Pursuant to Fed. R. App. P. 29(a)(4), 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 contributed money intended to fund the preparation or submission of this brief. All parties consented to the filing of this brief.

In pursuing these goals, ATAP has been at the forefront of efforts to combat PBM abuse. It has long worked with national and local actors to implement fair and balanced policies that protect patients and plans. And ATAP's state-policy team has developed a model state bill focusing on mandated disclosures and increased regulation to counter PBM misconduct that distorts the healthcare market, drives up costs, and blocks patient access to needed medications—while generating staggering profits for PBMs at the expense of patients and plans.

The Community Oncology Alliance is a non-profit organization dedicated to advocating for community-oncology practices and, first and foremost, the patients they serve. COA is the only national organization dedicated solely to independent, community oncology; its mission is to ensure that cancer patients receive quality, affordable, and accessible care in their own communities, keeping patients close to their homes, families, and support networks. Each year, more than 1.5 million people in the United States are diagnosed with cancer, and cancer-related deaths have steadily declined due to early detection, diagnosis, and treatment. Harmful PBM practices interfere with optimal patient care and increase the burdens on those suffering from this devastating disease. COA works with Congress, policymakers, and healthcare

stakeholders to shape a future where all Americans have access to quality, affordable cancer care.

American Pharmacies is a cooperative of independent pharmacies serving the professional, economic, and advocacy needs of its members. It represents the interests of more than 700 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 by leveraging collective buying power, advocating for beneficial legislation, and promoting common-sense regulation to address issues vital to the success of independent pharmacy. It recognizes that its own success ultimately advances the interests of patients and patient care—two areas negatively impacted by improper PBM practices.

These organizations—representing a variety of stakeholders operating on all sides of the healthcare industry—have a significant interest in this case. North Dakota has enacted a series of common-sense regulations 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*, 141 S. Ct. 474, 482 (2020). PBMs routinely use market

leverage to promote their own bottom line while hurting the interests of patients, plans, and healthcare providers. States have an urgent need to protect their core interests in the healthcare market and patient care, and amici have a distinct interest in preserving the full range of regulatory options to counteract PBM abuse.

PCMA's aggrandized view of ERISA preemption would interfere with legitimate state regulation in matters of traditional local concern, and jeopardize important state interests without promoting any of ERISA's objectives. Indeed, if accepted, PCMA would effectively leave PBMs unregulated in broad areas critical to patient access and medical care. Amici, representing a diverse array of interests, agree that North Dakota's modest regulations are not preempted for the reasons articulated in the State's brief. Amici submit this filing to offer a broader picture of the kind of PBM abuse that prompted the targeted safeguards at issue—and the obvious need for state regulation to check harmful practices without intruding on a single area addressed by ERISA itself.

SUMMARY OF ARGUMENT

PBMs engage in harmful practices that impair optimal patient care, distort the free market, and impose serious costs on every major stakeholder in

the healthcare industry. 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, just as North Dakota did here. The State's targeted regulation benefits all legitimate market participants, and does so without interfering with ERISA's regulatory scheme.

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). 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 greatly benefit patients and plans alike: they have tremendous market power—created by "pool[ing]" together massive groups of "health benefit providers" and creating networks of approved pharmacies—and they are positioned to leverage that power to extract discounts from drugmakers and pharmacies to 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 price concessions, PBMs fail to pass along the bulk of these concessions to patients or plans; they instead retain those savings for themselves. They construct "formularies" (*i.e.*, lists of covered drugs) to give preferential treatment to drugmakers who pay the highest rebates and fees. Those payments are again primarily diverted to the PBMs' own bottom line, rather than defraying the costs of care. These profit-driven activities distort the healthcare market and limit patient access to drugs—especially where formulary decisions are driven by a PBM's profit potential instead of medical necessity or accepted clinical standards. Yet PBMs avoid scrutiny by resisting transparency and hiding conflicts of interest—making it difficult for industry stakeholders to detect or address PBMs' abuse of market power.

The end result is the opposite of what PBMs were originally designed to achieve: PBMs have become massive profit centers while (ironically) increasing patients' out-of-pocket costs, interfering with doctor-patient relationships, and impairing patient access to appropriate treatment.

Like other States, North Dakota enacted legislation to attack common features of PBM abuse. These provisions prevent the improper imposition of PBM fees, prohibit PBM "gag orders" that prevent informed patient

decisions, increase PBM transparency, and expose PBM efforts to profit at the expense of patients and plans. In a unanimous decision, the Supreme Court recently endorsed Arkansas's regulatory effort to curb PBMs' attempt to profit on an artificial spread between plan payments and pharmacy reimbursement costs—actions that threatened to drive pharmacies out of business.[2] North Dakota's regulatory efforts are cut from the same cloth and address related PBM misconduct. This sort of regulation is essential to protect traditional state and local interests.

B. Contrary to PCMA's views, 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.

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[2] That particular tactic also resulted in States—and patients—paying more for generics than they should: the Ohio Auditor of State found that PBMs charged the State a spread of more than 31% for generic drugs. 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>. Following Ohio's audit, a wave of other States have likewise highlighted PBM misconduct. *E.g.*, Pa. Dep't of the Auditor General, *Auditor General DePasquale Calls on Senate to Join Fight for Lower Prescription Costs by Passing Bills to Increase Oversight of PBMs* (Jan. 23, 2020) <https://tinyurl.com/pa-pbm-audit> (flagging lack of transparency and other problems associated with PBMs, including their role in rising prescription-drug costs).

Under the Supreme 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—which is presumably why PCMA itself has now abandoned the contrary argument.

Second, PBM regulation does not have any prohibited connection with ERISA plans. These provisions regulate the relationship between PBMs and pharmacies; they do not require plans to do anything. They do not direct which benefits to provide, who is eligible to receive those benefits, or when that coverage is authorized. They do not mandate that any ERISA plans exist or disband, or intrude on any area covered by ERISA. The regulations affect only how PBMs—as third-party intermediaries—happen to operate. And while such 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 free to structure 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 local governments 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 useful intermediaries between plans, drug manufacturers, and pharmacies. But PBMs have instead leveraged their dominant market power to benefit themselves. They have distorted the healthcare market and adopted abusive practices with serious consequences (both economic and health-related) for patients these systems are ultimately designed to serve. Oversight is necessary to correct these destructive practices and restore cost savings and patient access to medical treatment.

While the federal government can regulate PBMs directly in some markets, the States are in an optimal position to address these issues. A broad coalition of States, like North Dakota, have enacted responsible regulation to restore a working healthcare system and curb widespread PBM abuse.

1. In their earliest form, PBMs were small companies 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 the PBM industry has since evolved, with small entities replaced by market behemoths. The industry has now 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 nearly 90% of the relevant market (N.D. Appx. 36), 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. For years now, those

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

three PBMs ranked higher on the Fortune 500 than every drugmaker and nearly every insurance company. See Fortune 500 <https://fortune.com/fortune500/>. In 2017, the PBM industry boasted revenues between $350 to $400 billion, exceeding the returns of the top ten drugmakers (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 drugmakers. Their oligopolistic power lets them exert tremendous pressure on all other industry stakeholders, including drugmakers and pharmacies. But rather than use their market power to drive down prices and improve healthcare, PBMs have instead used their power and influence to benefit themselves.

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, PBMs extract rebates and

discounts for the PBMs' bottom line, while increasing the cost of consumer medicine and limiting patients' access to necessary treatments.

a. On the drugmaker side, PBMs abuse the system in 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 pay higher "copays" for drugs on the non-preferred tiers, which encourages use of the preferred drug. *Ibid.* PBMs demand "rebates" from drugmakers—payments due each time a prescription is filled—to secure preferred access on the formulary, assigning preferential treatment to drugmakers 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: rather than constructing formularies based on medical considerations (a drug's effectiveness, safety, ease of administration, or cost), PBMs favor drugmakers willing to pay 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 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 evidence shows this occurs even when PBM customers *require* that rebates be returned to the plans. PBMs have asymmetric access to information; they shield drugmaker contracts as "proprietary" and often declare those agreements off-limits "to the plans." *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> (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 plans (and others) to verify PBM "compliance with program rules." *Fraud & Abuse*, 84 Fed. Reg. at 2,343.

Worse still, PBMs manipulate what little information they provide customers. For example, some PBMs use a definitional sleight-of-hand, treating brand-name drugs as generics (or generics as brands) whenever 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 have been found to 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 with accounting tricks to "hide their profits," Balto, *supra*, at 5, such as classifying rebates as "administrative expenses." For example, a recent lawsuit between a PBM and a drugmaker revealed the PBM was charging the drugmaker an "administrative fee" for an opioid-overdose treatment nearly *15 times higher* than the associated rebate; that

"administrative fee" soared immediately after the manufacturer hiked the drug's price, strongly suggesting the so-called "fees" were actually hidden rebates. Cmplt. 15-16, *Express Scripts, Inc., et al.* v. *kaléo, Inc.*, No. 17-cv-01520 (E.D. Mo. May 16, 2017) (in a four-month period, Express Scripts invoiced $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 drug's price increase). Because the PBMs' profits are disguised, plans struggle to exercise whatever leverage they have to resist unfair contractual terms or the PBMs' anti-competitive conduct.[4]

In short, PBMs use drugmaker discounts, rebates, and other price concessions as a giant source of profit. Indeed, according to experts, 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 are not passed along to plans or beneficiaries. Wharton Public Policy Initiative, *Pharmacy*

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[4] One study suggested that similar schemes allowed PBMs servicing Medicare Plan D plans to "underestimat[e] rebates" 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).

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 adds systemic costs that could otherwise offset research and development (on the manufacturer side) or better health and wellbeing (on the patient side). Balto, *supra*, at 5. But rather than improve either end of the healthcare system, these amounts instead often contribute only to the intermediaries' bottom line.[5]

b. PBMs' abusive practices do not merely absorb savings that could otherwise go to plans and patients; their practices also exert *upward* pressure on drug list prices, leading experts to believe 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).

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[5] PBMs are further sheltering rebates in new contracting entities known as "rebate aggregators"—entities that retain the majority of the rebate while PBMs say (with a straight face) that most of their *direct* share was passed along to clients. See Jonathan E. Levitt, et al., Frier Levitt, *Cautionary Tale: Plan Sponsors Losing Manufacturer Rebate Dollars to PBMs through Rebate Aggregators* (Apr. 15, 2021) < https://tinyurl.com/pbm-rebate-aggregator>.

The dynamic is predictable: because PBMs give the best formulary placement to those paying the highest price concessions, drugmakers increase 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.* The scheme thus encourages manufacturers to raise list prices only to immediately discount 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>.

Nor is this merely a theoretical risk. A Pfizer senior executive testified before Congress that Pfizer had been dissuaded from dropping 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 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 broken market, competition actually *increases* prices because it is not based on the lowest price but the highest percentage-based concession.

c. These activities do not benefit the actual participants in the healthcare market (those making or dispensing critical drugs, providing care, or the patients themselves), but they do maximize profits for PBMs, which have had record returns 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>. The largest PBMs, for example, experienced 70% profit growth between 2015 and 2017. *Ibid.*; see Balto, *supra*, at 2 (noting the adjusted profit-per-prescription for one large PBM went up 500% between 2003 and 2017). It is thus little surprise that an industry profiting from suspect practices seeks to preserve the recent regulatory void.

3. PBM financial gains have been exacted at the expense of actual stakeholders in the prescription-drug industry: those patients who need critical

treatments and care, plan sponsors who do not receive the benefit of their PBM bargain, and drugmakers and pharmacies squeezed by PBM practices.

a. First, PBM abuses increase drug costs for patients. Manufacturer rebates are often applied *after* the point of sale, while a consumer's point-of-sale payments (*e.g.*, co-pays, co-insurance, etc.) are keyed to the drug's *list* price. That means "many rebates 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 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 increases (to accommodate a PBM's rebate demands), patients pay a higher price at the pharmacy, whatever the rebate might be. See, *e.g.*, Sood, *supra*, at 1, 3-5. PBM practices thus lead to pharmaceutical-benefit coverage that artificially costs more and covers less.

These PBM business practices are unsurprisingly a major driving factor behind the constant rise in drug prices. Those price increases have been steady for over 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 expensive and specialty medicines, including those required to treat patients for cancer, rheumatological disorders, and other serious conditions.[6] And yet, on average, manufacturers' net drug prices are flat or decreasing.[7] Experts have confirmed that PBMs are a main source of the problem: "most of the increase[s] in drug spending were rebates pocketed by PBMs."[8] HHS

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[6] 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).

[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>.

[8] 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 (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).

likewise found PBM "rebate arrangements" were one of the largest barriers to reducing costs, and noted the PBMs' role in creating "significant distortions in the [drug] distribution chain." *Fraud & Abuse*, 84 Fed. Reg. at 2,340. Aside from maximizing PBM profits, these practices are a main factor behind Americans paying the highest prices for medications anywhere in the world. See, *e.g.*, Dayen, *supra*.[9]

b. Abusive PBM business practices also harm the quality of patient care and impair access to prescription drugs.

First, PBMs sometimes refuse to cover safe and effective drugs because the manufacturer is unwilling to match a rebate paid by another company. When PBMs construct formularies based on rebates and concessions instead of quality care, patients ultimately suffer. It may prevent medications from becoming available in the first instance and even patients losing access to drugs that have proven effective in an ongoing treatment—as when PBMs alter a formulary mid-year based on their own bottom-line economics despite lacking any medical justification for the change.

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[9] 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>.

These practices can have grave effects on quality of care. 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, "step therapy," and "non-medical switching" are among the tactics leveraged by PBMs to maintain a formulary bringing in the highest revenues, regardless of the disruption to patient care.[10]

Take step therapy. This is one of the utilization controls that PBMs frequently use to ensure patients are driven toward products with the greatest price concession. And it has a direct impact on patient care: one study found that treatment effectiveness dropped 27% for patient groups in plans with step therapy. 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-

[10] 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.

therapy-pbm>. Yet step therapy is still used to steer patients toward drugs that maximize PBM profits rather than improve patient care.

These tactics are so pervasive and disruptive that some have questioned whether they amount to practicing 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), and entrusting it instead to an entity that has a duty to maximize profit for anonymous shareholders.

Finally, PBMs' pharmacy-side abuses—such as those at issue in *Rutledge*—have caused pharmacies to close, which (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). The impact is particularly harmful for specialty pharmacies integrated at the point of care, such as in oncologists'

or urologists' offices. These pharmacies provide important care coordination, patient education, and side-effect management that improve the quality of care and reduce wasteful spending from unnecessary prescription refills (see https://communityoncology.org/issue-brief-in-house-and-specialty-pharmacies/). Patients suffer when PBM practices drive these critical access points out of business.

4. In the face of this extraordinary market abuse, States have started taking 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>.[11] And nearly all States have now enacted legislation regulating PBMs. See, *e.g.*, States' Amicus Br. 14-21, *Rutledge* v. *PCMA*, No. 18-540 (filed March 2, 2020). Congress is assuredly aware of these expansive legislative efforts,

[11] 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).

and yet there is no indication the federal government views this state action as inconsistent with ERISA's uniform national scheme.

Moreover, these legislative efforts transcend party lines. Even conservative legislators, traditionally wary of government interference in free markets, have recognized that the PBM market is dysfunctional. In fact, 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 has confirmed that market forces alone will not cure PBM misconduct. Legislative and regulatory efforts are necessary to reverse and prevent the widespread, devastating healthcare and market harms caused by PBMs' abusive practices. The North Dakota provisions at issue here take a meaningful, yet modest, step in achieving these important public-policy objectives.

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

As *Rutledge* confirms, States can regulate PBMs without running afoul of ERISA. PBM regulations fall squarely within the heartland of traditional state regulation. See *New York State Conference of Blue Cross & Blue Shield Plans* v. *Travelers Ins. Co.*, 514 U.S. 645, 655 (1995)). 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. *Rutledge*, 141 S. Ct. at 480-481; *Travelers*, 514 U.S. at 656. Under the Supreme 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).

North Dakota's regulations do neither of those things. They generally target PBMs' interactions with *other parties*, without singling out *any* plan (much less exclusively *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 any meaningful connection to ERISA and thus fall outside ERISA's ambit.

PCMA's position extends ERISA preemption far beyond its intended scope, and intrudes in an area where state regulation is both appropriate and urgently warranted. It treats *Rutledge* as a minor after-thought—a position unlikely to be shared by the unanimous *Rutledge* Court. This Circuit should follow the Supreme Court's lead and reaffirm 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 economic 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. Which, presumably, is why PCMA itself now concedes this issue. Br. 5.

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.*, *Rowe*, 429 F.3d at 305. A rule prohibiting self-dealing, for example, does not dictate the scope or nature of any plan's coverage—it dictates *what the PBM itself* can do. *Travelers*, 514 U.S. at 668. It does not require any employer to create or abandon 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.*,

Rutledge, 141 S. Ct. at 482; *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 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, prohibiting gag clauses, and forbidding PBM self-dealing change anything—besides PBM bad behavior.[12]

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[12] PCMA insists that North Dakota's provisions "limit[] the choices that plan sponsors may make in designing plan benefits." Br. 16. Yet all sponsors can still have the same substantive coverage for the same employees under the same plan. These regulations simply ensure that a third-party middleman discloses the true cost of coverage and avoids impermissible conflicts, etc. If it is permissible for a State to *directly regulate* those costs (*Rutledge*, *supra*), how can it be impermissible for a State to take the lesser step of merely requiring disclosure—especially when the disclosure targets the *PBM intermediary*, not the plan itself? PCMA never says.

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 ERISA rules or standards dictating the substance or administration of an ERISA plan. See 136 S. Ct. at 945. It merely dictates how PBMs—as non-ERISA entities offering third-party services 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 impairing access to safe medical treatment and distorting proper market function. And given the lack of any demonstrable impact on any federal interest in

ERISA, there is no reason to presume that Congress (which has since remained silent) intended to set aside widespread state regulation in this area.[13]

CONCLUSION

The lower court's ERISA judgment should be affirmed.

Respectfully submitted.

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July 1, 2021

[13] Laws *requiring* certain minimum benefits are distinguishable, because they effectively mandate additional coverage by making it impracticable *not* to extend certain benefits to plan participants. See, *e.g.*, *Metropolitan Life Ins. Co.* v. *Massachusetts*, 471 U.S. 724, 739 (1985). 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.

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I hereby certify that on July 1, 2021, an electronic copy of the foregoing Brief was filed with the Clerk of Court for the U.S. Court of Appeals for the Eighth Circuit, using the appellate CM/ECF system. I further certify that all parties in the case are represented by lead counsel who are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

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