No. 18-540

IN THE

Supreme Court of the United States

LESLIE RUTLEDGE, in her official capacity as Attorney General of the State of Arkansas,

Petitioner,

v.

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,

Respondent.

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

BRIEF OF ARKANSAS PHARMACISTS ASSOCIATION, NATIONAL COMMUNITY PHARMACISTS ASSOCIATION, AMERICAN PHARMACISTS ASSOCIATION, NATIONAL ALLIANCE OF STATE PHARMACY ASSOCIATIONS, AND FIFTY-ONE OTHER PHARMACIST ASSOCIATIONS AS *AMICI CURIAE* SUPPORTING PETITIONER

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INTERESTS OF *AMICI CURIAE*[*]

Amici curiae are trade associations that represent pharmacists, including pharmacy owners, managers, technicians, students, and pharmaceutical scientists. Because *amici*'s members interact regularly with patients and pharmacy benefit managers (PBMs), they can offer a unique perspective on the need for State regulation of PBMs. Just as important, because *amici*'s members are subject to a host of State and local laws and regulations, they can provide insight into how this Court's decision regarding the preemptive force of the Employee Retirement Income Security Act of 1974 could affect (and, if erroneously decided, severely limit) the States' exercise of their historic police powers to regulate everything from wages to standards for pharmacy practice.

Amici are comprised of organizations that advocate on behalf of community-based, independent pharmacists and the profession more generally:

The Arkansas Pharmacists Association (APA) was founded in 1882 and represents over 2,400 members consisting of pharmacists, pharmacy students, and other members of the industry located within Arkansas. APA's members are directly affected by the State law that is the subject of this litigation.

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[*] Counsel for each party has consented in writing to the filing of this brief. No counsel for any party authored this brief in whole or in part. No person or entity—other than *amici*, their members, or their counsel—made a monetary contribution specifically for the preparation or submission of this brief.

The National Community Pharmacists Association (NCPA) was founded in 1898 and represents the interests of owners, managers, and employees of nearly 22,000 independent community pharmacies across the United States. NCPA's members employ over 250,000 people on a full- or part-time basis and dispense forty percent of the nation's retail prescriptions.

The American Pharmacists Association (APhA) is the largest association of pharmacists in the United States and advances the interests of the entire pharmacy profession. Founded in 1852, APhA consists of more than 62,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in the profession.

The National Alliance of State Pharmacy Associations (NASPA) promotes leadership, sharing, learning, and policy exchange among State pharmacy associations and pharmacy leaders nationwide, and provides educational and advocacy support to pharmacists, patients, and communities working together to improve public health. NASPA was founded in 1927 as the National Council of State Pharmacy Association Executives.

The remaining *amici* are State-level associations representing the interests of pharmacists from forty-eight of the remaining forty-nine States and the District of Columbia. They are comprised of the Alabama Pharmacy Association, Alaska Pharmacists Association, Arizona Pharmacy Association, California Pharmacists Association, Colorado Pharmacists

Society, Connecticut Pharmacists Association, Delaware Pharmacists Society, Florida Pharmacy Association, Georgia Pharmacy Association, Hawaii Pharmacists Association, Idaho Pharmacists Association, Illinois Pharmacists Association, Indiana Pharmacists Association, Iowa Pharmacy Association, Kansas Pharmacists Association, Kentucky Pharmacists Association, Louisiana Independent Pharmacies Association, Louisiana Pharmacists Association, Maine Pharmacy Association, Maryland Pharmacists Association, Massachusetts Pharmacists Association, Michigan Pharmacists Association, Minnesota Pharmacists Association, Mississippi Independent Pharmacists Association, Mississippi Pharmacists Association, Missouri Pharmacy Association, Montana Pharmacy Association, Nebraska Pharmacists Association, New Hampshire Pharmacists Association, New Jersey Pharmacists Association, New Mexico Pharmacists Association, North Carolina Association of Pharmacists, North Dakota Pharmacists Association, Ohio Pharmacists Association, Oklahoma Pharmacists Association, Oregon State Pharmacy Association, Pennsylvania Pharmacists Association, Pharmacists Society of the State of New York, Pharmacy Society of Wisconsin, Rhode Island Pharmacists Association, South Carolina Pharmacy Association, South Dakota Pharmacists Association, Tennessee Pharmacists Association, Texas Pharmacy Association, Utah Pharmacy Association, Vermont Pharmacists Association, Virginia Pharmacists Association, Washington D.C. Pharmacy Association, Washington State Pharmacy Association, West Virginia Pharmacists Association, and Wyoming Pharmacy Association.

SUMMARY OF THE ARGUMENT

In recent years, PBMs have profoundly affected the practice of pharmacy and the relationship between pharmacists and their patients. PBMs are prescription-drug middlemen—though they do not carry any inventory. On the demand side, PBMs enter into contracts with health insurers and plans to deliver insurer- or plan-sponsored prescription drug benefits to beneficiaries. On the supply side, PBMs contract (separately) with pharmacies to provide reimbursement for the drugs that pharmacies acquire from wholesalers and dispense to the insurer's or plan's beneficiaries. This case focuses on the supply side—that is, the relationship between PBMs and pharmacies.

In the opinion of many States, Arkansas among them, the conduct of PBMs has jeopardized the safe and efficient delivery of prescription drugs to patients. Because of an imbalance in market power, PBMs can impose take-it-or-leave-it terms on small pharmacies and even large retail chains. For example, PBMs have granted themselves unilateral authority to determine how much they reimburse pharmacies for the generic prescription drugs they dispense to patients. As another example, PBMs have barred pharmacists from informing patients of instances in which the patient could pay less out of pocket for a prescription drug than that patient would pay if the claim were processed through the PBM. And PBMs have prevented pharmacists from dispensing certain prescription drugs, even though those pharmacists are licensed to do so, in order to

steer patients to mail-order pharmacies owned by PBMs.

In response to these and other practices, nearly all States and the District of Columbia have enacted laws regulating PBMs. These laws range from rate reimbursement and transparency regulations to consumer protections designed to ensure that patients are not harmed by PBM business practices. They also include PBM licensing and audit requirements.

This case focuses on one aspect of the relationship between PBMs and pharmacies—the use of negative reimbursements. In recent years, PBMs have increasingly reimbursed pharmacies below their cost to acquire prescription drugs from wholesalers. Because one of the main sources of PBMs' profits is the difference between what they charge plans and what they reimburse pharmacies for a particular drug (known as the "spread"), PBMs have an enormous financial incentive to widen that difference. For example, when the State of Ohio investigated the PBMs responsible for servicing the State's Medicaid plans, it discovered that PBMs had profited $224.8 million off this difference in a single year. Dave Yost, *Ohio's Medicaid Managed Care Pharmacy Services Auditor of State Report* 2 (Aug. 16, 2018).[1]

PBMs' use of negative reimbursements is inhibiting access to pharmacy care, which, for many Americans, is their most accessible form of health care. For example, the Arkansas General Assembly had

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[1] https://ohioauditor.gov/auditsearch/Reports/2018/Medicaid_Pharmacy_Services_2018_Franklin.pdf.

before it evidence that, over the last decade, more than ten percent of the State's independent pharmacies had closed—largely due to PBM reimbursement practices. J.A. 218-19, 222-23. And the effect of these practices is not limited to independent pharmacies. In recent years, Walmart has attributed significant financial losses to negative reimbursements from PBMs. Nathan Layne, *Walmart has a drug problem*, Business Insider, Aug. 18, 2015.[2] As the District Court cogently summarized the reality that faced the General Assembly: "It is undisputed that Arkansas pharmacies were in economic distress, that [PBM-reimbursement] lists are confidential and unregulated, and that contracts allow PBMs to reimburse pharmacies for generic drugs in any manner they see fit." *PCMA* v. *Rutledge*, 240 F. Supp. 3d 951, 963 (E.D. Ark. 2017).

In response, the Arkansas General Assembly enacted Act 900, which includes rate regulations designed to place limits on the practice of "negative reimbursements." The Act effectuates this purpose by setting up a pharmacy appeal procedure that allows a PBM to deny a pharmacy's appeal only if it can demonstrate that the drug in question could have been purchased below the amount the PBM reimbursed the pharmacy through a wholesaler who does business in Arkansas. Ark. Code § 17-92-507(c)(4)(C)(ii). And even if the PBM carries this initial burden, it must reimburse the pharmacy above its cost of acquisition if the pharmacy's primary wholesaler does not sell the PBM's suggested version

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[2] https://www.businessinsider.com/r-wal-marts-drug-problem-pharmacy-business-drags-on-profit-2015-8.

of the drug for less than the pharmacy paid. *Id.* § 17-92-507(c)(4)(C)(iii). The Act also requires PBMs to update their generic reimbursement lists in the event that a pharmacy's appeal is ultimately upheld, *id.* § 17-92-507(c)(4)(C)(i), (iii), and periodically to ensure the list accurately reflects the prices charged by wholesalers in the State, *id.* § 17-92-507(c)(2). Finally, the Act empowers a pharmacy to decline to dispense a drug, rather than appeal, if dispensing the drug would result in a negative reimbursement. *Id.* § 17-92-507(e).

Laws like Arkansas's do not encroach upon any fundamental area of ERISA regulation. ERISA is concerned about uniform plan administration, which is an internal-facing function affecting plans and their beneficiaries—*e.g.*, who is eligible for coverage, what coverage is available, what information must be reported and disclosed to beneficiaries, and what duties the plan owes its beneficiaries.

ERISA does not purport to regulate the terms by which a welfare plan or PBM does business with the external providers who supply the goods and services that the plan's beneficiaries consume. And this Court has wisely preserved that distinction—because otherwise, ERISA would preempt State laws regulating everything from "medical-care quality standards" and "hospital workplace" conditions to "hospital rates." *Cal. Div. of Labor Standards Enforcement* v. *Dillingham Constr., N.A.*, 519 U.S. 316, 328-29 (1997).

Notably, the Respondent, Pharmaceutical Care Management Association (PCMA), has acknowledged

elsewhere that PBM-pharmacy reimbursements have nothing to do with ERISA plan administration. In an appeal before the Second Circuit in which PCMA argued that PBMs are not ERISA fiduciaries, PCMA emphasized that "'setting and/or adjusting' [pharmacy-reimbursement] lists, 'while it would . . . ultimately [affect] plan assets[,] is not an exercise of discretion over plan management or plan assets.'" Br. of PCMA *et al.* as *Amici Curiae* 21, *Doe* v. *Express Scripts, Inc.*, No. 18-346 (2d Cir. June 20, 2018) (2018 WL 3185904) (quoting *In re Express Scripts, Inc. PBM Litig.*, No. 4:05-md-1672, 2008 WL 2952787, at *9 (E.D. Mo. July 30, 2008)). Or as PCMA puts it, pharmacy reimbursements "'relate to the basic administration of [*the PBM's] own business*,'" not the plan's. *Id.* at 19 (emphasis added) (alteration in original) (quoting *Moeckel* v. *Caremark, Inc.*, 622 F. Supp. 2d 663, 693 (M.D. Tenn. 2007)).

In deeming Act 900 preempted, the United States Court of Appeals for the Eighth Circuit not only departed from this Court's precedents, but it also risked the preemption of a host of State laws, including those regulating pharmacy practice standards. For example, the Eighth Circuit held that ERISA preempts Act 900's decline-to-dispense provision, *PCMA* v. *Rutledge*, 891 F.3d 1109, 1112-13 (8th Cir. 2018), which, PCMA argues, interferes with plan administration "because Arkansas pharmacies can decline to dispense drugs to plan members," Br. for Resp't in Opp'n 13. Yet, the same could be said about a variety of State laws that dictate when pharmacists may (or must) decline to dispense drugs in certain situations—such as when a pharmacist has a religious objection to dispensing a drug or be-

lieves a patient is abusing opioids. *See, e.g.*, Ark. Code § 20-16-304(4), (5); Ark. Admin. Code § 070.00.7-07-04-0006(c). This Court has rejected the view that ERISA would result in the preemption of such laws precisely because it "could scarcely see the end of ERISA's pre-emptive reach, and the words 'relate to' would limit nothing." *Dillingham*, 519 U.S. at 329.

Equally troubling, the Eighth Circuit's judgment risks immunizing PBMs from federal and State regulation when they are servicing ERISA plans. Under ERISA, third-party service providers (like PBMs) may be held liable only if "they cross the line from adviser to fiduciary," *Mertens* v. *Hewitt Assocs.*, 508 U.S. 248, 262 (1993), or if they are "a transferee of ill-gotten trust assets," *Harris Tr. & Sav. Bank* v. *Salomon Smith Barney, Inc.*, 530 U.S. 238, 251 (2000). But courts have held that PBMs are not acting as fiduciaries or dealing in plan assets when they reimburse pharmacies for dispensing drugs. *See, e.g.*, *Chi. Dist. Council of Carpenters Welfare Fund* v. *Caremark, Inc.*, 474 F.3d 463, 474 (7th Cir. 2007) (holding that a PBM is not liable under ERISA for "any additional savings that [the PBM] could extract from [pharmacies]"); *PCMA* v. *Rowe*, 429 F.3d 294, 300-01 (1st Cir. 2005) (holding that PBMs are not ERISA fiduciaries), *cert. denied*, 547 U.S. 1179 (2006). And PBMs have repeatedly disclaimed that they act as ERISA fiduciaries or deal in plan assets when they contract with pharmacies—or anyone else. *See, e.g.*, Br. of PCMA *et al.* as *Amici Curiae* 11-12, *Express Scripts*, No. 18-346 (2d Cir.).

As a result, the Eighth Circuit's blanket finding of preemption—whenever a State law regulates PBMs that manage benefits for entities that "'include'" ERISA plans, *Rutledge*, 891 F.3d at 1112 (quoting *PCMA* v. *Gerhart*, 852 F.3d 722, 729 (8th Cir. 2017))—risks insulating PBMs from State regulation even as courts hold that ERISA does not regulate PBMs either. That troubling result should not stand.

The judgment of the court of appeals should be reversed.

ARGUMENT

Writing for a unanimous Court, Justice Thomas recognized that it would be "'unsettling'" if ERISA "result[ed] in the pre-emption of traditionally state-regulated substantive law in those areas where ERISA has nothing to say." *Dillingham*, 519 U.S. at 330 (quoting *N.Y. Conf. of Blue Cross & Blue Shield Plans* v. *Travelers Ins. Co.*, 514 U.S. 645, 665 (1995)). Perhaps for this reason, the Court has held that the presumption against preemption gives way only in "fundamental area[s] of ERISA regulation." *Gobeille* v. *Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 946 (2016); *see also De Buono* v. *NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 813-14 & n.10 (1997) (applying the presumption against preemption where ERISA had nothing to say—the "regulation of the health care industry").

According to the Court, there are four fundamental areas of ERISA regulation—all related to the "administration of benefit plans": (1) "reporting and disclosure mandates, §§ 101-111, 29 U.S.C. §§ 1021-

1031," (2) "participation and vesting requirements, §§ 201-211, 29 U.S.C. §§ 1051-1061," (3) "funding standards, §§ 301-308, 29 U.S.C. §§ 1081-1086," and (4) "fiduciary responsibilities for plan administrators, §§ 401-414, 29 U.S.C. §§ 1101-1114." *Travelers*, 514 U.S. at 651.

Although ERISA preemption extends beyond these areas, it is still tied to ERISA's goal of ensuring uniform plan administration—by preempting State laws mandating certain benefits, *Shaw* v. *Delta Air Lines, Inc.*, 463 U.S. 85, 97 (1983), or dictating who is eligible for coverage, *Egelhoff* v. *Egelhoff*, 532 U.S. 141, 147-48 (2001). Relatedly, this Court has deemed preempted State laws that interfere with ERISA's uniform enforcement mechanisms, which are aimed at enforcing the terms of the plan or remedying an act that violates ERISA. *See, e.g.*, *Ingersoll-Rand Co.* v. *McClendon*, 498 U.S. 133, 142-44 (1990).

ERISA's preemptive reach is limited to a plan's internal functions and remedies related to those functions—for example, who is eligible for benefits, what benefits are available, what information must be reported and disclosed to beneficiaries, and what duties the plan owes its beneficiaries. For welfare plans in particular, ERISA does not purport to regulate the external providers who supply the goods and services that the plan's beneficiaries ultimately consume—unless those providers are acting as ERISA fiduciaries. *Pegram* v. *Herdrich*, 530 U.S. 211, 231, 236 (2000) (holding that the physician of an HMO who provided care to an ERISA beneficiary was not a

fiduciary and was not liable under ERISA, but was answerable under a State malpractice action).

I. State Laws Regulating the Relationship Between PBMs and Pharmacies Are Not Preempted By ERISA.

Arkansas and other States have regulated in an area left entirely unoccupied by ERISA: the relationship between PBMs and pharmacies. Laws like Arkansas's regulate downstream from any benefits determination—that is, they do not affect who is eligible for coverage or which drugs are covered. Instead, they regulate the goods and services that a plan, as a market participant, purchases on behalf of its members.

Laws like Arkansas's fit comfortably within the States' historic police powers and this Court's ERISA preemption jurisprudence. Indeed, a contrary rule (like the Eighth Circuit's) would risk the preemption of a host of State laws that have nothing to do with plan administration.

A. PBMs Are Harming the Practice of Pharmacy and the Relationship Between Pharmacists and Their Patients.

PBMs are intermediaries between pharmacies on the supply side, and insurers, self-insured entities, health maintenance organizations, and public and private health plans on the demand side. They are also immensely profitable. The three largest PBMs—OptumRx (a subsidiary of UnitedHealth Group), CVS Caremark (a subsidiary of CVS Health), and Express Scripts (a subsidiary of Cigna Corpora-

tion)—have occupied spots among the top twenty-five companies on the Fortune 500.[3]

PBMs have plan- and pharmacy-facing functions—with distinct contractual relationships governing each. PBMs contract with health insurers and plans, including ERISA plans, to process claims and facilitate payments for the pharmaceutical products and services that beneficiaries consume. By doing so, PBMs aggregate the demand of the beneficiaries of all of the insurers and plans with whom those PBMs contract. The three largest PBMs claim to provide PBM services for more than 268 million Americans—which would amount to over eighty-five percent of all Americans with health insurance.[4]

PBMs contract separately with pharmacies to supply prescription drugs to the beneficiaries of the plans the PBMs service. Because the three largest

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[3] Express Scripts was a subsidiary of Express Scripts Holding Company, which ranked twenty-fifth on the Fortune 500 until it was acquired by Cigna Corporation. Fortune, *2018 Fortune 500*, https://fortune.com/fortune500/2018. CVS Health and UnitedHealth Group are currently among the top ten companies on the Fortune 500. Fortune, *2019 Fortune 500*, https://fortune.com/fortune500/2019/search/.

[4] *See* CVS Health, *Pharmacy Benefits Management*, https://cvshealth.com/about/our-offerings/pharmacy-benefits-management (claiming to provide PBM services for "102 million plan members"); Express Scripts, *What's a Pharmacy Benefit Manager?*, https://www.express-scripts.com/corporate/articles/whats-pharmacy-benefit-manager (claiming to provide PBM services for "100 million people"); OptumRx, *Pharmacy benefit management solutions*, https://professionals.optumrx.com/services/pbm.html (claiming to provide PBM services for "over 66 million members").

PBMs control about eighty-five percent of the market for beneficiaries with prescription-drug coverage, independent and large chain pharmacies have limited bargaining power when negotiating with PBMs. As examples, Walmart has attributed significant financial losses to its business dealings with PBMs, *see* Layne, *Walmart has a drug problem*, Business Insider, and Walgreens sustained a loss of $4 billion because of a business dispute with Express Scripts, *see* Bruce Japsen, *Walgreens and Express Scripts Reach Deal*, N.Y. Times, July 19, 2012.[5]

PBM-pharmacy contracts generally grant PBMs unilateral authority to dictate the amount of reimbursement paid to pharmacies for generic drugs, require pharmacies to fill and dispense prescriptions regardless of the amount the pharmacy is reimbursed, and impose a variety of other restrictions on the practice of pharmacy, including what information pharmacists may discuss with their patients and which drugs they are authorized to dispense. The use of these provisions, which is discussed in more detail below, severely harms pharmacies and their patients.

At the heart of this case is the use of "negative reimbursements," which touches upon one of the principal means by which PBMs make money—through "spread pricing." PBMs use spread pricing to profit off the difference between what they reimburse pharmacies and what they charge insurers and plans for a particular drug. To achieve this spread, PBMs

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[5] https://www.nytimes.com/2012/07/20/business/walgreen-and-express-scripts-settle-their-dispute.html.

maintain two sets of price lists. Allison Dabs Garrett & Robert Garis, *Leveling the Playing Field in the Pharmacy Benefit Management Industry*, 42 Val. U. L. Rev. 33, 40 (2007). PBMs use maximum allowable cost (MAC) lists to set the amount they reimburse pharmacies for dispensing generic drugs. PBMs then use a second list to set the amount they charge insurers and plans, and this amount is usually higher than the amount the PBM pays pharmacies. *Id.* Although the spread varies depending on the pharmacy, health plan, and drug, it can be substantial. For example, one study reported a spread as high as $200 for a single transaction. Robert Garis & Bartholomew Clark, *The Spread: Pilot Study of an Undocumented Source of Pharmacy Benefit Manager Revenue*, 44(1) J. Am. Pharms. Ass'n 15, 18 (2004). And the cumulative effect of these spreads is substantial. *E.g.*, Yost, *Ohio's Medicaid Managed Care Pharmacy Services Auditor of State Report* 2 (determining that PBMs profited $224.8 million from spread pricing in a single year servicing Ohio's Medicaid program).[6]

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[6] PCMA might respond that some PBMs do not profit off the spread, but instead offer pass-through-pricing arrangements. Under this model, PBMs purport to charge plans the exact cost of the drug that the PBM pays to the pharmacy, plus an administrative fee. But pass-through arrangements are not usually offered by the three largest PBMs, which comprise approximately eighty-five percent of the marketplace. Hayes Decl., ¶ 21, *Rutledge*, 240 F. Supp. 3d 951 (E.D. Ark.) (No. 4:15-cv-510), Dkt. No. 77-5. And pass-through arrangements are still subject to manipulation by PBMs. *Id.* ¶¶ 19-20 (explaining that PBMs can manipulate pass-through arrangements so that one plan subsidizes another); *accord* Br. for Pet'r 6 (citing J.A. 318-

Because much of a PBM's revenue is based on the spread between the price paid to the pharmacy and the price received from the benefit plan, PBMs have an enormous financial incentive to widen that spread. One way PBMs have done so is through negative reimbursements.

Over the last decade, PBMs have expanded the use of negative reimbursements. J.A. 218-19. This, in turn, has severely restricted patient access to pharmacies and pharmacy services. For example, evidence suggests that abusive PBM reimbursement practices have driven more than sixteen percent of independent rural pharmacies out of business. Abiodun Salako *et al.*, *Update: Independently Owned Pharmacy Closures in Rural America, 2003-2018*, RUPRI Center for Rural Health Policy Analysis (July 2018).[7] In addition, shrinking and even negative margins mean that some pharmacies must make do with less staff, leading to less face-to-face consultation with patients, less time to follow-up for adherence, and reduced efforts to prevent adverse drug interactions.

Adding to the unfairness, pharmacies do not learn what they will be reimbursed for a given drug until the point of sale. J.A. 229-30. That is because PBMs do not disclose their MAC lists to pharmacies and instead treat them as proprietary and confidential. J.A. 126, 135-36, 229-30.

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19) (describing the manipulation of pass-through arrangements).

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

PBMs also do not disclose their MAC lists to insurers and health plans. As a result, insurers and plans often do not know how much PBMs are profiting off their arrangements. Katherine Eban, *Painful prescription*, Fortune, Oct. 10, 2013 (discussing conflicts among PBMs and their customers associated with undisclosed spreads).[8] And sometimes these spreads lead PBMs to push drugs that are more costly to the plan because they produce wider margins for the PBM. *See id.* For these and other reasons, the First Circuit recognized that "'[w]hether and how a PBM actually saves an individual benefits provider customer money with respect to the purchase of a particular prescription drug is largely a mystery to the benefits provider.'" *Rowe*, 429 F.3d at 298 (quoting *PCMA* v. *Rowe*, No. 05-cv-1606, 2005 WL 757608, at *2 (D. Me. Feb. 2, 2005)).

To maintain pricing secrecy, PBMs typically include gag clauses in their contracts with pharmacies, prohibiting pharmacists from disclosing to patients and plans the amount that the PBM reimbursed the pharmacy for dispensing a drug. This, in turn, can have real financial consequences for patients. For example, a patient may end up purchasing a needlessly expensive drug when there is a cheaper alternative, or the PBM may charge the patient a copay (*e.g.*, $20) that exceeds the cost that the pharmacy would otherwise charge for the drug if the patient declined to use his or her insurance (*e.g.*, $8). In these situations, pharmacists would be able to save patients money, but gag clauses prevent pharmacists from alerting patients to this fact. Robert Pear, *Why*

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[8] https://fortune.com/2013/10/10/painful-prescription/.

Your Pharmacist Can't Tell You That $20 Prescription Could Cost Only $8, N.Y. Times, Feb. 24, 2018.[9] And for twenty-eight percent of all generic prescriptions, the copayment exceeds the cost the patient would otherwise pay for her prescription. Karen Van Nuys, *et al.*, *Research Letter: Frequency and Magnitude of Co-payments Exceeding Prescription Drug Costs*, J. Am. Med. Ass'n, Mar. 13, 2018.[10] As a result, Congress recently passed legislation barring PBMs from enforcing gag clauses when the patient is a beneficiary under Medicare Part D. Know the Lowest Price Act of 2018, Pub. L. No. 115-262, 132 Stat. 3670. But no similar federal law applies to other plans—leaving States to fill the void.

PBMs have generated profits in a variety of other ways as well—all with negative consequences for patients and pharmacies. For example, PBMs often impose fees upon pharmacies after the point of sale that further reduce the amount of money that the pharmacy receives from the PBM on any given claim. These fees are not reflected in the amount that is charged at the point of sale, which is used to generate a patient's copayment or coinsurance obligation. As a result, patients end up paying more out of pocket than they would if the fee were assessed at the time the claim was processed. To illustrate, a prescription might cost $100 at the point of sale, requiring the patient to pay $20 to cover the plan's copayment obligation of twenty percent, but the PBM may then recoup $20 in post-sale fees charged to the

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[9] https://www.nytimes.com/2018/02/24/us/politics/pharmacy-benefit-managers-gag-clauses.html.

[10] https://jamanetwork.com/journals/jama/fullarticle/2674655.

pharmacy—which means the patient's co-pay should have been only $16 (*i.e.*, twenty percent of $80). The Centers for Medicare and Medicaid Services (CMS) has recognized this problem as it relates to beneficiaries under Medicare Part D. *See* CMS, *Fact Sheet: Medicare Part D – Direct and Indirect Remuneration (DIR)* (Jan. 19, 2017).[11] The same problem exists for other plans, including ERISA plans.

In addition to extracting revenue from pharmacies, plans, and patients, PBMs have started leveraging their market power to capture a share of the retail pharmacy market. Darrel Rowland, *Specialty drugs: The new arena for pharmacy benefit manager profits?*, Columbus Dispatch, Apr. 24, 2019.[12] PBMs have accomplished this by prohibiting their network pharmacies from distributing "specialty drugs," which are typically higher-cost drugs that require special handling, and by simultaneously expanding the designation of "specialty drugs" to include non-specialty medications that have been on the market for a long time. *Id.* PBMs then require patients to use mail-order pharmacies owned by the PBMs. *Id.*

CMS has expressed concern that PBMs are using pharmacy contracts "in a way that inappropriately limits dispensing of specialty drugs to certain pharmacies"—in ways that have nothing to do with patient health. CMS, *Medicare Program; Contract*

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[11] https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir.

[12] https://www.dispatch.com/news/20190423/specialty-drugs-new-arena-for-pharmacy-benefit-manager-profits.

Year 2019 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, 56,410 (Nov. 28, 2017). This practice then negatively affects patients by requiring them to go through mail-order pharmacies for medications that they should rightfully be able to obtain at their corner drug store. And this practice can lead to negative health consequences as well—particularly for patients on medications sensitive to temperature extremes. Alex Smith, *Extreme Temperatures May Pose Risks To Some Mail-Order Meds*, NPR, Jan. 7, 2019.[13]

PBMs also engage in the highly questionable practice of reimbursing their own affiliated pharmacies substantially more than they pay non-affiliated pharmacies. CVS Caremark, for example, paid CVS pharmacies forty-six percent more for generic drugs than it paid pharmacies at Walmart and Sam's Club. Marty Schladen & Cathy Candisky, *CVS paid itself far more than some major competitors*, Columbus Dispatch, Jan. 20, 2019 (citing a report by the State of Ohio).[14] And CVS Caremark paid itself over *five times* as much as it reimbursed independent pharmacies in Arkansas for some medications—or $324.91 more on a single transaction. Linette Lopez, *What CVS is doing to mom-and-pop pharmacies in*

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[13] https://www.npr.org/sections/health-shots/2019/01/07/673806506/extreme-temperatures-may-pose-risks-to-some-mail-order-meds.

[14] https://www.dispatch.com/news/20190120/cvs-paid-itself-far-more-than-some-major-competitors-report-says.

the US will make your blood boil, Business Insider, Mar. 30, 2018.[15] Adding insult to injury, CVS sent letters to independent pharmacists in Arkansas and Ohio stating that selling their businesses to CVS was an "attractive and practical option" in the face of "declining reimbursements." *Id.* (linking to CVS letter).

B. States Are Regulating Abusive PBM Conduct in Areas Unrelated to Plan Administration.

In response to these and other practices, States have enacted a variety of laws regulating PBMs. The focus of this litigation is on laws regulating the rates at which PBMs reimburse pharmacies. But States have also enacted laws addressing the other issues discussed above. None of these laws regulates plan administration.

Arkansas, for example, has placed limits on negative reimbursements through the law at issue in this case. Under Act 900, a pharmacy may appeal a negative reimbursement on the ground that it was below the pharmacy's cost of acquisition. Ark. Code § 17-92-507(c)(4)(A)(i). A PBM may initially deny an appeal upon a showing that the drug could have been purchased below the amount the PBM reimbursed the pharmacy through a wholesaler who does business in Arkansas. *Id.* § 17-92-507(c)(4)(C)(ii). But if the appealing pharmacy's primary wholesaler does not sell the PBM's suggested version of the drug for less than the pharmacy paid, then the PBM must

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[15] https://www.businessinsider.com/cvs-squeezing-us-mom-and-pop-pharmacies-out-of-business-2018-3.

uphold the appeal and adjust the pharmacy's reimbursement. *Id.* § 17-92-507(c)(4)(C)(iii). The Act also requires PBMs to update their MAC reimbursement lists in the event that a pharmacy's appeal is upheld, *id.* § 17-92-507(c)(4)(C)(i), (iii), and periodically to ensure the list accurately reflects the prices charged by wholesalers in the State, *id.* § 17-92-507(c)(2). Finally, the Act empowers a pharmacy to decline to dispense a drug, rather than appeal, if dispensing the drug would result in a negative reimbursement. *Id.* § 17-92-507(e).

Arkansas's regulation of negative reimbursements is a model for responsible State legislation. As the District Court recognized, Act 900's provisions ensure that reimbursements are fair and market-driven, rather than arbitrary and capricious. *Rutledge*, 240 F. Supp. 3d at 962-63. In addition, by allowing a PBM to deny an appeal based on the availability of a drug at less than an appealing pharmacy's cost of acquisition, Act 900 still encourages pharmacies to seek the best deal available. *See id.*; *see also* J.A. 236-37. At the same time, the Act's substantive standards ensure that PBMs cannot arbitrarily deny contractually available appeals when no pharmacy could procure a drug at the PBM's stated amount of reimbursement. *Rutledge*, 240 F. Supp. 3d at 962-63.

Other States, like North Dakota, have regulated the use of gag clauses, undisclosed fees, and the shift of patients from retail to PBM-controlled mail-order pharmacies. *See, e.g.*, N.D. Cent. Code §§ 19-02.1-16.1, 19-02.1-16.2. Among other things, North Dakota's law allows pharmacists to provide "relevant in-

formation to a patient if the patient is acquiring prescription drugs," *id.* § 19-02.1-16.1(7), and permits pharmacists to disclose to patients and payors information regarding the reimbursement paid to the pharmacy, *id.* § 19-02.1-16.1(5). Another provision regulates undisclosed fees related to claims. *Id.* § 19-02.1-16.1(2). And still other provisions reassert the State's role over dispensing by authorizing pharmacies to fill a prescription that is otherwise covered by an insurer or plan if the pharmacy is authorized to do so under its State and federal licenses. *Id.* § 19-02.1-16.2(5); *see id.* §§ 19-02.1-16.1(11), 19-02.1-16.2(4) (restricting PBMs from imposing accreditation standards that are "inconsistent with, more stringent than, or in addition to the federal and state requirements for licensure as a pharmacy"); *see also id.* § 19-02.1-16.2(2) (requiring PBMs that have an ownership interest in a pharmacy to disclose to plan sponsors, upon request, any difference between the amount paid to the pharmacy and the amount charged to the plan).

Shortly after North Dakota's law went into effect, PCMA challenged it in federal court, claiming that ERISA preempted these and other provisions. *See PCMA* v. *Tufte*, 326 F. Supp. 3d 873 (D.N.D. 2018), *appeal pending*, No. 18-2926 (8th Cir.). At the same time, PCMA conceded in that litigation that the provisions it challenged do "not increase coverage or benefits," and that those provisions, "in large part, only define the relationship between *pharmacies* and PBMs or third-party payers." Mem. in Support of PCMA's Mot. for Summ. J. 21, *Tufte*, 326 F. Supp. 3d 873 (D.N.D.) (No. 1:17-cv-141), Dkt. No. 33-1 (2018

WL 9561645) (emphasis in original). That case remains pending before the Eighth Circuit.

C. States May Regulate the Goods and Services that the Beneficiaries of ERISA Plans Consume without Triggering Preemption Under ERISA.

In *Travelers*, *Dillingham*, and *De Buono*, this Court clarified that when a plan (or its agent) enters the marketplace for goods or services that its beneficiaries ultimately consume, the States may regulate those transactions without triggering preemption by ERISA. *De Buono*, 520 U.S. at 816; *Dillingham*, 519 U.S. at 329; *Travelers*, 514 U.S. at 649; *accord* Br. for Pet'r 13-14, 46. Otherwise, ERISA would preempt everything from medical standards to wage laws, because such State regulations would "invariably affect the cost and price of services" paid for by ERISA plans. *Travelers,* 514 U.S. at 660. Thus, in *Dillingham,* the Court rejected a preemption claim involving a State law that required ERISA plans to pay a mandatory wage for certain apprenticeship services. 519 U.S. at 329-30. As Justice Thomas explained for a unanimous Court, the wages "to be paid" and "the substantive standards to be applied" in deciding wages are "quite remote from the areas with which ERISA is expressly concerned." *Id.*

Arkansas's law is no different. It regulates the cost of providing prescription drugs to beneficiaries. It operates in the same way that a State wage law might regulate the amount that a plan-operated clinic would have to pay a nurse who provided medical services to a beneficiary. Indeed, *De Buono*

addressed a similar situation. There, this Court rejected a claim by a plan-operated medical center that ERISA preempted a State tax on the income of such centers. 520 U.S. at 814-16. Applying *Travelers* and *Dillingham,* the Court held that, whether direct or indirect, a "state tax, or other law, that increases the cost of providing benefits to covered employees will have some effect on the administration of ERISA plans, but that simply cannot mean that every state law with such an effect is pre-empted by the federal statute." *Id.* at 816.

In *De Buono,* the Court also clarified the types of State laws that Congress intended to displace—such as a State law that dictates "a method of calculating pension benefits that federal law permits" or a law that "required employers to provide certain benefits." *Id.* at 815. Act 900 does none of these things. Unlike a State law that dictates a method for calculating a pension, which interferes with the benefit itself, Act 900 regulates the *cost of a good* that an ERISA plan purchases for its beneficiaries in the same way that the wage law at issue in *Dillingham* dictated the *costs of services* that an ERISA plan was required to pay. 519 U.S. at 329-30. In addition, Act 900 does not require plans to make particular drugs available to beneficiaries or dictate who is eligible for coverage. In short, it is agnostic to plan design.

ERISA also does not preempt State laws that regulate other aspects of the relationship between PBMs and pharmacies. These laws do not regulate plan administration. Instead, they regulate what information a pharmacist may discuss with her patients, establish the terms and conditions by which

one business may charge fees to another (*e.g.*, mandating the disclosure of such fees), and determine who is qualified to dispense prescription drugs—all of which involve areas of traditional State concern. *See Travelers*, 514 U.S. at 661 (explaining that "general health care regulation" is not preempted by ERISA).

These laws also differ markedly from the State law that was before this Court in *Gobeille* v. *Liberty Mutual Insurance Co.*, 136 S. Ct. 936 (2016). In that case, Vermont required plans (and their agents) to report "detailed information about *claims and plan members*." *Id.* at 945 (emphasis added). This, in turn, touched upon a "fundamental area of ERISA regulation," *id.* at 946, because ERISA includes a variety of provisions that impose reporting, disclosure, and recordkeeping obligations on ERISA plans and third parties when they are acting in the capacity of a plan administrator, *id.* at 944 (discussing ERISA's reporting, disclosure, and recordkeeping obligations).

Laws that regulate the relationship between PBMs (or even plans) and pharmacies are different. They do not mandate particular benefits or dictate eligibility determinations, nor do they require reporting or disclosure about central aspects of plan administration. Instead, these laws regulate the goods and services that a plan (or its agent) might purchase for its beneficiaries like they would for any other purchaser in that marketplace. And this Court has recognized that any "incidental reporting" requirements associated with market participation do not bear on plan administration. *Id.* at 946; *Dillingham*, 519 U.S. at 329-33 (holding that ERISA did not preempt

a State law that required incidental reporting of wages); *see also* Br. for Pet'r 25-30.

In supplemental briefing filed in this case, PCMA described State regulation of PBM-pharmacy reimbursements as a "crazy-quilt of conflicting rules governing the administration of prescription drug benefits," Supp. Br. for Resp't 3, but it acknowledged elsewhere that PBM-pharmacy reimbursements have nothing to do with plan administration. Indeed, before the Second Circuit, PCMA emphasized that "'setting and/or adjusting' MAC lists, 'while it would . . . ultimately [affect] plan assets[,] is not an exercise of discretion over plan management or plan assets.'" Br. of PCMA *et al.* as *Amici Curiae* 21, *Express Scripts*, No. 18-346 (2d Cir.) (quoting *Express Scripts, Inc.*, *PBM Litig.*, 2008 WL 2952787, at *9). PCMA argued, instead, that PBM-pharmacy reimbursements "'relate to the basic administration of [*the PBM's] own business*.'" *Id.* at 19 (emphasis added) (alteration in original) (quoting *Moeckel*, 622 F. Supp. 2d at 693). Picking up on this distinction, one court noted that PCMA had explained the effect that laws like Arkansas's may have on PBMs' "business practices," but not on "how ERISA plans are administered." *Tufte*, 326 F. Supp. 3d at 887. That distinction is fatal to PCMA's claims of preemption.

D. The Eighth Circuit's Decision Risks the Preemption of a Host of State Laws Regulating Everything from Pharmacy-Practice Standards to Controlled Substances Acts.

State regulation of pharmacy is robust—as is the regulation of health care more generally. The Eighth Circuit's judgment risks preempting such laws as applied to ERISA plans.

Most obviously, the Eighth Circuit's decision to preempt a State rate regulation jeopardizes the States' historic authority to control health care rates. Yet in *Travelers*, this Court recognized that, at the time of ERISA's passage, there was comprehensive State "hospital reimbursement regulation" and not a hint that Congress intended to preempt such laws. 514 U.S. at 667 n.6. The Court explained that rate regulations do "not bind plan administrators to any particular choice." *Id.* at 659. And they do not "preclude uniform administrative practice or the provision of a uniform interstate benefit package if a plan wishes to provide one." *Id.* at 660. Instead, they "simply bear[ ] on the costs of benefits and the relative costs of competing insurance to provide them." *Id.* All of this supported the Court's "conclusion that ERISA was not meant to pre-empt basic rate regulation." *Id.* at 667 n.6; *see also* Br. for Pet'r 19-25.

The same holds true for wages. Consider a rural State facing a nursing shortage. In response, it enacts a law mandating a minimum wage to attract nurses to address the shortage. This law would un-

questionably regulate the amount that a plan-operated clinic pays the nurses it employs to provide medical services to its beneficiaries. But *De Buono* rejected a similar claim of preemption by such a clinic. 520 U.S. at 814-16. And *Dillingham* held that a State law regulating apprenticeship wages was not preempted by ERISA. 519 U.S. at 330-31. It is impossible to reconcile those holdings with the Eighth Circuit's conclusion that ERISA preempts State laws that regulate "MAC price lists or rates." *Rutledge*, 891 F.3d at 1112.

The Eighth Circuit's judgment also risks preempting State controlled substances laws and pharmacy-practice regulations bearing on the stocking and dispensing of medication. Numerous States, Arkansas included, regulate when pharmacists may (or must) decline to dispense medications—based on concerns about diversion and abuse, and even because of religious objections. *See, e.g.*, Ark. Admin. Code § 070.00.7-07-04-0006(c); Ark. Code § 20-16-304(4). In addition, many States have provided pharmacists with autonomy to determine which drugs they will stock, taking into account the financial, moral, and ethical considerations of the pharmacist. *See* Erica L. Norey, *Duty to Fill? Threats to Pharmacists' Professional and Business Discretion,* 52 N.Y. L. Sch. L. Rev. 95, 105-06 (2007) (discussing variations among the States in providing pharmacists with stocking discretion). Yet, here too, the Eighth Circuit held that Act 900's decline-to-dispense provision, which grants pharmacists the discretion not to dispense drugs in certain situations, is preempted as applied to ERISA plans. *Rutledge*, 891 F.3d at 1112-13; *see also* Br. for Pet'r 47-48 (ex-

plaining that the Eighth Circuit's holding risks preempting any State law "permitting providers to elect to deny services").

The Eighth Circuit's decision also could be read to threaten pharmacy licensing and practice standards. For example, PCMA has argued that, based on *Rutledge* and *Gerhart*, ERISA preempts North Dakota's regulation of pharmacy licensing and accreditation standards and overrides that State's regulation of the information that pharmacists can share with their patients. *See* Corrected Br. of Appellant 19-24, *PCMA* v. *Tufte*, No. 18-2926 (8th Cir. Mar. 27, 2019) (2019 WL 1493555). According to PCMA, these and other provisions interfere with how a PBM structures its benefits. *Id.* But of course, the same could be said about myriad other State laws bearing on "medical-care quality standards." *Dillingham*, 519 U.S. at 329. A plan or third-party administrator might decide, for example, that it is cheaper to employ unlicensed doctors to provide health care benefits to the plan's beneficiaries. But no one would seriously contend that ERISA would preempt State laws that preclude plans from employing unlicensed physicians. *See De Buono*, 520 U.S. at 816 (rejecting claims that ERISA preempted a State tax imposed directly upon a plan-operated clinic); Br. for Pet'r Br. 46 (discussing State regulation of pharmacy).

Similarly, nothing in ERISA restricts the information that providers can share with their patients. *Cf. Gobeille*, 136 S. Ct. at 945-46 (addressing only whether ERISA preempts State reporting and disclosure obligations that relate to "plan administration"). Under PCMA's argument, ERISA would preempt a

host of State laws that require providers to make disclosures about the costs of health care, including State laws mandating the disclosure of hospital charges.[16]

As this Court recognized, "if ERISA were concerned with any state action—such as medical-care quality standards or hospital workplace regulations—that increased costs of providing certain benefits, and thereby potentially affected the choices made by ERISA plans, we could scarcely see the end of ERISA's pre-emptive reach, and the words 'relate to' would limit nothing." *Dillingham*, 519 U.S. at 329. There is no support for the Eighth Circuit's limitless view of ERISA preemption.

II. The Eighth Circuit's Holding Risks Immunizing PBMs from State and Federal Regulation When They Are Servicing ERISA Plans.

The Eighth Circuit's judgment also risks creating a legal vacuum in which PBMs are not subject to State or federal regulation when they are servicing ERISA plans. According to the Eighth Circuit, ERISA preempts State regulation of PBMs that manage benefits for entities that "'include'" ERISA plans. *Rutledge*, 891 F.3d at 1112 (quoting *Gerhart*, 852 F.3d at 729). At the same time, PBMs may not be subject to regulation under ERISA because liability for third-party service providers rises and falls

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[16] *See, e.g.,* Fla. Stat. § 395.107(2) ("A facility must publish and post a schedule of charges for the medical services offered to patients."); 20 Ill. Comp. Stat. § 2215/4-4(a) (similar); Me. Rev. Stat. tit. 22, § 1718-B(2)(A) (similar).

based on fiduciary status or the receipt of plan assets. And most courts have held that PBMs are not fiduciaries and do not deal in plan assets when they reimburse pharmacies. The Eighth Circuit's holding therefore invites a disturbing lack of accountability.

Under this Court's precedents, there are only two ways that a third-party service provider can be held liable under ERISA:

First, "[p]rofessional service providers . . . become liable for damages when they cross the line from adviser to fiduciary." *Mertens*, 508 U.S. at 262. ERISA employs a functional approach to determine fiduciary status: a person is a fiduciary only "to the extent" she, among other things, exercises "discretionary authority or discretionary control" over plan "management," 29 U.S.C. § 1002(21)(A)(i), exercises "authority or control" over plan "assets," *id.*, or has "discretionary authority or discretionary responsibility" in the plan's "administration," *id.* § 1002(21)(A)(iii).

Where a party is alleged to have breached a fiduciary duty under ERISA, "the threshold question is. . . whether that person was acting as a fiduciary (that is, was performing a fiduciary function) when taking the action subject to complaint." *Pegram*, 530 U.S. at 226. At the same time, an ERISA service provider does not become a fiduciary "merely because it administers or exercises discretionary authority over its own . . . business." *Id.* at 223.

Courts have near universally held that PBMs are not ERISA fiduciaries when they "negotiate with [pharmacies] to pay less than the amount [the health plan] would later reimburse [them], allowing [PBMs]

to pocket the difference." *Chi. Dist. Council*, 474 F.3d at 473; *accord Rowe*, 429 F.3d at 300-01; *In re Express Scripts/Anthem ERISA Litig.*, 285 F. Supp. 3d 655, 680 (S.D.N.Y. 2018), *appeal pending*, No. 18-346 (2d Cir.); *In re UnitedHealth Grp. PBM Litig.*, No. 16-cv-3352, 2017 WL 6512222, at *9-10 (D. Minn. Dec. 19, 2017); *Express Scripts, Inc. PBM Litig.*, 2008 WL 2952787, at *9; *Moeckel*, 622 F. Supp. 2d at 677; *Bickley* v. *Caremark Rx, Inc.*, 361 F. Supp. 2d 1317, 1332 (N.D. Ala. 2004), *aff'd*, 461 F.3d 1325 (11th Cir. 2006); *but cf. Negron* v. *Cigna Health & Life Ins.*, 300 F. Supp. 3d 341, 357 (D. Conn. 2018) (holding that the plaintiffs had plausibly alleged that a PBM was a fiduciary in using spread pricing). PCMA, for its part, has argued that PBMs are not ERISA fiduciaries in the "negotiation and execution of all PBM contracts, whether such contracts are with health plans, plan administrators . . . , or pharmacies that join a PBM's network," and that, "[o]rdinarily, PBMs' performance under those contracts will be non-fiduciary functions as well." Br. of PCMA *et al.* as *Amici Curiae* 12, *Express Scripts*, No. 18-346 (2d Cir.). And PBMs have disclaimed fiduciary status in their contracts with insurers and plans. *See, e.g.*, *Chi. Dist. Council*, 474 F.3d at 467.

Second, a non-fiduciary can be liable under ERISA if it is "a transferee of ill-gotten trust assets." *Harris Tr.*, 530 U.S. at 251. In this situation, the non-fiduciary's liability stems from the receipt of plan assets. *Id.*

But here, too, courts have recognized that PBMs are not dealing in plan assets when they set pharmacy reimbursement rates, *Chi. Dist. Council*, 474 F.3d

at 473, and that their profit off the spread is simply "an advantageous contractual agreement with an ERISA plan," *Bickley*, 361 F. Supp. 2d at 1332. These holdings negate any finding that a PBM has liability under ERISA by virtue of being a transferee of ill-gotten plan assets.

Given this landscape, the Eighth Circuit's blanket finding of preemption involving PBMs that service ERISA plans risks insulating PBMs from State regulation even though they are not subject to any meaningful substantive regulation under ERISA. *See also* Br. for Pet'r 34-35 (noting the dangers of leaving providers without any State or federal remedy). That troubling lack of accountability should be rejected. After all, preemption is, at its heart, an inquiry into conflict among federal and State law. U.S. Const. art. VI, cl. 2. It therefore would be "'unsettling'" if ERISA "result[ed] in the pre-emption of traditionally state-regulated substantive law in those areas where ERISA has nothing to say." *Dillingham*, 519 U.S. at 330 (quoting *Travelers*, 514 U.S. at 665).

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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