No. 15-3292

IN THE
United States Court of Appeals for the Eighth Circuit

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,

Plaintiff-Appellant,

– v. –

NICK GERHART, IN HIS OFFICIAL CAPACITY AS INSURANCE COMMISSIONER OF THE STATE OF IOWA, *et al.*,

Defendants-Appellees.

On Appeal From a Final Judgment of the United States District Court for the Southern District of Iowa (Jarvey, J.)

BRIEF OF THE NATIONAL COMMUNITY PHARMACISTS ASSOCIATION AND THE IOWA PHARMACY ASSOCIATION AS *AMICI CURIAE* SUPPORTING DEFENDANTS-APPELLEES AND AFFIRMANCE

Gary W. Howell
KATTEN MUCHIN ROSENMAN LLP
525 West Monroe Street
Chicago, IL 60661-3693
312-902-5200

Howard R. Rubin
Counsel of Record
Robert T. Smith
Daniel Lipton
KATTEN MUCHIN ROSENMAN LLP
2900 K Street, NW – Suite 200
Washington, DC 20007-5118
202-625-3500

Counsel for Amici Curiae

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, *amici curiae* state as follows:

1. The National Community Pharmacists Association has no parent corporation, and no publicly-traded company owns 10% or more of its stock.

2. The Iowa Pharmacy Association has no parent corporation, and no publicly-traded company owns 10% or more of its stock.

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STATEMENT OF INTEREST OF *AMICI CURIAE*

Amici curiae are two trade associations that represent independent pharmacists at the national and state levels: the National Community Pharmacists Association (NCPA) and the Iowa Pharmacy Association (IPA). Founded in 1898, NCPA represents the interests of the owners, managers, and employees of more than 22,000 independent, community pharmacies across the United States. Together, NCPA's members employ over 300,000 full-time employees and dispense nearly half of the nation's retail prescriptions. IPA, in contrast, represents pharmacists throughout Iowa. Founded in 1885, IPA is comprised of more than 2,000 members, including pharmacists, pharmacy owners, student pharmacists, and technicians, who collectively practice and own pharmacies in all of Iowa's 99 counties.[1]

As the national and state representatives of community pharmacists, including many of the pharmacists serving Iowa's rural communities, *amici* have a profound interest in the outcome of this case. The Iowa legislature passed the challenged legislation to ensure that Iowans continue to have access to prescription drugs. It did so by imposing modest regulations on pharmacy benefit managers (PBMs), whose abusive practices otherwise threaten the pharmacists that provide Iowans with access to their medications. Indeed, prior to enacting the challenged legislation, the Iowa

[1] All parties consent to the filing of this brief. No counsel for any party in this case 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.

legislature found that the abusive practices of PBMs had already caused the closure of nearly two dozen pharmacies in Iowa. *Infra* at 11-12.

As explained below, PBMs are the quintessential middlemen of the pharmaceutical industry. On the demand side, PBMs contract with health insurers and plans to ensure that beneficiaries receive their insurer- or plan-sponsored prescription drug benefits. PBMs do so by contracting separately, on the supply side, with pharmacies to provide reimbursement for the drugs that the pharmacies dispense to covered beneficiaries.

At their best, PBMs offer insurers and plan sponsors economies of scale that could theoretically help lower overall prescription-drug costs, but at their worst, PBMs have abused their market power and used a lack of transparency to reap record profits at the expense of pharmacists, insurers, plan sponsors, government payors, and even patients. Because of these abusive practices, PBMs have been sued by every segment of the prescription drug market, resulting in hundreds of millions of dollars in fines and settlements. *E.g.*, Mark Meador, *Squeezing the Middleman: Ending Underhanded Dealing in the Pharmacy Benefit Management Industry Through Regulation*, 20 Annals of Health Law 77, 85-94 (2011) (collecting lawsuits as of 2011).

In enacting the challenged legislation, the Iowa legislature was concerned with two abusive supply-side practices of PBMs—specifically, spread pricing and negative reimbursements to pharmacies—the combination of which threatens pharmacies and, in turn, patients' access to medicine. Spread pricing occurs when PBMs use two

separate, undisclosed maximum allowable cost (MAC) lists in any given transaction, one to charge the insurer, health plan, or plan sponsor to fill a beneficiary's prescription, and a second list to reimburse the pharmacy for filling that prescription. A91 (1st Am. Compl. ¶ 29) (acknowledging that PBMs use two lists). This allows PBMs to pocket the undisclosed difference (spread) between what they reimburse a pharmacy and what they charge the insurer or plan for that prescription. In addition, PBMs have increasingly reimbursed pharmacies at less than the pharmacies' costs to acquire the drugs that they dispense to patients. Pharmacies are losing money on every such drug that they dispense, which threatens access to the medicine that these pharmacies deliver to patients.

Critically, independent pharmacies cannot simply refuse to do business with PBMs, much less insist upon fair contractual terms. PBMs manage drug benefits for 95% of all Americans with prescription-drug benefits. Refusing to do business with PBMs on their terms means foregoing the opportunity to serve more than 200 million Americans. Thus, PBMs are able to impose take-it-or-leave-it contracts on pharmacies, which fear the loss of the large base of patients that each PBM controls. For that reason, even large pharmacies, like those managed by CVS, Walgreens, and Kmart, have struggled to secure fair treatment from PBMs. *See, e.g.*, Compl., *Kmart Corp. v. Catamaran*, No. 2015-L-8920 (Ill. Cir. Ct., Cook Cnty.) (filed Aug. 31, 2015) (*available at* http://www.scribd.com/doc/277500936/Kmart-Catamaran#scribd) [hereinafter Kmart Compl.]; Bruce Japsen, *Walgreen and Express Scripts Reach Deal*, N.Y.

Times, July 19, 2012, at B2 (*available at* http://www.nytimes.com/2012/07/20/business/walgreen-and-express-scripts-settle-their-dispute.html?_r=1).

Faced with this reality, the Iowa legislature enacted the challenged legislation, which imposes three modest forms of regulation on PBMs' supply-side activities with pharmacies in Iowa (the legislation does not regulate the PBMs' demand-side activities with insurers and plan sponsors). *First*, the legislation includes a substantive provision that requires PBMs to utilize nationally-recognized data when setting maximum "reimbursement" amounts paid to pharmacies for certain generic drugs; it does not regulate what a PBM may ultimately charge an insurer or plan sponsor for those drugs. Iowa Code § 510B.8(2). *Second*, the legislation requires PBMs to disclose how they calculate their reimbursement amounts in any contracts with Iowa pharmacies and gives contracting pharmacies a chance to contest the reimbursement amount through an appeals process to be established by the PBMs. *Id.* § 510B.8(3). *Finally*, the legislation requires PBMs to submit certain information to the Iowa Insurance Commission upon the Commissioner's request. *Id.* § 510B.8(1).

As *amici* explain more fully below, the District Court properly dismissed the claims of the PBMs' national trade association, the Pharmaceutical Care Management Association (PCMA), which sought to invalidate the Iowa law on a variety of federal- and State-law grounds. PCMA has abandoned all but two of these claims on appeal. It is left arguing that the Iowa law is preempted by the Employee Retirement Income Security Act (ERISA), and that the law's alleged burden on interstate commerce

outweighs its putative benefits in violation of the dormant Commerce Clause. Each claim, however, is premised on an erroneous understanding of the relevant law.

In order to maintain its ERISA claim, PCMA ignores a critical distinction between PBMs and ERISA plans—specifically, PCMA presupposes that a regulation of PBMs is necessarily a preempted form of regulation of ERISA plans. PCMA Br. 30 & n.7. But PCMA is mistaken. The Iowa law does not regulate ERISA plans; it regulates the PBMs' supply-side interactions with Iowa pharmacies. Even assuming that, at its worst, the law has the effect of increasing the costs that ERISA plans might ultimately pay for certain prescriptions within Iowa (far from a foregone conclusion), the Supreme Court has held that a regulation that "simply bears on the costs of benefits" does not "function as a regulation of an ERISA plan" and is, therefore, not preempted by ERISA. *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Insur. Co.*, 514 U.S. 645, 659-60 (1995). To hold otherwise—that is, "to read the pre-emption provision as displacing all state laws affecting costs and charges"—"would read the limitation language" out of ERISA's preemption clause. *Id.* at 661. The same is true with regard to PCMA's challenge to the Iowa law.

PCMA's remaining claim under the dormant Commerce Clause fairs no better. No doubt, PCMA is bringing an undue-burden claim under *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970), and it argues that "the fact-intensive character" of such a claim counsels against "premature dismissal," PCMA Br. 57-60. But that does not mean that such a claim is "not susceptible to resolution on a motion to dismiss," as PCMA

argues. *Id.* at 57. To the contrary, federal appellate courts regularly affirm the dismissal of such claims where the allegations fail to present a cognizable burden on interstate commerce. *E.g.*, *Grand River Enters. Six Nations v. Beebe*, 574 F.3d 929, 942 (8th Cir. 2009) (upholding dismissal of a *Pike* claim). Among the many deficiencies of PCMA's operative complaint, it fails to demonstrate any cognizable harm under *Exxon Corp. v. Governor of Md.*, 437 U.S. 117 (1978). There, the Supreme Court rejected a challenge to a State law that required petroleum manufacturers to divest their interests in petroleum retailers located within the State, holding that the Commerce Clause "protects the interstate market, not particular interstate firms, from prohibitive or burdensome regulations." *Id.* at 127-28. The same logic applies here. The fact that PBMs may be forced to relinquish a portion of their ample profits—Express Scripts alone reported annual profits of over $2 billion in 2014, *see* Express Scripts Holding Co., Annual Report for 2014 on Form 10-K at 32 (Feb. 23, 2015) (*available at:* http://www.sec.gov/Archives/edgar/data/1532063/000153206315000004/esrx-12312014x10k.htm)—demonstrates a burden only to PBMs, not interstate commerce.

In short, PCMA has failed to allege facts showing its entitlement to relief on either of the two claims it presses on appeal. Accordingly, this Court should affirm the judgment of the District Court.

BACKGROUND

Pharmaceutical drugs flow through commerce in a "relatively straightforward" path—generally from drug manufacturers to wholesalers to retail pharmacies and, finally, to consumers. Congressional Budget Office, *Prescription Drug Pricing in the Private Sector* at 1 (Jan. 2007) (*available at* https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/01-03-prescriptiondrug.pdf) [hereinafter CBO Report]. The "flow of payments," however, "is more complicated." *Id.*

A. PBMs as Middlemen: Their Supply- and Demand-Side Activities

PBMs are brokers, or "middlemen," in the flow of payments between drug manufacturers, retail pharmacies, and health plans. *PCMA v. Rowe*, 429 F.3d 294, 298 (1st Cir. 2005). They provide health plans with "access to an established network of pharmacies, where customers of health benefit providers can obtain drugs at set prices," and they "negotiate volume discounts and rebates with drug manufacturers by pooling substantial numbers of health benefit providers." *Id.*

As middlemen, PBMs can extract revenue at each stage of the sales of pharmaceuticals—from reimbursing pharmacies to coordinating the disbursement of payments by health-plan payors. Although PBMs participate in the markets for both brand-name and generic drugs, CBO Report at 6-8, this particular appeal concerns Iowa's attempt to regulate PBMs in the market for generics, PCMA Br. 6.

On the supply side of the generic-drug market, PBMs set reimbursements that they will pay to pharmacies for prescriptions dispensed to covered beneficiaries. A91;

accord CBO Report at 12. Retail pharmacies, although they receive reimbursements through PBMs, are still responsible for acquiring the drugs through separate transactions with drug manufacturers and/or wholesalers. A83. When the PBMs set generic reimbursements for retail pharmacies, they use maximum allowable cost (MAC) lists, CBO Report at 20, which set "upper payment limit[s] on the ingredient costs" for generic drugs, *id.* at 26. Because PBMs maintain multiple MAC lists, frequently change those lists, and do not readily disclose them, pharmacies typically do not learn the amount of reimbursement until the moment they dispense any given drug to a covered beneficiary. *See* A91-93; Kmart Compl. ¶ 20.

On the demand side, PBMs work with health plans to determine how much they will charge the health plan when pharmacies dispense prescription drugs to the plans' beneficiaries. PBMs set this price for generics using a second MAC list for health plans that is typically higher than the MAC list used to reimburse the pharmacy. Robert Garis, *Leveling the Playing Field in the Pharmacy Benefit Management Industry*, 42 Val. U. L. Rev. 33, 40 (2007); A91 (1st Am. Compl. ¶ 29) (acknowledging that PBMs maintain two sets of MAC lists for any given transaction). The difference between the amount PBMs pay pharmacies and the amount they charge health plans is called a "pricing spread" or a "retail spread" and is pocketed by the PBM. Indeed, "[m]uch of a PBM's revenue is based on the 'retail spread' between the price paid to the pharmacy and the price received from the benefit plan." Dep't of Labor, *Advisory Council on Emp. Welfare and Pension Benefits, PBM Compensation and Fee Disclosure* at 7

(Nov. 2014) (*available at* http://www.dol.gov/ebsa/pdf/2014ACreport1.pdf) [hereinafter DOL Advisory Council Report]. Although the spread varies depending on the pharmacy, health plan, and drug, the spread 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).

B. PBMs Abuse Their Position As Middlemen

As the United States Court of Appeals for the First Circuit recognized, the role of PBMs as intermediaries—particularly in combination with the "fact that there is little transparency" in their dealings with manufacturers and health plans—gives PBMs "the opportunity to engage in activities that may benefit the drug manufacturers and PBMs financially to the detriment of the health benefit providers." *Rowe*, 429 F.3d at 298. Those same attributes—leveraged buying power and little transparency—allow PBMs to enrich themselves at the expense of pharmacies as well.

As PCMA acknowledges in its pleadings, certain key transactions by PBMs are shrouded in secrecy. *E.g.*, A93-94. Although PCMA celebrates this lack of transparency, *id.,* various government and private actors have been frustrated by their inability to evaluate and regulate the fairness of PBMs' business practices.

For example, as the DOL Advisory Council recently observed, the manner in which PBMs derive direct and indirect compensation for their services creates potential conflicts of interest with their business partners—conflicts that PBMs fail to

disclose to their partners. DOL Advisory Council Report at 3, 11-12. In fact, PBMs go to great lengths to prevent their business partners, including pharmacies, from auditing their records to uncover these conflicts. *Id.* at 5; Garis, *Leveling the Playing Field*, *supra*, at 40.

Over the past decade, these potential conflicts have repeatedly materialized into actual conflicts between PBMs and the health plans they purport to benefit. In 2008, for example, Attorneys General from dozens of States settled consumer protection claims against one of the largest PBMs for promoting certain drugs that increased medical costs for consumers and health plans, but resulted in higher profits for the PBM through rebates. *In re Express Scripts, Inc.*, Assurance of Voluntary Compliance and Discontinuance (filed May 27, 2008) (*available at* https://www.express-scripts.com/sitemap/docs/AVC.pdf); *see also* Katherine Eban, *Painful prescription: Pharmacy benefit managers make out better than their customers*, Fortune, Oct. 10, 2013 (*available as reprinted at:* http://katherineeban.com/2013/10/23/painful-prescription-fortune-com/) (discussing conflicts between PBMs and their customers).

Retail pharmacies also have suffered, particularly as the market for PBMs has become more consolidated. Garis, *Leveling the Playing Field*, *supra*, at 36. Pharmacies have observed that PBMs use "the combined economic power of [their] Plan Sponsors to reduce the contractual amount [they] pay[] to retail pharmacies below the levels that would prevail in a competitive marketplace." *In re Pharmacy Benefit Managers Antitrust Litig.*, 582 F.3d 432, 436 (3d Cir. 2009). In fact, the reimbursements PBMs

offer to pharmacies may not even cover the costs retail pharmacies incur in acquiring the drugs from wholesalers or manufacturers. *See* Brief in Support of Attorney General's Response to Plaintiff's Motion for Preliminary Injunction at 6-10, *PCMA v. Rutledge*, No. 15-cv-510 (E.D. Ark.) (filed Sept. 22, 2015) [DE-20] (documenting complaints to the Attorney General where reimbursements by PBMs were lower than pharmacies' acquisition costs); *accord* Kmart Compl. ¶ 3 (claiming that "Kmart now loses money" on many prescriptions filled by a particular PBM).

C. Enactment of Section 510B.8

In enacting Section 510B.8, the Iowa legislature sought to address only a handful of the many documented abuses by PBMs. After conducting a nine-month investigation into relationships between PBMs and pharmacies in the State, the Iowa Insurance Commissioner determined that PBMs' business practices were responsible for the closure of twenty-three retail pharmacies in the State. Rep. Vander Linden, Video Remarks on H.F. 2297, An Act Relating to the Regulation of Pharmacy Benefits Managers, at 1:50:30-1:52:16 (Mar. 4, 2014).[2] In addition, the Iowa legislature found that Iowa pharmacies, which were not being reimbursed the full amount of their drug acquisition costs, had no recourse to demand higher reimbursements from PBMs. Rep. Ourth, Video Remarks on H.F. 2297, at 1:52:22-1:55:10. This in turn

[2] The Video Remarks are available at http://coolice.legis.iowa.gov/Cool-ICE/default.asp?Category=Billinfo&Service=ArchiveBill&vid=934&offset=6646&iDate=2014-03-04&hbill=HF2297.

was threatening the closure of additional pharmacies and restricting access to pharmaceutical drugs in southern Iowa. *Id.*

In an effort to clamp down on these documented abuses, the Iowa legislature determined that the State needed to increase transparency in the PBM industry and ensure a more level playing field between pharmacies and PBMs. Rep. Forbes, Video Remarks on H.F. 2297, at 1:56:10-1:56:57. Accordingly, the legislature enacted Section 510B.8 to regulate PBM activity in the State in three key respects. Subsection 1 authorizes the Insurance Commissioner to require PBMs to submit information to the Commissioner showing how PBMs calculate their MAC lists for any contracts with Iowa pharmacies. Subsection 2 requires PBMs to utilize nationally-recognized data when setting maximum reimbursement amounts for pharmacies related to certain prescription drugs. And Subsection 3 requires PBMs to give contracting pharmacies an opportunity to challenge PBM reimbursements through an appeals process to be established by the PBMs.

D. Procedural History

Shortly after Section 510B.8 was enacted into law, PCMA brought a legal challenge in the United States District Court for the Southern District of Iowa, raising a series of claims under federal and State law. A16-47; A81-113. The District Court ultimately dismissed all of PCMA's claims for failure to state a claim. A54-74; A118-133. On appeal, PCMA has abandoned all but its express-ERISA-preemption and undue-burden (*Pike*-balancing) claims.

ARGUMENT

I. Iowa's PBM Law Is Not Preempted By ERISA.

PCMA argues that each of the Iowa law's provisions—referred to throughout as Subsections 1, 2, and 3—are preempted by ERISA's preemption clause. PCMA's argument, however, is premised on the assumption that PBMs stand in the shoes of ERISA plans, and that any regulation of PBMs is therefore necessarily preempted by ERISA. PCMA Br. 30 & n.7. But PCMA is badly mistaken.

ERISA's preemption clause only preempts State laws "insofar as" they "relate to" an ERISA plan, 29 U.S.C. § 1144(a), and the Supreme Court has cautioned against applying "uncritical literalism" when interpreting the meaning of this clause, *Travelers*, 514 U.S. at 656. "If 'relate to' were taken to extend to the furthest stretch of its indeterminacy, then for all practical purposes pre-emption would never run its course, for really, universally, relations stop nowhere." *Id.* at 655 (alterations and second set of quotation marks omitted). Accordingly, the Supreme Court has held that a "'law "relates to" an employee benefit plain, in the normal sense of that phrase, if it has a connection with or reference to such a plan.'" *Id.* at 656.

Properly understood, the Iowa law has no forbidden "connection with" nor "reference to" any ERISA plan. The Iowa law acts upon *PBMs*, not ERISA plans; it regulates the PBMs' *relationships with pharmacies*, not their relationships with ERISA plans; and it imposes, at most, only *indirect costs* on ERISA plans, which the Supreme

Court has held is legally insufficient to give rise to ERISA preemption. As a result, Iowa's regulation of PBMs is not preempted by ERISA.

A. Because The Iowa Law Simply Regulates A PBM's Supply-Side Relationship With Pharmacies And Has, At Most, Only An Indirect Economic Effect On An ERISA Plan, It Does Not Have An Impermissible "Connection With" Any ERISA Plan.

The Iowa law does not have an impermissible "connection with" any ERISA plan. The Supreme Court has explained that, in determining whether a State law has a forbidden "connection with" an ERISA plan, a reviewing court must look beyond the statute's "unhelpful text," *Travelers*, 514 U.S. at 656, and consider instead "'the objectives of the ERISA statute as a guide to the scope of the state law that Congress understood would survive,' as well as to the nature of the effect of the state law on ERISA plans," *Cal. Div. of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc.*, 519 U.S. 316, 325 (1997). Thus, both the *nature of the State regulation* and *who* is being regulated are critically important in determining whether any given State law has a forbidden "connection with" an ERISA plan.

Travelers is particularly helpful in unlocking the Supreme Court's "connection with" jurisprudence. In that case, New York had passed a law that required hospitals to "collect surcharges from patients covered by a commercial insurer but not from patients insured by a Blue Cross/Blue Shield plan." 514 U.S. at 649-50. The Court acknowledged that, although this law plainly made the Blues a more attractive alternative for ERISA plans, the law "simply bears on the costs of benefits and the

relative costs of competing insurance to provide them." *Id.* at 659-60. Because an indirect economic regulation "does not bind plan administrators to any particular choice," the Court held that it does not "function as a regulation of an ERISA plan itself," and it is, therefore, not preempted by ERISA. *Id.* at 659.

The Court cited three reasons why indirect economic regulations are not preempted by ERISA. *First*, there was nothing remarkable about cost variations within the world of healthcare services, which can vary "'dramatically across regions." *Id.* at 660. The Court theorized that, even in the absence of state regulation, the "common character of rate differentials" rendered it "unlikely that ERISA pre-emption was meant to bar such indirect economic influences." *Id.* *Second*, the Court noted that "the existence of other common state action with indirect economic effects on a plan's costs leaves the intent to pre-empt even less likely." *Id.* As the Court explained: "Quality standards, for example, set by the State in one subject area of hospital services but not another would affect the relative cost of providing those services over others and, so, of providing different packages of health insurance benefits. Even basic regulation of employment conditions will invariably affect the cost and price of services." *Id.* And yet, Congress did not understand that any such laws would be preempted. *Id.* *Finally*, the Court explained that the preemption clause would know no limit if it displaced State laws "affecting costs and charges on the theory that they indirectly related to ERISA plans." *Id.* at 661.

The Iowa law is not meaningfully different from the indirect economic regulation that the Supreme Court sustained in *Travelers*. Section 510B.8 regulates PBMs, not ERISA plans. *See* Iowa Code § 510B.8. At most, PCMA alleges that the law imposes some unquantified, indirect economic cost on ERISA plans. For example, Subsection 2 may yield higher costs for PBMs, which may, in turn, pass on some or all of these increased costs to ERISA plans. Similarly, Subsections 1 and 3 may impose administrative costs on PBMs, which may, in turn, pass along these costs to ERISA plans. Critically, however, the Iowa law "does not bind *plan administrators* to any particular choice." *Travelers*, 514 U.S. at 659 (emphasis added). It does not, for example, dictate which kinds of prescriptions a PBM and, in turn, an ERISA plan may offer. Thus, under *Travelers*, the Iowa law does not "function as a regulation of an ERISA plan itself." *Id.* at 659.

In arguing that the Iowa law could bear an impermissible "connection with" an ERISA plan, PCMA relies heavily on *Egelhoff v. Egelhoff*, 532 U.S. 141 (2001), *see* PCMA Br. 22-23, 39-40, but that reliance is mistaken. *Egelhoff* falls squarely within a line of cases that the Supreme Court distinguished in *Travelers*.

Egelhoff involved a State law that provided that a beneficiary's status was automatically revoked upon divorce. 532 U.S. at 143. To the extent that an ERISA plan provided a different way to determine revocation of a beneficiary's status, the operation of this law would have overridden eligibility for and payment of benefits as

determined by the plan. *Id.* at 148-49. Based on this, the Supreme Court held that the law was preempted.

The law at issue in *Egelhoff* is easily distinguishable from the types of indirect economic regulations at issue in *Travelers* and here. Indeed, although *Egelhoff* was decided after *Travelers*, it falls squarely within a line of cases that the Supreme Court distinguished in *Travelers*. Specifically, the Supreme Court distinguished between (1) State laws that dictated how plans calculate or pay for specific benefits, *Travelers*, 514 U.S. at 657-58 (citing *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85 (1983); *Alessi v. Raybestos-Manhattan, Inc.*, 451 U.S. 504 (1981); and *FMC Corp. v. Holliday*, 498 U.S. 52 (1990)), and (2) State laws that have the effect of increasing the costs of services and commodities that might ultimately be passed on to an ERISA plan (as in *Travelers*). The law at issue in *Egelhoff* plainly falls into the former category—as do the other cases relied upon by PCMA—because it directly regulated the availability of benefits under an ERISA plan. PCMA Br. 39-40 (relying upon *Egelhoff*, *FMC*, and *Alessi*). The Iowa law, in contrast, does not regulate the benefits that an ERISA plan may or may not offer its beneficiaries. At most, it might indirectly affect plan costs.

In this way, the alleged effect of the Iowa law is no different than a State law that affects the operations of healthcare providers. Even though such regulations could result in an indirect increase in costs for ERISA plans, they are not preempted by ERISA. As the Supreme Court explained, "laws with only an indirect economic effect on the relative costs of various health insurance packages in a given State are a

far cry from those 'conflicting directives' from which Congress meant to insulate ERISA plans." *Travelers*, 514 U.S. at 649.

PCMA also insinuates that the Subsections 2 and 3 of the Iowa law act as a direct regulation of ERISA plans because they limit the "*use* of MAC pricing to a narrow category of drugs," PCMA Br. 41 (emphasis in original), and intrude upon "a plan's payment of benefits," *id.* at 47. But PCMA is mistaken.

The Iowa law does not regulate the MAC lists that a PBM may use to charge an ERISA plan for its services. As PCMA itself acknowledges, PBMs utilize two distinct MAC lists: "After the prescription is filled, the PBM *reimburses the pharmacy at a contractually-agreed negotiated rate* minus the co-pay collected by the pharmacy from the plan participant. The PBM then *separately* bills the health plan at the *rate negotiated between the PBM and the health plan*." A91 (1st Am. Compl. ¶ 29) (emphasis added). Properly understood, Subsection 2 and its enforcement mechanism, Subsection 3, only regulate the data that PBMs may use to set "maximum *reimbursement* amounts" that the PBMs *pay* to pharmacies for certain drugs—not the amount that they *charge* insurers or plans. Iowa Code § 510B.8(2) (emphasis added). For this reason, the Iowa law does not directly regulate any plan's payment of benefits—as PCMA misleadingly contends. PCMA Br. 47.

Finally, PCMA argues that the reporting obligations that Subsection 1 imposes on *PBMs* are somehow inconsistent with the reporting obligations that ERISA imposes on *plan administrators*. *Id.* at 48-49. But once again, these arguments

are premised on the mistaken assumption that a regulation of a PBM is necessarily a regulation of an ERISA plan itself. Nothing in the Iowa law imposes reporting obligations on ERISA plans. *See* Iowa Code § 510B.8(1). At most, PCMA claims that the Iowa law may impose upon PBMs additional compliance costs, which they may or may not pass along to ERISA plans. Yet, *Travelers* holds that these types of indirect costs do not rise to the level of an impermissible "connection with" ERISA. 514 U.S. at 649.

B. The Iowa Law Regulates PBMs, Not ERISA Plans, And It Therefore Does Not Have Any Impermissible "Reference To" Any ERISA Plan.

As an alternative basis for reversal, PCMA argues that the Iowa law is preempted because a related portion of the Iowa Code includes a definitional provision that defines PBMs to include those entities that "'perform[] pharmacy benefits management services' for 'covered entit[ies],'" and exempts from the definition of a covered entity "'a self-funded health coverage plan that is exempt from state regulation pursuant to [ERISA].'" PCMA Br. 53 (quoting Iowa Code § 510B.1(2), (7)-(9)). Invoking *Prudential Insurance Co. v. National Park Medical Center, Inc.*, 154 F.3d 812 (8th Cir. 1998), PCMA argues that ERISA preempts any State law that makes a reference to ERISA. PCMA Br. 51-54. But PCMA is again mistaken.

Contrary to PCMA's argument, *National Park* found an impermissible reference to ERISA, not simply because the State law referred to ERISA, but also because the law at issue in that case *directly regulated* how "health care insurer[s]" administered

"health benefit plan[s]," but then exempted any ERISA plans from regulation. 154 F.3d at 814-15. In other words, a mere reference to ERISA is not enough. *Cf. In Home Health, Inc. v. Prudential Ins. Co.*, 101 F.3d 600, 604 (8th Cir. 1996) (explaining that "'[s]ome state actions may affect employee benefit plans in too tenuous, remote, or peripheral a manner to warrant a finding that the law 'relates to' the plan'" (quoting *Shaw*, 463 U.S. at 101 n.21)). In contrast, the Iowa law does not regulate health benefit plans; it regulates *PBMs*.

The law at issue here is not unlike a law upheld by this Court in *Express Scripts, Inc. v. Wenzel*, 262 F.3d 829 (8th Cir. 2001). In that case, a State law precluded *HMOs*, not ERISA plans, from requiring participants to fill certain prescriptions at mail order pharmacies, but a later section of the challenged law included a separate provision that exempted ERISA plans from any of the requirements contained throughout the relevant Code. *Id.* at 831-32. The District Court held that this did not constitute an impermissible reference to ERISA, and that, even if it did, the law fell within ERISA's insurance savings clause. *Express Scripts, Inc. v. Wenzel*, 102 F. Supp. 2d 1135, 1141-44, 1148-54 (W.D. Mo. 2000). According to the District Court, unlike the law at issue in *National Park*, the challenged law "regulates only HMOs and does not regulate ERISA plans." *Id.* at 1143. It deemed "[t]his difference dispositive," because "[e]ven in the absence of [the law's] 'exemption,' [the law] would still apply only to HMOs and not ERISA plans." *Id.* In short, the challenged law merely "mention[ed] health benefit plans, and d[id] not regulate them." *Id.* at 1144. In affirming the judgment of the

District Court, the Eighth Circuit did not challenge this analysis. *Express Scripts*, 262 F.3d at 838. Instead, it affirmed the District Court on its alternative holding—that, no matter what, the challenged law fell within ERISA's insurance savings clause. *Id.* But even in affirming on this alternative basis, this Court was still forced to confront the appellant's contention that the State law was not really a regulation of insurance, and that it therefore "should be preempted like the Arkansas law in [*National Park*]." *Id.* at 835. In rejecting this contention, this Court emphasized that the challenged law was "directed at HMOs," not ERISA plans. *Id.* at 836. For that reason, this Court agreed with the District Court that *National Park* did not demand preemption where a law makes a reference to ERISA but does not directly regulate any ERISA plan.

The Iowa law is no different. It regulates PBMs, not ERISA plans. The Iowa law, therefore, does not "'act[] *immediately and exclusively* on ERISA plans,'" nor is the existence of an ERISA plan "'*essential* to the law's operation.'" *Express Scripts*, 102 F. Supp. 2d at 1142 (emphasis added) (quoting *Dillingham*, 519 U.S. at 325), *aff'd*, 262 F.3d at 835-36. Thus, the Iowa law does not make a forbidden "reference to" ERISA.

C. The D.C. Circuit's Decision In *PCMA v. District of Columbia* Does Not Warrant A Finding of ERISA Preemption Here.

Although PCMA does nothing to develop the point, it suggests through a footnote that preemption is compelled here by the decision of the United States Court of Appeals for the District of Columbia Circuit in *PCMA v. District of Columbia*, 613 F.3d 179 (D.C. Cir. 2010). PCMA Br. 30 n.7. Even if it were permissible for PCMA

to develop this argument for the first time in its reply brief, *but see Bakalis v. Golembeski*, 35 F.3d 318, 326 n.8 (7th Cir. 1994) (holding that an argument "made only in a footnote in the opening brief" and "not fully developed until the reply brief . . . is deemed waived"), this Court should reject the argument for two independent reasons.

As an initial matter, the State law at issue here is distinguishable from the law challenged in *PCMA v. District of Columbia*. There, the District of Columbia attempted to regulate PBMs' *demand-side* activities with ERISA plans by dictating that PBMs owed the plans they serve: (1) a "fiduciary duty," (2) disclosure obligations related to conflicts of interest, and (3) pass-back obligations to ensure that plans received any benefit or payment that a PBM received from pharmaceutical manufacturers. 613 F.3d at 183, 185. As discussed above, the Iowa law, in contrast, is focused exclusively on the PBMs' *supply-side* interactions with pharmacies and imposes, at most, only an indirect economic cost on ERISA plans. As even the D.C. Circuit recognized, a law that imposes "an 'indirect economic influence . . . [on] a plan's shopping decisions'" is not preempted by ERISA. *Id.* at 186 (quoting *Travelers*, 514 U.S. at 659-60).

But even if the Iowa law somehow constitutes a demand-side regulation (it doesn't), this Court should not follow *PCMA v. District of Columbia*, which conflicts with the First Circuit's decision in *PCMA v. Rowe*, 429 F.3d 294 (1st Cir. 2005). Stated simply, the First Circuit's reasoning is far more compelling.

In *Rowe*, the First Circuit properly recognized that the imposition of demand-side regulations on PBMs—in that case, establishing under State law that PBMs owe

fiduciary duties to the insurers and plans that they serve—in no way relates to the separate fiduciary obligations that ERISA imposes upon plans vis-à-vis beneficiaries. 429 F.3d at 301. Under ERISA, a person is a fiduciary only "to the extent" that he or she engages in certain discretionary management or administrative control "with respect to a plan." 29 U.S.C. § 1002(21)(A). The law at issue in *Rowe* regulated a PBM's conduct as *service provider to a plan*, not any exercise of the *plan's* fiduciary obligations to beneficiaries. 429 F.3d at 301.

The law at issue in *PCMA v. District of Columbia* was no different, but the D.C. Circuit nevertheless held that *any* non-waiveable regulation of a PBM's relationship with an ERISA plan is preempted by ERISA. It reached this decision without much regard for the nature of the regulation or the functions that PBMs perform, claiming instead that, as practical matter, ERISA plans cannot be expected to do without PBMs, and that this is somehow relevant to the preemption analysis. 613 F.3d at 187-89. That was error.

In holding that the District of Columbia's law was preempted, the D.C. Circuit departed from the Supreme Court's admonishment that courts must avoid interpretations of ERISA that measure preemption based on "infinite relations" to an ERISA plan. *Travelers*, 514 U.S. at 656. As the Supreme Court has explained, preemption must be measured instead by "the objectives of the ERISA statute" and "the scope of the state law that Congress understood would survive." *Id.*

Properly understood, the imposition of State-law duties on PBMs as service providers is not preempted by ERISA. Such duties may yield an indirect benefit or detriment to ERISA plans, but they do not "preclude uniform administrative practice [by an ERISA plan] or the provision of a uniform interstate benefit package if a plan wishes to provide one." *Id.* at 660. Indeed, a contrary holding would mean that a claim for malpractice—another State-created duty—is preempted anytime it is brought by an ERISA plan against a service provider to that plan. But, of course, that is not the law. *E.g.*, *Gerosa v. Savasta & Co.*, 329 F.3d 317, 324 (2d Cir. 2003) ("[S]tate-law malpractice or negligence claims against non-fiduciary plan advisors, such as accountants, attorneys, and consultants, are not preempted.") (collecting authorities); *cf. Home Health*, 101 F.3d at 604-07 (holding that ERISA does not preempt a healthcare provider's negligent misrepresentation claim against an ERISA plan administrator).

Moreover, the D.C. Circuit's decision creates a blind spot in the law. The Supreme Court has held that "[p]rofessional service providers" become liable for damages under ERISA *only if* "they cross the line from adviser to fiduciary." *Mertens v. Hewitt Assocs.*, 508 U.S. 248, 262 (1993). And yet, the D.C. Circuit held that PBMs are immune from regulation by the States even when they are *not* acting as fiduciaries on behalf of a plan. This illogical outcome would leave PBMs immune from any form of regulation. Thus, even if *PCMA v. District of Columbia* cannot be distinguished (it can), this Court should decline to adopt its holding as the law within the Eighth Circuit.

* * *

In sum, the Iowa law has no impermissible "connection with" nor "reference to" any ERISA plan. It regulates the PBMs' supply-side relationship with pharmacies, not their demand-side relationship with ERISA plans. At most, the Iowa law is alleged to impose indirect costs on ERISA plans, but that is legally insufficient to give rise to preemption under ERISA. Thus, the District Court did not err in dismissing PCMA's ERISA-preemption claim.

II. The Dormant Commerce Clause Does Not Protect PBMs' Profit Margins from State Regulation.

PCMA has argued on appeal that Commerce Clause claims under *Pike* are "factbound and not susceptible to resolution on a motion to dismiss." PCMA Br. 57. This argument, however, presumes that PCMA has alleged a cognizable harm under the Commerce Clause. It has not.

No doubt, *Pike* balancing claims require courts to evaluate whether a particular regulation "imposes a burden on interstate commerce that outweighs any benefits received." *Grand River*, 574 F.3d at 942. Yet, in the absence of a cognizable burden, a *Pike* balancing claim is ripe for dismissal. *Id.* (upholding dismissal of *Pike* claim on pleadings); *Freedom Holdings, Inc. v. Spitzer*, 357 F.3d 205, 218 (2d Cir. 2004) (same); *Doran v. Mass. Turnpike Auth.*, 348 F.3d 315, 322 (1st Cir. 2003) (same); *Goldfarb v. Supreme Court of Virginia*, 766 F.2d 859, 865 n.5 (4th Cir. 1985) (same).

Here, PCMA has failed to allege a cognizable theory of harm under the dormant Commerce Clause. Indeed, PCMA's claim is not unlike the one rejected by the Supreme Court in *Exxon Corp. v. Governor of Maryland*, 437 U.S. 117 (1978).

In *Exxon*, the Supreme Court considered a claim that a Maryland statute, which prohibited petroleum producers from operating retail service stations in the State, *id.* at 119-20, "impermissibly *burden[ed]* interstate commerce," *id.* at 127. The plaintiffs in *Exxon* further alleged that the Maryland statute would force refiners to stop selling oil in Maryland, and would deprive consumers of certain services. *Id.* The Court rejected the claim, finding fault with the "notion that the Commerce Clause protects the particular *structure* or *methods of operation* in a retail market." *Id.* at 127 (emphasis added). Yet, that is exactly what PCMA is asking this Court to find.

Many of PCMA's alleged burdens on interstate commerce are nothing more than potential financial and administrative inconveniences that will allegedly befall PBMs that operate in Iowa. PCMA Br. 66-67 (arguing that Subsection 1 of the law will force PBMs to disclose proprietary MAC lists); *id.* at 71 (arguing that Subsection 2 will force PBMs to implement Iowa-specific changes and incur expenses in so doing). But burdens on the PBM industry alone are not cognizable interstate burdens.

As the Supreme Court has recognized, the "[Commerce] Clause protects the interstate market, not particular interstate firms." *Exxon*, 437 U.S. at 127. To illustrate, the Supreme Court held that a State law that imposed truck-length restrictions was unconstitutional, not because it regulated the trucking industry, but

because it "substantially burden[ed] the interstate flow of goods" by requiring trucks to stop and change trailers at the State's borders or bypass the State altogether. *Kassel v. Consolid. Freightways Corp.*, 450 U.S. 662, 671 (1981) (plurality). No similar burden exists here.

PCMA also argues that Subsection 2 will minimize the financial incentive for Iowa pharmacies to purchase generic equivalents, PCMA Br. 70-71, and that the law "eventually will raise generic drug prices for health plans and their participants nationwide," *id.* at 71 (quotation marks and citations omitted). But PCMA's alleged theory of harm—if it ever comes to fruition—is little more than a thinly-veiled plea to have the courts protect the profit margins of its members.

Subsection 2 does not regulate the price that consumers or health plans pay for generic drugs. To the extent that the Iowa law regulates any transaction, it is the amount of money that PBMs reimburse to pharmacies after they dispense generics to covered beneficiaries. Indeed, as PCMA fully acknowledges in its pleadings, PBMs already maintain a spread between the reimbursements they pay to pharmacies and the amounts they bill to health plans. A91 (1st Am. Compl. ¶ 29). And this spread can be substantial, even for a single transaction. Garis, *Spread*, *supra*, at 16.

To be sure, in the event that Subsection 2 requires PBMs to pay retail pharmacies fairer reimbursements, PBMs may choose to charge health plans more money to preserve their profit margins. But the Iowa law does not compel such a result.

Alternatively, health plans may force PBMs to fully absorb the alleged costs of complying with Subsection 2. But "the fact that an interstate company stands to lose money is not of constitutional significance under the dormant Commerce Clause." *Alliance of Auto Mfrs., Inc. v. Currey*, 984 F. Supp. 2d 32, 58 (D. Conn. 2013) (citing *CTS Corp. v. Dynamics Corp.*, 481 U.S. 69, 88 (1987)). And any harm to PBMs' profit margins does not become a cognizable harm simply because the generic-drug market is a national market. *Exxon*, 437 U.S. at 128 (rejecting argument that "because the economic market for petroleum products is nation-wide, no State has the power to regulate the retail marketing of gas").

CONCLUSION

For the foregoing reasons and for those stated in Defendants-Appellees' Brief, this Court should affirm the judgment of the District Court.

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Respectfully submitted,

/s/ Robert T. Smith

Howard R. Rubin
Counsel of Record
Robert T. Smith
Daniel Lipton
KATTEN MUCHIN ROSENMAN LLP
2900 K Street, NW – Suite 200
Washington, DC 20007-5118
202-625-3500
howard.rubin@kattenlaw.com
robert.smith1@kattenlaw.com
daniel.lipton@kattenlaw.com

Gary W. Howell
KATTEN MUCHIN ROSENMAN LLP
525 West Monroe Street
Chicago, IL 60661-3693
312-902-5200
gary.howell@kattenlaw.com

Counsel for Amici Curiae

CERTIFICATE OF COMPLIANCE

Pursuant to Rules 29(c)(7) and 32(a)(7)(C)(i) of the Federal Rules of Appellate Procedure, I hereby certify that this brief is in compliance with the type form and volume requirements. Specifically, this *amici curiae* brief is proportionately spaced; uses a Roman-style, serif typeface (Garamond) of 14-point; and contains **6,999 words**, exclusive of the material not counted under Rule 32(a)(7)(B)(iii) of the Federal Rules of Appellate Procedure.

In addition, pursuant to Rule 28A(h)(2) of the Eighth Circuit Rules of Appellate Procedure, I hereby certify that the electronic version of this brief has been scanned and that the brief is virus free.

/s/ Robert T. Smith
Robert T. Smith
Counsel for Amici Curiae

CERTIFICATE OF SERVICE

I hereby certify that I had the foregoing *Amici Curiae* Brief electronically filed by tendering it to the Office of the Clerk of the United States Court of Appeals for the Eighth Circuit on February 3, 2016.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system. I further certify that I served paper-copies of the brief on all counsel of record using the addresses listed in the Court's CM/ECF system.

/s/ Robert T. Smith
Robert T. Smith
Counsel for Amici Curiae