ORAL ARGUMENT NOT SCHEDULED

IN THE UNITED STATES COURT OF APPEALS
For the District of Columbia Circuit

No. 07-7062

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,
Appellant,
v.
DISTRICT OF COLUMBIA, *et al*.,
Appellees.

On Appeal from a Decision of the United States District Court
for the District of Columbia

BRIEF *AMICI CURIAE* OF AARP, LEGAL COUNSEL FOR THE ELDERLY AND THE PRESCRIPTION ACCESS LITIGATION PROJECT IN SUPPORT OF APPELLEES

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CORPORATE DISCLOSURE STATEMENTS OF *AMICI CURIAE*

Pursuant to Rule 26.1(b) of the Federal Rules of Appellate Procedure and D.C. Circuit Rule 26.1, *amici curiae* AARP, Legal Counsel for the Elderly (LCE), and the Prescription Access Litigation (PAL) Project state the following:

AARP is a nonpartisan, not-for-profit corporation with no parent company and issues no stock. Therefore, no publicly-held company has a 10% of or greater ownership interest in AARP. AARP provides information and resources, and advocates on legislative, consumer, and legal issues. Through a wholly-owned subsidiary, AARP Services, Inc., AARP makes available endorsed products and services through third party providers, including prescription drug plans. Legal entities related to *amicus curiae* AARP, includes AARP Services, Inc., AARP Foundation, Legal Counsel for the Elderly, AARP Financial, AARP Global Network, and Focalyst.

The Internal Revenue Service has determined that AARP is organized and operated exclusively for the promotion of social welfare pursuant to section 501(c)(4) of the Internal Revenue Code and is exempt from income tax. AARP is also organized and operated as a non-profit corporation pursuant to the provisions of title 29, section 618, of the D.C. Code.

LCE is a not-for-profit corporation with no parent company and issues no stock. Therefore, no publicly-held company has a 10% of or greater ownership interest in LCE. LCE is the primary provider of legal services and advocacy for the elderly population in the District of Columbia.

PAL is a project of Community Catalyst, a nonprofit, nonpartisan national advocacy organization that builds consumer and community participation in the shaping of the U.S. health system to ensure quality, affordable health care for all. Community Catalyst has no parent company and issues no stock.

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STATEMENTS OF INTEREST

AARP is a nonpartisan, nonprofit membership organization of over 39 million persons, age 50 or older, dedicated to addressing the needs and interests of older persons. Approximately 89,000 AARP members, more than 60% of DC's 50+ population, live in the District of Columbia.

Participants and beneficiaries in private, employer-sponsored employee benefit plans rely on the Employee Retirement Income Security Act (ERISA) to protect their rights under those plans. 29 U.S.C. § 1001 *et seq.* Contrary to ERISA's purpose, however, a statute that was designed to safeguard employee benefits has too frequently been used to deprive employees of rights and protections which state law provides. Although the Supreme Court has recognized that health care regulation is an area of traditional state concern, ERISA has often been used to challenge state attempts to regulate health care and provide better protections for its citizens. AARP has long advocated against attempts to extend ERISA preemption to state laws that serve an essential state interest in regulation that advances the welfare of its citizens – here a law that attempts to lower drug costs.

AARP advocates at the state and national level for access to affordable health care and for controlling costs without compromising quality, and supported

passage of the Access Rx Act of 2004, D.C. Code §§ 48-831.1 to -833.09 [Access Rx] in the District of Columbia. Since May of 2004, AARP's Public Policy Institute has issued a series of reports that closely monitor the pricing actions of the pharmaceutical industry. *See e.g.,* AARP, *Brand Name Drug Prices Climb Again in 2006*, RX WATCHDOG REPORT (March 2007), *available at* http://assets.aarp.org/www.aarp.org_/cs/elec/watchdog_march_2007.pdf. Finally, AARP filed a brief as *amici curiae* in parallel litigation concerning Maine's Pharmacy Benefit Manager (PBM) transparency law. *Pharm. Care Mgmt. Ass'n (PCMA) v. Rowe*, 429 F.3d 294 (1st Cir. 2005).

Legal Counsel for the Elderly (LCE) is a legal services provider to older D.C. residents and an affiliate of AARP. It has handled numerous denials of health care and long term care benefits to District seniors. In support of recent prescription drug legislation, LCE has hosted numerous community seminars to educate seniors. Additionally, LCE assists seniors in completing applications for prescription drug benefits. Further, LCE represents many low-income seniors who have to choose between purchasing prescription medications and paying for basic necessities such as food, clothing, and shelter.

The Prescription Access Litigation Project LLC (PAL) is a project of Community Catalyst, Inc., a nonprofit, nonpartisan organization that builds

consumer and community participation in the shaping of the U.S. health system to ensure quality, affordable health care for all. PAL is a coalition of over 130 organizations in 35 states and the District of Columbia. The organizations in PAL's coalition have a combined membership of over 13 million people, and include state and local organizations representing consumers and seniors, statewide health care access coalitions, and labor unions, including a number of organizations based in the District of Columbia: AIDS Action, Alliance for Retired Americans, American Federation of Labor – Congress of Industrial Organizations (AFL-CIO), American Federation of State County and Municipal Employees (AFSCME), the Association for Community Affiliated Plans, the DC Primary Care Association (DC PCA), the Government Accountability Project, the National Women's Health Network, Service Employees International Union (SEIU), and USAction. PAL works to end illegal prescription drug price inflation by pharmaceutical manufacturers and others by facilitating the participation of consumers, advocacy organizations and third party payors (health plans, union benefit funds and others) in class action litigation challenging such price inflation practices. PAL joined AARP's *amicus curiae* brief in the litigation described above concerning Maine's PBM transparency law. *PCMA v. Rowe, supra.*

PAL is concerned that price inflation and lack of pricing transparency is blocking access to vitally needed medications for a significant segment of the U.S. population. Given PBMs' importance to the ability of most Americans to afford their needed medications, PAL feels strongly that transparency is vital to ensure that the interests of consumers and their health plans are being fairly and adequately protected by the PBMs with which they contract to manage their prescription drug benefits.

Thus, all *amici curiae* have a substantial interest in the issues presented on appeal that are addressed in this brief - the District of Columbia's interest in lowering the costs of prescription drugs and whether ERISA preempts legislation aimed at achieving that goal.

ARGUMENT[1]

I. ERISA DOES NOT PREEMPT ACCESS RX BECAUSE IT DOES NOT RELATE TO AN ERISA PLAN.

Amici contend that appellant has not met the considerable burden of overcoming the presumption that ERISA does not preempt Access RX – a state law regulating health care providers. *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 654 (1995). First, Access RX

1 *Amici* do not address the collateral estoppel issue before the court. *Amici* were granted permission to file by the court on August 8, 2007.

does not reference ERISA plans; plans still may choose whether they even use a pharmacy benefit manager. Second, Access RX does not have a significant connection with an ERISA plan because it is not a law that mandates benefit structures or plan administration, binds employers or plan administrators to particular choices, or provides alternate enforcement mechanisms. There is no significant connection with an ERISA plan because Access RX does not regulate a principal ERISA relationship. Finally, Access RX does not provide an alternative enforcement mechanism.

A. The Presumption Against Preemption Applies to Access RX Because It Regulates Health Care -- an Area of Traditional State Concern.

When Congress passed ERISA, it limited a State's power to regulate only to the extent that its laws relate to employee benefit plans. ERISA § 514(a), 29 U.S.C. § 1144(a).[2] With its unanimous decision in *Travelers*, the Court specifically adopted the traditional presumption that federal law, in this case ERISA, should not preempt state laws unless it is clear that Congress intended to do so. *Id*. at 654-55 (1995), quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (consideration of whether a federal law preempts state law starts

2 ERISA § 514(a) states, in pertinent part, that ERISA "shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan."

with “the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.”); *accord*, *PCMA v. Rowe*, 429 F.3d at 301 (“the language of ERISA preemption provision is not as broad as it seems”); *Board of Tr. of the Hotel & Rest. Employees Int’l Union Local 25 v. Madison Hotel*, 97 F.3d 1479, 1487 n. 13 (D.C. Cir. 1996) (recognizing the limits *Travelers* placed on the breadth of ERISA preemption). The Supreme Court reinforced this presumption against preemption in *Cal. Div. of Labor Standards Enforcement v. Dillingham Constr.*, 519 U.S. 316 (1997). The Court held that there must be an "indication in ERISA . . . [or] its legislative history of any intent on the part of Congress to preempt" a traditionally state-regulated area of law. *Id.* at 331. *Dillingham* reaffirmed that a state law only "relates to" an ERISA plan if it refers to or has a significant connection with an ERISA plan. *Id.* at 324.

In order for a state law to reference an ERISA plan, the state law must act immediately and exclusively upon an ERISA plan, or the existence of an ERISA plan is essential to the law’s operation. *Dillingham*, 519 U.S. at 325. In order to determine whether the law has a significant connection to an ERISA plan, a court must examine ERISA’s objectives to determine whether the type of state law at issue is one that Congress would <u>not</u> have intended to preempt and then analyze the

effect the state law has on ERISA plans. *Id.* at 332. "[I]f 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 preemptive reach." *Id.* at 329; *accord*, *Egelhoff v. Egelhoff*, 532 U.S. 141, 147 (2001). Moreover, if the law merely "alters the incentives" which exist for an ERISA plan, "but does not dictate the choices," then the law is not sufficiently connected with an ERISA plan to require preemption. *Dillingham*, 519 U.S. at 333.

In *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund,* 520 U.S. 806 (1997), the Court held that ERISA did not preempt New York from imposing a gross receipts tax on medical centers which were owned and operated by an ERISA-covered employee benefit plan. The Court emphasized its preemption paradigm, stating that any 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 preempted by the federal statute." *Id.* at 816. The Court concluded that this state law was "one of 'myriad state laws' of general applicability that impose some burdens on

the administration of ERISA plans but nevertheless do not 'relate to' them within the meaning of [ERISA]. . . ." *Id.* at 815, quoting *Travelers*, 514 U.S. at 668.

The Court's more recent analysis of ERISA preemption cases demonstrates a conscientious application of this presumption so that state laws only relate to an employee benefit plan, and therefore are preempted, if they truly impact ERISA's core concerns. *Compare Egelhoff*, 532 U.S. 141 (state law governing the payment of benefits is preempted) and *Boggs v. Boggs*, 520 U.S. 833 (1997) (state law governing entitlement to benefits is preempted), *with De Buono*, 520 U.S. 806 (state tax on gross receipts with minimal impact on plan administration is not preempted), and *Dillingham*, 519 U.S. 316 (prevailing wage statute posed no requirement on ERISA plans and is not preempted). Because health plans were not a focus of Congress' concern during the enactment of ERISA, ABA Section of Labor and Employment Law, EMPLOYEE BENEFITS LAW lxviii-lxix (2d ed. 2000), and health issues are a traditional area of state concern, *Travelers*, 514 U.S. at 654-55, generally state health laws are not preempted.

ERISA's preemption clause simply does not reach Access RX because the state law merely requires PBMs to provide certain disclosures to <u>any</u> customer of a PBM and to perform their duties to their customers in accordance with fiduciary standards. Access RX functions to regulate health care – a traditional area of state

power which Congress did not intend to limit when it enacted ERISA. *Travelers*, 514 U.S. at 654-55.

B. Access RX Has No Reference To ERISA Plans Because It Functions Regardless of the Entity that Purchases a PBM's Services.

In *Dillingham*, the Court held that for a state law to reference an ERISA plan, the state law must act immediately and exclusively upon an ERISA plan or the existence of an ERISA plan is essential to the law's operation. The Court declined to find that the state prevailing wage law made a reference to ERISA plans because apprenticeship programs need not necessarily be ERISA plans, and the employer could pay apprentices out of its general assets.[3] The Court found that the prevailing wage law functioned regardless of whether an ERISA plan existed. *Dillingham*, 519 U.S. at 325.

Significantly, like the prevailing wage law in *Dillingham*, Access RX functions irrespective of whether an ERISA plan is involved. It functions regardless of the entity (e.g., an individual, a church plan, a governmental plan) which purchases the services of a PBM as a medical service provider. Access RX makes no reference to ERISA plans, and is not preempted on that basis. *See id.* at

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3 Significantly, in *Dillingham*, although most if not all apprenticeship plans were ERISA plans, the Court still found that there was no reference to an ERISA plan. *Dillingham*, 519 U.S. at 322-23, 334.

328; *PCMA v. Rowe*, 429 F.3d at 304; *accord, La. Health Serv. & Indem. Co. v. Rapides Healthcare Sys.*, 461 F.3d 529, 536-37 (5th Cir. 2006) (reference prong is inapplicable to assignment statute because "it applies to insurance companies, employee benefit trusts, self-insurance plans, and other entities" . . . .).

C. Access RX Does Not Have A Significant Connection With ERISA Plans.

1. Access RX does not mandate employee benefit structures, bind employers or administrators to particular choices, preclude uniform administrative practices, or provide alternate enforcement mechanisms to obtain benefits.

In *Travelers*, the Supreme Court recognized that three types of state laws will always will always have a connection to an ERISA plan and thus be preempted: (1) state laws that mandate employee benefit structures or their administration; (2) state laws that bind employers or plan administrators to particular choices or preclude uniform administrative practice, thereby functioning as regulations of ERISA plans themselves; and (3) state laws providing alternate enforcement mechanisms for employees to obtain ERISA plan benefits. *Travelers*, 514 U.S. at 657-60; *accord*, *Board of Tr. of the Hotel & Rest. Employees Int'l Union Local 25 v. Madison Hotel*, 97 F.3d at 1487 n. 13. Accordingly, preemption will not occur if a state law has only a "tenuous, remote, or peripheral" connection

with" benefit plans. *District of Columbia v. Greater Wash. Bd. of Trade*, 506 U.S. 125, 130 (1992).

Since *Travelers*, the Court has attempted to provide guidance on the types of laws that fall into these categories. State laws that interfere with ERISA's distribution of benefits scheme or a plan's administrative functions have been found to be preempted. *See, e.g., Egelhoff*, 532 U.S. at 146; *UNUM Life Ins. Co. of Am. v. Ward*, 526 U.S. 358, 378-79 (1999); *Boggs*, 520 U.S 833. In contrast, where the state statute merely alters the economic incentives involved, ERISA does not preempt the state law. *See, e.g., De Buono*, 520 U.S. at 815; *Dillingham*, 519 U.S. at 334.

Access RX does not address who will receive benefits, the kind of benefits to be paid, or how those benefits will be paid. *See, e.g., Egelhoff*, 532 U.S. at 141 (2001); *Boggs*, 520 U.S. 833 (1997); *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724 (1985); *La. Health Serv. & Indem. Co. v. Rapides Healthcare Sys.*, 461 F.3d at 538-37. Unlike the statutes involved in *Egelhoff* and *Boggs*, nothing in Access RX dictates procedures to guide processing of claims and disbursement of benefits. *Egelhoff*, 532 U.S. at 148 (quoting *Fort Halifax Packing & Co. v. Coyne*, 482 U.S. 1, 9 (1987)). For an ERISA plan, Access RX is triggered only if it decides to employ a PBM as a provider of medical services. The plan maintains

that choice at all times. *Dillingham*, 519 U.S. at 325*; PCMA v. Rowe*, 429 F.3d at 303 (nothing in the Maine PBM law compels ERISA plans to reevaluate their working relationships with PBMs). In a somewhat different context, in *Washington Physicians Serv. Ass'n v. Gregoire*, 147 F.3d 1039 (9th Cir. 1998), the Ninth Circuit found that a state's alternative provider statute did not have a significant connection with an ERISA plan because the statute required action solely by health providers; it did not require an ERISA plan to do anything. Merely because a state law regulates a service provider to an ERISA plan does not mean that it 'relates to' an ERISA plan." *Id.* at 1045.

Thus, Access RX does not bind the employer or the plan administrator to any particular choice concerning benefits or administrative practices. The plan may be structured in whatever manner the employer or administrator desires. *PCMA v. Rowe*, 429 F.3d at 303 (Maine PBM law applies to a wide variety of situations with an appreciable number that have no linkage to ERISA plans). Instead, Access RX requires the PBM as medical service provider to meet certain obligations.

Moreover, RX Access does not provide an alternate enforcement mechanism. In *Aetna Health Inc. v. Davila*, 542 U.S. 200 (2004), the Court decided whether claims alleging that a plan administrator's refusal to provide

coverage for treatment recommended by their physicians which resulted in injury to the participant could be brought as state tort claims or must be brought as benefit claims under ERISA. The Court characterized the claims as merely ones to rectify a wrongful denial of benefits, not "to remedy any violation of a legal duty independent of ERISA." *Id.* at 214. The Court held that because these lawsuits were, at bottom, requests for benefits, the lawsuits must be brought in federal, not state, court. Failure to recognize these claims as benefit claims would have resulted in a state law cause of action that duplicates, supplements or supplants the ERISA civil enforcement remedies under § 502. *Id.* Once the Court found that these state claims were really benefit claims, it held that the claims were completely preempted under ERISA.

Here, similar to *Davila*, the real issue is whether any potential claims which may be brought under Access RX may also be brought under ERISA. The PBMs have claimed that they are not subject to or regulated under ERISA. Thus, by the PBM's own admisison, there is no cause of action against PBMs under ERISA's civil enforcement provisions. *Cf. PCMA v. Rowe*, 429 F.3d at 305 (PBM law does not touch upon rights expressly guaranteed by ERISA). Merely because Access RX couches a PBM's obligation to its customers in terms of fiduciary duty does

not make the PBM a fiduciary under ERISA.[4] Indeed, under appellant's argument, all attorneys representing ERISA-covered employee benefit plans would be ERISA fiduciaries because state ethics rules provide that attorneys owe their clients a fiduciary duty. RESTATEMENT (3D) OF THE LAW GOVERNING LAWYERS §§ 1, 48 (2000); *see e.g.*, D.C. RULES OF PROFESSIONAL CONDUCT Rule 1.7 at 34, 45 (2007), *available at* www.dcbar.org/new_rules/Rule.cfm. This is not the law. *See* Section 2 *infra* at 15; *see also Gerosa v. Savasta & Co.*, 329 F.3d 317, 324 (2d Cir. 2003) (collecting cases). Consequently, Access RX does not provide an alternative enforcement mechanism to ERISA.

Accordingly, unlike other state statutes found to be preempted, Access RX does not "implicate[] an area of core ERISA concern," *Egelhoff*, 532 U.S. at 147, and thus does not fall into any of the three categories of state laws that the Court has recognized will always have a connection with an ERISA plan. At most, Access RX alters the incentives but does not dictate the choices for an ERISA plan.

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4 Because the great weight of authority is that state law claims against non-fiduciaries who provide services to plans are not preempted, *Gerosa v. Savasta & Co.*, 329 F.3d 317, 324 (2d Cir. 2003), PCMA bootstraps its preemption argument to its assertion that a PBM is an ERISA fiduciary for purposes of analysis under Access Rx. *See PCMA v. Rowe*, 429 F.3d 294, 301 (1st Cir. 2005) (finding Maine statute imposes merely ministerial, not discretionary, duties on PBMs).

See, e.g., De Buono, 520 U.S. at 815; *Dillingham*, 519 U.S. at 334. Hence, Access RX does not relate to an ERISA plan and is not preempted.

2. Access RX does not have a significant connection with ERISA plans because there is no clear indication that Congress intended to preempt laws concerning the relationship of service providers to ERISA plans.

Where the state law regulates health care, there must be an "indication in ERISA . . . [or] its legislative history of any intent on the part of Congress to preempt" this traditionally state-regulated area of law. *See Pegram v. Herdrich*, 530 U.S. 211, 237 (2000); *Dillingham*, 519 U.S. at 331; *Travelers,* 514 U.S. at 654-55.

Nothing in ERISA or its legislative history evinces a clear legislative intent to preempt traditional state laws of general applicability that do not affect the relations among the principal ERISA entities – the employer, the plan fiduciaries, the plan, and the beneficiaries. *See e.g., Penny/Ohlmann/Nieman, Inc. v. Miami Valley Pension Corp.*, 399 F.3d 692 (6th Cir. 2005); *Carpenters Local Union No. 26 v. U. S. Fid. & Guar. Co.*, 215 F.3d 136 (1st Cir. 2000); *Arizona State Carpenters Pension Trust Fund v. Citibank*, 125 F.3d 715 (9th Cir. 1997); *Coyne & Delany Co. v. Selman*, 98 F.3d 1457, 1468 (4th Cir. 1996). When a state law does not regulate an ERISA-governed relationship, it will not be preempted. *See*

id.; *Hospice of Metro Denver, Inc. v. Group Health Ins. of Okla., Inc.*, 944 F.2d 752, 756 (10th Cir. 1991) (law affecting the relations between an ERISA entity and an outside party is not preempted). Quite simply, if there is no regulation of an ERISA-governed relationship, more likely than not, there will be no significant effect on the structure, administration, or the type of benefits provided by the plan. *Id.*

Likewise, if the principal ERISA entities are not being regulated in their ERISA capacities, then there is no ERISA-governed relationship. *Arizona State Carpenters*, 125 F.3d at 724. Conversely, but analytically parallel, the Supreme Court has recognized that "lawsuits against ERISA plans for run-of-the-mill state-law claims such as unpaid rent, failure to pay creditors, or even torts committed by an ERISA plan" are against the plan in a capacity other than as a plan -- *i.e.*, as a commercial entity -- and are not preempted. *Mackey v. Lanier Collection Agency & Serv. Inc.*, 486 U.S. 825, 833 (1988).

Accordingly, the weight of authority is that state law claims against non-fiduciaries who provide services to plans, such as accountants, actuaries, attorneys, and consultants are not preempted. *See, e.g., Gerosa v. Savasta & Co.*, 329 F.3d 317; *LeBlanc v. Cahill*, 153 F.3d 134 (4th Cir. 1998); *Arizona State Carpenters*, 125 F.3d 715; *Airparts Co. v. Custom Benefit Serv.*, 28 F.3d 1062 (10th Cir. 1994).

Access RX does not regulate an entity acting in an ERISA capacity -- that is, these claims do not impact plan administration or the payment of benefits. Instead, Access RX regulates the services provided by PBMs to the covered entities which purchase such services. A purchaser-provider relationship does not fit within the traditional ERISA relationships. Instead, the relationship between PBMs and covered entities are traditional commercial relationships where claims have been held not to be preempted. *Mackey,* 486 U.S. at 833; *Arizona State Carpenters*, 125 F.3d at 724; *Coyne & Delany*, 98 F.3d at 1471. The state law at issue, which provides purchasers information concerning the service they have purchased, cannot be preempted because those claims do not significantly impact any ERISA-governed relationship. While Access RX regulates PBMs as a provider of medical services, the mere fact that the PBM provides those services to an ERISA plan does not mean Access RX relates to an ERISA plan.

II. ACCESS RX IS A LEGITIMATE STATE LAW AIMED AT LOWERING RUNAWAY DRUG COSTS.

Appellant asserts that Access RX constitutes a regulatory taking because it requires PBMs to disclose to their clients terms of PBMs' contracts with pharmaceutical companies and other information that appellant characterizes as trade secrets. Brief of Appellant at 58. According to Appellants "the economic

burden imposed by Title II is enormous, and an public benefit is speculative at best." *Id.* *Amici* will show the legitimate state interest in lowering the increasingly heavy burden of prescription drug costs, how secretive actions of PBMs drive up those costs, and how PBM business transparency such as that required by Access RX brings down drug expenses and thus relates centrally to the District of Columbia's health care concerns.

A. High Prescription Drug Costs Threaten Older Consumers' Health.

High prices for prescription drugs have serious, harmful consequences for millions of consumers. Drug manufacturers increased their prices for a sample of 93 brand-name prescription drugs widely used by older Americans, on average, 6.2 percent in 2006. General inflation during that period was 3.2 percent. The steep price increase came on top of six consecutive years in which manufacturers increases were often double and sometime triple the Consumer Price Index, seeding cumulative increases far higher than inflation. AARP, *Brand Name Drug Prices Climb Again in 2006, RX WATCHDOG REPORT* (March 2007)*, available at* http://assets. aarp.org/www.aarp.org_/cs/elec/watchdog_march_2007.pdf. The effects on consumers of high prescription drug prices are well understood--consumers' demand is inelastic and they forgo their medicines when costs become

too high. A study of older adults found that eighteen percent of persons with chronic conditions such as heart disease and depression skip some of their prescription medicines because of out-of-pocket cost pressure, and fourteen percent do so at least every month. John D. Piette *et al.*, *Cost Related Medication Underuse Among Chronically Ill Adults: the Treatments People Forego, How Often, and Who is at Risk*, 94 AM. J. PUB. HEALTH 1782 (2004). "The consequences of cost-related medication underuse include increased emergency department visits, psychiatric admissions and nursing home admissions, as well as decreased health status." *Id.* at 1782.

Numerous other studies of Medicare beneficiaries age 65 and older, done prior to and subsequent to passage of amendments to the Medicare Act providing prescription drug coverage, showed the same pattern-people foregoing prescription medications because of cost.[5] *See* Dana Gelb Safran *et al.*, *Prescription Drug Coverage and Seniors: Findings From a 2003 National Survey*, HEALTH AFFAIRS (April 19, 2005), *available at* http://content.healthaffairs.org/ cgi/reprint/hlthaff.w5.152v1; *see also* Geoffrey F. Joyce *et al.*, *Pharmacy Benefit*

5 Medicare Part D extends drug coverage to Medicare beneficiaries but has a hole in the coverage-the so-called donut hole-during which the beneficiary is solely responsible for payment until coverage kicks in again after expenditures reach a higher level.

Caps and the Chronically Ill, 26 HEALTH AFFAIRS 1333 (2007) (pharmacy benefit caps are associated with rates of discontinuation across the most common therapeutic classes and that a majority of those who discontinue use fail to reinstate therapy once coverage resumes); Patricia Neuman *et al., Medicare Prescription Drug Benefit Progress Report: Findings From a 2006 National Survey of Seniors Health Affairs*, 26 HEALTH AFFAIRS W630 (2007), *available at* http://content.healthaffairs.org/cgi/reprint/26/5/w630 (seniors without drug coverage reported using significantly fewer medications but had higher rates of out-of-pocket spending and cost-related nonadherence than seniors in Part D plans or with other sources of drug coverage); John Hsu *et al., Unintended Consequences of Caps on Medicare Drug Benefits,* 354 NEW ENG. J. MED. 2349 (2006) (the difference in consumption between beneficiaries with and those without caps on their benefits were substantially larger than during the months after the subjects exceeded the cap than during the earlier months).

As policy makers struggle to find ways to control the exorbitant costs of prescription drugs and provide access to medications, attention has focused on the important role that PBMs play in determining costs and access to drugs.

B. The PBM Industry Is a Key Marketplace Entity Greatly Influencing Prescription Drug Prices.

During the growth and development of the managed care industry in the 1970's, formularies – lists of drugs approved or favored for payment by a health care provider or health plan – began to be commonly used to control inpatient and outpatient pharmacy benefits for both inpatient and outpatient medical care. As drug spending started to outpace overall healthcare spending, HMOs subcontracted with private firms to provide centralized and computerized prescription claims processing and mail-service pharmacies. GAO, *Pharmacy Benefit Managers: Early Results on Ventures With Drug Manufacturers* at 5 (GAO/HEHS-96-45 Nov. 1995), *available at* http://www.gao.gov/archive/1996/ he96045.pdf.

In the 1990s, the scope and importance of the PBM industry exploded within the health care field.[6] In just one year, from 1993 to 1994, the number of people participating in PBM programs increased by almost 50 percent.[7] Today, there are

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6 Arnold J. Rosoff, *Symposium: The Changing Face of Pharmacy Benefits Management: Information Technology Pursues a Grand Mission*, 42 ST. LOUIS U. L.J. 1 (Winter 1998) [Rosoff]. The author attributes this growth first to "the increasing importance of the prescription drug component in health care, heightened by the development of powerful new drugs and the expansion of prescription drug benefits under health plans (citation omitted). The second factor was the growth of managed care, whose search for less costly alternatives to surgery and inpatient care led to greater use of drugs." *Id.* at 8.

7 *Id.* at 2. In 1993, forty PBMs administered prescription drug benefits for over 100,000,000 people. Elizabeth L. Mitchell, *The Potential for Self-Interested*

estimated to be 40 to 50 sizeable PBMs operating in the United States administering drug plans for approximately 200 million Americans; 84 percent of all people who have a form of health insurance which provides drug coverage have it administered through a PBM. Robert F. Atlas, *The Role of PBMs in Implementing the Medicare Prescription Drug Benefit*, HEALTH AFFAIRS (Oct. 28, 2004), *available at* http://content.healthaffairs.org/cgi/content/full/hlthaff.w4.504/DC1; Regina Sharlow Johnson, *PBMs: Ripe for Regulation*, 57 FOOD DRUG L.J. 323, 326 (2002) [Johnson]; Milt Freudenheim, *Drug Middlemen Are Facing Pressure Over Rising Prices*, N.Y.TIMES, Jan. 5, 2002.

PBMs contract with heath plans to help them administer prescription drug coverage for their consumer beneficiaries. PBMs perform a variety of tasks including paying claims, negotiating price discounts with drug manufacturers, running and contracting with pharmacy networks, establishing and encouraging use of formularies, performing drug utilization management, and sometimes consulting with health plans to advise them how to manage their prescription benefits. *See* Rosoff, *supra*, 11-23. PBMs do not manufacture, distribute, prescribe, or ultimately even pay for prescription drugs, yet they often determine

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Behavior by Pharmaceutical Manufacturers Through Vertical Integration With Pharmacy Benefit Managers: The Need for a New Regulatory Approach, 54 FOOD DRUG L.J. 151, 152 (1999).

which drug a patient will receive and at what price. They act as middlemen by creating relationships with the drug manufacturers, retail pharmacies, and pharmacists and then brokering business arrangements with the health plans which are the PBM's clients. *See generally* Johnson, *supra*, 328-334.

While expanding to cover a greater proportion of Americans, the PBM industry simultaneously became more consolidated. Today, the PBM market is dominated by three major companies: Medco Health Solutions, Caremark Rx (which merged with Advance PCS in March 2004), and Express Scripts. These three companies control 43 percent of the covered lives in the industry, and a second tier of five companies control an additional 27 percent. AIS Market Data, *PBM Market Share by Enrollment, available at* http://www.aishealth.com/MarketData/PharmBenMgmt/PBM_market01.html (last visited December 17, 2007). The major PBMs have become some of the most profitable companies in the country: On the 2007 Fortune 500 list, Medco was number 54 (higher than its former parent, drug manufacturer, Merck), Caremark was number 58, and Express Scripts was number 132. *Fortune 500 Largest U.S. Corporations,* Fortune, *available at* http://www.cnn.com/magazines/fortune/fortune500/2007/full_list/.

C. New Research Questions The Degree To Which PBMs Reduce Health Care Costs.

Appellant asserts that PBMs provide a valuable social service by lowering the costs of prescription drugs. Brief of Appellant at 3-5. However, as the costs of drugs continue to climb precipitously, researchers have begun to investigate the degree to which PBMs actually provide savings to their customers. Particularly contentious are rebates that PBMs negotiate with manufacturers but then fail to pass on fully to the PBMs' clients. Some industry observers claim that such "rebates" account for 10 percent of the money Americans spend on prescription drugs. Julian E. Barnes, *When is a Rebate a Kickback?*, U.S. NEWS & WORLD REPORT, Aug. 4, 2002, *available at* http://www.usnews.com/usnews/biztech/articles/020812/archive_022264_3.htm [Barnes]. "Many PBMs make their real money from drug manufacturer rebates and from manipulation of network pharmacy discounts," says Gerry Purcell, a former PBM executive. Robert McCarthy, *PBMs in a Jaundiced Eye*, 11(5) DRUG BENEFIT TRENDS 26 (May 1999), *available at* http://www.medscape.com/viewarticle/416871. PBMs are able to keep such revenue, explains Purcell, because they are not made to disclose it. *Id.*; Barnes, *supra*.

Two PBM tactics that have garnered particular attention are "spread pricing" and rebates that PBMs negotiate with drug manufacturers. Spread pricing refers to low rates that a PBM negotiates with pharmacy networks but does not pass on to

its clients. Robert Garis *et. al.*, *Examining the Value of Pharmacy Benefit Management Companies,* 61 AM J. HEALTH-SYST PHARM. 81, 83-84 (2004) [Garis, *Value of PBMs*]; Mark Siracuse, Robert Garis & Bartholomew Clark, *Abstract 11: Further Evidence to Support Hidden Sources of PBM Revenue; Preliminary Results*, 45(2) J. AM. PHARM. ASSOC. 222 (2005) [Siracuse]. In an especially egregious example, a PBM billed an client $215 for a generic stomach medication, Ranitidine, but only paid the pharmacy $15 for the drug. Robert Garis & Bartholomew Clark, *The Spread: Pilot Study of an Undocumented Source of Pharmacy Benefit Manager Revenue*, 44(1) J. AM. PHARM. ASSOC. 15, 18 (2004) [Garis, *The Spread*]. A team at Creighton University is conducting an empirical study to examine the difference between what PBMs charge clients and what they pay dispensing pharmacies. In a preliminary study of 1,516 prescription transactions, the researchers found an average spread of $2.20 per prescription, a substantial sum considering the hundreds of millions of prescriptions processed by PBMs every year. Siracuse, *supra*, at 222. The researchers are expecting to soon publish an expanded study of 20,000 transactions. They concluded in their pilot study:

> What seems clear from this navigation of the PBM maze is that prescription benefit plan sponsors . . . should insist on full disclosure of cash flows to and through the PBM that is administering their drug

> benefit. Without this level of scrutiny, the plan sponsor cannot be sure if its PBM is providing a good service for a fair price or is acting primarily in its own interest.

Garis, *The Spread, supra*, at 85.

Another PBM practice recently under increased scrutiny is that of negotiating rebates with drug manufacturers. PBMs routinely make arrangements with drug manufacturers wherein the manufacturers pay rebates to PBMs for favoring the drug makers' products on formularies. Garis, *Value of PBMs*, *supra*, at 83. *See also* James Langenfeld & Robert Maness, *The Cost of PBM "Self-Dealing" under a Medicare Prescription Drug Benefit* (Sept. 2003), *available at* http://www. ncpanet.org/pdf/pbm_selfdealing090903.pdf [Langenfeld]. These arrangements are usually kept secret, as appellant believes they should be, Brief of Appellant at 5-6, allowing PBMs to keep rebates for themselves without informing their clients. Because PBMs typically retain 30 percent of manufacturers' rebates, they have an incentive to engage in drug switching to drugs paying higher rebates, even if that drug costs the end payer more. Langenfeld, *supra*, at 4-5. In cases that Medco settled with 20 states and the Justice Department, it was alleged that Medco switched patients' medications to drugs that would give Medco greater rebates, without passing along the savings to its clients or informing doctors and patients that the switch would increase rebates paid to Medco. Linda Loyd, *Medco Settles*

With U.S., 20 States, PHILADELPHIA INQUIRER, Apr. 27, 2004. In another case, a PBM received 15 to 20 percent of drug costs back from manufacturers in the form of rebates but passed on just 3 to 4 percent to its clients. Garis, *Value of PBMs*, *supra*, at 83. Under fire for such rebates, PBMs have tried to hide them behind such labels as "health management fees" and "educational grants," which not only conceal the rebates from their clients but also from auditors and Medicaid, which is owed the "best price" drug manufacturers offer to any other entity. Barnes, *supra*.

The problem of drug switching or substitution is heightened when PBMs act both as a plan administrator and the seller of drugs through its own mail order pharmacy. A study found evidence that in such situations, prescription costs increased due to drug switching. Lagenfeld, *supra*. The conflict of interest can arise in PBMs' mail order pharmacies because as both dispenser and claims adjudicator:

> it has both the incentive and ability to dispense higher priced products to its patients and to earn profits on the difference between its [post-rebate] acquisition costs and its inflated price. Although this process may not occur frequently, if it occurs on only 1 to 5 % of sales it can result in substantial costs to payers and consumers.

Id. at 2. The study's authors estimated that PBM self-dealing could cost the Medicare program and beneficiaries as much as $30 billion from 2004 to 2013. *Id.* at 25.

In contrast to the above studies, appellant advances a General Accountability Office (GAO) study that stated, "The average price PBMs negotiated for drugs from retail pharmacies was about 18 percent below the average cash price customers would pay at retail pharmacies for 14 selected brand-name drugs." Brief of Appellant at 4; GAO, *Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies*, at 4 (GAO-03-196 Jan. 2003). That GAO finding was immediately qualified: "These price savings may overstate PBMs' negotiating success because, absent a PBM, plans would likely manage their own drug benefits and also attempt to negotiate discounts with retail pharmacies." *Id.* at 4. The GAO concedes that in preparing the report, "We did not independently verify information provided by plans, PBMs, or pharmacies." *Id.* at 3. Furthermore, it did not investigate the rebates PBMs receive from manufacturers: "While information on the size of these payments was unavailable, PBMs' public financial information suggests that rebates or other payments from drug manufacturers may be a large source of PBM earnings." *Id.* at 6. The GAO report was requested by Senator Byron L. Dorgan, who asked, "Do these rebates have the perverse incentive of actually pushing higher-cost medicine onto the patient?" Milt Freudenheim, *Pharmacy Benefit*

Companies Won't Disclose Fees, N.Y. TIMES, Jan. 10, 2003. Upon reviewing the report, Senator Dorgan remarked:

> I'm very disappointed that the GAO did not obtain information from the PBMs that would have allowed us to get to the bottom of this . . . If even GAO, the investigatory arm of Congress, is unable to get this type of information about the financial arrangements of PBMs . . . then it is more important than ever that any legislation that would use PBMs . . . provide for strict oversight of PBMs and shine some sunshine on their use.

Notes from Capitol Hill, AMERICA'S PHARMACIST, Feb. 2003, *available at* http://www.ncpanet. org/leg_gov/notes_from_capitol_hill/2003/february.shtml.

D. Some PBMs Offer Transparency.

States' interest in PBM transparency has created not only legislation but also a market for new, non-traditional PBMs. Wisconsin turned to Navitus Health Solutions, founded in 2003, to serve as PBM for its state employee health plans, and as a result the state spent less on prescription drugs in 2004 than the year before and achieved average drug savings of 30.6 percent. Guy Boulton, *State Gets Prescription for Savings*, MILWAUKEE JOURNAL SENTINEL, June 6, 2005 [Boulton]. Navitus charges a flat, per person monthly rate for its services and promises clients complete transparency. Gary Harki, *W. Va. Prescription Drug Program Could be Good Medicine*, CLARKSBURG EXPONENT TELEGRAM, June 13, 2005 [Harki]. Wisconsin Department of Employee Trust Funds Secretary Eric

Stanchfield explains that the state turned to Navitus because "we wanted to see where the dollars went," adding, "[f]rankly, we've saved more than we expected." Boulton, *supra*. Wisconsin's success inspired West Virginia to adopt a similar program and has drawn the attention of other states and of corporations including General Motors. Harki, *supra*; Boulton, *supra*. Indeed, corporations' growing interest in transparency has led even some major PBMs to offer services similar to those available through Navitus. In its dealings with thirty companies working together as "RxCollaborative," Medco earlier this year agreed to disclose to the companies all rebates and discounts from drug manufacturers, to pass on all savings to them, and to charge them only an administrative fee. Ellen Beck, *HealthBiz: The Battle for PBM Transparency*, UNITED PRESS INTERNATIONAL, Feb. 3, 2005, *available at* http://washingtontimes.com/upi-breaking/20050203-054507-4985r.htm. A simple Google search reveals a PBM advertising itself as completely transparent, www.medimpact.com, and expert advice to payers on comparing transparent PBM bids. *See*, *e.g.*, www.aishealth.com/DrugCosts/DBN_Transparency_Expert.html. Dire protections that transparency requirements will destroy whatever PBMs actually provide are overblown and unfounded.

Alternative PBM business models, and legislation such as Access RX all demonstrate the existence of both a problem with traditional PBMs and of a

legitimate state interest in solving that problem. Additionally, the responses of some PBMs, such as Medco, to these actions show that transparency in the PBM industry is neither as dangerous as appellant suggests, nor are all PBMs are uniformly opposed to transparency provisions.

CONCLUSION

PBM practices such as spread pricing and failing to pass on rebates to their clients contribute to the oppressive problem of prescription drug costs. States have tried to protect their citizens from such PBM behaviors by a variety of methods including lawsuits, turning to new PBM business models, and legislation like Access RX. Access RX would shed light on PBM dealings to ensure that health care expenses are fair and appropriate and to avoid the types of problems that have led governments to have to sue PBMs.

Appellant has not met the considerable burden of overcoming the traditional presumption that a federal law – ERISA – does not preempt Access RX, a state law regulating health care, a traditional area of state regulation. For the foregoing reasons, *amici* urge the Court to affirm the judgment of the District Court.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH RULE 32(A)

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7) and Circuit Rule 32(a)(2) because: this brief contains _______ words, (excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii)) as determined by the word counting feature of WordPerfect 12.

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CERTIFICATE OF SERVICE

I certify that on December 20, 2007 the original and 14 copies of the foregoing Brief *Amici Curiae* of AARP, Legal Counsel for the Elderly and the Prescription Access Litigation Project in Support of Appellees were Federal Expressed to Mark Langer, Clerk of U.S. Court of Appeals for the District of Columbia Circuit, and 2 copies were Federal Expressed to the following counsel:

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